Progress Report Scanning Cover Sheet

5U10HD021364-20

PI Name:WALSH, MICHELEOrg:CASE WESTERN RESERVE UNIVERSITYStart Date:04/01/2005Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:6902653Rec'd Date:02/03/2005

Department of Health and Human Services Public Health Services		Review Gro ZHD1- MCHG-B		Activity U10	Grant Number HD21364-19	20
Grant Progress Report		Total Project From: 04/0			Through: 03/31/20	006
		From: 04/0		·u.	Through: 03/31/2	006
1. TITLE OF PROJECT Multicenter Network of Neonatal Intensive Care Units					200	
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	3 AP	PLICANT OR	GANIZATION			······································
(Name and address, street, city, state, zip code)	(Na	ame and addre	ss, street, cit	ty, state, zi		
Michele C. Walsh, M.D., M.S.		ase Wester		e Unive	ersity 1	
Case Western Reserve University		900 Euclio				-
Rainbow Babies & Children's Hospital		eveland, C)hio 441(06-7015		2
11100 Euclid Avene					سیبی شیمی ۲۰۰	:
Cleveland, Ohio 44106-6010 2b. E-MAIL ADDRESS		ITITY IDENTIF		IMBED	<u> </u>	·
mcw3@cwru.edu		I-1018992-		JNIDER		-
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT	<u> </u>			MINISTR	ATIVE OFFICIAL	<u> </u>
Department of Pediatrics					esearch Adm	in.
2d. MAJOR SUBDIVISION		ase Weste				-
School of Medicine		0900 Euclio			· · · · ·	
· · · ·	C	leveland, C	Dhio 4410	06-4919)	
		L: medres				
6. HUMAN SUBJECTS		. VERTEBRA	-	-		
No 6a. Research Exempt 6b. Human Subjects Assurance	No.	🛛 No			7a. If "Yes," IACUC	approval Date
	[Yes				
If Exempt ("Yes" in 6a): Exemption No.	7	b. Animal W		ance No.		
		A3145-	-01			
If Not Exempt ("No" in 6a):						
IRB approval dateMultiple						
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD				-	_	
8a. DIRECT \$157,656 8b. TOTAL \$241,214				Not Pre	sly Reported	
10. PERFORMANCE SITE(S) (Organizations and addresses) Case Western Reserve University	-	PRINCIPAL IN ROGRAM DIR		n 2a)	EL 216-844-3759	
Department of Pediatrics		nele C. Wa			ax 216-844-3380	
10900 Euclid Avenue	11b. A	DMINISTRAT		AL TI	EL 216-368-3794	
Cleveland, Ohio 44106		E (Item 5) e Duli		F/	AX 216-368-4805	
					NING FOR APPLICA	
	ORGA	ANIZATION (tem 14)			
	1	Anne D		n fam	Decembra A	dmin
		216-368		n ior	Research A	_4805
	TEL	medres@		du	FAX DIG SOU	1000
12. Corrections to Page 1 Face Page	E-MA	IL		·		
IRB approval dates: 09/04; 01/05; 04/04; 11/04; 12/	/04: 08	3/04 - see a	attached			
13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURA	NCE: 1 d	certify that the		RE OF PI/P	D NAMED IN 2a.	DATE
statements herein are true, complete and accurate to the best of my know any false, fictitious, or fraudulent statements or claims may subject n			(In ink. "Pe	ər" signatul	re not acceptable.)	allasland
administrative penalties. I agree to accept responsibility for the scientific co to provide the required progress reports if a grant is awarded as a result of t	nduct of t	the project and	Michel	: ('. l	Nalsh	01/00/10005
14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTAI	NCE: I ce	ertify that the	1		FICIAL NAMED IN	DATE
statements herein are true, complete and accurate to the best of my knowle obligation to comply with Public Health Services terms and conditions if a gr			11c. (In ini acceptable		gnature not	,
result of this application. I am aware that any false, fictitious, or fraudulent s may subject me to criminal, civil, or administrative penalties.				inns	rei	1/28/05
, conjective to community of the deministrative periodices.						

Pages 3 through 9 redacted for the following reasons: Not responsive to the request.

	GRANT NUMBER	<u> </u>
PROGRESS REPORT SUMMARY	HD21364	
	PERIOD COVERED BY	THIS REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH
Michele C. Walsh, MD MS	04/01/2004	03/31/2005
APPLICANT ORGANIZATION		· · · · · · · · · · · · · · · · · · ·
Case Western Reserve University		
TITLE OF PROJECT (Repeat title shown in Item 1 on first pag	e)	
Multicenter Network of Neonatal Intensive Care Un	its	
A. Human Subjects (Complete Item 6 on the Face Page)		••••••••••••••••••••••••••••••••••••••
Involvement of Human Subjects 🛛 🛛 No Cha	nge Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals No Cha	nge Since Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS.		

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims: The overall aim of the NRN is to improve the health of newborns by conducting clinical trials to identify safe and efficacious therapies. The mature network has more than fulfilled this mission in 2004.

B. Studies and Results:

1. Randomized Trials: Not responsive

D. Plans:

Not responsive

In 2005 Not responsive	
	In addition, Case will continue to serve on the planning
	d continue the pilot of the oxygen saturation arm. Full enrollment in the main
trial will begin in early 2005.	sponsive

E. Publications:

Pages 12 through 42 redacted for the following reasons: Not responsive **Progress Report Scanning Cover Sheet**

5U10HD021364-22

 PI Name:
 WALSH, MICHELE

 Org:
 CASE WESTERN RESERVE UNIVERSITY

 Start Date:
 04/01/2007

 Snap:
 N/A (NEEDS TO BE BOOKMARKED)

 Appl ID:
 7219975

 Rec'd Date:
 02/05/2007

Department of Health and Human Services Public Health Services	Review Group Type Activity Grant Number ZHD1DSRA10 5 U10 5 U10 HD021364-22	2			
	Total Project Period				
Creat Dramas Desert	From: 01/01/1986 Through: 03/31/2011				
Grant Progress Report	Requested Budget Period				
	From: 04/01/2007 Through 03/31/2008				
 TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Res 	search Notwork				
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	3. APPLICANT ORGANIZATION				
(Name and address, street, city, state, zip code)	(Name and address, street, city, state, zip code)				
WALSH, MICHELE C RAINBOW BABIES/CHILDRENS HOSP	CASE WESTERN RESERVE UNIVERSITY 10900 EUCLID AVENUE				
DEPT OF PEDIATRICS/DIV OF NEONATO	10900 EUCEID AVENDE				
11100 EUCLID AVENUE					
2b. E-MAIL ADDRESS MCW3@CASE.EDU	4 ENTITY IDENTIFICATION NUMBER 1341018992A1				
2c DEPARTMENT, SERVICE LABORATORY, OR EQUIVALEN					
PEDIATRICS	Director, Grants & Contracts CASE WESTERN RESERVE UNIVERSITY				
2d. MAJOR SUBDIVISION					
SCHOOL OF MEDICINE	10900 EUCLID AVENUE				
	Cleveland, OH 44106-4919				
	E-MAIL medres@case.edu				
6 HUMAN SUBJECTS	7 VERTEBRATE ANIMALS				
No 6a Research Exempt 6b Human Subjects Assurance	ze No. 7a. If "Yes," IACUC approv.	al Dat			
Ves Vo Ves FWA00004428	Yes				
If Exempt ("Yes" in 6a) 6c. NIH-Defined Phase III	7b Animal Welfare Assurance No.				
Exemption No Clinical Trial No No					
	A3145-01 FEB 0 5 2007				
Exemption No Clinical Trial No S If Not Exempt ("No" in 6a) Full IRB or	A3145-01 FEB 0 5 2007				
Exemption No Clinical Trial No No If Not Exempt ("No" in 6a) Full IRB or Expedited Rev	A3145-01 FEB 0 5 2007				
Exemption No Clinical Trial No Clinical Trial No S If Not Exempt ("No" in 6a) IRB approval date Full IRB or Expedited Rev 8. COSTS REQUESTED FOR NEXT BUDGET PERIOD 8a DIRECT \$ 168,019 10. PERFORMANCE SITE(S) (Organizations and addresses)	A3145-01 FEB 0 5 2007 iew 9 INVENTIONS AND PATENTS No Yes If Yes. Not Previously Reported 11a. PRINCIPAL INVESTIGATOR TEL (216) 844-3387				
Exemption No Clinical Trial No S If Not Exempt ("No" in 6a) IRB approval date Full IRB or Expedited Rev 8. COSTS REQUESTED FOR NEXT BUDGET PERIOD 8a DIRECT \$ 168,019 (bb. TOTAL \$:259,589) 10. PERFORMANCE SITE(S) (Organizations and addresses) Division of Neontology	A3145-01 FEB 0 5 2007 iew 9 INVENTIONS AND PATENTS 9 INVENTIONS AND PATENTS No Yes If Yes. Previously Reported 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) (212) 211 2200				
Exemption No Clinical Trial No S If Not Exempt ("No" in 6a) IRB approval date Full IRB or Expedited Rev 8. COSTS REQUESTED FOR NEXT BUDGET PERIOD 8a. DIRECT \$ 168,019 (bb. TOTAL \$, 259,589) 10. PERFORMANCE SITE(S) (Organizations and addresses) Division of Neontology Rainbow Babies and Childrens Hospital	A3145-01 FEB 0 5 2007 iew 9 INVENTIONS AND PATENTS 9 INVENTIONS AND PATENTS No Yes 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) Michele Walsh 11b. ADMINISTRATIVE OFFICIAL				
Exemption No Clinical Trial No S If Not Exempt ("No" in 6a) IRB approval date Full IRB or Expedited Rev 8. COSTS REQUESTED FOR NEXT BUDGET PERIOD 8a DIRECT \$ 168,019 (bb. TOTAL \$:259,589) 10. PERFORMANCE SITE(S) (Organizations and addresses) Division of Neontology	A3145-01 FEB 0 5 2007 iew 9 INVENTIONS AND PATENTS 9 INVENTIONS AND PATENTS Previously Reported No Yes Previously Reported 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) TEL (216) 844-3387 Michele Walsh FAX (216) 844-3380 11b. ADMINISTRATIVE OFFICIAL NAME (Item 5) TEL (216) 368- 4432				
Exemption No If Not Exempt ("No" in 6a) IRB approval date Clinical Trial No Full IRB or Expedited Rev COSTS REQUESTED FOR NEXT BUDGET PERIOD Sa DIRECT \$ 168,019 Clinical Trial No Full IRB or Expedited Rev Clinical Trial No Full IRB O Full Rev Sub Clinical Trial No Full Rev Sub Clinical Trial No Full Rev Sub Clinical Trial No Full Rev Sub Clinical Trial No No Sub Clinical Trial No No Sub Clinical Trial No Sub Clinical Trial No No Sub Clinical Trial No No Sub Clinical Trial No	A3145-01 FEB 0 5 2007 iew 9 INVENTIONS AND PATENTS 9 INVENTIONS AND PATENTS No Yes 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) Michele Walsh 11b. ADMINISTRATIVE OFFICIAL				
Exemption No If Not Exempt ("No" in 6a) IRB approval date Clinical Trial No Full IRB or Expedited Rev COSTS REQUESTED FOR NEXT BUDGET PERIOD Sa DIRECT \$ 168,019 Clinical Trial No Full IRB or Expedited Rev Clinical Trial No Full IRB O Full Rev Sub Clinical Trial No Full Rev Sub Clinical Trial No Full Rev Sub Clinical Trial No Full Rev Sub Clinical Trial No No Sub Clinical Trial No No Sub Clinical Trial No Sub Clinical Trial No No Sub Clinical Trial No No Sub Clinical Trial No	A3145-01 FEB 0 5 2007 iew 9 INVENTIONS AND PATENTS 9 INVENTIONS AND PATENTS Previously Reported 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) Previously Reported Michele Walsh FAX (216) 844-3380 11b. ADMINISTRATIVE OFFICIAL NAME (Item 5) TEL (216) 368- 4432 Cynthia O. Case FAX (216) 368-4805 11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14) FOR APPLICANT				
Exemption No If Not Exempt ("No" in 6a) IRB approval date Clinical Trial No Full IRB or Expedited Rev COSTS REQUESTED FOR NEXT BUDGET PERIOD Sa DIRECT \$ 168,019 Clinical Trial No Full IRB or Expedited Rev Clinical Trial No Full IRB O Full Rev Sub Clinical Trial No Full Rev Sub Clinical Trial No Full Rev Sub Clinical Trial No Full Rev Sub Clinical Trial No No Sub Clinical Trial No No Sub Clinical Trial No Sub Clinical Trial No No Sub Clinical Trial No No Sub Clinical Trial No	A3145-01 FEB 0 5 2007 iew 9 INVENTIONS AND PATENTS 9 INVENTIONS AND PATENTS No Yes Yes Previously Reported No Yes 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) TEL Michele Walsh FAX 11b. ADMINISTRATIVE OFFICIAL NAME (Item 5) TEL Cynthia O. Case FAX 11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14) NAME Cynthia O. Case				
Exemption No If Not Exempt ("No" in 6a) IRB approval date Clinical Trial No Full IRB or Expedited Rev COSTS REQUESTED FOR NEXT BUDGET PERIOD Sa DIRECT \$ 168,019 Clinical Trial No Full IRB or Expedited Rev Clinical Trial No Full IRB O Full Rev Clinical Trial No Full Rev Clinical Trial No Full Rev Clinical Trial No Full Rev Full Rev Full R	A3145-01 FEB 0 5 2007 iew 9 INVENTIONS AND PATENTS				
Exemption No If Not Exempt ("No" in 6a) IRB approval date Clinical Trial No Full IRB or Expedited Rev COSTS REQUESTED FOR NEXT BUDGET PERIOD Sa DIRECT \$ 168,019 Clinical Trial No Full IRB or Expedited Rev Clinical Trial No Full IRB O Full Rev Clinical Trial No Full Rev Clinical Trial No Full Rev Clinical Trial No Full Rev Full Rev Full R	A3145-01 FEB 0 5 2007 iew 9 INVENTIONS AND PATENTS 9 INVENTIONS AND PATENTS No Yes Yes Previously Reported No Yes 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) TEL Michele Walsh FAX 11b. ADMINISTRATIVE OFFICIAL NAME (Item 5) TEL Cynthia O. Case FAX 11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14) NAME Cynthia O. Case				

13 APPLICANT ORGANIZATION CERTIFICATI statements herein are true complete and accurate obligation to comply with Public Health Services ter result of this application. I am aware that any faise may subject me to commal civil or administrative p	to the best of my knowledge, and accept the ms and conditions if a grant is awarded as a fictitious, or fraudulent statements or claims	SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Per" signature not acceptable UMHUAO COSC	131107
PHS 2590 (Rev. 04/06)	Face Page	. 0	Form Page 1

Pages 3 through 14 redacted for the following reasons: Not responsive

	vvaisn, ivlichele C	
PROGRESS REPORT SUMMARY	GRANT NUMBER HD-21364-22	
	PERIOD COVERED BY	THIS REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH
Michele C. Walsh	April 1, 2006	March 31, 2007
APPLICANT ORGANIZATION Case Western Reserve University	<u></u>	
TITLE OF PROJECT (Repeat title shown in Item 1 on first pag NICHD Cooperative Multicenter Neonatal Research		
A. Human Subjects (Complete Item 6 on the Face Page) Involvement of Human Subjects	nge Since Previous Submission	Change

B. Verteb	rate Animals (Complete Item 7 on the	Face Pa	ige)
Use	of Vertebrate Animals	\boxtimes	No Change Since Previous Submission
			

C. Select Agent Research	No Change Since Previous Submission	Change
D. Multiple PI Leadership Plan	No Change Since Previous Submission	Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Tables indicating the enrollment in each trial by the CWRU site in the current period are attached.

Progress Report:

Not responsive	
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Change

Intervention Trials: Not responsive

Not responsive

2. SUPPORT trial: This factorial trial of two interventions (oxygen saturation in two different ranges; and early use of CPAP in the delivery room vs intubation for surfactant) has continued enrollment in 2006. The pace of enrollment slowed with the recompetition of the network, but is now again in full swing. CWRU has enrolled 50 (10.5%) of the 473 patients to date. In addition, we are participating in 4 secondary studies to the main trial including: a. desaturation secondary that evaluates the impact of the oxygen saturation intervention on the frequency and intensity of desaturations; b. MRI secondary: that evaluates the impact of the interventions on MRI findings at 36 weeks corrected age; c. Growth secondary: evaluates the impact of the oxygen saturation intervention on growth at 36 weeks.; d. Pulmonary outcomes secondary: evaluates the impact of the impact of the interventions on pulmonary symptoms at 6, 9, 12 and 18 months of age. The trial is scheduled to continue enrollment until 2009.

Network Publications in 2006:

Not responsive

Pages 17 through 25 redacted for the following reasons: Not responsive

Neonatal Research Network 2006 Race/Gender Tables Ethnicity and Race Information (Support by Center)

Center: Case Western

Table of Et	hnicity	by Gend	er		
Ethnicity(Ethnic Category)			ender(Gender)		
Frequency	Male	Female	Unknown or not reported	Total	
Hispanic or Latino	0	1	0	1	
Not Hispanic or Latino	13	10	0	23	
Unknown or not reported	0	0	2	2	
Total	13	11	2	26	

Table of I	Race by	Gender			
Race(Race)	G	Gender(Gender)			
Frequency	Male	Female	Unknown or not reported	Total	
Black	5	9	0	14	
White	8	2	0	10	
Unknown or not reported	0	0	2	2	
Total	13	11	2	26	

Table of Hispanic/Latino Race by Gender				
Race for Hispanic/Latino Subjects	Gender(Gender)			
Frequency	Female	Total		
Black	1	1		
Total	1	1		

Pages 27 through 39 redacted for the following reasons: Not responsive **Progress Report Scanning Cover Sheet**

5U10HD021364-23

PI Name:WALSH, MICHELEOrg:CASE WESTERN RESERVE UNIVERSITYStart Date:04/01/2008Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7391191Rec'd Date:02/06/2008

Form Approved Throug	gh 11/30/2010)						ON	AB No. 0925-0001
Departme	ent of Health a Public Health			Review Group ZHD1DSRA1	Type 5	Activity U10		nt Number U10 HD0	21364-23)
				Total Project Period					
•	-		-	From: 04/01/198	6	Th	ough:	03/31/20	11
Grant	Progr	ess I	Report	Requested Budget P					
				From: 04/01/200	8	Thi	ough:	03/31/20	09
1. TITLE OF PROJEC NICHD Cooper		licenter	Neonatal Resea	arch Network				2008	
2a. PROGRAM DIREC				2b. E-MAIL ADDRES	S				
(Name and address	s, street, city,	state, zip	code)	mcw3@case					
Michele C. Wa	lsh			2c. DEPARTMENT, S				R EQUIVALE	INT
11100 Euclid Avenue RBC Suite 3100			Pediatrics/Sc		Medicine	Э			
Rainbow Babie	es and Chi	ildrens	Hospital	2d. MAJOR SUBDIVI	SION				
Cleveland, OH	44106-60)10				Γ.			
				^{2e. Tel:} 216-844-3	387	га	^{x:} 210	6-844-3380)
3a. APPLICANT ORG/ (Name and address		state, zip	code)	^{3b. Tel:} 216-368-4	4432	Fa	^{x:} 21	6-368-480	5
Case Western Reserve University 10900 Euclid Avenue			^{3c. DUNS:} 07-775	-8407					
Cleveland, OH 44106-4919			4. ENTITY IDENTIF 1341018992A		NUMBER		<u>.</u>		
6. HUMAN SUBJECT	S 🗖 No		 /es	5. NAME, TITLE AN			AINIST	RATIVE OFF	
	If Exempt ("Y		If Not Exempt ("No" ir						
Exempt 6a): 6a):			Cyninia O. Ca						
🗙 No 🔲 Yes	Exemption N	0.	IRB approval date	Director, Office	e of Gra	ants & Co	ntrac	CIS	
6b. Federal Wide Ass	urance No. F	WA000	04428	Tel: 216-368-4432	2	Fa	×: 21(6-368-4805	5
6c. NIH-Defined Phase	e III			E-MAIL:					
Clinical Trial	o 🗙 Yes			medres@case.	edu				
7. VERTEBRATE ANI	IMALS 🗵	No C	Yes	10. PROJECT/PERF	ORMANC	E SITE(S)	-		
7a. If "Yes," IACUC ap	pproval Date			Organizational Name	Case	vvestern	Res	erve Univ.	
7b. Animal Welfare As	surance No.			DUNS: 07-775-84	407				
8. COSTS REQUEST	TED FOR NE	XT BUDG	ET PERIOD	Street 1: 10900	Eucli	d Ave.			
8a. DIRECT \$ 286,0	74 8	b. TOTAL	\$ 449,136	Street 2:					··· ·· ·
9. INVENTIONS AND	PATENTS	X No	Yes	^{City:} Cleveland		Co	ounty:	Cuyahoga	
lf "Yes, 🔲 Previou	usly Reported			State: OH		Pr	ovince	:	
Not Pre	eviously Repo	rted		Country: USA		Zir	Zip/Postal Code: 44106 -4919		06 -4919
				Congressional Distric	^{ts:} 11	I			
11. NAME AND TITLE			IG FOR APPLICANT	ORGANIZATION (Item	13)	·····			
Cynthia O. Case	e, Director	, Office	of Grants & Co	ntracts					
TEL: 216-368-443	2		FAX: 216-368-	4805		E-MAIL: m	edres	s@case.e	du
12. Corrections to Pag	e 1 Face Pag	θ							
				ANCE: Looptity that the Id	RIGNAT				DATE
obligation to comply w	e true, complete with Public Heal on. I am aware	and accur th Services that any fa	ate to the best of my know terms and conditions if a ilse, fictitious, or frauduler	wledge, and accept the grant is awarded as a	(In ini		\sim		2/5/18
PHS 2590 (Rev. 11/07)			<u> </u>	Face Page	-1-				Form Page 1

Pages 3 through 4 redacted for the following reasons: Not responsive Neonatal Research Network 2007 Race/Gender Tables (randomized 1/1-11/30) Support Protocol Case Western University

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and the second s	and the second		
2	2	0	4
8	14	0	22
0	0	1	1
10	16	1	27

	NE VAL DE NE VAL DE DE		
Acres 4	NEE AR		
7	7	0	14
3	9	0	12
0	0	1	1
10	16	1	27

Neonatal Research Network 2007 Race/Gender Tables (randomized 1/1-11/30) Hispanic subjects ONLY (table 3) Support Protocol

Table of race by genderracegenderFrequencyFemaleMaleTotalWhite224Total224

Center ID number=Case Western University

Pages 7 through 12 redacted for the following reasons: Not responsive

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Alrway Pressure & Pulse Oximetry			
Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	11-04-29	11/5/07	10/29/08
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	11-04-29	Submitted completion on last continuing review of SUPPORT	
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	11-04-29	11/5/07	10/29/08
Breathing Outcomes (SUPPORT Study Secondary)	11-04-29	11/5/07	10/29/08
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	11-04-29	11/5/07	10/29/08

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive		•	

*** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.

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Pages 16 through 45 redacted for the following reasons: Not responsive Progress Report Scanning Cover Sheet

5U10HD021364-24

PI Name:WALSH, MICHELEOrg:CASE WESTERN RESERVE UNIVERSITYStart Date:04/01/2009Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7608718Rec'd Date:02/02/2009

Department of Health Public Heal		Review Group ZHD1DSRA10	Type 5	Activity U10	Grant Number 5 U10 HD021364-24
	In Services	Total Project Period	<u> </u>		0 0 10 11002 1304-24
	_	From: 04/01/1986 Through: 03/31/2011			
Grant Prog	ress Report	Requested Budget F			
		From: 04/01/200	9	Th	rough: 03/31/2010
1. TITLE OF PROJECT NICHD Cooperative M	ulticenter Neonatal Res	earch Network			
2a. PROGRAM DIRECTOR / PRIN	ICIPAL INVESTIGATOR	26. E-MAIL ADDRES			
(Name and address, street, city Michele C. Walsh	r, state, zip code)	Michele.Wal			
Rainbow Babies/ Childrens Hosp Dept of Pediatrics/Div of Neonatology		Pediatrics			DRY, OR EQUIVALENT
Cleveland, Ohio 44106	2d. MAJOR SUBDIV				
		2e. Tel: 216-844-	3387	Fa	x: 216-844-3380
3a. APPLICANT ORGANIZATION (Name and address, street, city,		3b. Tei:		Fa	
CASE WESTERN RESERVE UNIVERSITY 10900 EUCLID AVE CLEVELAND, OH 44106-4919		3c. DUNS: 07775	8407		FEB 0 2 2009
		4. ENTITY IDENTIFICATION NUMBER 1341018992A1			
6. HUMAN SUBJECTS	Yes	5. NAME, TITLE AN	D ADDR	ESS OF AD	MINISTRATIVE OFFICIAL
6a. Research If Exempt (" Exempt 6a):	Yes" in If Not Exempt ("No" i				
No Yes	, ,				& Forecasting land, Oh 44106-4919
6b. Federal Wide Assurance No.	FWA00004428	Tel: 216-368-44	32	Fa	x: 216-368-0929
6c. NIH-Defined Phase III Clinical Trial 🔲 No 🕅 Yes		E-MAIL: medres(@case.	edu	
7. VERTEBRATE ANIMALS	No Yes	10. PROJECT/PERF	ORMAN	CE SITE(S)	
7a. If "Yes," IACUC approval Date	,	Organizational Name	: Case	Western	Reserve University
7b. Animal Welfare Assurance No.		DUNS: 0777584	07		
8. COSTS REQUESTED FOR NE	EXT BUDGET PERIOD	Street 1: 10900	Euclid	Avenue	
8a. DIRECT \$175,414	8b. TOTAL \$271,014	Street 2:			
9. INVENTIONS AND PATENTS	No Yes	City: Cleveland		Co	ounty: Cuyahoga
lf "Yes, 📃 Previously Reporte	d	State: Ohio		Pr	ovince:
Not Previously Rep	orted	Country: USA		Zi	p/Postal Code: 44106-491
		Congressional Distric	ts: 11tl	n	
11. NAME AND TITLE OF OFFIC Robin L Bissell, Director					
TEL: 216-368-4432	FAX: 216-36	3-0929	• <u> </u>	E-MAIL: M	edres@case.edu
12. Corrections to Page 1 Face Pa	ge			<u>. </u>	
obligation to comply with Public Hei	te and accurate to the best of my kno alth Services terms and conditions if a re that any false, fictitious, or fraudule	wledge, and accept the grant is awarded as a	SIGNATU		ICIAL NAMED IN DATE

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Pages 3 through 14 redacted for the following reasons: Not responsive

Principal Investigator/Program Director (Last, Fir	^{rst, Middle):} Walsh, Michele C	
PROGRESS REPORT SUMMARY	GRANT NUMBER HD-21364-24	
	PERIOD COVERED BY TH	IIS REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECT	TOR FROM	THROUGH
Michele C. Walsh	April 1, 2008	March 31, 2009
APPLICANT ORGANIZATION Case Western Reserve University TITLE OF PROJECT (Repeat title shown in Item 1 on		
NICHD Cooperative Multicenter Neonatal Re		
A. Human Subjects (Complete Item 6 on the Face Page Involvement of Human Subjects	e) No Change Since Previous Submission	
B. Vertebrate Animals (Complete Item 7 on the Face Pa	-	Change
Use of Vertebrate Animals	No Change Since Previous Submission	Change
C. Select Agent Research	No Change Since Previous Submission	Change
D. Multiple PI Leadership Plan	No Change Since Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS.		

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Tables indicating the enrollment in each trial at the CWRU site in the current period are attached.

Progress Report:

The NRN has completed another productive year including two high impact publications in the New England Journal of Medicine. The NRN has 3 observational studies in progress, and 6 randomized controlled intervention trials, and several additional studies in development. Case Western Reserve University has continued to be a productive member of the Network.

Observational studies: Not responsive

ngs de

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Intervention Trials:

<u>1 SUPPORT trial:</u> This factorial trial of two interventions (oxygen saturation in two different ranges; and early use of CPAP in the delivery room vs intubation for surfactant) has continued enrollment in 2008. The pace of enrollment slowed with the recompetition of the network, but is now again in full swing. CWRU has enrolled 104 (8%) of the 1258 patients to date (target enrollment 1300). In addition, we are participating in 4 secondary studies to the main trial including: a. desaturation secondary that evaluates the impact of the oxygen saturation intervention on the frequency and intensity of desaturations; b. MRI secondary: that evaluates the impact of the intervention on growth at 36 weeks.; d. Pulmonary outcomes secondary: evaluates the impact of the impact of the interventions on pulmonary symptoms at 6, 9, 12 and 18 months of age. The trial is scheduled to complete enrollment in 2009. Two year followup will continue until 2011. Developmental evaluations at 6-7 years of age are planned.

Network Publications in 2008:

<u>Abstracts:</u>

Ambalavanan, N., Walsh, M., and the NICHD Neonatal Research Network. Factors Contributing to Inter-Center Differences in Rates of Bronchopulmonary Dysplasia or Death in Very Low Birth Weight Infants. (Presented, to the Society for Pediatric Research, Honolulu, Hawaii, May 2-6, 2008)

PHS 398/2590 (Rev. 09/04, Reissued 4/2006)

Pages 17 through 27 redacted for the following reasons: Not responsive

Categories	Females	Males	Unknown	total
Ethnic - Hisp or Latino	1	0	0	1
Ethnic - Not Hisp or Latino	13	11	0	24
Ethnic - Unknown	0	0	0	0
Ethnicity: Total of All Subjects	14	11	0	25
Amer Indian/Alaska	0	0	0	0
Asia	0	0	0	0
Hawaiian or Other Pacific	0	0	0	0
Black or African Amer	7	8	0	15
White	7	3	0	10
More than One	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of all	14	11	0	25
Hispanic: Amer Indian/Alaska	0	0	0	0
Hispanic: Asia	0	0	0	0
Hispanic: Hawaiian or Other Pacific	0	0	0	0
Hispanic: Black or African Amer	1	0	0	1
Hispanic: White	0	0	0	0
Hispanic: More than One	0	0	0	0
Hispanic: Unknown or Not Reported	0	0	0	0
Hispanic: Racial Categories: Total of al	1	0	0	

Inclusion Enrollment Report for the Support Study for Center 3

Total includes patients entered into study or status obtained on and between 01/01/08 and 12/31/08 Report created on 01/21/09

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NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

1

08.11.06

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	11-04-29	12/5/08	9/22/09
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	11-04-29	12/5/08	9/22/09
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	11-04-29	12/5/08	9/22/09
Breathing Outcomes (SUPPORT Study Secondary)	11-04-29	12/5/08	9/22/09
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	11-04-29	12/5/08	9/22/09

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PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	<u>APPROVED</u> <u>THROUGH</u>
Not responsive			

08.11.06

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

4

*** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.

08.11.06

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Page 33 redacted for the following reason: Not responsive **Progress Report Scanning Cover Sheet**

5U10HD021364-25

PI Name:WALSH, MICHELEOrg:CASE WESTERN RESERVE UNIVERSITYStart Date:04/01/2010Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7798608Rec'd Date:02/01/2010

Department of Health and Human Services Public Health Services		Review Group ZHD1DSRA10	Type 5	Activity U10	Grant Number 5 U10 HD021	364-25		
			Total Project Period					
	D		From: 04/01/1986 Through: 03/31/2011					
Grant	Progress	Report	Requested Budget Period					
			From: 04/01/201	0	Taro	ugh: 03/31/201	1	
1. TITLE OF PROJEC	ст erative Multicente	r Noonatal Rosa	arch Notwork					
·	CTOR / PRINCIPAL IN		2b. E-MAIL ADDRES	s			<u> </u>	
(Name and addres	s, street, city, state, zip		michele.walsh@cwru.edu					
	HELE C ABIES/CHILDRE		2c. DEPARTMENT, S	SERVICE,	LABORATOR	RY, OR EQUIVALE	ENT	
	DIATRICS/DIV C		Pediatrics			······		
11100 EUCLID AVENUE			2d. MAJOR SUBDIVI Neonatology	SION				
			2e. Tel: 2168443	387	Fax	2168443380		
3a. APPLICANT ORG		anda)	3b. Tel: 216-368-	4432	Fax	216-386-092	<u>9</u>	
(Name and address, street, city, state, zip code) CASE WESTERN RESERVE UNIVERSITY			07775	0407		_		
10900 EUCLID AVE			3c. DUNS: 07775	8407		FEB O	1 2010	
CLEVELAND, OH 44106-4919			4. ENTITY IDENTIF 1341018992		NUMBER			
6. HUMAN SUBJECT	S No No	ſes	5. NAME, TITLE AN	D ADDRE	ESS OF ALIMI	NISTRATIVE OFF	ICIAL	
6a. Research Exempt	If Exempt ("Yes" in 6a):	If Not Exempt ("No" in 6a):						
No 🗌 Yes	Director of Research Accounting and Forecasting, School of Medicine,							
		multiple	Case Mestern [Dacania	a l Iniversit	··· <i>›</i>		
6b. Federal Wide Ass	urance No. FWA00	004428	Tel: 216-368-44	32	Fax:	216-386-092	9	
6c. NIH-Defined Phase Clinical Trial			E-MAIL: MEDRES	-				
7. VERTEBRATE AN	IMALS 🖾 NO 🗌	Yes	10. PROJECT/PERF					
7a. If "Yes," IACUC a	pproval Date		Organizational Name: Case Western Reserve University					
7b. Animal Welfare As	surance No.		DUNS: 07775840	07				
8. COSTS REQUES	TED FOR NEXT BUDG	ET PERIOD	Street 1: 10900 Euclid Ave, Cleveland, Ohio 44106-4919					
8a. DIRECT \$	86. TOTAL	. \$	Street 2:					
9. INVENTIONS AND	PATENTS No	Yes	City: Cleveland		Cou	nty: Cuyahoga	а	
If "Yes, 🗌 Previou	usly Reported		State: OH		E: D	vinne.		
Not Pre	eviously Reported		Country: USA		Zip/I	Zip/Postal Code: 44106		
			Congressional Distric	ts:	I			
	E OF OFFICIAL SIGNIN Director of Rese		•		ol of Media	cine		
TEL: 216-368-44	32	FAX: 216-368	-0929		E-MAIL: me	dres@case.e	du	
12. Corrections to Pag	le 1 Face Page		<u></u>					
statements herein are obligation to comply v result of this application	ANIZATION CERTIFIC e true, complete and accur with Public Health Services on. I am aware that any fe iminal, civil, or administrati	ate to the best of my know terms and conditions if a ilse, fictitious, or fraudulent	ledge, and accept the 1 grant is awarded as a	SIGNATUR			DATE 1/29/20/C	
PHS 2590 (Rev. 06/09)			Face Page		/		Form Page 1	

Pages 3 through 13 redacted for the following reasons: Not responsive

Program Director/Principal Investigator (Las	t, First, Middle):	^{e):} Walsh, Michele C			
		GRANT NUMBER			
PROGRESS REPORT SUMMA	ARY	HD-21364-25			
		PERIOD COVERED BY TH	IIS REPORT		
PROGRAM DIRECTOR / PRINCIPAL INVESTIGA	ATOR	FROM	THRO	JGH	
Michele C. Walsh		April 1, 2010	March	n 30, 2010	
APPLICANT ORGANIZATION		- I ,			
Case Western Reserve University					
TITLE OF PROJECT (Repeat title shown in Item 1 NICHD Cooperative Multicenter Neonata A. Human Subjects (Complete Item 6 on the Face Pa	Research I				
Involvement of Human Subjects	No Chang	e Since Previous Submission		Change	
B. Vertebrate Animals (Complete Item 7 on the Face	Page)				
Use of Vertebrate Animals	No Chang	e Since Previous Submission		Change	
C. Select Agent Research	No Chang	e Since Previous Submission		Change	
D. Multiple PD/PI Leadership Plan	No Chang	e Since Previous Submission		Change	
E. Human Embryonic Stem Cell Line(s) Used	No Chang	e Since Previous Submission		Change	
SEE PHS 2590 INSTRUCTIONS.					

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Tables indicating the enrollment in each trial at the CWRU site in the current period are attached.

Progress Report:

Intervention Trials:

1. <u>SUPPORT trial</u>: This factorial trial of two interventions (oxygen saturation in two different ranges; and early use of CPAP in the delivery room vs. intubation for surfactant) completed enrollment in 2009. The primary manuscript was written and submitted to New England Journal of Medicine. CWRU has enrolled 107 (8.1%) of the 1316 patients. In addition, we participated in 4 secondary studies to the main trial including: a. desaturation secondary largely conducted only at CWRU that evaluates the impact of the oxygen saturation intervention on the frequency and intensity of desaturations; b. MRI secondary: that evaluates the impact of the oxygen saturation intervention on MRI findings at 36 weeks corrected age; c. Growth secondary: evaluates the impact of the oxygen saturation interventions on growth at 36 weeks.; d. Pulmonary outcomes secondary: evaluates the impact of the interventions on pulmonary symptoms at 6, 9, 12 and 18 months of age. Two year follow-up will continue until 2011. Developmental and Pulmonary evaluations at 6-7 years of age have been proposed.

Pages 16 through 33 redacted for the following reasons:

Site IRB Information

Center	Center Name	Protocol	IRB Number:	Participating:	IRB Date	Expiration Date	Copy of Consent	Certificate or Waiver	Certificate/ Waiver Date
Center 03	Case Western Reserve University	Protocol Not responsive	Number:	Participating:	Date	Date	Consent	or Waiver	Waiver Date
		SUPPORT SUPPORT-Breathing Outcomes SUPPORT-Growth SUPPORT-Neuroimaging		Y Y Y Y	10/02/2008 05/11/2008 05/11/2006 05/11/2006	09/22/2009 12/05/2006 12/05/2006 12/05/2006	Y Y Y Y		

Pages 35 through 42 redacted for the following reasons: Not responsive Progress Report Scanning Cover Sheet

5U10HD021373-23

PI Name:TYSON, JONOrg:UNIVERSITY OF TEXAS HLTH SCI CTR
HOUSTONStart Date:04/01/2007Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7219993Rec'd
Date:02/05/2007

Form Approved Through 09/50/2007	OMB N8. 0925-0001
Department of Health and Human Services Public Health Services	Review Group Type Activity Grant Number ZHD1DSRA10 2 J10 2 U10 HD021373-23
	Total Project Period
	From: 07/17/1998 Through: 03/ 31/2011
Grant Progress Report	Requested Budget Period
	From: 04/01/2007 Through: 03/31/2008
1. TITLE OF PROJECT	
Multicenter Network of Neonatal Intensive	Care Units
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code) Jon E. Tyson MD,MPH Univ of Texas Health Science Center Center for Clinical Research & EBM PO Box 20708, MSB 2.106 Houston, TX 77030	 APPLICANT ORGANIZATION (Name and address, street, city, state, zip code) The University of Texas Health Science Center at Houston PO box 20036 Houston, TX 77225-0036
2b. E-MAIL ADDRESS Kathleen.A.Kennedy@uth.tmc.edu	4. ENTITY IDENTIFICATION NUMBER 1741761309A3
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVAL Center for Clinical Research & EBM 2d. MAJOR SUBDIVISION	LENT 5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL Grants Director, Office of Sponsored Projects The University of Texas Health Science Cnt at Houston PO Box 20036
Medical School	Houston, TX 77225-0036 E-MAIL: osp@uth.tmc.edu
6. HUMAN SUBJECTS	7. VERTEBRATE ANIMALS
No6a. Research Exempt6b. Human Subjects AssuYesNoYesFWA0667	urance No. No 7a. If "Yes," IACUC approval Date
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III	7b. Animal Welfare Assurance No.
	Yes A 3413-01
If Not Exempt ("No" in 6a): IRB approval date various	
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVENTIONS AND PATENTS
8a. DIRECT \$172,190 8b. TOTAL \$255,702	No Yes If "Yes," Previously Reported
10. PERFORMANCE SITE(S) (Organizations and addresses)	11a. PRINCIPAL INVESTIGATOR TEL 713-500-5651 OR PROGRAM DIRECTOR (<i>Item 2a</i>)
UT- Medical School	Jon E. Tyson FAX 713-500-0519
6431 Fannin Street	11b. ADMINISTRATIVE OFFICIAL TEL 713-500-3999
Houston, TX 77030	NAME (Item 5) Catherine Moore FAX 713-500-0355
Children's Memorial Hermann Hospital	11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)
6411 Fannin Street	NAME Catherine Moore
Houston, TX 77030	TITLE Grants Director
LBJ Hospital	
5656 Kelley Street	TEL 713-500-3999 FAX 713-500-0355
Houston, TX 77026	E-MAIL osp@uth.tmc.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICAT statements herein are true, complete and accurate obligation to comply with Public Health Services ter result of this application. I am aware that any false may subject me to criminal, civil, or administrative p	to the best of my knowledge, and accept the ms and conditions if a grant is awarded as a , fictitious, or fraudulent statements or claims	SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Per" signature not acceptable.)	DATE
PHS 2590 (Rev. 04/06)	Face Page 1		Form Page 1

The University of Texas - Houston CENTER Grant # 2 U10 HD021373-23 Principal Investigator: Jon E. Tyson, MD, MPH

Protocol #	Protocol Name	Approval Date	Expiration Date
Not responsive			
HSC-MS-04-415	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in	10/20/2006	9/30/2007
	Extremely Low Birth Weight Infants (SUPPORT TRIAL)	10,20,2000	0,00,200.
Not responsive			

Pages 4 through 15 redacted for the following reasons: Not responsive

Principal Investigator/Program Director (Last, First, Middle):	Tyson, Jon E.	
PROGRESS REPORT SUMMARY	GRANT NUMBER 2 U10 HD021373-23	
· · · · · · · · · · · · · · · · · · ·	PERIOD COVERED BY THIS RE	EPORT
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH
Jon E. Tyson, MD, MPH	04/01/2006	03/31/2007
APPLICANT ORGANIZATION The University of Texas Health Science Center at Hou TITLE OF PROJECT (Repeat title shown in Item 1 on first page) Multicenter Network of Neonatal Intensive Care Units	uston, Medical School	
B. Vertebrate Animals (Complete Item 7 on the Face Page)	Since Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS.		
WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Targeted/Planned Enrollment Format Page.	Inclusion Enrollment Report Format	t Page and, if necessary,

As indicated below, UT Houston continues to be a large Network Center whose faculty continue to be highly committed to helping the Network to be as productive as possible.

Patient Enrollment in Network Studies. As indicated in the December 31, 2006 Monthly Report, our center is consistently a high performer in enrollment in Network studies. Our rank among the 16 Centers for total number of infants enrolled in various studies in 2006 is shown below:

Not responsive

Support – 3

Faculty involvement and Leadership in Network Studies. To augment enthusiasm for the Network,

Not responsive

Pages 17 through 23 redacted for the following reasons: Not responsive

Neonatal Research Network 2006 Race/Gender Tables Ethnicity and Race Information (Support by Center)

Center: University of Texas - Houston

Table of Ethn	icity by Go	ender		
Ethnicity(Ethnic Category)				
Frequency	Male	Female	Total	
Hispanic or Latino	3	2	5	
Not Hispanic or Latino	11	11	22	
Total	14	13	27	

Table of Race by Gender							
Race(Race)	Gender)						
Frequency	Male	Female	Total				
Black	7	8	15				
White	7	5	12				
Total	14	13	27				

Table Race of Hispanic/Latino	Subjects	by Gend	er
Race for Hispanic/Latino Subjects Gender(Gend			
Frequency	Male	Female	Total
White	3	2	5
Total	3	2	5

Pages 25 through 49 redacted for the following reasons: Not responsive Progress Report Scanning Cover Sheet

5U10HD021373-24

PI Name:KENNEDY, KATHLEENOrg:UNIVERSITY OF TEXAS HLTH SCI CTR
HOUSTONStart Date:04/01/2008Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7391319Rec'd
Date:01/30/2008

Form Approved Throu	gh 11/30/2010					OMB No. 0925-000
Departmo	ent of Health and Huma Public Health Service		Review Group ZHD1DSRA10	Type 5	Activity U10	Grant Number 5 U10 HD021373-24
			Total Project Period			
Grant	Progress	Report	From: 07/17/1998 Through: 03/31/2011			
Orant	Togress	Report	Requested Budget P			
1. TITLE OF PROJE	<u>ст</u>		From: 04/01/2008	3	Thre	ough: 03/31/2009
NICHD Coop	erative Multicente	er Neonatal Rese				
	CTOR / PRINCIPAL IN ss, street, city, state, zip		2b. E-MAIL ADDRES		Buth tmo	odu
	Kennedy MD, MPH		Kathlen.A.Ke	• •	-	.eau DRY, OR EQUIVALENT
	ealth Science Ce					I Research & EBM
Center for Clinical Research & EBM		2d. MAJOR SUBDIVI	SION			
	6431 Fannin St, MSB # 2.106 Houston, TX 77030		Medical Scho	loc		
			2e. Tel: 713-500-	5651	Fax	c 713-500-0519
	a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)			-3999	Fax	c 713-500-0355
The University of Texas Health Science Center at Houston P O Box 20036 Houston, TX 77225-0036		3c. duns: 80077	1594		SAN 3 0 2008	
		4. ENTITY IDENTIF 1741761309/		NUMBER		
6. HUMAN SUBJECTS 🗌 No 🛛 Yes			5. NAME, TITLE AN	D ADDRE	SS OF ADM	INISTRATIVE OFFICIAL
6a. Research Exempt 🔀 No 🗌 Yes	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date Various	Johnna K. Kincaid, Exec Dir Sponsored Projects Adm The Univ of TX Health Science Center at Houston P O Box 20036 Houston,TX 77225-0036			
6b. Federal Wide Ass	urance No. FWA-0	 667	тек 713-500-39			c 713-500-0355
6c. NIH-Defined Phase Clinical Trial	e		E-MAIL: osp@uth			
7. VERTEBRATE AN		Yes	10. PROJECT/PERF	ORMANCI	E SITE(S)	•·····
7a. If "Yes," IACUC a	pproval Date		Organizational Name: University of Texas Health Sc Center Houston Medical School DUNS: 800771594			
7b. Animal Welfare As						······································
	TED FOR NEXT BUDG		Street 1: 6431 Fannin St			
8a. DIRECT \$171,9	89 8b. TOTAI	∟\$255,404	Street 2:			······································
9. INVENTIONS AND	PATENTS No	Yes	city: Houston		Cou	unty: Harris
	usly Reported		State: TX		Pro	ovince:
Not Pre	eviously Reported		Country: USA		Zip	/Postal Code: 77030
			Congressional Distric	ts: 25	l	
		NG FOR APPLICANT C		13)		
TEL: 713-500-39	99	FAX: 713-500-	-0355	I	E-MAIL: OS	p@uth.tmc.edu
12. Corrections to Pag	je 1 Face Page	<u></u>	<u>,</u>			<u>.</u>
statements herein are obligation to comply result of this applicati may subject me to cri	e true, complete and accur with Public Health Services ion. I am aware that any fa iminal, civil, or administrati		ledge, and accept the grant is awarded as a t statements or claims	SIGNATUR		CIAL NAMED IN Kincaid
PHS 2590 (Rev. 11/07)		Face Page 1	J		

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Page 3 redacted for the following reason: Not responsive

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	<u>APPROVED</u> <u>THROUGH</u>
Not responsive			
			-

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Vot responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	HSC-MS-04-415	9/21/07	8/31/08
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	HSC-MS-04-415	9/28/07	8/31/08
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	HSC-MS-04-415	9/28/07	8/31/08
Breathing Outcomes (SUPPORT Study Secondary)	HSC-MS-04-415	9/28/07	8/31/08
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	HSC-MS-04-415	9/28/07	8/31/08

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PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

*** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.

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Pages 7 through 9 redacted for the following reasons: Not responsive

		Renneuy, Rauneen /	٦.		
		GRANT NUMBER			
PROGRESS REPORT SL	IMMARY	5 U10 HD021373-23	3		
		PERIOD COVERED BY	THIS REPORT	<u></u>	
PROGRAM DIRECTOR / PRINCIPAL INVE	STIGATOR	FROM	THROL	JGH	
Kathleen A. Kennedy MD,MPH		4/01/2007	3/31/2	800	
APPLICANT ORGANIZATION	·				
The University of Texas Health Scie	nce Center at	Houston Medical School			
TITLE OF PROJECT (Repeat title shown in	Item 1 on first pa	ge)			
NICHD Cooperative Multicenter New	onatal Researc	ch Network			
A. Human Subjects (Complete Item 6 on the	e Face Page)		-	·····	
Involvement of Human Subjects	No Cr	ange Since Previous Submission		Change	
B. Vertebrate Animals (Complete Item 7 on	the Face Page)				
Use of Vertebrate Animals	No Cr	ange Since Previous Submission		Change	
C. Select Agent Research	No Cr	ange Since Previous Submission		Change	
D. Multiple PI Leadership Plan	No Cr	ange Since Previous Submission		Change	

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

As detailed below, UT-Houston continues to contribute a large number of subjects to Network studies while having faculty who are committed and productive in helping the Network achieve its goals:

Patient Enrollment in Network Studies: As indicated in the November 30, 2007 Monthly Report, our center is consistently a high performer in enrollment in Network studies. Our rank among the 16 Centers for total number of infants enrolled in various studies in 2007 is shown below:

SUPPORT - 5

Faculty involvement and Leadership in Network Studies: To maximize enthusiasm and contributions Not respo

Pages 11 through 21 redacted for the following reasons: Not responsive

Neonatal Research Network 2007 Race/Gender Tables (randomized 1/1-11/30) Support Protocol University of Tex-Houston

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Table of ethnic	by gend	er	
ethnic	gend	er	
Frequency	Female	Male	Total
Hispanic or Latino	1	3	4
Not Hispanic or Latino	4	6	10
Total	5	9	14

Table of race by gender						
race	gend	er				
Frequency	Female	Male	Total			
Black	3	5	8			
White	2	4	6			
Total	5	9	14			

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Pages 23 through 26 redacted for the following reasons: Not responsive Progress Report Scanning Cover Sheet

5U10HD021373-25

PI Name:KENNEDY, KATHLEENOrg:UNIVERSITY OF TEXAS HLTH SCI CTR
HOUSTONStart Date:04/01/2009Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7610888Rec'd
Date:01/30/2009

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For

Department of Health and Human Services Public Health Services			Review Group ZHD1DSRA10	Type 5	Activity U10	Grant Number 5 U10 HD021373-25
Grant Progress Report		Total Project Period From: 07/17/199 Requested Budget F		Thro	ugh: 03/31/2011	
			From: 04/01/200		Thro	ough: 03/31/2010
1. TITLE OF PROJE		er Neonatal Rese	arch Network			
(Name and address, street, city, state, zip code)			2b. E-MAIL ADDRES Kathleen.A.K 2c. DEPARTMENT, S Pediatrics - C	Cennedy SERVICE, Center fo	LABORATO	c.edu RY, OR EQUIVALENT Research & EBM
6431 Fannin Houston, TX	St, MSB <mark># 2</mark> .106 77030		2d. MAJOR SUBDIVI Medical Scho	loc		•
·····		•	2e. Tel: 713-500-	····		713-500-0519
3a. APPLICANT ORG (Name and address	ANIZATION s, street, city, state, zip	code)	3b. Tel: 713-500-	-3999	Fax	713-500-0355
The University of Texas Health Science Center at Houston			3c. DUNS: 80077	1594		JAN 3 0 2009
P O Box 20036 Houston, TX 77225-0036			4. ENTITY IDENTIF 1741761309		NUMBER	
6. HUMAN SUBJECTS No Yes			5. NAME, TITLE AN	ID ADDRE	SS OF ADMI	NISTRATIVE OFFICIAL
6a. Research Exempt No Yes	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date Various	Jodi Ogden, The Univ of T P O Box 200 Houston, TX	Г <mark>exas</mark> H 36	lealth Scie	or ence Center at Houston
6b. Federal Wide Ass	urance No. FWA-0	667	Tel: 713-500-39	99	Fax	x:713-500-0355
6c. NIH-Defined Phase Clinical Trial 🔲 N			E-MAIL: osp@uth	n.tmc.ed	lu	
7. VERTEBRATE AN	IMALS 🛛 NO	Yes	10. PROJECT/PERF	ORMANCE	E SITE(S)	· · · · · · · · · · · · · · · · · · ·
7a. If "Yes," IACUC a	pproval Date		Organizational Name: Univ of Texas Health Sc Ctr Medical School			
7b. Animal Welfare As	surance No.		DUNS: 800771594			
8. COSTS REQUES	TED FOR NEXT BUDG	GET PERIOD	Street 1: 6431 Fannin St			
8a. DIRECT \$170,64	46 86. ТОТА	L \$253,409	Street 2:		********	
9. INVENTIONS AND		Yes	city: Houston		Cou	nty: Harris
	usly Reported		State: TX		Prov	vince:
🔛 Not Pre	eviously Reported		Country: USA		Zip/	Postal Code: 77030
		a.	Congressional Distric	ts: 25	·	
		NG FOR APPLICANT C or, Office of Spons	•	13)		
TEL: 713-500-39	99	FAX: 713-500-	0355	 E	E-MAIL: OSP	o@uth.tmc.edu
12. Corrections to Pag	le 1 Face Page					
		ATION AND ACCEPTA		SIGNATUF		IAL NAMED IN DATE

obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. Face Page

PHS	2590 ((Rev. 11/07)

Pages 3 through 7 redacted for the following reasons: Not responsive Program Director/Principal Investigator (Last, First, Middle):

Kennedy, Kathleen A.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD021373-24			
	PERIOD COVERED B	Y THIS REPORT		
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	FROM	THROUGH		
Kathleen A. Kennedy MD,MPH	4/01/2008	3/31/2009		
	······································			

APPLICANT ORGANIZATION

The University of Texas Health Science Center at Houston Medical School

TITLE OF PROJECT (Repeat title shown in Item 1 on first page) NICHD Cooperative Multicenter Neonatal Research Network

Α.	Human Subjects (Complete Item 6 on the Face	Page)	
	Involvement of Human Subjects	\boxtimes	No Change Since Previous Submission	Change
В.	Vertebrate Animals (Complete Item 7 on the Fa	ace Pa	ge)	
	Use of Vertebrate Animals	\boxtimes	No Change Since Previous Submission	Change
C.	Select Agent Research	\boxtimes	No Change Since Previous Submission	Change
D.	Multiple PI Leadership Plan	\boxtimes	No Change Since Previous Submission	Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

As detailed below, UT-Houston continues to contribute a large number of subjects to Network studies while having faculty who are committed and productive in helping the Network achieve its goals:

Patient Enrollment in Network Studies:As detailed in the December 31, 2008 Monthly Report, our centeris consistently a solid performer in enrollment in Network studies.Our rank among the participating NetworkNot responsivearious studies in 2008 is shown below:

SUPPORT ~ 10" of 17 (6" of 17 for enrollment to date)

Faculty Involvement and Leadership in Network Studies: To maximize enthusiasm and contributions

Not responsive

Pages 9 through 11 redacted for the following reasons: Not responsive

UT-Houston NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
SUPPORT Study with MRI, Breathing Outcomes, Postnatal Growth & Antenatal screening	HSC-MS-04-415	8/20/08	7/31/09
Not responsive			

Pages 13 through 39 redacted for the following reasons: Not responsive



Inclusion Enrollment Report for the Support Study for Center 18

Categories	Females.	Males	Unknown	total
Ethnic - Hisp or Latino	13	19	0	32
Ethnic - Not Hisp or Latino	19	19	0	38
Ethnic - Unknown	0	0	0	0
Ethnicity: Total of All Subjects	32	38	0	70
Amer Indian/Alaska	0	0	0	0
Asia	2	1	0	3
Hawaiian or Other Pacific	0	0	0	0
Black or African Amer	10	12	0	22
White	20	24	0	44
More than One	0	1	0	1
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of all	32	38	0	70
Hispanic: Amer Indian/Alaska	0	0	0	0
Hispanic: Asia	0	0	0	0
Hispanic: Hawaiian or Other Pacific	0	0	0	0
Hispanic: Black or African Amer	0	1	0	1
Hispanic: White	13	18	0	31
Hispanic: More than One	0	0	0	0
Hispanic: Unknown or Not Reported	0	0	0	0
Hispanic: Racial Categories: Total of al	13	19	0	32

Pages 41 through 44 redacted for the following reasons: Not responsive

5U10HD021373-26

PI Name:KENNEDY, KATHLEENOrg:UNIVERSITY OF TEXAS HLTH SCI CTR
HOUSTONStart Date:04/01/2010Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7798560Rec'd
Date:02/01/2010

Form Approved Throu	igh 06/30/2012						lo. 0925-0001	
Departm	ent of Health and Hum Public Health Service		Review Group ZHD1DSRA10	Type 5	Activity U10	Grant Number 5 U10 HD021373	9-26	
			Total Project Period					
Grant	Drograce	Donort	From: 07/17/1998 Through: 03/31/2011					
Gran	Progress	Report	Requested Budget Period					
		·····	From: 04/01/201	0	Thr	ough: 03/31/2011		
1. TITLE OF PROJE NICHD Coop		er Neonatal Rese	arch Network					
	CTOR / PRINCIPAL IN		2b. E-MAIL ADDRES	-				
(Name and address, street, city, state, zip code) Kathleen A. Kennedy MD, MPH		Kathleen.A.K			C.EDU RY, OR EQUIVALENT			
	ealth Science Ce					I Research & EBI	М	
	nical Research 8	EBM	2d. MAJOR SUBDIV					
	St, MSB # 2.106		Medical Scho					
Houston, TX	77030		2e. Tel: 713-500-	5651	Fax	c 713-500-0519		
3a. APPLICANT ORG			зь. теl: 713-500-					
(Name and address, street, city, state, zip code) The University of Texas Health Science at Houston P.O. Box 20036		3b. Tel: 713-300-	-2888	Fax	c 713-500-0355			
		3c. DUNS: 80077	1594			-17		
						FEB		
		4. ENTITY IDENTIF		NUMBER		•		
	<u> </u>		1 741761309					
6. HUMAN SUBJECT			1				2010	
Exempt	6a. ResearchIf Exempt ("Yes" in 6a):If Not Exempt ("No" in 6a):		Whitney C. H P O Box 200		n, Grants I	Director	0	
🛛 No 🗌 Yes	Exemption No.	IRB approval date	Houston, TX		-0036			
		L						
6b. Federal Wide Ass	urance No. FWA-0	667	Tel: 713-500-39	99	Fax	c 713-500-0355		
6c. NIH-Defined Phase Clinical Trial N			E-MAIL: OSP@uth	n.tmc.e	du			
7. VERTEBRATE AN	IMALS 🛛 NO	Yes	10. PROJECT/PERF	ORMAN	CE SITE(S)			
7a. If "Yes," IACUC a	pproval Date		-	Univ	of Texas I	Health Sc Ctr Med	dical	
			School	04				
7b. Animal Welfare As			DUNS: 800771594					
	TED FOR NEXT BUDG		Street 1: 6431 Fannis Street					
8a. DIRECT \$175,6		\$260,808	Street 2:					
9. INVENTIONS AND	PATENTS 🛛 No	Yes	city: Houston		Co	unty: Harris		
	usly Reported		State: Texas		Pro	ovince:		
Not Previously Reported		Country: USA		Zip	/Postal Code: 77030			
		Congressional Districts: 9						
11. NAME AND TITLE	E OF OFFICIAL SIGNI	NG FOR APPLICANT C	RGANIZATION (Item	13)			· = =,	
Whitney Housto	n, Grants Directo	r						
TEL: 713-500-39	99	FAX: 713-500-	-0355		E-MAIL: OS	p@uth.tmc.edu		
12. Corrections to Pag	je 1 Face Page							
					^			
		ATION AND ACCEPTA		SIGNAT			TE	
obligation to comply v	with Public Health Services	ate to the best of my knowl s terms and conditions if a g	grant is awarded as a		^w]- 	/		
	ion. I am aware that any fa iminal, civil, or administrati	alse, fictitious, or fraudulent ve penalties.	statements or claims		Wall	(Howsty (-27-10	
PHS 2590 (Rev. 06/09			Face Page	V			Form Page 1	
					1			

Pages 3 through 6 redacted for the following reasons: Not responsive

	GRANT NUMBER 5 U10 HD021373-25				
	PERIOD COVERED BY THIS REPORT				
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	FROM	THROUGH			
Kathleen A. Kennedy MD,MPH	4/01/2009	3/31/2010			

APPLICANT ORGANIZATION

The University of Texas Health Science Center at Houston Medical School

TITLE OF PROJECT (Repeat title shown in Item 1 on first page) NICHD Cooperative Multicenter Neonatal Research Network

Α.	Human Subjects (Complete Item 6 on the Face	e Page)		·	
	Involvement of Human Subjects	N 🛛	o Change Since Previous Submission		Change
Β.	Vertebrate Animals (Complete Item 7 on the Fa	ace Page)		
	Use of Vertebrate Animals	N 🛛	lo Change Since Previous Submission		Change
C.	Select Agent Research	N 🛛	o Change Since Previous Submission		Change
D.	Multiple PI Leadership Plan	N 🛛	lo Change Since Previous Submission		Change
E	Human Embryonic Stem Cell Line(s) Used	N	o Change Since Previous Submission		Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

As detailed below, UT-Houston continues to contribute a large number of subjects to Network studies while having multiple faculty who are committed to helping the Network achieve its goals:

Patient Enrollment in Network Studies: As detailed in the December 31, 2009 Monthly Report, our center remains a solid performer in enrollment in Network studies. Our rank among the participating Network Centers for number of infants enrolled in various studies in 2009 is shown below: Not responsive

SUPPORT – 6th of 20

Faculty Involvement and Leadership in Network Studies: To maximize enthusiasm and contributions from

Pages 8 through 16 redacted for the following reasons: Not responsive

Categories	Females	Males	Unknown	total
Ethnic - Hisp or Latino	0	0	0	0
Ethnic - Not Hisp or Latino	2	2	0	4
Ethnic - Unknown	0	0	0	0
Ethnicity: Total of All Subjects	2	2	0	4
Amer Indian/Alaska	0	0	0	0
Asia	0	0	0	0
Hawaiian or Other Pacific	0	0	0	0
Black or African Amer	1	1	0	2
White	1	1	0	2
More than One	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of all	2	2	0	4
Hispanic: Amer Indian/Alaska	0	0	0	0
Hispanic: Asia	0	0	0	0
Hispanic: Hawaiian or Other Pacific	0	0	0	0
Hispanic: Black or African Amer	0	0	0	0
Hispanic: White	0	0	0	0
Hispanic: More than One	0	0	0	0
Hispanic: Unknown or Not Reported	0	0	0	0
Hispanic: Racial Categories: Total of al	0	0	0	0

Inclusion Enrollment Report for the Support Study for Center 18

•

Pages 18 through 19 redacted for the following reasons: Not responsive

UT-Houston NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED <u>THROUGH</u>
Not responsive			
SUPPORT Study with MPL Broathing Outcomes			
SUPPORT Study with MRI, Breathing Outcomes, Postnatal Growth & Antenatal screening	HSC-MS-04-415	7/15/09	6/30/10

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. *

Pages 21 through 54 redacted for the following reasons: Not responsive Progress Report Scanning Cover Sheet

5U10HD021385-20

PI Name: Org: Start Date: Snap: Appl ID: Rec'd Date: SHANKARAN, SEETHA WAYNE STATE UNIVERSITY 04/01/2005 N/A (NEEDS TO BE BOOKMARKED) 6926081 02/03/2005

Form Approved Through 09/30/200	70			2			OMB No. 0925-00
	th and Human Services alth Services		Review Group	5	Activity U10	Grant Number HD021385-	20
		Ē	Total Project Per	iod			
Grant Proc	ress Report		From: 04/01/1		Th	rough: 03/31/2(006
Oranterrog			Requested Budg				
1. TITLE OF PROJECT	· · · · · · · · · · · · · · · · · · ·		From: 04/01/2	2005	Th	rough: 03/31/2(006
	er Network of Neonatal Ir	ntens	sive Care Ur	nits			
2a. PRINCIPAL INVESTIGATOR ((Name and address, street, city SHANKARAN, SEETH	DR PROGRAM DIRECTOR /, state, zip code)	3. A (N	APPLICANT ORC Name and addres	GANIZATI	city, state, z		B
CHILDREN'S HOSPIT	-	S	ponsored P	rogram	Administ	tration	
DEPARTMENT OF PE	DIATRICS		56 W. KIRB	•	m 4002		u
3901 BEAUBIEN			ETROIT, M	48202			t ->
DETROIT, MI 48201		_	·····				72
2b. E-MAIL ADDRESS sshankar@med.wayne.e	.du		ENTITY IDENTIF		NUMBER		α
2c. DEPARTMENT, SERVICE, LA							
PEDIATRICS			IRECTOR,				7
2d. MAJOR SUBDIVISION							d Prog. Admir
SCHOOL OF MEDICI	NE	5	40 E. CANF	IELD, #	#1128, DI	ETROIT, MI	48201
		E-M/	AIL: orspsma	ail@way	ne.edu		
6. HUMAN SUBJECTS			7 VERTEBRAT	E ANIMA	LS	·	
No 6a. Research Exempt Yes No	6b. Human Subjects Assurance 00002460	No.	🛛 No 🗌 Yes		7	a. If "Yes," IACU	JC approval Date
If Exempt ("Yes" in 6a):	6c. NIH-Defined Phase III		7b. Animal Welf	are Assura	ance No.		
Exemption No.	Clinical Trial 🗌 No 🗌 Yes						
If Not Exempt ("No" in 6a): IRB approval date 01/13/20	005 - Expedited Revie	w					
8. COSTS REQUESTED FOR N			VENTIONS AN	D PATEN	тs		
8a. DIRECT \$163,974	8b. TOTAL \$244,321	\boxtimes	No 🗌 Yes	lf "Yes,"		iously Reported	
				(FOTION	····	Previously Report	
10. PERFORMANCE SITE(S) (On CHILDREN'S HOSPIT			PRINCIPAL IN PROGRAM DIRE		em 2a)		
3901 BEAUBIEN	بە بە				FAX	-	
DETROIT, MI 48201			ADMINISTRATI IE (Item 5)	VE OFFIC		L _ 313-577-1	445
·					FAX	x 313-577-1	348
HUTZEL HOSPITAL 3980 JOHN R	SINAI-GRACE HOSP. 6071 W. OUTER DR.	11c.	NAME AND TIT ORGANIZATIO			SNING FOR APPL	ICANT
DETROIT, MI 48201	DETROIT, MI 48238	NAM	^{IE} Michael	Anders	son		
•		TITL	.E Grant ar	nd Cont	tract Offic	cer III	
		TEL	313-577-	1445		FAX 313-577	/-1348
		E-M	AIL manders	so@me	ed.wayne	edu	
12. Corrections to Page 1 Face Pa	age	_ I					

statements any false, fi administrati	AL INVESTIGATOR/PROGRAM DIRECTOR ASSU herein are true, complete and accurate to the best of my k ictitious, or fraudulent statements or claims may subject me ive penalties. I agree to accept responsibility for the scient ide the required progress reports if a grant is awarded as a	nowledge. I am aware that to criminal, civil, or ific conduct of the project		DATE 1/28/0	75
statements obligation to result of this	NT ORGANIZATION CERTIFICATION AND ACCE herein are true, complete and accurate to the best of my k o comply with Public Health Services terms and conditions s application. I am aware that any false, fictitious, or fraudu t me to criminal, civil, or administrative penalties.	nowledge, and accept the	SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Reg" signature not acceptable.)	DATE DATE [0]	05
PHS 2590 (Re	v 09/04)	Face Page		Form Pag	ge 1

Pages 3 through 11 redacted for the following reasons: Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD2138520				
	PERIOD COVERED BY TH	IS REPORT			
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Seetha Shankaran, MD	FROM 04/01/04	THROUGH 03/31/05			
APPLICANT ORGANIZATION Wayne State University					
TITLE OF PROJECT (Repeat title shown in Item 1 on first pag Cooperative Multicenter Network of Neonatal Intens	•				
A. Human Subjects (Complete Item 6 on the Face Page)					
Involvement of Human Subjects 🛛 🛛 No Cha	nge Since Previous Submission	Change			
B. Vertebrate Animals (Complete Item 7 on the Face Page)	-	<u> </u>			
	nge Since Previous Submission				

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The Wayne State University site has been a member of the NICHD Neonatal Research Network since establishment of the Network in 1986.

Not responsive. Not related to SUPPORT.

Pages 13 through 20 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT

Total Planned Enrollment: 28

Ethnic October		Sex/Gender	· · ·
Ethnic Category	Females	Males	Total
Hispanic or Latino			· .
Not Hispanic or Latino	14	14	28
Ethnic Category: Total of All Subjects *			28
Racial Categories		· · ·	
American Indian/Alaska Native			
Asian			ann ann an 2014
Native Hawaiian or Other Pacific Islander			
Black or African American	12	12	24
White	2	2	4
Racial Categories: Total of All Subjects *	· ·	· · · · ·	28

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 22 through 33 redacted for the following reasons: Not responsive. Not related to SUPPORT.

NICHD NEONATAL RESEARCH NETWORK PROTOCOLS & APPROVAL DATES

Title	Approval Date(s)
Not responsive. Not related to SUPPORT.	
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely	
Low Birth Weight Infants	IRB approval pending

Progress Report Scanning Cover Sheet

5U10HD021385-22

PI Name:	SHANKARAN, SEETHA
Org:	WAYNE STATE UNIVERSITY
Start Date:	04/01/2007
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	7219989
Rec'd Date:	02/07/2007

Form Approved Through 09/30/2007				OMB No. 0925-000		
Department of Health and Human Services Public Health Services	Review Group	D Type	Activity U10	Grant Number HD021385 - 22		
	Total Project Period					
Creat Drawness Demart	From: 04/01/1991 Through: 03/31/2011					
Grant Progress Report	Requested Bu	udget Period				
	From: 04/0	1/07	т	Through: 03/31/08		
1. TITLE OF PROJECT				inolgi. Coro noc		
NICHD Cooperative Multicenter Neonatal Res	search Netwo	ork				
 2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code) Seetha Shankaran, M.D. Division of Neonatal/Perinatal Medicine 3901 Beaubien Blvd Detroit, MI 48201. 	Wayne S 5057 Wo	address, stre State Univ	et, city, state, rersity Suite 1302			
2b. E-MAIL ADDRESS sshankar @med.wayne.edu	4. ENTITY ID 13860284		ON NUMBER	2.1		
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT				TRATIVE OFFICIAL		
Pediatrics			rd Service	S.		
2d. MAJOR SUBDIVISION		Antoine,				
Medicine	Detroit, MI 48201					
				6.75		
			ned.wayne.	edu		
6. HUMAN SUBJECTS	and the second second	EBRATE ANI	MALS			
No 6a. Research Exempt 6b. Human Subjects Assuranc Yes No Yes 00002460	e No. X No			7a. If "Yes," IACUC approval Date		
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III	7b. Anima	al Welfare As	surance No.	FEB 0 7 2007		
Exemption No. Clinical Trial 🛛 No 🗌 Y	res			FED 0 1 2001		
If Not Exempt ("No" in 6a): IRB approval date 1-23-07 X Expedited Revi	iew					
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVENTION	NS AND PAT	ENTS			
8a. DIRECT \$157,907 8b. TOTAL \$237,650	⊠ No 🛛	Yes If "Ye		eviously Reported t Previously Reported		
10. PERFORMANCE SITE(S) (Organizations and addresses)	11a. PRINCIP			EL (313) 745-1436		
Children's Hospital of Michigan	OR PROGRAM	VI DIRECTOR		AX (313) 745-5867		
Detroit, MI 48201	11b. ADMINIS	TRATIVE OF	TI OLA	EL (313) 577-1445		
Hutzel Hospital	NAME (Item 5)	11			
Detroit, MI 48201	Carole Bach FAX (313) 577-1348					
Detroit, Wi 40201	11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT					
	Contraction of the second	ZATION (Ite				
	Michael Anderson					
	TITLE C.			TATA T		
	TEL (31:	3) 577-955		FAX (313) 577-1348		

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	02/05/07
	-

Form Page 1

Pages 3 through 4 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle):		Shankaran, Seetha			
PROGRESS REPORT SUMMARY		GRANT NUMBER HD021385			
	2001	PERIOD COVERED BY THIS REPORT			
PRINCIPAL INVESTIGATOR OR PROGRA	M DIRECTOR	FROM	THROUGH		
Seetha Shankaran, M.D.		4-1-07	3-31-08		
APPLICANT ORGANIZATION					
Wayne State University					
NICHD Research Network Study					
이는 그는 것은 것은 것을 알았는 것이다. 그는 것은 것을 많은 것을 가지 않는 것을 많이 하는 것이다.	Face Page)	e Since Previous Submission	Change		
A. Human Subjects (Complete Item 6 on the	Face Page)	e Since Previous Submission	Change		
A. Human Subjects (Complete Item 6 on the Involvement of Human Subjects	Face Page)	e Since Previous Submission e Since Previous Submission	Change		
Involvement of Human Subjects B. Vertebrate Animals (Complete Item 7 on 1	Face Page) No Change the Face Page) No Change				

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

lot responsive.	Not related to SUPPORT.	

SUPPORT Study

The SUPPORT study has enrolled 7 subjects for 2006. This is the most challenging study for the Wayne State University Network site. The Wayne State University PI has involved both Neonatal and Obstetric colleagues in discussions on the SUPPORT study and made presentations to the faculty in Obstetrics. In additon, reminders to the Neonatal faculty and fellows are presented every week. In October, 4 SUPPORT beepers were purchased and an on-call beeper system was instituted.

Principal Investigator/Program Director (Last, First, Middle): Shankaran, Seetha

In December, Dr. Beena Sood was designated as the SUPPORT Principal Investigator. The MRI Secondary study to evaluate MRI studies of neonates in the SUPPORT trial was not approved by the Wayne State University IRB as an amendment. Therefore, the protocol was resubmitted as a full protocol for review by the entire IRB. The Growth Secondary study was initiated with 8 patients that were enrolled. The antenatal screening and content study was also initiated as well as the Breathing Outcomes study.

Not responsive. Not related to SUPPORT.

Pages 7 through 15 redacted for the following reasons: Not responsive. Not related to SUPPORT. Principal Investigator/Program Director (Last, First, Middle):

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT

Total Planned Enrollment: 36

Ethnic Category	Sex/Gender				
Ethnic Category	Females	Males	Total		
Hispanic or Latino					
Not Hispanic or Latino	18	18	36		
Ethnic Category: Total of All Subjects *	18	18	36		
Racial Categories					
American Indian/Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American	12	12	24		
White	6	6	12		
Racial Categories: Total of All Subjects *	18	18	36		

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 17 through 22 redacted for the following reasons:

Principal Investigator/Program Director (Last, First, Middle): Shankaran, Seetha

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	SUPPORT Study		
Total Enrollment:	8	Protocol Number:	
Grant Number:	HD021385		

Ethnic Category	Sex/Gender					
	Females	Males	Unknown or Not Reported	Total		
Hispanic or Latino		·	1	**		
Not Hispanic or Latino						
Unknown (individuals not reporting ethnicity)						
Ethnic Category: Total of All Subjects*				*		
Racial Categories						
American Indian/Alaska Native						
Asian						
Native Hawaiian or Other Pacific Islander			· · · · · ·			
Black or African American	6	1	1	7		
White		1	1	1		
More Than One Race						
Unknown or Not Reported			1			
Racial Categories: Total of All Subjects*	6	2		8 *		

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	1		1 M N N	
Asian			1	
Native Hawaiian or Other Pacific Islander		-		
Black or African American				
White				
More Than One Race				
Unknown or Not Reported			91	
Racial Categories: Total of Hispanics or Latinos**				**

* These totals must agree.

** These totals must agree.

Page 24 redacted for the following reason: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD021385-23

PI Name:SHANKARAN, SEETHAOrg:WAYNE STATE UNIVERSITYStart Date:04/01/2008Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7414058Rec'd Date:02/13/2008

Form Approved Throug	gh 11/30/2010					OME	3 No. 092	25-0001
Departme	ent of Health and Huma Public Health Service		Review Group	Type 5	Activity U10	Grant Number HD021385	23	
			Total Project Period					
Grant	Progress	Ronart	From: 04/01/199		Thr	ough: 03/31/2011		
Grant	riogiess	Nepon	Requested Budget F	Period				
			From: 04/01/08		Thr	ough: 03/31/08		
1. TITLE OF PROJEC		er Neonatal Rese	arch Network					
2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)		2b. E-MAIL ADDRES			······································	<u></u>		
Seetha Shank			sshankar@rr 2c. DEPARTMENT, S					
	onatal/Perinatal	Medicine	Pediatrics	SERVICE,	LABORATC	DRY, OR EQUIVALE	{ 7	
Children's Ho	spital of Michiga	n	2d. MAJOR SUBDIVI	<u> CION</u>			<u></u>	
3901 Beaubie			Medicine	51014				
Detroit, MI 48	3201		2e. Tel: (313) 745	5-1436	Γ.e.	(313) 745 596	:7	
3a. APPLICANT ORGANIZATION						« (313) 745-586	·······	
	ANIZATION s, street, city, state, zip	code)	3b. Tel: (313) 57	7-2294	Fax	x: (313) 57 7- 505	5	2008 ored
Wayne State	-	,	3c. DUNS: 00-196	2 2 2 2 2 4		FE	R 12	2008
	ard, Suite 6402		3c. DUNS: 00-190	J-2224		f 100	***	
Detroit, MI 48	3202		4. ENTITY IDENTIF	ICATION I	NUMBER		······	<u></u>
			1-386-02-842	28-A1				
6. HUMAN SUBJECT	S No	Yes	5. NAME, TITLE AN	ID ADDRE	SS OF ADM	INISTRATIVE OFFIC	CIAL	
	If Exempt ("Yes" in	If Not Exempt ("No" in	Carole Bach	,Directo	r, Pre-Av	vard Services, S	Sponsc	ored
Exempt	6a): Exemption No.	6a): IRB approval date	Programs Ac			,	•	
			5057 Woodw	/ard, Su	ite 6402,	Detroit, MI 48	202	
6b. Federal Wide Ass	urance No. 000024	160	- Теl: (313) 577-2	294	Fa	x: (313) 577-505	55	
6c. NIH-Defined Phase			E-MAIL: Orspsma				-	
Clinical Trial 🛛 N			E-MAIL. Orspania	in wway	ne.euu			
7. VERTEBRATE AN	IMALS NO	Yes	10. PROJECT/PERF	ORMANCI	E SITE(S)			
7a. If "Yes," IACUC a	pproval Date		Organizational Name	: Childr	en's Hos	pital of Michiga	า	
7b. Animal Welfare As	surance No.		DUNS: 07-637-7	316		,		
8. COSTS REQUES	TED FOR NEXT BUDG	GET PERIOD	Street 1: 3901 B	eaubien	Blvd	<u></u>		
8a. DIRECT \$157,7	03 86. тота	L \$237,343	Street 2:		<u></u>			
9. INVENTIONS AND	PATENTS No	☐ Yes	city: Detroit		Co	unty: Wayne		<u></u>
	usly Reported		State: MI			ovince:		
	eviously Reported		Country: USA		Ziŗ	p/Postal Code: 482	01	. <u> </u>
			Congressional Distric	ots: 13	<u> </u>			
11 NAME AND TITL		NG FOR APPLICANT	DRGANIZATION (Iten	2 13)	·	······································	<u></u>	
	son, Grant and C							
TEL: (313) 577-9)554	fax: (313) 57	7-1348		E-MAIL: M	anderso@med.	wayne	3 2008 sored
12. Corrections to Pag	ge 1 Face Page							
			ANCE: Loodify that the	SIGNATI		ICIAL NAMED IN	DATE,	
statements herein ar	e true, complete and accu	CATION AND ACCEPT irate to the best of my know	wledge, and accept the	11. (In ink			021	1 ~
result of this applicat	tion, 1 am aware that any t	es terms and conditions if a false, fictitious, or frauduler	a grant is awarded as a nt statements or claims	minh	W) (log	MARKE	2_10	X/ 08
may subject me to c	riminal, civil, or administra	tive penalties.	Face Page				Form	Page 1
PHS 2590 (Rev. 11/07)							

Pages 3 through 4 redacted for the following reasons: Not responsive. Not related to SUPPORT. Shankaran, Seetha

		· · · · · · · · · · · · · · · · · · ·	
PROGRESS REPORT SU	MMARY	GRANT NUMBER HD 021385	
		PERIOD COVERED BY THI	SREPORT
PROGRAM DIRECTOR / PRINCIPAL INVES	STIGATOR	FROM	THROUGH
Seetha Shankaran, MD		4/1/08	3/31/09
APPLICANT ORGANIZATION Wayne State University		79 (1997 - C. 1997), 1997 - 19	
TITLE OF PROJECT (Repeat title shown in NICHD Neonatal Research Network		ge)	
A. Human Subjects (Complete Item 6 on the	Face Page)		
Involvement of Human Subjects	🔀 🛛 No Ch	ange Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on t	he Face Page)		
Use of Vertebrate Animals	🔀 🛛 No Ch	ange Since Previous Submission	Change
C. Select Agent Research	No Ch	ange Since Previous Submission	Change
D. Multiple PI Leadership Plan	No Ch	ange Since Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS			

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

See attached

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Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

<u>The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth</u> <u>Weight Infants (SUPPORT Study):</u>

During 2007 there was a tremendous increase in enrollment of the infants in the SUPPORT Study at the Wayne State University site. Dr. Beena Sood assumed responsibility as site Principal Investigator for the SUPPORT Study and the Co-Research Coordinator Betty Billian was also assigned responsibility for this study and all SUPPORT secondary studies. During 2006 seven subjects were enrolled in the study, in 2007 this number increased to 31. The increase in recruitment was due to the changes that were made to the screening and recruitment process and collaboration ensured of the Neonatology faculty and fellows. The overall recruitment goal of three subjects to be enrolled per month was met and exceeded following the second half of 2007.

Not responsive. Not related to SUPPORT.

Pages 8 through 18 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Protocol Number:

Study Title: SUPPORT Total Enrollment: 31

Grant Number:

HD021385

	by Ethnicity and Race Sex/Gender					
Ethnic Category	Females	Males	Unknown or Not Reported	Total		
Hispanic or Latino	1	0	0	1 *		
Not Hispanic or Latino	1	2	0	3		
Unknown (individuals not reporting ethnicity)	12	15	0	27		
Ethnic Category: Total of All Subjects*	14	17	0	31 *		
Racial Categories						
American Indian/Alaska Native	0	0	0	0		
Asian	0	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0	0		
Black or African American	11	17	0	28		
White	3	0	0	3		
More Than One Race	0	0	0	0		
Unknown or Not Reported	0	0	0	0		
Racial Categories: Total of All Subjects*	14	17	0	31 *		
PART B. HISPANIC ENROLLMENT REPORT: Numb	er of Hispanio	cs or Latinos	s Enrolled to Da	ite (Cumulative		
Racial Categories	Females	Males	Unknown or Not Reported	Total		
American Indian or Alaska Native	0	0	0	0		
Asian	0	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0	0		
Black or African American	0	0	0	0		
White	1	0	0	1		
More Than One Race	0	0	0	0		
		0	0	0		
Unknown or Not Reported	0	0	U	0		

* These totals must agree. ** These totals must agree. Pages 20 through 24 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT

Total Planned Enrollment: 36

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category		Sex/Gender			
	Females	Males	Total		
Hispanic or Latino	0	0	0		
Not Hispanic or Latino	18	18	36		
Ethnic Category: Total of All Subjects *	18	18	36		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	14	14	28		
White	4	4	8		
Racial Categories: Total of All Subjects *	18	18	36		

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 26 through 29 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes - secondary to SUPPORT

Total Planned Enroliment: 26

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category		Sex/Gender			
	Females	Males	Total		
Hispanic or Latino	2	1	3		
Not Hispanic or Latino	13	10	23		
Ethnic Category: Total of All Subjects *	15	11	26		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	11	9	20		
White	4	2	6		
Racial Categories: Total of All Subjects *	15	11	26		

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 31 through 35 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD021385-24

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PI Name:	SHANKARAN, SEETHA
Org:	WAYNE STATE UNIVERSITY
Start Date:	04/01/2009
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	7615668
Rec'd Date:	02/06/2009

Form Approved Through 11/30/2010				OMB No. 0925-0001
Department of Health and Human Services Public Health Services	Review Group	Туре	Activity U10	Grant Number HD021385 - 74
	Total Project Period	1		
Court Deserves Desert	From: 04/01/19	91	10.47	Fhrough: 3/31/2011
Grant Progress Report	Requested Budget	Period		
	From: 04/1/09		1	Fhrough: 03/31/10
1. TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Rsea				
2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	2b. E-MAIL ADDRE	SS		
(Name and address, street, city, state, zip code)	sshankar@		· · · · · · · · · · · · · · · · · · ·	
Seetha Shankaran, MD Division of Neonatal-Perinatal Medicine Children's Hospital of Michigan	2c. DEPARTMENT, Pediatrics	SERVICE	, LABORA	TORY OR EQUIVALENT
3901 Beaubien, 4 H 46 Detroit, MI. 48201	2d. MAJOR SUBDI Medicine	VISION		
	2e. Tel: 313 745	-1436		Fax: 313 745 -5867
3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)	3b. Tel: 313 57	7-2294	1B	Fax: 313 577-5055
Wayne State University	3c. DUNS: 00-19	6-2224	2	
5057 Woodward, Suite 6402	100. DONG. 00 10	O LLL		FEB 0 6 2009
Detroit, MI 48202	4. ENTITY IDENT 1-386-02-84		NUMBER	, LD 0 6 2009
6. HUMAN SUBJECTS No Yes	5. NAME, TITLE A	ND ADDR	ESS OF A	DMINISTRATIVE OFFICIAL
6a. Research If Exempt ("Yes" in 6a): If Not Exempt ("No" in 6a): No Yes Exemption No. IRB approval date	o" in Carole Bach, Director, Pre-Award Services, Spons			
6b. Federal Wide Assurance No. 00002460	Tel: 313 577-2	294		Fax 313 577-5055
6c. NIH-Defined Phase III Clinical Trial No Yes	E-MAIL: Orspsm	ail@wa	yne.edu	1
7. VERTEBRATE ANIMALS No Yes	10. PROJECT/PER	FORMAN	CE SITE(S)
7a. If "Yes," IACUC approval Date	Organizational Name: Children's Hospital of Michigan			
7b. Animal Welfare Assurance No.	DUNS: 07-637-			
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	Street 1: 3901 I	Beaubie	n	
8a. DIRECT \$239,353 8b. TOTAL \$360,227	Street 2:			
9. INVENTIONS AND PATENTS No Yes	City: Detroit	City: Detroit County: Wayne		County: Wayne
If "Yes, D Previously Reported	State: Michigan	1		Province:
Not Previously Reported	Country: USA			Zip/Postal Code: 48201
	Congressional Dist	ricts: 13		
11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT	ORGANIZATION (Ite	em 13)		
TEL: 313 577-1445 FAX: 313 57	7-1348		E-MAIL:	
12. Corrections to Page 1 Face Page			Incases	anna Gread International Inter
April Spraggins, Grant and Contract Officer III				
13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPT statements herein are true, complete and accurate to the best of my kno obligation to comply with Public Health Services terms and conditions if result of this application. I am aware that any false, fictitious, or fraudule may subject me to criminal, civil, or administrative penalties.	wledge, and accept the a grant is awarded as a	SIGNAT 11. (In i		FFICIAL NAMED IN DATE
PHS 2590 (Rev. 11/07)	Face Page	1900	1.4	Form Page

Face	

Pages 3 through 11 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): S	ha
--	----

Program Director/Principal Investigator (Las	t, First, Middle):	Shankaran, Seetha		
PROGRESS REPORT SUMMARY		GRANT NUMBER HD 021385		
		PERIOD COVERED BY	THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGA	TOR	FROM	THROUGH	
Seetha Shankaran, MD		04/01/2009	03/31/2010	
APPLICANT ORGANIZATION Wayne State University TITLE OF PROJECT (Repeat title shown in Item 1 NICHD Neonatal Research Network	on first page)			
A. Human Subjects (Complete Item 6 on the Face	Page)			
Involvement of Human Subjects	No Change	e Since Previous Submission	Change	
B. Vertebrate Animals (Complete Item 7 on the Face Page)				
Use of Vertebrate Animals	No Change	a Since Previous Submission	Change	
C. Select Agent Research	No Chang	e Since Previous Submission	Change	
D. Multiple PD/PI Leadership Plan	No Chang	e Since Previous Submission	Change	
SEE QUE 2500 INCTOLICTIONS				

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

See Attached

Not responsive. Not related to SUPPORT.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study):

During 2008 the goal of recruiting 2-3 infants per month was met with an enrollment of 28 infants in the SUPPORT Study at the Wayne State University site. In 2007 Dr. Beena Sood assumed responsibility as site Principal Investigator for the SUPPORT Study. The NRN enrollment target was met after Dr. Sood made changes to the recruitment process and obtained the collaboration of the Neonatology faculty and fellows for this study.

Postnatal Growth secondary SUPPORT Study:

The secondary study for the SUPPORT trial called Postnatal Growth of infants also recruited 28 subjects at the Wayne State University site.

Antenatal consent secondary SUPPORT Study:

Screening for the Antenatal Consent SUPPORT Study was completed at the Wayne State University site in March 2008 after the NRN target of 50 SUPPORT study enrolled babies per site was met. At the Wayne state University site a total of 151 mothers were approached for this study. The SUPPORT Neuro-imaging secondary study recruited 1 infant in 2008.

Breathing Outcomes secondary SUPPORT Study:

The Breathing Outcomes Secondary Support Study also continued successfully with enrollment of 10 subjects and completion of the 18-Month Follow-up among 6 subjects during 2008.

ot responsive. Not related to SUPPORT.

Pages 15 through 17 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes - secondary to SUPPORT

Total Planned Enrollment: 8

TARGETED/PLANNED ENROLLMENT: Number of Subjects				
Ethnia Catagony	Sex/Gender			
Ethnic Category	Females	Males	Total	
Hispanic or Latino	σ	0	0	
Not Hispanic or Latino	4	4	8	
Ethnic Category: Total of All Subjects *	4	4	8	
Racial Categories				
American Indian/Alaska Native	0	0	0	
Asian	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	
Black or African American	4	3	7	
White	0	1	1	
Racial Categories: Total of All Subjects *	4	4	8	

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 19 through 22 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome - secondary to SUPPORT

Total Planned Enrollment: 4

TARGETED/PLANNED ENROL	LMENT: Number of Subjec	ts		
Ethnia Catagony	Sex/Gender			
Ethnic Category	Females	Males	Total	
Hispanic or Latino	0	0	0	
Not Hispanic or Latino	1	3	4	
Ethnic Category: Total of All Subjects *	1	3	4	
Racial Categories				
American Indian/Alaska Native	0	0	0	
Asian	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	
Black or African American	1	2	3	
White	0	1	1	
Racial Categories: Total of All Subjects *	1	3	4	

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Post-natal Growth - secondary to SUPPORT

Total Planned Enrollment: 5

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Catagony		Sex/Gender			
Ethnic Category	Females	Males	Total		
Hispanic or Latino	0	0	0		
Not Hispanic or Latino	2	3	5		
Ethnic Category: Total of All Subjects *	2	3	5		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	2	2	4		
White	0	1	1		
Racial Categories: Total of All Subjects *	2	3	5		

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 25 through 28 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT Study

Total Planned Enrollment: 5

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Catagory		Sex/Gender			
Ethnic Category	Females	Males	Total		
Hispanic or Latino	0	0	0		
Not Hispanic or Latino	2	3	5		
Ethnic Category: Total of All Subjects *	2	3	5		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	2	2	4		
White	0	1	1		
Racial Categories: Total of All Subjects *	2	3	5		

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 30 through 31 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Breathing Outcomes - secondary to SUPPORT	
Total Enrollment:	10	Protocol Number:
Grant Number:	HD021385	

Sex/Gender					
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	1	0	0	1 **	
Not Hispanic or Latino	0	0	0	0	
Jnknown (individuals not reporting ethnicity)	6	3	0	9	
Ethnic Category: Total of All Subjects*	7	3	0	10 *	
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	4	2	0	6	
White	3	1	0	4	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*		3	0	10 *	

EPOI inos Enrolled to Date (Cumulative) iper o or La

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	1	0	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	1	0	0	1 **

* These totals must agree. ** These totals must agree.

Pages 33 through 35 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Post-natal Growth of Infants in the SUPPORT Study						
Total Enroliment:	28	Protocol Number:	المست القادي ويوسد ومسترجب من ويون والمنابع المسترجب والمسترجب والمسترجب والمسترجب والمسترجب والمسترج والمراول والوم				
Grant Number:	HD021385						

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race						
		S	ex/Gender			
Ethnic Category	Females	Males	Unknown or Not Reported	Total		
Hispanic or Latino	0	0	0	0 **		
Not Hispanic or Latino	0	0	0	0		
Unknown (individuals not reporting ethnicity)	7	21	0	28		
Ethnic Category: Total of All Subjects*	7	21	0	28 *		
Racial Categories						
American Indian/Alaska Native	0	0	0	0		
Asian	1	0	0	1		
Native Hawaiian or Other Pacific Islander	0	0	0	0		
Black or African American	6	20	0	26		
White	0	1	0	1		
More Than One Race	0	0	0	0		
Unknown or Not Reported	0	0	0	0		
Racial Categories: Total of All Subjects*	7	21	0	28 *		
	difference of the second	時代である。				
PART B. HISPANIC ENROLLMENT REPORT: Num			s Enrolled to Da	ate (Cumulative)		
Racial Categories	Females	Males	Unknown or Not Reported	Total		
American Indian or Alaska Native	0	0	C	0		
Asian	0	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	C	0		

* These totals must agree.

More Than One Race

Black or African American

Unknown or Not Reported

Racial Categories: Total of Hispanics or Latinos**

White

** These totals must agree.

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Pages 37 through 38 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Neuroimaging & Neurodevelopmental Outcome - SUPPORT secondary						
Total Enrollment:	1	Protocol Number:					
Grant Number:	HD021385						

	Sex/Gender					
Ethnic Category	Females	Males	Unknown or Not Reported	Total		
Hispanic or Latino	0	0	0	0 **		
Not Hispanic or Latino	0	0	0	0		
Unknown (individuals not reporting ethnicity)	0	1	0	1		
Ethnic Category: Total of All Subjects*	0	1	0	1 *		
Racial Categories						
American Indian/Alaska Native	0	0	0	0		
Asian	0	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0	0		
Black or African American	0	1	0	1		
White	0	0	0	0		
More Than One Race	0	0	0	0		
Unknown or Not Reported	0	0	0	0		
Racial Categories: Total of All Subjects*	0	1	0	1 *		

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	SUPPORT	 	
Total Enroliment:	28	 Protocol Number:	
Grant Number:	HD021385		

by Li	thnicity and Race	S	ex/Gender	
Ethnic Category	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	7	21	0	28
Ethnic Category: Total of All Subjects*	7	21	0	28 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	1	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	6	20	0	26
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	7	21	0	28 *
	Market Serie		型教育教育 生 生	
PART B. HISPANIC ENROLLMENT REPORT: N	lumber of Hispani	cs or Latino	s Enrolled to Da	ate (Cumulative)
Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
				\

Racial Categories: Total of Hispanics or Latinos**	0	0	0	
Unknown or Not Reported	0	0	0	
More Than One Race	0	0	0	
White	0	0	0	
Black or African American	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	

* These totals must agree.

Asian

** These totals must agree.

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** 0

Progress Report Scanning Cover Sheet

5U10HD021385-25

PI Name:	SHANKARAN, SEETHA
Org:	WAYNE STATE UNIVERSITY
Start Date:	04/01/2010
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	7802140
Rec'd Date:	02/01/2010

Form Approved Through 06/30/2012				OMB No. 0925-0001		
Department of Health and Human Services Public Health Services	Review Group	Type S	Activity U10	Grant Number HD 021385 - US		
	Total Project Period					
Grant Progress Report	From: 09/30/200		Th	rough: 03/31/2011		
Stant Progress Report	Requested Budget F	Period				
	From: 4/1/2010		Th	rough: 3/31/2011		
1. TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Re	search Network					
2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)	2b. E-MAIL ADDRES		una adu			
Seetha Shankaran, MD	sshankar@n		•	ORY, OR EQUIVALENT		
Division of Neonatal-Perinatal Medicine	Pediatrics	SERVICE		OKI, OK EQUIVALENT		
Children's Hospital of Michigan	2d. MAJOR SUBDIV	SION	·			
Detroit, MI 48201	Medicine					
	2e. Tel: 313 745-	1436	Fa	ax: 313 745-5867		
3a. APPLICANT ORGANIZATION						
(Name and address, street, city, state, zip code)	3b. Tel: 313 577	-0307	Fa	ax: 313 577-5055		
Wayne State University	3c. DUNS: 00-19	5-2224				
5057 Woodward, Suite 13201 Detroit, MI 48202				FEB 0 1 2010		
	4. ENTITY IDENTIF 1-386-02-84		INUMBER	FEBOT		
6. HUMAN SUBJECTS No Yes						
6. HUMAN SUBJECTS INO Yes 6a. Research If Exempt ("Yes" in If Not Exempt ("No"						
Exempt 6a): 6a):	i into any i . i	Timothy P. Foley, Research Manager Sponsored Programs Administration				
No Yes Exemption No. IRB approval date				1, Detroit, MI 48202		
6b. Federal Wide Assurance No. 00002460	Tel: 313 577-83	57	Fa	ax: 313 577-5055		
6c. NIH-Defined Phase III Clinical Trial 🛛 No 🗋 Yes	E-MAIL: orspsma	iil.wayr	ne.edu			
7. VERTEBRATE ANIMALS No Yes	10. PROJECT/PERF	10. PROJECT/PERFORMANCE SITE(S)				
7a. If "Yes," IACUC approval Date	Organizational Name: Children's Hospital of Michigan					
7b. Animal Welfare Assurance No.	DUNS: 38-1357	duns: 38-1357994				
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	Street 1: 3901 B	Street 1: 3901 Beaubien				
8a. DIRECT \$247,196 8b. TOTAL \$372,030	Street 2:					
9. INVENTIONS AND PATENTS No Yes	city: Detroit		C	ounty: Wayne		
If "Yes, 🔲 Previously Reported	State: MI		Pi	rovince:		
Not Previously Reported	Country: USA	<u></u>	Zi	p/Postal Code: 48201		
	Congressional Distri	cts: 13				
11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICAN Lisa Gruenawald, Grant and Contract Officer III	•	1 13)				
TEL: 313 577-6596 FAX: 313 57	77-5055		E-MAIL: a	h8208@med.wayne.edu		
12. Corrections to Page 1 Face Page			1			
13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEI	PTANCE: I certify that the	SIGNATI	JRE OF OFF			
statements herein are true, complete and accurate to the best of my ki obligation to comply with Public Health Services terms and conditions	nowledge, and accept the	11. (In in		6		
result of this application. I am aware that any false, fictitious, or fraudu		$\neg \overleftarrow{\cdot}$	14	1/29/10		
may subject me to criminal, civil, or administrative penalties. PHS 2590 (Rev. 06/09)	Face Page		- 10	Form Page 1		
	Ŭ					

Pages 3 through 13 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle):	Shankaran, Seetha					
PROGRESS REPORT SUMMARY		GRANT NUMBER HD 021385					
			PERIOD COVERED BY THIS REPORT				
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR		FROM	THROUGH				
Seetha Shankaran		04/1/2010	03/31/2011				
APPLICANT ORGANIZATION Wayne State University TITLE OF PROJECT (Repeat title shown in Ite NICHD Neonatal Research Network	m 1 on first page)						
A. Human Subjects (Complete Item 6 on the Face	e Page)						
Involvement of Human Subjects		e Since Previous Submission	Change				
B. Vertebrate Animals (Complete Item 7 on the F	ace Page)						
Use of Vertebrate Animals	No Change	e Since Previous Submission	Change				
C. Select Agent Research	No Change	e Since Previous Submission	Change				
D. Multiple PD/PI Leadership Plan	No Change	e Since Previous Submission	Change				
E. Human Embryonic Stem Cell Line(s) Used	No Chang	e Since Previous Submission	Change				

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

See Attached

Not responsive. Not related to SUPPORT.

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Not responsive. Not related to SUPPORT.

<u>The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low</u> <u>Birth Weight Infants (SUPPORT Study):</u>

With the SUPPORT study completing accrual in February 2009, one subject was enrolled in 2009 for a total enrollment of 68 infants at the Wayne State University site. In 2007 Dr. Beena Sood assumed responsibility as site Principal Investigator for the SUPPORT Study. The NRN enrollment target was met after Dr. Sood made changes to the recruitment process and obtained the collaboration of the Neonatology faculty and fellows for this study. To date the SUPPORT Study follow-up visit rate is >93%. DR Sood is co-author of the two SUPPORT manuscripts accepted for publication in the New England Journal of Medicine.

Postnatal Growth secondary SUPPORT Study:

The secondary study for the SUPPORT trial called Postnatal Growth of infants also recruited a total of 68 subjects at the Wayne State University site.

Antenatal consent secondary SUPPORT Study:

Screening for the Antenatal Consent SUPPORT Study was completed at the Wayne State University site in March 2008 after the NRN target of 50 SUPPORT study enrolled babies per site was met. At the Wayne state University site a total of 151 mothers were approached for this study.

Neuroimaging and Neurodevelopmental Outcome secondary SUPPORT Study:

A total of 12 subjects were enrolled into this study at the Wayne State University site, with no additional infants recruited in 2009. Of these, 8 surviving subjects with successful brain MRI's continue to be tracked for the study assessment at 6 years of age.

Breathing Outcomes secondary SUPPORT Study:

The Breathing Outcomes Secondary Support Study also continued successfully with enrollment of an additional 7 subjects and completion of the 18-Month interviews among 9 subjects during 2009 for a total of 23 having completed the four protocol interviews.

Pages 17 through 27 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Breathing Outcomessecondary to SUPPORT		
Total Enrollment:	7	Protocol Number:	
Grant Number:	HD021385		

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	2	5	0	7
Ethnic Category: Total of All Subjects*	2	5	0	7 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	2	5	0	7
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	2	5	0	7 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

Pages 29 through 33 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	SUPPORT	/	
Total Enrollment:	1	Protocol Number:	
Grant Number:	HD021385		

	hber of Subjects thnicity and Rac		ate (Cumulativ	e)	
Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total	
Hispanic or Latino	0	0	0	0	**
Not Hispanic or Latino	0	0	0	0	
Unknown (individuals not reporting ethnicity)	0	1	0	1	
Ethnic Category: Total of All Subjects*	0	1	0	1	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	0	1	0	1	
White	0	0	0	0	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	-
Racial Categories: Total of All Subjects*	0	1	0	1	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

Pages 35 through 36 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD027851-15

PI Name:
Org:
Start Date:
Snap:
Appl ID:
Rec'd Date:

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STOLL, BARBARA EMORY UNIVERSITY 04/01/2005 N/A (NEEDS TO BE BOOKMARKED) 6891940 02/03/2005

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Form Approved Through 09/30/2007	OMB No. 0925-0001
Department of Health and Human Services Public Health Services	Review GroupTypeActivityGrant NumberZHD1 MCHG-B5U10HD 27851-15
	Total Project Period
Grant Progress Report	From: 04/01/1991 Through: 03/31/2006
Grant Progress Report	Requested Budget Period
	Inrough: 03/31/2006
1. TITLE OF PROJECT	
Multicenter Network of Neonatal Intensive Ca 2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	IS APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code)	(Name and address, street, city, state, zip code)
Barbara J. Stoll	(Name and address, street, city, state, zip code)
Emory University, Dept. of Pediatrics	Ofc of Sponsored Programs
2015 Uppergate Drive, NE	1784 N Decatur Rd, Suite 510
Atlanta, GA 30322	Atlanta, GA 30322
	1784 N Decatur Rd, Suite 510 Atlanta, GA 30322 4. ENTITY IDENTIFICATION NUMBER 1580566256A1
26. E-MAIL ADDRESS	4. ENTITY IDENTIFICATION NUMBER O
barbara stoll@oz.ped.emory.edu	1580566256A1
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT	
Pediatrics	Assoc V President for Research
2d. MAJOR SUBDIVISION	Emory University, Ofc of Sponsored Programs
School of Medicine	1784 N Decatur Rd, Suite 510
	Atlanta, GA 30322
	E-MAIL.
6. HUMAN SUBJECTS	7. VERTEBRATE ANIMALS
No 6a. Research Exempt 6b. Human Subjects Assurance	ze No. 🛛 No 7a. If "Yes," IACUC approval Date
X Yes No Yes FWA00005792	Yes
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III	7b. Animal Welfare Assurance No.
Exemption No. Clinical Trial No Ye	95
If Not Exempt ("No" in 6a):	
IRB approval date	iew i i i i i i i i i i i i i i i i i i
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVENTIONS AND PATENTS
8a, DIRECT \$180,097 8b, TOTAL \$ 230,527	🛛 No 🔲 Yes If "Yes," 🔲 Previously Reported
	Not Previously Reported
10. PERFORMANCE SITE(S) (Organizations and addresses)	11a. PRINCIPAL INVESTIGATOR TEL 404-727-5740
Grady Memorial Hospital	OR PROGRAM DIRECTOR (<i>Item 2a</i>) A Barbara J Stoll M D FAX 404-727-5737
80 Jessie Hill Jr., PO 26015, Atlanta GA 3030	
	NAME (Item 5)
Crawford Long Hospital	Marilyn Surbey FAX 404-727-2509
550 Peachtree St, NE, Atlanta, GA 30365	11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT
	ORGANIZATION (Item 14)
Egleston Children's Hospital	NAME Jackie Bendall
1405 Clifton Rd, NE, Atlanta, GA 30322	TITLE Assoc. Director
· · · · · · · · · · · · · · · · · · ·	TEL 404-727-2503 FAX 404-727-2509
	E-MAIL osp@emory.edu
12 Corrections to Page 1 Face Page	

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12. Corrections to Page 1 Face Page

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13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR As statements herein are true, complete and accurate to the best of any false, fictitious, or fraudulent statements or claims may subje administrative penalties. I agree to accept responsibility for the s	my knowledge. I am aware that ct me to criminal, civil, or		ot acceptable.)	DATE
and to provide the required progress reports if a grant is awarded 14. APPLICANT ORGANIZATION CERTIFICATION AND AC statements herein are true, complete and accurate to the best of obligation to comply with Public Health Services terms and condition obligation to comply with Public Health Services terms and condition obligation to comply with Public Health Services terms and condition obligation to comply with Public Health Services terms and condition obligation to comply with Public Health Services terms and condition obligation to comply with Public Health Services terms and condition obligation to comply with Public Health Services terms and condition obligation to comply with Public Health Services terms and condition obligation to comply with Public Health Services terms and condition obligation to comply with Public Health Services terms and condition obligation to comply with Public Health Services terms and condition obligation to comply with Public Health Services terms and condition obligation to comply with Public Health Services terms and condition obligation to complete the set of the terms and condition obligation to complete the set of the terms and condition obligation to complete the terms and terms and the terms and	I as a result of this application. CCEPTANCE: I certify that the my knowledge, and accept the	SIGNATURE OF OFFICI. 11c. (In ink. "Per" signat acceptable.)	AL NAMED IN	1-31-05 DATE
result of this application. I am aware that any false, fictitious, or f may subject me to criminal, civil, or administrative penalties.	raudulent statements or claims	Sachi Be	rdell	1-31-05
PHS 2590 (Rev. 09/04)	Face Page	0		Form Page 1

Pages 3 through 8 redacted for the following reasons: Not responsive.

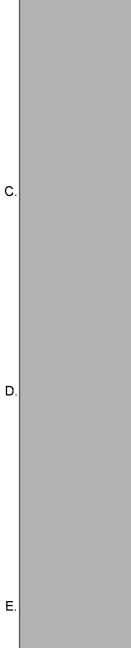
Principal Investigator/Program Director (Last, First, Middle	e): <u>Stoll, Barbara J.</u>	
PROGRESS REPORT SUMMARY	GRANT NUMBER HD 27851-15	
	PERIOD COVERED BY TH	IIS REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH
Barbara J. Stoll	01/01/04	12/31/04
APPLICANT ORGANIZATION		
Emory University		
TITLE OF PROJECT (Repeat title shown in Item 1 on first page	e)	· · · · · · · · · · · · · · · · · · ·
Multicenter Network of Neonatal Intensive Care Uni	ts	
A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	nge Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals X No Char	nge Since Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS.		

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The Emory Regional Perinatal Center has been participating in the NICHD multicenter network of neonatal intensive care units since April 1991. These have been an exciting and productive 13 years. We have participated in on-going neonatal network projects and have been active in the planning stages and review of new projects.

On-going Projects:

A. Not responsive



Β.

G.

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J.

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- M. <u>Studies in the Planning Stages</u>:
 1. SUPPORT Study A RCT comparing early delivery room CPAP to intubation and surfactant use in ELBW and a strategy of moderate vs. lower oxygen saturation is to begin in 2005.
 - 2. Fluid and sodium restriction reduces the incidence of BPD in ELBW infants. An unmasked pilot study of different fluid and sodium regimens for the first 10 days of life will be started in 2005.

Principal Investigator/Program Director (Last, First, Middle): <u>Stoll, Barbara J.</u> Not responsive.

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Pages 13 through 25 redacted for the following reasons: Not responsive.

		1			
HIC-ID	Protocol Title	Status	Current Approval Date	Expiration Date	Notes
	Not responsive.	+ Status	Amnoval Date	Date	notes
1197-2003					
695-2000					
010-2004					
171-2001					
170-2001					
196-99					
364-2004					
504-2004					
349-2002					
105-91					
103-91					
322-99					
(14 2001					
614-2001					
818-2003					
717-93					<u> </u>
631-2000					
	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low				
1158-2004	Birth Weight Infants	Approved	12/28/04	12/27/05	

Emory - Protocols

Personal identifier

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Pages 27 through 124 redacted for the following reasons: Not responsive.



Institutional Review Board

Susie Buchter Pediatrics 1490/001/1AA Grady Hospital

RE: NOTIFICATION OF PROTOCOL APPROVAL

PI: Susie Buchter

IRB ID: 1158-2004

TITLE: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants

DATE: December 29, 2004

The research proposal referenced above was reviewed and APPROVED under the Full review process. This approval is valid from 12/28/2004 until 12/27/2005. Thereafter, continued approval is contingent upon the submission of a renewal form that must be reviewed and approved by the IRB prior to the expiration date of this study.

A partial waiver of authorization has been granted by the Emory University IRB for the purpose of determining eligibility or recruiting subjects for this protocol. This waiver was reviewed and approved under the review procedure note above. The approval is granted based on this board's determination that all criteria for waiver of authorization have been met. As subjects are enrolled, you are required to obtain authorization. The PHI that may be used or disclosed for this use is limited to: Consent cannot be sought unless maternal records can be reviewed. Subjects will be identified by numbers only.

Any serious adverse events or issues resulting from this study should be reported immediately to the IRB and to any sponsoring agency (if any). Amendments to protocols and/or revisions to informed consent forms/process must have approval of the IRB before implemented.

All inquires and correspondence concerning this protocol must include the IRB number and the name of the Principal Investigator.

If you have any questions or concerns, please contact the IRB office at 404-727-5646 or at email address: irb@emory.edu. Our web address is http://www.emory.edu/IRB. Thank you.

Sincerely,

ames W. Keller, MD Chairman, Institutional Review Board

Cc: Ellen Hale R.N., Barbara J. Stoll MD

Emory University 1256 Briarcliff Road 4th Floor, South Wing Atlanta, Georgia 30306 An equal opportunity, affirmative action university Tel 404.727.5646 Fax 404.727.1358 IRB@emory.edu

PAGE 2 of 2 - PROTOCOL APPROVAL

This approval is valid from 12/28/2004 until 12/27/2005.

IRB ID: 1158-2004

DATE: December 29, 2004

The above referenced protocol was approved including the information below. Please review this information for accuracy. If there are any discrepancies, please notify the IRB office.

Informed Consents Associated with this protocol:

Version Date 12/28/2004	Description Main Consent:Surfact	tant Positive Airway
5 /11/2004	HIPAA Authorization	1
Personnel		Human Subjects Education Certification Information
Hale, Ellen	Protocol Contact	CITI - MED 1, 2, 3, 4, 5, 6, 7, 10, 12, 14 (22-Sep-2003)
Hurlburt, Teri	Study Nurse	CITI - MED 1, 2, 3, 4, 5, 6, 7, 10, 12, 14 (24-Sep-2003)
Blackwelder, Ann M	Study Nurse	CITI - MED 1, 2, 3, 4, 5, 6, 7, 10, 12, 14 (22-Sep-2003)
Buchter, Susie	Main Investigator	CITI - MED 1, 2, 3, 7, 12, 14, 17 (16-Oct-2004)
Stoll, Barbara J.	Co-Investigator	CITI - MED 1, 2, 3, 4, 5, 6, 7, 10, 11, 12, 14 (03-Oct-2003)

Number of Approved Emory Subjects 75

(This number indicates the number of subjects you can consent.)

Sites

Crawford Long Hospital Grady Memorial Hospital

Funding Agencies NICHD

Emory University School of Medicine Consent to be a Research Subject

<u>Title</u>: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants

Principal Investigator: Susie Buchter, M.D., P.I. Barbara J. Stoll, M.D., Co-P.I.

Sponsor's Name: National Institute of Child Health and Human Development (NICHD)

Introduction/Purpose:

You are being asked to volunteer your baby for a research study. There is a possibility that your baby will be born between 16 and 12 weeks early (24-28 weeks gestational age). Babies born this early usually have difficulty breathing. Their lungs are not mature enough to work well so that the babies can breathe on their own. Most all babies born at this early age will need assistance breathing and or extra oxygen. If needed, this support begins at birth in the delivery room.

This study will look at the use of CPAP in the delivery room. CPAP is positive pressure applied with a facemask to help keep the lungs inflated. This study will also look at the levels of oxygen saturation (oxygen levels in the blood) in premature babies.

It is known that the breathing problems of babies can be improved by putting a liquid in the lungs (surfactant). This liquid is put into the lungs by placing a tube in the windpipe (intubation). Afterwards, breathing is supported with a breathing machine and or extra oxygen.

However, when babies get this support for a long time, their lungs can become injured. This may cause the baby to be dependent upon the extra support for a long time. Studies from Europe have suggested that early CPAP can reduce the need for intubation in very premature infants.

There is no standard way to use CPAP/Positive End Expiratory Pressure for resuscitation in the delivery room for tiny premature infants. This pressure is given using a mask placed on the baby's face. The pressure may also be given using prongs placed in the infant's nostrils. The pressure is produced using current breathing machines. There are also special devices that are designed to deliver such pressures.

Studies have suggested that the use of early CPAP and trying not to use a breathing machine may have a better outcome for babies. These babies may also have a decreased need for surfactant therapy. These babies may also have a decreased need for additional oxygen. The current commonly used treatment is surfactant administration. Surfactant is produced by the normal lung. It is lacking in very preterm infants. Its use has been connected with a decrease in death and respiratory problems. Both the uses of CPAP and surfactant may be good. There has not been a study to compare the use of CPAP with surfactant treatment begins after delivery and continues in the NICU.

Retinopathy of Prematurity (ROP) is a common eye problem in tiny premature infants. Blood vessels that nourish the preterm infant's eyes are not fully developed. Small vessels in the retina

(part of the eye) may have periods of increased or rapid and wild growth. Over time ROP can get better or get worse. Usually ROP will heal without any problems. If the ROP is worse than usual, there is a chance that the blood vessels will grow out of control. If this happens, surgery may be needed to prevent scars inside the eye. These scars can cause severe vision loss.

Getting extra oxygen for a long time can also damage the baby's eyes. Another study has shown that less eye surgery was needed in special nurseries using lower oxygen limits.

There are two purposes of this study. First of all, we will compare two different types of care in the delivery room. We will compare infants who receive delivery room CPAP and those who have a breathing tube and surfactant given. Secondly, we will compare low range (85-89%) oxygen saturation levels with a high range (91-95%). We want to know if a lower oxygen level in babies can prevent this bad eye problem.

This study is being performed at Grady Memorial Hospital and Crawford W. Long Hospital. Fifteen other medical centers in the U.S. are also part of this study. The National Institute of Child Health and Human Development (NICHD) sponsors this research. Your baby will only be eligible for this study if you deliver between 24 and 27 weeks. The study will last about two years and will enroll about 1300 infants nationally. About 75 babies will be studied at Emory.

Procedures:

If you agree to this study and give consent for your baby, the following will happen. Prior to delivery, your baby will be assigned to one of two treatments. Assignment will be random (like flipping a coin). In the first treatment group, your baby would be placed on CPAP in the delivery room to help with their breathing. If your baby is in the second treatment group, a tube will be placed in his/her trachea (windpipe) to help with their breathing. After the tube is placed, a dose of Surfactant will be given in the tube. Both of these treatment groups are current standards of care for preterm babies in the delivery room.

At the same time that your baby is assigned to the above treatment group, he/she will also be randomly (like flipping a coin) assigned to a high or low oxygen monitoring group. Your baby will be treated using either a lower (85-89%) or higher (91-95%) oxygen saturation range. We will start this monitoring of oxygen saturation by 2 hours of age. Both of the ranges for oxygen used in this study are within the range that we currently use in our NICU. In this study we will try to maintain your baby within one of these 2 ranges. Each of these 4 possible treatment groups is considered the standard of care in the NICU at Emory. The study will take place during the entire time your baby is on oxygen while he/she is in the NICU.

A final eye exam will be done at 3 months corrected age (3 months after your due date for this baby). If your baby has been discharged from the hospital prior to this, an outpatient eye appointment will be scheduled. This eye appointment is part of standard of care. As part of the study, we will collect information about the eye exam. We may need to request a copy of your baby's eye exam if it is done before discharge.

Your baby will be followed for this study until he/she is discharged from the hospital. As part of standard of care the Emory Developmental Progress Clinic (DCP) will follow your baby. At 18 months of age, he/she will be seen in the DPC as part of our routine follow-up program. At the 18 month visit you will be asked to allow your baby to be part of a follow up study. You will be asked to sign a separate consent. Information will be shared with the NICHD Follow-up Study of very

tiny premature babies. At that time we will look at your baby's growth. We will also perform physical and neurological testing and developmental testing.

<u>Risks:</u>

The treatments talked about in this study are all standard of care. However, intubation, administration of surfactant and CPAP are not without risk. Risks of intubation may include improper placement of tube and windpipe damage from the tube. Risks of surfactant could be unequal distribution of the liquid and bleeding into the lungs. Another risk could be delayed surfactant use while CPAP is being used. Risks of CPAP could be damage to the nose and overinflation of the lungs. There is no predictable increase in risks above standard of care for your baby. Some unknown risks may be learned during the study. If this happens, the research team will let you know.

Benefits:

If either treatment group is found to be a better way to treat babies, your baby may benefit from the study. But taking part in this study may not benefit your baby. Doctors may learn new things that may help babies in the future.

Alternatives:

You may choose not to have your baby take part in this study and your baby will continue to get the standard of care. The current standard of care at Grady and Crawford Long is to assess the baby's breathing at birth. The majority of babies born at this early date will be intubated and given surfactant. A few will receive CPAP in the delivery room or later in the intensive care nursery. Both of the ranges for oxygen used in this study are within the range that we currently use in our NICU.

Confidentiality:

People other than those doing the study may look at both medical charts and study records. Agencies that make rules and policy about how research is done have the right to review these records. So do agencies that pay for the study. Those with the right to look at your baby's study records include the Food and Drug Administration, the Office for Human Research Protections, National Institute of Child Health and Human Development, the Emory University Institutional Review Board, and Grady's Research Oversight Committee. Records can also be opened by court order. We will keep your baby's records private to the extent allowed by law. We will do this even if outside review occurs. We will use a study number rather than your baby's name on study records where we can. Your baby's name and other facts that might point to him/her will not appear when we present this study or publish its results.

Costs and Compensation:

There will be no cost to you or your baby for being in this study. You will not be paid for being in this study. If your baby is injured as a result of this research, medical care will be available. However, Emory University (including Crawford Long Hospital) and the Grady Health System have not set aside funds to pay for this care or to compensate you if a mishap occurs. If you believe your baby has been injured by this research, you should contact Dr. Susie Buchter, the investigator in charge at 404-778-1450.

Contact Persons:

Call Dr. Susie Buchter at (404) 778-1450 if you have questions about this study or if you feel your baby has been harmed from being in this study. If you have any questions or concerns about

your rights as a participant in this research study, contact James W. Keller, M.D., Chairman, Emory University Institutional Review Board, at (404) 727-5646. If your baby is a patient at Grady Hospital you may contact Dr. Curtis Lewis, Senior Vice President for Medical Affairs, at (404) 616-4261.

New Findings:

We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information.

Voluntary Participation and Withdrawal:

Participation in the study is voluntary. You have the right to refuse to let your baby be in this study. If you decide to let your baby be in this study and change your mind, you have the right to drop out at any time. This decision will not affect in any way your baby's current or future medical care. This decision will not affect any other benefits to which you are otherwise given.

Although your infant will be treated according to a specific plan (protocol), individual circumstances may arise. In such cases, your infant's health will always be considered more important than strictly following the study. Changes will be discussed before they are made whenever possible.

We will give you a copy of this consent form to keep.

If you're willing to volunteer your baby for this research, please sign below.

Subject's name

Subject's legally authorized representative

Time

Person Obtaining Consent

Date

Date

Time

IRB#: 1158-2004

Consent Form Approval Period FROM: <u>228-04</u> TO: <u>12-27-0</u>5 AUTHORIZATION: <u><u>4</u>]</u>



YOUR CHILD'S PRIVACY

The privacy of your child's medical record is important to us. Before we start our research we want to tell you about a law that protects your medical record, and the information you give us for this study. The law is called the Health Insurance Accountability and Portability Act or HIPAA for short.

Under HIPAA, your child's personal health information that identifies them receives greater protection. We will now tell you more about how we will protect your child's health information for this study.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants

Dr. Susie Buchter, Principal Investigator Dr. Barbara J. Stoll, Co-Principal Investigator

Authorization to Use or Disclose Health Information that Identifies You for a Research Study

Subject Name:

Study Number:

If you sign this document, you voluntarily give permission to the people or groups of people listed below to use or disclose (release) your child's health information that identifies them in connection with Research Study that is described below:

Research Study: This study is being conducted by the National Institute of Child Health and Human Development (NICHD). The purpose of this study is to compare infants who receive delivery room

Version Date: 5/11/04

CPAP and who have strict guidelines for having a breathing tube placed with infants who have the tube placed and surfactant given in the delivery room. This study will also compare low range oxygen saturation levels with a high range to determine if a lower range results in decreased threshold eye disease and/or need for eye surgery.

People That Will Use or Disclose You Information and Purpose of Use/Disclosure: The following individuals or groups are people who will be conducting the Research Study or who have the job of monitoring and regulating research and who will use or disclose your child's health information to do this work (the "Information Recipients"):

- National Institute Child Health and Human Development (NICHD)
- Research Triangle Institute (RTI)
- Emory University Institutional Review Board
- Grady Research Oversight Committee (ROC)
- Crawford Long Medical Executive Committee
- U.S. Food and Drug Administration

By signing this document you agree to allow these Information Recipients to use or disclose your child's health information that identifies them for the Research Study, or to monitor or regulate research. In addition, your child's health information may be used or disclosed as required by law, and it may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and/or conducting public health surveillance, investigations or interventions.

Description of Health Information that Will be Used or Disclosed

The Researchers and Regulators may use or disclose the following health information about your child:

- Medical Record
- Laboratory Results

Revoking your Authorization:

You do not have to sign this Authorization. In addition, if you sign this Authorization, later, you may change your mind at any time and revoke (take back) this Authorization. If you want to revoke this Authorization you must write to: Dr. Susie Buchter, P.O. Box 26015, 80 Jesse Hill, Jr. Drive Atlanta, GA 30303.

Attached is pre-printed revocation letter to Dr. Susie Buchter for your use.

If you revoke your Authorization, the Researchers will not collect any more health information that identifies your child, but they may use or disclose information that you already gave them in order to notify any of the other Researchers that you have revoked your authorization; to maintain the integrity or reliability of the Research Study; and to comply with any law that they are required to obey.

Other Items You Should Know:

The Information Recipients who work for Emory University School of Medicine are required by HIPAA to protect your child's health information. However, some of the other Information Recipients who receive your child's health information do not work for Emory University School of Medicine, and they may not be required by HIPAA to protect your child's health information. These Information Recipients may share your child's information with others without your permission if the law permits them to do so.

You do not have to sign this authorization form, but if you do not, your child may not participate in the Research Study or receive research-related treatment. They may still receive non-research related treatment.

If the Research Study involves medical treatment, then, in order to maintain the integrity of the research study, you generally will not have access to your child's personal health information related to this Research Study until the study is complete. When the study is complete, then, at your request, you may generally have access to any of your child's personal health information related to the research that makes up a part of the medical information and/or billing records that your child's health care providers use to make decisions about them. If access to this information is needed before the end of the Research Study for your child's treatment, then the information will be provided to your child's physician.

If your child's identifying information is removed from your child's health information, then the information that remains will not be subject to this authorization and it may be used or disclosed for other purposes.

Expiration Date: This authorization will expire when the research study ends on

As a study participant, if you have any questions regarding the study, you may call Dr. Susie Buchter the study's Principal Investigator at (404) 778-1450. If you have any questions regarding your child's rights as a study subject, you may call Dr. James W. Keller, Chairman of the Emory University Institutional Review Board at (404) 727-5646.

A copy of this authorization form will be given to you. Also, a copy of this authorization may be placed in your medical record.

Signature of Study Subject OR Subject's Legal Authorized Representative

Date

Time

Printed Name of Study Subject OR Subject's Legally Authorized Representative

Relationship to Study Subject:

Signature of Person Obtaining Authorization

Date

Time

September 7, 2004

IRB#: 1158-200-1

Consent Form Approval Period FROM: <u>2-28-04</u>TO: <u>12-27-05</u> AUTHORIZATION: <u>11</u> Thank You for Your Participation

Version Date: 5/11/04

Pages 134 through 165 redacted for the following reasons: Not responsive. Progress Report Scanning Cover Sheet

5U10HD027851-17

PI Name:
Org:
Start Date:
Snap:
Appl ID:
Rec'd Date:

STOLL, BARBARA EMORY UNIVERSITY 04/01/2007 N/A (NEEDS TO BE BOOKMARKED) 7219985 02/07/2007

Form Approved Through 09/30/2007	OMB No. 0925-000 Review Group Type Activity Grant Number					
Department of Health and Human Services Public Health Services	ZHD1 MCHG-B 5 U10 HD 027851-17					
	Total Project Period					
Grant Progress Report	From: 04/01/2006 Through: 03/31/2011					
orant rogrood roport	Requested Budget Period					
	From: 04/01/2007 Through: 03/31/2008					
1. TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Rese						
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code) Barbara J. Stoll Emory University School of Medicine Department of Pediatrics 2015 Uppergate Drive, N.E. Atlanta, GA 30322	3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code) Emory University Office of Sponsored Programs 1784 N. Decatur Rd, Suite 510 Atlanta, GA 303222					
2b. E-MAIL ADDRESS barbara_stoll@oz.ped.emory.edu	4. ENTITY IDENTIFICATION NUMBER 1580566256A1					
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT	5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL					
Pediatrics 2d. MAJOR SUBDIVISION School of Medicine	Director for Research Emory University, Ofc of Sponsored Programs 1784 N Decatur Rd, Suite 510 Atlanta, GA 30322 E-MAIL:					
6. HUMAN SUBJECTS	1					
No 6a. Research Exempt 6b. Human Subjects Assurance Yes No Yes If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III Exemption No. Clinical Trial No	No. No 7a. If "Yes," IACUC approval Date Yes 7b. Animal Welfare Assurance No.					
If Not Exempt ("No" in 6a): IRB approval date	A-3180-01					
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVENTIONS AND PATENTS					
8a. DIRECT \$ 177,751 8b. TOTAL \$ 229,477	No Yes If "Yes," Previously Reported					
 PERFORMANCE SITE(S) (Organizations and addresses) Grady Memorial Hospital 80 Jesse Hill, Jr. Dr, PO 26015 	11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a)TEL 404-727-5740Barbara StollFAX					
Atlanta GA 30303	11b. ADMINISTRATIVE OFFICIAL NAME (Item 5)TEL 404-727-2503Shawn AkkermanFAX 404-727-2509					
Crawford Long Hospital 550 Peachtree St, Atlanta, GA 30365 Egleston Children's Hospital 1405 Clifton Rd, NE, Atlanta, GA 30322	11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14) NAME NAME Director TITLE Office of Sponsored Programs TEL 404-727-2503 FAX 404-727-2509 E-MAIL osp@emory.edu					

PHS 2590 (Rev. 04/06) Face Page		Form Page
13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	11c. (In ink. "Per" signature not	DATE 2/5/07

Form Page 1

Pages 3 through 5 redacted for the following reasons: Not responsive.

Principal Investigator/Program Director (Last, First, I	Middle): Stoll, Barbara J	Stoll, Barbara J			
PROGRESS REPORT SUMMARY	GRANT NUMBER HD 027851-17				
	PERIOD COVERED BY TH	PERIOD COVERED BY THIS REPORT			
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Barbara J. Stoll	R FROM 04/01/2006	THROUGH 03/31/2007			
APPLICANT ORGANIZATION					
Emory University					
Emory University TITLE OF PROJECT (Repeat title shown in Item 1 on firs NICHD Cooperative Multicenter Neonatal Rese					
TITLE OF PROJECT (Repeat title shown in Item 1 on firs NICHD Cooperative Multicenter Neonatal Rese A. Human Subjects (Complete Item 6 on the Face Page)		Change			
TITLE OF PROJECT (Repeat title shown in Item 1 on firs NICHD Cooperative Multicenter Neonatal Rese A. Human Subjects (Complete Item 6 on the Face Page)	o Change Since Previous Submission	Change			
TITLE OF PROJECT (Repeat title shown in Item 1 on firs NICHD Cooperative Multicenter Neonatal Rese A. Human Subjects (Complete Item 6 on the Face Page) Involvement of Human Subjects X N B. Vertebrate Animals (Complete Item 7 on the Face Page	o Change Since Previous Submission	Change			
TITLE OF PROJECT (Repeat title shown in Item 1 on firs NICHD Cooperative Multicenter Neonatal Rese A. Human Subjects (Complete Item 6 on the Face Page) Involvement of Human Subjects X N B. Vertebrate Animals (Complete Item 7 on the Face Page Use of Vertebrate Animals X N	o Change Since Previous Submission				

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The Emory Regional Perinatal Center has been participating in the NICHD multicenter network of neonatal intensive care units since April 1991. These have been an exciting and productive 15 years. We have participated in on-going neonatal network projects and have been active in the planning stages and review of new projects.

Not responsive.

Not responsive.

Not responsive.

Not responsive.

H. <u>SUPPORT – Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants</u>: This prospective randomized, factorial 2x2 design study will compare CPAP and a permissive ventilatory strategy begun in the delivery room and continuing in the NICU with early surfactant and mechanical ventilation AND a lower oxygen saturation level (85% to 89%) vs. a higher one (91% to 95%) until the infant is no longer requiring oxygen or until 36 weeks. The study began in 2004 and Emory entered 34 patients as of December 31, 2006.

Dr. S. Buchter is the Emory PI for the SUPPORT Trial.

Principal Investigator/Program Director (Last, first, middle):

Stoll, Barbara J

GRANT NUMBER HD 027851-17

CHECKLIST

1. PROGRAM INCOME (See instructions.)

All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

In signing the application Face Page, the authorized organizational representative agrees to comply with the following policies, assurances and/or certifications when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

 Human Subjects Research

 Research Using Human Embryonic Stem
 Cells · Research on Transplantation of Human Fetal Tissue · Women and Minority Inclusion Policy . Inclusion of Children Policy . Vertebrate Animals

3. FACILITIES AND ADMINSTRATIVE (F&A) COSTS

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

· Debarment and Suspension · Drug- Free Workplace (applicable to new [Type 1] or revised/resubmission [Type 1] applications only) . Lobbying . Non-Delinquency on Federal Debt . Research Misconduct · Civil Rights (Form HHS 441 or HHS 690) · Handicapped Individuals (Form HHS 641 or HHS 690) . Sex Discrimination (Form HHS 639-A or HHS 690) · Age Discrimination (Form HHS 680 or HHS 690) · Recombinant DNA Research, Including Human Gene Transfer Research . Financial Conflict of Interest (except Phase I SBIR/STTR) Prohibited Research
 Select Agent Research
 PI Assurance STTR ONLY: Certification of Research Institution Participation.

F&A costs will not be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

DHHS Agreement dated:	June 23, 2006			No Fa	cilities and Administrati	ve Costs Requested.
NO DHHS Agreement, but	t rate established with				Date	
CALCULATION*						
Entire proposed budget period:	Amount of base \$ Add to		x Rate applied s from Form Page 2		% = F&A costs \$ ew total on Face Page,	51,726
*Check appropriate box(es):				r	_	
Salary and wages base	\boxtimes	Modified total di	irect cost base	E	Other base (Expla	in)

Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary.):

KEY PERSONNEL REPORT

GRANT NUMBER HD 027851-17

Place this form at the end of the signed original copy of the application. Do not duplicate.

		SSN		Designt Data of Birth	Months I	Devoted	to Project
Name	Degree(s)	(last 4 digits)	Role on Project (e.g. PI, Res. Assoc.)	Date of Birth (MM/DD/YY)	Cal	Acad	Summe
Barbara J. Stoll	MD	8946	PI	08/26/50	1.2		
Ira Adams-Chapman	MD	8254	F/U PI	10/15/65	1.2		
Ellen Hale	BS	4732	Research Coord.	06/30/48	12.0		
Ann Blackwelder	MS	4110	Research Nurse	07/24/44	12.0		
Michelle Tidwell	BSN	5276	Research Nurse	08/13/78	12.0		

Center 09: Emory - Protocols 2007 PI: Dr. Barbara J. Stoll

Protocol #	Protocol Title	Status	Current Approval Date	Expiration Date	Notes
esponsive.		1			
158-2004	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	Approved	10/11/2006	10/10/07	
1158-2004 responsive.	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	Approved	10/11/2006	10/10/07	
1.1	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	Approved	10/11/2006	10/10/07	
1.1	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	Approved	10/11/2006	10/10/07	

Pages 12 through 51 redacted for the following reasons: Not responsive **Progress Report Scanning Cover Sheet**

5U10HD027851-18

PI Name:	STOLL, BARBARA
Org:	EMORY UNIVERSITY
Start Date:	04/01/2008
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	7391187
Rec'd Date:	02/25/2008

http://type5.era.nih.gov/ice_type_five/printcoversheet.cfm

2/25/2008

Form Approved Through 11/30/2010	•	OMB No. 0925-0001			
Department of Health and Human Services Public Health Services		Review Group Type Activity Grant Number ZHD1 MCHG-B 5 U10 HD 027851-18			
		Total Project Period			
Grant Progress Report	rt	From: 04/01/2006 Through: 03/31/2011			
		Requested Budget Period			
1. TITLE OF PROJECT	<u>.</u>	From: 04/01/2008 Through: 03/31/2009			
NICHD Cooperative Multicenter Neona	atal Rese	earch Network			
2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGAT	DR	2b. E-MAIL ADDRESS			
(Name and address, street, city, state, zip code) Barbara J. Stoll, MD		barbara_stoll@oz.ped.emory.edu			
Emory University School of Medicine		2c DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Pediatrics			
Department of Pediatrics		2d. MAJOR SUBDIVISION			
2015 Uppergate Drive, N.E. Atlanta, GA 30322		School of Medicine			
		29. Tel: 404-727-5740 Fax: 404-727-5737			
3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)		3b. Tel: 404-727-2503 Fax: 404-727-2509			
Emory University		30. DUNS: 066469933			
Office of Sponsored Programs 1599 Clifton Rd, 4 th Floor		3c. DUNS: 066469933 FEB 25 2008			
Atlanta, GA 30322		4. ENTITY IDENTIFICATION NUMBER			
		1580566256A1			
6. HUMAN SUBJECTS No Yes 6a. Research If Exempt ("Yes" in If Not Exer	mot ("No" in	5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL Holly Sommers			
Exempt 6a): 6a):		Acting Director			
No Yes Exemption No. IRB approv		Office of Sponsored Programs			
		1599 Clifton Rd NE, 4th Floor Atlanta GA 303			
6b. Federal Wide Assurance No. FWA0005792		Tel: 404 727 2507 Fax: 404 727 2509			
6c. NIH-Defined Phase III Clinical Trial No Yes	_	E-MAIL: osp@emory.edu			
7. VERTEBRATE ANIMALS No Yes		10. PROJECT/PERFORMANCE SITE(S)			
7a. If "Yes," IACUC approval Date		Organizational Name: Grady Memorial Hospital - Primary			
7b. Animal Welfare Assurance No. A-3180-01		DUNS: 066469933			
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD)	Street 1: 80 Jessie Hill Jr. Drive			
8a. DIRECT \$177,550 8b. TOTAL \$229,21	7	Street 2:			
9. INVENTIONS AND PATENTS No CY Yes		city: Atlanta County: Fulton			
lf "Yes, 🔲 Previously Reported		State: Georgia Province:			
Not Previously Reported		Country: USA Zip/Postal Code: 30303			
		Congressional Districts:			
11. NAME AND TITLE OF OFFICIAL SIGNING FOR API Holly Sommers	PLICANT C	RGANIZATION (Item 13)			
TEL: 404 727-2508 FAX:	404 72	27-2509 E-MAIL: osp@emory.edu			
12. Corrections to Page 1 Face Page					
13. APPLICANT ORGANIZATION CERTIFICATION AND statements herein are true, complete and accurate to the best obligation to comply with Public Health Services terms and co result of this application. I am aware that any faise, fictilious, of	of my knowl nditions if a g	ledge, and accept the 11. (In ink) grant is awarded as a 2/5/00			

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Pages 3 through 4 redacted for the following reasons: Not responsive

Program Director/Principal Investigator (Last, First, Middle):	Stoll, Barbara J			
PROGRESS REPORT SUMMARY	GRANT NUMBER HD 027851-18 PERIOD COVERED BY THIS REPORT			
<u> </u>				
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	FROM	THROUGH		
Barbara J. Stoll	04/01/2007	03/31/2008		

APPLICANT ORGANIZATION Emory University School of Medicine

TITLE OF PROJECT (Repeat title shown in Item 1 on first page) NICHD Cooperative Multicenter Neonatal Research Network

A.	A. Human Subjects (Complete Item 6 on the Face Page)					
•	Involvement of Human Subjects	\boxtimes	No Change Since Previous Submission		Change	
В.	Vertebrate Animals (Complete Item 7 on the Fa	ace Pa	ge)			
	Use of Vertebrate Animals	\boxtimes	No Change Since Previous Submission		Change	
C.	Select Agent Research	\boxtimes	No Change Since Previous Submission		Change	
D.	Multiple PI Leadership Plan	\boxtimes	No Change Since Previous Submission		Change	

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

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Not responsive

Program Director/Principal Investigator (Last, First, Middle): Stoll, Barbara J.

• .

Not responsive

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H. <u>SUPPORT – Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants</u>: This prospective randomized, factorial 2x2 design study will compare CPAP and a permissive ventilatory strategy begun in the delivery room and continuing in the NICU with early surfactant and mechanical ventilation AND a lower oxygen saturation level (85% to 89%) vs. a higher one (91% to 95%) until the infant is no longer requiring oxygen or until 36 weeks. The study began in 2004 and Emory entered 59 patients as of December 31, 2007.

Dr. S. Buchter is the Emory PI for the SUPPORT Trial.

Not responsive

Not responsive

Pages 8 through 9 redacted for the following reasons: Not responsive

Center 09: Emory – Protocols 2007 PI: Dr. Barbara J. Stoll

IHC-ID	Protocol Title	Status	Current Approval Date	Expiration Date	Notes
Not responsive		<u>}</u>			
1158-2004	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	Approved	9/25/07	9/24/08	
Not responsive					

Pages 11 through 53 redacted for the following reasons: Not responsive

Neonatal Research Network 2007 Race/Gender Tables (randomized 1/1-11/30) Support Protocol Emory University

▔▖▖▝▝▖▔▝▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖▖	
	ALC: NO
ային հուշատեղիանել է չինչին է հայտանին է ինչպես է հայտելին հայտարանանանումներների ոլեզիանանը, ինչենների կերթ	
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Pages 55 through 58 redacted for the following reasons: Not responsive Neonatal Research Network 2007 Race/Gender Tables (randomized 1/1-11/30) Hispanic subjects ONLY (table 3) Support Protocol

Center ID number=Emory University

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Progress Report Scanning Cover Sheet

5U10HD027851-19

PI Name:	STOLL, BARBARA
Org:	EMORY UNIVERSITY
Start Date:	04/01/2009
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	7618285
Rec'd Date:	02/10/2009

Form Approved Throu	gh 11/30/2010					0	MB No. 0925-0001
Departme	ent of Health and Hum Public Health Service		Review Group ZHD1 MCHG-B	Type 5	Activity U10	Grant Number HD 027851-1	9
			Total Project Period		4		
Cront	Drogrado	Dement	From: 04/01/200	6	Thr	ough: 03/31/201	1
Grant Progress Report		Requested Budget F	Period		- <u></u>		
		From: 04/01/200	9	Thr	ough: 03/31/201	0	
1. TITLE OF PROJE		er Neonatal Rese	earch Network				
2a. PROGRAM DIRE	CTOR / PRINCIPAL IN	VESTIGATOR	2b. E-MAIL ADDRES	-			<u></u>
Barbara J. St	s, street, city, state, zij	o code)	barbara_stoil	-	-		
	sity School of M	edicine	2c. DEPARTMENT, 8 Pediatrics	SERVICE,	-	RY, OR EQUIVAL	ENT
•	ate Drive, N.E.		2d. MAJOR SUBDIVI				
Atlanta, GA 3			School of Me	dicine			
· ····································			2e. Tel: 404-727-	5740	Fax	c 404-727-573	37
	s, street, city, state, zip	code)	3b. Tel: 404-727-	-2503	Fax	c 404-727-250)9
Emory Univer	nsored Programs		3c. DUNS: 0664	69933			
1599 Clifton		>				f	EB 1 0 2009
Atlanta, GA			4. ENTITY IDENTIF 1580566256			• 	
6. HUMAN SUBJECT	S 🗌 No 🛛	Yes	5. NAME, TITLE AN	ID ADDRE	SS OF ADN	INISTRATIVE OF	
6a. Research Exempt	If Exempt ("Yes" in 6a):	If Not Exempt ("No" in 6a):	Sarah Whit	e, Dir	ector		
	Exemption No.	IRB approval date	Office of				
		various date				ailstop 159	9-001-1BA
6b. Federal Wide Ass		0005792	Atlanta, C Tel: 404 727 25		:∠ Fa:	×: 404 727 2	509
6c. NIH-Defined Phase	e III		1	emory.	edu	404 /2/ 2	202
Clinical Trial N	o _ Yes						
7. VERTEBRATE AN	IMALS 🖾 No 🛛	Yes	10. PROJECT/PERF	ORMANCI	E SITE(S)		
7a. If "Yes," IACUC a	pproval Date		Organizational Name: Grady Memorial Hospital - Primary				
	ssurance No. A-3180		DUNS: 066469933				
8. COSTS REQUES	TED FOR NEXT BUDG	GET PERIOD	Street 1: 80 Jessie Hill Jr. Drive				
8a. DIRECT \$178,9	91 86. тота	∟\$231,078	Street 2:				
9. INVENTIONS AND	PATENTS No	Yes	city: Atlanta		Co	unty: Fulton	
	usly Reported		State: Georgia		Pro	ovince:	
🛄 Not Pri	eviously Reported		Country: USA Zip/Postal Code: 30303		0303		
			Congressional Distric	ts:		A BOOM AND A CONTRACT OF A	
	E OF OFFICIAL SIGNI te, Director	NG FOR APPLICANT	ORGANIZATION (Item	13)	<u></u>		
TEL: 404 727	2503	FAX: 404 72	7 2509		E-MAIL:	osp@emory.e	 du
12. Corrections to Pag				L		<u>oop(d.or);;;;</u>	
		CATION AND ACCEPT, rate to the best of my know		SIGNATUI		CIAL NAMED IN	DATE
obligation to comply	with Public Health Service	is terms and conditions if a alse, fictitious, or frauduler	grant is awarded as a			sho	219/09
may subject me to cr	iminal, civil, or administrat			Sil	10	Nno	
PHS 2590 (Rev. 11/07	")		Face Page		[Form Page 1
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Pages 3 through 5 redacted for the following reasons: Not responsive

Program Director/Principal Investigator (Last, First, Midd	^{lle):} Stoll, Barbara J				
PROGRESS REPORT SUMMARY	GRANT NUMBER HD 027851-19				
	PERIOD COVERED BY THI	SREPORT			
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	FROM	THROUGH			
Barbara J. Stoll	04/01/2008	03/31/2009			
Emory University School of Medicine TITLE OF PROJECT (Repeat title shown in Item 1 on first pa NICHD Cooperative Multicenter Neonatal Research	• /				
A. Human Subjects (Complete Item 6 on the Face Page)		· · · · · · · · · · · · · · · · · · ·			
Involvement of Human Subjects 🛛 🛛 No Cl	ange Since Previous Submission	Change			
B. Vertebrate Animals (Complete Item 7 on the Face Page)					
. Use of Vertebrate Animals No Cl	ange Since Previous Submission	Change			
C. Select Agent Research 🛛 🔀 No Cl	nange Since Previous Submission	Change			
D. Multiple PI Leadership Plan 🛛 No Cl	ange Since Previous Submission	Change			

SEE PHS 2590 INSTRUCTIONS.

Not responsive

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The Emory Regional Perinatal Center has been participating in the NICHD multicenter network of neonatal intensive care units since April 1991. These have been an exciting and productive 15 years. We have participated in on-going neonatal network projects and have been active in the planning stages and review of new projects.

H. <u>SUPPORT – Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants</u>: This prospective randomized, factorial 2x2 design study will compare CPAP and a permissive ventilatory strategy begun in the delivery room and continuing in the NICU with early surfactant and mechanical ventilation AND a lower oxygen saturation level (85% to 89%) vs. a higher one (91% to 95%) until the infant is no longer requiring oxygen or until 36 weeks. The study began in 2004. To date, 1259 infants have been randomized into the SUPPORT study, 86 of these from Emory.

Dr. S. Buchter is the Emory PI for the SUPPORT Trial.

Not responsive

Not responsive

V

Pages 9 through 13 redacted for the following reasons: Not responsive

Inclusion Enrollment Report for the Support Study for Personal Identifier

Categories	Females	Males	Unknown	total
Ethnic - Hisp or Latino	2	1	0	3
Ethnic - Not Hisp or Latino	15	8	0	23
Ethnic - Unknown	0	0	0	0
Ethnicity: Total of All Subjects	17	9	0	26
Amer Indian/Alaska	0	0	0	0
Asia	0	0	0	0
Hawaiian or Other Pacific	0	0	0	0
Black or African Amer	14	5	0	19
White	1	3	0	4
More than One	0	0	0	0
Unknown or Not Reported	2	1	0	3
Racial Categories: Total of all	17	9	0	26
Hispanic: Amer Indian/Alaska	0	0	0	0
Hispanic: Asia	0	0	0	0
Hispanic: Hawaiian or Other Pacific	0	0	0	0
Hispanic: Black or African Amer	0	0	0	0
Hispanic: White	0	0	0	0
Hispanic: More than One	0	0	0	0
Hispanic: Unknown or Not Reported	2	1	0	3
Hispanic: Racial Categories: Total of al	2	1	0	3

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
lot responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	1158-2004	9/25/08	9/24/09
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	1158-2004	9/25/08	9/24/09
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	1158-2004	9/25/08	9/24/09
Breathing Outcomes (SUPPORT Study Secondary)	1158-2004	9/25/08	9/24/09
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	1158-2004	9/25/08	9/24/09

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

*** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
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Pages 18 through 69 redacted for the following reasons: Not responsive

NICHD Neonatal Research Network

THE SURFACTANT POSITIVE AIRWAY PRESSURE AND PULSE OXIMETRY TRIAL IN EXTREMELY LOW BIRTH WEIGHT (ELBW) INFANTS

OBJECTIVE: The Primary hypotheses to be tested: 1) relative to infants managed with prophylactic/early surfactant and conventional ventilation that the use of early CPAP and a permissive ventilatory strategy in infants of less than 28 weeks gestation with continuing CPAP in the NICU will result in an increased survival without BPD at 36 weeks. 2) relative to infants managed with a higher SpO₂ range, the use of a lower SpO₂ range (85-89%) will result in an increase in survival without the occurrence of threshold ROP and/or the need for surgical intervention.

ORGANIZATION		OUTCOME MEASURES	
Clinical centers:	<u>Network</u> : Case Western Reserve, University of Alabama, Brown University, University of Cincinnati, Indiana University, Emory University, University of Miami, Stanford University, University of Texas-Dallas, University of Texas-Houston, Wayne State University, Yale University, Duke University, Wake Forest University, UCSD, University of Rochester	Primary: Secondary:	 There are two primary outcomes: The percentage of infants surviving without BPD (using the Physiologic Definition) The percentage of infants surviving without severe ROP (threshold diseases or the need for surgery). The five minute Apgar score The percentage of infants with death or
Subcommittee	Neil Finer MD, Michele Walsh MD, Edward Donovan MD, Waldemar Carlo MD, Shanaz Duara MD, Rosemary Higgins, MD, Kenneth Poole, PhD, Ruth Everett, RN, Wade Rich, RRT		 The percentage of manna with dealer of neurodevelopmental impairment at 18 months The total duration of mechanical ventilation during the entire NICU stay
DESIGN			 The percent of infants alive and off ventilation by day 7 The proportion of infants receiving surfactant treatment
Type: Major inclusion criteria: Treatment groups: Level of masking: Randomization: Sample size:	 Prospective, randomized, factorial 2x2 design multi-center trial Inborn Infants Infants with a gestational age of 24 0/7 to 27 6/7 weeks Infants without known major congenital malformations There are four treatment groups: Early CPAP and permissive ventilation management with an assignment to low SpO₂ range; Early CPAP and permissive ventilation management with an assignment to high SpO₂ range; Early Surfactant and conventional ventilator management with an assignment to low SpO₂ range. Early Surfactant and conventional ventilator management with an assignment to high SpO₂ range. Early Surfactant and conventional ventilator management with an assignment to high SpO₂ range. Mode of Ventilatory Support will be unmasked High or Low SpO₂ ranges will be masked to the PI and Coordinators Stratified by gestational age group (24-25 6/7 and 26 - 27 6/7). Goal = 1310 Based on 80% power for detecting an absolute difference of 10% in the 		 The incidence of air leaks on admission and overall The incidence of BPD at 36 weeks using the physiologic definition of BPD The incidence of death The proportion of infants with severe IVH The proportion of infants with PVL The proportion of infants with threshold ROP and requiring surgery for ROP The proportion of infants requiring endotracheal intubation before 10 minutes of age The proportion of infants with of air leaks on admission and overall The proportion of oxygen supplementation The precentage of pulse oximetry values > 90% A decreased incidence of blindness of at least one eye at 18-22 month follow-up The proportion of infants with who develop necrotizing enterocolitis (NEC)
SCHEDULED EVALUAT	two primary outcomes and the NDI secondary outcome.		 The proportion of infants with cerebral palsy at 18-22 month follow-up
Pre- randomization: Post-	Eligibility In-hospital clinical outcomes		TUDIES Neurodevelopmental Outcome: A Secondary to Surfactant Positive Airway e Oximetry Trial (SUPPORT)
randomization;	• 18-22 month follow-up	Randomization:	 3//2005 – until the sample size has been reached.
MANAGEMENT PROTO Delivery Room Management:	Resuscitate using CPAP: If necessary, initial PPV settings PIP 15-25, PEEP 5. Transport on CPAP.	Follow-up:	 3/2003 – Unit the sample size has been reached. 18 - 22 Month Follow-up (through 5/2008)
	 If intubated for resuscitation: Give Surfactant within 1 hour of age. For intubation use NRP Guidelines. Transport with PPV according to SOC 	<u>CONCLUSIONS</u> The study is ongoing	
NICU Admission	Implement the Pulse Oximeter within 2 hours	DATA CENTER	
		RTI. International	06/02/2005

Pages 71 through 77 redacted for the following reasons: Not responsive

Form Approved Through 1	1/30/2010					C	MB No. 0925-0001
	of Health and Huma blic Health Services		Review Group ZHD1 MCHG-B	Type 5	Activity U10	Grant Number HD 027851-	19
			Total Project Period				
Grant Progress Report		From: 04/01/2006 Through: 03/31/2011 Requested Budget Period					
			From: 04/01/2009	<u> </u>	Thr	rough: 03/31/20	10
1. TITLE OF PROJECT NICHD Coopera			arch Network				
2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code) Barbara J. Stoll, MD			2b. E-MAIL ADDRES	-	d omonu		
		barbara_stoll 2c. DEPARTMENT, S	-	•		ENT	
Emory University		edicine	Pediatrics	2	0.0010110		
Department of P			2d. MAJOR SUBDIVI	SION			
2015 Uppergate Atlanta, GA 303			School of Me	dicine			
			2e. Tel: 404-727-	5740	Fax	x: 404-727-57	37
3a. APPLICANT ORGANIA (Name and address, str		code)	3b. Tel: 404-727-	2503	Fa	x: 404-727-25	09
Emory University Office of Sponsored Programs 1599 Clifton Rd, 4 th Floor Atlanta, GA 30322			3c. duns: 0664	69933			
			4. ENTITY IDENTIFI 1580566256		NUMBER	······································	
6. HUMAN SUBJECTS		/es	5. NAME, TITLE AN	D ADDRE	SS OF ADM	INISTRATIVE OF	FICIAL
6a. Research If Exempt ("Yes" in If Not Exempt ("No" in Exempt Exempt 6a); 6a);			Sarah White, Director				
	, emption No.	IRB approval date	Office of			-	
		various date	1599 Clift Atlanta, G			ailstop 159	99-001 - 1BA
6b. Federal Wide Assuran	nce No. FWAO	005792	Tel: 404 727 25		Fa	^{x:} 404 727 2	2509
6c. NIH-Defined Phase III Clinical Trial No	Yes		E-MAIL: OSP@	emory.	edu		
7. VERTEBRATE ANIMA	LS 🛛 NO 🗌	Yes	10. PROJECT/PERFO	ORMANCE	E SITE(S)		
7a. If "Yes," IACUC appro	oval Date		Organizational Name:	Grad	y Memoi	rial Hospital -	Primary
7b. Animal Welfare Assura			DUNS: 0664698	933			
8. COSTS REQUESTED	FOR NEXT BUDG	ET PERIOD	Street 1: 80 Jes	sie Hill	Jr. Drive		
8a. DIRECT \$178,991	8b. TOTAL	. \$231,078	Street 2:				
9. INVENTIONS AND PA		Yes	city: Atlanta		Co	unty: Fulton	
If "Yes, Previously			State: Georgia		Pro	ovince:	
	usly Reported		Country: USA		Zip	p/Postal Code: 3	30303
			Congressional Distric	ts:			
11. NAME AND TITLE OF Sarah White,		NG FOR APPLICANT C	RGANIZATION (Item	13)			
TEL: 404 727 250)3	FAX: 404 727	2509		E-MAIL:	osp@emory.e	edu
12. Corrections to Page 1	Face Page						
obligation to comply with I	e, complete and accur Public Health Services I am aware that any fa	ate to the best of my know terms and conditions if a lise, fictitious, or fraudulent	ledge, and accept the 1 grant is awarded as a	SIGNATOF		icial named in / MAC	DATE 219/09
PHS 2590 (Rev. 11/07)	, ern, er ganningoog		Face Page	<u>-</u>	1-0		Form Page 1
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Pages 79 through 81 redacted for the following reasons: Not responsive Program Director/Principal Investigator (Last, First, Middle): Stoll Barbara J

	•••••		
	GRANT NUMBER		
PROGRESS REPORT SUMMARY	HD 027851-19		
	PERIOD COVERED BY	THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	FROM	THROUGH	
Barbara J. Stoll	04/01/2008	03/31/2009	
APPLICANT ORGANIZATION			

Emory University School of Medicine

TITLE OF PROJECT (Repeat title shown in Item 1 on first page) NICHD Cooperative Multicenter Neonatal Research Network

 A. Human Subjects (Complete Item 6 on the Face	Page)	
Involvement of Human Subjects	No Change Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the Fa	ace Page)	
Use of Vertebrate Animals	No Change Since Previous Submission	Change
C. Select Agent Research	No Change Since Previous Submission	Change
 D. Multiple PI Leadership Plan	No Change Since Previous Submission	Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The Emory Regional Perinatal Center has been participating in the NICHD multicenter network of neonatal intensive care units since April 1991. These have been an exciting and productive 15 years. We have participated in on-going neonatal network projects and have been active in the planning stages and review of new projects.

H. <u>SUPPORT – Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants</u>: This prospective randomized, factorial 2x2 design study will compare CPAP and a permissive ventilatory strategy begun in the delivery room and continuing in the NICU with early surfactant and mechanical ventilation AND a lower oxygen saturation level (85% to 89%) vs. a higher one (91% to 95%) until the infant is no longer requiring oxygen or until 36 weeks. The study began in 2004. To date, 1259 infants have been randomized into the SUPPORT study, 86 of these from Emory.

Dr. S. Buchter is the Emory PI for the SUPPORT Trial.

Not responsive

Pages 85 through 89 redacted for the following reasons: Not responsive

Inclusion Enrollment Report for the Support Study for Personal Indenifier

Categories, See See	Females	Males	Unknown	total
Ethnic - Hisp or Latino	2	1	0	3
Ethnic - Not Hisp or Latino	15	8	0	23
Ethnic - Unknown	0	0	0	0
Ethnicity: Total of All Subjects	17	9	0	26
Amer Indian/Alaska	0	0	0	0
Asia	0	0	0	0
Hawaiian or Other Pacific	0	0	0	0
Black or African Amer	14	5	0	19
White	1	3	0	4
More than One	0	0	0	0
Unknown or Not Reported	2	1	0	3
Racial Categories: Total of all	17	9	0	26
Hispanic: Amer Indian/Alaska	0	0	0	0
Hispanic: Asia	0	0	0	0
Hispanic: Hawaiian or Other Pacific	0	0	0	0
Hispanic: Black or African Amer	0	0	0	0
Hispanic: White	0	0	0	0
Hispanic: More than One	0	0	0	0
Hispanic: Unknown or Not Reported	2	1	0	3
Hispanic: Racial Categories: Total of al	2	1	0	3

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	1158-2004	9/25/08	9/24/09
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	1158-2004	9/25/08	9/24/09
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	1158-2004	9/25/08	9/24/09
Breathing Outcomes (SUPPORT Study Secondary)	1158-2004	9/25/08 ·	9/24/09
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	1158-2004	9/25/08	9/24/09

	PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive				

*** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

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Pages 94 through 145 redacted for the following reasons: Not responsive

NICHD Neonatal Research Network

THE SURFACTANT POSITIVE AIRWAY PRESSURE AND PULSE OXIMETRY TRIAL IN EXTREMELY LOW BIRTH WEIGHT (ELBW) INFANTS

OBJECTIVE: The Primary hypotheses to be tested: 1) relative to infants managed with prophylactic/early surfactant and conventional ventilation that the use of early CPAP and a permissive ventilatory strategy in infants of less than 28 weeks gestation with continuing CPAP in the NICU will result in an increased survival without BPD at 36 weeks. 2) relative to infants managed with a higher SpO₂ range, the use of a lower SpO₂ range (85-89%) will result in an increase in survival without the occurrence of threshold ROP and/or the need for surgical intervention.

ORGANIZATION		OUTCOME MEASURES	
Clinical centers:	<u>Network</u> : Case Western Reserve, University of Alabama, Brown University, University of Cincinnati, Indiana University, Emory University, University of Miami, Stanford University, University of Texas-Dallas, University of Texas-Houston, Wayne State University, Yale University, Duke University, Wake Forest University, UCSD, University of Rochester	Primary: Secondary:	 There are two primary outcomes: The percentage of infants surviving without BPD (using the Physiologic Definition) The percentage of infants surviving without severe ROP (threshold diseases or the need for surgery). The five minute Apgar score
Subcommittee	Neil Finer MD, Michele Walsh MD, Edward Donovan MD, Waldemar Carlo MD, Shanaz Duara MD, Rosemary Higgins, MD, Kenneth Poole, PhD, Ruth Everett, RN, Wade Rich, RRT		 The percentage of infants with death or neurodevelopmental impairment at 18 months The total duration of mechanical ventilation during the entire NICU stay
<u>DESIGN</u>			 The percent of infants alive and off ventilation by day 7 The proportion of infants receiving surfactant treatment
Type: Major inclusion criteria: Treatment groups:	 Prospective, randomized, factorial 2x2 design multi-center trial Inborn Infants Infants with a gestational age of 24 0/7 to 27 6/7 weeks Infants witho will receive full resuscitation as necessary Infants without known major congenital malformations There are four treatment groups: Early CPAP and permissive ventilation management with an assignment to low SpO₂ range; Early Surfactant and conventional ventilator management with an assignment to high SpO₂ range; 		 The proportion of mains receiving surfactant treatment The incidence of air leaks on admission and overall The incidence of BPD at 36 weeks using the physiologic definition of BPD The incidence of death The proportion of infants with severe IVH The proportion of infants with PVL The proportion of infants with threshold ROP and requiring surgery for ROP The proportion of infants requiring endotracheat intubation before 10 minutes of age The proportion of infants with of air leaks on admission and overall
Level of masking:	 assignment to low SpO₂ range. Early Surfactant and conventional ventilator management with an assignment to high SpO₂ range. Mode of Ventilatory Support will be unmasked High or Low SpO₂ ranges will be masked to the PI and Coordinators 		 The duration of oxygen supplementation The percentage of pulse oximetry values > 90% A decreased incidence of blindness of at least one eye at 18-22 month follow-up
Randomization: Sample size:	 Stratified by gestational age group (24-25 6/7 and 26 - 27 6/7). Goal = 1310 Based on 80% power for detecting an absolute difference of 10% in the two primary outcomes and the NDI secondary outcome. 		 The proportion of infants who receive postnatal steroids to prevent or treat BPD The proportion of infants with who develop necrotizing enterocolitis (NEC) The proportion of infants with cerebral palsy at 18-22 month follow-up
SCHEDULED EVALUAT	IONS	OPTIONAL SECONDARY STU	
Pre- randomization:	Eligibility	1) Neuroimaging and Ne	eurodevelopmental Outcome: A Secondary to Surfactant Positive Airway Oximetry Trial (SUPPORT)
Post- randomization:	In-hospital clinical outcomes 18-22 month follow-up	TIMETABLE	
MANAGEMENT PROTO	COLS	Randomization:	 3//2005 – until the sample size has been reached.
Delivery Room Management:	 Resuscitate using CPAP: If necessary, initial PPV settings PIP 15-25, PEEP 5. Transport on CPAP. 	Follow-up:	 18 - 22 Month Follow-up (through 5/2008)
	 If intubated for resuscitation; Give Surfactant within 1 hour of age. For intubation use NRP Guidelines. Transport with PPV according to SOC 	<u>CONCLUSIONS</u> The study is ongoing	
NICU Admission	Implement the Pulse Oximeter within 2 hours	DATA CENTER	
		RTI, International	06/02/2005

Pages 147 through 149 redacted for the following reasons: Not responsive Program Director/Principal Investigator (Last, first, middle):

Stoll, Barbara J

GRANT NUMBER 2 U10 HD 027851

CHECKLIST

		CHEU	NLI31			
1. PROGRAM INCOME (See ins All applications must indicate whet anticipated, use the format below t	her program income is a		ng the period(s) for	r which grant s	support is requested.	If program income is
Budget Period	Anticipa	ted Amount			Source(s)	
2. ASSURANCES/CERTIFICATIO	ONS (See instructions.	.)	••••••			
In signing the application Face Pa- listed in the application instruction listed in Part I, 4.1 under Item 14 (Form Page 5).	ge, the authorized organ s when applicable. Des	nizational repres	vidual assurances	/certifications	are provided in Part	III of the PHS 398, and
3. FACILITIES AND ADMINSTRA Indicate the applicant organizat established with the appropriate D for-profit organizations, the rate of Agency Cost Advisory Office.	tion's most recent F HHS Regional Office, or	r, in the case of	organizations additional ir Institutional Innovation R	, grants to ind astructions p National Res Research/Sma	lividuals, and confere rovided for Resea search Service Awa	ants, grants to Federal ince grants. Follow any arch Career Awards, ards, Small Business ilogy Transfer Grants, s.
DHHS Agreement dated:				No Faci	lities and Administrat	ive Costs Requested.
NO DHHS Agreement, but ra	ate established with				Date	
Entire proposed budget period:	Amount of base \$	178,991	_x Rate applied	29.10	% = F&A costs \$	52,086
	Add to to	tal direct costs f	rom Form Page 2	and enter nev	v total on Face Page,	item 8b.
*Check appropriate box(es):						
Salary and wages base	М	odified total dire	ect cost base		Other base (Expla	ain)
Off-site, other special rate, or	more than one rate inv	olved (Explain)				
Explanation (Attach separate sh	eet, if necessary.):					

Progress Report Scanning Cover Sheet

5U10HD027851-20

PI Name: Org: Start Date: Snap: Appl ID: Rec'd Date:

STOLL, BARBARA EMORY UNIVERSITY 04/01/2010 N/A (NEEDS TO BE BOOKMARKED) 7800920 02/16/2010

•

Form Approved Throu	ugh 11/30/2010		Nd			OMB No. 0925-000	
Department of Health and Human Services Public Health Services			Review Group ZHD1 MCHG-B	Type 5	Activity U10	Grant Number HD 027851-20	
			Total Project Period				
Grant Progress Report			From: 04/01/200		Th	rough: 03/31/2011	
Glain	riogiess	Report	Requested Budget F	Period			
			From: 04/01/201	0	Th	rough: 03/31/2011	
1. TITLE OF PROJE NICHD Coop		er Neonatal Rese	earch Network				
2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code) Barbara J. Stoll, MD		2b. E-MAIL ADDRES	-				
		barbara_stol					
	rsity School of M	edicine	Pediatrics	SERVICE	, LABORATO	DRY, OR EQUIVALENT	
•	ate Drive, N.E.		2d. MAJOR SUBDIVI School of Me				
			2e. Tel: 404-727-	_	Fa	x: 404-727-5737	
3a. APPLICANT ORG (Name and addres	SANIZATION is, street, city, state, zip	(code)	3b. Tel: 404-727-	2503	Fa	x: 404-727-2509	
Emory Unive	rsity, Office of Sp Rd NE, Mailstop:	onsored Prog.	3c. DUNS: 06646	9933		FEB 1 6 201	
Atlanta, GA 30322			4. ENTITY IDENTIFICATION NUMBER 1580566256A1				
6. HUMAN SUBJECT		Yes	5. NAME, TITLE AN			INISTRATIVE OFFICIAL	
6a. Research	If Exempt ("Yes" in	If Not Exempt ("No" in			\$	Emory University	
Exempt No 🗌 Yes	6a): Exemption No.	6a): IRB approval date	Cessandra Murphy, PhD Assistant Director Office of Sponsored Programs			Office of Sponsored Programs	
	·	various date	Office of Spons		aus	1599 Clifton Road, 4th Floor Mailstop: 1599-001-1BA	
6b Federal Wide Ass	surance No. FWA0	005792	Теі: 404-727-25(x: 404-727-250922			
6c. NIH-Defined Phas		,000,02	E-MAIL: osp@emory.edu				
Clinical Trial							
7. VERTEBRATE AN	IMALS No	Yes	10. PROJECT/PERFO	DRMANC	E SITE(S)		
7a. If "Yes," IACUC a			Organizational Name:	Grady	/ Memoria	al Hospital - Primary	
	ssurance No. A-3180	-01	DUNS: 066469933				
	TED FOR NEXT BUDG		Street 1: 80 Jessi		Ir. Drive		
8a. DIRECT \$180,7		_ \$233,347	Street 2:				
		-			·	, 	
9. INVENTIONS AND	PATENTS No	Yes	city: Atlanta		Co	unty: Fulton	
	usly Reported		_{State:} Georgia		Pro	ovince:	
Not Pro	eviously Reported		Country: USA		Zip	/Postal Code: 30303	
			Congressional District	s: 05	<u></u>		
11. NAME AND TITLE	E OF OFFICIAL SIGNI	NG FOR APPLICANT O	RGANIZATION (Item	13)			
TEL: 404-727-25	03	FAX: 404-727-	2509		E-MAIL: OS	p@emory.edu	
12. Corrections to Pag	ge 1 Face Page						
	ANIZATION CERTIFIC	ATION AND ACCEPTA	NCE: 1 certify that the IS				
statements herein and obligation to comply v	e true, complete and accur with Public Health Services on, I am aware that any fa	ate to the best of my knowles terms and conditions if a g alse, flotitious, or fraudulent	edge, and accept the 1 grant is awarded as a	i (in ink)) []	Dhup 2/5/1	
may subject me to cri	minal, civil, or administrati		Face Page			Form Page 1	

Pages 3 through 5 redacted for the following reasons: Not responsive

Program Director/Principal Investigator (Last,	First, Middle)	ⁱⁱ Stoll, Barbara J			
PROGRESS REPORT SUMMAR	RY	GRANT NUMBER HD 027851-20			
		PERIOD COVERED BY TH	IIS REPORT		
PROGRAM DIRECTOR / PRINCIPAL INVESTIGAT	OR	FROM	THROL	JGH	
Barbara J. Stoll		04/01/2009	03/31/	2010	
APPLICANT ORGANIZATION Emory University School of Medicine TITLE OF PROJECT (Repeat title shown in Item 1 of NICHD Cooperative Multicenter Neonatal		•			
A. Human Subjects (Complete Item 6 on the Face Pa	age)		······································		
Involvement of Human Subjects		nge Since Previous Submission		Change	
B. Vertebrate Animals (Complete Item 7 on the Face	Page)			-	
Use of Vertebrate Animals	No Char	nge Since Previous Submission		Change	
C. Select Agent Research	No Char	nge Since Previous Submission		Change	
D. Multiple PI Leadership Plan	No Char	ige Since Previous Submission		Change	
SEE PHS 2590 INSTRUCTIONS					

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The Emory Regional Perinatal Center has been participating in the NICHD multicenter network of neonatal intensive care units since April 1991. These have been an exciting and productive 15 years. We have participated in on-going neonatal network projects and have been active in the planning stages and review of new projects.

G. <u>SUPPORT – Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants</u>: This prospective randomized, factorial 2x2 design study will compare CPAP and a permissive ventilatory strategy begun in the delivery room and continuing in the NICU with early surfactant and mechanical ventilation AND a lower oxygen saturation level (85% to 89%) vs. a higher one (91% to 95%) until the infant is no longer requiring oxygen or until 36 weeks. Study enrollment was completed in 2009 with 1316 infants randomized into the study, 86 from Emory. 64 infants from Emory were enrolled in the growth secondary study and 5 infants were entered into the neuroimaging secondary study. Two primary papers have been submitted for publication.

Dr. S. Buchter is the Emory PI for the SUPPORT Trial.

Not responsive

Pages 10 through 24 redacted for the following reasons: Not responsive

Inclusion Enrollment Report for the Support Study for Personal Identifier

Categories	Females	Males	Unknown	total
Ethnic - Hisp or Latino	0	0	0	0
Ethnic - Not Hisp or Latino	0	1	0	1
Ethnic - Unknown	0	0	0	0
Ethnicity: Total of All Subjects	0	1	0	1
Amer Indian/Alaska	0	0	0	0
Asia	0	0	0	0
Hawaiian or Other Pacific	0	0	0	0
Black or African Amer	0	1	0	1
White	· 0	0	0	0
More than One	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of all	0	1	0	1
Hispanic: Amer Indian/Alaska	0	0	0	0
Hispanic: Asia	0	0	0	0
Hispanic: Hawaiian or Other Pacific	0	0	0	0
Hispanic: Black or African Amer	0	0	0	0
Hispanic: White	0	0	0	0
Hispanic: More than One	0	0	0	0
Hispanic: Unknown or Not Reported	0	0	0	0
Hispanic: Racial Categories: Total of al	0	0	0	0

Pages 26 through 27 redacted for the following reasons: Not responsive

Center 09: Emory – Protocols 2010 PI: Dr. Barbara J. Stoll

IHC-ID	Protocol Title	Status	Current Approval Date	Expiration Date	Notes
					ROC CHOA
Not responsive					
1158-2004	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	Approved	9/20/09	9/19/10	
Not responsive					
			<u>.</u>		

Pages 29 through 77 redacted for the following reasons: Not responsive Progress Report Scanning Cover Sheet

5U10HD027853-15

PI Name:	DONOVAN, EDWARD
Org:	UNIVERSITY OF CINCINNATI
Start Date:	04/01/2005
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appi ID:	6895910
Rec'd Date:	02/03/2005

Form Approved Through 09/30/2007			•		OMB No. 0925-0001
Department of Health and Human Services Public Health Services	Re	eview Group	Type 5	Activity U10	Grant Number HD27853-15
	Та	otal Project Per	riod		
Grant Progress Report	Fr	om: 04/01/1	991	Th	rough: 03/31/2006
Giant Flogress Report		equested Budg	et Period	i	
	Fr	om: 04/01/2	2005	Th	rough: 03/31/2006
1. TITLE OF PROJECT					
Cooperative Multicenter Neonatal Research Ne					
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)		PLICANT ORO			in code)
Edward F. Donovan, M.D.		iversity of			,,,
University of Cincinnati) Box 6705			
Department of Pediatrics	Cir	ncinnati, O	hio 452	267-0553	
PO Box 670541					+
Cincinnati, Ohio 45267-0541			٠,		
2b. E-MAIL ADDRESS	4. <i>∽</i> EN	TITY IDENTIF	ICATION	NUMBER	
edward.donovan@cchmc.org		16000 ⁹ 89A			د - به المعرف br>المعرف المعرف br>المعرف المعرف
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT	5. TIT	LE AND ADD	RESS OF		
Pediatrics					Programs 🗠
2d. MAJOR SUBDIVISION		iversity of		nati	
College of Medicine	1	Box 6705			
	Cir	ncinnati, O	hio 452	267-0553	·
	E-MAIL	-: tana.hou	ush@ud	.edu	
6. HUMAN SUBJECTS		VERTEBRAT	E ANIMA	ALS	· · · · · · · · · · · · · · · · · · ·
No 6a. Research Exempt 6b. Human Subjects Assurance	No.	No		7	a. If "Yes," IACUC approval Date
X Yes FWA00003152] Yes			
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III		. Animal Welfa	are Assui	ance No.	
Exemption No. Clinical Trial 🛛 No 🗌 Yes		•			
If Not Exempt ("No" in 6a):					
IRB approval date see attached	~				
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INV	ENTIONS ANI		ITS	· · · · · · · · · · · · · · · · · · ·
8a. DIRECT \$155,466 8b. TOTAL \$237,863	No 🛛	Yes	lf "Yes,"	🔲 Prev	iously Reported
				🗌 Not F	Previously Reported
10. PERFORMANCE SITE(S) (Organizations and addresses)		RINCIPAL IN			_ 513-
Department of Pediatrics	ORPR	OGRAM DIRE	CTOR ((FA) (FA	< 513-
University of Cincinnati	11h A	DMINISTRATI			
PO Box 670541		(Item 5)			513-558-5540
Cincinnati, Ohio 45267-0541	Tana	Housh		FAX	< 513-558 - 1755
					NING FOR APPLICANT
	NAME	RGANIZATIO		14)	
	1	r an a r re	-		
	TITLE			•	ored Programs
	TEL	513-558-			FAX 513-558-1755
	E-MAIL	- tana.hou	ush@u	c.edu	
12. Corrections to Page 1 Face Page					· · · · ·

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR As statements herein are true, complete and accurate to the best of any false, fictitious, or fraudulent statements or claims may subject administrative penalties. I agree to accept responsibility for the se and to provide the required progress reports if a grant is awarded	my knowledge. I am aware that ct me to criminal, civil, or cientific conduct of the project		DATE Jan. 26, 2005
14. APPLICANT ORGANIZATION CERTIFICATION AND AC statements herein are true, complete and accurate to the best of obligation to comply with Public Health Services terms and condit result of this application. I am aware that any false, fictitious, or fi may subject me to criminal, civil, or administrative penalties.	my knowledge, and accept the ions if a grant is awarded as a	SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Per" signature not acceptable.)	DATE 2/1/05
PHS 2500 (Rev. 09/04)	Face Page		Form Page 1

l

Neonatal Research Network Protocols January 1, 2005 – December 31, 2005

Cincinnati Children's Hospital Medical Center (CCHMC) Good Samaritan Hospital (GSH) University Hospital (UH)

Protocol	Institutional Project No. (Last IRB Approval Date)
Not responsive. Not related to SUPPORT.	
The Surfactant Positive Airway	
Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Pilot)	UH: 04-8-6-1 (November 10, 2004)
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Trial)	CCHMC: (Submission Pending) GSH: (Approval Pending January 28, 2005 Review) UH: 04-5-20-1 (October 13, 2004

GDB at GSH IRB: Annual progress report not required, as of August 2001.

Edward F. Donovan, M.D.

Pages 4 through 8 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (La	st, first, middle): Do	onovan, Edward F., M.D.
PROGRESS REPORT SUMMARY	GRANT NUMBER 5U10HD 27853-15	
	PERIOD COVERED BY THIS R	EPORT
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Edward F. Donovan, M.D.	4/01/04	3/31/0 5
APPLICANT ORGANIZATION		·
University of Cincinnati		· · · · · · · · · · · · · · · · · · ·
TITLE OF PROJECT (Repeat title shown in Item 1 on first page)	· · · · · · · · · · · · · · · · · · ·	· · ·
Cooperative Multicenter Neonatal Research Netw	vork	,
A. Human Subjects (Complete Item 6 on the Face Page)	· · · · · · · · · · · · · · · · · · ·	
Involvement of Human Subjects X No Change Since	e Previous Submission Change)
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals X No Change Sin	ce Previous Submission 🗌 Chan	ge
В.		
·		

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

a. SPECIFIC AIMS

For the April 1, 2005 to March 31, 2006 grant year, the primary objectives of the NICHD Multicenter Neonatal Research Network (Network) are the development and conduct of large sample size, clinical studies designed to evaluate and improve preventive, diagnostic and therapeutic strategies employed in the care of newborn humans.

b. STUDIES AND RESULTS (enrollment tables for the 2004 calendar year are found below)



c. SIGNIFICANCE of completed studies

Not responsive. Not related to SUPPORT.

). pn on (iv)

(v)

(iii)

d. PLANS

 (i) Not responsive. Not related to SUPPORT.
 (ii) (iii) It is anticipated that the following proposed Network trials will begin in Cincinnati sometime in 2002: Not responsive. Not related to SUPPORT. SUPPORT Pilot (projected annual Cincinnati enrollment 12); SUPPORT trial (main, projected

Enrollment projections for the SUPPORT Trial must be tempered by assumptions that remain to be tested: (1) the start-up date is uncertain; (2) there is increasing sensitivity about enrolling the same subject in more than one study particularly when invasive procedures such as blood drawing are involved.

(iv) Dr. Donovan will continue as Chair of the Network Publications Subcommittee.

annual Cincinnati enrollment 34).

- (v) Dr. Donovan will continue as a member of the Not responsive. Not related to SUPPORT and SUPPORT.
 (vi) Not responsive. Not related to SUPPORT.
- (vi) Not responsive. Not related to SUPPORT.
 (vii) Dr. Vivek Narendran will serve as Cincinnati PI of the SUPPORT Pilot and SUPPORT Trial.
 (viii) Not responsive. Not related to SUPPORT.
 (ix) Dr. Kurt Schibler has submitted a secondary study to the SUPPORT Trial to evaluate genetic predisposition to BPD.
 (xi) Not responsive. Not related to SUPPORT.
 (xii)

Human Subjects - Research Training

Not responsive. Not related to SUPPORT.

Pages 11 through 24 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT Pilot

Total Planned Enrollment: January 1, 2005 – December 31, 2005

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Sex/Gender		r		
	Females	Males	Total		
Hispanic or Latino	0	1	1		
Not Hispanic or Latino	6	5	11		
Ethnic Category Total of All Subjects*	6	6	12		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	1	3	4		
White	5	3	8		
Racial Categories: Total of All Subjects *	6	6	12		

*The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories Total of All Subjects."

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT Trial

Total Planned Enrollment: January 1, 2005 – December 31, 2005

Ethnic Category		Sex/Gende	r
	Females	Males	Total
Hispanic or Latino	0	1	1
Not Hispanic or Latino	18	15	33
Ethnic Category Total of All Subjects*	18	16	34
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	5	4	9
White	13	12	25
Racial Categories: Total of All Subjects *	18	16	34

*The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories Total of All Subjects."

Pages 27 through 29 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD027853-17

PI Name:SCHIBLER, KURTOrg:CHILDREN'S HOSPITAL MED CTR
(CINCINNATI)Start Date:04/01/2007Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7219991Rec'd
Date:01/30/2007

Department of Health	and Human Services	Review Group	Туре	Activity	Grant Number	
Public Heal	th Services		5	U10	HD027853-17	
		Total Project Per				
Grant Prog	ress Report	From: 04/01/1		Th	rough: 03/31/2011	
oranie rog. coo nopon		Requested Budg				
1. TITLE OF PROJECT		From: 04/01/2	2007	Th	rough: 03/31/2008	
	ulticenter Neonatal Rese	arch Network				
2a. PRINCIPAL INVESTIGATOR ((Name and address, street, city) Kurt R. Schibler, M.D. Division of Neonatolog Children's Hospital Res 3333 Burnet Avenue	DR PROGRAM DIRECTOR /, state, zip code) y	3. APPLICANT (Name and ad	organiza dress, stree Hospital Neonato et Avenu	t, city, state, z Medical C blogy, ML		
Cincinnati, Ohio 45229	-3039	1000000				
2b. E-MAIL ADDRESS kurt.schibler@cchmc.org		4. ENTITY IDEN 131083393		N NUMBER		
2c. DEPARTMENT, SERVICE, LA	BORATORY, OR EQUIVALENT	a construction of the second sec			RATIVE OFFICIAL	
Division of Neonatology					Research Acct.	
2d. MAJOR SUBDIVISION Children's Hospital Research Foundation		Children's Hospital Medical Center 3333 Burnet Avenue ML 7030 Cincinnati, Ohio 45229-3039				
		E-MAIL: peter	.koch@co	chmc.org		
6. HUMAN SUBJECTS		7. VERTEB	RATE ANIM	ALS		
No 6a. Research Exempt ⊠ Yes No	6b. Human Subjects Assurance FWA00002988	No. No		7	a. If "Yes," IACUC approval Date	
If Exempt ("Yes" in 6a):	6c. NIH-Defined Phase III	7b. Animal V	Velfare Assu	Irance No.		
Exemption No.	Clinical Trial 🛛 No 🗌 Ye	s				
If Not Exempt ("No" in 6a): IRB approval date	Full IRB <u>or</u>	w				
8. COSTS REQUESTED FOR N	EXT BUDGET PERIOD	9. INVENTIONS	AND PATE	NTS		
8a. DIRECT \$145,022	8b. TOTAL \$217,533		es If "Yes		iously Reported Previously Reported	
10. PERFORMANCE SITE(S) (On	ganizations and addresses)	11a. PRINCIPAL OR PROGRAM I		(Item 2a)		
Division of Neonatolog		11b. ADMINISTR		FA		
Children's Hospital Re	search Foundation	NAME (Item 5)		ICIAL TE	L 513) 636-4583	
3333 Burnet Avenue		Peter C. Koch FAX (513) 636-1392				
					GNING FOR APPLICANT	
Cincinnati, Ohio 45229		ORGANIZA NAME Peter	C. Koch			
		NAME Peter	C. Koch		rog. & Research Acct.	
		NAME Peter	C. Koch V.P., Spo	onsored P	rog. & Research Acct.	
		NAME Peter TITLE Asst TEL (513)	C. Koch V.P., Spo 636-4583	onsored P	rog. & Research Acct. FAX (513) 636-1392	

obligation to comply with Public Health Services	ate to the best of my knowledge, and accept the terms and conditions if a grant is awarded as a lse, fictitious, or fraudulent statements or claims	SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Per" signature not acceptable.)	DATE 1/25/07
PHS 2590 (Rev. 04/06)	Face Page		Form Page 1
	(1)		

 -	-	~	

Active Neonatal Research Network Protocols: Institutional Review Board (IRB) Last Approval & Expiration Dates

Center: 11 Grant No. 2 U10 HD027853-16

Protocol Name	IRB Site	IRB Protocol No.	Last Approval Date	Expiration Date
lot responsive. Not related to SUPPORT.				
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Trial)	CCHMC GSH UC	05-03-51 2005.01001GS 04-5-20-01	09/26/06 12/15/06 10/11/06	05/08/07 12/14/07 10/11/07

RB Sites: Cincinnati Children's Hospital Medical Center (CCHMC Good Samaritan Hospital (GSH) University of Cincinnati (UC) for University Hospital

*GDB at GSH IRB: As of August 2001, annual progress report is not required.

U,

Kurt R. Schibler, M.D.

Pages 4 through 8 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle):	

Schibler, Kurt R., M.D.

		· · · · · · · · · · · · · · · · · · ·	
PROGRESS REPORT SUN	IMARY	GRANT NUMBER 2 U10 HD027853-16	
		PERIOD COVERED BY THI	S REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM	DIRECTOR	FROM	THROUGH
		April 1, 2006	March 31, 2007
APPLICANT ORGANIZATION Cincinnati Children's Hospital Medica	l Center		
TITLE OF PROJECT (Repeat title shown in It Cooperative Multicenter Neonatal Re		,	
A. Human Subjects (Complete Item 6 on the F	Face Page)		
Involvement of Human Subjects	🔀 🛛 No Char	nge Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on th	e Face Page)		
Use of Vertebrate Animals	No Char	nge Since Previous Submission	Change
C. Select Agent Research	No Char	nge Since Previous Submission	Change
D. Multiple PI Leadership Plan	No Char	nge Since Previous Submission	Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. SPECIFIC AIMS

For the April 1, 2006 to March 31, 2007 grant year, the primary objectives of the NICHD Multicenter Neonatal Research Network (Network) are the development and conduct of large sample size, clinical studies designed to evaluate and improve preventative, diagnostic, and therapeutic strategies employed in the care of newborn infants.

B. STUDY RESULTS Not responsive. Not related to SUPPORT. 7. Enrollment in the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT) - a factorial design randomized multicenter trial to test the hypotheses that: 1) relative to infants managed with prophylactic early surfactant and conventional ventilation that the use of early CPAP and a permissive ventilatory strategy in infants less than 28 weeks gestation with continuing CPAP in the NICU will result in an increased survival without BPD at 36 weeks gestation and 2) relative to infants managed at a higher SpO2 range that the use of a lower SpO2 range (85% to 89%) will result in an increased survival without occurrence of threshold ROP and /or need for surgical intervention. Additionally, our center is contributing subjects to two secondary studies to SUPPORT, the Growth Study and the Pulmonary Outcomes Study.

Not responsive. Not related to SUPPORT.

D. PLANS

Not responsive. Not related to SUPPORT.

1. For the calendar year 2007, continued enrollment and conduct to completion of the following studies Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

SUPPORT Trial (27).

5. Dr. Schibler will continue as a member of the Network Protocol, Genomics, and SUPPORT Subcommittees Not responsive. Not related to SUPPORT.

9. Dr. Vivek Narendran will serve as the Cincinnati PI of the SUPPORT Trial.

Pages 12 through 15 redacted for the following reasons: Not responsive. Not related to SUPPORT. Principal Investigator/Program Director (Last, First, Middle): Schibler, Kurt, Ryan, M.D.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

 Study Title:
 The SUrfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants

 Total Enrollment:
 16 (Jan. 1 - Dec. 31, 2006)
 Protocol Number:
 N/A

 Grant Number:
 2 U10 HD027853-16
 Protocol Number:
 N/A

		S	Sex/Gender		
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	0	0	0	0	**
Not Hispanic or Latino	5	11	0	16	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	5	11	0	16	*
Racial Categories		4			
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	4	4	0	8	
White	1	7	0	8	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	5	11	0	16	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

PHS 398/2590 (Rev. 09/04, Reissued 4/2006)



Pages 17 through 19 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The SUrfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants

Total Planned Enrollment: 27 (Jan. 1 - Dec. 31, 2007)

Ethnic Category		Sex/Gender	1
	Females	Males	Total
Hispanic or Latino	0	0	0
Not Hispanic or Latino	11	16	27
Ethnic Category: Total of All Subjects *	11	16	27
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	6	7	13
White	5	9	14
Racial Categories: Total of All Subjects *	11	16	27

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."



Page 21 redacted for the following reason: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD027853-18

PI Name:SCHIBLER, KURTOrg:CHILDREN'S HOSPITAL MED CTR
(CINCINNATI)Start Date:04/01/2008Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7392640Rec'd
Date:02/05/2008

Department of Health and Human Services Public Health Services Review Group Type Activity Grant Number HD027853-18 Carant Progress Report Total Project Period From: 0.4/01/1991 Through: 0.3/31/2009 1. TTLE OF PROJECT NICHD Cooperative Multicenter Neonatal Research Network Imough: 0.3/31/2009 2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code) Activity Offen Kurt R. Schibler, M.D. Division of Neonatology Children's Hospital Medical Center Fmom: Division of Neonatology Children's Hospital Research Foundation 3333 Burnet Avenue S. APPLICANT ORGANISTRATIVE OFFICIAL Network Pmom 2b. EMAIL ADDRESS Kurt. schibler@cchmc.org 4. ENTITY IDENTIFICATION NUMBER 1310833936A1 Stepsored Prog. & Research Acct. 2d. MAJOR SUBDIVISION 5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL Asst V.P., Sponsored Prog. & Research Acct. Children's Hospital Medical Center 3333 Burnet Avenue Stepsored Prog. & Research Acct. Children's Hospital Research Foundation 5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL Asst V.P., Sponsored Prog. & Research Acct. Children's Hospital Research Foundation 5. TITLE AND ADDRESS of Administratrive ofFicial Asst V.P., Sponsored Prog. &
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IRB approval date Image: Cost of the second secon
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10. PERFORMANCE SITE(S) (Organizations and addresses) 11a. PRINCIPAL INVESTIGATOR TEL (513) 636-3972
Division of Neonatology OR PROGRAM DIRECTOR (Item 2a) FAX (513) 636-4404
Children's Hospital Research Foundation 11b. ADMINISTRATIVE OFFICIAL TEL 513) 636-4583
Cincinnati Ohio 45229-3039
11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)
NAME Peter C. Koch
TITLE Asst V.P., Sponsored Prog. & Research Acct.
TEL (513) 636-4583 FAX (513) 636-1392
E-MAIL peter.koch@cchmc.org

12. Corrections to Page 1 Face Page

statements herein are true, complete and accu obligation to comply with Public Health Service	false, fictitious, or fraudulent statements or claims	DATE 1/31/08
PHS 2590 (Rev. 04/06)	Face Page	Form Page 1

Active Neonatal Research Network Protocols: Institutional Review Board (IRB) Last Approval & Expiration Dates

	Center:	11
Grant No.	5 U10 F	ID027853-16

Protocol Name	IRB Site	IRB Protocol No.	Last Approv al Date	Expiration Date
Not responsive. Not related to SUPPORT.				
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Trial)	CCHMC GSH UC	05-03-51 2005.01001GS 04-5-20-01	05/08/07 11/16/07 10/10/07	05/07/08 10/01/08 10/10/08

IRB Sites: Cincinnati Children's Hospital Medical Center (CCHMC) Good Samaritan Hospital (GSH) University of Cincinnati (UC) for University Hospital

*GDB at GSH IRB: As of August 2001, annual progress report is not required.

Pages 4 through 7 redacted for the following reasons: Not responsive. Not related to SUPPORT.

PROGRESS REPORT SU		GRANT NUMBER 2 U10 HD027853-17	
	PERIOD COVE	RED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVES	TIGATOR FROM	THROUGH	
Kurt R. Schibler, M.D.	April 1, 2007	March 31, 2008	
APPLICANT ORGANIZATION		••••••••••••••••••••••••••••••••••••••	
Cincinnati Children's Hospital Medica	al Center		
TITLE OF PROJECT (Repeat title shown in	tem 1 on first page)		
Cooperative Multicenter Neonatal Re	esearch Network		
A. Human Subjects (Complete Item 6 on the	Face Page)		
Involvement of Human Subjects	No Change Since Previous Su	ubmission Change	
B. Vertebrate Animals (Complete Item 7 on t	he Face Page)		
Use of Vertebrate Animals	No Change Since Previous Su	ubmission Change	
C. Select Agent Research	No Change Since Previous Su	ubmission Change	
D. Multiple PI Leadership Plan	No Change Since Previous Su	ubmission Change	

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. SPECIFIC AIMS

For the April 1, 2007 to March 31, 2008 grant year, the primary objectives of the NICHD Multicenter Neonatal Research Network (Network) are the development and conduct of large sample size, clinical studies designed to evaluate and improve preventative, diagnostic, and therapeutic strategies employed in the care of newborn infants.

B. STUDY RESULTS

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

7. Enrollment in the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT) - a factorial design randomized multicenter trial to test the hypotheses that: 1) relative to infants managed with prophylactic early surfactant and conventional ventilation that the use of early CPAP and a permissive ventilatory strategy in infants less than 28 weeks gestation with continuing CPAP in the NICU will result in an increased survival without BPD at 36 weeks gestation and 2) relative to infants managed at a higher SpO2 range that the use of a lower SpO2 range (85% to 89%) will result in an increased survival without occurrence of threshold ROP and /or need for surgical intervention. Additionally, our center is contributing subjects to two secondary studies to SUPPORT, the Growth Study and the Pulmonary Outcomes Study. Subjects are also being accrued at Cincinnati for a sub-study to the Pulmonary Outcomes Study looking at Oxygen Exposure and Oxidant Stress.

C. SIGNIFICANCE OF COMPLETED STUDIES Not responsive. Not related to SUPPORT.



Not responsive. Not related to SUPPORT.

D. PLANS

1. For the calendar year 2008, continued enrollment and conduct to completion of the following studies

	SUPPORT Trial (29),	
Not responsive. Not related to SUPPORT.		

4. Dr. Schibler will continue as a member of the Network Protocol, Genomics, and SUPPORT Subcommittees. Not responsive. Not related to SUPPORT.

8. Dr. Vivek Narendran will serve as the Cincinnati PI of the SUPPORT Trial.

Not responsive. Not related to SUPPORT.

þ.

Pages 11 through 17 redacted for the following reasons: Not responsive. Not related to SUPPORT. Program Director/Principal Investigator (Last, First, Middle): Schibler, Kurt, Ryan, M.D.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	The Surfactant Positive Airway Pres	sure and Pulse Oximetry Trial in ELBW Infants
Total Enroliment:	29 (Jan. 1 - Nov. 30, 2007)	Protocol Number: N/A
Grant Number:	2 U10 HD027853-16	

Sex/Gender					
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	0	0	0	0	**
Not Hispanic or Latino	14	12	0	26	
Unknown (individuals not reporting ethnicity)	0	0	3	3	
Ethnic Category: Total of All Subjects*	14	12	3	29	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	1	0	0	1	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	3	4	0	7	
White	10	8	0	18	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	3	3	
Racial Categories: Total of All Subjects*	14	12	3	29	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

Pages 19 through 27 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants

Total Planned Enrollment: 29 (Jan. 1 - Dec. 31, 2008)

TARGETED/PLANNED ENROL	LMENT: Number of Subject	ts	
Ethnic Category		Sex/Gender	
	Females	Males	Total
Hispanic or Latino	0	0	0
Not Hispanic or Latino	12	17	29
Ethnic Category: Total of All Subjects *	12	17	29
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	6	7	13
White	6	10	16
Racial Categories: Total of All Subjects *	12	17	29

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 29 through 30 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD027853-19

PI Name:SCHIBLER, KURTOrg:CHILDREN'S HOSPITAL MED CTR
(CINCINNATI)Start Date:04/01/2009Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7612126Rec'd
Date:02/03/2009

Department of Health and Human S	ervices	Review Group ZHD1DSRA10	Туре	Activity U10	Grant Number 5U10HD027853-19
Public Health Services		Total Project Period	5	010	DU IUHUU27803-19
_		From: 04/01/199	1	- 	aught 02/21/2011
Grant Progress Re	eport	Requested Budget F	-	ihr	ough: 03/31/2011
		From: 04/01/200	9	Thr	ough: 03/31/2010
1. TITLE OF PROJECT		•	·		
NICHD Cooperative Multicenter I					
2a. PROGRAM DIRECTOR / PRINCIPAL INVES (Name and address, street, city, state, zip content of the street of the		25. E-MAIL ADDRES kurt.schibler(-	c ora	
Schibler, Kurt R.			-		DRY, OR EQUIVALENT
Division of Neonatology		Pediatrics	·	-	
Children's Hospital Research For 3333 Burnet Avenue	undation	2d. MAJOR SUBDIV	ISION		······································
Cincinnati, Ohio 45229-3039		Neonatology	,		
		2e. Tel: (513) 630	6-3972	Fa	x: (513) 636-4404
3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip coo		3b. Tel: (513) 63	6-4583	Fa	x: (513) 636-1392
Children's Hospital Medical Cent		0. DUNG 07409	4012		
3333 Burnet Avenue		3c. DUNS: 07128	4913		FEB 0 3 2009
Cincinnati, Ohio 45229-3039		4. ENTITY IDENTIF		NUMBER	
		31-0833936			
6. HUMAN SUBJECTS 🗌 No 🛛 Yes		5. NAME, TITLE AN		ESS OF ADM	MINISTRATIVE OFFICIAL
6a. Research If Exempt ("Yes" in If J Exempt 6a): 6a	Not Exempt ("No" in				sored Progrograms
). B approval date	3333 Burnet			
		Cincinnati, C	nio 452	29-3039	
6b. Federal Wide Assurance No. FWA0000	2988	Tel: (513) 636-1	363	Fa	x: (513) 636-1392
6c. NIH-Defined Phase III		E-MAIL: tana.hou	ush@co	hmc.org	
Clinical Trial No Yes			0.000		
	'es	10. PROJECT/PERF			
7a. If "Yes," IACUC approval Date				en's Hos	pital Medical Center
7b. Animal Welfare Assurance No.		DUNS: 0712849	13		
8. COSTS REQUESTED FOR NEXT BUDGET	PERIOD	Street 1: 3333 B	urnet A	venue	
8a. DIRECT \$145,957 8b. TOTAL \$2	218,936	Street 2:		^	
9. INVENTIONS AND PATENTS No] Yes	city: Cincinnati		Co	ounty: Hamilton
If "Yes, 🔲 Previously Reported		State: Ohio		Pro	ovince:
Not Previously Reported		Country: USA		Zip	D/Postal Code: 45229-3039
		Congressional Distric	cts: OH-	001	······································
11. NAME AND TITLE OF OFFICIAL SIGNING Tana Housh, Manager, Sponsored					
теь: (513) 636-1363	FAX: (513)636			E-MAIL: ta	na.housh@cchmc.org

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

DATE 1/30/09

Face Page l

Form Page 1

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Active Neonatal Research Network Protocols: Institutional Review Board (IRB) Last Approval & Expiration Dates

Center: 11 Grant No.: HD027853-19					
Protocol Name	IRB Site	IRB Protocol No.	Last Approval Date	Expiration Date	
t responsive. Not related to SUPPORT.					
he Surfactant Positive Airway Pressure					

RB Sites: Cincinnati Children's Hospital Medical Center (CCHMC) Good Samaritan Hospital (GSH) University of Cincinnati (UC) for University Hospital

*GDB at GSH IRB: As of August 2001, annual progress report is not required.

L

Pages 4 through 8 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Las	st, First, Middle):	Schibler, Kurt R., M.D	
PROGRESS REPORT SUMM	ARY	GRANT NUMBER 2 U10 HD027853-19	
		PERIOD COVERED BY TH	HIS REPORT
PROGRAM DIRECTOR / PRINCIPAL INVESTIG/	ATOR	FROM	THROUGH
Kurt R. Schibler, M.D.		April 1, 2008	March 31, 2009
APPLICANT ORGANIZATION Cincinnati Children's Hospital Medical Ce TITLE OF PROJECT (Repeat title shown in Item	1 on first page)	×	<u> </u>
Cooperative Multicenter Neonatal Resea	arch Network		
A. Human Subjects (Complete Item 6 on the Face Involvement of Human Subjects		e Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the Fa	ice Page)		
Use of Vertebrate Animals	No Chang	e Since Previous Submission	Change
C. Select Agent Research	No Chang	e Since Previous Submission	Change
D. Multiple PD/PI Leadership Plan	No Chang	e Since Previous Submission	Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. SPECIFIC AIMS

For the April 1, 2008 to March 31, 2009 grant year, the primary objectives of the NICHD Multicenter Neonatal Research Network (Network) are the development and conduct of large sample size, clinical studies designed to evaluate and improve preventative, diagnostic, and therapeutic strategies employed in the care of newborn infants.

B. STUDY RESULTS

Not responsive. Not related to SUPPORT.

6. Enrollment in the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT) - a factorial design randomized multicenter trial to test the hypotheses that: 1) relative to infants managed with prophylactic early surfactant and conventional ventilation that the use of early CPAP and a permissive ventilatory strategy in infants less than 28 weeks gestation with continuing CPAP in the NICU will result in an increased survival without BPD at 36 weeks gestation and 2) relative to infants managed at a higher SpO2 range that the use of a lower SpO2 range (85% to 89%) will result in an increased survival without occurrence of threshold ROP and /or need for surgical intervention. Additionally, our center is contributing subjects to two secondary studies to SUPPORT, the Growth Study and the Pulmonary Outcomes Study. Subjects are also being accrued at Cincinnati for a sub-study to the Pulmonary Outcomes Study looking at Oxygen Exposure and Oxidant Stress.

C. SIGNIFICANCE OF COMPLETED STUDIES

Not responsive. Not related to SUPPORT.

ì.

Not responsive. Not related to SUPPORT.

D. PLANS

1. For the calendar year 2009, continued enrollment and conduct to completion of the following studies Not responsive. Not related to SUPPORT.

	SUPPORT Trial (6)	
Not responsive. Not related to SUPPORT.		

Not responsive. Not related to SUPPORT.

4. Dr. Schibler will continue as a member of the Network Protocol, Genomics, and SUPPORT Subcommittees. Not responsive. Not related to SUPPORT.

8. Dr. Vivek Narendran continues to serve as the Cincinnati PI of the SUPPORT Trial.

Not responsive. Not related to SUPPORT.

Pages 12 through 18 redacted for the following reasons: Not responsive. Not related to SUPPORT. Program Director/Principal Investigator (Last, First, Middle): Schibler, Kurt R., M.D.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	SUPPORT TRIAL		
Total Enrollment:	<u>24 (01/01/08 - 12/31/08)</u>	Protocol Number: <u>N / A</u>	
Grant Number:	HD027853-19		

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race Sex/Gender Unknown or Ethnic Category Females Males Not Reported Total ** Hispanic or Latino 0 0 0 0 Not Hispanic or Latino 10 14 0 24 Unknown (individuals not reporting ethnicity) 0 0 0 0 * Ethnic Category: Total of All Subjects* 14 10 0 24 **Racial Categories** American Indian/Alaska Native 0 0 0 0 Asian 0 0 0 0 Native Hawaiian or Other Pacific Islander 0 0 0 0 Black or African American 4 5 0 9 White 6 9 0 15 More Than One Race 0 0 0 0 0 Unknown or Not Reported 0 0 0 * Racial Categories: Total of All Subjects* 10 14 0 24

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categorie s	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

PHS 398/2590 (Rev. 11/07)

18

Pages 20 through 28 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT TRIAL

Total Planned Enrollment: 6

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TARGETED/PLANNED ENRO	LLMENT: Number of Subjec	ts	
Ethnic Category			
	Females	Males	Total
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	3	6
Ethnic Category: Total of All Subjects *	3	3	6
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	1	2
White	2	2	4
Racial Categories: Total of All Subjects *	3	3	6

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 30 through 32 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD027853-20

PI Name:SCHIBLER, KURTOrg:CHILDREN'S HOSPITAL MED CTR
(CINCINNATI)Start Date:04/01/2010Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7799066Rec'd
Date:02/02/2010

Form Approved Through 06/30/2012						OMB No. 0925-0001		
Department of Health and Human Services Public Health Services		Review Group ZHD1DSRA10	Туре 5	Activity U10	Grant Number 5 U10 HD027853-20			
Grant Progress Report			Total Project Period					
			From: 04/01/199	1	Thro	ough: 03/31/2011		
			Requested Budget Period					
			From: 04/01/201	0	Thro	ugh: 03/31/2011		
1. TITLE OF PROJECT	tioont		arah Natwark					
NICHD Cooperative Mul			2b. E-MAIL ADDRES	<u> </u>	<u>-</u>	· · · · · · · · · · · · · · · · · · ·		
2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)			kurt.schibler		c.ora			
Schibler, Kurt R.						RY, OR EQUIVALENT		
Division of Neonatology			Pediatrics					
Children's Hospital Rese 3333 Burnet Avenue	earcn	Foundation	2d. MAJOR SUBDIVI	SION		·····		
Cincinnati, Ohio 45229-	3039		Neonatology					
	0000		2e. Tel: (513) 636	6-3972	Fax	: (513) 636-4044		
3a. APPLICANT ORGANIZATION (Name and address, street, city, s	tate, zip	code)	3b. Tel: (513) 63	6-4583	Fax	: (513) 636-1392		
Children's Hospital Med	ical Ce	enter	3c. DUNS: 07128	4913				
3333 Burnet Avenue	2020			1010		FEB 0 2 2010		
Cincinnati, Ohio 45529	.3039		4. ENTITY IDENTIFICATION NUMBER 31-0833936					
6. HUMAN SUBJECTS No	\square	Yes	5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL					
6a. Research ExemptIf Exempt ("Yes" in 6a): Exempt NoIf Not Exempt ("No" in 6a): IRB approval date0YesExemption No.			Tana Housh, Manager, Sponsored Programs 3333 Burnet Avenue ML 7030 Cincinnati, Ohio 45229-3039					
6b. Federal Wide Assurance No. F	WA00	002988	Tel: (513) 636-1363 Fax: (513) 636-1392					
6c. NIH-Defined Phase III			E-MAIL: tana.housh@cchmc.org					
Clinical Trial No X Yes								
7. VERTEBRATE ANIMALS	No [Yes	10. PROJECT/PERFORMANCE SITE(S)					
7a. If "Yes," IACUC approval Date			Organizational Name: Children's Hospital Medical Center					
7b. Animal Welfare Assurance No.			DUNS: 071284913					
8. COSTS REQUESTED FOR NEX		GET PERIOD	Street 1: 3333 Burnet Avenue					
8a. DIRECT \$. TOTA	L \$	Street 2:					
9. INVENTIONS AND PATENTS No Yes			City: Cincinnati		Cou	nty: Hamilton		
Not Previously Reported		State: Ohio		Prov	vince:			
		Country: USA			Zip/Postal Code: 45229-3039			
		Congressional Districts: OH-001						
11. NAME AND TITLE OF OFFICIA Tana Housh, Manager, Sp				,	<u> </u>			
TEL: (513) 636-1363		FAX: (513) 63	6-1392		E-MAIL: tan	a.housh@cchmc.org		
12. Corrections to Page 1 Face Page	9	- I						

,

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the SIGNATURE OF OFFICIAL NAMED IN 13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: Tcertify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

PHS 2590 (Rev. 06/09)
Face Page 11. (In ink) Lough

1/29/10

DATE

Active Neonatal Research Network Protocols: Institutional Review Board (IRB) Last Approval & Expiration Dates

	Grant N	o.: HD027853		
Protocol Name Not responsive. Not related to SUPPORT.	IRB Site	IRB Protocol No.	Last Approval Date	Expiration Date
	1			
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT	CCHMC GSH	05-03-51 2005.01001GS	05/05/2009 08/28/2009	05/04/2010 08/27/2010
Trial)	UC	04-5-20-01	09/23/2009	09/23/2010

Center: 11 Grant No.: HD027853

IRB Sites: Cincinnati Children's Hospital Medical Center (CCHMC) Good Samaritan Hospital (GSH) University of Cincinnati (UC) for University Hospital

*GDB at GSH IRB: As of August 2001, annual progress report is not required.

Pages 4 through 7 redacted for the following reasons: Not responsive. Not related to SUPPORT. Schibler, Kurt R.

	•						
ARY	GRANT NUMBER 5 U10 HD027853-20						
	PERIOD COVERED BY THIS REPORT						
ATOR	FROM	THROUGH March 31, 2010					
	April 1, 2009						
enter							
	- /						
'age)							
Involvement of Human Subjects No Char		Change					
e Page)							
No Cr	nange Since Previous Submission	Change					
No Cr	nange Since Previous Submission	Change					
No Ch	nange Since Previous Submission	Change					
⋈ No Cł	ange Since Previous Submission	Change					
	GATOR Genter 1 on first pa arch Netw Page) No Cr No Cr No Cr	ARY 5 U10 HD027853-20 PERIOD COVERED BY TH GATOR FROM April 1, 2009 Genter 1 on first page) arch Network Yage) No Change Since Previous Submission					

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. SPECIFIC AIMS

For the April 1, 2009 to March 31, 2010 grant year, the primary objectives of the NICHD Multicenter Neonatal Research Network (Network) are the development and conduct of large sample size, clinical studies designed to evaluate and improve preventative, diagnostic, and therapeutic strategies employed in the care of newborn infants.

B. STUDY RESULTS

Not responsive. Not related to SUPPORT.

2. Enrollment in the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT) - a factorial design randomized multicenter trial to test the hypotheses that: 1) relative to infants managed with prophylactic early surfactant and conventional ventilation that the use of early CPAP and a permissive ventilatory strategy in infants less than 28 weeks gestation with continuing CPAP in the NICU will result in an increased survival without BPD at 36 weeks gestation and 2) relative to infants managed at a higher SpO2 range that the use of a lower SpO2 range (85% to 89%) will result in an increased survival without BCP and /or need for surgical intervention was completed in 2009. Our center also contributed subjects to two secondary studies to SUPPORT, the Growth Study and the Pulmonary Outcomes Study. The two primary manuscripts resulting from this study have been submitted to the New England Journal of Medicine and are under review. These works are entitled " Randomized Trial of Oxygen Saturation Targets in Extremely Premature Infants" and "The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extrmely Low Birth Weight Infants - The SUPPORT Trial".

Not responsive. Not related to SUPPORT.

D. PLANS Not responsive. Not related to SUPPORT.

7. Dr. Schibler will continue as a member of the Network Protocol, Genomics, and SUPPORT Subcommittees. Not responsive. Not related to SUPPORT.

Pages 11 through 25 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	SUPPORT Trial		
Total Enrollment:	<u>1 - January 1 - December 31, 2009</u>	Protocol Number:	Ν/Α
Grant Number:	5U10HD027853 - 19		

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total			
Hispanic or Latino	0	0	0	0	**		
Not Hispanic or Latino	0	1	0	1			
Unknown (individuals not reporting ethnicity)	0	0	0	0			
Ethnic Category: Total of All Subjects*	0	1	0	1	*		
Racial Categories							
American Indian/Alaska Native	0	0	0	0			
Asian	0	0	0	0			
Native Hawaiian or Other Pacific Islander	0	0	0	0			
Black or African American	0	0	0	0			
White	0	1	0	1			
More Than One Race	0	0	0	0			
Unknown or Not Reported	0	0	0	0			
Racial Categories: Total of All Subjects*	0	1	0	1	*		

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

Pages 27 through 29 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027871-15

PI Name:
Org:
Start Date:
Snap:
Appl ID:
Rec'd Date:

EHRENKRANZ, RICHARD YALE UNIVERSITY 04/01/2005 N/A (NEEDS TO BE BOOKMARKED) 6891935 02/02/2005

Form Appr	oved Through 9/30/200	7							0	MB No. 0925-0001
<u> </u>		Ith and Human Services ealth Services		Review Gr	roup	Type 5	Activity U10		Grant Number HD 27281-15	
				Total Proje	ect Per	riod				
	Grant Broc	Trace Papart		From: 04/01/1991 Through: 03/31/2006						
	Grant Frog	gress Report		Requested Budget Period						
				From: 04	1/01/2	2005		Throu	igh: 03/31/200	6
	OF PROJECT Derative Multicente	er Neonatal Research N	etw	ork						
		OR PROGRAM DIRECTOR	3.	APPLICAN						
	and address, street, city			(Name and a			city, state	, zip o	code)	
	nkranz, Richard A			Yale University 47 College Street, Suite 203						
	University						uite 20	3		1.7
	artment of Pediatri			PO Box 2				-		EE BE
	Cedar Street/PO E			New Hav	/en, (CT 065	20-804	•7		1
	Haven, CT 06520									
	ADDRESS d.ehrenkranz@yale	e.edu		ENTITY IDE 06064697		ICATION	NUMBER	ł		
		BORATORY, OR EQUIVALENT							TIVE OFFICIAL	
Pedia			_					-	ontract Admi	nistration
	RSUBDIVISION			47 Colleg			uite 20	3		7
Scho	ol of Medicine			PO Box 2						
				New Hav	/en, (CT 065	20-804	7		
			E-1	MAIL: grai	ntsm	d@ema	il.med.y	ale.e	edu	
6. HUMAN				7. VERTE	BRAT	E ANIMA	LS			
		6b. Human Subjects Assurance	No.	⊠ No				7a.	If "Yes," IACUC	approval Date
Yes	🛛 No 🗌 Yes	FWA00002571		T Yes						
	("Yes" in 6a):	6c. NIH-Defined Phase III		7b. Animal	l Welfa	are Assura	ance No.			
Exemption		Clinical Trial 🛛 No 🗌 Yes	•	A32	30-0	1				
	npt ("No" in 6a):	Full IRB or		1						
IRB approv	val date See list	Expedited Revie	w							
8. COSTS	S REQUESTED FOR N	EXT BUDGET PERIOD	9.	INVENTION	IS AND	D PATEN	TS		· · · · · · · · · · · · · · · · · · ·	
	т \$197,019	8b. TOTAL \$221,812		No 🗌 Y	Yes	lf "Yes,"			sly Reported viously Reported	
10 PERFC	ORMANCE SITE(S) (Or	ganizations and addresses)	11:	a. PRINCIP		/ESTIGAT		EL	203-688-232	
	rtment of Pediatri			PROGRAM			em 2a)			
	University School			<u>-</u>				AX	203-688-542	26
	Cedar Street		1	D. ADMINIST			IAL T	EL	203-785-468	39
PO B	lox 208064			ME (Item 5) ebecca Ba		he		AX	203-785-41	50
New	Haven, CT 06520)-8064							NG FOR APPLIC	
			'``	ORGANIZ						
		NA	ME Reb	ecca	a Balen	tine / V	erna	a Lingis	-	
			ТП	LE Assi	t / As	ssoc Di	rector	Gra	nts & Contra	ct Admin
			TE						× 203-785-4	
		TEL203-785-4689FAX203-785-4159E-MAILgrantsmd@email.med.yale.edu								
•				grar	าเรท	a@ema	all.med.	.yale	e.eau	
12. Correct	tions to Page 1 Face Pa	ge								
		PROGRAM DIRECTOR ASSURA							IAMED IN 2a.	DATE
any faise	e, fictitious, or fraudulent sta	te and accurate to the best of my know atements or claims may subject me to	crimi	nal, civil, or	1	"Δ" ^	er signati		ot acceptable.)	1. la -lair
		accept responsibility for the scientific s reports if a grant is awarded as a re-				Kill	\mathcal{X}_{λ}	SUN	No Kra. AD	112005
		CERTIFICATION AND ACCEPT			t the S				AL NAMED IN	DATE
stateme	nts herein are true, complet	te and accurate to the best of my know	vledg	e, and accept i	the 1	11c. (In in	nk. "Per" s			4
obligation to comply with Public Health Services terms and conditions if a result of this application. I am aware that any false, fictitious, or fraudulen may subject me to criminal, civil, or administrative penalties.							een 1	X-		1/30/05-

statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.
PHS 2590 (Rev. 09/04)
Face Page

Form Page 1

Principal Investigator/Program Director (Last, First, Middle):

Yale IRB#:

Approval Date:

Title of Protocol:

Not responsive. Not related to SUPPORT.

27163

January 12, 2005

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight infants (the SUPPORT Trial) Pages 4 through 6 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Ehrenkranz, Richard A

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······································	GRANT NUMBER					
PROGRESS REPORT SUMMARY	U10 HD 27871-15					
	PERIOD COVERED BY 1	THIS REPORT				
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH				
Richard A. Ehrenkranz, MD	04/01/2004	03/31/2005				
APPLICANT ORGANIZATION	• ····································					
Yale University School of Medicine						
TITLE OF PROJECT (Repeat title shown in Item 1 on first pag	e)	······				
Cooperative Multicenter Neonatal Research Netwo	rk					
A. Human Subjects (Complete Item 6 on the Face Page)		······································				
Involvement of Human Subjects No Cha	nge Since Previous Submission	Change				
B. Vertebrate Animals (Complete Item 7 on the Face Page)						
Use of Vertebrate Animals No Cha	nge Since Previous Submission	Change				
SEE PHS 2590 INSTRUCTIONS.						
WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. L Targeted/Planned Enrollment Format Page.	ise Inclusion Enrollment Report	Format Page and, if necessary,				
During the 14th year of Yale's participation in the N	IH Multicenter Network o	f Neonatal Intensive Care Units,				
Not responsive. Not related to SUPPORT.						

Pages 8 through 19 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD027871-17

PI Name: Org: Start Date: Snap: Appl ID: Rec'd Date:

EHRENKRANZ, RICHARD YALE UNIVERSITY 04/01/2007 N/A (NEEDS TO BE BOOKMARKED) 7219970 02/05/2007

	Review	Group	Туре	Activity	OMB No. 0925-000 Grant Number		
Department of Health and Human Services Public Health Services	Review	Sloup	5	U10	HD 27281-17		
	Total Pr	Total Project Period HD27871-17					
Creant Dreamon Poport	From:	04/01/199	1	Th	rough: 03/31/2011		
Grant Progress Report		ted Budget F	Period				
		04/01/200	7	Th	rough: 03/31/2008		
1. TITLE OF PROJECT	lotwork						
Cooperative Multicenter Neonatal Research N 2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	the second second second second second second second second second second second second second second second se	LICANT OR		ION			
(Name and address, street, city, state, zip code)		e and addres	ss, street	, city, state, z	ip code)		
Ehrenkranz, Richard A		Universi					
Yale University		Box 2080		Suite 203			
Department of Pediatrics 333 Cedar Street/PO Box 208064				520-8047			
New Haven, CT 06520-8064	, item	naven,	01 000	20 0041			
2b. E-MAIL ADDRESS	4. ENTI	TY IDENTIF	ICATION	NUMBER			
richard.ehrenkranz@yale.edu		46973					
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALEN					RATIVE OFFICIAL		
Pediatrics		ollege S			ontracts Administration		
2d. MAJOR SUBDIVISION School of Medicine		Box 2080		buile 203			
ochoor of medicine		New Haven, CT 06520-8047					
	E-MAIL:	grantsm	d@ema	ail.med.ya	e.edu		
6. HUMAN SUBJECTS	7. V	ERTEBRAT	E ANIMA	ALS			
No 6a. Research Exempt 6b. Human Subjects Assurance	e No.	No		7	a. If "Yes," IACUC approval Date		
Yes No Yes FWA00002571		Yes					
		7b. Animal Welfare Assurance No. FEB 0 1 2007					
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III	7b. /	Animal vven	1071004				
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 13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.
 SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Per" signature not acceptable.)

 PHS 2590 (Rev. 04/06)
 Face Page

 DATE

30 Form Page 1

Yale IRB#: Approval Date: Title of Pro	<u>tocol:</u>
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Not responsive. Not related to SUPPORT.

0410027163

January 24, 2007

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight infants (the SUPPORT Trial); includes Breathing Outcomes and Growth secondaries

Not responsive. Not related to SUPPORT.

Pages 4 through 5 redacted for the following reasons: Not responsive. Not related to SUPPORT.

		^{):} Ehrenkranz, Richard A	
		GRANT NUMBER	
PROGRESS REPORT SU	MMARY	HD 27281-17	
		PERIOD COVERED BY TH	
PRINCIPAL INVESTIGATOR OR PROGRAM	DIRECTOR	FROM	THROUGH 03/31/2007
Richard A Ehrenkranz, MD		04/01/2006	03/31/2007
APPLICANT ORGANIZATION			
Yale University School of Medicine			
TITLE OF PROJECT (Repeat title shown in I		•	
Cooperative Multicenter Neonatal Re	esearch Netwo	rk .	
A. Human Subjects (Complete Item 6 on the	Face Page)		
Involvement of Human Subjects	No Cha	nge Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on t	ne Face Page)	-	
Use of Vertebrate Animals	<u>5</u>	nge Since Previous Submission	Change
C. Select Agent Research	No Cha	nge Since Previous Submission	Change
D. Multiple PI Leadership Plan	No Cha	nge Since Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS.			
WOMEN AND MINORITY INCLUSION: See PHS Targeted/Planned Enrollment Format Page. During the 16th year of Yale's partici		·	
WE: ot responsive. Not related to SUPPORT.		· .	
			y
(5) continued to enroll infants into the	Surfactant Po	sitive Airway Pressure and	d Pulse Oximetry Trial in ELBV
			· · · · · · · · · · · · · · · · · · ·
Infants (SUPPORT Trial),			

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Screening for enrollment in the SUPPORT trial began in May 2005 at Yale; as of 12/31/06 we have screened 63 women who have presented in preterm labor at 24° to 27^{6} weeks gestation. Consent was sought from 51 eligible women; 5 infants were randomized (9.8% of eligible deliveries). Consent was also obtained for an eligible sixth infant who was not randomized because she was born during the trial's temporary suspension from November 22, 2005 to February 22, 2006. The Inclusion Enrollment Report provides data on the 5 randomized infants. Review of consent procedures and participation in the Antenatal Consent Secondary Study have demonstrated that consents have been obtained from slightly more than 50% of the eligible women approached, but that only about 20% of the consented women deliver within the randomization window. The objectives of the SUPPORT Trial are (1) to see whether management of infants with early CPAP and a permissive ventilatory strategy compared to prophylactic/early surfactant and conventional ventilation will result in increased survival without bronchopulmonary dysplasia and (2) to see whether management of infants with a lower SpO₂ range (85% to 89%) compared to a higher SpO₂ range (91% to 95%) will result in increased survival without the occurrence of threshold retinopathy of prematurity (ROP) and/or the need for surgical intervention.

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Pages 8 through 17 redacted for the following reasons: Not responsive. Not related to SUPPORT. Principal Investigator/Program Director (Last, First, Middle): Ehrenkranz, Richard A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	The Surfactant Positive	Airway Pressure and Pulse Oximetry Trial in ELBW Infants
Total Enrollment:	5	Protocol Number: Yale IRB# 0410027163
Grant Number:	HD 27281	

Ethnic Category		S	ex/Gender		
	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	0	1	0	1	**
Not Hispanic or Latino	3	1	0	4	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	3	2	0	5	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	2	1	0	3	
White	1	1	0	2	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	3	2	0	5	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	1	0	1 **

* These totals must agree.

** These totals must agree.

PHS 398/2590 (Rev. 09/04, Reissued 4/2006)

Pages 19 through 21 redacted for the following reasons: Not responsive. Not related to SUPPORT. Progress Report Scanning Cover Sheet

5U10HD027871-18

PI Name: Org: Start Date: Snap: Appl ID: Rec'd Date: EHRENKRANZ, RICHARD YALE UNIVERSITY 04/01/2008 N/A (NEEDS TO BE BOOKMARKED) 7391534 02/04/2008

Form Approved Through 09/30/2007					OMB No. 0925-0001
Department of Health and Human Services Public Health Services	Review Grou		Type 5	Activity U10	Grant Number HD 2 728 1-18 2787
· · · · · · · · · · · · · · · · · · ·	Total Project	t Period			•
	From: 04/0	01/1991		Thr	ough: 03/31/2011
Grant Progress Report	Requested I		eriod		
	From: 04/0	1/2008		Thr	ough: 03/31/2009
1. TITLE OF PROJECT	prom. 0 // 0				
Cooperative Multicenter Neonatal Research Ne	etwork				
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	3. APPLICA				
(Name and address, street, city, state, zip code) Ehrenkranz, Richard A	Yale Ur			city, state, zip	p code)
Yale University	4			uite 203	
Department of Pediatrics	PO Box	-			() () ()
333 Cedar Street/PO Box 208064	New Ha	aven, C	T 065	20-8047	
New Haven, CT 06520-8064					2008
2b. E-MAIL ADDRESS	4. ENTITY I	DENTIFI	CATION	NUMBER	· · · · · · · · · · · · · · · · · · ·
richard.ehrenkranz@yale.edu	0606469	973			
2C. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT	1				ATIVE OFFICIAL
Pediatrics					ontracts Administration
2d. MAJOR SUBDIVISION		-	•	uite 203	
School of Medicine	PO Box	-		20-8047	
		aven, C	1 000	20-0047	
	E-MAIL: a	rantsmd	@ema	il.med.yale	e.edu
6. HUMAN SUBJECTS	<u> </u>	TEBRATE		·	
lea Research Exempt leb Human Subjects Assurance					a. If "Yes," IACUC approval Date
$ \boxed{\begin{array}{c} N_0 \\ \hline \end{array}} \\ \boxed{\begin{array}{c} N_0 \\ \hline \end{array}} \\ \boxed{\begin{array}{c} N_0 \\ \hline \end{array}} \\ \boxed{\begin{array}{c} Yes \end{array}} \\ \boxed{\begin{array}{c} N_0 \\ \hline \end{array}} \\ \boxed{\begin{array}{c} Yes \end{array}} \\ \boxed{\begin{array}{c} Yes \end{array}} \\ \boxed{\begin{array}{c} FWA00002571 \end{array}} \\ \boxed{\begin{array}{c} FWA00002571 \end{array}} \\ \boxed{\begin{array}{c} FWA00002571 \end{array}} \\ \boxed{\begin{array}{c} FWA00002571 \end{array}} \\ \boxed{\begin{array}{c} FWA00002571 } \\ \boxed{\begin{array}{c} FWA00002571 } \\ \hline \end{array}} \\ \boxed{\begin{array}{c} FWA000002571 } \\ \hline{\begin{array}{c} FWA000002571 } \\ \hline \end{array}} \\ \boxed{\begin{array}{c} FWA000002571 } \\ \hline \end{array} \\ \boxed{\begin{array}{c} FWA000002571 } \\ \hline \end{array}} \\ \boxed{\begin{array}{c} FWA000002571 } \\ \hline \end{array} \\ \boxed{\begin{array}{c} FWA000002571 } \\ \hline \end{array} \\ \boxed{\begin{array}{c} FWA000002571 } \\ \hline \end{array} \\ \boxed{\begin{array}{c} FWA000002571 } \\ \hline \end{array}} \\ \boxed{\begin{array}{c} FWA000002571 } \\ \hline \end{array} \\ \boxed{\begin{array}{c} FWA000002571 } \\ \hline \end{array} \\ \hline \end{array} \\ \boxed{\begin{array}{c} FWA000002571 } \\ \hline \end{array} \\ \hline \end{array} \\ \hline \end{array} \\ \\ \boxed{\begin{array}{c} FWA000002571 } \\ \hline \end{array} \\ \hline \\ \hline$					
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III		nal Welfa	re Assura	ince No.	
Exemption No. Clinical Trial No Ye	s				
If Not Exempt ("No" in 6a):					
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVENTIO				
8a. DIRECT \$229,252 8b. TOTAL \$378,933		Yes	lf "Yes,"		ously Reported reviously Reported
10. PERFORMANCE SITE(S) (Organizations and addresses)	11a, PRINC				······
Department of Pediatrics	OR PROGRA				
Yale University School of Medicine				FAX	203-688-5426
333 Cedar Street	11b. ADMINI NAME (Item		EOFFIC		203-785-4689
PO Box 208064	Rebecca E		е	FAX	203-785-4159
New Haven, CT 06520-8064					NING FOR APPLICANT
	ORGAN	NIZATION	l (Item 1	4)	
	NAME RE	ebecca	Balen	tine / Rita	Nigri / Penrhyn Cook
	TITLE De	epDir / ,	Associ	Dir / Exec	Dir, Grant & Contract Adm
	TEL 20	3-785-4	689		FAX 203-785-4159
	E-MAIL an	antsmo	l@ema	ہ ail.med.ya	ale.edu
12. Corrections to Page 1 Face Page			<u> </u>		

 13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.
 SIGNATURE OF OFFICIAL NAMED IN 110. (In jhk. "Per" signature not address the address terms and conditions if a grant is awarded as a may subject me to criminal, civil, or administrative penalties.

 PHS 2590 (Rev. 04/06)
 Face Page

 DATE 908

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Yale IRB#:	Approval <u>Date:</u>	Expiration <u>Date:</u>	Title of Protocol:
Not responsive. Not related to SUP	PORT.		
0410027163	02/22/07	02/22/08	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight infants (the SUPPORT Trial); includes Breathing Outcomes and Growth secondaries
Not responsive. Not related to SL	JPPORT.		

Pages 4 through 5 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Fincipal investigator/Frogram Directo	i (Last, Frist, Middle).	Ehrenkranz, Richard A	
PROGRESS REPORT SU	MMARY	GRANT NUMBER HD 27281-18	
		PERIOD COVERED BY TH	IS REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM	M DIRECTOR	FROM	THROUGH
Richard A Ehrenkranz, MD		04/01/2007	03/31/2008
APPLICANT ORGANIZATION Yale University School of Medicine			•
TITLE OF PROJECT (Repeat title shown in Cooperative Multicenter Neonatal Re			
A. Human Subjects (Complete Item 6 on the	Face Page)		
Involvement of Human Subjects	No Chang	e Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on t	he Face Page)		
Use of Vertebrate Animals	🔀 No Chang	e Since Previous Submission	Change
C. Select Agent Research	No Chang	e Since Previous Submission	Change

D. Multiple PI Leadership Plan	No Change Since Previous Submission

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

During the 17th year of Yale's participation in the NIH Multicenter Network of Neonatal Intensive Care Units, we:

Not responsive. Not related to SUPPORT.

(5) continued to enroll infants into the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT Trial),

Not responsive. Not related to SUPPORT.

Change

Not responsive. Not related to SUPPORT.

Screening for enrollment in the SUPPORT trial began in May 2005 at Yale; as of 11/30/07 we have screened 105 women who have presented in preterm labor at 24° to 27⁶ weeks gestation. Consent was sought from 93 eligible women; 21 infants have been randomized (22.6% of eligible deliveries). An additional consented infant who was born within the gestational age eligibility window was not randomized because she was born during the trial's temporary suspension from November 22, 2005 to February 22, 2006. The Inclusion Enrollment Report provides data on the 21 randomized infants. Review of consent procedures and participation in the Antenatal Consent Secondary Study have demonstrated that consents have been obtained from slightly more than 50% of the eligible women approached, but that only about 35% of the consented women deliver within the randomization window. Consent for the Breathing Outcomes and the Growth secondary studies are included in the consent for the main trial; Yale is not participating in the MRI secondary study. The objectives of the SUPPORT Trial are (1) to see whether management of infants with early CPAP and a permissive ventilatory strategy compared to prophylactic/early surfactant and conventional ventilation will result in increased survival without bronchopulmonary dysplasia and (2) to see whether management of infants with a lower SpO₂ range (85% to 89%) compared to a higher SpO₂ range (91% to 95%) will result in increased survival without the occurrence of threshold retinopathy of prematurity (ROP) and/or the need for surgical intervention.

Pages 8 through 15 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infar					
Total Enrollment:	21 (as of 12/31/07)	Protocol Number:	Yale IRB# 0410027163			
Grant Number:	HD 27281-18					

		Sex/Gender						
Ethnic Category	Females	Males	Unknown or Not Reported	Total				
Hispanic or Latino	2	1	0	3 **				
Not Hispanic or Latino	12	6	0	18				
Unknown (individuals not reporting ethnicity)	0	0	0	0				
Ethnic Category: Total of All Subjects*	14	7	0	21 *				
Racial Categories								
American Indian/Alaska Native	0	0	0	0				
Asian	0	1	0	1				
Native Hawaiian or Other Pacific Islander	0	0	0	0				
Black or African American	6	3	0	9				
White	6	3	0	9				
More Than One Race	2	0	0	2				
Unknown or Not Reported	0	0	0	0				
Racial Categories: Total of All Subjects*	14	7	0	21 *				

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	2	1	0	3
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	2	1	0	3 **

* These totals must agree.

** These totals must agree.

Pages 17 through 20 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD027871-19

PI Name:	EHRENKRANZ, RICHARD
Org:	YALE UNIVERSITY
Start Date:	04/01/2009
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	7615669
Rec'd Date:	02/10/2009

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Department of Health and Human Services Public Health Services			Review Group	Type 5	Activity U10	Grant Number HD 27281-10	27871-19		
				Total Project Period					
Grant Progress Report		From: 04/01/1991 Through: 03/31/2011							
Orant	Grant rogress report			Requested Budget	Period				
			From: 04/01/09		Thro	ugh: 03/31/10	· · · · · · · · · · · · · · · · · · ·		
1. TITLE OF PROJE Cooperative	Multicenter Ne	onatal	Research Ne	etwork					
2a. PROGRAM DIRE	CTOR / PRINCIPAL	INVEST	IGATOR	2b. E-MAIL ADDRE	SS				
(Name and addres Ehrenkranz, I	s, street, city, state	, zip code	9)	richard.ehre					
Yale Universi				2c. DEPARTMENT, Pediatrics	SERVICE	, LABORATOI	RY, OR EQUIVALE	NT	
Department o	•			2d. MAJOR SUBDIV			·		
333 Cedar St				School of M					
PO Box 2080				2e. Tel: 203-688	3-2320	Fax	203-688-5426	3	
3a. APPLICANT ORG	CT 06520-806			·	·				
(Name and address	s, street, city, state,	zip code))	3b. Tel: 203-785	5-4689	Fax	203-785-4159	9	
Yale Universi		n		3c. DUNS: 04-32	20-7562				
PO Box 2080	treet, Suite 203	3					<u> </u>	2009	
	CT 06520-804	7		4. ENTITY IDENTI 060646973	FICATION	NUMBER			
6. HUMAN SUBJECT	'S 🗌 No 🛛 [Yes		5. NAME, TITLE A		ESS OF AOM	INISTRATIVE OFFI	CIAL	
6a. Research Exempt	If Exempt ("Yes" in 6a):	n lf No 6a):	ot Exempt ("No" in	William Timrud/ David Knapp / Jeri Barney					
	Exemption No.	IRB	approval date				Intract Admin		
		Se	e list p.2	4/ College	St, Suite	e 203, New	/ Haven, CT 00	5520-8047	
6b. Federal Wide Ass	surance No. FWA	400002	2571]Tel: 203-785 - 40	589	Fax	203-785-4159	Ð	
6c. NIH-Defined Phas Clinical Trial 🕅 N	· · · · · · · · · · · · · · · · · · ·			E-MAIL: gcat3@yale.edu					
7. VERTEBRATE AN	IIMALS 🛛 No	Ye	S	10. PROJECT/PERFORMANCE SITE(S)					
7a. If "Yes," IACUC a	pproval Date			Organizational Name: Applicant					
7b. Animal Welfare As	ssurance No.			DUNS:					
8. COSTS REQUES	TED FOR NEXT BU	UDGET P	PERIOD	Street 1:					
8a. DIRECT \$231,4	19 86. то	TAL \$38	32,738	Street 2:					
9. INVENTIONS AND		No 🗌	Yes	City:		Coi	inty:		
lf "Yes, 🔲 Previo	usly Reported			State:		Pro	vince:		
	eviously Reported			Country: Zip/Postal Code:					
			Congressional Districts:						
11. NAME AND TITL David Knapp, M		GNING F	OR APPLICANT (DRGANIZATION (Ite	·m 13)				
TEL: 203-785-4689 FAX: 203-785-			-4159		E-MAIL: gC	at3@yale.edu			
12. Corrections to Pag	ge 1 Face Page	I	- 		•				
obligation to comply result of this applicat	e true, complete and a with Public Health Ser tion. I am aware that a	accurate to rvices term any false, fi	the best of my know s and conditions if a ictitious, or fraudulen	ledge, and accept the	SIGNATU 11. (In in			DATE 1-27-09	
PHS 2590 (Rev. 11/07	riminal, civil, or admini 7)	istrative pe	nanies.	Face Page		in In	78	Form Page 1	

Yale I	<u>RB#:</u>	Approval <u>Date:</u>	Expiration <u>Date:</u>	<u>Title of Protocol:</u>
Not responsive. Not	related to SUPPOF	RT.		
041002	27163	02/22/08	02/22/09	The Surfactant Positive Airway Pressure and Pulse
				Oximetry Trial in Extremely Low Birth Weight infants (the SUPPORT Trial); includes Breathing
		,		Outcomes and Growth secondaries
Not responsive.	Not related to SU	PPORT.		

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Pages 4 through 5 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Ehrenkranz, Richard A

	GRANT NUMBER				
PROGRESS REPORT SUMMARY	HD 27281-19				
	PERIOD COVERED E	BY THIS REPORT			
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	FROM	THROUGH			
Richard A. Ehrenkranz, MD	04/01/08	03/31/09			
APPLICANT ORGANIZATION					

Yale University School of Medicine

2						
TITLE OF PROJECT (Repeat title shown in Item 1 on first page) Cooperative Multicenter Neonatal Research Network						
A. Human Subjects (Complete Item 6 on the	· · · · · · · · · · · · · · · · · · ·					
Involvement of Human Subjects	No Change Since Previous Submission	Change				
B. Vertebrate Animals (Complete Item 7 on	the Face Page)					
Use of Vertebrate Animals	No Change Since Previous Submission	Change				
C. Select Agent Research	No Change Since Previous Submission	Change				
D Multiple PD/PLLeadership Plan	No Change Since Previous Submission	Change				

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

During the 18th year of Yale's participation in the NIH-Multicenter Network of Neonatal Intensive Care Units, we:

WC: Not responsive. Not related to SUPPORT.

(5) continued to enroll infants into the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT Trial),

Not responsive. Not related to SUPPORT.

Screening for enrollment in the SUPPORT trial began in May 2005 at Yale; as of 12/31/08 we have screened 166 women who have presented in preterm labor at 24° to 27⁶ weeks gestation. Consent was sought from 148 eligible women; 36 infants have been randomized (24.3% of eligible deliveries). An additional consented infant who was born within the gestational age eligibility window was not randomized because she was born during the trial's temporary suspension from November 22, 2005 to February 22, 2006. The Inclusion Enrollment Report provides data on the 36 randomized infants. Based on the Antenatal Consent Secondary Study, consents have been obtained from slightly more than 50% of the eligible women approached, but that only about 35% of the consented women have delivered within the randomization window. Consent for the Breathing Outcomes and the Growth secondary studies are included in the consent for the main trial; Yale is not participating in the MRI secondary study. Developmental follow-up assessments of study participants have been performed at 18 to 22 months corrected age. The objectives of the SUPPORT Trial are (1) to see whether management of infants with early CPAP and a permissive ventilatory strategy compared to prophylactic/early surfactant and conventional ventilation will result in increased survival without bronchopulmonary dysplasia and (2) to see whether management of infants with a lower SpO₂ range (85% to 89%) compared to a higher SpO₂ range (91% to 95%) will result in increased survival without the occurrence of threshold retinopathy of prematurity (ROP) and/or the need for surgical intervention.

Pages 8 through 18 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	The Surfactant and Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants				
Total Enrollment:	36	Protocol Number:	Yale IRB# 0410027163		
Grant Number:	HD 27281-19				

	Sex/Gender					
Ethnic Category	Females	Males	Unknown or Not Reported	Total		
Hispanic or Latino	4	2		6	**	
Not Hispanic or Latino	18	12		30		
Unknown (individuals not reporting ethnicity)						
Ethnic Category: Total of All Subjects*	22	14		36	*	
Racial Categories						
American Indian/Alaska Native						
Asian		1		1		
Native Hawailan or Other Pacific Islander						
Black or African American	9	6		15		
White	11	7		18		
More Than One Race	2	<u> </u>		2		
Unknown or Not Reported		··········				
Racial Categories: Total of All Subjects*	22	14		36	*	

PART B. HI\$PANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total	
American Indian or Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American					
White	4	2		6	
More Than One Race					
Unknown or Not Reported					
Racial Categories: Total of Hispanics or Latinos**	4	2		6 *	**

These totals must agree.

** These totals must agree.

Pages 20 through 23 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD027871-20

PI Name:
Org:
Start Date:
Snap:
Appl ID:
Rec'd Date:

EHRENKRANZ, RICHARD YALE UNIVERSITY 04/01/2010 N/A (NEEDS TO BE BOOKMARKED) 7799786 02/01/2010

Form Approved Throu	igh 06/30/2012					OMB No. 0925-0001	
Departm	ent of Health and Huma Public Health Service		Review Group	Type 5	Activity U10	Grant Number HD 27871-20	
			Total Project Period				
Grant	Drogroes	Donort	From: 04/01/199	1	Thr	ough: 03/31/2011	
Gran	Progress	Report	Requested Budget P	eriod			
		From: 04/01/2010	D	Thr	rough: 03/31/2011		
1. TITLE OF PROJE							
		atal Research Ne					
	CTOR / PRINCIPAL IN ss, street, city, state, zig		2b. E-MAIL ADDRES	-			
Ehrenkranz, I			richard.ehren	-			
Yale Universi			Pediatrics	ERVICE,	LABORATC	DRY, OR EQUIVALENT	
Department o	of Pediatrics						
333 Cedar St			2d. MAJOR SUBDIVI				
PO Box 2080			1		_	000 000 5400	
	CT 06520-8064		2e. Tel: 203-688-	2320	Fa	x: 203-688-5426	
3a. APPLICANT ORG (Name and address Yale Universi	s, street, city, state, zip	code)	3b. Tel: 203-785-	4689	Fa	x: 203-785-4159	
	treet, Suite 203		3c. DUNS: 04-320)-7562		FEB 0 1 2010	
	CT 05520-8047		4. ENTITY IDENTIFI 06-0646973	CATION	NUMBER	FED 0 1 COM	
6. HUMAN SUBJECT	rs 🗌 No 🗌 `	Yes	5. NAME, TITLE AN	D ADDRE	SS OF ADM	INISTRATIVE OFFICIAL	
6a, Research Exempt No 🛛 Yes	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date See list p.2	 ⁱⁿ William Timrud / David Knapp Grants & Contract Administration 47 College St, Suite 203, New Haven, CT 06520-80 		ation		
	urance No. FWA00	<u> </u>	Ты: 203-785-468	20	F -	x: 203-785-4159	
		002571					
6c. NIH-Defined Phase Clinical Trial N			E-MAIL: gcat3@yale.edu				
7. VERTEBRATE AN	IIMALS 🛛 NO 🗌	Yes	10. PROJECT/PERFO	ORMANC	E SITE(S)		
7a. If "Yes," IACUC a	pproval Date		Organizational Name: Yale University				
7b. Animal Welfare As	ssurance No.		DUNS: 04-320-7562				
8. COSTS REQUES	TED FOR NEXT BUDG	BET PERIOD	Street 1: 47 Colle	ge Stre	et, Ste 2	03	
8a. DIRECT \$238,3	37 86. ТОТАІ	_\$394,448	Street 2:				
9. INVENTIONS AND	PATENTS No	Yes	City: New Haver)	Co	unty: New Haven	
	usly Reported		State: CT		Pro	Province.	
Not Pre	eviously Reported		Country: United S	states	Zip	/Postal Code: 06520	
			Congressional Districts: CT-003				
		NG FOR APPLICANT O	•	13)			
TEL: 203-785-46	89	FAX: 203-785-	-4159	1	E-MAIL: go	at3@yale.edu	
12. Corrections to Pag	ge 1 Face Page						
obligation to comply v	ledge, and accept the grant is awarded as a statements or claims	iGNATUF 1. (In ink,		CIAL NAMED IN DATE			
PHS 2590 (Rev. 06/09)		Face Page			/ Form Page 1	
						₹ -	

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Yale IRB#:	Approval <u>Date:</u>	Expiration <u>Date:</u>	Title of Protocol:
Not responsive. Not related to SU	PPORT.		
0410027163	02/22/09	02/22/10	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight infants (the SUPPORT Trial); includes Breathing Outcomes, Growth and Antenatal Screening and Consent secodaries
Not responsive. Not related to SUF	PPORT.		

Pages 4 through 5 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle)	Ehrenkranz, Richard	
PROGRESS REPORT SUMMARY	GRANT NUMBER HD 27871-20	
	PERIOD COVERED BY THIS R	EPORT
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	FROM	THROUGH
Richard A. Ehrenkranz, MD	04/01/08	03/31/09
APPLICANT ORGANIZATION Yale University School of Medicine	·	
TITLE OF PROJECT (Repeat title shown in Item 1 on first page		
Cooperative Multicenter Neonatal Research Networ	k	
A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects 🛛 🛛 No Char	nge Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals No Cha	nge Since Previous Submission	Change
C. Select Agent Research No Char	nge Since Previous Submission	Change
D. Multiple PD/PI Leadership Plan 🛛 🛛 No Chai	nge Since Previous Submission	Change
E. Human Embryonic Stem Cell Line(s) Used No Cha	nge Since Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS.		

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

In the 19th yr of Yale's participation in the NIH Multicenter Network of Neonatal Intensive Care Units, we: Int responsive. Not related to SUPPORT.

(3) continued to enroll infants into the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT Trial), Not responsive. Not related to SUPPORT.

Screening for enrollment in the SUPPORT trial began in May 2005 at Yale; study enrollment was terminated on February 27, 2009 when 1310 infants had been reached. We screened 171 women who have presented in preterm labor at 24° to 27⁶ weeks gestation; 152 were eligible. Consent was sought from 122 eligible women; 37 infants have been randomized (24.3% of eligible deliveries). An additional consented infant who was born within the gestational age eligibility window was not randomized because she was born during the trial's temporary suspension from November 22, 2005 to February 22, 2006. The Inclusion Enrollment Report provides data on the 37 randomized infants. Participation in the Antenatal Consent Secondary Study have demonstrated that consents had been obtained from slightly more than 50% of the eligible women approached, but that less than about 35% of the consented women deliver within the randomization window. Consent for the Breathing Outcomes (n=31) and the Growth (n=32) secondary studies are included in the consent for the main trial; Yale is not participating in the MRI secondary study. Developmental follow-up assessments of all expected study participants have so far been performed at 18 to 22 months corrected age. Data analyses addressing the 2 main hypotheses were completed by the fall of 2009, abstracts were submitted to the 2010 Pediatric Academic Societies Annual Meeting, and manuscripts are currently under review by the New England Journal of Medicine. The trial concluded (1) that CPAP as used in this study is an effective evidence-based alternative to intubation and surfactant in preterm infants and (2) that lower oxygen saturation (85-89%) targeting did not significantly decrease the combined outcome of severe retinopathy or death, but resulted in an increase in mortality and a substantial decrease in severe retinopathy among survivors.

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Pages 8 through 16 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants				
Total Enroliment:	37	Protocol Number: Yale IRB# 0410027163			
Grant Number:	HD 27281-20				

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race					
Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total	
Hispanic or Latino	4	2		6	**
Not Hispanic or Latino	19	12		31	
Unknown (individuals not reporting ethnicity)					
Ethnic Category: Total of All Subjects*	23	14		37	*
Racial Categories					
American Indian/Alaska Native					
Asian		1		1	
Native Hawaiian or Other Pacific Islander					
Black or African American	9	6		15	
White	12	7		19	
More Than One Race	2				
Unknown or Not Reported					
Racial Categories: Total of All Subjects*	23	14		37	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	4	2		6
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	4	2		6 **

* These totals must agree.

** These totals must agree.

Pages 18 through 21 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD027880-15

PI Name: Org: Start Date: Snap: Appl ID: Rec'd Date: STEVENSON, DAVID STANFORD UNIVERSITY 04/01/2005 N/A (NEEDS TO BE BOOKMARKED) 6895922 02/03/2005

Form Appr	oved Through 09/30/200	7						OMB No. 0925-0001
	Department of Healt	h and Human Services	Review Group	p Typ	be	Activity	- 1	Grant Number
	Public Healt	h Services			5	U10		HD27880-15
			Total Project	Period:		N .		
	Grant Prog	ross Poport	From:	04/0)1/91	Thro	ugh:	03/31/06
	Grant Prog	ress Report	Requested Bu	udget Pe	riod:	·····		T****)
			From:	04/0)1/05	Thro	ugh:	03/31/06
1. TITLE	OF PROJECT							2
Mult	icenter Network of	Neonatal Intensive Care L	Jnits					, j
		OR PROGRAM DIRECTOR	3. APPLICAN					1 1-2
	e and address, street, cit	y, state, zip code)	(Name and	addres	s, street,	city, state, zi	p code)
	enson, David K.		01					
	ford University		Stanfor					ng tauna unanacina A t
	t. of Pediatrics	F				nent Grou		
	Welch Rd. Rm 31					Modular B)	07
	nford, CA 94305-5	/3	Stanfor					
	IL ADDRESS		4. ENTITY ID			NUMBER		,
	venson@stanford		194115					
		BORATORY, OR EQUIVALENT	5. TITLE ANI				ALIVE	OFFICIAL
	iatrics					Manager		
2d. MAJC	OR SUBDIVISION		Stanfor			ant Crou	-	
						nent Grou		
Scho	ool of Medicine				-	Modular B)	
			Stanfor	-				
		·	E-MAIL: rich				eau	
		Ch. Liveran Cubiasta Assurance No.	7. VERTE	BRAIE	ANIMAL	-	14 W) /	
∏ No X Yes	6a. Research Exempt	6b. Human Subjects Assurance No. FWA935	No Yes			/a.	if res	," IACUC approval Date
	("Yes" in 6a):	6c. NIH-Defined Phase III	7b. Anima	l Welfare	Assura	nce No		
Exemption		Clinical Trial X No Yes		213-0				
If Not Exe	mpt ("No" in 6a):							
IRB appro	4.4.10.0.10							
8. COST	S REQUESTED FOR NE		9. INVENTIC			ITS		
8a. DIREC		86.TOTAL \$			"Yes,"	Previou:	sly Re	ported
	256,404	366,530				Not Prev	viously	Reported
10. PERF		ganizations and addresses)	11a. PRINCI	PAL INV	ESTIGA	TOR TEL	((650) 723-5711
		-	OR PROGRA	M DIRE	CTOR (ltem 2a) FAX	(650) 725-8351
Star	nford University		Stevenso	n, Dav	/id K.			
	ool of Medicine		11b. ADMINI			ICIAL TEL	((650) 498-5591
	artment of Pediatr	ics	NAME (Item5			FAX		(650) 498-5876
	nford, CA 94305		Richard K	-	h			(000) 400 0070
Otar			11c. NAME A	AND TIT	LE OF C	DFFICIAL SIG	NING	FOR APPLICANT
					d K. S	mith		,
								-
						ocess Ma	-	
					98-58	•		(650) 498-5876
			E-MAIL T	ichard	.smith	@stanfor	d.edu	
12 Corre	ections to Page 1 Face Page							

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANC statements herein are true, complete and accurate to the best of my knowled any false, fictitious, or fraudulent statements or claims may subject me administrative penalties. I agree to accept responsibility for the scientific c and to provide the required progress reports if a grant is awarded as a result of	dge. I am aware that (In Ink. Per signature not acceptable.) to criminal, civil, or conduct of the project	DATE (2405
14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANC statements herein are true, complete and accurate to the best of my knowle obligation to comply with Public Health Services terms and conditions if a g result of this application. I am aware that any false, fictitious, or fraudulent may subject me to criminal, civil, or administrative penalties.	edge, and accept the 11c. (In ink "Per" signature not	DATE
PHS 2590 (Rev. 09/04)	Face Page	Form Page 1

Pages 3 through 8 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle):	Stevenson, David K	ζ.
PROGRESS REPORT SUMMARY	GRANT NUMBER HD27880-15	······································
	PERIOD COVERED BY	THIS REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH
David K. Stevenson, MD	04/01/04	03/31/05
APPLICANT ORGANIZATION		
Stanford University		
TITLE OF PROJECT (Repeat title shown in Item 1 on first page)		
Cooperative Multicenter Network of Neonatal Intensive	e Care Units	
A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects 🛛 🛛 No Chang	e Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals No Chang	e Since Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS.	······	

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Specific Aims

The specific aim of the NICHD Cooperative Multicenter Network of Neonatal Intensive Care Units is to facilitate a consortium of academic tertiary health care centers in the rigorous evaluation of treatment and management strategies for neonates, particularly low birth weight infants. Through the efforts of the NICHD Neonatal Research Network, common protocols are used to evaluate these strategies in order to provide answers more rapidly, and consume fewer resources, than would be possible if individual centers acted alone.

Studies and Results

Not responsive	e. Not related	IO SUPPORT		

Pages 10 through 16 redacted for the following reasons: Not responsive. Not related to SUPPORT. Not responsive. Not related to SUPPORT.

Plans

During the -15 grant year our plan is to:

Not responsive. Not related to SUPPORT.

open enrollment in Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth . Weight Infants; Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

•

Human Subjects

Current Institutional Review Board approval dates for activities described in this document are listed in the table below.

Protocol	Protocol #	Approval Date
Not responsive. Not related to SUPPORT.		
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	95793	pending

Inclusion enrollment report tables follow.

Pages 19 through 33 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle):	Stevenson, David	K
PROGRESS REPORT SUMMARY	GRANT NUMBER HD27880-15 (SC	IDA)
	PERIOD COVERED B	Y THIS REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH
David K. Stevenson, MD	04/01/04	03/31/05
APPLICANT ORGANIZATION Stanford University		
TITLE OF PROJECT (Repeat title shown in Item 1 on first page) Cooperative Multicenter Network of Neonatal Intensive	e Care Units (SCIDA	 \)
A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects No Change	e Since Previous Submissio	n Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals No Change	e Since Previous Submissio	n Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Specific Aims

The question of comparative predictive capabilities of cranial ultrasound (US) and brain MRI with respect to neurodevelopmental outcome remains the specific aim of this study. The original project has been modified slightly: it is now a secondary study to the upcoming Network Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT). This change allows for a more powerful and substantial research effort, as it now is linked with a randomized control. Linking this research with SUPPORT will also allow thorough and significant evaluation of early and later potential protective or deleterious neuroradiologic findings associated with SUPPORT ventilation and oxygenation strategies. Perhaps most important, linking this study with SUPPORT will provide a unique opportunity to examine the independent associations of both specific neuroimaging findings and clinical respiratory interventions on early childhood neurodevelopmental outcomes among extremely preterm infants in the NICHD Neonatal Research Network.

Studies and Results

Neuroimaging and Neurodevelopmental Outcome: A Secondary to Surfactant Positive Airway Pressure and Pulse Oximetry Trial

This is a prospective study of cranial US at 7-14 days of age ("early"), 35-42 weeks ("late") postmenstrual age (PMA) and brain MRI at 35-42 weeks PMA among infants enrolled in SUPPORT. All SUPPORT subjects will have the US assessments and a subset of subjects, from centers able to participate in the MRI protocol, will have brain MRIs. The study will:

- Obtain consistently performed, timed and interpreted neuroimaging studies in extremely preterm infants enrolled in SUPPORT.
- Compare early and late US and MRI findings between Low and High SpO₂ groups, and between Early CPAP and Control ventilation groups.
- Utilize the NICHD Neonatal Research Network follow-up programs to assess neurodevelopmental outcomes at 18-22 months corrected age, as described in SUPPORT.
- Examine the independent associations of neuroimaging findings with neurodevelopmental outcomes through logistic regression modeling.

The study hypotheses are:

- Multivariate modeling will demonstrate that conventional brain MRI at 35-42 weeks PMA will be superior to cranial US in predicting neurodevelopmental outcome at 18-22 months corrected age.
- There will be insufficient evidence to reject the null hypothesis that no differences exist in frequency of Death/Grade 3/4 IVH or Death/PVL on early or late US between Low and High SpO₂ groups, or between Early CPAP and Control ventilation groups.

Principal Investigator/Program Director (Last, First, Middle): Stevenson, David K.

• There will be insufficient evidence to reject the null hypothesis that the frequency of Death/abnormal findings on conventional brain MRI at 35-42 weeks postmenstrual age (PMA) are not different between Low and High SpO2 groups, or between Early CPAP and Control ventilation groups.

The project has been approved by the Network protocol review committee as well as the SUPPORT subcommittee and is currently undergoing external review.

Significance

Neuroimaging and Neurodevelopmental Outcome: A Secondary to Surfactant Positive Airway Pressure and Pulse Oximetry Trial

Cranial ultrasound (US) is currently used for brain imaging in the extremely preterm population, but this modality cannot detect subtle brain injury that may be responsible for later neuromotor and cognitive delay. Magnetic resonance imaging (MRI) can identify brain structural abnormalities and white matter injury better than cranial US. SUPPORT will evaluate if permissive ventilation strategies and lower SpO₂ targets will result in increased rates of survival without BPD and increased rates of survival without retinopathy of prematurity (ROP) among 24-27+6/7 week EGA infants. It is not known whether differing ventilation and oxygenation management approaches could lead to adverse consequences with respect to brain injury. Extremely premature infants are at very high risk for neuromotor and neurodevelopmental impairment, with reported rates of cerebral palsy (CP) ranging from 11-20%, and of severe cognitive delay ranging from 30-60%. Whether MRI can predict neurodevelopmental outcome better than early and/or late cranial US among preterm infants is not yet known, but small preliminary studies are promising. The NICHD Neonatal Research Network is uniquely positioned to embark upon such a project, which will be the first multicenter, prospective study to investigate these important questions.

Plans

Over the next year, the plan for the secondary study is to complete the review process, finalize funding, and undertake enrollment among SUPPORT subjects.

Publications None

Not responsive. Not related to SUPPORT.

Pages 36 through 40 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

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PI Name:
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VAN MEURS, KRISA STANFORD UNIVERSITY 04/01/2007 N/A (NEEDS TO BE BOOKMARKED) 7220618 02/01/2007

Department of Health and Human Services	Review Group	Туре	Activity	OMB No. 0925-0001 Grant Number
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Grant Progress Report	Requested Budg	get Period:		
	From: C	04/01/2007	Through	: 03/31/2008
1. TITLE OF PROJECT				
Multicenter Network of Neonatal Intensive Care				
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	3. APPLICANT			
(Name and address, street, city, state, zip code)			city, state, zip co	ode)
Van Meurs, Krisa P	Stanford L			
Stanford University			nent Group	
Dept of Pediatrics	1215 Wel			
750 Welch Road, #315	Stanford,			
2b. E-MAIL ADDRESS	4. ENTITY IDEN		NUMBER	
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Yes No Yes FWA00000935 If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III Exemption No. Clinical Trial No Yes If Not Exempt ("No" in 6a): Image: Clinical Trial No Yes IRB approval date 10/31/2006 Image: Clinical Trial Expedited Review	Yes 7b. Animal W A321		nce No.	
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PHS 2590 (Rev. 04/06)

Form Page 1

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Principal Investigator/Program Director (Last, First, Middle):	V
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Van Meurs, Krisa P.

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SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Specific Aims

The specific aim of the NICHD Cooperative Multicenter Network of Neonatal Intensive Care Units is to facilitate a consortium of academic tertiary health care centers in the rigorous evaluation of treatment and management strategies for neonates, particularly low birth weight infants. Through the efforts of the NICHD Neonatal Research Network, common protocols are used to evaluate these strategies in order to provide answers more rapidly, and consume fewer resources, than would be possible if individual centers acted alone.

Studies and Results

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Pages 8 through 9 redacted for the following reasons: Not responsive. Not related to SUPPORT. Not responsive. Not related to SUPPORT.

I. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT employs a 2X2 factorial design to compare two approaches to early respiratory management and to compare two levels of oxygen saturation among infants born at 24 up to 28 weeks of gestation. The respiratory management arm of the trial is a randomized, unmasked controlled comparison of "standard" extremely low birth weight delivery room resuscitation: intubation, early surfactant administration, and mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management guidelines are in place during the first 14 days after delivery and will allow comparison of the two approaches with the primary hypothesis that the CPAP approach will reduce the incidence of death and/or bronchopulmonary dysplasia at 36 weeks postmenstrual age. The oxygen saturation arm of SUPPORT will compare a saturation range or 85-89% with a range of 91-95% and will be in place from shortly after delivery to 36 weeks postmenstrual age, or until the infant is off all support and in room air for 72 hours with saturations at or above the target range. The hypothesis is that maintaining infants at lower oxygen saturations from birth will result in an increase in survival without threshold retinopathy of prematurity (ROP) and/or the need for surgical intervention. This arm of the SUPPORT project is masked through the use of altered pulse oximeters.

There are four secondary studies associated with SUPPORT: antenatal screening and consent, neuroimaging and neurodevelopmental outcome, breathing outcomes, and postnatal growth. The antenatal screening and consent secondary is a cohort study designed to determine the resources required and challenges encountered in the process of obtaining informed antenatal consent and enrolling an eligible infant. The neuroimaging and neurodevelopmental outcome secondary is a prospective study of cranial ultrasound at 7-14 days of age ("early"), 35-42 weeks ("late") postmenstrual age and brain magnetic resonance imaging (MRI) at 35-42 weeks postmenstrual age among infants enrolled in SUPPORT. The study hypotheses are:

- multivariate modeling will demonstrate that conventional brain MRI at 35-42 weeks postmenstrual age will be superior to cranial ultrasound in predicting neurodevelopmental outcome at 18-22 months corrected age,
- there will be insufficient evidence to reject the null hypothesis that no differences exist in frequency of death/grade 3/4 intraventricular hemorrhage or death/periventricular leukomalacia on early or late cranial ultrasound between the two oxygen saturation groups, or between the two ventilation management groups,
- there will be insufficient evidence to reject the null hypothesis that the frequency of death/abnormal findings on conventional brain MRI at 35-42 weeks postmenstrual age are not different between the two oxygen saturation groups, or between the two ventilation management groups.

The breathing outcomes secondary is a longitudinal follow-up study of SUPPORT infants. The goal is to improve understanding of symptomatic airway dysfunction among surviving study subjects. The hypotheses are that infants randomized to the lower oxygen saturation range will have less symptomatic airway

dysfunction and a reduced need for outpatient pulmonary care in the first two years and that infants randomized to CPAP in the respiratory arm of the main trial will have less symptomatic airway dysfunction and a reduced need for outpatient pulmonary care in the first two years.

The postnatal growth secondary follows somatic growth during the subjects' hospitalization and at 18-22 month follow-up. The hypotheses are that infants in the lower oxygen saturation range will have better in-hospital and long-term growth and that trajectories of growth in-hospital will be better for infants in the low oxygen saturation group. At Stanford, screening for SUPPORT began in April, 2005.

Study-wide enrollment was suspended for several months, beginning in November of 2005, at the request of the Data Safety and Monitoring Committee while a concern about the high oxygen saturations seen among infants receiving room air was resolved. Enrollment re-opened in mid-April 2006. Stanford has enrolled 14 patients to date. The Stanford center is participating in all four secondary studies and is preparing to begin neurodevelopmental follow-up of the early enrollees.

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Pages 12 through 13 redacted for the following reasons: Not responsive. Not related to SUPPORT. Not responsive. Not related to SUPPORT.

I. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT compares two approaches to early respiratory management in an effort to reduce bronchopulmonary dysplasia and two levels of oxygen saturation to reduce ROP among infants born at 24 up to 28 weeks of gestation. The use of continuous positive airway pressure (CPAP) or positive end expiratory pressure (PEEP) during delivery room resuscitation and continuing after admission to the NICU among ELBW infants has been advocated by some investigators for many years. This is based on a number of primarily retrospective studies which suggest that early CPAP may be associated with improved outcomes including a decreased need for mechanical ventilation, a decreased need for surfactant therapy, and a decrease in oxygen supplementation and/or death at 28 days after delivery and at 36 weeks postmenstrual age. PEEP has been shown to help maintain functional residual capacity and CPAP was shown to improve oxygenation in very low birth weight neonates with respiratory distress over 30 years ago in the pre-surfactant era. Currently there are no guidelines regarding the use of PEEP in the delivery room but studies have shown that preemies who do not achieve a functional residual capacity are more likely to develop hyaline membrane disease and require mechanical ventilation. Although studies conducted before the introduction of surfactant and antenatal steroids are difficult to assess in the current day, there is a consistent body of recent evidence that suggests that the

use of CPAP can reduce the need for intubation, reduce the need for surfactant administration, improve lung mechanics, reduce lung injury, and improve the outcome of very low birth weight infants. There has not, however, been a randomized controlled comparison of what is for many the gold standard of ELBW delivery room resuscitation: intubation, early surfactant administration, and mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management arm of the SUPPORT project will address the primary hypothesis that the CPAP approach will reduce the incidence of death or bronchopulmonary dysplasia at 36 weeks postmenstrual age.

Retinopathy of prematurity (ROP) has been recognized for 50 years as a morbidity associated with premature birth and oxygen toxicity. Although it has long been known that the incidence of ROP increases as oxygen exposure increases and gestational age decreases, the point at which oxygen exposure triggers the pathophysiology of the disorder remains undetermined. The disease is currently thought to occur in two phases: an acute injury during which the retinal blood vessels are damaged and a second phase occurring several weeks later when disorganized blood vessel growth occurs. There have been a few randomized trials of oxygen saturation management (higher versus lower) in the second phase, including the Network's STOP ROP trial in the early 1990s, which have not provided definitive answers to the question of oxygen management among ELBW infants. There is however, evidence suggesting that many of the morbidities experienced by the ELBW population is the result of oxygen toxicity. Retrospective cohort studies suggest that the use of lower oxygen saturation ranges beginning at birth coupled with strict nursery policies may result in fewer cases of severe ROP. However, data on the actual oxygen saturations maintained are generally not available. In addition, the neurodevelopmental outcome of infants managed at lower oxygen saturations will be an important factor in any future recommendations surrounding the use of supplemental oxygen and oxygen

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D. Plans

During the -17 grant year our plan is to:

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• '	continue enrollment in Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth	
	Weight Infants and the associated secondary studies;	
•	begin neurodevelopmental follow-up for children enrolled in SUPPORT;	
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Human Subjects

Current Institutional Review Board approval dates for open protocols from the Cooperative Multicenter Network of Neonatal Intensive Care Units are listed in the table below.

Protocol	Site	Protocol #	Approval Date
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The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in	A	95793	12/19/2006
Extremely Low Birth Weight Infants			
			-

Inclusion enrollment report tables follow.

Pages 18 through 25 redacted for the following reasons: Not responsive. Not related to SUPPORT. Principal Investigator/Program Director (Last, First, Middle): Van Meurs, Krisa P.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants					
14	Protocol Number:				
HD27880-17					
	Weight Infants 14				

		S	ex/Gender		
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	3	5	0	8	**
Not Hispanic or Latino	2	4	0	6	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	5	9	0	14	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	0	1	0	1	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	0	1	0	1	
White	5	7	0	12	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	5	9	0	14	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	3	5	0	8
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or	3	5	0	8 **

* These totals must agree.

** These totals must agree.

Pages 27 through 35 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD027880-18

PI Name: Org: Start Date: Snap: Appl ID: Rec'd Date: VAN MEURS, KRISA STANFORD UNIVERSITY 04/01/2008 N/A (NEEDS TO BE BOOKMARKED) 7391696 02/04/2008

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Form Approved Through 09/30/2007				OMB No. 0925-0001
Department of Health and Human Services	Review Group	Туре	Activity	Grant Number
Public Health Services		5	<u>U10</u>	HD027880-18
•	Total Project P			
Grant Progress Report		04/01/1991	Through:	03/31/2011
Department of Health and Human Services Public Health Services Grant Progress Report 1. TITLE OF PROJECT Multicenter Network of Neonatal Intensive Care 2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code) Van Meurs, Krisa P Stanford University, School of Medicine Dept. of Pediatrics, 750 Welch Road, #315 Stanford, CA 94305 2b. E-MAIL ADDRESS vanmeurs@stanford.edu 2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Pediatrics 2d. MAJOR SUBDIVISION School of Medicine 6. HUMAN SUBJECTS No 6a. Research Exempt Amage No 6b. Human Subjects Assurance I X Yes X No Yes FWA00000935 If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III Clinical Trial X No Yes Full IRB or IRB approval date 10/16/07 8. COSTS REQUESTED FOR NEXT BUDGET PERIOD 8a. DIRECT \$ 8b. TOTAL \$	Requested Bud			02/24/2000
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6. HUMAN SUBJECTS		RATE ANIMALS		
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-	Van Meurs	<u>, Krisa P</u>	FAX	(650) 725-8351
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Stanford, CA 94305	Richard K.	Smith	FAX	(650) 498-5876
	11c. NAME AN	ND TITLE OF O	FFICIAL SIGNING	FOR APPLICANT
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12. Corrections to Page 1 Face Page				······································

13.	APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the	SIGNATURE OF OFFICIAL NAMED IN 11c. DATE
	statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a	
	result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	Can mil 18

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Pages 3 through 8 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle):	Van Meurs, Krisa P.
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PROGRESS REPORT SUMMARY		GRANT NUMBER HD27880-18			
		PERIOD COVERED BY THIS REPORT			
PRINCIPAL INVESTIGATOR OR PROGRA	M DIRECTOR	FROM	THROUGH		
Krisa P. Van Meurs, M.D.		04/01/2007	03/31/2008		
APPLICANT ORGANIZATION					
Stanford University					
TITLE OF PROJECT (Repeat title shown in	Item 1 on first pag	e)			
Cooperative Multicenter Network of	Neonatal Inten	sive Care Units			
A. Human Subjects (Complete Item 6 on the	e Face Page)				
Involvement of Human Subjects	🔀 No Cha	ange Since Previous Submission	Change		
B. Vertebrate Animals (Complete Item 7 on	the Face Page)				
Use of Vertebrate Animals	No Cha	ange Since Previous Submission	Change		
C. Select Agent Research	No Cha	ange Since Previous Submission	Change		
D. Multiple PI Leadership Plan	🔀 🛛 No Cha	ange Since Previous Submission	Change		
D. Multiple PI Leadership Plan SEE PHS 2590 INSTRUCTIONS.					

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enroliment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Specific Aims

The specific aim of the NICHD Cooperative Multicenter Network of Neonatal Intensive Care Units is to facilitate a consortium of academic tertiary health care centers in the rigorous evaluation of treatment and management strategies for neonates, particularly low birth weight infants. Through the efforts of the NICHD Neonatal Research Network, common protocols are used to evaluate these strategies in order to provide answers more rapidly, and consume fewer resources, by providing larger population bases than would be possible if individual centers acted alone. In addition, usage of the multicenter model tests potential therapies across an array of practice differences, a superior approach in the assessment of innovation.

Studies and Results

Not responsive. Not related to SUPPORT.

Pages 10 through 11 redacted for the following reasons: Not responsive. Not related to SUPPORT. Not responsive. Not related to SUPPORT.

I. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT employs a 2X2 factorial design to compare two approaches to early respiratory management and to compare two levels of oxygen saturation among infants born at 24 up to 28 weeks of gestation. The respiratory management arm of the trial is a randomized, unmasked controlled comparison of "standard" extremely low birth weight delivery room resuscitation including immediate intubation, early surfactant administration, and continued mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management guidelines are in place during the first 14 days after delivery and will allow comparison of the two approaches with the primary hypothesis that the CPAP approach will reduce the incidence of death and/or bronchopulmonary dysplasia at 36 weeks postmenstrual age. The oxygen saturation arm of SUPPORT will compare target a saturation range of 85-89% with a range of 91-95% utilized from shortly after delivery to 36 weeks postmenstrual age, or until the infant is off all respiratory support and in room air for 72 hours with saturations at or above the target range. The hypothesis is that maintaining infants at lower oxygen saturations from birth will result in an increase in survival without threshold retinopathy of prematurity (ROP) and/or the need for surgical intervention. This arm of the SUPPORT project is masked through the use of altered pulse oximeters.

There are four secondary studies associated with SUPPORT: antenatal screening and consent, neuroimaging and neurodevelopmental outcome, breathing outcomes, and postnatal growth. The antenatal screening and consent secondary is a cohort study designed to determine the resources required and challenges encountered in the process of obtaining informed antenatal consent and enrolling an eligible infant. The neuroimaging and neurodevelopmental outcome secondary was developed by Dr Susan Hintz of Stanford University as her MSCIDA project. It is a prospective study of cranial ultrasound at 7-14 days of age ("early"), 35-42 weeks ("late") postmenstrual age and brain magnetic resonance imaging (MRI) at 35-42 weeks postmenstrual age among infants enrolled in SUPPORT. The study hypotheses are:

- multivariate modeling will demonstrate that conventional brain MRI at 35-42 weeks postmenstrual age will be superior to cranial ultrasound in predicting neurodevelopmental outcome at 18-22 months corrected age,
- there will be insufficient evidence to reject the null hypothesis that no differences exist in frequency of death/grade 3/4 intraventricular hemorrhage or death/periventricular leukomalacia on early or late cranial ultrasound between the two oxygen saturation groups, or between the two ventilation management groups,
- there will be insufficient evidence to reject the null hypothesis that the frequency of death/abnormal findings on conventional brain MRI at 35-42 weeks postmenstrual age are not different between the two oxygen saturation groups, or between the two ventilation management groups.

The breathing outcomes secondary is a longitudinal follow-up study of SUPPORT infants. The goal is to improve understanding of symptomatic airway dysfunction among surviving study subjects. The hypotheses are that infants randomized to the lower oxygen saturation range will have less symptomatic airway dysfunction and a reduced need for outpatient pulmonary care in the first two years and that infants randomized to CPAP in the respiratory arm of the main trial will have less symptomatic airway dysfunction and a reduced need for outpatient pulmonary care in the first two years and that infants randomized to compatient pulmonary care in the first two years.

The postnatal growth secondary follows somatic growth during the subjects' hospitalization and at 18-22 month follow-up. The hypotheses are that infants in the lower oxygen saturation range will have better in-hospital and long-term growth and that trajectories of growth in-hospital will be better for infants in the low oxygen saturation group.

At Stanford, screening for SUPPORT began in April, 2005. Study-wide enrollment was suspended for several months beginning in November of 2005 at the request of the Data Safety and Monitoring Committee during which time a concern about the high oxygen saturations seen among infants receiving room air was resolved. Enrollment re-opened in mid-April 2006. Stanford has enrolled 34 patients, (47% of eligible) to date. The Stanford center is participating in all four secondary studies and neurodevelopmental follow-up at 18 months corrected age is underway.

Not responsive. Not related to SUPPORT.

Pages 14 through 16 redacted for the following reasons: Not responsive. Not related to SUPPORT. Not responsive. Not related to SUPPORT.

I. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT compares two approaches to early respiratory management in an effort to reduce bronchopulmonary dysplasia and two levels of oxygen saturation to reduce ROP among infants born at 24 up to 28 weeks of gestation. The use of continuous positive airway pressure (CPAP) or positive end expiratory pressure (PEEP) during delivery room resuscitation and continuing after admission to the NICU among ELBW infants has been advocated by some investigators for many years based on a number of primarily retrospective studies which suggest that early CPAP may be associated with improved outcomes including a decreased need for mechanical ventilation, a decreased need for surfactant therapy, and a decrease in oxygen supplementation and/or death at 28 days after delivery and at 36 weeks postmenstrual age. PEEP has been shown to help maintain functional residual capacity and CPAP was shown to improve oxygenation in very low birth weight neonates with respiratory distress over 30 years ago in the pre-surfactant era. Currently there are no guidelines regarding the use of PEEP in the delivery room but studies have shown that preemies who do not achieve a functional residual capacity are more likely to develop hyaline membrane disease and require mechanical ventilation. Although studies conducted before the introduction of surfactant and antenatal steroids are difficult to assess in the current day, there is a consistent body of recent evidence that suggests that the use of CPAP can reduce the need for intubation, reduce the need for surfactant administration, improve lung mechanics, reduce lung injury, and improve the outcome of very low birth weight infants. There has not, however, been a randomized controlled comparison of what is for many the gold standard of ELBW delivery room resuscitation: intubation, early surfactant administration, and mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management arm of the SUPPORT project will address the primary hypothesis that the CPAP approach will reduce the incidence of death or bronchopulmonary dysplasia at 36 weeks postmenstrual age.

Retinopathy of prematurity (ROP) has been recognized for 50 years as a morbidity associated with premature birth and oxygen toxicity. Although it has long been known that the incidence of ROP increases as oxygen exposure increases and gestational age decreases, the point at which oxygen exposure triggers the pathophysiology of the disorder remains undetermined. The disease is currently thought to occur in two phases: an acute injury during which the retinal blood vessels are damaged and a second phase occurring several weeks later when disorganized blood vessel growth occurs. There have been a few randomized trials of oxygen saturation management (higher versus lower) in the second phase, including the Network's STOP ROP trial in the early 1990s, which have not provided definitive answers to the question of oxygen management among ELBW infants. There is however, evidence suggesting that many of the morbidities experienced by the ELBW population are the result of oxygen toxicity. Retrospective cohort studies suggest that the use of lower oxygen saturation ranges beginning at birth coupled with strict nursery policies may result in fewer cases of severe ROP. However, data on the actual oxygen saturations maintained are generally not available. In addition, the neurodevelopmental outcome of infants managed at lower oxygen saturations will be an important factor in any future recommendations surrounding the use of supplemental oxygen and oxygen saturations in preterm infants.

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

D. Plans

During the -18 grant year our plan is to:

νu	ing the flo grant year our plants to.
•	Not responsive. Not related to SUPPORT.
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•	continue enrollment in SUPPORT and the associated secondary studies;
٠	Not responsive. Not related to SUPPORT.
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Human Subjects

Current Institutional Review Board approval dates for open protocols from the Cooperative Multicenter Network of Neonatal Intensive Care Units are listed in the table below.

Protocol Title	Site	Protocol #	Approval Date	Expiration Da
responsive. Not related to SUPPORT.				
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	A	95793	12/18/2007	12/17/200
Including the following secondary studies:				
Antenatal Screening and Consent in a Research Network Model Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT				
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network	,			
SUPPORT Study				
Breathing Outcomes t responsive. Not related to SUPPORT.				
		I	L	I

Pages 20 through 28 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants					
Total Enrollment:	34	Protocol Number:				
Grant Number:	HD27880-18					

	Sex/Gender						
Ethnic Category	Females	Males	Unknown or Not Reported	Total			
Hispanic or Latino	8	13	0	21	**		
Not Hispanic or Latino	6	7	0	13			
Unknown (individuals not reporting ethnicity)	0	0	0	0			
Ethnic Category: Total of All Subjects*	14	20	0	34	*		
Racial Categories							
American Indian/Alaska Native	0	0	0	0			
Asian	0	1	0	1			
Native Hawaiian or Other Pacific Islander	0	0	0	0			
Black or African American	0	1	0	1			
White	14	18	0	32			
More Than One Race	0	0	0	0			
Unknown or Not Reported	0	0	0	0			
Racial Categories: Total of All Subjects*	14	20	0	34	*		

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	8	13	0	21
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	8	13	0	** 21

* These totals must agree.

** These totals must agree.

Pages 30 through 36 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Van Meurs, Krisa P.

PROGRESS REPORT SUMMARY		GRANT NUMBER HD27880-18 [SCIDA (Hintz)]				
		PERIOD COVERED BY	THIS REP	ORT		
PRINCIPAL INVESTIGATOR OR PROGRAM DIRE	CTOR	FROM	Т	HROUGH		
Krisa P. Van Meurs, M.D.		04/01/2007	0	3/31/2008		
APPLICANT ORGANIZATION Stanford University						
TITLE OF PROJECT (Repeat title shown in Item 1 Cooperative Multicenter Network of Neona	atal Inten	•	۹)			
 A. Human Subjects (Complete Item 6 on the Face P Involvement of Human Subjects B. Vertebrate Animals (Complete Item 7 on the Face 	No Cha	nge Since Previous Submission		Change		
Use of Vertebrate Animals	No Cha	nge Since Previous Submission		Change		
C. Select Agent Research	No Cha	nge Since Previous Submission		Change		
D. Multiple PI Leadership Plan	No Cha	nge Since Previous Submission		Change		

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Dr. Hintz was the 2004-2007 recipient of the MSCIDA. She proposed, developed and initiated the secondary study to SUPPORT titled *Neuroimaging and Neurodevelopmental Outcome: A Secondary to Surfactant Positive Airway Pressure and Pulse Oximetry Trial* within the context of the MSCIDA project. This is a prospective study of cranial ultrasound (CUS) at 7-14 days of age ("early"), 35-42 weeks ("late") postmenstrual age and brain magnetic resonance imaging (MRI) at 35-42 weeks postmenstrual age among infants enrolled in SUPPORT. We will evaluate and compare the capabilities of early and late cranial US and brain MRI to predict neuromotor and neurodevelopmental outcome at 18-22 months corrected age. We will also determine if ventilatory or oxygen saturation interventions are associated with differences in the outcomes of death or abnormal neuroimaging findings among patients enrolled in this secondary.

Of the 17 sites actively participating in SUPPORT, 15 are also enrolling in this secondary. Currently, more than 330 patients have been enrolled in this secondary, and more than 240 have completed neuroimaging including the near-term MRI. By the time that SUPPORT closes enrollment (expected March-June 2009), we expect that 350-400 patients will have complete neuroimaging. Therefore, this will be by far the largest study of specifically timed neuroimaging to predict neurodevelopmental outcome in preterm infants. Importantly, the only other large cohort focusing on neuroimaging and neurodevelopmental outcome included only 167 patients, of which just 95 were <28 weeks EGA (Woodward, NEJM 2006;355:685-694). The SUPPORT Neuroimaging cohort is unique among other cohorts, and the Network is therefore in an outstanding position to substantially contribute to the understanding of neonatal neuroimaging and prediction of long-term neurodevelopmental outcome. Dr. Hintz has recently submitted to the Steering Committee a proposal for 6-7 year follow-up of this important cohort of premature infants.

Dr. Hintz also completed a Masters in Epidemiology with the support of the MSCIDA mechanism, receiving her degree in April 2006.

Pages 38 through 40 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027880-19

PI Name:
Org:
Start Date:
Snap:
Appl ID:
Rec'd Date:

1

VAN MEURS, KRISA STANFORD UNIVERSITY 04/01/2009 N/A (NEEDS TO BE BOOKMARKED) 7612129 01/29/2009

Form Approved Through 11/30/2010	• · · · · · · · · · · · · · · · · · · ·			OMB No. 0925-0001		
Department of Health and Human Services	Review Group	Туре	Activity	Grant Number		
Public Health Services		5	U10	HD027880-19		
	Total Project Peri	od:				
Grant Progress Report		4/01/1991	Through:	03/31/2011		
Grant rogress Report	Requested Budge					
	From: 0	4/01/2009	Through:	03/31/2010		
1. TITLE OF PROJECT						
Multicenter Network of Neonatal Intensive Care						
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	2b. E-MAIL ADD	RESS				
(Name and address, street, city, state, zip code)	vanmeu	rs@stanfo	rd.edu			
Van Meurs, Krisa P	2c. DEPARTMEN	NT, SERVICE,	LABORATORY, O	REQUIVALENT		
Stanford University, School of Medicine	Pediatri					
Dept. of Pediatrics, 750 Welch Road, #315	2d. MAJOR SUB	DIVISION				
Stanford, CA 94305		of Medicine	2			
Staniold, OA 94505			•			
	2e. Tel: (650)	723-5711	Fax:	725-8351		
3a. APPLICANT ORGANIZATION	^{3b. Tel:} (650)	498-5591	Fax:	(650) 498-5876		
(Name and address, street, city, state, zip code)						
Stanford University	3c. DUNS: 0092	214214				
Research Management Group						
301 Ravenswood Ave., 2nd Floor	4. ENTITY IDEN					
-		41156365A				
Menlo Park, CA 94025-3434	1					
6. HUMAN SUBJECTS 🔲 No 🔀 Yes	5. TITLE AND A	DDRESS OF A	ADMINISTRATIVE	OFFICIAL JAN 2 9 LUUS		
6a. Research If Exempt ("Yes" in If Not Exempt ("No" in	Richard K					
Exempt 6a): 6a):		Process N				
X No Yes Exemption No. IRB approval date		Research Management Group 301 Ravenswood Ave., 2nd Floor				
6b. Federal Wide Assurance No.	4		-			
00000935	Menio Pai	rk, CA 940	25-3434			
6c. NIH-Defined Phase III	Tel: (650)	498-5591		Fax: (650) 498-5876		
Clinical Trial 🔀 No 📃 Yes	E-MAIL: richar	d smith@s	tanford edu			
7. VERTEBRATE ANIMALS X No Yes	10. PROJECT/PE					
	ſ		• •			
7a. If "Yes," IACUC approval Date	Organizational Na	inne.	Sta	nford University		
7b. Animal Welfare Assurance No. A3213-01	DUNS:			009214214		
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	Street 1:	Stanford	University, So	chool of Medicine		
8a. DIRECT \$ 246,418 8b. TOTAL \$ 351,745	Street 2:			Welch Road, #315		
9. INVENTIONS AND PATENTS XNo Yes	city: Stanford		County:	Santa Clara		
	State: Californi		Province:	Gaina Giara		
If "Yes," Previously Reported	Country: USA		Zip/Postal	Code: 94305		
Not Previously Reported	Congressional Dis		<u></u>	<u> </u>		
			14th			
11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICAN	ORGANIZATION	(Item 13)				
Richard K. Smith, Research Process Manag	er					
			—			
Tel: (650) 498-5591 FAX: (650) 4	498-3876	E-WA	" ^{L:} richard.sm	ith@stanford.edu		
12. Corrections to Page 1 Face Page						
13. APPLICANT ORGANIZATION CERTIFICATION AND ACCE			OF OFFICIAL NA	VED IN DATE		
that the statements herein are true, complete and accurate						
knowledge, and accept the obligation to comply with Publ terms and conditions if a grant is awarded as a result of thi				all 127/09		
aware that any false, fictitious, or fraudulent statements or o		11110	or h	nd 1/09		
me to criminal, civil, or administrative penalties.	· ·	[
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	-					

Pages 3 through 9 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle):	/a	aı
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Van Meu	s, Krisa P
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PROGRESS REPORT SUMMARY		GRANT NUMBER HD27880-19			
		PERIOD COVERED BY	THIS REPORT		
PROGRAM DIRECTOR / PRINCIPAL INVESTIC	GATOR	FROM	THROUGH		
Krisa P Van Meurs, MD		04/01/08	03/31/09		
APPLICANT ORGANIZATION Stanford University					
TITLE OF PROJECT (Repeat title shown in Item Cooperative Multicenter Network of Nec					
A. Human Subjects (Complete Item 6 on the Fac	e Page)		· · · · · · · · · · · · · · · · · · ·		
Involvement of Human Subjects	No Chi	ange Since Previous Submission	Change		
B. Vertebrate Animals (Complete Item 7 on the F	ace Page)				
Use of Vertebrate Animals	No Ch	ange Since Previous Submission	Change		
C. Select Agent Research	No Ch	ange Since Previous Submission	Change		
D. Multiple PD/PI Leadership Plan	No Ch	ange Since Previous Submission	Change		

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Specific Aims

The specific aim of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Cooperative Multicenter Network of Neonatal Intensive Care Units is to facilitate a consortium of academic tertiary health care centers in the rigorous evaluation of treatment and management strategies for neonates, particularly low birth weight infants. Through the efforts of the NICHD Neonatal Research Network, common protocols are used to evaluate these strategies in order to provide answers more rapidly, and consume fewer resources, by providing larger population bases than would be possible if individual centers acted alone. In addition, usage of the multicenter model tests potential therapies across an array of practice differences, a superior approach in the assessment of innovation.

Studies and Results

Not responsive. Not related to SUPPORT.

Pages 11 through 12 redacted for the following reasons: Not responsive. Not related to SUPPORT.

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H. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT employs a 2X2 factorial design to compare two approaches to early respiratory management and to compare two levels of oxygen saturation among infants born at 24 up to 28 weeks of gestation. The respiratory management arm of the trial is a randomized, unmasked controlled comparison of "standard" extremely low birth weight delivery room resuscitation including immediate intubation, early surfactant administration, and continued mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management guidelines are in place during the first 14 days after delivery and will allow comparison of the two approaches with the primary hypothesis that the CPAP approach will reduce the incidence of death and/or bronchopulmonary dysplasia at 36 weeks postmenstrual age. The oxygen saturation arm of SUPPORT will compare target a saturation range of 85-89% with a range of 91-95% utilized from shortly after delivery to 36 weeks postmenstrual age, or until the infant is off all respiratory support and in room air for 72 hours with saturations at or above the target range. The hypothesis is that maintaining infants at lower oxygen saturations from birth will result in an increase in survival without threshold retinopathy of prematurity (ROP) and/or the need for surgical intervention. This arm of the SUPPORT project is masked through the use of altered pulse oximeters.

There are four secondary studies associated with SUPPORT: antenatal screening and consent, neuroimaging and neurodevelopmental outcome, breathing outcomes, and postnatal growth. The antenatal screening and consent secondary is a cohort study designed to determine the resources required and challenges encountered in the process of obtaining informed antenatal consent and enrolling an eligible infant.

The breathing outcomes secondary is a longitudinal follow-up study of SUPPORT infants. The goal is to improve understanding of symptomatic airway dysfunction among surviving study subjects. The hypotheses are that infants randomized to the lower oxygen saturation range will have less symptomatic airway dysfunction and a reduced need for outpatient pulmonary care in the first two years and that infants randomized to CPAP in the respiratory arm of the main trial will have less symptomatic airway dysfunction and a reduced need for outpatient pulmonary care.

The postnatal growth secondary follows somatic growth during the subjects' hospitalization and at 18-22 month follow-up. The hypotheses are that infants in the lower oxygen saturation range will have better in-hospital and long-term growth and that trajectories of growth in-hospital will be better for infants in the low oxygen saturation group.

The neuroimaging and neurodevelopmental outcome secondary was developed by Dr Susan Hintz of Stanford University as her MSCIDA project. It is a prospective study of cranial ultrasound at 7-14 days of age ("early"), 35-42 weeks ("late") postmenstrual age and brain magnetic resonance imaging (MRI) at 35-42 weeks postmenstrual age among infants enrolled in SUPPORT. The study hypotheses are:

- multivariate modeling will demonstrate that conventional brain MRI at 35-42 weeks postmenstrual age will be superior to cranial ultrasound in predicting neurodevelopmental outcome at 18-22 months corrected age,
- there will be insufficient evidence to reject the null hypothesis that no differences exist in frequency of death/grade 3/4 intraventricular hemorrhage or death/periventricular leukomalacia on early or late cranial ultrasound between the two oxygen saturation groups, or between the two ventilation management groups,

 there will be insufficient evidence to reject the null hypothesis that the frequency of death/abnormal findings on conventional brain MRI at 35-42 weeks postmenstrual age are not different between the two oxygen saturation groups, or between the two ventilation management groups.

During 2008, the Steering Committee voted to fund Dr Hintz's proposal of 6-7 year neurodevelopmental followup to test the hypothesis that neonatal brain MRI will be superior to neonatal cranial ultrasound in predicting death after discharge or cognitive impairment and disability at 6-7 years. The project will also assess whether injury severity on neonatal MRI is associated with longitudinal cognitive and disability level changes. In addition, it will examine cognitive impairment and disability between ventilatory or oxygenation saturation SUPPORT intervention groups.

At Stanford, screening for SUPPORT began in April, 2005. Study-wide enrollment was suspended for several months beginning in November of 2005 at the request of the Data Safety and Monitoring Committee during which time a concern about the high oxygen saturations seen among infants receiving room air was resolved. Enrollment re-opened in mid-April 2006. Stanford has enrolled 55 patients, (49% of eligible) to date. The Stanford center is participating in all four secondary studies, neurodevelopmental follow-up at 18 months corrected age is underway, and preparations are being made to conduct extended follow-up at 6 years.

Pages 15 through 17 redacted for the following reasons: Not responsive. Not related to SUPPORT. H. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT compares two approaches to early respiratory management in an effort to reduce bronchopulmonary dysplasia (BPD) and two levels of oxygen saturation to reduce retinopathy of prematurity (ROP) among infants born at 24 up to 28 weeks of gestation. The use of continuous positive airway pressure (CPAP) or positive end expiratory pressure (PEEP) during delivery room resuscitation and continuing after admission to the NICU among ELBW infants has been advocated by some investigators for many years based on a number of primarily retrospective studies which suggest that early CPAP may be associated with improved outcomes including a decreased need for mechanical ventilation, a decreased need for surfactant therapy, and a decrease in oxygen supplementation and/or death at 28 days after delivery and at 36 weeks postmenstrual age. PEEP has been shown to help maintain functional residual capacity and CPAP was shown to improve oxygenation in very low birth weight neonates with respiratory distress several decades ago in the pre-surfactant era. Currently, there are no guidelines regarding the use of PEEP in the delivery room but studies have shown that preemies who do not achieve a functional residual capacity are more likely to develop hyaline membrane disease and require mechanical ventilation. Although studies conducted before the introduction of surfactant and antenatal steroids are difficult to assess in the current day, there is a consistent body of recent evidence that suggests that the use of CPAP can reduce the need for intubation, reduce the need for surfactant administration, improve lung mechanics, reduce lung injury, and improve the outcome of very low birth weight infants. There has not, however, been a randomized controlled comparison of what is for many the gold standard of ELBW delivery room resuscitation: intubation, early surfactant administration, and mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management arm of the SUPPORT project will address the primary hypothesis that the CPAP approach will reduce the incidence of death or BPD at 36 weeks postmenstrual age.

ROP has been recognized for 50 years as a morbidity associated with premature birth and oxygen toxicity. Although it has long been known that the incidence of ROP increases as oxygen exposure increases and gestational age decreases, the point at which oxygen exposure triggers the pathway of the disorder remains undetermined. The disease is currently thought to occur in two phases: an acute injury during which the retinal blood vessels are damaged and a second phase occurring several weeks later, when disorganized blood vessel growth occurs. There have been a few randomized trials of oxygen saturation management (higher versus lower) in the second phase, including the Supplemental Therapeutic Oxygen for Prethreshold ROP trial in the early 1990s, which have not provided definitive answers to the question of oxygen management among ELBW infants. There is however, evidence suggesting that many of the morbidities experienced by the ELBW population are the result of oxygen toxicity. Retrospective cohort studies suggest that the use of lower oxygen saturation ranges beginning at birth coupled with strict nursery policies may result in fewer cases of severe ROP. However, data on the actual oxygen saturations maintained are generally not available. In addition to ophthalmic outcome, the neurodevelopmental outcome of infants managed at lower oxygen saturations will be an important factor in any future recommendations surrounding the use of supplemental oxygen and oxygen saturations in preterm infants.

Not responsive. Not related to SUPPORT.

Page 19 redacted for the following reason: Not responsive. Not related to SUPPORT. Not responsive. Not related to SUPPORT.

Plans

During grant year 19. our plans are to:

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•	Complete enrollment in SUPPORT and the associated secondary studies;
	Continue 18 month neurodevelopmental follow-up of children enrolled in SUPPORT;
•	
•	Continue development and implementation of 6-year follow-up of children enrolled in the SUPPORT
	neuroimaging secondary study;
•	Not responsive. Not related to SUPPORT.
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Human Subjects

Current Institutional Review Board approval dates for protocols from the Cooperative Multicenter Network of Neonatal Intensive Care Units are listed in the table below.

Protocol Title Not responsive. Not related to SUPPORT.	Site	Protocol #	Approval Date	Expiration Date
				-
				-
				-
				-

Not responsive. Not related to SUPPORT.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	А	13756	12/17/2008	12/16/2009
Including the following secondary studies:				
Antenatal Screening and Consent in a Research Network Model				
Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT				
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network SUPPORT Study				
Breathing Outcomes				
Not responsive. Not related to SUPPORT.				

Inclusion enrollment report tables follow.

Pages 22 through 28 redacted for the following reasons: Not responsive. Not related to SUPPORT. Program Director/Principal Investigator (Last, First, Middle): Van Meurs, Krisa P

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth

Study Title:	Weight Infants
Total Enrollment:	55

Protocol Number: H

Grant Number:

HD27880-19

PART A. TOTAL ENROLLMENT REPORT: Numb by Eth	er of Subjects E inicity and Race		ate (Cumulative)		
Sex/Gender						
Ethnic Category	Females	Males	Unknown or Not Reported	Total		
Hispanic or Latino	12	16	0	28 **		
Not Hispanic or Latino	13	14	0	27		
Unknown (individuals not reporting ethnicity)	0	0	0	0		
Ethnic Category: Total of All Subjects*	25	30	0	55 *		
Racial Categories						
American Indian/Alaska Native	0	0	0	0		
Asian	2	4	0	6		
Native Hawaiian or Other Pacific Islander	0	1	0	1		
Black or African American	0	1	0	1		
White	23	24	0	47		
More Than One Race	0	0	0	0		
Unknown or Not Reported	0	0	0	0		
Racial Categories: Total of All Subjects*	25	30	0	55 *		
PART B. HISPANIC ENROLLMENT REPORT: Nu	mber of Hispani	cs or Latinos		te (Cumulative)		
Racial Categories	Females	Males	Unknown or Not Reported	Total		
American Indian or Alaska Native	0	0	0	0		
Asian	0	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0	0		
Black or African American	0	0	0	0		
White	12	16	0	28		
More Than One Race	0	0	0	0		
Unknown or Not Reported	0	0	0	0		

Racial Categories: Total of Hispanics or Latinos**

* These totals must agree. ** These totals must agree.

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Pages 30 through 42 redacted for the following reasons: Not responsive. Not related to SUPPORT.

5U10HD027880-20

PI Name:	VAN MEURS, KRISA
Org:	STANFORD UNIVERSITY
Start Date:	04/01/2010
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	7800310
Rec'd Date:	01/29/2010

Form Approved Through 06/30/2012				OMB No. 0925-000
Department of Health and Human Services	Review Group	Туре	Activity	Grant Number
Public Health Services		5	U10	5 U10 HD027880 20
	Total Project Pe			
Grant Progress Report	From:	04/01/91	Through:	03/31/10
Grant i rogi oco noport	Requested Budg			00/04/44
	From:	04/01/10	Through:	03/31/11
1. TITLE OF PROJECT				
NICHD Cooperative Multicenter Network of Ne	2b. E-MAIL ADI			
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	4			
(Name and address, street, city, state, zip code)		rs@stanfor		
Van Meurs, Krisa P.			, LABORATORY, (OR EQUIVALENT
Stanford University, School of Medicine	Pediatr	ics		
Department of Pediatrics	2d. MAJOR SU			
750 Welch Road Suite 315	School	of Medicin	е	
Stanford, CA 94305	2e. Tel: (650)	723-5711	Fax	(650) 725-8351
3a. APPLICANT ORGANIZATION	^{3b. Tel:} (650)	498-4103	β Γαχ.	(650) 498-5876
(Name and address, street, city, state, zip code)	20 DUNE: 00			
Stanford University	3c. DUNS: 009	9214214		
Research Management Group				·
301 Ravenswood Ave., 2nd Floor	4. ENTITY IDE		NUMBER	<u>ور .</u>
Menlo Park, CA 94025-3434	94-11563	365		
6. HUMAN SUBJECTS X No Yes	5. TITLE AND	ADDRESS OF	ADMINISTRATIVE	
6a. Research If Exempt ("Yes" in If Not Exempt ("No" in				6
Exempt 6a): 6a):		n Process I		2010
No X Yes Exemption No. IRB approval date			nent Group	oi lio
6b. Federal Wide Assurance No.	-		ve., 2nd Floor	
	Menio Pa	ark, CA 94	025-3434	
6c. NIH-Defined Phase III	Tel: (650) 498-4103	3	Fax: (650) 498-5870
Clinical Trial 🛛 No 📃 Yes	E-MAIL: karen	.fisher@sta	nford.edu	
7. VERTEBRATE ANIMALS X No Yes	10. PROJECT/F	PERFORMANC	E SITE(S)	
7a. If "Yes," IACUC approval Date	Organizational N			wfaud I Inius units
	-		Sta	nford University
7b. Animal Welfare Assurance No. A3213-01	DUNS: 00921	4214		
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	Street 1:	Stanford	University, So	chool of Medicine
Ba. DIRECT \$ 271,102 8b. TOTAL \$ 422,919	Street 2:	D	epartment of	Pediatrics
9. INVENTIONS AND PATENTS X No Yes	City: Stanfor		County:	Santa Clara
If "Yes," Previously Reported	State: CA		Province:	
	Country:		Zip/Posta	Code: 94305
Not Previously Reported				
Not Previously Reported	Congressional D	istricts:	14th	
			14th	
11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICA			14th	
			14th	
11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICAN Karen Fisher, Research Process Manager	NT ORGANIZATIO	0N (Item 13)		er@stanford.edu
11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICA Karen Fisher, Research Process Manager Tel: (650) 498-4103 FAX: (650)	NT ORGANIZATIO	0N (Item 13)		er@stanford.edu_
11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICA Karen Fisher, Research Process Manager Tel: (650) 498-4103 FAX: (650)	NT ORGANIZATIO	0N (Item 13)		er@stanford.edu_
 NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICAL Karen Fisher, Research Process Manager Tel: (650) 498-4103 FAX: (650) Corrections to Page 1 Face Page APPLICANT ORGANIZATION CERTIFICATION AND ACC 	498-5876	N (Item 13) E-M/	AIL: <u>Karen.Fishe</u> OF OFFICIAL NA	
 NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICATION AND ACC that the statements herein are true, complete and accurate 	498-5876 EPTANCE: I certite to the best of m	N (Item 13) E-M/ SIGNATURE y IN 11. (In ink	AIL: <u>Karen.Fishe</u> OF OFFICIAL NA	MED DATE
 NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICAT Karen Fisher, Research Process Manager Tel: (650) 498-4103 FAX: (650) Corrections to Page 1 Face Page APPLICANT ORGANIZATION CERTIFICATION AND ACC that the statements herein are true, complete and accurate knowledge, and accept the obligation to comply with Pub 	498-5876 EPTANCE: I certi e to the best of m lic Health Service	N (Item 13) E-M, SIGNATURE VIN 11. (In ink	AIL: <u>Karen.Fishe</u> OF OFFICIAL NA	MED DATE
 NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICAT Karen Fisher, Research Process Manager Tel: (650) 498-4103 FAX: (650) Corrections to Page 1 Face Page APPLICANT ORGANIZATION CERTIFICATION AND ACC that the statements herein are true, complete and accurate 	498-5876 EPTANCE: I certile to the best of m lic Health Service his application. I an	y SIGNATURE y IN 11. (In ink	AIL: <u>Karen.Fishe</u> OF OFFICIAL NA	MED DATE
 NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICAL Karen Fisher, Research Process Manager Tel: (650) 498-4103 FAX: (650) Corrections to Page 1 Face Page APPLICANT ORGANIZATION CERTIFICATION AND ACC that the statements herein are true, complete and accurate knowledge, and accept the obligation to comply with Pub terms and conditions if a grant is awarded as a result of th 	498-5876 EPTANCE: I certile to the best of m lic Health Service his application. I an	y SIGNATURE y IN 11. (In ink	AIL: <u>Karen.Fishe</u> OF OFFICIAL NA	MED DATE
 NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICAL Karen Fisher, Research Process Manager Tel: (650) 498-4103 FAX: (650) Corrections to Page 1 Face Page APPLICANT ORGANIZATION CERTIFICATION AND ACC that the statements herein are true, complete and accurate knowledge, and accept the obligation to comply with Pub terms and conditions if a grant is awarded as a result of th aware that any false, fictitious, or fraudulent statements or 	498-5876 EPTANCE: I certile to the best of m lic Health Service his application. I an	y SIGNATURE y IN 11. (In ink	AIL: <u>Karen.Fishe</u> OF OFFICIAL NA	MED DATE

Pages 3 through 8 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle):	Van Meurs, Krisa P	
		GRANT NUMBER	
PROGRESS REPORT SUM	MARY	HD27880-20	
		PERIOD COVERED BY TH	IS REPORT
PROGRAM DIRECTOR / PRINCIPAL INVEST	IGATOR	FROM	THROUGH
Krisa P Van Meurs, MD		04/01/09	03/31/10
Cooperative Multicenter Network of Network		e Care Units	· · · · · · · · · · · · · · · · · · ·
A. Human Subjects (Complete Item 6 on the Face	5		_
Involvement of Human Subjects	No Change	e Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the Fa	ace Page)		
Use of Vertebrate Animals	No Change	e Since Previous Submission	Change
C. Select Agent Research	No Change	e Since Previous Submission	Change
D. Multiple PD/PI Leadership Plan	No Change	e Since Previous Submission	Change
E. Human Embryonic Stem Cell Line(s) Used	No Change	e Since Previous Submission	Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Specific Aims

The specific aim of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Cooperative Multicenter Network of Neonatal Intensive Care Units is to facilitate a consortium of academic tertiary health care centers in the rigorous evaluation of treatment and management strategies for neonates, particularly low birth weight infants. Through the efforts of the NICHD Neonatal Research Network, common protocols are used to evaluate these strategies in order to provide answers more rapidly, and consume fewer resources, by providing larger population bases than would be possible if individual centers acted alone. In addition, usage of the multicenter model tests potential therapies across an array of practice differences, a superior approach in the assessment of innovation.

Studies and Results

Not responsive. Not related to SUPPORT.

Page 10 redacted for the following reason: Not responsive. Not related to SUPPORT. Not responsive. Not related to SUPPORT.

The oxygen saturation arm of SUPPORT compared target saturation ranges of 85-89% and 91-95% utilized from shortly after delivery to 36 weeks postmenstrual age, or until the infant was off all respiratory support and

G. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT employed a 2X2 factorial design to compare two approaches to early respiratory management and to compare two levels of oxygen saturation among infants born at 24 up to 28 weeks of gestation. The respiratory management arm of the trial was a randomized, unmasked controlled comparison of "standard" extremely low birth weight delivery room resuscitation including immediate intubation, early surfactant administration, and continued mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management guidelines were in place during the first 14 days after delivery to allow comparison of the two approaches with the primary hypothesis that the CPAP approach would reduce the incidence of death and/or bronchopulmonary dysplasia at 36 weeks postmenstrual age. The primary outcomes were non-significantly reduced in the CPAP group when adjusted for gestational age, center and familial clustering. More infants were alive and off mechanical ventilation by day 7 and fewer required intubation or postnatal steroids for BPD.

in room air for 72 hours with saturations at or above the target range. The hypothesis was that maintaining infants at lower oxygen saturations from birth would result in an increase in survival without threshold retinopathy of prematurity (ROP) and/or the need for surgical intervention. This arm of the SUPPORT project was masked through the use of altered pulse oximeters. Lower oxygen saturation targeting did not significantly decrease the combined outcome of severe retinopathy or death but did result in a decrease in severe retinopathy among survivors. Interestingly, the lower saturation also resulted in increased mortality.

There are four secondary studies associated with SUPPORT: antenatal screening and consent, neuroimaging and neurodevelopmental outcome, breathing outcomes, and postnatal growth. The antenatal screening and consent secondary is a cohort study designed to determine the resources required and challenges encountered in the process of obtaining informed antenatal consent and enrolling an eligible infant.

The breathing outcomes secondary is a longitudinal follow-up study of SUPPORT infants. The goal is to improve understanding of symptomatic airway dysfunction among surviving study subjects. The hypotheses are that infants randomized to the lower oxygen saturation range will have less symptomatic airway dysfunction and a reduced need for outpatient pulmonary care in the first two years and that infants randomized to CPAP in the respiratory arm of the main trial will have less symptomatic airway dysfunction and a reduced need for outpatient pulmonary care.

The postnatal growth secondary follows somatic growth during the subjects' hospitalization and at 18-22 month follow-up. The hypotheses are that infants in the lower oxygen saturation range will have better in-hospital and long-term growth and that trajectories of growth in-hospital will be better for infants in the low oxygen saturation group.

The neuroimaging and neurodevelopmental outcome secondary was developed by Dr Susan Hintz of Stanford University as her MSCIDA project. It is a prospective study of cranial ultrasound at 7-14 days of age ("early"), 35-42 weeks ("late") postmenstrual age and brain magnetic resonance imaging (MRI) at 35-42 weeks postmenstrual age among infants enrolled in SUPPORT. The study hypotheses are:

- Multivariate modeling will demonstrate that conventional brain MRI at 35-42 weeks postmenstrual age will be superior to cranial ultrasound in predicting neurodevelopmental outcome at 18-22 months corrected age,
- There will be insufficient evidence to reject the null hypothesis that no differences exist in frequency of death/grade 3/4 intraventricular hemorrhage or death/periventricular leukomalacia on early or late cranial ultrasound between the two oxygen saturation groups, or between the two ventilation management groups,
- There will be insufficient evidence to reject the null hypothesis that the frequency of death/abnormal findings on conventional brain MRI at 35-42 weeks postmenstrual age are not different between the two oxygen saturation groups, or between the two ventilation management groups.

During 2008, the Steering Committee voted to fund Dr Hintz's proposal of 6-7 year neurodevelopmental followup to test the hypothesis that neonatal brain MRI will be superior to neonatal cranial ultrasound in predicting death after discharge or cognitive impairment and disability at 6-7 years. The project will also assess whether injury severity on neonatal MRI is associated with longitudinal cognitive and disability level changes. In addition, it will examine cognitive impairment and disability between ventilatory or oxygenation saturation SUPPORT intervention groups.

At Stanford, screening for SUPPORT began in April, 2005. Study-wide enrollment was suspended for several months beginning in November of 2005 at the request of the Data Safety and Monitoring Committee during which time a concern about the high oxygen saturations seen among infants receiving room air was resolved. Enrollment re-opened in mid-April 2006 and closed in February 2009. Stanford enrolled 56 patients, (45% of eligible). The Stanford center is participating in all four secondary studies, neurodevelopmental follow-up at 18 months corrected age is underway, and preparations are being made to conduct extended follow-up at 6 years, including maintaining family contact. Two manuscripts describing the primary outcomes of the respiratory management and oximetry targets have been submitted to the New England Journal of Medicine.

Pages 13 through 16 redacted for the following reasons: Not responsive. Not related to SUPPORT. G. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT compares two approaches to early respiratory management in an effort to reduce bronchopulmonary dysplasia (BPD) and two levels of oxygen saturation to reduce retinopathy of prematurity (ROP) among infants born at 24 up to 28 weeks of gestation. The use of continuous positive airway pressure (CPAP) or positive end expiratory pressure (PEEP) during delivery room resuscitation and continuing after admission to the NICU among ELBW infants has been advocated by some investigators for many years based on a number of primarily retrospective studies which suggest that early CPAP may be associated with improved outcomes including a decreased need for mechanical ventilation, a decreased need for surfactant therapy, and a decrease in oxygen supplementation and/or death at 28 days after delivery and at 36 weeks postmenstrual age. PEEP has been shown to help maintain functional residual capacity and CPAP was shown to improve oxygenation in very low birth weight neonates with respiratory distress several decades ago in the pre-surfactant era. Currently, there are no guidelines regarding the use of PEEP in the delivery room but studies have shown that preemies who do not achieve a functional residual capacity are more likely to develop hyaline membrane disease and require mechanical ventilation. Although studies conducted before the introduction of surfactant and antenatal steroids are difficult to assess in the current day, there is a consistent body of recent evidence that suggests that the use of CPAP can reduce the need for intubation, reduce the need for surfactant administration, improve lung mechanics, reduce lung injury, and improve the outcome of very low birth weight infants. There has not, however, been a randomized controlled comparison of what is for many the gold standard of ELBW delivery room resuscitation: intubation, early surfactant administration, and mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management arm of the SUPPORT project addressed the primary hypothesis that the CPAP approach will reduce the incidence of death or BPD at 36 weeks postmenstrual age.

ROP has been recognized for 50 years as a morbidity associated with premature birth and oxygen toxicity. Although it has long been known that the incidence of ROP increases as oxygen exposure increases and gestational age decreases, the point at which oxygen exposure triggers the pathway of the disorder remains undetermined. The disease is currently thought to occur in two phases: an acute injury during which the retinal blood vessels are damaged and a second phase occurring several weeks later, when disorganized blood vessel growth occurs. There have been a few randomized trials of oxygen saturation management (higher versus lower) in the second phase, including the Supplemental Therapeutic Oxygen for Prethreshold ROP trial in the early 1990s, which have not provided definitive answers to the question of oxygen management among ELBW infants. There is however, evidence suggesting that many of the morbidities experienced by the ELBW population are the result of oxygen toxicity. Retrospective cohort studies suggest that the use of lower oxygen saturation ranges beginning at birth coupled with strict nursery policies may result in fewer cases of severe ROP. However, data on the actual oxygen saturations maintained are generally not available. In addition to ophthalmic outcome, the neurodevelopmental outcome of infants managed at lower oxygen saturations will be an important factor in any future recommendations surrounding the use of supplemental oxygen and oxygen saturations in preterm infants.

Not responsive. Not related to SUPPORT.

Pages 18 through 19 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Plans

During grant year 20, our plans are to:

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٠	Continue 18 month neurodevelopmental follow-up of children enrolled in SUPPORT;
•	Continue development and implementation of 6-year follow-up of children enrolled in the SUPPORT
	neuroimaging secondary study; Not responsive. Not related to SUPPORT.
•	Not responsive. Not related to SUPPORT.
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Human Subjects

Current Institutional Review Board approval dates for protocols from the Cooperative Multicenter Network of Neonatal Intensive Care Units are listed in the table below.

Protocol Title	Site	Protocol #	Approval Date	Expiration Date
Not responsive. Not related to SUPPORT.				
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	А	13756	10/27/2009	10/26/2010
Including the following secondary studies:				
Antenatal Screening and Consent in a Research Network Model				
Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT				
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network SUPPORT Study				
Breathing Outcomes Not responsive. Not related to SUPPORT.				
Not responsive. Not related to SUPPORT.				

Pages 22 through 28 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Surfactant Positive Airway Pressure Weight Infants	and Pulse Oximetry Trial in Extremely Low Birth
Total Enrollment:	56	Protocol Number: G

Grant Number: HD27880-20

Ethnic Category

PART A. TOTAL ENROLLMENT REPORT:	RT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race			
		Sex/Gender Unknown or		

Females

Males

40

Not Reported

Total

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**

Hispanic or Latino	12	16	0	28	**
Not Hispanic or Latino	13	15	0	28	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	25	31	0	56	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	2	4	0	6	
Native Hawaiian or Other Pacific Islander	0	1	0	1	
Black or African American	0	2	0	2	
White	23	24	0	47	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	25	31	0	56	*
		State 1			*******

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	12	16	0	28
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	12	16	0	28 **

* These totals must agree. ** These totals must agree.

Pages 30 through 47 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

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5U10HD027904-15

PI Name:OH, WILLIAMOrg:WOMEN AND INFANTS HOSPITAL-RHODE
ISLANDStart Date:04/01/2005Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:6895900Rec'd
Date:02/02/2005

Form Approved Through 09/30/2007	OMB No. 0925-000
Department of Health and Human Services Public Health Services	Review Group Type Activity Grant Number ZHD1 MCHG- 5 U10 HD27904-15 B(10)
	Total Project Period
Cront Brogroop Bonart	From: 04/01/1991 Through: 03/31/2006
Grant Progress Report	Requested Budget Period
	From: 04/01/2005 Through: 03/31/2006
1. TITLE OF PROJECT	
Multicenter Network Neonatal Intensive Care	•
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	3. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code) William Oh, M.D.	(Name and address, street, city, state, zip code)
Women & Infants Hospital of Rhode Island	101 Dudley Street
Depart of Pediatrics/Infant Development Center	Providence, RI 02905
101 Dudley Street	
Providence, RI 02905	
2b. E-MAIL ADDRESS WOh@wihri.org	4. ENTITY IDENTIFICATION NUMBER 1050258937A1
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT	
Neonatal-Perinatal Medicine	Vice President of Finance
2d. MAJOR SUBDIVISION	Women and Infants Hospital of Rhode Island
30 Hospital	101 Dudley Street
	Providence, RI 02905
	E-MAIL: JSutherl@wihri.org
6. HUMAN SUBJECTS	7. VERTEBRATE ANIMALS
No 6a. Research Exempt 6b. Human Subjects Assurance	e No. 7a. If "Yes," IACUC approval Date
Ves No Ves FWA00000056	Yes
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III	7b. Animal Welfare Assurance No.
Exemption No.	-
If Not Exempt ("No" in 6a):	
IRB approval date	ew
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVENTIONS AND PATENTS
8a. DIRECT \$176,687 8b. TOTAL \$246,125	🛛 No 🗌 Yes If "Yes," 🗌 Previously Reported
	Not Previously Reported
10. PERFORMANCE SITE(S) (Organizations and addresses)	11a. PRINCIPAL INVESTIGATOR TEL (401) 274-1122, x1432
Women & Infants Hospital of Rhode Island	OR PROGRAM DIRECTOR (Item 2a) William Oh, M.D. FAX (401) 453-7571
101 Dudley Street Providence, RI 02905-2499	11b. ADMINISTRATIVE OFFICIAL TEL (401) 274-1122, x2140
1 10VIdence, 11 02000-2400	NAME (Item 5)
	John M. Sutherland, III FAX (401) 453-7531
	11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT
	ORGANIZATION <i>(Item 14)</i> NAME Patrice M. DiMario
	TITLE Senior Vice President for Patient Support Services
	E-MAIL PDiMario@wihri.org
12. Corrections to Page 1 Face Page	

~

 PRINCIPAL INVESTIGATOR/PROGRAM DIRE statements herein are true, complete and accurate to the 	· · · · · · · · · · · · · · · · · · ·	SIGNATURE OF PI/PD NAMED IN 2a.	DATE
any false, fictitious, or fraudulent statements or claims administrative penalties. I agree to accept responsibili and to provide the required progress reports if a grant	may subject me to criminal, civil, or ity for the scientific conduct of the project		12/17/0
 APPLICANT ORGANIZATION CERTIFICATION statements herein are true, complete and accurate to to obligation to comply with Public Health Services terms 	the best of my knowledge, and accept the and conditions if a grant is awarded as a	11 e. (In ink. "Per" signature not acceptable.)	
result of this application. I am aware that any false, fic may subject me to criminal, civil, or administrative pen PHS 2590 (Rev. 09/04)		Jatuice M. Allam	12/21/04 Form Page 1

Pages 3 through 13 redacted for the following reasons: Not responsive

Principal Investigator/Program Director (Last, First, Middle):	Oh, William			
PROGRESS REPORT SUMMARY	GRANT NUMBER HD27904-15			
	PERIOD COVERED BY	THIS REPORT		
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH		
William Oh, M.D.	04/01/2004	03/31/2005		
APPLICANT ORGANIZATION Women & Infants Hospital of Rhode Island TITLE OF PROJECT (Repeat title shown in Item 1 on first page) Multicenter Network of Neonatal Intensive Care Units				
A. Human Subjects (Complete Item 6 on the Face Page)				
Involvement of Human Subjects No Change	Since Previous Submission	Change		
B. Vertebrate Animals (Complete Item 7 on the Face Page)				
Use of Vertebrate Animals No Change	Since Previous Submission	Change		
SEE PHS 2590 INSTRUCTIONS.				

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Specific Aims



Studies and Results

1.	Not responsive
2.	
3.	

5.

4.

Not responsive

7.

6.

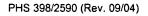
Plans

During the forthcoming year, we will continue our participation with the Network by performing the following tasks:



3.	Not responsive
4	We will participate in the SUPPORT Trial and are projecting a start date in early February 2005.
5.	Not responsive
6.	
7.	

Publications (Publications by our Maternal Lifestyle Study are listed separately)



Not responsive

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Pages 17 through 18 redacted for the following reasons: Not responsive

PATIENT ENROLLMENT NUMBERS FOR CALENDAR YEAR 2004

Study Protocol	Number of Patients Enrolled	Date of IRB review	Date IRB approved through
Not responsive	a (na nanana tatan a tatan ang ang ang ang ang ang ang ang ang a		
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	0 – enrollment to begin 2/2005	12/29/2004	11/29/2005

Pages 20 through 44 redacted for the following reasons: Not responsive **Progress Report Scanning Cover Sheet**

5U10HD027904-17

PI Name:LAPTOOK, ABBOTOrg:WOMEN AND INFANTS HOSPITAL-RHODE
ISLANDStart Date:04/01/2007Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7219968Rec'd
Date:01/31/2007

Tom Approved Through 03/30/20							ONB	140. 0923-0001
 2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code) Laptook, Abbot R. 101 Dudely Street Providence, RI 02905-2499 2b. E-MAIL ADDRESS alaptook@wihri.org 				Type 5	Activity U10	_		4-17
		Total Proje	ect Period		1			
Department of Health and Human Services Public Health Services Review Group ZHD1DSRA10 Type ZHD1DSRA10 Activ ZHD1DSRA10 Grant Progress Report Total Project Period From: 04/01/1991 Total Project Period From: 04/01/1991 1. TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Research Network 3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code) Laptook, Abbot R. 3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code) 1. Dudely Street Providence, RI 02905-2499 4. ENTITY IDENTIFICATION NUMB 1050258937A1 2b. E-MAIL ADDRESS alaptook@wihni.org 4. ENTITY IDENTIFICATION NUMB 1050258937A1 2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT 5. TITLE AND ADDRESS OF ADMIT Debra M. Paul 101 Dudley Street Providence, RI 02905 2d. MAJOR SUBDIVISION FWA00000056 6. HUMAN SUBJECTS FWA00000056 7. VERTEBRATE ANIMALS 7. No 6a. Research Exempti Bb. Human Subjects Assurance No. Cinical Trial No 7. No 6a. Research Exempti Bb. TOTAL S247,604 9. INVENTIONS AND PATENTS 8. DIRECT S177,749 8b. TOTAL S247,604 11. PRINCIPAL INVESTIGATOR NEW PROGRAM DIRECTOR (Item 2a) Abbot R. Laptook 110. Dudley Street Providence, RI 02905-2499 9. INVENTIONS AND PATENTS Abbot R. Laptook 11. PRINCIPAL INVESTIGATOR New Program Dintector (Item 2a) Abbot R. Laptook <td>T</td> <td>hrough</td> <td>: 03/31/2011</td> <td></td>	T	hrough	: 03/31/2011					
Grant Prog	ress Report	Requested	d Budget I	Period				
		From: 04	/01/200	7	TI	hrouah	03/31/2008	
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1. TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal 2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOF (Name and address, street, city, state, zip code) Laptook, Abbot R. 101 Dudely Street Providence, RI 02905-2499 2b. E-MAIL ADDRESS alaptook@wihri.org 2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVA 2d. MAJOR SUBDIVISION 6. HUMAN SUBJECTS No Yes No Ga. Research Exempt Yes No Yes FWA00000056 If Exempt ("Yes" in 6a): Exemption No. If Not Exempt ("No" in 6a): IRB approval date B. COSTS REQUESTED FOR NEXT BUDGET PERIOD Ba. DIRECT \$177,749 Bb. TOTAL \$247,604 10. PERFORMANCE SITE(S) (Organizations and addresses, Women & Infants Hospital of Rhode Island 101 Dudley Street	y, state, zip code)							
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	-2499)5-2499			
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2c. DEPARTMENT, SERVICE, LA	BORATORY, OR EQUIVALENT				ADMINIST	RATIV	E OFFICIAL	
	and Human Services Review Group ZHD1DSRA10 Typ ZHD1DSRA10 ress Report Total Project Period From: 04/01/1991 Requested Budget Perioc PROGRAM DIRECTOR y, state, zip code) 3. APPLICANT ORGANIZ (Name and address, str Women and Infar 101 Dudley Stree Providence, RI C -2499 4. ENTITY IDENTIFICAT 1050258937A1 BORATORY, OR EQUIVALENT 5. TITLE AND ADDRESS Debra M. Paul 101 Dudley Stree Providence, RI C BORATORY, OR EQUIVALENT 5. TITLE AND ADDRESS Debra M. Paul 101 Dudley Stree Providence, RI C 6b. Human Subjects Assurance No. FWA00000056 No 6c. NIH-Defined Phase III Clinical Trial No Clinical Trial No Sanizations and addresses) 9. INVENTIONS AND PA' (Sanizations and addresses) pital of Rhode Island 11a. PRINCIPAL INVEST OR PROGRAM DIRECTO Abbot R. Laptook 4.2499 11b. ADMINISTRATIVE O NAME (Item 5) Debra M. Paul							
20. MAJOR SUBDIVISION			-)5			
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		E-MAIL:	dpaul@	wihri.ora				
6 HUMAN SUBJECTS				_				
6a Research Exempt	6b. Human Subjects Assurance			,		7a lf	"Yes " IACUC, an	proval Date
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If Exempt ("Yes" in 6a):	6c. NIH-Defined Phase III	7b. An	imal Welf	are Assura	ince No.			
Exemption No.	Clinical Trial 🗌 No 🗌 Ye							
	Full IRB <u>or</u>							
IRB approval date	Expedited Review							
8. COSTS REQUESTED FOR N	EXT BUDGET PERIOD	. INVENT	IONS AN	D PATENT	S		JAA.	
8a. DIRECT \$ 177,749	85. TOTAL \$ 247,604	No [Yes	lf "Yes,"	Pre ⁻	viously	Reported	
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	pital of Rhode Island			•	· ·	x 4	401 453 7571	
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		Ervices ZHD1DSRA10 5 U10 5 U10 HD027904-17 Total Project Period Through: 03/31/2011 Requested Budget Period Through: 03/31/2011 Requested Budget Period From: 04/01/1991 Through: 03/31/2008 center Neonatal Research Network Proor: 04/01/2007 Through: 03/31/2008 Center Neonatal Research Network Proor: 04/01/2007 Through: 03/31/2008 Center Neonatal Research Network Providence, RI 02905-2499 Providence, RI 02905-2499 4. ENTITY IDENTIFICATION NUMBER 1050258937A1 Doc/258937A1 RATORY, OR EQUIVALENT THTLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL Debra M. Paul Debra M. Paul 101 Dudley Street Providence, RI 02905 Providence, RI 02905 Human Subjects Assurance No. Mo 7a. If "Yes," IACUC approval Date VA00000056 No Ta. If "Yes," IACUC approval Date WA00000056 No Yes No Yes Not Previously Reported No Yes Not Previously Reported No Yes Not Previously Reported Ital Trial No Yes						
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		TEL 4	01 274	1122 x 1	290	FAX	401 453 766	6
		E-MAIL P	odimario	o@wihri	.org	I		

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTA statements herein are true, complete and accurate to the best of my know obligation to comply with Public Health Services terms and conditions if a result of this application. I am aware that any false, fictitious, or fraudulen may subject me to criminal, civil, or administrative penalties.	ledge, and accept the grant is awarded as a	TIC. (In ink.		DATE 1/26/07
PHS 2590 (Rev. 04/06)	Face Page		•	Form/Page 1

Pages 3 through 17 redacted for the following reasons: Not responsive

PROGRESS REPORT SUM	IMARY	
PRINCIPAL INVESTIGATOR OR PROGRAM Laptook, Abbot R.	IDIRECTOR	
APPLICANT ORGANIZATION Women and Infants Hospital of Rhod	e Island	
TITLE OF PROJECT (Repeat title shown in It NICHD Cooperative Multicenter Neor	,	
A. Human Subjects (Complete Item 6 on the F	ace Page)	
Involvement of Human Subjects	No Chang	e Since Previous Submission
B. Vertebrate Animals (Complete Item 7 on th	e Face Page)	
Use of Vertebrate Animals	No Chang	e Since Previous Submission
C. Select Agent Research	No Chang	e Since Previous Submission
D. Multiple PI Leadership Plan	No Chang	e Since Previous Submission

Neonatal Research Network Progress Report for 2006-Brown University

The following summarizes activities of the Brown site and its investigators during 2006.

Support Trial

Specific Aims: 1) To determine if CPAP and/or a permissive ventilation begun in the delivery room and continued during the first 14 days of life improves survival without BPD compared to intubation, early surfactant and mechanical ventilation among infants born between 24-28 weeks gestation.

2) To determine if a lower oxygen saturation range (85-89%) improves the survival free of threshold ROP and/or need for surgical intervention compared to a higher oxygen saturation range (91-95%) for infants in oxygen or requiring pulmonary support among infants born between 24-28 weeks gestation.

Studies and results: This clinical trial has been extremely challenging due to antenatal consent, initiation of the study in the delivery room, and continuation of interventions for prolonged intervals in the NICU. Screening and the consent process is conducted 7 days a week by our Research Nurses and is labor intensive. The following summarizes the experience at Brown obtaining consents during 2006.

- Number of mothers screened: 145
- Number of mothers approached for consent: 117
- Reasons for not approaching for consent: short interval to delivery-11, personnel not available-11, anomalies-3, and other-3
- Consent obtained: 84
- Enrolled: 26

Once infants are enrolled, a communication algorithm insures that providers (fellows, respiratory therapists, nurses) at the delivery of consented mothers know to randomize the infant. The communication algorithm addresses movement of patients from Labor and Delivery to the Ante-partum floors, from the Ante-partum floors to home, and readmission to Labor and Delivery. Protocol violations have occurred in 3 areas of this study. These include use of high flow canulas in the first 14 days of the CPAP arm, use of steroids for ventilator dependence in the first 21 days, and use of non-study pulse oximeters for infants that require resumption of study pulse oximeters prior to 36 weeks gestation. Each of these protocol violations has been addressed with the appropriate NICU personnel to prevent recurrences.

Support Secondary – Neuroimaging and Neurodevelopment

Specific Aim: To determine if brain MRI performed at 35-42 weeks post-menstrual age is superior to cranial ultrasonography in predicting neurodevelopmental outcome at 18-22 months corrected age.

Studies performed: During 2006 10 of the 26 infants enrolled in Support have been consented. Imaging studies have been completed in 9 infants. Four of the 9 studies required sedation for acquisition of MRI images.

Support Secondary - Breathing Outcomes

Principal Investigator/Program Director (Last, First, Middle): Laptook, Abbot R.

Specific Aim: To determine the extent of symptomatic airway dysfunction and need for outpatient pulmonary care comparing Support infants with high vs low oxygen saturation and comparing CPAP vs conventional ventilation arm.

Studies performed: All Support infants have been enrolled in the Breathing outcomes study. During 2006 discharge baseline interviews were done in 17 patients and 6 month interviews were done on 2 patients.

Support Secondary – Antenatal screening and consent

Specific Aim: To determine factors that contribute to obtaining antenatal consents for neonatal studies. *Studies performed*: Of the mothers screened for Support (n=145), 117 were approached and 84 consents were obtained to gather information for this study.

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Plan for 04/01/07 - 03/31/08

1. Continue enrollment into the Support Trial and secondary studies

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Manuscripts Published or In Press Involving Brown Investigators:

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Pages 21 through 23 redacted for the following reasons: Not responsive Principal Investigator/Program Director (Last, First, Middle): Laptook, Abbot R.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants	
Total Enrollment:	26	Protocol Number: 04-0108
Grant Number:	5 U10 HD027904-17	

Ethnic Category		Sex/Gender					
	Females	Males	Unknown or Not Reported	Total			
Hispanic or Latino	0	6		6	**		
Not Hispanic or Latino	9	11		20			
Unknown (individuals not reporting ethnicity)							
Ethnic Category: Total of All Subjects*	9	17		26	*		
Racial Categories							
American Indian/Alaska Native							
Asian	1	1		2			
Native Hawaiian or Other Pacific Islander							
Black or African American	3	2		5			
White	5	14		19			
More Than One Race							
Unknown or Not Reported							
Racial Categories: Total of All Subjects*	9	17		26	*		

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	0	6		6
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	0	6		6 **

* These totals must agree. ** These totals must agree,

Pages 25 through 29 redacted for the following reasons: Not responsive

Laptook, Abbot R.

IRB Approvals for Brown (Center #14) FWA #00000056

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	04-0108 Active	10/16/06	10/15/07
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	05-0111 Active	10/16/06	10/15/07
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	05-0116 Active	11/20/06	11/19/07
Not responsive	-		
			-
Breathing Outcomes (SUPPORT Study Secondary)	06-0007 Active	12/18/06	12/17/07
Not responsive			

Pages 31 through 47 redacted for the following reasons: Not responsive **Progress Report Scanning Cover Sheet**

5U10HD027904-18

PI Name:LAPTOOK, ABBOTOrg:WOMEN AND INFANTS HOSPITAL-RHODE
ISLANDStart Date:04/01/2008Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7392302Rec'd
Date:01/31/2008

Form Approved Throug	gh 11/30/2010	į				ОМВ	No. 0925-0001		
Departme	ent of Health and Huma Public Health Service		Review Group ZHD1DSRA10	Туре 5	Activity U10	Grant Number 5 U10 HD02790	4-18		
			Total Project Period		<u> </u>				
Cront	Drograa	Donort	From: 04/01/199	1	Thro	ough: 03/31/2011			
Grant	Progress	кероп	Requested Budget F	eriod		<u> </u>			
			From: 04/01/200	в	Thro	ough: 03/31/2009			
1. TITLE OF PROJEC		er Neonatal Rese	arch Network						
2a. PROGRAM DIREC			2b. E-MAIL ADDRES	s					
	s, street, city, state, zip	code)	alaptook@wihri.org						
Laptook, Abb 101 Dudley S			2c. DEPARTMENT, S	SERVICE,	LABORATO	RY, OR EQUIVALEN	Г		
	RI 02905-2499								
			2d. MAJOR SUBDIVI	SION					
			2e. Tel: 401-274-	1122 12	221 Fax	: 401-453-7571	JAN		
3a. APPLICANT ORG	ANIZATION s, street, city, state, zip	code)	3b. Tel:		Fax	•	 &		
	nfants Hospital c								
101 Dudley S			3c. DUNS: 069-851-913						
Providence, F	RI 02905-2499		4. ENTITY IDENTIF 05-0258937	ICATION	NUMBER				
6. HUMAN SUBJECT	S No	Yes	5. NAME, TITLE AN	D ADDRE	SS OF ADM	INISTRATIVE OFFICI	IAL		
6a. Research If Exempt ("Yes" in If Not Exempt ("No" in		Debra M. Paul, VP for Finance/CFO							
Exempt 6a): 6a): 6a): IRB approval date			Women and Infants Hospital of Rhode Island						
			101 Dudley S	Street, F	Providenc	e, RI 02905-249	99		
6b. Federal Wide Ass	urance No. 000000)56	- теі: 401-274-11	22 2165	5 Fax	: 401-453-7571			
6c. NIH-Defined Phase	e III		E-MAIL: dpaul@v	vihri.orc	r				
Clinical Trial	o 🗌 Yes				,				
7. VERTEBRATE AN	IMALS 🛛 NO 🛛	Yes	10. PROJECT/PERFORMANCE SITE(S)						
7a. If "Yes," IACUC ap	pproval Date		Organizational Name: Women and Infants Hospital of RI						
7b. Animal Welfare As	surance No.		DUNS: 069-851-913						
8. COSTS REQUES	TED FOR NEXT BUDG	BET PERIOD	Street 1: 101 Dudley Street						
8a. DIRECT \$177,54	47 8b. TOTA	\$247,323	Street 2:	•					
9. INVENTIONS AND	PATENTS No	Yes	City: Providence)	Сог	inty:			
	usly Reported		State: RI		Pro	vince:			
∐ Not Pre	eviously Reported		Country: USA		Zip	Postal Code: 0290	5-2499		
			Congressional Distric	ts: RI-0	02				
		NG FOR APPLICANT C		13)					
Patrice DiMario,	Senior VP for Pa	atient Support Se	ervices						
TEL: 401-274-11	22 1290	FAX: 401-453	-7666		E-MAIL: pd	imario@wihri.or	g		
12. Corrections to Pag	je 1 Face Page				8 .000				
		ATION AND ACCEPTA	ANCE: Loodify that the				ATE		
statements herein are	e true, complete and accur	ate to the best of my know	ledge, and accept the	11. <i>(In ink</i>	·)		, , , , , , , , , , , , , , , , , , ,		
result of this applicati	on. I am aware that any fa	s terms and conditions if a alse, fictitious, or fraudulen		lat.	. A. G	Ellan	1/29/08		
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Pages 3 through 17 redacted for the following reasons: Not responsive

Program Director/Principal Investigator (Last, First	^{t, Middle):} Laptook, Abbot R.	
PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD027904-18	
	PERIOD COVERED BY 1	THIS REPORT
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Abbot R. Laptook, MD	FROM 04/01/2008	THROUGH 03/31/2009
APPLICANT ORGANIZATION Women and Infants Hospital of Rhode Island		
TITLE OF PROJECT (Repeat title shown in Item 1 on finite NICHD Cooperative Multicenter Neonatal Resonance Ne		
A. Human Subjects (Complete Item 6 on the Face Page)	•	
Involvement of Human Subjects	No Change Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the Face Pag	ge)	
Use of Vertebrate Animals	No Change Since Previous Submission	Change
C. Select Agent Research	No Change Since Previous Submission	Change
D. Multiple PI Leadership Plan	No Change Since Previous Submission	Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Neonatal Research Network Progress Report for 2007-Brown University

The following summarizes activities of the Brown site and its investigators during 2007. Information is based on 12 months and accounts for variances with the Inclusion Enrollment Reports which contain data for Jan – Nov 2007 as per the Program Officer.

Support Trial

Specific Aims: 1) To determine if CPAP and/or permissive ventilation begun in the delivery room and continued during the first 14 days of life improves survival without BPD compared to intubation, early surfactant and mechanical ventilation among infants born between 24-28 weeks gestation.

2) To determine if a lower oxygen saturation range (85-89%) improves the survival free of threshold ROP and/or need for surgical intervention compared to a higher oxygen saturation range (91-95%) for infants in oxygen or requiring pulmonary support among infants born between 24-28 weeks gestation. *Studies and results*: This clinical trial represents the largest percent of Network resources at Brown during 2007 due to antenatal consent and the complexities of the study (initiation in the delivery room, and

continuation for prolonged intervals in the NICU). Screening and the consent process is conducted 7 days a week by our Research Nurses and remains labor intensive. The following summarizes the experience at Brown obtaining consents during 2007.

- Number of mothers screened: 167
- Number of mothers approached for consent: 135
- Reasons for not approaching for consent: short interval to delivery-24, resuscitation not planned-2, anomalies-1, Ob requested mother not be approached-2, and social/psych concerns-2
- Consent obtained: 92
- Enrolled: 34

These numbers are slightly higher than 2006. We continue to reinforce a communication algorithm to insure that providers (fellows, respiratory therapists, nurses) at the delivery of consented mothers know to randomize the infant. The communication algorithm addresses movement of patients from Labor and Delivery to the Ante-partum floors, from the Ante-partum floors to home, and readmission to Labor and Delivery. The majority of protocol violations have occurred in 2 areas of this study. These are use of high flow canulas in the first 14 days of the CPAP arm, and use of non-study pulse oximeters for infants that require resumption of study pulse oximeters prior to 36 weeks gestation. The Network coordinator and Research Nurses continue to address these protocol violations with the appropriate NICU personnel to prevent recurrences.

Support Secondary – Neuroimaging and Neurodevelopment

Specific Aim: To determine if brain MRI performed at 35-42 weeks post-menstrual age is superior to cranial ultrasonography in predicting neurodevelopmental outcome at 18-22 months corrected age.

Studies performed: During 2007 a total of 23 infants have been consented for MRI imaging. Imaging studies has been completed in all 23 infants. Only three studies required sedation for acquisition of MRI images.

Support Secondary - Breathing Outcomes

Specific Aim: To determine the extent of symptomatic airway dysfunction and need for outpatient pulmonary care comparing Support infants with high vs low oxygen saturation and comparing CPAP vs conventional ventilation arm.

Studies performed: A total of 35 Support infants have been enrolled in the Breathing outcomes study (infants enrolled in 2006 may be consented in 2007 since parents are approached for consent prior to discharge). During 2007 interviews were completed in 34 patients at discharge, 22 patients at 6 months, 20 patients at 12 months and 13 patients at 18 months.

Support Secondary – Antenatal screening and consent

Specific Aim: To determine factors important to obtaining antenatal consents for neonatal studies. Studies performed: Screening was performed in 96 mothers, 79 were approached and 59 consents were obtained to gather information for this study.

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Activities of the Investigators at the Brown Site

Plan for 04/01/08 - 03/31/09

1.	Continue enrollment into the Support Trial and secondary studies	
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Manuscripts Published or In Press Involving Brown Investigators:

Not responsive

Pages 21 through 23 redacted for the following reasons: Not responsive

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

	The Surfactant Positive Airway Pre	ssure & Pluse Oxim	etry Trial in Extremely Low Birth
Study Title:	Weight Infants (SUPPORT Study)		
Total Enrollment:	31	Protocol Number:	04-0108
Grant Number:	5 U10 HD027904-18	_	

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

	Sex/Gender						
Ethnic Category	Females	Males	Unknown or Not Reported	Total			
Hispanic or Latino	3	2		5	**		
Not Hispanic or Latino	11	15		26			
Unknown (individuals not reporting ethnicity)							
Ethnic Category: Total of All Subjects*	14	17		31	*		
Racial Categories							
American Indian/Alaska Native							
Asian	0	1		1			
Native Hawaiian or Other Pacific Islander							
Black or African American	4	1		5			
White	10	15		25			
More Than One Race							
Unknown or Not Reported							
Racial Categories: Total of All Subjects*	14	17		31	*		

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	3	2		5
More Than One Race				
Unknown or Not Reported	· · · · · · · · ·			
Racial Categories: Total of Hispanics or Latinos**	3	2		5 **

* These totals must agree.

** These totals must agree.

Pages 25 through 29 redacted for the following reasons: Not responsive

Neonatal Research Network -IRB Approvals for Brown (Center #14) <u>FWA # 00000056</u>

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
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Neonatal Research Network -IRB Approvals for Brown (Center #14) <u>FWA # 00000056</u>

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	04-0108 Active	09/17/07	09/16/08
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	05-0111 Completed Inactive as of 09/17/07		
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	05-0116 Active	10/22/07	10/21/08
Reathing Outcomes (SUPPORT Study Secondary)	06-0007	11/26/07	11/25/08
Breathing Outcomes (SUPPORT Study Secondary)	Active	11/26/07	11/25/08
Not responsive			

Neonatal Research Network -IRB Approvals for Brown (Center #14) <u>FWA # 00000056</u>

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

Pages 33 through 51 redacted for the following reasons: Not responsive Progress Report Scanning Cover Sheet

5U10HD027904-19

PI Name:LAPTOOK, ABBOTOrg:WOMEN AND INFANTS HOSPITAL-RHODE
ISLANDStart Date:04/01/2009Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7612124Rec'd
Date:02/02/2009

Form Approved Throu	gh 11/30/2010						OMB No. 0925-000
Departm	ent of Health and Hum Public Health Service		Review Group ZHD1DSRA10	Type 5	Activity U10	Grant Number 5 U10 HD0	
			Total Project Period				
Grant	Progress	Report	From: 04/01/199		Th	rough: 03/31/2	011
Crain	11091033	Report	Requested Budget Period				
1. TITLE OF PROJE	<u>ст</u>		From: 04/01/200)9	Th	rough: 03/31/2	010
		er Neonatal Rese	arch Network				
	CTOR / PRINCIPAL IN		2b. E-MAIL ADDRES				
Laptook, Abb	is, street, city, state, zip ot R	0 COOB)	alaptook@w 2c. DEPARTMENT,	-			
Women and I	nfants Hospital F	Rhode Island	20. DEPARTMENT,	SERVICE,	LABURAT	URT, UR EQUIV	
101 Dudley S			2d. MAJOR SUBDIV	ISION		,	
Providence, F	RI 02905 2499						
			2e. Tel: 401 274	1122 x	1221 Fa	ax: 401 453 75	571
3a. APPLICANT ORG	ANIZATION s, street, city, state, zip	code)	3b. Tel:		Fa	ax;	
	nfants Hospital F						
101 Dudley S			3c. DUNS: 069851913				
Providence, F	RI 02905 2499		4. ENTITY IDENTIF		NUMBER	FEB	0 2 2009
			1050258937				
 HUMAN SUBJECT 6a. Research 	`S ☐ No ⊠` If Exempt ("Yes" in	Yes If Not Exempt ("No" in	5. NAME, TITLE AN		SS OF AD	MINISTRATIVE O	FFICIAL
Exempt 6a): 6a):		6a):	bobiamia		Hospital	Rhode Islan	d
		IRB approval date	Women and Infants Hospital Rhode Island Vice President for Finance/CFO			4	
			101 Dudley S				
			Providence,				
	urance No. FWA00	000056	Tel: 401 274 11.	22 x 216	65 Fa	ax: 401 453 75	531
6c. NIH-Defined Phase Clinical Trial			E-MAIL: dpaul@\	wihri.org	J		
7. VERTEBRATE AN		Yes	10. PROJECT/PERF	ORMANC	E SITE(S)		
7a. If "Yes," IACUC a			Organizational Name	: Wome	en and Ir	nfants Hospita	al RI
7b. Animal Welfare As			DUNS: 0698519			·	
8. COSTS REQUES	TED FOR NEXT BUDG		Street 1: Women and Infants Hospital Rhode Island				Island
8a. DIRECT \$176,2		∟\$245,529	Street 2: 101 Du				
		······································	city: Providence				
9. INVENTIONS AND	PATENTS [_] No	Yes				ounty:	
	usly Reported eviously Reported		State: RI			ovince:	0005 0400
	eviously Reported		Country:		Zij	p/Postal Code: 0	2905 2499
			Congressional Distric	cts: RI-00	02		
		NG FOR APPLICANT C atient Support Se	•	n 13)			<u> </u>
TEL: 401 274 112	22 1290	FAX: 401 453	7666		E-MAIL: p	dimario@wih	ri.org
12. Corrections to Pag	je 1 Face Page			I	·		
13. APPLICANT ORG	ANIZATION CERTIFIC	ATION AND ACCEPT	ANCE: I certify that the		RE OF OFF	ICIAL NAMED IN	DATE
statements herein are obligation to comply w	e true, complete and accur with Public Health Service	rate to the best of my know s terms and conditions if a	ledge, and accept the grant is awarded as a	11. (In ink)		1/26/09
	on. I am aware that any fa iminal, civil, or administrati	alse, fictitious, or fraudulen ive penalties.	t statements or claims	atrue	ie M. Ol	chlam	1/20/04
may subject me to cr	initial, civil, of Bulliniadau						Form Page

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Pages 3 through 6 redacted for the following reasons:

Program Director/Principal Investigato	or (Last, First, Midd	^{le):} Laptook, Abbot R.	
PROGRESS REPORT SUMMARY		GRANT NUMBER 5 U10 HD027904-19	
		PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR		FROM	THROUGH
Abbot R. Laptook, MD		04/01/2009	03/31/2010
APPLICANT ORGANIZATION Women and Infants Hospital of Rhoo TITLE OF PROJECT (Repeat title shown in NICHD Cooperative Multicenter Neo	Item 1 on first pa		
A. Human Subjects (Complete Item 6 on the		······································	
Involvement of Human Subjects	No Ch	ange Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on t	he Face Page)		
Use of Vertebrate Animals	No Ch	ange Since Previous Submission	Change
C. Select Agent Research	🔀 No Ch	ange Since Previous Submission	Change
D. Multiple PD/PI Leadership Plan	No Ch	ange Since Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS.			······································

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Neonatal Research Network Progress Report for 2008-Brown University

The following summarizes activities of the Brown site and its investigators during 2008.

Support Trial

Specific Aims: 1) To determine if CPAP and/or permissive ventilation begun in the delivery room and continued during the first 14 days of life improves survival without BPD compared to intubation, early surfactant and mechanical ventilation among infants born between 24-28 weeks gestation. 2) To determine if a lower oxygen saturation range (85-89%) improves the survival free of threshold ROP and/or need for surgical intervention compared to a higher oxygen saturation range (91-95%) for infants in oxygen or requiring pulmonary support among infants born between 24-28 weeks gestation. *Studies and results*: As in the recent years this clinical trial represents the largest percent of Network resources at Brown during 2008 due to antenatal consent and the complexities of the study (initiation in the delivery room, and continuation for prolonged intervals in the NICU). Screening and the consent process is conducted daily by our Research Nurses and remains labor intensive. A shared approach has been developed with another NIH funded study that requires antenatal consent (Cord clamping) to provide for an orderly process of approaching the mother for consent. The following summarizes the experience at Brown obtaining consents during 2008.

- Number of mothers who delivered in the study window: 64 Of the 64 mothers:
- Number of mothers consented: 31 (38 infants enrolled)
- Number of mothers who refused consent: 12
- Number of Obstetricians who refused mother to be approached: 2
- Number of mothers not approached due to insufficient time: 11
- Number of mothers not approached due to conflicting studies: 5
- Number of mothers not approached due to anomalies/twin IUFD: 3

Enrollment is comparable to 2008 and the Brown site has continued to be a high enrolling center. We continue to reinforce a communication algorithm to insure that providers (fellows, respiratory therapists, nurses) at the delivery of consented mothers know to randomize the infant. Similar to other centers the majority of protocol violations relate to use of high flow canulas in the first 14 days of the CPAP arm, and use of non-study pulse oximeters for infants that require resumption of study pulse oximeters prior to 36 weeks gestation. The Network Coordinator and Research Nurses continue to address these protocol violations with the appropriate NICU personnel to prevent recurrences.

Support Secondary – Neuroimaging and Neurodevelopment

Specific Aim: To determine if brain MRI performed at 35-42 weeks post-menstrual age is superior to cranial ultrasonography in predicting neurodevelopmental outcome at 18-22 months corrected age.

Studies performed: During 2008 a total of 18 infants have been consented for MRI imaging. Imaging studies has been completed in all 18 infants. Only four studies required sedation for acquisition of MRI images.

Support Secondary - Breathing Outcomes

Specific Aim: To determine the extent of symptomatic airway dysfunction and need for outpatient pulmonary care comparing Support infants with high vs low oxygen saturation and comparing CPAP vs conventional ventilation arm.

Studies performed: A total of 38 Support infants have been enrolled in the Breathing outcomes study. During 2008 interviews were completed in 38 patients at discharge, 33 patients at 6 months, 21 patients at 12 months and 23 patients at 18 months.

Support Secondary – Antenatal screening and consent

Specific Aim: To determine factors important to obtaining antenatal consents for neonatal studies. Studies performed: No data was collected in 2008 since the Brown center already reached the goal of fifty mothers delivered in the study window during 2007. To summarize studies from prior years: 145 mothers were screened, 117 were approached, and 84 consents were obtained.

Not responsive

Activities of the Investigators at the Brown Site

Plan for 04/01/09 - 03/31/10

1. Continue enrollment into the Support Trial and secondary studies

2.	Not responsive
3.	
4.	
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7	

Manuscripts Published or In Press Involving Brown Investigators:

Not responsive

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Pages 10 through 14 redacted for the following reasons: Not responsive

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in ELBW Infants

Study Title:	(SUPPORT Study))		
Total Enrollment:	38	Protocol Number: 04-0108	
Grant Number:	5 U10 HD027904-19		

		Sex/Gender					
Ethnic Category	Females	Males	Unknown or Not Reported	Total			
Hispanic or Latino	6	5	0	11	**		
Not Hispanic or Latino	15	11	0	26			
Unknown (individuals not reporting ethnicity)	0	1	0	1			
Ethnic Category: Total of All Subjects*	21	17	0	38	*		
Racial Categories							
American Indian/Alaska Native	0	0	0	0			
Asian	0	0	0	0			
Native Hawaiian or Other Pacific Islander	0	0	0	0			
Black or African American	3	3	0	6			
White	18	14	0	32			
More Than One Race	0	0	0	0			
Unknown or Not Reported	0	0	0	0			
Racial Categories: Total of All Subjects*	21	17	0	38	*		
		· · · ·	n ar t gr a through a	**************************************			

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	1	1	0	2
White	5	4	0	9
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	6	5	0	11 **

* These totals must agree.

** These totals must agree.

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Pages 16 through 18 redacted for the following reasons: Not responsive

Neonatal Research Network -IRB Approvals for Brown (Center #14) <u>FWA # 00000056</u>

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	04-0108 Active	08/25/08	08/24/09

01/30/09

1

<u>Neonatal Research Network -IRB Approvals for Brown (Center #14)</u> <u>FWA # 00000056</u>

- -

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Antenatal Screening & Consent in a Research Network Model - SUPPORT Study secondary (SUPPORT Antenatal Consent study)	05-0111 Completed Inactive as of 09/17/07		
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT (SUPPORT MRI Study)	05-0116 Active	08/25/08	08/24/09
Not responsive			
Breathing Outcomes- SUPPORT Study Secondary (SUPPORT Breathing outcomes Study)	06-0007 Active	10/27/08	10/26/2009
Not responsive			

01/30/09

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Neonatal Research Network -IRB Approvals for Brown (Center #14) <u>FWA # 00000056</u>

PROTOCOL NAME	<u>PROTOCOL</u> <u>NUMBER</u>	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
-Not responsive			
01/30/09		3	

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Pages 22 through 37 redacted for the following reasons: Not responsive

5U10HD027904-20

PI Name:LAPTOOK, ABBOTOrg:WOMEN AND INFANTS HOSPITAL-RHODE
ISLANDStart Date:04/01/2010Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7799080Rec'd
Date:01/29/2010

Form Approved Through 06/30/2012				OMB No. 0	925-0001
Department of Health and Human Services Public Health Services	Review Group ZHD1DSRA10	Type 5	Activity U10	Grant Number 5 U10 HD027904-20)
	Total Project Period	_l			
	From: 04/01/199	1	т	hrough: 03/31/2011	
Grant Progress Report	Requested Budget F	Period			
	From: 04/01/201	0	т	hrough: 03/31/2011	
1. TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Rese	arch Network				
2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code) Laptook, Abbot R. Women and Infants Hospital of RI 101 Dudley Street	2b. E-MAIL ADDRES alaptook@wi 2c. DEPARTMENT, S	ihri.org	LABORA	TORY, OR EQUIVALENT	
Providence, RI 02905 2499	2d. MAJOR SUBDIVI	ISION			
	2e. Tel: 401 274	1122 x	1221 F	Fax: 401 453 7571	
3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)	3b. Tel:		F	ax:	FEB
Women and Infants Hospital of RI 101 Dudley Street	3c. DUNS: 06985	1913			B 2 9
Providence, RI 02905 2499	4. ENTITY IDENTIF 1050258937		NUMBER		2010
6. HUMAN SUBJECTS No Yes 6a. Research If Exempt ("Yes" in 6a): If Not Exempt ("No" in 6a): No Yes Exemption No. IRB approval date	Debra M. Pa Women and	ul Infants	Hospita	DMINISTRATIVE OFFICIAL al of RI nce, RI 02905 2499	
6b. Federal Wide Assurance No. FWA00000056	теі: 401 274 112	22 x 21	65 F	Fax: 401 453 7531	
6c. NIH-Defined Phase III Clinical Trial No Yes	E-MAIL: dpaul@v	vihri.org	9		
7. VERTEBRATE ANIMALS No Yes	10. PROJECT/PERF	ORMANC	E SITE(S)	an an an an an an an an an an an an an a	
7a. If "Yes," IACUC approval Date	Organizational Name	: Wome	en and I	nfants Hospital of RI	
7b. Animal Welfare Assurance No. A 3922-01	DUNS: 0698519	13			
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	Street 1: 101 Due	dley Str	reet		
8a. DIRECT \$181,407 8b. TOTAL \$252,700	Street 2:				
9. INVENTIONS AND PATENTS No Yes	city: Providence		c	County:	
If "Yes, 🔲 Previously Reported	State: RI	_	 F	Province:	
Not Previously Reported	Country: United S	States	z	Zip/Postal Code: 02905 24	99
	Congressional Distric	ts: RI-0	02		
11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT C Robert W. Pacheco, Associate Vice President, Fir		13)			
TEL: 401 274 1122 x 2156 FAX: 401 453	7531		E-MAIL: r	wpacheco@wihri.org	
12. Corrections to Page 1 Face Page					
13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTA statements herein are true, complete and accurate to the best of my know obligation to comply with Public Health Services terms and conditions if a	ledge, and accept the	SIGNATUI		FICIAL NAMED IN DATE	
result of this application. I am aware that any false, fictitious, or fraudulent may subject me to criminal, civil, or administrative penalties.		An	. In	Techen 1.25	
PHS 2590 (Rev. 06/09)	Face Page	0		For	n Page 1

Pages 3 through 6 redacted for the following reasons: Not responsive

Program Director/Principal Investigator (Last,	First, Middle):	Laptook, Abbot R.	
		GRANT NUMBER	
PROGRESS REPORT SUMMAR	RY	5 U10 HD027904-20	
		PERIOD COVERED BY TH	IIS REPORT
PROGRAM DIRECTOR / PRINCIPAL INVESTIGAT	OR	FROM	THROUGH
Abbot R. Laptook, MD		04/01/2010	03/31/2011
APPLICANT ORGANIZATION			
Women and Infants Hospital of RI			
TITLE OF PROJECT (Repeat title shown in Item 1 d	on first page)	······	
NICHD Cooperative Multicenter Neonatal	Research	Network	
A. Human Subjects (Complete Item 6 on the Face Page	e)		
Involvement of Human Subjects	🛛 No Chang	ge Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the Face Pa	age)		
Use of Vertebrate Animals	No Chang	ge Since Previous Submission	Change
C. Select Agent Research	🛛 No Chang	ge Since Previous Submission	Change
D. Multiple PD/PI Leadership Plan	No Chang	e Since Previous Submission	Change
E. Human Embryonic Stem Cell Line(s) Used	No Chang	e Since Previous Submission	Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Neonatal Research Network Progress Report for 2009-Brown University The following summarizes activities of the Brown site and its investigators during 2009.

Support Trial

Specific Aims: 1) To determine if CPAP and/or permissive ventilation begun in the delivery room and continued during the first 14 days of life improves survival without BPD compared to intubation, early surfactant and mechanical ventilation among infants born between 24-28 weeks gestation. 2) To determine if a lower oxygen saturation range (85-89%) improves the survival free of threshold ROP and/or need for surgical intervention compared to a higher oxygen saturation range (91-95%) for infants in oxygen or requiring pulmonary support among infants born between 24-28 weeks gestation.

Studies and results: Enrollment into the Support trial ended February 27, 2009. The Brown site enrolled 4 infants in 2009 and enrolled 124 infants for the entire study (second highest of all Network centers). During enrollment of 2009, 6 mothers delivered in the study window and 4 were consented and enrolled. One mother refused consent and one mother was not approached due to anomalies.

Support Secondary – Neuroimaging and Neurodevelopment

Specific Aim: To determine if brain MRI performed at 35-42 weeks post-menstrual age is superior to cranial ultrasonography in predicting neurodevelopmental outcome at 18-22 months corrected age. Studies performed: During 2009 a total of 7 infants have been consented for MRI imaging. One infant during 2009 required conscious sedation to perform the MRI. A total of 59 infants have been enrolled into this secondary study and all infants have had a late cranial ultrasound and MRI acquired.

Support Secondary - Breathing Outcomes

Not responsive

Specific Aim: To determine the extent of symptomatic airway dysfunction and need for outpatient pulmonary care comparing Support infants with high vs low oxygen saturation and comparing CPAP vs conventional ventilation arm.

Studies performed: Three Support infants have been enrolled in the Breathing outcomes study. During 2009 interviews were completed in 11 patients at discharge, 32 patients at 6 months, 36 patients at 12 months and 32 patients at 18 months. A total of 108 infants have been enrolled in this secondary study (second highest of all Network sites).

Support Secondary – Neurodevelopmental Follow-up

Specific Aim: To determine the impact of the primary interventions of the Support trial (mode of pulmonary support, oxygen saturation range) on neurodevelopmental follow-up assessed at 18-22 months of corrected age.

Studies performed: During 2009 34 infants completed their follow-up evaluations as part of the Support trial. To date the follow-up rate at Brown for infants enrolled in the Support trial is 93.2%.

Activities of the Investigators at the Brown Site

Not responsive

Plan for 04/01/10 – 03/31/11

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3.	
4.	Continue to perform follow-up of ELBW infants as part of the Support trial and for the Registry of Mortality
	and Morbidity
5.	Not responsive
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9.

Manuscripts Published or In Press Involving Brown Investigators:

Pages 11 through 15 redacted for the following reasons: Not responsive

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in ELBW Infants

Study Little:	(SUPPORT Study))			
Total Enrollment:		Protocol Number:	04-0108	
Grant Number:	5 U10 HD027904-20			

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	2	2	0	4
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	2	2	0	4 *
Racial Categories	a a a anna a sha a anna a anna a anna a anna a anna a sha a a a a a a a a a a a a a a a a			
American Indian/Alaska Native	0	0	0	0
Asian	. 0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	1	0	0	1
White	1	2	0	3
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	2	2	0	4 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

Pages 17 through 20 redacted for the following reasons: Not responsive

Women & Infants Hospital

<u>FWA # 00</u>	000056		
PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	<u>APPROVED</u> <u>THROUGH</u>
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			-
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	04-0108 Active	07/20/09	07/19/10

01.19.2010

Women & Infants Hospital

FWA # 00000056

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Antenatal Screening & Consent in a Research Network Model - SUPPORT Study secondary (SUPPORT Antenatal Consent study)	05-0111 Completed Inactive as of 09/17/07		
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT (SUPPORT MRI Study)	05-0116 Active	07/14/09	07/14/10
Not responsive			
Breathing Outcomes- SUPPORT Study Secondary (SUPPORT Breathing outcomes Study)	06-0007 Active	09/14/09	09/13/10
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Women & Infants Hospital

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PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
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Women & Infants Hospital

FWA # 00000056

<u>FWA # 00</u>	0000.00		
PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

01.19.2010

Pages 25 through 45 redacted for the following reasons: Not responsive **Progress Report Scanning Cover Sheet**

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5U10HD034216-10

PI Name:CARLO, WALDEMAROrg:UNIVERSITY OF ALABAMA AT BIRMINGHAMStart Date:04/01/2005Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:6902654Rec'd Date:02/01/2005

Form Approved Through 09/30/2007		mon Sonvice	1	Review Group	Туре	Activity	Grant Num		No. 0925-000
Department of Health Public Heal						5 U10	HD34216		0
				Total Project Per				,	
Grant Prog	race	Report		From: 05/06/1			ough: 03/31	/2006	
Grant Progress Report				Requested Budg				م مر	
		<u> </u>	. I	From: 04/1/20	05	Thr	ough: 03/31	/2006	
1. TITLE OF PROJECT	Near	atal Pesaarah N	otwor	ŀ				.) 1	
2a. PRINCIPAL INVESTIGATOR OF		• •		R PPLICANT OR		ON .		1	
(Name and address, street, city,				ame and addres			p code)	22	
Carlo, Waldemar A				niv of Alaba			am		
Univ of Alabama@ Birm	-			10 20 th Stree					
Dept of Peds/Div of Nec			B	irmingham,	AL 352	294-0111		07	
619 S 20 th St 525 New H	Hillma	n Building							
Birmingham, AL 35233									
2b. E-MAIL ADDRESS				NTITY IDENTIF		NUMBER			
wcarlo@peds.uab.edu				536005396A6					
2c. DEPARTMENT, SERVICE, LABO Pediatrics	ORATO	RY, OR EQUIVALENT		ITLE AND ADD					_
2d. MAJOR SUBDIVISION				ir Office of (niv of Alaba				stration	1
School of Medicine				$10\ 20^{\text{th}}\ \text{St}\ \text{S}$					
				irmingham,					
· ·				•		234-0111			
		<u> </u>	E-MA	IL: ogcaapp	s@prov	vośt.uab.e	du		
6. HUMAN SUBJECTS				7. VERTEBRAT	'E ANIMA	LS			
		nan Subjects Assurance)005960	•No.	🛛 No	•	7	a. If "Yes," I/	ACUC ap	proval Date
Yes No Yes	WAU	1003900][Yes					
· · · · · · · · · · · · · · · · · · ·		Defined Phase III		7b. Animal Welfa		ance No.			
	linical	Trial 🛛 No 🗌 Yes	\$	A3255-0	1				
If Not Exempt ("No" in 6a):	4	Full IRB <u>or</u>							
IRB approval date Multiple		Expedited Revie	w						
8. COSTS REQUESTED FOR NEX	T BUD	GET PERIOD			D PATEN	TS			
8a. DIRECT \$243,839 8	b. TOT	al \$349,909	⊠ !	No 🗌 Yes	lf "Yes,"	=	ously Reporte		
<u>,</u>		<u></u>					reviously Rep		·····
10. PERFORMANCE SITE(S) (Orga				PRINCIPAL IN			205 934	1-4860	
University of Alabama a 619 19 th Street South	t Birn	lingnam				FAX	205 934	1-3100	
Birmingham, AL 35243	7335		11b. /	ADMINISTRATI					•
Birmingham, AL 35243	-1330			E (Item 5)					
			_	thia Christian		FAX			<u> </u>
				NAME AND TIT ORGANIZATIO			NING FOR A	PPLICAN	Т
-			NAM			ase, PhD			
*			TITLE	T GOTAL A			Deeeee		
				rioung v			Research		-
			TEL	205-934-		I	FAX 205-9	1/5-597	(
<u> </u>		·	E-MA	IL marchas	se@uat	o.edu			
12. Corrections to Page 1 Face Page	•								

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRE statements herein are true, complete and accurate to th any false, fictitious, or fraudulent statements or claims in administrative penalties. I agree to accept responsibility and to provide the required progress reports if a grant in the statement of the statement of	he best of my knowledge. I am aware that (/ may subject me to criminal, civil, or ty for the scientific conduct of the project		DATE 1/26/05
14. APPLICANT ORGANIZATION CERTIFICATION statements herein are true, complete and accurate to th obligation to comply with Public Health Services terms result of this application. I am aware that any false, fict may subject me to criminal, civil, or administrative pena	NAND ACCEPTANCE: I certify that the S ne best of my knowledge, and accept the and conditions if a grant is awarded as a itious, or fraudulent statements or claims alties.	SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. 'Per'' signatura pri) acceptable Long Control of Control of Control Control of Control of Cont	DATE 1/28/05
PHS 2590 (Rev. 09/04)	Face Page		Form Page 1

Form Page 1

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Pages 3 through 4 redacted for the following reasons: Not responsive

· · · · · · · · · · · · · · · · · · ·	irst, Middle):	Carlo, Waldemar A.	
PROGRESS REPORT SUMMAR	Y	GRANT NUMBER HD-34216-09	
		PERIOD COVERED BY TH	HIS REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM DIREC	TOR	FROM	THROUGH
Carlo, Waldemar A		04/01/2004	03/31/2005
APPLICANT ORGANIZATION University of Alabama at Birmingham			
TITLE OF PROJECT (Repeat title shown in Item 1 or	n first page)		
	h Network	•	
Cooperative Multi-center Neonatal Researc	h Network	Since Previous Submission	Change
A. Human Subjects (Complete Item 6 on the Face Page	h Network ge) No Change		Change
A. Human Subjects (Complete Item 6 on the Face Page Involvement of Human Subjects	h Network ge) No Change Page)		Change

A. Specific Aims	
Not responsive	
	He is the lead
investigator of the oxygenation arm of the SUPPORT trial.	
	1

Key personnel have fulfilled the requirements for annual human subject protection and HIPPA training.

- B. Studies and Results
 - 1. Ongoing Studies

The UAB investigators have activly participated in and recruited patients to all ongoing studies. We have no conflicts with other ongoing clinical research efforts and are, therefore, committed to full participation in the Network trials. The number of randomized participants remains consistently a very large percentage of the available population and enrollment at UAB consistently exceeds expectations.

In the randomized trials, UAB has consistently performed as one of the top three enrolling sites. In the observational studies, such as the generic data base, UAB ranks third in total numbers while having only one site. The gender and racial distribution of study participants is representative of the population at this center. These data show adequate representation of both genders and minority populations. These data also show active recruitment in all Studies Not responsive SUPPORT pilot, Not responsive

Protocol Title	Protocol Number	Approval Date
Not responsive		
Surfactant Positive Airway Pressure & Pulse Oximetry in Extremely LBW Infants (Incl Pilot)	F040719001	07/28/04
Not responsive	•	
	*R	enewal Pending
2: Protocol Development		
Not responsive		
SUPPORT: Dr. Carlo is the lead investigator of the oxygenation arm of the SUF	PORT trial and	is actively at
Assisting Dr. Finer in the development of the overall protocol.		
Not responsive		

Pages 7 through 97 redacted for the following reasons: Not responsive

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight

Total Planned Enrollment: 87

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category		Sex/Gender			
	Females	Males	Total		
Hispanic or Latino	2	2	4		
Not Hispanic or Latino	38	45	83		
Ethnic Category: Total of All Subjects *	40	47	87		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	1	0	1		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	20	20	40		
White	18	28	46		
Racial Categories: Total of All Subjects *	39	48	87		

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 99 through 116 redacted for the following reasons: Not responsive **Progress Report Scanning Cover Sheet**

5U10HD034216-12

PI Name:CARLO, WALDEMAROrg:UNIVERSITY OF ALABAMA AT BIRMINGHAMStart Date:04/01/2007Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7219964Rec'd Date:02/05/2007

Department of Health and Human Services	Review Group Type Activity Grant Number			
Public Health Services	Total Project Period	-		
	From: 04/01/2006 Through: 3/31/2011			
Grant Progress Report	Requested Budget Period	-		
	From: 04/01/2007 Through: 03/31/2007			
1. TITLE OF PROJECT				
Cooperative Multicenter Neonatal Researc		~		
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code) Carlo, Waldemar A Univ of Alabama at Bimringham Dept of Peds/Div of Neonatology 619 20 th St 525 New Hillman Building Birmingham, AL 35233	3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code) University of Alabama at Birmingham 710 20 th Street South Birmingham, AL 35294-0111			
2b. E-MAIL ADDRESS wcarlo@peds.uab.edu	4. ENTITY IDENTIFICATION NUMBER 1636005396A6	-		
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVAL		7		
Pediatrics	Assistant VP for Sponsored Research Administration 1530 3 rd Ave So, AB 1170	Assistant VP for Sponsored Research Administration		
2d. MAJOR SUBDIVISION School of Medicine	UAB Station			
	Birmingham, AL 35294			
	E-MAIL: ogcanga@uab.edu			
6. HUMAN SUBJECTS	7. VERTEBRATE ANIMALS	-		
No 6a. Research Exempt 6b. Human Subjects Assu Yes No Yes FWA00005960	urance No. No 7a. If "Yes," IACUC approval Date			
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III				
Exemption No. Clinical Trial No	Yes A3255-01			
If Not Exempt ("No" in 6a): IRB approval date Multiple				
3. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVENTIONS AND PATENTS	-		
Ba. DIRECT \$162,616 8b. TOTAL \$236,606	No Yes If "Yes," Previously Reported			
10. PERFORMANCE SITE(S) (Organizations and addresses)	0 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a)			
University of Alabama at Birmingham 619 20 th Street South	FAX 205-934-3100			
Birmingham, AL 35243-7335	11b. ADMINISTRATIVE OFFICIAL TEL 205 934-5266	7		
Durining lain, AL OOL TO TOOD	NAME (Item 5) Jane Fant FAX 205 9755977			
Dimingham, AE 00240 7000		-		
Dimingham, AL 00240 7000	11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT			
Darmingham, AE 00240 7000	11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)			
Dimingham, AL 00240 7000	ORGANIZATION <i>(Item 14)</i> NAME Jane Fant			
Dimingham, AL 00240 7000	ORGANIZATION (Item 14) NAME Jane Fant TITLE Asst VP for Sponsored Research Administration			
Durningham, AL 00240 7000	ORGANIZATION <i>(Item 14)</i> NAME Jane Fant			

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify statements herein are true, complete and accurate to the best of my knowledge, and accu obligation to comply with Public Health Services terms and conditions if a grant is awarded result of this application. I am aware that any false, fictitious, or fraudulent statements or may subject me to criminal, civil, or administrative penalties.	ept the 11c. (In ink. "Per" signature not acceptable) MMLE	2/1/07
PHS 2590 (Rev. 04/06) Face Page	0 0 0	Form Page 1

Pages 3 through 4 redacted for the following reasons: Not responsive

Principal Investig. , ² rogram Director (Last, First, Mide	^{dle):} Carlo, V.,Jemar A	
	GRANT NUMBER	
PROGRESS REPORT SUMMARY	HD34216-12	
	PERIOD COVERED BY THIS	REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH
Carlo, Waldemar A	04/01/2006	03/31/2007
APPLICANT ORGANIZATION University of Alabama at Birmingham		
TITLE OF PROJECT (Repeat title shown in Item 1 on first pa Cooperative Multi-center Neonatal Research Net		
A. Human Subjects (Complete Item 6 on the Face Page)	· · · ·	
Involvement of Human Subjects 🛛 🛛 No C	hange Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals No C	hange Since Previous Submission	Change
C. Select Agent Research No C	hange Since Previous Submission	Change
D. Multiple PI Leadership Plan	hange Since Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS		

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

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NOL	

A. Specific Aims

t responsive	
	Dr. Carla is the
	Dr. Carlo is the
and investigator in the ovygonation arm of the engains SUBDORT trial	

lead investigator in the oxygenation arm of the ongoing SUPPORT trial.

Key personnel have fulfilled the requirements for annual human subject protection and HIPPA training.

B. Studies and Results

1.Ongoing Studies

Not responsive

Page 6 redacted for the following reason: Not responsive also show active recruitment in all studies (GDB, Candidiasis, SUPPORT, PCV-7, and Follow-up for GDB, Hypothermia, and other trials).

Protocol Title	Protocol Number	Approval Date
Not responsive		
Surfactant Positive Airway Pressure & Pulse Oximetry in Extremely LBW Infants	F040719001	07/05/06
(SUPPORT)	1040719001	0//05/00
Neuroimaging and Neurodevelopmental Outcome: Secondary Study to SUPPORT	F050922007	09/01/06
Post Natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygenation	X060418004	07/05/06
Saturation (SUPPORT) Study: A Secondary Study to SUPPORT		
Breathing Outcomes Study: A Secondary Study to SUPPORT	X060120014	03/10/2006
NOLIESPONSIVE		
	*pending r	eapproval
2. Protocol Development		- 1. 1

C. Significance

Pages 8 through 27 redacted for the following reasons: Not responsive Principal Investigator/Program Director (Last, First, Middle): Carlo, Waudemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

SUrfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth

Total Enrollment:

Study Title:

37

Protocol Number: F040910010

Grant Number:

HD 34216-11

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race Sex/Gender Unknown or **Ethnic Category** Females Males Not Reported Total ** Hispanic or Latino 0 1 0 1 Not Hispanic or Latino 16 20 0 36 Unknown (individuals not reporting ethnicity) 0 0 0 0 * Ethnic Category: Total of All Subjects* 0 16 21 37 **Racial Categories** American Indian/Alaska Native 0 0 0 0 Asian 0 0 0 0 Native Hawaiian or Other Pacific Islander 0 0 0 0 Black or African American 10 8 0 18 White 6 13 0 19 More Than One Race 0 0 0 0 Unknown or Not Reported 0 0 0 0 * Racial Categories: Total of All Subjects* 16 21 0 37

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	1	0	1 **

* These totals must agree.

Principal Investigator/Program Director (Last, First, Middle): Carlo, Waluemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Neuroimaging and Neuro	odevelopmental Outcome: A Secondary Study to SUPPORT
Total Enrollment:	37	Protocol Number: F05092207
Grant Number:	HD 34216-11	

		S	Sex/Gender				
Ethnic Category	Females	Males	Unknown or Not Reported	Total			
Hispanic or Latino	0	1	0	1	**		
Not Hispanic or Latino	16	20	0	36			
Unknown (individuals not reporting ethnicity)	0	0	0	0			
Ethnic Category: Total of All Subjects*	16	21	0	37	*		
Racial Categories							
American Indian/Alaska Native	0	0	0	0			
Asian	0	0	0	0			
Native Hawaiian or Other Pacific Islander	0	0	0	0			
Black or African American	10	8	0	18			
White	6	13	0	19			
More Than One Race	0	0	0	0			
Unknown or Not Reported	0	0	0	0			
Racial Categories: Total of All Subjects*	16	21	0	37	*		

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	1	0	1 **

* These totals must agree.

Principal Investigator/Program Director (Last, First, Middle): Carlo, Waluemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Postnatal Growth of Infa	ants Enrolled in SUPPORT Stu	dy	
Total Enrollment:		Protocol Number:	X060418004	
Grant Number:	HD 34216-11			

	Sex/Gender					
Ethnic Category	Females	Males	Unknown or Not Reported	Total		
Hispanic or Latino	0	1	0	1	**	
Not Hispanic or Latino	16	20	0	36		
Unknown (individuals not reporting ethnicity)	0	0	0	0		
Ethnic Category: Total of All Subjects*	16	21	0	37	*	
Racial Categories						
American Indian/Alaska Native	0	0	0	0		
Asian	0	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0	0		
Black or African American	10	8	0	18		
White	6	13	0	19		
More Than One Race	0	0	0	0		
Unknown or Not Reported	0	0	0	0	1	
Racial Categories: Total of All Subjects*	16	21	0	37	*	

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	1	0	1 **

* These totals must agree.

Principal Investigato... rogram Director (Last, First, Middle): Carlo, Wa. ,nar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Breathing Outcomes Stu	udy: A Secondary Study to SUPPORT	
Total Enrollment:	33	Protocol Number: X060120014	
Grant Number:	HD 34216-11		

	Sex/Gender					
Ethnic Category	Females	Males	Unknown or Not Reported	Total		
Hispanic or Latino	0	1	0	1	**	
Not Hispanic or Latino	19	13	0	32		
Unknown (individuals not reporting ethnicity)	0	0	0	0	-	
Ethnic Category: Total of All Subjects*	19	14	0	33	*	
Racial Categories						
American Indian/Alaska Native	0	0	0	0		
Asian	1	0	0	1		
Native Hawaiian or Other Pacific Islander	0	0	0	0		
Black or African American	13	4	0	17		
White	5	10	0	15		
More Than One Race	0	0	0	0		
Unknown or Not Reported	0	0	0	0		
Racial Categories: Total of All Subjects*	19	14	0	33	*	

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	1	0	1 **

* These totals must agree.

Pages 32 through 37 redacted for the following reasons: Not responsive

This report format should NOT be used for data collection from study participants.

Study Title: SUrfactant Postive Airway Pressure and Pulse Oximetry Trial in Very Low Birth Weight Infants

Total Planned Enrollment: 48

TARGETED/PLANNED ENRO	LLMENT: Number of Subjec	ts	
Ethnic Category			
	Females	Males	Total
Hispanic or Latino	1	1	- 2
Not Hispanic or Latino	21	25	46
Ethnic Category: Total of All Subjects *	22	26	48
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	13	11	24
White	9	15	24
Racial Categories: Total of All Subjects *	22	26	48

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopment Outcome: A Secondary Study to SUPPORT

Total Planned Enroliment: 40

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Sex/Gender				
	Females	Males	Total		
Hispanic or Latino	1	1	2		
Not Hispanic or Latino	17	21	38		
Ethnic Category: Total of All Subjects *	18	22	40		
Racial Categories			. •		
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	11	9	20		
White	7	13	20		
Racial Categories: Total of All Subjects *	18	22	40		

This report format should NOT be used for data collection from study participants.

Study Title: Post Natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation Study

Total Planned Enrollment: 48

Ethnia Ostorom	Sex/Gender					
Ethnic Category	Females	Males	Total			
Hispanic or Latino	1	1	2			
Not Hispanic or Latino	21	25	46			
Ethnic Category: Total of All Subjects *	22	26	48			
Racial Categories						
American Indian/Alaska Native	0	0	0			
Asian	0	0	0			
Native Hawaiian or Other Pacific Islander	0	0	0			
Black or African American	13	11	24			
White	9	15	24			
Racial Categories: Total of All Subjects *	22	26	48			

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes Study: A Secondary Study to SUPPORT

Total Planned Enrollment: 35

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Sex/Gender				
	Females	Males	Total		
Hispanic or Latino	0	1	1		
Not Hispanic or Latino	20	14	34		
Ethnic Category: Total of All Subjects *	20	15	35		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	13	5	18		
White	6	11	17		
Racial Categories: Total of All Subjects *	9	16	35		

Pages 42 through 44 redacted for the following reasons: Not responsive **Progress Report Scanning Cover Sheet**

5U10HD034216-13

PI Name:CARLO, WALDEMAROrg:UNIVERSITY OF ALABAMA AT BIRMINGHAMStart Date:04/01/2008Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7392641Rec'd Date:01/29/2008

Form Approved Through 09/30/20	007						OMB No. 0925-000	
Department of Health and Human Services Public Health Services		Revie	w Group	Type 5 C# Q	Activity	Grant Number HD034216-13		
			Total Project Period					
Grant Prog	rocc	Poport		From: 04/01/2006 Through: 3/31/2011				
Grant Frog	1622	Report	Requ	ested Budget F	Period			
			From:	04/01/200	8	Thro	ough: 03/31/2009	
1. TITLE OF PROJECT								
Cooperative Multicent								
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)				PLICANT OR me and addres			code)	
Carlo, Waldemar A				(Name and address, street, city, state, zip code) University of Alabama at Birmingham				
Univ of Alabama at Bi	rmingh	am		30 3 rd Ave			C	
Dept of Peds/Div of N		logy	Bir	mingham,	AL 352	94-0111		
619 19 th St South, NH							JAN 2 9 2008	
Birmingham, AL 3523	3						MAN & & LOOG	
2b. E-MAIL ADDRESS			4. EN	TITY IDENTIF	ICATION	NUMBER		
wcarlo@peds.uab.edu				36005396A				
2c. DEPARTMENT, SERVICE, L	ABORATO	DRY, OR EQUIVALENT					ATIVE OFFICIAL	
Pediatrics			As	Assistant VP for Sponsored Research Administration				
2d. MAJOR SUBDIVISION			1530 3 rd Ave So, AB 1170					
School of Medicine			Birmingham, AL 35294-0111					
			E-MAII	-: ogcanga	a Mulah a	du		
6. HUMAN SUBJECTS	len uu	mon Subjects Acquirance	. I_	VERTEBRAT	IE ANIMA	-		
No 6a. Research Exempt No Yes		nan Subjects Assurance 0005960	^{e no.} [2	No		7a	. If "Yes," IACUC approval Date	
Yes No Yes			ĮĽ	Yes				
If Exempt ("Yes" in 6a):	6c. NIH	Defined Phase III	7t	. Animal Welf		ance No.		
Exemption No.	Clinical		es	A3255-0	1			
If Not Exempt ("No" in 6a):	_	Full IRB <u>or</u>						
IRB approval date Multiple		Expedited Revie	w		•			
8. COSTS REQUESTED FOR N	EXT BUD	GET PERIOD	9. INV	ENTIONS ANI	D PATEN	rs		
8a. DIRECT \$151,859	8b. ТОТ	al \$220,955	🛛 N	> 🗌 Yes	lf "Yes,"		ously Reported	
							eviously Reported	
10. PERFORMANCE SITE(S) (Or				RINCIPAL IN	-		205-934-4680	
University of Alabama 619 19 th Street South,						FAX	205-934-3100	
Birmingham, AL 3523		20	11b. A	DMINISTRATI	VE OFFIC	IAL TEL	205 934-5266	
Dirningham, Ac 5525	0		1	(Item 5)		1		
			Jane			FAX	205 975-5977	
							IING FOR APPLICANT	
			NAME	RGANIZATIO	-	4)		
			TITLE		•		esearch Administration	
			TEL	205 934-	5266	F	AX 205 975-5977	
			E-MAIL	- ogca@u	iab.edu			
12 Corrections to Page 1 Face P							<u></u>	

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACC statements herein are true, complete and accurate to the best of my		SIGNATURE OF OFFICIAL NAME	D IN DATE
obligation to comply with Public Health Services terms and condition result of this application. I am aware that any false, fictitious, or fract may subject me to criminal, civil, or administrative penalties.	ns if a grant is awarded as a	acte for Jave +	3 1/25/08
PHS 2590 (Rev. 04/06)	Face Page		Form Page 1

Pages 3 through 8 redacted for the following reasons: Not responsive

Principal Investigator/Program Director (Last, First, Middle):	Carlo, Waldemar A.			
,	GRANT NUMBER			
PROGRESS REPORT SUMMARY	HD34216-13			
	PERIOD COVERED BY THIS REPORT			
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH		
Carlo, Waldemar A	04/01/2007	03/31/2008		
APPLICANT ORGANIZATION				
Jniversity of Alabama at Birmingham				
Jniversity of Alabama at Birmingham FITLE OF PROJECT (Repeat title shown in Item 1 on first page)				
· · · · · · · · · · · · · · · · · · ·	ς			
TITLE OF PROJECT (Repeat title shown in Item 1 on first page)	<			
TITLE OF PROJECT (Repeat title shown in Item 1 on first page) Cooperative Multi-center Neonatal Research Network A. Human Subjects (Complete Item 6 on the Face Page)	Contractions Submission	Change		
TITLE OF PROJECT (Repeat title shown in Item 1 on first page) Cooperative Multi-center Neonatal Research Network A. Human Subjects (Complete Item 6 on the Face Page)	<u></u>	Change		
TITLE OF PROJECT (Repeat title shown in Item 1 on first page) Cooperative Multi-center Neonatal Research Network A. Human Subjects (Complete Item 6 on the Face Page) Involvement of Human Subjects B. Vertebrate Animals (Complete Item 7 on the Face Page)	<u></u>	Change		
TITLE OF PROJECT (Repeat title shown in Item 1 on first page) Cooperative Multi-center Neonatal Research Network A. Human Subjects (Complete Item 6 on the Face Page) Involvement of Human Subjects B. Vertebrate Animals (Complete Item 7 on the Face Page) Use of Vertebrate Animals No Change	e Since Previous Submission			

Targeted/Planned Enrollment Format Page.

Not responsive	

A. S	specific	Aims

Not responsive	
	Study
enrollments have been maintained in the top three of the 17 centers for specific studies	SUPPORT,
Not responsive	

Dr. Carlo is the lead investigator in the oxygenation arm of the ongoing SUPPORT trial, and serves as the chairman of the Publications Committee.

Key Personnel have fulfilled the requirements for annual human subject protection and HIPPA training.

B. Studies and Results

1. Ongoing Studies

Not responsive		

numbers of participants. The racial/gender distribution of study participants is representative of this site, showing adequate numbers of both genders and minority population. These data show active recruitment in all studies (GDB Candidiasis SUPPORT PCV-7 and Follow-up for GDB Hypothermia and other trials)

Protocol Title	Protocol Number	Approval Date
t responsive		
Surfactant Positive Airway Pressure & Pulse Oximetry in Extremely LBW Infants	F040719001	05/17/07
(SUPPORT)	1040719001	03/1//07
Neuroimaging and Neurodevelopmental Outcome: Secondary Study to SUPPORT	F050922007	05/17/07
Post Natal Growth of Infants Enrolled in the NICHD Neonatal Network	X060418004	05/17/07
Oxygenation Saturation (SUPPORT) Study: A Secondary Study to SUPPORT		
Breathing Outcomes Study: A Secondary Study to SUPPORT	X060120014	01/23/08
t responsive		

*pending reapproval

2. Protocol Development

SUPPORT: Dr. Carlo is the lead investigator of the oxygenation arm of the SUPPORT trial and continues to actively assist Dr. Finer in the overall protocol. Not respons

C. Significance

Pages 11 through 29 redacted for the following reasons: Not responsive

This report format should NOT be used for data collection from study participants.

SUrfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth

Total Enrollment: Grant Number:

Study Title:

49 HD 34216-12 Protocol Number: F040910010

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race Sex/Gender Unknown or Ethnic Category Females Males Total Not Reported Hispanic or Latino 1 0 0 Not Hispanic or Latino 23 25 0 48 Unknown (individuals not reporting ethnicity) 0 0 0 Ethnic Category: Total of All Subjects* 24 25 0 49

Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	1	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	16	13	0	29
White	8	11	0	19
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	24	25	0	49 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	. 0	0
White	1	0	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	1	0	0	1 **

* These totals must agree.

** These totals must agree.

**

*

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This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to S						
Total Enroliment:	49	Protocol Number: F05092207				
Grant Number:	HD 34216-12					

	Sex/Gender				
Females	Males	Unknown or Not Reported	Total		
1	0	0	1	**	
23	25	0	48		
0	0	0	0		
24	25	0	49	*	
0	0	0	0		
0	1	0	1		
0	0	0	0		
16	13	0	29		
8	11	0	19		
0	0	0	0		
0	0	0	0		
24	25	0	49	*	
	1 23 0 24 0 24 0 0 0 0 16 8 0 0 0 0	1 0 23 25 0 0 24 25 0 0 0 0 0 0 1 0 1 0 16 13 8 11 0 0 0 0	Females Males Not Reported 1 0 0 23 25 0 0 0 0 24 25 0 0 0 0 24 25 0 0 0 0 0 0 0 0 0 0 0 0 0 16 13 0 0 0 0 0 0 0 0 0 0	FemalesMalesNot ReportedTotal100123250480000242504900000000000010100000161302981101900000000	

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	1	0	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	1	0	0	1 **

* These totals must agree.

This report format should NOT be used for data collection from study participants.

Study Title:	Postnatal Growth of Infant	s Enrolled in SUPPORT Study	
Total Enrollment:	49	Protocol Number: X060418004	
Grant Number:	HD 34216-12		

		S	ex/Gender		
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	1	0	Ý 0	1	**
Not Hispanic or Latino	23	25	0	48	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	24	25	0	49	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	0	1	0	1	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	16	13	0	29	
White	8	11	0	19	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	24	25	0	49	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	1	0	0 -	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	1	0	0	1 **

* These totals must agree.

This report format should NOT be used for data collection from study participants.

Study Title:	Breathing Outcomes Stu	dy: A Secondary Study to SUPPORT	
Total Enrollment:	36	Protocol Number: X060120014	
Grant Number:	HD 34216-12		

	Sex/Gender				
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	0	0	0	0	**
Not Hispanic or Latino	16	20	0	36	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	16	20	0	36	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	10	13	0	23	
White	6	7	0	13	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	16	20	0	36	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	· 0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

Pages 34 through 37 redacted for the following reasons: Not responsive

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes Study: A Secondary Study to SUPPORT

Total Planned Enrollment: 35

Sex/Gender Males 1	Total
Males 1	Total
1	
	1
16	34
17	35
0	0
0	0
0	0
8	19
9	16
16	35
	9

Pages 39 through 41 redacted for the following reasons: Not responsive

This report format should NOT be used for data collection from study participants.

Study Title: SUrfactant Postive Airway Pressure and Pulse Oximetry Trial in Very Low Birth Weight Infants

Total Planned Enrollment: 48

TARGETED/PLANNED ENROLLMENT: Number of Subjects						
Ethnic Category		Sex/Gender				
	Females	Males	Total			
Hispanic or Latino	1	1	2			
Not Hispanic or Latino	21	25	46			
Ethnic Category: Total of All Subjects *	22	26	48			
Racial Categories						
American Indian/Alaska Native	0	0	0			
Asian	0	0	0			
Native Hawaiian or Other Pacific Islander	0	0	0			
Black or African American	13	11	24			
White	9	15	24			
Racial Categories: Total of All Subjects *	22	26	48			

This report format should NOT be used for data collection from study participants.

Study Title: Post Natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation Study

Total Planned Enrollment: 48

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Sex/Gender				
	Females	Males	Total		
Hispanic or Latino	1	1	2		
Not Hispanic or Latino	21	25	46		
Ethnic Category: Total of All Subjects *	22	26	48		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	13	11	24		
White	9	15	24		
Racial Categories: Total of All Subjects *	22	26	48		

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopment Outcome: A Secondary Study to SUPPORT

Total Planned Enrollment: 40

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category		Sex/Gender			
	Females	Males	Total		
Hispanic or Latino	1	1	2		
Not Hispanic or Latino	17	21	38		
Ethnic Category: Total of All Subjects *	18	22	40		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	11	9	20		
White	7	13	20		
Racial Categories: Total of All Subjects *	18	22	40		

Pages 45 through 46 redacted for the following reasons: Not responsive **Progress Report Scanning Cover Sheet**

5U10HD034216-14

PI Name:CARLO, WALDEMAROrg:UNIVERSITY OF ALABAMA AT BIRMINGHAMStart Date:04/01/2009Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7612140Rec'd Date:01/30/2009

Form Approved Through 11/30/2010					OMB No. 0925-0001
Department of Health and Human Services Public Health Services		Review Group	Type 5	Activity ULO	Grant Number HD034216-14
		Total Project Perio	bd		
Grant Progress Report		From: 04/01/20		Thro	bugh: 03/31/2011
Grant rogicss hop		Requested Budge	t Period		
		From: 04/01/20	009	Thro	bugh: 03/31/2010
1. TITLE OF PROJECT Cooperative Multicenter Neonatal Re	esearch Ne	twork			
2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIG	ATOR	2b. E-MAIL ADDR		al	
(Name and address, street, city, state, zip code) Waldemar A. Carlo		wcarlo@peds.uab.edu			
Univ of Alabama at Birmingham		2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Pediatrics			
Dept of Peds/Div of Neonatology		2d. MAJOR SUBD			······
619 19th St South, NHB 525		School of N			
Birmingham, AL 35233		2e, Tel: 205-93	4-4680	Fax	: 205-934-3100
3a. APPLICANT ORGANIZATION					
(Name and address, street, city, state, zip code)		3b. Tel: 205-93	4-5266	Fax	: 205-975-5977
University of Alabama at Birminghan 1530 3rd Ave South, AB 1170	ר	3c. DUNS: 0636	890705		JAN 3 0 2009
Birmingham, AL 35294-0111		4. ENTITY IDENT		NUMBER	
		163600539			
6. HUMAN SUBJECTS No Yes		5. NAME, TITLE		SS OF ADM	INISTRATIVE OFFICIAL
6a. Research If Exempt ("Yes" in If Not E	Exempt ("No" in	l			
Exempt 6a): 6a): No Yes Exemption No. IRB ap	proval date			of Grants	& Contracts Admin
No Yes Exemption No. IRB ap		1530 3rd Av			
		Birmingham			005 075 5077
6b. Federal Wide Assurance No. FWA0000596	50	Tel: 205-934-5	0200	Fax	: 205-975-5977
6c. NIH-Defined Phase III Clinical Trial No Yes		E-MAIL: ogcan;			
7. VERTEBRATE ANIMALS 🛛 No 🗌 Yes		10. PROJECT/PE	RFORMANC	E SITE(S)	
7a. If "Yes," IACUC approval Date		Organizational Nar	me: Unive	rsity of Al	abama at Birmingham
7b. Animal Welfare Assurance No. A3255-01	I	DUNS: 063690705			
8. COSTS REQUESTED FOR NEXT BUDGET PER	RIOD	Street 1: 1530 3 rd Ave South, AB 1170			
8a. DIRECT \$290,371 8b. TOTAL \$421	,802	Street 2:			
9. INVENTIONS AND PATENTS No Ye	es	City: Birmingh	am	Cou	unty: Jefferson
If "Yes, 🔲 Previously Reported		State: Alabam	а	Pro	vince:
Not Previously Reported		Country: USA	·· <u></u>	Zip/	Postal Code: 35294-0111
		Congressional Dis	tricts: 7	ee	
11. NAME AND TITLE OF OFFICIAL SIGNING FOR Lynn Stedman	APPLICANT O	RGANIZATION (It	em 13)		
TEL: 205-934-5266	x: 205-975-	-5977		E-MAIL: 09	ca@uab.edu
12. Corrections to Page 1 Face Page		<u></u>	į	-0	
13. APPLICANT ORGANIZATION CERTIFICATION		NCE: I certify that the			
statements herein are true, complete and accurate to the	best of my knowl	ledge, and accept the	11. (In ink		
obligation to comply with Public Health Services terms an result of this application. I am aware that any false, fictiti	ous, or fraudulent			eers	127)0
may subject me to criminal, civil, or administrative penalt PHS 2590 (Rev. 11/07)		Face Page	act	pru	Form Page 1
			5	, 0	rom rage i

Pages 3 through 4 redacted for the following reasons: Not responsive Program Director/Principal Investigator (Last, First, Middle):

Carlo, Waldemar A

		ound, maidemar /			
PROGRESS REPORT SUMMARY		GRANT NUMBER HD34216-14			
	PERIOD COVERED BY TH		IS REPORT		
PROGRAM DIRECTOR / PRINCIPAL INVE	STIGATOR	FROM	THROUGH		
Carlo, Waldemar A		04/01/2008	03/31/2009		
APPLICANT ORGANIZATION University of Alabama at Birmingham	n				
TITLE OF PROJECT (Repeat title shown in Cooperative Multicenter Neonatal R					
A. Human Subjects (Complete Item 6 on the	Face Page)				
Involvement of Human Subjects	🔀 No Cha	ange Since Previous Submission	Change		
B. Vertebrate Animals (Complete Item 7 on	the Face Page)				
Use of Vertebrate Animals	No Cha	ange Since Previous Submission	Change		
C. Select Agent Research	No Cha	ange Since Previous Submission	Change		
D. Multiple PD/PI Leadership Plan	🔀 No Cha	ange Since Previous Submission	Change		

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

Not responsive	
	Study
enrollments have been in the top two of the 16 centers for specific studies SUPPORT with	
secondaries, Not responsive). Not responsive	

Dr. Carlo is the lead investigator in the oxygenation arm of the ongoing SUPPORT trial, and serves as the chairman of the Publications and ^{Not responsive} Committees. Key personnel have fulfilled the requirements for annual human subject protection and HIPAA training

- B. Studies and Results
 - 1. Ongoing Studies

Not responsive		
		These data show active
recruitment in all studies	SUPPORT and secondaries, Not responsive	These data show active

SUPPORT: Dr. Carlo is the lead investigator of the oxygenation arm of the SUPPORT trial and continues to actively assist Dr. Finer in the overall protocol.

Protocol Title	Protocol Number	Approval Date *
Not responsive		Tippio tui Duio
Surfactant Positive Airway Pressure & Pulse Oximetry in Extremely LBW Infants	F040910010	05/08/08
(SUPPORT)		
Neuroimaging and Neurodevelopmental Outcome: Secondary Study to SUPPORT	F050922007	11/19/08
Post Natal Growth of Infants Enrolled SUPPORT Study	X060418004	06/04/08
Breathing Outcomes Study: A Secondary Study to SUPPORT	X060120014	01/15/09
Not responsive		

*All protocols approved for 1 year from Approval Date

C. Significance

Not responsive

Pages 7 through 15 redacted for the following reasons: Not responsive

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birhweight

Total Enrollment:

46

Protocol Number: F040910010

Grant Number: HD 34216-13

		S	ex/Gender		
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	2	2	0	4	**
Not Hispanic or Latino	20	22	0	42	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	22	24	0	46	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	10	12	0	22	
White	11	12	0	23	
More Than One Race	1	0	0	1	_
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	22	24	0	46	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	2	2	0	4
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	2	2	. 0	4 **

+ **-**

* These totals must agree. ** These totals must agree. Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A

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Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Neuroimaging and Neur	odevelopment: A Secondary Study to SUPPORT	
Total Enrollment:	44	Protocol Number: F050922007	
Grant Number:	HD 34216-13		

	<u> </u>	S	ex/Gender		
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	2	2	0	4	**
Not Hispanic or Latino	20	20	0	40	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	22	22	0	44	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	10	12	0	22	
White	11	10	0	21	
More Than One Race	1	0	0	1	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	22	22	0	44	*
PART B. HISPANIC ENROLLMENT REPORT: Numb	er of Hispanio	cs or Latinos	s Enrolled to Da	ate (Cumulativ	/e)
Racial Categories	Females	Males	Unknown or Not Reported	Total	
American Indian or Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	0	0	0	0	
White	2	2	0	4	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	

* These totals must agree.
** These totals must agree.

This report format should NOT be used for data collection from study participants.

Study Title: Post Natal Growth of Infants Enrolled in the NICHD SUPPORT Study Protocol Number: X06418004 Total Enrollment: 46 HD 34216-13 **Grant Number:**

PART A. TOTAL ENROLLMENT REPORT: Number by Ethnic	of Subjects E city and Race	nrolled to Da	ate (Cumulative)
		S	ex/Gender	
Ethnic Category	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	2	2	0	4 **
Not Hispanic or Latino	20	22	0	42
Unknown (individuals not reporting ethnicity)	. 0	. 0	0	0
Ethnic Category: Total of All Subjects*	22	24	0	46 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	10	12	0	22
White	11	12	0	23
More Than One Race	1	0	0	1
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	22	24	0	46 *
	and a second second second second second second second second second second second second second second second			
PART B. HISPANIC ENROLLMENT REPORT: Numb	er of Hispani	cs or Latinos	s Enrolled to Da	ate (Cumulative)
Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	2	2	0	4
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	2	2	0	4 **

* These totals must agree. ** These totals must agree.

PHS 398/2590 (Rev. 11/07)

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes Study: A Secondary Study to SUPPORT					
Total Enrollment:	39	Protocol Number:	X060120014		
Grant Number:	HD 34216-13				

		S	ex/Gender		
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	1	1	0	2	**
Not Hispanic or Latino	20	17	0	37	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	21	18	0	39	*
Racial Categories			•		
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	9	9	0	18	
White	11	9	0	20	
More Than One Race	1	0	0	1	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	21	18	0	39	*

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	1	· 1	0	2
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	1	1	0	2 **

* These totals must agree. ** These totals must agree.

Pages 20 through 28 redacted for the following reasons: Not responsive

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birthweight

Total Planned Enrollment: 24

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Sex/Gender				
	Females	Males	Total		
Hispanic or Latino	1	1	2		
Not Hispanic or Latino	. 10	12	22		
Ethnic Category: Total of All Subjects *	11	13	24		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	5	7	12		
White	6	6	12		
Racial Categories: Total of All Subjects *	11	13	24		

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopment: A Secondary Study to SUPPORT

Total Planned Enrollment: 22

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category		Sex/Gender			
	Females	Males	Total		
Hispanic or Latino	1	1	2		
Not Hispanic or Latino	9	11	20		
Ethnic Category: Total of All Subjects *	10	12	22		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	4	7	11		
White	6	5	11		
Racial Categories: Total of All Subjects *	10	12	22		

This report format should NOT be used for data collection from study participants.

Study Title: Pos Natal Growth of Infants Enrolled in the NICHD SUPPORT Study

Total Planned Enrollment: 24

TARGETED/PLANNED ENRO	LLMENT: Number of Subjec	ts			
Ethnic Category	Sex/Gender				
	Females	Males	Total		
Hispanic or Latino	1	1	2		
Not Hispanic or Latino	10	12	22		
Ethnic Category: Total of All Subjects *	11	13	24		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	5	7	12		
White	6	6	12		
Racial Categories: Total of All Subjects *	11	13	24		

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes Study: A Secondary Study to SUPPORT

Total Planned Enrollment: 40

TARGETED/PLANNED ENRO	LLMENT: Number of Subjec	ts		
Ethnic Category		Sex/Gender		
Ethnic Category	Females	Males	Total	
Hispanic or Latino	1	1	2	
Not Hispanic or Latino	20	18	38	
Ethnic Category: Total of All Subjects *	21	19	40	
Racial Categories				
American Indian/Alaska Native	0	0	0	
Asian	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	
Black or African American	12	10	22	
White	9	9	18	
Racial Categories: Total of All Subjects *	21	19	40	

Pages 33 through 53 redacted for the following reasons: Not responsive **Progress Report Scanning Cover Sheet**

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5U10HD034216-15

PI Name:CARLO, WALDEMAROrg:UNIVERSITY OF ALABAMA AT BIRMINGHAMStart Date:04/01/2010Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7803556Rec'd Date:02/01/2010

Form Approved Through 06/30/20	12					OMB No. 0925-0001		
Department of Health Public Hea	h and Human S Ith Services	ervices	Review Group ZHD1DSRA10	⊺ype 5	Activity U10	Grant Number 5 U10 HD034216-15		
			Total Project Period	.		<u>к</u> ,		
Grant Prog	rass Ra	anort	From: 05/06/1996 Through: 03/31/2011					
Grant Frog	1622 NG	sport	Requested Budget P	eriod				
			From: 04/01/2010	00	Thro	bugh: 03/31/2011		
1. TITLE OF PROJECT NICHD Cooperative M	ulticenter I	Neonatal Rese	arch Network					
2a. PROGRAM DIRECTOR / PRIN (Name and address, street, city			2b. E-MAIL ADDRES		du			
Waldemar A. Carlo, M	D		wcarlo@peds 2c. DEPARTMENT, S			RY, OR EQUIVALENT		
620 20 th St. S., NHB 525 Birmingham, AL 35294		Pediatrics						
			2d. MAJOR SUBDIVI School of Me		<u></u>	·····		
			2e. Tel: 205-934-	4680	Fax	а 205-934-310<mark>р</mark>1		
3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)		3b. Tel: (205) 934	4-5266	Fax	c (205) 975-5927			
University of Alabama	at Birming		3c. DUNS: 06369	0705		janual.		
1530 3 rd Avenue S, AB 1170 Birmingham, AL 35294-0111						201		
			4. ENTITY IDENTIF 1636005396/		NUMBER	6		
6. HUMAN SUBJECTS No Yes		5. NAME, TITLE AN	D ADDRE	SS OF ADM	INISTRATIVE OFFICIAL			
6a. Research If Exempt ("Yes" in 6a): If Not Exempt ("No" in 6a): No Yes Exemption No. IRB approval date						rants & Contracts Admin		
		B approval date	1530 3 rd Ave. South, AB 1170					
	0	2/25/09	Birmingham,	AL 352	94-0111			
6b. Federal Wide Assurance No.	FWA0000	5960	Tel: (205) 934-5	266	Fax	c (205) 975-5977		
6c. NIH-Defined Phase III Clinical Trial X No Yes			E-MAIL: ogcanga	@uab.e	edu			
7. VERTEBRATE ANIMALS] No 🗌 Y	/es	10. PROJECT/PERF	ORMANC	E SITE(S)	· · · · · · · · · · · · · · · · · · ·		
7a. If "Yes," IACUC approval Date	Э		Organizational Name	: Unive	rsity of Al	abama at Birmingham		
7b. Animal Welfare Assurance No	. A3255-01		DUNS: 06369070	05				
8. COSTS REQUESTED FOR N	EXT BUDGET	PERIOD	Street 1: 1530 3 ^{rt}	^d Ave S	outh, AB	1170		
8a. DIRECT \$299,352	8b. TOTAL \$4	134,845	Street 2:					
9. INVENTIONS AND PATENTS	No [] Yes	city: Birminghar	n	Со	unty: Jefferson		
If "Yes, 🔲 Previously Reporte	ed		State: AL		Pro	vince:		
Not Previously Rep			Country: USA		Zip	/Postal Code: 35294-0111		
			Congressional Distric	ts: AL-0	07			
11. NAME AND TITLE OF OFFIC								
Lynn Stedman, Interim D	irector, Of	tice of Grants a	and Contracts Ac	dministr	ation			
tel: (205) 934-5266		FAX: (205) 97	5-5977		E-MAIL: OG	ca@uab.edu		
12. Corrections to Page 1 Face Pa	age							
 APPLICANT ORGANIZATION statements herein are true, comple obligation to comply with Public Her result of this application. 1 am awa more unbiast me to estimate still. 	ete and accurate ealth Services ter ire that any false,	to the best of my know ms and conditions if a , fictitious, or fraudulent	ledge, and accept the grant is awarded as a			CIAL NAMED IN DATE		
may subject me to criminal, civil, or PHS 2590 (Rev. 06/09)	aurimistrative p		Face Page	j		Form Page 1		
				-		-		

Pages 3 through 4 redacted for the following reasons: Not responsive

Program Director/Principal Investigator	(Last, First, Middle):	Carlo, Waldemar A.	
PROGRESS REPORT SUM	IMARY	GRANT NUMBER HD34216-15	
		PERIOD COVERED BY TH	IS REPORT
PROGRAM DIRECTOR / PRINCIPAL INVES	TIGATOR	FROM	THROUGH
Carlo, Waldemar A.		04/01/2009	03/31/2010
APPLICANT ORGANIZATION University of Alabama at Birmingham			
TITLE OF PROJECT (Repeat title shown in It Cooperative Multi-center Neonatal Re	· •	{	
A. Human Subjects (Complete Item 6 on the Fac	ce Page)		
Involvement of Human Subjects	No Change	e Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the	Face Page)		
Use of Vertebrate Animals	· 🔀 No Change	e Since Previous Submission	Change
C. Select Agent Research	No Change	e Since Previous Submission	Change
D. Multiple PD/PI Leadership Plan	🔀 No Chang	e Since Previous Submission	Change

No Change Since Previous Submission

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

 \boxtimes

A. Specific Aims			
Not responsive			
			Study
enrollments have been in the top two of the 16 centers for specific studies		SUPPORT	with
secondaries, Not responsive			
			. Dr. Carlo was
the lead investigator in the oxygenation arm of the recently completed SUP	PORT	trial, and s	erves as the
chairman of the Publications ^{Not responsive}			
Key personnel have fulfilled the requirements for annual human su	ubject	protection	and HIPAA
training			

B. Studies and Results

1. Ongoing studies Not responsive

E. Human Embryonic Stem Cell Line(s) Used

SEE PHS 2590 INSTRUCTIONS.

The four-year-long SUPPORT Trial was completed during this year. This site contributed 184 out of 1312 participants. Two publications have been accepted in the NEJM. Results of the early primary outcomes of this factorial design study showed 1) lower oxygen saturation targeting did not significantly decrease the

Change

decrease in severe retinopathy of prematurity in survivors and 2) CPAP used early in the delivery room is an effective evidence-based alternative to intubation and surfactant in preterm infants.

Not responsive		
Protocol Title (NCT #)	Protocol Number	Approval Date
Breathing Outcomes Study: A Secondary Study to SUPPORT (NCT00233324)	X060120014	12/08/09
Follow-up Study: Follow-up of High Risk Infants (18 month follow-up) (NCT0009633)	X080120014 X080124010	02/13/09
Surfactant Positive Airway Pressure & Pulse Oximetry in Extremely LBW Infants	F040910010	01/13/10
(SUPPORT) (NCT00233324)		
Neuroimaging & Neurodevelopmental Outcome: Secondary to SUPPORT(NCT00233324)	F050922007	01/13/10
Post Natal Growth of Infants Enrolled SUPPORT Study (NCT00233324)	X060418004	12/17/09
Not responsive		
2. Protocol Development		
Not responsive		
		As lead
investigator of the oxygenation arm of the SUPPORT trial, Dr. Carlo is active	ely involved in pub	lication of
several papers from this trial. Not responsive		
C. Significance		
Not responsive		

Pages 7 through 17 redacted for the following reasons: Not responsive

This report format should NOT be used for data collection from study participants.

Study Title:	Breathing Outcome (secondary to S	UPPORT)
Total Enrollment:	15	Protocol Number: X060120014
Grant Number:	HD34216-15	

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race					
Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total	
Hispanic or Latino	0	0	0	0	**
Not Hispanic or Latino	10	5	0	15	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	10	5	0	15	*
Racial Categories	· · · · · · · · · · · · · · · · · · ·				_
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	6	2	0	8	
White	4	3	0	7	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	10	5	0	15	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

This report format should NOT be used for data collection from study participants.

Study Title:	Follow Up Stu	dy: Follow Up of High Risk Infants (18 m	onth follow-up)	
Total Enrollment:	63	Protocol Number:	X080124010	
Grant Number:	HD34216-15			

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total	
Hispanic or Latino	0	2	0	2	**
Not Hispanic or Latino	28	33	0	61	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	28	35	0	63	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	1	0	0	1	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	19	23	0	42	
White	8	12	0	20	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	28	35	0	63	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	2	0	2
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	2	0	2 **

* These totals must agree.

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Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Surfactant Positive Airway Pressure	and Pulse Oximetry Trial in Extremely Low Birth
7	Protocol Number: F040910010
HD34216-15	
	Neight Infants (SUPPORT Study) 7

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total	
Hispanic or Latino	0	0	0	0	**
Not Hispanic or Latino	5	2	0	7	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	5	2	0	7	*
Racial Categories			<u></u>		
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	1	0	0	1	
White	4	2	0	6	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	5	2	0	7	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

This report format should NOT be used for data collection from study participants.

Study Title:	Neuroimaging and Neurodevelopment Outcome (secondary to SUPPORT)						
Total Enrollment:	7	Protocol Number:	F050922007				
Grant Number:	HD34216-15						

	nber of Subjects E Ethnicity and Race		ate (Cumulative	9)	
Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total	
Hispanic or Latino	0	0	0	0	**
Not Hispanic or Latino	5	2	0	7	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	5	2	0	7	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	1	0	0	1	
White	4	2	0	6	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	5	2	0	7	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

This report format should NOT be used for data collection from study participants.

Study Title:	Postnatal Growth Study (secondary to SUPPORT)					
Total Enrollment:	: 7 Protocol Number: X060418004					
Grant Number:	HD34216-15					

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total	
Hispanic or Latino	0	0	0	0	**
Not Hispanic or Latino	5	2	0	7	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	5	2	0	7	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	1	0	0	1	
White	4	2	0	6	
More Than One Race	0	0	0	0	-
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	5	2	0	7	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

Pages 23 through 49 redacted for the following reasons: Not responsive **Progress Report Scanning Cover Sheet**

5U01HD036790-08

PI Name:POOLE, WILLIAMOrg:RESEARCH TRIANGLE INSTITUTEStart Date:06/01/2005Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:6902655Rec'd Date:03/31/2005

Form Approved Through 09/30/200)7					OME	No. 0925-0001	
	th and Human Services ealth Services	Review C	Group	Туре	Activity	Grant Number 5 U01 HD03679	90 - 08	
		Total Pro	ject Peri	iod	1			
		From: 0	8/01/1	998	Thr	ough: 05/31/2008		
Grant Prog	jress Report	Requeste						
		From: 0	-		Thr	ough: 05/31/2006		
1. TITLE OF PROJECT								
Data Ctr for the Coope	rative Neonatal Researc	h Network				,		
2a. PRINCIPAL INVESTIGATOR C	DR PROGRAM DIRECTOR	3. APPLICA			•••	1		
(Name and address, street, city	, state, zip code)				city, state, zij	p code)		
Abhik Das		Researc				·		
6110 Executive Blvd		3040 C			Id	بة • خ		
Suite 902		P.O. Bo				· ·		
Rockville, MD 20852-3	907	Researd	ch Tria	angle P	ark, NC 2	27709	,	
	•							
2b. E-MAIL ADDRESS		4. ENTITY I	DENTIF	ICATION	NUMBER	1.11 × 12	•	
adas@rti.org		56-0686	338			ла М ^а		
2c. DEPARTMENT, SERVICE, LA	BORATORY, OR EQUIVALENT	5. TITLE AN	D ADDF	RESS OF	ADMINISTR	ATIVE OFFICIAL	÷ 4.	
Social and Statistical Sci	ences	S. Kent	Walke	er			-	
2d. MAJOR SUBDIVISION	· ·	3040 Co	ornwa	llis Roa	hd	2005		
Statistics Research Div	vision	P.O. Bo	x 121	94			•	
		Resear	ch Tria	angle P	ark, NC 2	27709 🗟,		
	· · ·	E-MAIL: KV	valker(@rti.org				
6. HUMAN SUBJECTS		7. VER1	EBRAT		LS	k		
No 6a. Research Exempt	6b. Human Subjects Assurance	No. 🛛 No			. 78	a. If "Yes," IACUC a	pproval Date	
	FWA-3331	Yes				, m	المعلمان أسعاني	
	6c. NIH-Defined Phase III			are Assura		Or par		
If Exempt ("Yes" in 6a): Exemption No. 4	Clinical Trial X No Yes		ai vveira	ire Assura	ance No.	-ud		
If Not Exempt ("No" in 6a):								
IRB approval date						4		
	Expedited Revie					·		
8. COSTS REQUESTED FOR N	EXT BUDGET PERIOD	9. INVENTIC	NS AND	PATEN	-	-3		
8a. DIRECT \$1,666,084	8b. TOTAL \$2,926,157	⊠ No □	Yes	If "Yes,"	Previ	ously Reported		
					Not P	reviously Reported		
10. PERFORMANCE SITE(S) (Org		11a. PRINCI				301-770-8214		
Research Triangle Inst	litute	OR PROGRA	M DIRE	CTOR (It	em 2a) FAX	301-230-4646	1	
3040 Cornwallis Road			TDATE			. 'A () (
P.O. Box 12194		11b. ADMINIS				919-316-3531		
Research Triangle Par	k, NC 27709		-,		FAX	919-541-7148		
	· · · ·				FICIAL SIG	NING FOR APPLICA		
· .				^N <i>(item 1</i> Walker	4)			
	۲.				Officer			
			9-316-3	•		FAX 919-541-71	48	
,		E-MAIL kw	alker	@rti.org	l I	·		
12. Corrections to Page 1 Face Pa								
-	-							

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13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.	SIGNATURE OF PI/PD NAMED IN 2a. (In ink. "Per" signature not acceptable.)	DATE 3/24/05
statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Per" signature not acceptable.	DATE 3/29/05
PHS 2590 (Rev. 09/04) Eace Page	, (Form Page 1

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IRB Approval Dates

PROTOCOLS	APPROVALS
Not responsive	
SUPPORT Trial	Pending
Not responsive	

PHS 398/2590 (Rev. 09/04)

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Pages 4 through 16 redacted for the following reasons: Not responsive

Principal Investigator/Program Director	Das, Abhik	
PROGRESS REPORT SUMMARY	GRANT NUMBER HD36790	
	PERIOD COVERED BY	THIS REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH
W. Kenneth Poole	June 1, 2004	May 31, 2005
APPLICANT ORGANIZATION		
Research Triangle Institute		
TITLE OF PROJECT (Repeat title shown in Item 1 on first page	e)	· · · · · · · · · · · · · · · · · · ·
Cooperative Multicenter Neonatal Data Center		
A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects No Cha	nge Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals No Cha	nge Since Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS.		· · ·

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

a. Specific Aims

b. Studies and Results

The seventh year funding period for the DCC has been spent supporting the investigators in bringing up new protocols and supporting the site investigators in the preparation of manuscripts and abstracts for the Pediatric Academic Societies (PAS) and the American Academy of Pediatrics (AAP). The active studies, including those enrolling infants and those with manuscripts in preparation were: Not responsive

SUPPORT and Not responsive
At the end of year 7 of the funding cycle the data
management intrastructures are in place for all studies except some central data editing programming for
Not responsive and SUPPORT ^{Not responsive}
and SOPPOR

During the 2004 PAS meetings in May, Network investigators presented nineteen abstracts. These are listed in Table 1. In the months of October, November and the early part of December, the DCC supported investigators in the preparation of over thirty abstracts for SPR 2005. Those accepted for presentation are listed in Table 2. In addition, Dr. Krisa Van Meurs submitted a late breaking abstract entitled **"Inhaled Nitric Oxide for Preterm Infants with Severe Respiratory Failure"**.

Table 1. Abstracts Presented at the 2004 Pediatric Academic Society

PHS	398/2590	(Rev	09/04	۱
1110	330/2330	(1104)	00/04	,

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 Table 2.
 NICHD Neonatal Research Network 2004 PAS Presentations (Moscone West Convention Center, San Francisco, CA)

PHS 398/2590 (Rev. 09/04)

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Page 20 redacted for the following reason: Not responsive

Maynard R Rasmussen, Wade Rich, Gregory S Rasmussen and Neil Finer	Prospective Evaluation of Altered Pulse Oximeters Designed To Produce Different Oxygen Exposures for ELBW Infants: Pilot for the SUPPORT Trial
Not responsive	

In terms of manuscript support, the Network had it best year ever in 2004. There were 20 articles published and 12 that were accepted for publication. Eight manuscripts are under internal review or are being put in final draft form. The published and accepted manuscripts are given below.

Manuscripts

Not responsive

Published

Not responsive PHS 398/2590 (Rev. 09/04) Page 20 Continuation Format Page Pages 22 through 31 redacted for the following reasons: Not responsive

Progress Report Scanning Cover Sheet

5U01HD036790-09

PI Name: Org: Start Date: Snap: Appl ID: Rec'd Date: DAS, ABHIK RESEARCH TRIANGLE INSTITUTE 06/01/2006 N/A (NEEDS TO BE BOOKMARKED) 7068473 03/30/2006

Department of Health and Human Services	Review Group Type Activity Grant Number 5 40 U01 HD036790 - 09		
Public Health Services	5 40 U01 HD036790 - 09 Total Project Period		
Grant Progress Report	From: 08/01/1998 Through: 05/31/2008 Requested Budget Period		
	From: 06/01/2006 Through: 05/31/2007		
1. TITLE OF PROJECT	Prom: 00/01/2000 Through: 00/31/2007		
Data Coordinating Center for the Cooperative	Multicenter Neonatal Research Network		
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	3. APPLICANT ORGANIZATION		
(Name and address, street, city, state, zip code)	(Name and address, street, city, state, zip code) Research Triangle Institute		
Abhik Das			
6110 Executive Blvd, Suite 902	PO Box 12194		
Rockville, MD 20852-3907	3040 Cornwallis Road Research Triangle Park, NC 27709 MAR 3 0 2006		
	Research Triangle Park, NC 27709 MAR 3 0 2000		
2b. E-MAIL ADDRESS	4. ENTITY IDENTIFICATION NUMBER		
adas@rti.org	1560586338A1		
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Statistics and Epidemiology	5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL S. Kent Walker		
2d. MAJOR SUBDIVISION	3040 Cornwallis Road		
Social and Statistical Sciences	P.O. Box 12194 Research Triangle Park, NC 27709		
	E-MAIL: kwalker@rti.org		
6. HUMAN SUBJECTS	7. VERTEBRATE ANIMALS		
□ No	De No. X No 7a. If "Yes," IACUC approval Date		
Yes No Yes FWA No. 3331	Yes		
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III	7b. Animal Welfare Assurance No.		
Exemption No. 4 Clinical Trial 🛛 No 🗋 Ye	35		
If Not Exempt ("No" in 6a): Full IRB or Expedited Review	iew		
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVENTIONS AND PATENTS		
	9. INVENTIONS AND PATENTS		
8a. DIRECT \$1,688,966 8b. TOTAL \$2,948,905 10. PERFORMANCE SITE(S) (Organizations and addresses)	No Yes If "Yes," Previously Reported Not Previously Reported		
8a. DIRECT \$1,688,966 8b. TOTAL \$2,948,905 10. PERFORMANCE SITE(S) (Organizations and addresses) Research Triangle Institute	No Yes If "Yes," Previously Reported Not Previously Reported 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a)		
8a. DIRECT \$1,688,966 8b. TOTAL \$2,948,905 10. PERFORMANCE SITE(S) (Organizations and addresses) Research Triangle Institute 3040 Cornwallis Raod	No Yes If "Yes," Previously Reported Not Previously Reported Not Previously Reported 11a, PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) TEL 301-770-8214 FAX 301-230-4646		
8a. DIRECT \$1,688,966 8b. TOTAL \$2,948,905 10. PERFORMANCE SITE(S) (Organizations and addresses) Research Triangle Institute 3040 Cornwallis Raod P.O. Box 12194	No Yes If "Yes," Previously Reported Not Previously Reported Not Previously Reported 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) TEL 301-770-8214 FAX 301-230-4646 11b. ADMINISTRATIVE OFFICIAL NAME (Item 5) TEL 919-316-3531		
8a. DIRECT \$1,688,966 8b. TOTAL \$2,948,905 10. PERFORMANCE SITE(S) (Organizations and addresses) Research Triangle Institute 3040 Cornwallis Raod	No Yes If "Yes," Previously Reported Not Previously Reported Not Previously Reported 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) TEL 301-770-8214 FAX 301-230-4646 11b. ADMINISTRATIVE OFFICIAL NAME (Item 5) TEL 919-316-3531 S. Kent Walker FAX 919-541-6624		
8a. DIRECT \$1,688,966 ab. TOTAL \$2,948,905 10. PERFORMANCE SITE(S) (Organizations and addresses) Research Triangle Institute 3040 Cornwallis Raod P.O. Box 12194	No Yes If "Yes," Previously Reported Not Previously Reported Not Previously Reported 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) TEL 301-770-8214 FAX 301-230-4646 11b. ADMINISTRATIVE OFFICIAL NAME (Item 5) TEL 919-316-3531 S. Kent Walker FAX 919-541-6624 11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT Signing For Applicant		
8a. DIRECT \$1,688,966 ab. TOTAL \$2,948,905 10. PERFORMANCE SITE(S) (Organizations and addresses) Research Triangle Institute 3040 Cornwallis Raod P.O. Box 12194	No Yes If "Yes," Previously Reported Not Previously Reported Not Previously Reported 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) TEL 301-770-8214 FAX 301-230-4646 11b. ADMINISTRATIVE OFFICIAL NAME (Item 5) TEL 919-316-3531 S. Kent Walker FAX 919-541-6624 11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14) SIGNING FOR APPLICANT		
8a. DIRECT \$1,688,966 ab. TOTAL \$2,948,905 10. PERFORMANCE SITE(S) (Organizations and addresses) Research Triangle Institute 3040 Cornwallis Raod P.O. Box 12194	No Yes If "Yes," Previously Reported Not Previously Reported Not Previously Reported 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) TEL 301-770-8214 FAX 301-230-4646 11b. ADMINISTRATIVE OFFICIAL NAME (Item 5) TEL 919-316-3531 S. Kent Walker FAX 919-541-6624 11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14) NAME NAME S. Kent Walker		
8a. DIRECT \$1,688,966 8b. TOTAL \$2,948,905 10. PERFORMANCE SITE(S) (Organizations and addresses) Research Triangle Institute 3040 Cornwallis Raod P.O. Box 12194	No Yes If "Yes," Previously Reported Not Previously Reported Not Previously Reported 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) TEL 301-770-8214 FAX 301-230-4646 11b. ADMINISTRATIVE OFFICIAL NAME (Item 5) TEL 919-316-3531 S. Kent Walker FAX 919-541-6624 11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14) NAME NAME S. Kent Walker TITLE Sr. Contracting Officer		
8a. DIRECT \$1,688,966 ab. TOTAL \$2,948,905 10. PERFORMANCE SITE(S) (Organizations and addresses) Research Triangle Institute 3040 Cornwallis Raod P.O. Box 12194	No Yes If "Yes," Previously Reported Not Previously Reported Not Previously Reported 11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) TEL 301-770-8214 FAX 301-230-4646 11b. ADMINISTRATIVE OFFICIAL NAME (Item 5) TEL 919-316-3531 S. Kent Walker FAX 919-541-6624 11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14) NAME NAME S. Kent Walker		

	TITLE S TEL 9	Sr. Contracting Officer 19-316-3531 walker@rti.org	FAX 919-541-	6624
12. Corrections to Page 1 Face Page				
13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR AS statements herein are true, complete and accurate to the best of m any false, fictitious, or fraudulent statements or claims may subject administrative penalties. I agree to accept responsibility for the so and to provide the required progress reports if a grant is awarded	my knowledge. I am av ct me to criminal, civil, o cientific conduct of the p	ware that (In ink. "Per" signatur project		DATE 3/28/06
14. APPLICANT ORGANIZATION CERTIFICATION AND AC statements herein are true, complete and accurate to the best of n obligation to comply with Public Health Services terms and conditi result of this application. 1 am aware that any false, fictitious, or fra may subject me to criminal, civil, or administrative penalties.	my knowledge, and acc ions if a grant is awarde	cept the 11c. (In ink. "Per" sig		DATE 3/28/06
PHS 2590 (Rev. 09/04)	Face Page	- AV		Form Page

Page 3 redacted for the following reason: Not responsive

IRB Approval Dates

PROTOCOLS	APPROVALS
Not responsive	
12. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (The SUPPORT Trial)	• 03/21/2006
a. Sub-study: Antenatal Screening and Consent in a Research	
Network Protocol	03/21/2006
b. Sub-study: Breathing Outcomes Study	03/21/2006
c. Sub-study: Neuroimaging and Neurodevelopmental Outcome	
Study (MRI)	03/21/2006
Not responsive	

Pages 5 through 25 redacted for the following reasons: Not responsive

Principal Investigator/Program Director (Last, Firs	t, Middle): <u>Das Abhik</u>					
PROGRESS REPORT SUMMARY	GRANT NUMBER U01 HD36790					
	PERIOD COVERED BY	THIS REPORT				
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Abhik Das	FROM June 1, 2005					
APPLICANT ORGANIZATION Research Triangle Institute	· · ·					
TITLE OF PROJECT (Repeat title shown in Item 1 on first pa Cooperative Multicenter Neonatal Data Center	ge)					
A. Human Subjects (Complete Item 6 on the Face Page)	·····					
	nange Since Previous Submission	Change				
B. Vertebrate Animals (Complete Item 7 on the Face Page)						
Use of Vertebrate Animals	nange Since Previous Submission	Change				
SEE PHS 2590 INSTRUCTIONS.						
Targeted/Planned Enrollment Format Page. a. Specific Aims responsive						
b. Studies and Results The eighth year funding period for the DCC has new protocols and supporting the site investigator Pediatric Academic Societies (PAS) meetings. The with manuscripts in preparation are	s in the preparation of ma	nuscripts and abstracts for the				
SUPPORT, Not responsive	. Stu	idies on the horizon include the				
lot responsive		In addition, the DCC has also				
spent substantial effort in developing and fielding	4 secondary studies to the ot responsive	SUPPORT trial (breathing				
outcomes, MRI, antenatal consent, and growth).						
At the end of year 8 of the funding cycle the da	ata management infrastru					

including the ^{Not responsive} except some central data editing programming for the SUPPORT growth and breathing outcomes secondary studies),^{Not responsive} During the 2005 PAS meetings in May, Network investigators presented thirty-two abstracts. These are listed in Exhibit 1 below. In addition, during the months of October, November and the early part of December, 2005, the DCC supported investigators in the preparation of twenty-five abstracts for the 2006 PAS meetings. Those accepted for presentation are listed in Exhibit 2 below.

Exhibit 1. Abstracts Presented at the 2005 Pediatric Academic Society

Not responsive

Pages 28 through 29 redacted for the following reasons: Not responsive

In terms of manuscript support, the Network had it best year ever in 2005. There were 26 articles published in 2005. Currently there are 8 that were accepted for publication. Twenty manuscripts are under internal review or are being put in final draft form. The published and accepted manuscripts are given below.

Manuscripts

Not responsive

Published

Not responsive

PHS 398/2590 (Rev. 09/04)

Continuation Format Page

Not responsive

Continuation Format Page

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3:

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In Press

Not responsive

Other activities of the DCC during the eighth funding cycle have included: Not responsive

Plans for Year 9

During the next funding period, the DCC will:

Not responsive

Pages 34 through 39 redacted for the following reasons: Not responsive **Progress Report Scanning Cover Sheet**

5U01HD036790-10

PI Name:DAS, ABHIKOrg:RESEARCH TRIANGLE INSTITUTEStart Date:06/01/2007Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7247248Rec'd Date:03/29/2007

Form Approved Through 09/30/2007					OMB No. 0925-0001	
Department of Health and Human Services Public Health Services	Review	Group	Type	Activity	Grant Number U01 HD036790 ~ / 0	
	Total Project Period					
Crant Brogroop Bonart	From: (08/01/1998	3	Thro	ough: 05/31/2008	
Grant Progress Report	Request	ted Budget Po	eriod			
	From: (06/01/2007	,	Thro	ough: 05/31/2008	
1. TITLE OF PROJECT		· · · ·				
Data Coordinating Center for the Cooperative					etwor	
 2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code) Abhik Das 6110 Executive Blvd, Suite 902 Rockville, MD 20852-3907 	(Name Rese PO I 3040	ICANT ORG and address earch Tria Box 12194 Cornwal earch Tria	s, street, c angle In 4 Ilis Roa	sity, state, zip stitute d	MAR 2 9 2007	
2b. E-MAIL ADDRESS adas@rti.org		TY IDENTIFI 586338A1		NUMBER		
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Statistics and Epidemiology 2d. MAJOR SUBDIVISION Social and Statisitcal Sciences						
	E-MAIL:	kwalker@				
6. HUMAN SUBJECTS No Yes 6a. Research Exempt Yes 6b. Human Subjects Assurance FWA No. 3331	No.	/ERTEBRATI No Yes	E ANIMAL		. If "Yes," IACUC approval Date	
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III Exemption No. Clinical Trial No		Animal Welfa	re Assura	nce No.		
Exemption No. Clinical Trial No Ye If Not Exempt ("No" in 6a): If Bapproval date Full IRB or IRB approval date See next pg Expedited Review						
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVE	NTIONS AND	PATENT	s		
8a. DIRECT \$1,702,065 8b. TOTAL \$2,946,080	No No	Yes	lf "Yes,"		ously Reported reviously Reported	
10. PERFORMANCE SITE(S) (Organizations and addresses)		INCIPAL INV			301-770-8214	
Research Triangle Institute PO Box 12194		GRAM DIRE		FAX	301-230-4646	
3040 Cornwallis Road	11b. ADN	MINISTRATIV	E OFFIC	IAL TEL	919-316-3531	
Research Triangle Park, NC 27709	NAME (II S. Kent	_{tem 5)} t Walker		FAX		
· .		ME AND TITI GANIZATION S. Kent V	\ (Item 14		IING FOR APPLICANT	
	TITLE	Sr. Contr	acting	Officer		
	TEL	919-316-3	3531	ŀ	AX 919-541-7148	
	E-MAIL	kwalker@)rti ora	I		
12. Corrections to Page 1 Face Page	.1					

13. APPLICANT ORGANIZATION CERTIFICATION Al statements herein are true, complete and accurate to the b obligation to comply with Public Health Services terms and result of this application. I am aware that any false, fictition may subject me to criminal, civil, or administrative penaltie	est of my knowledge, and accept the conditions if a grant is awarded as a us, or fraudulent statements or claims	11c. (In ink.	"Per" signature not	DATE 3 /28/07
PHS 2590 (Rev. 04/06)	Face Page		······································	Form Page 1

	Current NRN IRB App	Total Dates (20		
	BROTOCOL S	APPROVAL	R=Renewal	EXPIRATION DATE
[PROTOCOLS	DATE	l= Initial	
	Not responsive		E= Exemption	
1.				
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b.				
12.				
	The Surfactant Positive Airway Pressure and		R	· · · · ·
13.	Pulse Oximetry Trial in Extremely Low Birth	03/23/2007	'`	03/23/08
	Weight Infants (The SUPPORT Trial)			
а.	Sub-study: Antenatal Screening and Consent in		R	00/00/07
	a Research Network Protocol Sub-study:	03/21/2006		03/23/07
		03/21/2006	R	03/23/07
b.	Sub-Study: Breathing Outcomes Study Sub-	50/2 I/2000		
	study:			
c.		03/21/2006	R	03/23/07
	Sub-Study: Neuroimaging and			
۱ <u> </u>	Neurodevelopmental Outcome Study (MRI):			
	Not responsive			
14.				
'4.				
L				
	•			

Current NRN IRB Approval Dates (2006 - 2007)

Principal Investigator/Program Director (Last, First, Middle): Das, Abhik

	PROTOCOLS	APPROVAL DATE	R=Renewal I= Initial E= Exemption	EXPIRATION DATE
15.	Not responsive			
16.				
17.				

Pages 5 through 26 redacted for the following reasons: Not responsive

Principal Investigator/Program Director (Last, First, Middle):	Das, Abhik	
PROGRESS REPORT SUMMARY	GRANT NUMBER U01 HD36790	
	PERIOD COVERED BY THIS F	REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH
Abhik Das	June 1, 2007	May 31, 2008
APPLICANT ORGANIZATION Research Triangle Institute		
TITLE OF PROJECT (Repeat title shown in Item 1 on first page) Cooperative Multicenter Neonatal Data Center		
A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects 🛛 🖄 No Chang	e Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals No Chang	e Since Previous Submission	Change
C. Select Agent Research No Chang	e Since Previous Submission	Change
D. Multiple PI Leadership Plan No Chang	e Since Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS.		

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

a. Specific Aims

b. Studies and Results

The ninth year funding period for the DCC has been spent supporting the investigators in bringing up new protocols, including bringing new Network sites onboard, and supporting the site investigators in the preparation of manuscripts and abstracts for the Pediatric Academic Societies (PAS) meetings. The active studies, including those enrolling infants and those with manuscripts in preparation are: Not responsive

SUPPORT, Not responsive

Studies on the horizon include the Not responsive

In addition, the DCC has also spent substantial effort in developing and fielding 4 secondary studies to the SUPPORT trial (breathing outcomes, MRI, antenatal consent, and growth).

Principal Investigator/Program Director (Last, First, Middle): Das, Abhik

Not responsive

Not responsive

Not responsive

The DCC accomplished several other tasks in the 9th year. Some of the more critical ones are highlighted below:

• Initiation of regular site clinical monitoring visits, specially for the SUPPORT trial

During the 2006 PAS meetings in May, Network investigators presented thirty-three abstracts. These are listed in Exhibit 1 below. In addition, during the months of October, November and the early part of December, 2006, the DCC supported investigators in the preparation of twelve abstracts for the 2007 PAS meetings, as well as one late-breaker submission. Those accepted for presentation are listed in Exhibit 2 below.

Exhibit 1. Abstracts Presented at the 2006 Pediatric Academic Society

Page 29 redacted for the following reason: Not responsive Not responsive

Not responsive

Exhibit 2. Abstracts Accepted for Presentation at the 2007 Pediatric Academic Society

In terms of manuscript support, the Network published 15 articles published in 2006. Currently there are 7 that have been accepted for publication. Twenty manuscripts are under external or internal review or are being put in final draft form. The published and accepted manuscripts are given below.

Manuscripts Published in 2006

Not responsive

Manuscripts In Press

Principal Investigator/Program Director (Last, First, Middle): Das, Abhik Not responsive

Other activities of the DCC during the ninth funding cycle have included:

Not responsive
Image: A state of the st

Plans for Year 10

During the next funding period, the DCC will:



Pages 34 through 41 redacted for the following reasons: Not responsive Progress Report Scanning Cover Sheet

5U10HD036790-12

PI Name:DAS, ABHIKOrg:RESEARCH TRIANGLE INSTITUTEStart Date:04/01/2009Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7630611Rec'd Date:01/29/2009

Form Approved Through 11/30/201	0					3 No. 0925-0001
Department of Health Public Heal		Review Group	Type S	Activity	Grant Number UH HD36790	-17 · arim
	· ·	Total Project Per	od			
		From: 08/01/1	998	Thre	ough: 03/31/2013	
Grant Progr	ess Repon	Requested Budg	et Period			
		From: 04/01/2	009	Thre	ough: 03/31/2010	
 TITLE OF PROJECT Data Coordinating Cen 	ter for the Coope	rative Neonatal Rese	arch Net	work		
2a. PROGRAM DIRECTOR / PRIN	-					<u></u>
(Name and address, street, city		adas@rti.c				
Abhik Das, Ph.D.			-	, LABORATO	RY, OR EQUIVALEN	<u>іт</u>
Research Triangle Inst		Statistics a	and Epide	emiology		
6110 Executive Blvd, S Rockville, MD 20852-3		2d. MAJOR SUB				
	501	Social and	Statisitc	al Science	S	
	. ,	2e. Tel: 301-77	'0-8214	Fax	: 301-230-4646	
3a. APPLICANT ORGANIZATION (Name and address, street, city,	state zin code)	3b. Tel: 919-5	41-5957	Fax	: 919-541-6624	
Research Triangle Insti			00040-			
PO Box 12194		3c. DUNS: 004	868105			
3040 Cornwallis Road		4. ENTITY IDEN	TIFICATION			
Research Triangle Par	k, NC 27709	15605863				¹ JAN 29
6. HUMAN SUBJECTS	Yes	5. NAME, TITLE	AND ADDF	ESS OF ADM	INISTRATIVE OFFIC	JAL
6a. Research If Exempt ("		pt ("No" in Contract S	pecialist			
Exempt 6a):	6a): No. IRB approva	DO Boy 11	-	40 Cornwal	llis Road	
No Yes Exemption 1			•	Park, NC 2		
6b. Federal Wide Assurance No.	EN/A 2221	 	5057	F	c 919-541-6624	
	FVVA 3331				° 919-041-0024	
6c. NIH-Defined Phase III Clinical Trial No X Yes		E-MAIL: ekapla	an@rti.or	g .		
7. VERTEBRATE ANIMALS	No Yes	10. PROJECT/PE	RFORMAN	CE SITE(S)		
7a. If "Yes," IACUC approval Date		Organizational Na	me: Rese	earch Trian	igle Institiute	
7b. Animal Welfare Assurance No.		DUNS: 00486	8105		-	
8. COSTS REQUESTED FOR NE		Street 1: PO E		<u></u>		
	8b. TOTAL \$2,999,6			·	Dunk	
9. INVENTIONS AND PATENTS	🛛 No 🗌 Yes	city: Researc	n i riangi			
If "Yes, Previously Reported		State: NC			ovince:	
Not Previously Rep	bried	Country: US		Zip	/Postal Code: 2770)9
		Congressional Di	stricts: NC	-4th		
11. NAME AND TITLE OF OFFIC		LICANT ORGANIZATION	tem 13)			
David Faucette, Sr. Cont	act Negotiator					
TEL: 919-541-7176	FAX: 9	19-316-7344		E-MAIL: dh	f@rti.org	
12. Corrections to Page 1 Face Pa	ge					
 APPLICANT ORGANIZATION statements herein are true, completion 		•		· · ·	-	DATE 1/28/2009
obligation to comply with Public He result of this application. I am awar	alth Services terms and cor	nditions if a grant is awarded as a		ning - La		112012009
result of this application. I am awar		a nauquient statements of claims	Na	ned Th	com	
may subject me to criminal, civil, or	administrative penalties.					Form Page 1

Program Director/Principal Investigator (Last, First, Middle): Das, Abhik

R=Renewal **EXPIRATION RTI IRB** APPROVAL I= Initial DATE PROTOCOLS Number DATE E= Exemption Not responsive 1. 2. 3. 4. 5. 6, а. 7. 8. 9. 10. 11. a. b. 12. R The Surfactant Positive Airway Pressure and 13. Pulse Oximetry Trial in Extremely Low Birth 11286 03/20/08 03/23/09 Weight Infants (The SUPPORT Trial) Sub-study: Antenatal Screening and Consent in a R а. 03/20/08 03/23/09 Research Network Protocol Sub-study: R 03/23/09 03/20/08 b. Sub-Study: Breathing Outcomes Study Sub-study: 03/20/08 R 03/23/09 Sub-Study: Neuroimaging and C. Neurodevelopmental Outcome Study (MRI): Not responsive d. 14.

Current NRN IRB Approval Dates (2008 – 2009)

	PROTOCOLS Not responsive	RTI IRB Number	APPROVAL DATE	R=Renewal I= Initial E= Exemption	EXPIRATION DATE
15.					
16.					
17.					
18.					
19.					
20.					
21.					
22.					
23. 24.					
25.					
26.					
27.	Extended follow-up at 6-7 years of age of patients enrolled in the Neuroimaging and Neurodevelopmental Outcome Secondary to SUPPORT.		Under development		

Program Director/Principal Investigator (Last, First, Middle): Das, Abhik

PHS 398/2590 (Rev. 11/07)

Pages 5 through 37 redacted for the following reasons: Not responsive

PROGRESS REPORT SUMMARY	ANT NUMBER 01 HD036790			
PE				
	RIOD COVERED BY			
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	NOD COVERED DI	THIS REPORT		
	OM	THROUGH		
Abhik Das 6/*	1/2008	3/31/2009		
APPLICANT ORGANIZATION				
RTI International				
TITLE OF PROJECT (Repeat title shown in Item 1 on first page)				
Data Center for the Cooperative Neonatal Research Netw	vork			
A. Human Subjects (Complete Item 6 on the Face Page)		······································		
Involvement of Human Subjects No Change Sinc	e Previous Submission	Change		
B. Vertebrate Animals (Complete Item 7 on the Face Page)				
Use of Vertebrate Animals No Change Sinc	e Previous Submission	Change		
C. Select Agent Research No Change Sinc	No Change Since Previous Submission			
D. Multiple PD/PI Leadership Plan No Change Sinc	e Previous Submission	Change		
SEE PHS 2590 INSTRUCTIONS.				

a. Specific Aims Not responsive

p. oludico alla Resalto	b.	Studies	and	Results
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The eleventh year funding period for the NRN DCC has been spent supporting the investigators in bringing up new protocols, including the support of collaborating sites that are not members of the Network, but recruit or follow up patients for specific trials and studies, and supporting the site investigators in the preparation of manuscripts for peer reviewed journal publication and abstracts for the Pediatric Academic Societies (PAS) meetings. The active studies enrolling infants and those with manuscripts in preparation are:

SUPPORT	
Studies on the horizon for which substantial effort was ex	kpended in developing
study materials and forms include the Not responsive	
	In year 11 the DCC
has also spent substantial effort in developing and fielding 4 secondary studies to the	SUPPORT trial
(breathing outcomes, MRI, antenatal consent, and growth), as well as Not responsive	

Not responsive

Numerous statistical analyses, including primary analyses for Not responsive

as well as presentation of 3rd interim monitoring report for the SUPPORT trial to the NRN DSMC. Further details regarding presentations and publications are provided below.

During the 2008 PAS meetings in May, Network investigators presented 13 abstracts. These are listed in Exhibit 1 below. In addition, during the months of October, November and the early part of December, 2008, the DCC supported investigators in the preparation of 19 abstracts for the 2009 PAS meetings. Those submitted for presentation are listed in Exhibit 2 below. All these abstracts are based on statistical analyses conducted by DCC statisticians.

Program Director/Principal Investigator (Last, First, Middle): Das, Abhik

Exhibit 1. Abstracts Presented at the 2008 Pediatric Academic Society



Not responsive

In terms of manuscript support, as of the end of September 2008, the Network had published 14 articles in 2008, with 11 that have been accepted for publication in peer reviewed journals. More than twenty manuscripts are under various stages of development. Barring a handful of single-center ancillary studies, all of these were supported by statisticians at the DCC, who are listed as co-authors. The published and accepted manuscripts are presented below.

Manuscripts Published in 2008

Program Director/Principal Investigator (Last, First, Middle): Das, Abhik

Manuscripts In Press

Not responsive

Not responsive

Plans for Year 12

During the next funding period, the DCC will:

Program Director/Principal Investigator (Last, First, Middle): Das, Abhik

•	Not responsive
•[Perform close-out operations for the SUPPORT trial that is expected to complete enrollment in early 2009; Not responsive
•	NOLTESPOILSIVE
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sponsiv	e

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Pages 46 through 53 redacted for the following reasons: Not responsive

5U10HD036790-13

PI Name:	DAS, ABHIK
Org:	RESEARCH TRIANGLE INSTITUTE
Start Date:	04/01/2010
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	7798585
Rec'd Date:	01/29/2010

Form Approved Through 06/30/2012					OMB	No. 0925-0001
Department of Health and Human Se Public Health Services	ervices	Review Group ZHD1DSRA03	Type 5	Activity U10	Grant Number 5 U10 HD0: 3	790.12
		Total Project Period	•			
Grant Brograss Ba	nort	From: 08/01/1998	3	Thr	ough: <u>3/31/2013</u>	
Grant Progress Re	port	Requested Budget P	eriod			
		From: 04/01/2010	2	Thr	_{rough:} 3/31/2011	
1. TITLE OF PROJECT Data Coordinating Center for the		erative Neonatal	Resear	rch Netwo	ork	
2a. PROGRAM DIRECTOR / PRINCIPAL INVES		2b. E-MAIL ADDRES	S			
(Name and address, street, city, state, zip cod Abhik Das, Ph.D.	e)	adas@rti.org			ORY, OR EQUIVALEN	
Research Triangle Institute 6110 Executive Blvd, Suite 902		Statistics and			KT, OK EQUIVALEN	1
Rockville, MD 20852-3907		2d. MAJOR SUBDIVI	-			_
					nmental Science	S
		2e. Tel: 301-770-	8214	Fa	x: 301-230-4646	
3a. APPLICANT ORGANIZATION		3b. Tel: 919-990-	8489	Fa	x: 919-541-6624	-11
(Name and address, street, city, state, zip code Research Triangle Institute	e)					Ë
3040 Cornwallis Road		3c. DUNS: 00486	8105			2
PO Box 12194		4. ENTITY IDENTIF	CATION	NUMBER		
Research Triangle Park, NC 2770)9	1560586338/				2010
6. HUMAN SUBJECTS No Yes		5. NAME, TITLE AN	D ADDRE	SS OF ADM	MINISTRATIVE OFFIC	
	lot Exempt ("No" in	Sherri Spinks	s, Sr. C	ontract S	pecialist	
Exempt 6a): 6a) No Yes Exemption No. IRE	: 3 approval date	3040 Cornwa			•	
		Research Tri	angle F	Park, NC	27709	
6b. Federal Wide Assurance No. FWA 3331		Tel: 919-990-84	89	Fa	x: 919-541 - 6624	
6c. NIH-Defined Phase III Clinical Trial 🔄 No 🔀 Yes		E-MAIL: spinks@	rti.org			
7. VERTEBRATE ANIMALS No	es	10. PROJECT/PERF	ORMANC	E SITE(S)		
7a. If "Yes," IACUC approval Date		Organizational Name	Resea	arch Triai	ngle Institute	
7b. Animal Welfare Assurance No.		DUNS: 00486810	05			
8. COSTS REQUESTED FOR NEXT BUDGET	PERIOD	Street 1: 3040 Co	ornwalli	s Road		
8a. DIRECT \$1,714,249 8b. TOTAL \$3	,012,622	Street 2: PO Box	12194			
9. INVENTIONS AND PATENTS No	Yes	City: Research 7	Friangle	Park Co	unty: Durham	
lf "Yes, 🔲 Previously Reported		State: NC		Pro	ovince:	
Not Previously Reported		Country: US		Zip	o/Postal Code: 2770	9
		Congressional Distric	ts: NC -	4th		
11. NAME AND TITLE OF OFFICIAL SIGNING F Timothy Weinzapfel, Director of Cor		RGANIZATION (Item	13)			
TEL: 919-541-5906	FAX: 919-541-	-6624		E-MAIL: tir	nw@rti.org	
12. Corrections to Page 1 Face Page						
13. APPLICANT ORGANIZATION CERTIFICATIO	ON AND ACCEPTA	NCE: I certify that the	GNATU			DÁTE
statements herein are true, complete and accurate to obligation to comply with Public Health Services term	o the best of my know	ledge, and accept the	1. (In ink			
result of this application. I am aware that any false,	fictitious, or fraudulent		2	//	\mathcal{C}	1-28-3010
may subject me to criminal, civil, or administrative pe PHS 2590 (Rev. 06/09)		Face Page	-/	/		Form Page 1

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				00,09,09		03/23/10
	14.					

Current NRN IRB Approval Dates (2009 - 2010)

	PROTOCOLS	RTI IRB Number	APPROVAL DATE	R=Renewal l= Initial E= Exemption SC= Study closeout	EXPIRATION DATE
15.	Not responsive			closeout	
16.					
17.					
18.					
19.					
20.					
21.					
22.					
23.					
24.					
25.					
26.					
27.	Extended follow-up at 6-7 years of age of patients enrolled in the Neuroimaging and Neurodevelopmental Outcome Secondary to SUPPORT.		Under development		

* New IRB process for Data Coordinating Center Submissions; received 'overall project approval' 04/15/2009 for these protocols

Pages 5 through 27 redacted for the following reasons: Not responsive

Program Director/Principal Investigator (Last	, First, Middle):	Das, Abhik		
		GRANT NUMBER	······	
PROGRESS REPORT SUMMA	RY	5 U10 HD036790		
		PERIOD COVERED BY TH	IS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGA	TOR	FROM	THROL	JGH
Abhik Das		04/01/2009	03/31/	2010
APPLICANT ORGANIZATION		- <u> </u>	I	
RTI International				
TITLE OF PROJECT (Repeat title shown in Item 1	on first page)			
Data Center for the Cooperative Neonata	l Research l	Network		
A. Human Subjects (Complete Item 6 on the Face Pag	ge)	· · · · · · · · · · · · · · · · · · ·		
Involvement of Human Subjects	No Chang	e Since Previous Submission		Change
B. Vertebrate Animals (Complete Item 7 on the Face F	Page)			
Use of Vertebrate Animals	No Chang	e Since Previous Submission		Change
C. Select Agent Research	No Chang	e Since Previous Submission		Change
D. Multiple PD/PI Leadership Plan	No Chang	e Since Previous Submission		Change
E. Human Embryonic Stem Cell Line(s) Used	No Chang	e Since Previous Submission		Change
SEE PHS 2590 INSTRUCTIONS.				

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

a. Specific Aims

b. Studies and Results

The twelfth year funding period for the NRN DCC has been spent supporting the investigators in bringing up new protocols, including the support of collaborating sites that are not members of the Network, but recruit or follow up patients for specific trials and studies, and supporting the site investigators in the preparation of manuscripts for peer reviewed journal publication and abstracts for the Pediatric Academic Societies (PAS) meetings. The active studies enrolling infants and those with manuscripts in preparation are:

SUPPORT; Not responsive	
	Significant preparatory activities also occurred for
the ^{Not responsive}	, as well as the approved School-age

follow up for the SUPPORT neuroimaging secondary study.

Other activities for the DCC in year 12 included substantial effort in supporting the reading of, and abstracting and keying the data from Not responsive and the SUPPORT neuroimaging secondary study, as well as analyzing the primary outcomes from the SUPPORT trial and the Not responsive and the support of

At the end of year 12 of the funding cycle the data management infrastructures are in place for all actively enrolling studies, and work is ongoing on developing study materials for the Not responsive

SUPPORT	Neuroimaging 6-7	Year Follow up studies.	<u>Completed or near</u>	<u>complete</u> studies :	such as
SUPPORT	Not responsive			while the pri	mary analysis from
the SLIDDC	DT trial was come	lated and two papars of	provided to the NE IN	٨	

the SUPPORT trial was completed and two papers submitted to the NEJM.

A complete list of the critical tasks accomplished by the DCC in year 12 is presented below:

•	Not responsive
•	Development of study materials and forms for the SUPPORT Neuroimaging School Age Follow Up Study
	Development of study materials and forms for the SUPPORT Neuroimaging School Age Follow Up Study (ongoing) and Not responsive
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In year 12 the DCC conducted numerous statistical analyses. Aside from the major ones mentioned previously, this included presentation of the 4th interim monitoring report for the SUPPORT trial to the NRN DSMC. Further details regarding presentations and publications are provided below.

During the 2009 PAS meetings in May, Network investigators presented 19 abstracts. These are listed in Exhibit 1 below. In addition, during the months of October, November and the early part of December, 2009, the DCC supported investigators in the preparation of 18 abstracts for the 2010 PAS meetings. Those submitted for presentation are listed in Exhibit 2 below. All these abstracts are based on statistical analyses conducted by DCC statisticians.



Exhibit 2. Abstracts Submitted for the 2010 Pediatric Academic Society Meeting

Carlo, W., Finer, N., and on behalf of the SUPPORT Subcommittee for the NICHD Neonatal Research Network. Randomized Trial of Oxygen Saturation Targets in Premature Infants-the SUPPORT Trial. (Submitted to the Society for Pediatric Research, Vancouver, Canada, May 1-4, 2010).

Finer, N., Carlo, W., and On behalf of the SUPPORT Subcommittee and the NICHD Neonatal Research Network. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants The SUPPORT Trial. (Submitted to the Society for Pediatric Research, Vancouver, Canada, May 1-4, 2010).

Not responsive

In terms of manuscript support, the Network published 19 articles in 2009, with 4 that have been accepted for publication in peer reviewed journals. More than twenty manuscripts are under various stages of development. Barring a handful of single-center ancillary studies, all of these were supported by statisticians at the DCC, who are listed as co-authors. The published and accepted manuscripts are presented below.

Manuscripts Published in 2009

Not responsive

Other activities of the DCC during the eleventh funding cycle have included:

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c. Plans for Year 13 During the next funding period, the DCC will:

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	primary analyses for s	primary analyses for SUPPORT Follow up	primary analyses for SUPPORT Follow up, Not responsive	primary analyses for SUPPORT Follow up, Not responsive



Pages 36 through 44 redacted for the following reasons: Not responsive

Development of Line 14h and Livenen Considered					OMB No. 0925-0001
Department of Health and Human Services Public Health Services	Review Group	Type 5	U10	Grant N HD4	umber 10461-05
	Total Project Pe				00/04/00
Grant Progress Report	1.10111.)5/15/01	T	rough:	03/31/06
	Requested Bud	get Period 04/01/05	т		03/31/06
1. TITLE OF PROJECT	From:		· ·	nrough:	
Cooperative Multicenter Neonatal Network					
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)	3. APPLICANT OR (Name and addre			zip code)	e (Prode
Neil Finer, MD	The Regents	s of the L	Iniversi	y of Cali	
University of California, San Diego	University of			Diego	ang ang ang ang
Department of Pediatrics	9500 Gilman La Jolla, Cal	-		034	4-94-54
9500 Galman Drive La Jolla, CA 92093		ionna o	2030-0	554	07
2b. E-MAIL ADDRESS	4. ENTITY IDENTI	FICATION	UMBER		
nfiner@ucsd.edu	1956006144A	.1			
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Peds/Neonatology	5. TITLE AND ADD			RATIVE OF	FICIAL
2d. MAJOR SUBDIVISION	OCGA/UCSI				
School of Medicine	9500 Gilman		934		
	La Jolla, Cal			934	
	E-MAIL: khitčke	y@ucsd	edu		
6. HUMAN SUBJECTS	7. VERTEBRA	TE ANIMAL	.S		•
No 6a. Research Exempt 6b. Human Subjects Assurance	No. No			7a. If "Yes	," IACUC approval Date
	Yes				
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III Exemption No. Clinical Trial No	7b. Animal Wel	fare Assura	nce No.		
If Not Exempt ("No" in 6a):		· '			
IRB approval date 11/18/04	w				
			<u>^</u>		
B. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVENTIONS AN	ID PATENT	s		
B. COSTS REQUESTED FOR NEXT BUDGET PERIOD Ba. DIRECT \$ 216,644 8b. TOTAL \$ 329,299	9. INVENTIONS AN	ID PATENT If "Yes,"	Pre	viously Rep Previously I	
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Pages 2 through 3 redacted for the following reasons: Nonresponsive (unrelated to SUPPORT) Principal Investigator/Program Director (Last, First, Middle): Finer, Neil

GRANT NUMBER 5 U10 HD40461-05 PROGRESS REPORT SUMMARY PERIOD COVERED BY THIS REPORT PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR THROUGH FROM FINER, NEIL 04/01/2005 03/31/2006 APPLICANT ORGANIZATION The Regents of the University of California University of California San Diego TITLE OF PROJECT (Repeat title shown in Item 1 on first page) **Cooperative Multicenter Neonatal Research Network** A. Human Subjects (Complete Item 6 on the Face Page) Involvement of Human Subjects X No Change Since Previous Submission Change B. Vertebrate Animals (Complete Item 7 on the Face Page) Use of Vertebrate Animals X No Change Since Previous Submission Change SEE PHS 2590 INSTRUCTIONS. WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page. I Name UCSD IRB # Sharp Mary Birch IRB# Date of Approval Protocol Name Date of Approval SUPPORT 08/26/2004 041093 10/20/2004 041069 IRB Letters Attached. Nonresponsive (unrelated to SUPPORT)

Principal Investigator/Program Director (Last, First, Middle): Finer, Neil N.

UCSD Division of Neonatology in conjunction with Sharp Mary Birch Hospital is currently starting it's fifth year of 5 in the NICHD Neonatal Network. The Neonatal Network was formed in 1986, the National Institute of Child Health and Human Development (NICHD) established the Neonatal Research Network to conduct multi-center clinical trials in neonatal medicine and management. The Network is currently funded as a cooperative agreement between 16 Clinical Centers, the Data Coordinating Center (Research Triangle Institute), and the NICHD. The Steering Committee for the Network consists of the Principal Investigator from each Clinical Center, the Data Coordinating Center, and the NICHD Neonatal Research program officer. The Steering Committee has the responsibility of establishing study protocols and monitoring their implementation. For the year of 2004-2005, San Diego site has

Dr. Finer is the Principal Investigator for the the Surfactant Positive Airway Pressure and Oxygenation Trial (SUPPORT), which has recently begun enrolling patients. This is a prospective, randomized, factorial 2X2 design multi-center trial. The individual factors being tested are:

1) A prospective comparison of CPAP and a permissive ventilatory strategy begun in the delivery room and continuing in the NICU with early (< 30 minutes) surfactant and mechanical ventilation.

2) A prospective comparison of a lower (SpO2 range of 85% to 89%) with a higher more conventional SpO2 range (91% to 95%) until the infant is no longer requiring ventilatory support or oxygen.

The primary hypotheses are: 1) Relative to infants managed with prophylactic surfactant and conventional ventilation the use of early CPAP and a permissive ventilatory strategy in infants of less than 28 weeks gestation with continuing CPAP in the NICU will result in an increased survival without BPD at 36 weeks. •2). Relative to infants managed with a higher SpO2 range the use of a lower SpO2 range (85% to 89%) will result in an increase in survival without the occurrence of threshold ROP and/or the need for surgical intervention.

Pages 6 through 14 redacted for the following reasons: Nonresponsive (unrelated to SUPPORT) **Progress Report Scanning Cover Sheet**

5U10HD040492-05

PI Name:	GOLDBERG, RONALD
Org:	DUKE UNIVERSITY
Start Date:	04/01/2005
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	6891943
Rec'd Date:	02/11/2005

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Form Approved Through 5/2004					OMB No. 0925-0001	
Department of Health and Human Services Public Health Services		Review Group	Type 5	Activity U10	Grant Number HD40492-05	
		Total Project Period				
Grant Progress Report	:	From: 5/1/01			Through: 3/31/06	
	i	Requested Budg	et Perio	d:		
		From: <u>4/1/05</u>			Through: 3/31/06	
1. TITLE OF PROJECT					2.2m	
Cooperative Multicenter Neonatal Research Netw						
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)		PLICANT ORGAN			o code)	
Goldberg, Ronald N.	Duke	University			•	
204D Bell Bldg	DUM	IC 3001			-	
Box 3179 Med Ctr	Durh	am, NC 277 ²	10			
Durham, NC 27710					Resolution Anno Anna	
					~	
2b. E-MAIL ADDRESS	4. EN	TITY IDENTIFICA	TION NU	MBER	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
goldb008@mc.duke.edu	56-0	532129				
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT	<u> </u>	LE AND ADDRES	S OF AL	MINISTRA		
Pediatrics	1	Dir., Grants &				
2d. MAJOR SUBDIVISION		IC 3001				
	Durh	am, NC 277 ²	10			
School of Medicine						
	E-MAIL	.: gcmail@mc	.duke.	edu		
6. HUMAN SUBJECTS		VERTEBRATE A	NIMALS	;		
No 6a. Research Exempt 6b. Human Subjects Assurance N	No. 🗹	No		-	7a. If "Yes," IACUC approval Date	
X Yes No Yes M1106] Yes		,		
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III	75	o. Animal Welfare	e Assura	nce No.		
Exemption No. Clinical Trial 🛛 No 🗌 Yes		5				
If Not Exempt ("No" in 6a):	-				·	
IRB approval date 9/15/04						
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD		ENTIONS AND P			·····	
1		_	_	-	5	
8a. DIRECT \$ 143,058 8b. TOTAL \$ 220,309		רי Yes If או Yes If	res, [5	y Reported iously Reported	
10. PERFORMANCE SITE(S) (Organizations and addresses)	11a. P	RINCIPAL INVES			L (919) 681-6024	
Duke University, Durham, NC	OR PR	OGRAM DIRECT	OR (Item	12a1	× (919) 681-6065	
Bake oniversity, Barnani, No				FA	~ (919) 081-0005	
		DMINISTRATIVE	OFFICIA	L TE	∟ (919) 684-5175	
		(Item 5)			× (919) 684-6278	
		a S. Wilkins				
	ORGA	NIZATION (Item 1	4)		IING FOR APPLICANT	
		R. Sanders				
	TITLE	Dean, Scho	ol of N	ledicine		
	TEL	(919) 684-51	75		FAX (919) 684-6278	
	E-MAIL	penne006@	mc.du	ike.edu	· ·	

12. Corrections to Page 1 Face Page

obligation to comply with Public Health Services terms and con result of this application. I am aware that any false, fictitious, c may subject me to criminal, civil, or administrative penalties. PHS 2590 (Rev. 05/01)	nditions if a grant is awarded as a	cceptable R. Jan	1/26/05
14. APPLICANT ORGANIZATION CERTIFICATION AND statements herein are true, complete and accurate to the best	of my knowledge, and accept the 11	IGNATURE OF OFFICIAL NAMED IN 1c. (In ink. "Per" signature not	DATE
any false, fictitious, or fraudulent statements or claims m administrative penalties. I agree to accept responsibility for th to provide the required progress reports if a grant is awarded a	ay subject me to criminal, civil, or the scientific conduct of the project and as a result of this application.	(well goldbermi)	1/26/05
 PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR statements herein are true, complete and accurate to the best 	st of my knowledge. I am aware that	IGNATURE OF PI/PD NAMED IN 2a. In ink. "Per" signature not acceptable.)	DATE

Pages 3 through 12 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Midd	^{ie):} Goldberg, Ronald Norr	man
PROGRESS REPORT SUMMARY	GRANT NUMBER 5U10 HD40492-05	
	PERIOD COVERED BY TH	IIS REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH
Goldberg, Ronald N.	4/01/04	03/31/05
APPLICANT ORGANIZATION		
Duke University		
TITLE OF PROJECT (Repeat title shown in Item 1 on first page	ge)	
Cooperative Multicenter Neonatal Research Netwo	ork	
A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects 🛛 🛛 No Cl	nange Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals No Cl	nange Since Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS.		
WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions	Use Inclusion Enroliment Report F	armat Page and if necessary

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

a. Specific Aims The specific aims have not changed. Duke will: 1) conduct Network protocols; 2) provide investigator experience and institutional support to fulfill Network objectives; 3) propose novel opportunities for research in medical care and healthcare economics.

b. Studies and Results

Aim #1: Conduct Network studies

Not responsive. Not related to SUPPORT.

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hr.

9. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants. This protocol is currently under review by our IRB. We have begun in-house training for nursing, MDs, and respiratory therapists and hosted an in-service conducted by personnel from a SUPPORT pilot study center.

Not responsive. Not related to SUPPORT.

d. Plans We will continue recruiting subjects for Network trials. We will continue to encourage faculty and fellows to develop hypothesis-based queries for the GDB. We will participate in the final stages of development of the Network's first DNA bank. New studies we plan to develop for 2005 include: 1) Prospective DNA repository as secondary to the SUPPORT trial.

Not responsive. Not related to SUPPORT.

Pages 15 through 46 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD040492-07

PI Name:
Org:
Start Date:
Snap:
Appl ID:
Rec'd Date:

GOLDBERG, RONALD DUKE UNIVERSITY 04/01/2007 N/A (NEEDS TO BE BOOKMARKED) 7219965 02/02/2007

Department of Health and Human Services Public Health Services	Review Group	Type Activ 5 U10		Grant Number HD040492-07	
	Total Project Period				
Grant Progress Report	From: 5/1/01		Throu	_{gh:} 3/31/11	
oranti rogioco noport	Requested Budget From: 4/1/07	Period	Throu	_{gh:} 3/31/08	
 TITLE OF PROJECT Cooperative Multicenter Neonatal Research N 	etwork				
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)	3. APPLICANT OF (Name and addre	GANIZATION ess, street, city, sta	ate, zip c	ode)	
Goldberg, Ronald N.	Duke Unive	rsity			
204D Bell Bldg	2424 Erwin	Rd.			
Box 3179 Med Ctr	Suite 1103 I	Hock Plaza			
Durham, NC 27710	Durham, NC	27705			
b. E-MAIL ADDRESS goldb008@mc.duke.edu	4. ENTITY IDENTI 56-0532129		ER		
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Pediatrics	5. TITLE AND ADD	DRESS OF ADMIN	ISTRAT	IVE OFFICIAL	
2d. MAJOR SUBDIVISION	Dir., Resear	ch Administra	ation		
	2424 Erwin Rd.				
School of Medicine	Suite 1103 Hock Plaza				
	Durham. NC				
	E-MAIL: gcmail@	mc.duke.edu			
. HUMAN SUBJECTS	7. VERTEBRA	TE ANIMALS		and the second second	
No 6a. Research Exempt 6b. Human Subjects Assurance XI Yes X No Yes 00009025			7a.	If "Yes," IACUC approval Date	
X Yes 00000020	Yes	fare Assurance N			
Exemption No. Clinical Trial No X Yes		fare Assurance N	0.	FEB 0 2 2007	
f Not Exempt ("No" in 6a): RB approval date 05/17/2006	w			2007	
COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVENTIONS AN	D PATENTS			
Ba. DIRECT \$ 146,128 8b. TOTAL \$ 227,784	🕅 No 🗆 Yes	If "Yes,"		sly Reported viously Reported	
0. PERFORMANCE SITE(S) (Organizations and addresses)	11a. PRINCIPAL IN		TEL	(919) 668-1592	
Duke University, Durham, NC	OR PROGRAM DIR		FAX	(919) 681-6065	
	11b. ADMINISTRATIVE OFFICIAL TEL (919) 684-5175 NAME (Item 5)				
	Mollie C. Sykes FAX (919) 684-6278				
	ORGANIZATIO	ON (Item 14)	SIGNI	NG FOR APPLICANT	
	NAME R. Sanders Williams				
	TEL (919) 684			x (919) 684-6278	
	and the second second		1.4		
	E-MAIL akuehn	wurke.eau			

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATI 11c. (In acceptat
may subject the to chiminal, civil, or authinistrative penalties.	K

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IGNATURE OF OFFICIAL NAMED IN	DATE
1c. (In ink. "Per" signature not	01/29/2007
N. Jan sem	

Pages 3 through 5 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Principal Investigator/Program Directo	r (Last, First, Middle):	Goldberg, Ronald N.	
PROGRESS REPORT SU	MMARY	GRANT NUMBER 5U10 HD040492-07	
		PERIOD COVERED BY THI	S REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM	I DIRECTOR	FROM	THROUGH
Ronald Goldberg		4/1/06	3/31/07
APPLICANT ORGANIZATION Duke University	·		
TITLE OF PROJECT (Repeat title shown in I Cooperative Multicenter Neonatal Re			
A. Human Subjects (Complete Item 6 on the	Face Page)		······································
Involvement of Human Subjects	No Change	e Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on t	he Face Page)		
Use of Vertebrate Animals	No Change	e Since Previous Submission	Change
C. Select Agent Research	No Change	e Since Previous Submission	Change
D. Multiple PI Leadership Plan	No Change	e Since Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS.		· · · · · · · · · · · · · · · · · · ·	

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

6. Project Report Summary

6A. Specific Aims. The specific aims have not changed. Duke will: 1) conduct Network protocols; 2) provide investigator experience and institutional support to fulfill Network objectives; 3) propose novel opportunities for research in medical care.

Duke University fully supports the Aims and has provided additional space adjacent to the intensive care nursery, and an environment rich in collaborators to bring novel ideas and methods to the Network. The Duke Network research group is stable: Dr. Ronald Goldberg is the site PI, the alternate PI is Dr. Michael Cotten who completed a Master's in Clinical Research in 2006. The follow-up PI is Dr. Ricki Goldstein. Kathy Auten, Melody Lohmeyer, and Charles Vajdl continue as Network Study Coordinator, Follow-Up coordinator, and Data Entry technician. The Clinical Research Group also includes one full time and three part time study nurses, and a nurse coordinator for non-Network studies.

Dr. Goldberg serves on multiple study subcommittees, continues on the Publication subcommittee and chairs the Genomics subcommittee. Dr. Cotten is a consultant on the Genomics subcommittee. 6B. Studies and Results.

Duke-Initiated Network Studies

g

7. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT) in ELBW Infants. For SUPPORT, we have coordinated the efforts of nursing, MDs, and respiratory therapists. We are participating in the 4 SUPPORT secondary studies, Breathing Outcomes, SUPPORT MRI, Growth, and Consent.

Not responsive. Not related to SUPPORT.

Pages 8 through 12 redacted for the following reasons: Not responsive. Not related to SUPPORT. Principal Investigator/Program Director (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	NICHD SUPPORT Trial: Bre	eathing Outcomes Protocol	
Total Enrollment:	1	Protocol Number: Pro00000022	
Grant Number:	5U10 HD 40492-05		

Ethnic Category	Sex/Gender					
	Females	Males	Unknown or Not Reported	Total		
Hispanic or Latino	0	0	0	0	**	
Not Hispanic or Latino	3	3	0	6		
Unknown (individuals not reporting ethnicity)	0	0	0	0		
Ethnic Category: Total of All Subjects*	3	3	0	6	*	
Racial Categories						
American Indian/Alaska Native	0	0	0	0		
Asian	0	0	0	0	•	
Native Hawaiian or Other Pacific Islander	0	0	0	0		
Black or African American	2	3	0	5		
White	1	0	0	1		
More Than One Race	0	0	0	0		
Unknown or Not Reported	0	0	0	0		
Racial Categories: Total of All Subjects*	3	3	0	6	*	

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

Principal Investigator/Program Director (Last, First, Middle):

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial: Breathing Outcomes Protocol

Total Planned Enrollment: 40

Ethnic Category	Sex/Gender					
	Females	Males	Total			
Hispanic or Latino	2	2	4			
Not Hispanic or Latino	17	19	36			
Ethnic Category: Total of All Subjects *	19	21	40			
Racial Categories						
American Indian/Alaska Native	0	0	0			
Asian	0	0	0			
Native Hawaiian or Other Pacific Islander	0	0	0			
Black or African American	10	14	24			
White	9	7	16			
Racial Categories: Total of All Subjects *	19	21	40			

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 15 through 22 redacted for the following reasons: Not responsive. Not related to SUPPORT. Principal Investigator/Program Director (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Post-natal Growth of Infants	Enrolled in the NICHD SUPPORT Study: A Secondary Study
11	Protocol Number: 6921-06
5U10 HD 40492-05	
	11

Ethnic Category	Sex/Gender					
	Females	Males	Unknown or Not Reported	Totaí		
Hispanic or Latino	0	0	0	0	**	
Not Hispanic or Latino	6	5	0	11		
Unknown (individuals not reporting ethnicity)	0	0	0	0		
Ethnic Category: Total of All Subjects*	6	5	0	11	*	
Racial Categories						
American Indian/Alaska Native	0	0	0	0		
Asian	0	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0	0		
Black or African American	6	4	0	10		
White	0	1	0	1		
More Than One Race	0	0	0	0		
Unknown or Not Reported	0	0	0	0		
Racial Categories: Total of All Subjects*	6	5	0	11	*	

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

Pages 24 through 26 redacted for the following reasons: Not responsive. Not related to SUPPORT. Principal Investigator/Program Director (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Title: Neuroimaging and Neurodevelopment Outcome: A Secondary to SUPPORT			
Total Enrollment:	1	Protocol Number: Pro00000001		
Grant Number:	5U10 HD 40492-05			

		S	Sex/Gender		
Ethnic Category	Females	Males	Unknown or Not Reported	Total	1
Hispanic or Latino	0	0	0	0	**
Not Hispanic or Latino	1	0	0	1	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	1	0	0	1	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	1	0	0	1	
White	0	0	0	0	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	1	0	0	1	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

PHS 398/2590 (Rev. 09/04, Reissued 4/2006)

Principal Investigator/Program Director (Last, First, Middle):

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT

Total Planned Enrollment: 15

Ethnia Catagony	Sex/Gender					
Ethnic Category	Females	Males	Total			
Hispanic or Latino	0	1	1			
Not Hispanic or Latino	7	7	14			
Ethnic Category: Total of All Subjects *	7	8	15			
Racial Categories						
American Indian/Alaska Native	0	0	0			
Asian	0	0	0			
Native Hawaiian or Other Pacific Islander	0	0	0			
Black or African American	4	5	9			
White	3	3	6			
Racial Categories: Total of All Subjects *	7	8	15			

Pages 29 through 31 redacted for the following reasons: Not responsive. Not related to SUPPORT.

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway and Pulse Oximetry Trial in ELBW Infants

Total Planned Enrollment: 30

Ethnia Ostanami	Sex/Gender					
Ethnic Category	Females	Males	Total			
Hispanic or Latino	1	2	3			
Not Hispanic or Latino	13	14	27			
Ethnic Category: Total of All Subjects *	14	16	30			
Racial Categories						
American Indian/Alaska Native	0	1	1			
Asian	0	0	0			
Native Hawaiian or Other Pacific Islander	0	0	0			
Black or African American	8	10	18			
White	6	5	11			
Racial Categories: Total of All Subjects *	14	16	30			

Page 33 redacted for the following reason: Not responsive. Not related to SUPPORT.

IRB APPROVAL STUDY TITLE PI IRB# EXPIRATION DATE Not responsive. Not related to SUPPORT.	E
Not responsive. Not related to SUPPORT.	
Surfactant Positive	
Airway Pressure and Pulse Oximetry Trial in	
ELBW Infants Cotten 6921-06 4/7/200	7
Postnatal Growth of Infants Enrolled in the	
NICHD SUPPORT	
Study Cotten 6921-05 4/7/200 Anetnatal Consent	7
Secondary to	
SUPPORT Cotten 6921-05 4/7/200	7
NICHD SUPPORT Trial: Breathing Outcomes	
Protocol Goldstein Pro0000022 2/28/200	7
Neuroimaging and Neurodevelopment: A	
Secondary to	_
SUPPORT Goldstein Pro00000001 6/11/200	1

Pages 35 through 39 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD040492-08

PI Name: Org: Start Date: Snap: Appl ID: Rec'd Date: GOLDBERG, RONALD DUKE UNIVERSITY 04/01/2008 N/A (NEEDS TO BE BOOKMARKED) 7406725 02/04/2008

Form Approved Through 9/30/2007				OMB No. 0925-0001
Department of Health and Human Services Public Health Services	Review Group	Type 5	Activity U10	Grant Number HD040492-08
Grapt Prograss Papart	Total Project Period From: 5/1/01		Thro	bugh: 3/31/11
Grant Progress Report	Requested Budget Pe From: 4/1/08	eriod	Thr	_{bugh:} 3/31/09
1. TITLE OF PROJECT				Jugn
Cooperative Multicenter Neonatal Research Ne				
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)	 APPLICANT ORG (Name and addres) 			code)
Goldberg, Ronald N.	Duke Univers		, ,,,	
204D Bell Bldg	2200 West M	ain Stre	et	
Box 3179 Med Ctr	Suite 820 Erv	vin Squ	are Plaza	FEB 0 4 2000
Durham, NC 27710	Durham, NC	•		
2b. E-MAIL ADDRESS goldb008@mc.duke.edu	4. ENTITY IDENTIFI 56-0532129	CATION	NUMBER	
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT	5. TITLE AND ADDR			ATIVE OFFICIAL
Pediatrics	Dir., Researc			
2d. MAJOR SUBDIVISION	2200 West M	ain Stre	eet	
School of Medicine	Suite 820 Erv	vin Squ	are Plaza	à
	Durham, NC			·
	E-MAIL: gcmail@r	nc.duke	.edu	
6. HUMAN SUBJECTS	7. VERTEBRAT	E ANIMAL		
No 6a. Research Exempt 6b. Human Subjects Assurance Image: No Image: No Image: No 00009025			78	a. If "Yes," IACUC approval Date
	Yes			
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III Exemption No. Clinical Trial No	7b. Animal Welfa	re Assura	nce No.	
If Not Exempt ("No" in 6a):				
IRB approval date 05/11/2007		-		
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVENTIONS AND		⁻ -	
8a. DIRECT \$ 289,183 8b. TOTAL \$ 451,125	🗵 No 🗖 Yes	lf "Yes,"		ously Reported reviously Reported
10. PERFORMANCE SITE(S) (Organizations and addresses)	11a. PRINCIPAL INV	ESTIGAT		(919) 668-1592
Duke University, Durham, NC	OR PROGRAM DIRE		m 2a)	. ,
•	116. ADMINISTRATI		FAX	
	NAME (Item 5)			(919) 684-5175
	Mollie C. Sykes		FAX	
	11c. NAME AND TIT ORGANIZATIO			NING FOR APPLICANT
	NAME Mollie C.			
	TITLE Associate	•	Research	า
	TEL (919) 684-9	5175	ļ	FAX (919) 684-6278
	E-MAIL meghan.r	nalone	I	
40. Or westing the Dame of Faces Dame	U			

12. Corrections to Page 1 Face Page

PHS 2590 (Rev. 04/06) Face Page		Form Page 1
obligation to comply with Public Health Services terms and conditions if a grant is awarded as a	SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Per" signature not acceptable.)	DATE 01/28/2008

Pages 3 through 9 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Goldberg, Ronald N.

		Coluborg, Ronald H.	
		GRANT NUMBER	
PROGRESS REPORT SUM	<i>I</i> IARY	5U10 HD040492 08	
		PERIOD COVERED BY T	HIS REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM D	IRECTOR	FROM	THROUGH
Ronald Goldberg,		4/1/07	3/31/08
APPLICANT ORGANIZATION			
Duke University			
TITLE OF PROJECT (Repeat title shown in Iten	n 1 on first page	e)	
Cooperative Multicenter Neonatal Rese	earch Netwo	rk	
A. Human Subjects (Complete Item 6 on the Fac	ce Page)		
Involvement of Human Subjects	🛛 No Cha	nge Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the I	Face Page)		
Use of Vertebrate Animals	🛛 No Cha	nge Since Previous Submission	Change
C. Select Agent Research	No Cha	nge Since Previous Submission	Change
D. Multiple PI Leadership Plan	No Cha	nge Since Previous Submission	Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

6. Project Report Summary

6A. Specific Aims. The specific aims have not changed. Duke will: 1) conduct Network protocols; 2) provide investigator experience and institutional support to fulfill Network objectives; 3) propose novel opportunities for research in medical care. The Duke School of Medicine and Department of Pediatrics fully support these Aims. The Duke Network research group is stable: Drs. Ronald Goldberg, Michael Cotten, and Ricki Goldstein continue as PI, alternate, and follow-up PI. Kathy Foy, previously the Network research nurse, now serves as Network Study Coordinator. The Neonatology Clinical Research Group is managed by Kim Fisher FNP, PhD, who will support Ms. Foy in her new role. Dr. Goldberg serves on the Publications, Early Onset Sepsis, Probiotics, and Inositol subcommittees and chairs the Genomics subcommittee. Dr. Cotten is a consultant on the Genomics subcommittee.

6B. Studies and Results.

Active Duke-Initiated Network Studies

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

6. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT) in ELBW Infants. Nursing, MDs, and respiratory therapists collaborate to conduct this study. We are participating in the 4 SUPPORT secondary studies.

Not responsive. Not related to SUPPORT.

Pages 12 through 16 redacted for the following reasons: Not responsive. Not related to SUPPORT.

This report format should NOT be used for data collection from study participants.

Study Title: Antenatal Consent Secondary Study to SUPPORT

Total Planned Enrollment: 90 Study Currently Closed

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Sex/Gender				
	Females	Males	Total		
Hispanic or Latino	9	0	9		
Not Hispanic or Latino	81	0	81		
Ethnic Category: Total of All Subjects *	90	0	90		
Racial Categories					
American Indian/Alaska Native	3	0	3		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	54	0	54		
White	33	0	33		
Racial Categories: Total of All Subjects *	90	0	90		

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Antenatal Consent Secondary Study to SUPPORT				
Total Enrollment:	140	Protocol Number:	6921-07		
Grant Number:	5U10 HD 40492-07	_			

	nicity and Race Sex/Gender					
Ethnic Category	Females	Males	Unknown or Not Reported	Total		
Hispanic or Latino	0	0	0	0	**	
Not Hispanic or Latino	0	0	0	0		
Unknown (individuals not reporting ethnicity)	140	0	0	140		
Ethnic Category: Total of All Subjects*	140	0	0	140	*	
Racial Categories						
American Indian/Alaska Native	0	0	0	0		
Asian	0	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0	0		
Black or African American	0	0	0	0		
White	0	0	0	0		
More Than One Race	0	0	0	0		
Unknown or Not Reported	140	0	0	140		
Racial Categories: Total of All Subjects*	140	0	0	140	*	

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

PHS 398/2590 (Rev. 09/04, Reissued 4/2006)

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial: Breathing Outcomes Protocol

Total Planned Enrollment: 10

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Sex/Gender				
	Females	Males	Total		
Hispanic or Latino	1	1	2		
Not Hispanic or Latino	4	4	8		
Ethnic Category: Total of All Subjects *	5	5	10		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	2	3	5		
White	3	2	5		
Racial Categories: Total of All Subjects *	5	5	10		

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	NICHD SUPPORT Trial: Breathing Outcomes Protocol					
Total Enroliment:	7 Protocol Number: Pro00000022					
Grant Number:	5U10 HD 40492-07	-				

	hnicity and Race		ex/Gender	<u> </u>		
		Unknown or				
Ethnic Category	Females	Males	Not Reported	Total		
Hispanic or Latino	0	0	0	0 **		
Not Hispanic or Latino	4	3	0	7		
Unknown (individuals not reporting ethnicity)	0	0	0	0		
Ethnic Category: Total of All Subjects*	4	3	0	7 *		
Racial Categories						
American Indian/Alaska Native	0	0	0	0		
Asian	0	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0	0		
Black or African American	3	3	0	6		
White	1	0	0	1		
More Than One Race	0	0	0	0		
Unknown or Not Reported	0	0	0	0		
Racial Categories: Total of All Subjects*	4	3	0	7 *		

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

PHS 398/2590 (Rev. 09/04, Reissued 4/2006)

Pages 21 through 28 redacted for the following reasons: Not responsive. Not related to SUPPORT.

This report format should NOT be used for data collection from study participants.

Study Title: Post-natal Growth of Infants Enrolled in the NICHD SUPPORT Study

Total Planned Enrollment: 30

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Sex/Gender				
	Females	Males	Total		
Hispanic or Latino	1	2	3		
Not Hispanic or Latino	13	14	27		
Ethnic Category: Total of All Subjects *	14	16	30		
Racial Categories					
American Indian/Alaska Native	0	1	1		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	8	10	18		
White	6	5	11		
Racial Categories: Total of All Subjects *	14	16	30		

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Post-natal Growth of Infants E	Enrolled in the NICHD SUPPORT Study: A Secondary Study
Total Enrollment:	34	Protocol Number: <u>6921-07</u>
Grant Number:	5U10 HD 40492-07	

	Sex/Gender				
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	0	2	0	0	**
Not Hispanic or Latino	16	13	0	29	
Unknown (individuals not reporting ethnicity)	1	2	0	3	_
Ethnic Category: Total of All Subjects*	17	15	0	34	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	1	0	0	1	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	10	10	0	20	
White	5	5	0	10	
More Than One Race	0	0	0	0	
Unknown or Not Reported	1	2	0	3	
Racial Categories: Total of All Subjects*	17	17	0	34	*
			<u>. </u>	<u></u>	

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	2	0	2
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	2	0	2 **

* These totals must agree.

** These totals must agree.

Pages 31 through 34 redacted for the following reasons: Not responsive. Not related to SUPPORT.

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT

Total Planned Enrollment: 15

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Sex/Gender				
	Females	Males	Total		
Hispanic or Latino	0	1	1		
Not Hispanic or Latino	7	7	14		
Ethnic Category: Total of All Subjects *	7	8	15		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	4	5	9		
White	3	3	6		
Racial Categories: Total of All Subjects *	7	8	15		

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

1

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Neuroimaging and Neurodevelopment Outcome:Secondary to SUPPORT				
Total Enrollment:	6	Protocol Number: Pro0000001			
Grant Number:	5U10HD40492-07				

	Sex/Gender				
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	0	0	0	0 **	
Not Hispanic or Latino	3	3	0	6	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	3	3	0	6 *	
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	1	0	0	1	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	1	1	0	2	
White	1	2	0	3	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	3	3	0	6 *	

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

Pages 37 through 38 redacted for the following reasons: Not responsive. Not related to SUPPORT.

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway and Pulse Oximetry Trial in ELBW Infants

Total Planned Enrollment: 30

TARGETED/PLANNED ENROLLMENT: Number of Subjects							
Ethnic Category	Sex/Gender						
	Females	Males	Total				
Hispanic or Latino	1	2	3				
Not Hispanic or Latino	13	14	27				
Ethnic Category: Total of All Subjects *	14	16	30				
Racial Categories							
American Indian/Alaska Native	0	1	1				
Asian	0	0	0				
Native Hawaiian or Other Pacific Islander	0	0	0				
Black or African American	8	10	18				
White	6	5	11				
Racial Categories: Total of All Subjects *	14	16	30				

Page 40 redacted for the following reason: Not responsive. Not related to SUPPORT.

NRN IRB APPROVALS

PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH

	PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
	Not responsive. Not related to SUPPORT.			
	The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	6921-07-4R2	4/5/2007	4/7/2008
	Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	6921-07-4R2	4/5/07	4/7/08
	Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	Pro00000001	4/28/07	5/3/08
	Breathing Outcomes (SUPPORT Study Secondary)	Pro00000022	12/5/2007	1/29/2010
	Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	6921-07-4R2	4/5/2007	4/7/2008

Pages 43 through 73 redacted for the following reasons: Not responsive. Not related to SUPPORT. Progress Report Scanning Cover Sheet

5U10HD040492-09

PI Name: Org: Start Date: Snap: Appl ID: Rec'd Date: GOLDBERG, RONALD DUKE UNIVERSITY 04/01/2009 N/A (NEEDS TO BE BOOKMARKED) 7603064 02/02/2009

Form Approved Throug	gh 11/30/2010							OMB No. 092	5-0001
Department of Health and Human Services Public Health Services			Review Group	Type 5	Activity U10	Grant Nu HD04	imber 0492-09		
				Total Project Period From: 5/1/01 Through: 3/31/11					
Grant	Progre	ss R	eport		Period	T	trough: 010		
- · · ·			Requested Budget Period From: 4/1/09 Through: 3/31/10						
1. TITLE OF PROJE Cooperative M		eonata	I Research Net	work					
2a. PROGRAM DIREC				2b. E-MAIL ADDRE		a adu			
(Name and address, street, city, state, zip code)			goldb008@mc.duke.edu 2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT				·		
Goldberg, Ronaid N. 204D Bell Bldg			Pediatrics						
Box 3179 Med				2d. MAJOR SUBDIN	/ISION				
Durham, NC 2				School of M		•			
201101,110 -				^{2e. ⊤el:} (919) 668	3-1592	F	^{ax:} (919) 6	81-6065	
3a. APPLICANT ORG (Name and address		ate, zip co	ode)	^{3b. Tel:} (919) 68	4-5175	F	^{ax:} (919) 6	84-6278	
Duke Universit 2200 West Ma	•			^{3c. DUNS:} 04438	37793			FEB 0 2 200	99
Suite 820 Erwi		laza		4. ENTITY IDENTI	FICATION				
Durham, NC 2	•			56-0532129	- OK HON				
6. HUMAN SUBJECT	'S 🗍 No	X Ye	95	5. NAME, TITLE A		ESS OF AD	MINISTRAT		
6a. Research	If Exempt ("Yes		f Not Exempt ("No" in	Mollie C. Syke	es, Exe	cutive Di	rector, Re	s. Admin	
Exempt	6a): Exemption No.		∂a): RB approval date	2200 West M	ain St.,	Suite 82	0 Erwin S	quare Plaza	
	,		07/17/2008	Durham, NC	27705				
6b. Federal Wide Ass	urance No. 00	00902	5	Tel: (919) 684-5	175	F	[:] ax: (919) 6	84-6278	
6c. NIH-Defined Phas				E-MAIL:			(/ -		
Clinical Trial 🛛 🕅 N	o 🔀 Yes			gcmail@mc.du	uke.edu				
7. VERTEBRATE AN	IMALS 🛛 N	。 🛛	Yes	10. PROJECT/PER					
7a. If "Yes," IACUC a	pproval Date			Organizational Nam	_{ie:} Duke	e Univers	ity		
7b. Animal Welfare As	surance No.			DUNS: 0443877	793				
8. COSTS REQUES	TED FOR NEXT	T BUDGE	T PERIOD	Street 1:		····	<u> </u>		
8a. DIRECT \$ 201,4	1 41 8 b.	TOTAL	§ 314,248	Street 2:			<u> </u>		
9. INVENTIONS AND	PATENTS	X No	Yes	^{City:} Durham		C	County:		
lf "Yes, 🔲 Previo	usly Reported			State: NC		P	Province:		
🗌 Not Pre	eviously Reporte	ed		Country: United States		z	Zip/Postal Code:		
				Congressional Distr	icts:				
11. NAME AND TITL	E OF OFFICIAL	SIGNING	G FOR APPLICANT C	RGANIZATION (Ite	m 13)	·	<u> </u>		
Cynthia O. Cas		e of Re				<u>.</u>			
TEL: (919) 684-51			FAX: (919) 684	-6278		E-MAIL: la	aurie.henr	ry@duke.edu	
12. Corrections to Pag	je 1 Face Page								
13. APPLICANT ORG								ED IN DATE	
obligation to comply	with Public Health ion. I am aware th	Services t nat any fais	e to the best of my know erms and conditions if a se, fictitious, or freudulent penalties.	grant is awarded as a	1 (in ir		$\wedge \wedge$	e 01/29/2	2009
PHS 2590 (Rev. 11/07			<u> </u>	Face Page				Form	Page 1

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Pages 3 through 10 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middl	^{e):} Goldberg, Ronald N.	Goldberg, Ronald N.				
PROGRESS REPORT SUMMARY		GRANT NUMBER 5U10-HD040492-09					
		PERIOD COVERED BY TH	PERIOD COVERED BY THIS REPORT				
PROGRAM DIRECTOR / PRINCIPAL INVEST	IGATOR	FROM	THROUGH				
Goldberg, Ronald N.		04/01/2008	03/31/2009				
APPLICANT ORGANIZATION							
Duke University TITLE OF PROJECT (Repeat title shown in Ite							
TITLE OF PROJECT (Repeat title shown in Ite Cooperative Multicenter Neonatal Res	earch Netwo						
TITLE OF PROJECT (Repeat title shown in Ite Cooperative Multicenter Neonatal Res A. Human Subjects (Complete Item 6 on the Fi	earch Netwo	ork					
TITLE OF PROJECT (Repeat title shown in Ite Cooperative Multicenter Neonatal Res	earch Netwo ace Page) No Ch		Change				
TITLE OF PROJECT (Repeat title shown in Ite Cooperative Multicenter Neonatal Res A. Human Subjects (Complete Item 6 on the Finite Item 6 on the Finite Involvement of Human Subjects	earch Netwo ace Page) No Ch Face Page)	ork	Change				
TITLE OF PROJECT (Repeat title shown in Ite Cooperative Multicenter Neonatal Res A. Human Subjects (Complete Item 6 on the Fa Involvement of Human Subjects B. Vertebrate Animals (Complete Item 7 on the	earch Netwo ace Page) No Ch Face Page) No Ch	ork ange Since Previous Submission					

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

6. Project Report Summary

6A. Specific Aims. The specific aims have not changed. Duke will: 1) conduct Network protocols; 2) provide investigator experience and institutional support to fulfill Network objectives; 3) propose novel opportunities for research. The Duke School of Medicine and Department of Pediatrics fully support the Aims. Duke added the University of North Carolina Chapel Hill as a satellite site January 2009. The addition doubles potential enrollment and adds intellectual depth. Drs. Ronald Goldberg, Michael Cotten, and Ricki Goldstein continue as PI, alternate, and follow-up PI. Drs. Matthew Laughon and Diane Marshall will lead trials and follow-up at UNC. Kim Fisher FNP PhD, director of Neonatology clinical research operations at Duke, serves as Network coordinator. Ginnie Bose, is the UNC coordinator. Dr. Goldberg serves on the

6B. Studies and Results. Active Duke-Initiated Network Studies Not responsive. Not related to SUPPORT.

3. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT).

Nursing, MDs, and respiratory therapists collaborate to conduct this study. We are participating in the 4 SUPPORT secondary studies.

Not responsive. Not related to SUPPORT.

6D. Plans

Duke investigators continue to develop novel studies for the Network:

Not responsive. Not related to SUPPORT.

2. Do Interactions of oxygen exposure and genetic variations influence ROP risk? Evidence suggests genetic variation contributes to risk of ROP. At the January 2009 Steering Committee, Drs. Cotten and John Dagle's (Iowa) concept to collect DNA from SUPPORT participants during follow-up was approved. The study will test ROP-oxygen-genetic variation interactions in key angiogenic and oxygen sensitive pathways.

PHS 398/2590 (Rev. 11/07)

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Pages 13 through 15 redacted for the following reasons: Not responsive. Not related to SUPPORT.

This report format should NOT be used for data collection from study participants.

Study Title: Antenatal Consent Secondary Study to SUPPORT

Total Planned Enrollment: 90 Study Currently Closed

TARGETED/PLANNED ENROLLMENT: Number of Subjects							
Ethnic Category	Sex/Gender						
	Females	Males	Total				
Hispanic or Latino	9	0	9				
Not Hispanic or Latino	81	0	81				
Ethnic Category: Total of All Subjects *	90	0	90				
Racial Categories							
American Indian/Alaska Native	3	0	3				
Asian	0	0	0				
Native Hawaiian or Other Pacific Islander	0	0	0				
Black or African American	54	0	54				
White	33	0	33				
Racial Categories: Total of All Subjects *	90	0	90				

This report format should NOT be used for data collection from study participants.

Study Title:	Antenatal Consent Secondary Study to SUPPORT				
Total Enrollment:	140	Protocol Number:	6921-07		
Grant Number:	5U10 HD 040492-08				

	Sex/Gender				
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	0	0	0	0	**
Not Hispanic or Latino	0	0	0	0	
Unknown (individuals not reporting ethnicity)	140	0	0	140	
Ethnic Category: Total of All Subjects*	140	0	0	140	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	0	0	0	0	
White	0	0	0	0	
More Than One Race	0	0	0	0	
Unknown or Not Reported	140	0	0	140	
Racial Categories: Total of All Subjects*	140	0	0	140	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree. ** These totals must agree.

Pages 18 through 33 redacted for the following reasons: Not responsive. Not related to SUPPORT.

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT

Total Planned Enrollment: 15

MENT: Number of Subjec	ts			
Sex/Gender				
Females	Males	Total		
0	1	1		
7	7	14		
7	8	15		
0	0	0		
0	0	0		
0	0	0		
4	5	9		
3	3	6		
7	8	15		
	Females 0 7 7 7 0 0 0 0 0 0 0 0 0 0 0 0 3	Females Males 0 1 7 7 7 8 0 0 0 0 0 0 0 0 0 0 0 0 3 3		

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

	Sex/Gender				
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	0	0	0	0	**
Not Hispanic or Latino	6	8	0	14	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	6	8	0	14	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	1	0	0	1	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	3	5	0	8	
White	2	3	0	5	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	6	8	0	14	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

PHS 398/2590 (Rev. 11/07)

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants Follow Up

Total Planned Enrollment: 8

TARGETED/PLANNED ENROL	LMENT: Number of Subjec	ts			
Ethnic Category	Sex/Gender				
	Females	Males	Total		
Hispanic or Latino	1	1	2		
Not Hispanic or Latino	3	3	6		
Ethnic Category: Total of All Subjects *	4	4	8		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	2	2	4		
White	2	2	4		
Racial Categories: Total of All Subjects *	4	4	8		

This report format should NOT be used for data collection from study participants.

Study Title:	Surfactant Positive Airway Pressure	and Pulse Oximetry Trial in ELBW Infants Follow Up
Total Enrollment:	18	Protocol Number: 6921
Grant Number:	5U10HD40492-08	

		Sex/Gender				
Ethnic Category	Females	Males	Unknown or Not Reported	Total		
Hispanic or Latino	0	0	0	0	**	
Not Hispanic or Latino	11	7	0	18		
Unknown (individuals not reporting ethnicity)	0	0	0	0		
Ethnic Category: Total of All Subjects*	11	7	0	18	*	
Racial Categories						
American Indian/Alaska Native	0	0	0	0		
Asian	1	0	0	1	_	
Native Hawaiian or Other Pacific Islander	0	0	0	0		
Black or African American	9	5	0	14		
White	1	2	0	3		
More Than One Race	0	0	0	0		
Unknown or Not Reported	0	0	0	0		
Racial Categories: Total of All Subjects*	11	7	0	18	*	

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree. ** These totals must agree.

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial: Breathing Outcomes Protocol

Total Planned Enrollment: 10

Ethnic Cotagory	Sex/Gender				
Ethnic Category	Females	Males	Total		
Hispanic or Latino	1	1	2		
Not Hispanic or Latino	4	4	8		
Ethnic Category: Total of All Subjects *	5	5	10		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	2	3	5		
White	3	2	5		
Racial Categories: Total of All Subjects *	5	5	10		

This report format should NOT be used for data collection from study participants.

Study Title:	NICHD SUPPORT Trial: Breathin	g Outcomes Protocol
Total Enrollment:	14	Protocol Number: Pro00000022
Grant Number:	5U10 HD040492-08	

		Sex/Gender						
Ethnic Category	Females	Males	Unknown or Not Reported	Totai				
Hispanic or Latino	0	0	0	0	**			
Not Hispanic or Latino	6	8	0	14				
Unknown (individuals not reporting ethnicity)	0	0	0	0				
Ethnic Category: Total of All Subjects*	6	8	0	14	*			
Racial Categories								
American Indian/Alaska Native	0	0	0	0				
Asian	0	0	0	0				
Native Hawaiian or Other Pacific Islander	0	0	0	0				
Black or African American	4	6	0	10				
White	2	2	0	4	-			
More Than One Race	0	0	0	0				
Unknown or Not Reported	0	0	0	0				
Racial Categories: Total of All Subjects*	6	8	0	14	*			

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree. ** These totals must agree.

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Pages 40 through 45 redacted for the following reasons: Not responsive. Not related to SUPPORT.

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway and Pulse Oximetry Trial in ELBW Infants

Total Planned Enroliment: 30

TARGETED/PLANNED ENROLLMENT: Number of Subjects								
Ethnic Category	Sex/Gender							
	Females	Males	Total					
Hispanic or Latino	1	2	3					
Not Hispanic or Latino	13	14	27					
Ethnic Category: Total of All Subjects *	14	16	30					
Racial Categories								
American Indian/Alaska Native	0	1	1					
Asian	0	0	0					
Native Hawaiian or Other Pacific Islander	0	0	0					
Black or African American	8	10	18					
White	6	5	11					
Racial Categories: Total of All Subjects *	14	16	30					

This report format should NOT be used for data collection from study participants.

Study Title:	Surfactant Positive Airway Pressure	and Pulse Oximetry Trial in ELBW Infants
Total Enrollment:	62	Protocol Number: 6921
Grant Number:	5U10 HD 040492-08	

	Sex/Gender							
Ethnic Category	Females	Males	Unknown or Not Reported	Total				
Hispanic or Latino	0	3	0	3	**			
Not Hispanic or Latino	27	29	0	56				
Unknown (individuals not reporting ethnicity)	1	2	0	3				
Ethnic Category: Total of All Subjects*	28	34	0	62	*			
Racial Categories								
American Indian/Alaska Native	0	1	0	1				
Asian	2	0	0	2				
Native Hawaiian or Other Pacific Islander	0	0	0	0				
Black or African American	17	20	0	37				
White	8	11	0	19				
More Than One Race	0	0	0	0				
Unknown or Not Reported	1	2	0	3				
Racial Categories: Total of All Subjects*	28	34	0	62	*			

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	3	0	3
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	3	0	3 **

* These totals must agree.

** These totals must agree.

Pages 48 through 49 redacted for the following reasons: Not responsive. Not related to SUPPORT.

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			

1

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	6921	3/20/2008	4/7/2009
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	6921	3/20/2008	4/7/2009
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	Pro00000001	4/21/2008	5/3/09
Breathing Outcomes (SUPPORT Study Secondary)	Pro00000022	12/5/2007	12/04/2009
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	6921	3/20/2008	4/7/2009

Pages 52 through 55 redacted for the following reasons: Not responsive. Not related to SUPPORT.

5U10HD040492-10

P! Name:	GOLDBERG, RONALD
Org:	DUKE UNIVERSITY
Start Date:	04/01/2010
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	7795203
Rec'd Date:	02/01/2010

Form Approved Through 06/30/2012				OMB No. 0925-0001		
Department of Health and Human Services Public Health Services	Review Group	Type 5	Activity U10	Grant Number HD040492-10		
	Total Project Perio	đ		· · ·		
	From: 5/1/01		Th	rough: 3/31/11		
Grant Progress Report	Requested Budget	Requested Budget Period				
	From: 4/1/10		Th	rough: 3/31/11		
1. TITLE OF PROJECT Cooperative Multicenter Neonatal Research	I Network					
2a, PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)	26. E-MAIL ADDRE goldb008@		a adu			
Goldberg, Ronald N.				ORY, OR EQUIVALENT		
2424 Erwin Road	Pediatrics			• - ·		
Box 2739 Med Ctr	2d. MAJOR SUBDI	VISION		and a second second second second second second second second second second second second second second second		
Durham, NC 27710	School of M	ledicine	Э			
	^{2e. Tel:} (919) 66			^{3x:} (919) 681-6065		
3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)	^{3b.} Tel: (919) 68			^{ax:} (919) 684-6278		
Duke University 2200 West Main St.	3c. DUNS: 0443	87793				
Suite 820 Erwin Square Plaza						
Durham, NC 27705	4. ENTITY IDENT 56-0532129	IFICATIO	NNUMBER			
6. HUMAN SUBJECTS No X Yes	5. NAME, TITLE /		RESS OF AD	MINISTRATIVE OFFICIAL		
6a: Research If Exempt ("Yes" in II Not Exempt ("No" in Cynthia O. C	ase, Di	r, Office o	f Research Admin		
Exempt 6a): 6a): No Type Exemption No. IRB approval di	DDDDD March M	2200 West Main St., Suite 820 Erwin Square Plaza				
No Yes Exemption No. IRB approval da	Duting MO			•		
6b. Federal Wide Assurance No. 00009025	Tel: (919) 684-5			^{ax:} (919) 684-6278		
6c. NIH-Defined Phase III	E-MAIL:					
Clinical Trial 🔲 No 🔀 Yes	gcmail@mc.d	uke.edu				
7. VERTEBRATE ANIMALS X No Yes	10. PROJECT/PEF			anan and a second a second and a second a second a second a		
7a. If "Yes," IACUC approval Date	Organizational Nan	Organizational Name: Duke University				
7b. Animal Welfare Assurance No.	DUNS: 044387	793				
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	Street 1:					
8a. DIRECT \$ 207,194 8b. TOTAL \$ 322,404	Street 2:					
9. INVENTIONS AND PATENTS INO Yes	^{Cily:} Durham		c	countý:		
If "Yes, D Previously Reported	State: NC		P	rovince		
Not Previously Reported	Country: United	States	Z	ip/Postal Code:		
	Congressional Dist	ricts: NC		••••••••••••••••••••••••••••••••••••••		
11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLIC	ANT ORGANIZATION (II)					
Laurie A. Henry, MBA, CRA, Assistant Direct	or, ORA					
TEL: (919) 684-5175 FAX: (919) 684-6278		E-MAIL: d	avis126@mc.duke.edu		
12. Corrections to Page 1 Face Page	NALA COMPANY OF THE REPORT OF THE COMPANY.			2011-1914-19-9-1919-1919-1914-1914-1914-1		
13 APPLICANT OBCANIZATION CEPTICICATION AND AC		leichter		TOTAL REALON DE LA COM		
 APPLICANT ORGANIZATION CERTIFICATION AND AC statements herein are true, complete and accurate to the best of r statements herein are true. 	ny knowledge, and accept the	11. (In i		FICIAL NAMED IN DATE		
obligation to comply with Public Health Services terms and conditi result of this application. I am aware that any falso, flotitious, or fr	ons if a grant is awarded as a audulent statements or claims	110	/	01/19/2010		
may subject me to criminal, civil, or administrative penalties. PHS 2590 (Rev. 06/09)	Ener Bern	Hau	me	vient		
	Face Page			Form Page 1		

 $+ i \frac{1}{2}$

Pages 3 through 14 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle):	Goldberg, Ronald N.				
PROGRESS REPORT SUM	MARY	GRANT NUMBER 5U10-HD040492-10				
		PERIOD COVERED BY THIS REPORT				
PROGRAM DIRECTOR / PRINCIPAL INVEST	IGATOR	FROM	THROUGH			
Goldberg, Ronald N.		04/01/2009	03/31/2010			
APPLICANT ORGANIZATION Duke University						
TITLE OF PROJECT (Repeat title shown in Ite Cooperative Multicenter Neonatal Res						
A. Human Subjects (Complete Item 6 on the Face	Page)					
Involvement of Human Subjects	No Chang	ge Since Previous Submission	Change			
B. Vertebrate Animals (Complete Item 7 on the Fa	ace Page)					
Use of Vertebrate Animals	No Chang	ge Since Previous Submission	Change			
C. Select Agent Research	No Chang	ge Since Previous Submission	Change			
D. Multiple PD/PI Leadership Plan	🔀 No Chang	ge Since Previous Submission	Change			
E. Human Embryonic Stem Cell Line(s) Used	No Chang	ge Since Previous Submission	Change			

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

6. Project Report Summary

6A. Specific Aims. The specific aims have not changed. Duke will: 1) conduct Network protocols; 2) provide investigator experience and institutional support to fulfill Network objectives; 3) propose novel opportunities for research. The Duke School of Medicine and Department of Pediatrics fully support the Aims. Duke added the University of North Carolina Chapel Hill (UNC) as a satellite site January 2009. The addition doubled potential enrollment and added intellectual depth. Drs. Ronald Goldberg, Michael Cotten, and Ricki Goldstein continue as PI, alternate, and follow-up PI. Drs. Matthew Laughon and Diane Marshall are leading trials and follow-up at UNC. Sandra Grimes is the Duke Network coordinator. Gennie Bose is the UNC coordinator. Dr. Goldberg serves on Not responsive. Not related to SUPPORT.

			Dr. (Cotten is a consultant on the		
subcommittee. Dr. Goldstein is on the	е	subcommitte	ee.	Drs. Goldberg and Laughon	serve on the	Э
Not responsive. Not related to SUPPORT.		subcommitte	ee, a	and on the ^{Not responsive. Not related to}	SUPPORT.	

6B. Studies and Results.

Duke-Initiated Network Studies

Not responsive. Not related to SUPPORT.

Active Network Studies.

<u>3. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT).</u> Duke has participated in the four SUPPORT secondary studies. Duke's SUPPORT follow-up rate is 94.59% through 12/31/09.

OD. Plans

Duke and UNC investigators continue to develop and present novel studies for the Network: Not responsive. Not related to SUPPORT.

3. Do Interactions of oxygen exposure and genetic variations influence ROP risk? Evidence suggests genetic variation contributes to risk of ROP. At the January 2009 Steering Committee, Drs. Cotten and John Dagle's (Iowa) concept to collect DNA from SUPPORT participants during follow-up was approved. The protocol will be developed to test ROP-oxygen-genetic variation interactions in key angiogenic and oxygen sensitive pathways.

Pages 17 through 22 redacted for the following reasons: Not responsive. Not related to SUPPORT.

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial: Breathing Outcomes Study

Total Planned Enrollment: 0-study closed

TARGETED/PLANNED ENROLLMENT: Number of Subjects				
Ethnic Category	Females	Males	Total	
Hispanic or Latino	0	0	0	
Not Hispanic or Latino	0	0	0	
Ethnic Category: Total of All Subjects *	0	0	0	
Racial Categories				
American Indian/Alaska Native	0	0	0	
Asian	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	
Black or African American	0	0	0	
White	0	0	0	
Racial Categories: Total of All Subjects *	0	0	0	

Program Director/Principal Investigator (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	NICHD SUPPORT	Trial: Breathing Outcomes Study		
Total Enrollment:	30	Protocol Number:	Pro00000022	
Grant Number:	5U10HD040492-09			

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 '
Not Hispanic or Latino	12	15	0	27
Unknown (individuals not reporting ethnicity)	0	3	0	3
Ethnic Category: Total of All Subjects*	12	18	0	30 '
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	2	0	2
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	8	9	0	17
White	4	4	0	8
More Than One Race	0	0	0	0
Unknown or Not Reported	0	3	0	3
Racial Categories: Total of All Subjects*	12	18	0	30 '

			Sex/Gender Unknown or	
Racial Categories	Females	Males	Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	. 0
Native Hawaiian or Other Pacific Islander	0	. 0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

Pages 25 through 32 redacted for the following reasons: Not responsive. Not related to SUPPORT.

This report format should NOT be used for data collection from study participants.

Study Title: Post-natal Growth of Infants Enrolled in the NICHD SUPPORT Study

Total Planned Enrollment: 0-study closed to enrollment

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Females	Males	Total		
Hispanic or Latino	0	0	0		
Not Hispanic or Latino	0	0	0		
Ethnic Category: Total of All Subjects *	0	0	0		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	0	0	. 0		
White	0	0	0		
Racial Categories: Total of All Subjects *	0	0	0		

This report format should NOT be used for data collection from study participants.

Study Title:Post-natal Growth of Infants Enrolled in the NICHD SUPPORT Study: A Secondary StudyTotal Enrollment:49Protocol Number:Pro00015378Grant Number:5U10 HD 40492-07

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total	
Hispanic or Latino	0	2	0	2	**
Not Hispanic or Latino	23	21	0	44	
Unknown (individuals not reporting ethnicity)	1	2	0	3	
Ethnic Category: Total of All Subjects*	24	25	0	49	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	1	0	0	1	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	13	14	0	27	
White	9	9	0	18	
More Than One Race	0	0	0	0	
Unknown or Not Reported	1	2	0	3	
Racial Categories: Total of All Subjects*	24	25	0	49	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	2	0	2
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	2	0	2 **

* These totals must agree.

** These totals must agree.

Pages 35 through 42 redacted for the following reasons: Not responsive. Not related to SUPPORT.

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT

Total Planned Enrollment: 0

TARGETED/PLANNED ENROLLMENT: Number of Subjects				
Ethnic Category	Females	Males	Total	
Hispanic or Latino	0	0	0	
Not Hispanic or Latino	0	0	0	
Ethnic Category: Total of All Subjects *	0	0	0	
Racial Categories				
American Indian/Alaska Native	0	0	0	
Asian	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	
Black or African American	0	0	0	
White	0	0	0	
Racial Categories: Total of All Subjects *	0	0	0	

This report format should NOT be used for data collection from study participants.

Study Title:	Neuroimaging and Neuro	developmental Outcome: A S	econdary to SUPPORT	
Total Enroliment:	21	Protocol Number:	Pro00000001	
Grant Number:	5U10HD040492-09			

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total	
Hispanic or Latino	0	0	0	0	**
Not Hispanic or Latino	8	13	0	21	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	8	13	0	21	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	0	3	0	3	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	5	4	0	9	
White	4	4	0	8	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	1	0	1	
Racial Categories: Total of All Subjects*	9	12	0	21	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

Pages 45 through 46 redacted for the following reasons: Not responsive. Not related to SUPPORT.

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway and Pulse Oximetry Trial in ELBW Infants

Total Planned Enrollment: 0-study closed to enrollment

TARGETED/PLANNED ENROLLMENT: Number of Subjects				
Ethnic Category	Females	Males	Total	
Hispanic or Latino	0	0	0	
Not Hispanic or Latino	0	0	0	
Ethnic Category: Total of All Subjects *	0.	0	0	
Racial Categories				
American Indian/Alaska Native	0	0	0	
Asian	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	
Black or African American	0	0	0	
White	0	0	0	
Racial Categories: Total of All Subjects *	0	0	0	

This report format should NOT be used for data collection from study participants.

Study Title:Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW InfantsTotal Enrollment:64Protocol Number: Pro00015378Grant Number:5U10HD040492-09Protocol Number: Pro00015378

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total	
Hispanic or Latino	0	3	0	3	**
Not Hispanic or Latino	28	30	0	58	
Unknown (individuals not reporting ethnicity)	1	2	0	3	
Ethnic Category: Total of All Subjects*	29	35	0	64	*
Racial Categories					
American Indian/Alaska Native	0	1	0	1	
Asian	2	0	0	2	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	17	20	0	37	
White	9	12	0	21	
More Than One Race	0	0	0	0	
Unknown or Not Reported	1	2	0	3	
Racial Categories: Total of All Subjects*	29	35	0	64	*
			<u> </u>		·

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	3	0	3
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	3	0	3 **

* These totals must agree.

** These totals must agree.

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Follow Up

Total Planned Enrollment: 10

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Females	Males	Total		
Hispanic or Latino	1	1	2		
Not Hispanic or Latino	4	4	8		
Ethnic Category: Total of All Subjects *	5	5	10		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	2	3	5		
White	3	2	5		
Racial Categories: Total of All Subjects *	5	5	10		

This report format should NOT be used for data collection from study participants.

Study Title:Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Follow UpTotal Enrollment:35Grant Number:5U10HD040492-09

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 *
Not Hispanic or Latino	20	13	0	33
Unknown (individuals not reporting ethnicity)	0	2	0	2
Ethnic Category: Total of All Subjects*	20	15	0	35 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	1	1	0	2
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	13	11	0	24
White	6	1	0	7
More Than One Race	0	0	0	0
Unknown or Not Reported	0	2	0	2
Racial Categories: Total of All Subjects*	20	15	0	35 *
			v.	
PART B. HISPANIC ENROLLMENT REPORT: N	lumber of Hispanic	s or Latino	s Enrolled to Date	e (Cumulative
Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

Pages 51 through 55 redacted for the following reasons: Not responsive. Not related to SUPPORT.

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	<u>APPROVED</u> <u>THROUGH</u>
lot responsive. Not elated to SUPPORT.			
			[-
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	Pro00015378	3/20/2009	4/7/2010
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	Pro00000001	4/21/2009	5/3/2010
Breathing Outcomes (SUPPORT Study Secondary)	Pro00000022	12/5/2009	12/04/2010
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	Pro00015378	3/20/2009	4/7/2010

Not responsive. Not related to SUPPORT.

56

Page 58 redacted for the following reason: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD040498-05

PI Name:O'SHEA, TOrg:WAKE FOREST UNIVERSITY HEALTH
SCIENCESStart Date:04/01/2005Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:6942324Rec'd
Date:01/31/2005

Department of Health and Human Services Public Health Services	Review Group Type Activity Grant Number 5-U10 HD40498-05
	Total Project Period
Orent Dreament Devent	From: 5/14/01 Through: 3/31/06
Grant Progress Report	Requested Budget Period
	From: 4/1/05 Through: 3/31/06
1. TITLE OF PROJECT	
Cooperative Multicenter Neonatal Research Ne	etwork
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	3. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code) O'Shea, T. Michael	(Name and address, street, city, state, zip code) Wake Forest University Health Sciences
Wake Forest University Health Sciences	
Medical Center Boulevard	Medical Center Boulevard Gradient Winston-Salem, NC 27157
Winston-Salem, NC 27157	
2b. E-MAIL ADDRESS moshea@wfubmc.edu	4. ENTITY IDENTIFICATION NUMBER
	5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Pediatrics	Director, Grants Management, Controllers Office
2d. MAJOR SUBDIVISION	Wake Forest University Health Sciences
School of Medicine	Medical Center Boulevard
	Winston-Salem, NC 27157
	E-MAIL: nihawards@wfubmc.edu
6. HUMAN SUBJECTS	7. VERTEBRATE ANIMALS
No 6a. Research Exempt 6b. Human Subjects Assurance	No. No. 7a. If "Yes," IACUC approval Date
X Yes X No ☐ Yes FWA00001435	Yes
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III	7b. Animal Welfare Assurance No.
Exemption No. Clinical Trial No Yes	A3391-01
If Not Exempt ("No" in 6a):	{
IRB approval date	w
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVENTIONS AND PATENTS
8a. DIRECT \$138,990 8b. TOTAL \$199,451	No 🗍 Yes If "Yes," 📋 Previously Reported
	Not Previously Reported
10. PERFORMANCE SITE(S) (Organizations and addresses)	11a. PRINCIPAL INVESTIGATOR TEL 336-716-2529
Wake Forest University Health Sciences	OR PROGRAM DIRECTOR (Item 2a)
Medical Center Boulevard	
Winston-Salem, NC 27157	11b. ADMINISTRATIVE OFFICIAL TEL 336-716-2406
	Marty Dozier FAX 336-716-6705
	11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT
Forsyth Medical Center	ORGANIZATION (Item 14)
3333 Silas Creek Parkway	NAME KIM VARGAS, MBA
Winston-Salem, NC 27103	TITLE DIRECTOR, GRANTS ADMINISTRATION
	TEL 336-716-4548 FAX 336-716-4480
	E-MAIL nihawards@wfubmc.edu
12. Corrections to Page 1 Face Page	
11c. Sheila L. Vrana, PhD is no longer with our	r institution
13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURA	
15. FRINCIPAL INVESTIGATION FOOGRAM DIRECTOR ASSURA statements herein are true, complete and accurate to the best of my know any false ficilities or fraudulent statements or claims may subject me to	wledge. I am aware that (In ink. "Per" signature not acceptable.)

statements herein are true, complete and accurate to the best of my knowledge. I an aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.	(In ink. "Per" signature not acceptable.) T. Millan O'Slea
14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictilious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Pop" signature not acceptable.)

1/25/05

DATE

1/a

Pages 3 through 4 redacted for the following reasons: Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5-U10 HD40498-05				
	PERIOD COVERED BY THIS REPORT				
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Thomas Michael O'Shea	FROM 04/01/05	THROUGH 03/31/06			
APPLICANT ORGANIZATION Wake Forest University Health Sciences					
TITLE OF PROJECT (Repeat title shown in Item 1 on first pag Cooperative Multicenter Neonatal Research Netwo	,				
A. Human Subjects (Complete Item 6 on the Face Page)					
	inge Since Previous Submission	Change			
B. Vertebrate Animals (Complete Item 7 on the Face Page)					
Use of Vertebrate Animals 🛛 🕅 No Cha	inge Since Previous Submission	Change			
SEE PHS 2590 INSTRUCTIONS.					

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

I. SPECIFIC QUESTIONS:

1) Has there been a change in the other support of key personnel since the last reporting period? NO

2) Will there be, in the next budget period, a significant change in the level of effort for key personnel from what was approved for this project (defined as a 25% reduction)? NO

3) Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total budget? NO

II. SPECIFIC AIMS: The specific aims (listed below) have not been modified.

III. STUDY RESULTS

SPECIFIC AIM 1: Identify priority issues for research by the Neonatal Research Network (NRN).

The PI has served on the Protocol Review Subcommittee in GY01-04. This committee facilitates the development of new protocols. In GY04, this subcommittee reviewed sixteen protocols, including three secondary studies for SUPPORT, two studies o^{Not responsive. Not related to SUPPORT.}

The P.I. is serving on the Subcommittees for two studies which

Ongoing Projects:

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

7. SUPPORT Trial – This study is being reviewed by the IRBs at both Forsyth Medical Center and Wake Forest University Baptist Medical Center (Brenner Children's Hospital.

Not responsive. Not related to SUPPORT.

Pages 8 through 18 redacted for the following reasons: Not responsive. Not related to SUPPORT.

IRB Approvals

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (The SUPPORT Trial) Institutional Project Number from IRB: BG04-653 WFUBMC IRB approval date: Provisional date 1/11/05

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (The SUPPORT Trial) Institutional Project Number from IRB: FMC010605 FMC IRB approval date: Provisional date 1/13/05 Pages 21 through 22 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

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5U10HD040521-05

PI Name:	PHELPS, DALE
Org:	UNIVERSITY OF ROCHESTER
Start Date:	04/01/2005
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	6895896
Rec'd Date:	02/04/2005

•	alth and Human Services Health Services	Review Group Type Activity Grant Number
		Total Project Period From: 5/1/2001 Through: 3/31/2006
Grant Pro	gress Report	Requested Budget Period From: 4/1/2005 Through: 3/31/2006
1. TITLE OF PROJECT	······································	
Rochester Center-Mu	Iticenter Neonatal Resea	arch Network
2a. PRINCIPAL INVESTIGATOR		3. APPLICANT ORGANIZATION
(Name and address, street, c Dale L. Phelps, MD	ity, state, zip code)	(Name and address, street, city, state, zip code)
University of Rochest	er	Department of Pediatrics
•	rics, Rm 4-3265, Box 65	1 601 Elmwood Ave
601 Elmwood Ave	100, 1011 1 0200, DOX 00	Rochester, NY 14642-8777
Rochster, NY 14642-	8651	
2b. E-MAIL ADDRESS	······	4. ENTITY IDENTIFICATION NUMBER
dale_phelps@urmc.roc	•	1160743209A1
	ABORATORY, OR EQUIVALENT	
Pediatrics 2d. MAJOR SUBDIVISION		Donna Galloway, Sr. Research Administrator
School of Medicine a	nd Dentistry	University of Rochester
	na Dentistry	5th Floor Hylan Building
		Rochester, NY 14627
		E-MAIL: donna.galloway@rochester.edu
6. HUMAN SUBJECTS		7. VERTEBRATE ANIMALS
	6b. Human Subjects Assurance M1357	^{e No.} No 7a. If "Yes," IACUC approval Date
		Yes
If Exempt ("Yes" in 6a):	6c. NIH-Defined Phase III Clinical Trial No X Yes	7b. Animal Welfare Assurance No.
Exemption No. If Not Exempt ("No" in 6a):		
IRB approval date 03/09/04	Full IRB or Expedited Revie	
8. COSTS REQUESTED FOR M		9. INVENTIONS AND PATENTS
8a. DIRECT \$146,886	86. TOTAL \$234,283	No Yes If 'Yes," Previously Reported
	00. TOTAL \$204,200	Not Previously Reported
10. PERFORMANCE SITE(S) (O	rganizations and addresses)	11a. PRINCIPAL INVESTIGATOR TEL (585)-275-2972
Department of Pediat		OR PROGRAM DIRECTOR (Item 2a)
University of Rochest		
School of Medicine ar	•	NAME (Item 5)
		Donna Galloway FAX (585)-275-9492
601 Elmwood Avenue	-8777	11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)
601 Elmwood Avenue		NAME Donna Galloway
601 Elmwood Avenue		
601 Elmwood Avenue		NAME Donna Galloway

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECT statements herein are true, complete and accurate to the b any false, fictitious, or fraudulent statements or claims may administrative penalties. I agree to accept responsibility fo and to provide the required progress reports if a grant is av	est of my knowledge. I am aware that subject me to criminal, civil, or r the scientific conduct of the project		er Signature not acceptable.)	1/28/05
14. APPLICANT ORGANIZATION CERTIFICATION Al statements herein are true, complete and accurate to the b obligation to comply with Public Health Services terms and result of this application. I am aware that any false, fictition may subject me to criminal, civil, or administrative penalties	est of my knowledge, and accept the conditions if a grant is awarded as a us, or fraudulent statements or claims		OF OFFICIAL NAMED IN "Per" signature not	DATE
PHS 2590 (Rev. 09/04)	Face Page	-00-		Form Page 1

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Pages 3 through 6 redacted for the following reasons: Not responsive

Principal Investigator/Program Director (Last, First, Middle):	Phelps, Dale L			
PROGRESS REPORT SUMMARY	GRANT NUMBER HD40521			
	THIS REPORT			
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH		
Dale L. Phelps, MD	Phelps, MD 4/1/2004 3/31/2005			
APPLICANT ORGANIZATION University of Rochester, Department of Pediatrics				
TITLE OF PROJECT (Repeat title shown in Item 1 on first page) Rochester Center - Multicenter Neonatal Research N	etwork			
A. Human Subjects (Complete Item 6 on the Face Page)				
Involvement of Human Subjects 🛛 🛛 No Change	e Since Previous Submission	Change		
B. Vertebrate Animals (Complete Item 7 on the Face Page)				
Use of Vertebrate Animals No Change	Since Previous Submission	Change		
SEE PHS 2590 INSTRUCTIONS.				

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

I. Personnel: All personnel with any contact with research subjects or their data have passed the required education course on the Ethical Conduct of Research in Human Subjects. Listing pp 18-19.

II. Protocols: (See listings for IRB approval dates p20)

Not responsive

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Protocols (continued) Not responsive

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9.

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Not responsive

- (10.) SUPPORT: Local PI: N. Laroia with D. Phelps. The IRB approval for this study is in review (since Nov.) pending with written consent. Training and in-service is ongoing and we anticipate few difficulties as we have been participating in the Australian based COIN study which is quite similar. The COIN study will not be permitted to compete for SUPPORT eligible infants once SUPPORT begins. This was prearranged with both COIN and NRN investigators. Fellows and attendings will be responsible for obtaining consent.
- III. Committee Work: Phelps serves on the Protocol (vice chair) and Concurrent Trials Service Committees.

IV. Summary:	
Not responsive	
V. Human Subjects	
Not responsive	
Not responsive and possibly Not responsive	New in the 05 year will be the protocols for SUPPORT,
Not responsive	
PHS 398/2590 (Rev. 05/01)	Page 8 Continuation Format Page

Pages 10 through 20 redacted for the following reasons: Not responsive

	RSRB #	Date Approved or re-approved	Title		
	Not responsive				
			The SUPPORT Study of Ea	arly CPAP in Low	
	10486	Pending	Gestation Infants		
<u>F</u>	Former Protocc	ols, now closed:			
(Grant #1_U1	0 HD40521			
		L. Phelps, MD			,
(Principal Inves	itigator Printed Name)	Dale L. Phelps, MD		
	Signature:	Dale	- Olufs	مىس	1/26/2005
_	Business Offic	ial Printed Name)	SENIOR UNIX 24.105	DONNA GALLOWAY RESEARCH ADMINI /ERSITY OF ROCHE	STRA

Listing of Protocol and IRB numbers and dates: 1/5/05

Pages 22 through 25 redacted for the following reasons: Not responsive Progress Report Scanning Cover Sheet

5U10HD040689-05

PI Name:ROSENFELD, CHARLESOrg:UNIVERSITY OF TEXAS SW MED
CTR/DALLASStart Date:04/01/2005Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:6895903Rec'd
Date:01/31/2005

Form Approved Through 09/30/200	77						c	OMB No. 0925-000
Department of Health and Human Services Public Health Services		F	Review Group	Type 5	Activity U10		ant Number D 040689-	05
		-	Total Project Peri	iod	_			
Grant Progress Report			-rom: 4/1/200		тт	hrough	: 3/31/200	6
Orant i rog	Jiess Report		Requested Budge					· •
		[I	-rom: 4/1/200	5	Т	hrough	: 3/31/200	6 :
1. TITLE OF PROJECT	er Neonatal Research Ne	two	-le					·
2a. PRINCIPAL INVESTIGATOR			R PPLICANT ORG			•		
(Name and address, street, city			ame and addres			zip cod	le)	<u></u>
Charles R. Rosenfeld,	M.D.	U	T Southwes	tern Me	edical C	enter	• • • • •	a-ri-sina •a_ •biase ● ●
UT Southwestern Med	ical Center	D	epartment o	f Pedia	trics			06
Dept. of Pediatrics		5	323 Harry H	ines Bl	vd.			6
5323 Harry Hines Blvd		D	allas, TX 75	5390-90	063			
Dallas, TX 75390-906	3							
2b. E-MAIL ADDRESS		4. E	NTITY IDENTIFI	CATION	NUMBER			
charles.rosenfeld@utsou	thwestern.edu	17	756002868A4	Ļ				
2c. DEPARTMENT, SERVICE, LA	BORATORY, OR EQUIVALENT	5. T	ITLE AND ADDF	RESS OF	ADMINIST	RATIV	E OFFICIAL	
Pediatrics		A	ssociate Dea	an for F	Researc	h		
2d. MAJOR SUBDIVISION] U	T Southwes	tern Me	edical C	enter		
School of Medicine			323 Harry H					
		D	allas, TX 75	5390-91	105			
		E-MA	IL: grants.m	igt@uts	outhwes	tern.e	du	
6. HUMAN SUBJECTS		· [;	7. VERTEBRAT	E ANIMAI	LS			
No 6a. Research Exempt	6b. Human Subjects Assurance	No.	⊠ No			7a. If	"Yes," IACU	C approval Date
Yes No Yes	FWA 00005087		Yes					
If Exempt ("Yes" in 6a):	6c. NIH-Defined Phase III Clinical Trial X No Yes	1	7b. Animal Welfa	ire Assura	ance No.			
Exemption No. If Not Exempt ("No" in 6a):								
IRB approval date see attache		N						
8. COSTS REQUESTED FOR NE	EXT BUDGET PERIOD			PATEN	rs			
8a. DIRECT \$150,337	8b. TOTAL \$234,526	 	No 🗌 Yes	lf "Yes,"		-	Reported	
							usly Reporte	
10. PERFORMANCE SITE(S) (Org			PRINCIPAL INV			EL 2	214-648-39	903
UT Southwestern Med			ROGRAM DIRE			•x 2	214-648-24	481
5323 Harry Hines Blvd			ADMINISTRATI				214-648-44	
Dallas, TX 75390-906	3	NAM	E (Item 5)					
			mas R. Boetto				214-648-44	
			NAME AND TIT ORGANIZATION			GNING	FOR APPLI	CANT
		NAM						
		TITL			-		h	
		TEL	214-648-4	4494		FAX	214-648-	-4474
		E-MA	IL grants.m	gt@uts	southwe	stern	.edu	
12. Corrections to Page 1 Face Pa	ge							

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13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSUR statements herein are true, complete and accurate to the best of my kno any false, fictitious, or fraudulent statements or claims may subject me t administrative penalties. I agree to accept responsibility for the scientifi and to provide the required progress reports if a grant is awarded as a r	wledge. I am aware that	(In inj. Per"	OF PI/PD NAM signature not ac	ceptable.)	DATE 1/26/05
14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEP statements herein are true, complete and accurate to the best of my kno obligation to comply with Public Health Services terms and conditions if result of this application. I am aware that any false, fictitious, or fraudulumay subject me to criminal, civil, or administrative penalties.	owledge, and accept the a grant is awarded as a ent statements or claims	Anc. (In ink.	OF OFFICIAL N "Per" signature	not	DATE 1/28/01
PHS 2590 (Rev. 09/04)	Face Page	y			Form Page 1

Pages 3 through 5 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle):	Rosenfeld, Charles	s R.	
PROGRESS REPORT SUMMARY	GRANT NUMBER 5-U10-HD 040689-05		
	PERIOD COVERED BY THIS REPORT		
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH	
Charles R. Rosenfeld	04/01/05	03/31/06	
APPLICANT ORGANIZATION UT Southwestern Medical Center			
TITLE OF PROJECT (Repeat title shown in Item 1 on first page) Cooperative Multicenter Network of Neonatal Intensi			
A. Human Subjects (Complete Item 6 on the Face Page)			
Involvement of Human Subjects No Chang	e Since Previous Submissio	n Change	
B. Vertebrate Animals (Complete Item 7 on the Face Page)			
Use of Vertebrate Animals No Chang	e Since Previous Submissio	n Change	
SEE PHS 2590 INSTRUCTIONS.			
WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Us Targeted/Planned Enrollment Format Page.	e Inclusion Enrollment Rep	port Format Page and, if necessary,	

Progress Report: The Network site at UT-Southwestern Medical Center participated in all Network studies during 2003. Attached patient enrollment reports for 2004 reflect grant activity. Each study is summarized below: Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

During the coming funding period, 2005-2006, we will continue to recruit patients to the ongoing studies outlined above. We hope to initiate a new study entitled the SUPPORT Trial, Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW. IRB approval is pending. We are also actively participating in the design of new studies examining fluid and electrolyte balance and therapy in the VLBW.

Pages 8 through 29 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD040689-07

PI Name:SANCHEZ, PABLOOrg:UNIVERSITY OF TEXAS SW MED
CTR/DALLASStart Date:04/01/2007Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7219971Rec'd
Date:01/30/2007

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Department of Health and Human Services Public Health Services	Review Group Type Activity Grant Number 5 U10 HD 040689-007			
	Total Project Period			
	From: 4/1/2006 Through: 3/31/2011			
Grant Progress Report	Requested Budget Period			
	From: 4/1/07 Through: 3/31/08			
1. TITLE OF PROJECT	From: 4/1/07 Through: 3/31/08			
NICHD Cooperative Multicenter Neonatal Rese	arch Network			
 2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code) Pablo J. Sánchez, M.D. University of Texas Southwestern Medical Ctr Department of Pediatrics 5323 Harry Hines Boulevard Dallas, Texas 75390-9063 	 APPLICANT ORGANIZATION (Name and address, street, city, state, zip code) University of Texas Southwestern Medical Center Department of Pediatrics 5323 Harry Hines Boulevard Dallas, Texas 75390-9063 			
2b. E-MAIL ADDRESS pablo.sanchez@utsouthwestern.edu	4. ENTITY IDENTIFICATION NUMBER 1756002868A4			
	E-MAIL: grants.mgt@utsouthwestern.edu			
6. HUMAN SUBJECTS No Yes No Yes No Yes 6a. Research Exempt FWA 00005087 FWA 00005087	7. VERTEBRATE ANIMALS No. 7a. If "Yes," IACUC approval Date Yes			
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III	7b. Animal Welfare Assurance No.			
Exemption No.	<u>5</u>			
If Not Exempt ("No" in 6a): IRB approval date see page #10	v			
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVENTIONS AND PATENTS			
8a. DIRECT \$173,887 8b. TOTAL \$ 273,003	No Yes If "Yes," Previously Reported			
10. PERFORMANCE SITE(S) (Organizations and addresses) UT Southwestern Medical Center	11a. PRINCIPAL INVESTIGATOR TEL 214-648-3753 OR PROGRAM DIRECTOR (Item 2a)			
5323 Harry Hines Boulevard	Pablo J. Sánchez, M.D. FAX 214-648-2481			
Dallas, Texas 75390-9063	11b. ADMINISTRATIVE OFFICIAL TEL 214-648-4494 NAME (Item 5)			
	Ron Isaacson, PhD FAX 214-648-4474			
	11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)			
	NAME Perrie M. Adams, PhD			
	Int. NAME AND THEE OF OFFICIAL SIGNING FOR AFFEICANT ORGANIZATION (Item 14) NAME Perrie M. Adams, PhD TITLE Associate Dean for Research TEL 214-648-4494 FAX 214-648-4474			
	TEL 214-648-4494 FAX 214-648-4474			
	E-MAIL grants.mgt@utsouthwestern.edu			

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCE statements herein are true, complete and accurate to the best of my k obligation to comply with Public Health Services terms and conditions result of this application. I am aware that any false, fictitious, or fraudu may subject me to criminal, civil, or administrative penalties.	nowledge, and accept the if a grant is awarded as a	11c. (lh ink. acceptable.)	"Per" signature not	DATE 1/16/07
PHS 2590 (Rev. 04/06)	Face Page	/	43	Form Page 1

Pages 3 through 6 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Principal Investigator/Program Direct	or (Last, First, Middle):	Sanchez, Pablo J.	
PROGRESS REPORT SUMMARY		GRANT NUMBER	
		5 U10 HD 040689-06	
		PERIOD COVERED BY THIS	REPORT
PRINCIPAL INVESTIGATOR OR PROGRA	M DIRECTOR		THROUGH
Pablo J. Sánchez		4/01/06	3/31/07
APPLICANT ORGANIZATION			
University of Texas Southwestern	Medical Center		
TITLE OF PROJECT (Repeat title shown in	Item 1 on first page)		
Cooperative Multicenter Network of	f Neonatal Intens	sive Care Units	
A. Human Subjects (Complete Item 6 on the	e Face Page)		
Involvement of Human Subjects	🔀 No Chang	e Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on	the Face Page)		
Use of Vertebrate Animals	No Chang	e Since Previous Submission	Change
C. Select Agent Research	No Chang	e Since Previous Submission	Change
D. Multiple DL Leadership Dien		a Since Previous Submission	Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The UT Southwestern Dallas (UTSW) site participated in the following Neonatal Research Network (NRN) studies during 2006. These studies are enthusiastically supported by members of the Neonatology Division, as well as by the Pediatric Department, Parkland Memorial Hospital (PMH) and Children's Medical Center Dallas (CMCD). A list of IRB approvals and patient enrollment tables are provided with this grant.

Not responsive. Not related to SUPPORT.

3. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT). This study evaluates whether early use of nasal CPAP and a permissive ventilatory strategy in infants <28 wk of gestation results in a 10% increased survival without BPD, assesses the use of a lower oxygen saturation range on retinopathy of prematurity and survival, and whether these practices result in decreased mortality and neurodevelopmental impairment at 18-22 months corrected age. In 2006, we enrolled 14 infants, and all are part of the **Growth** assessment and **Breathing Outcomes** substudies. Eight of these infants (9 eligible) are enrolled in the **MRI** secondary study which will correlate neuroimaging with PHS 2590 (Rev. 04/06) Page 6 neurodevelopmental outcome. We also have enrolled 30 mothers in the Antenatal Consent substudy.

Pages 9 through 10 redacted for the following reasons: Not responsive. Not related to SUPPORT.

CENTER 04

Grant # 5-U10-HD 040689-06 Principal Investigator: Pablo J. Sánchez, MD

Protocol #	Protocol Name	Approval Date	Expiration Date
Not responsive. Not related to	D SUPPORT.		
012005-019	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT) with Growth and Breathing Outcomes Substudies	10/16/06	4/02/07
042006-061	Antenatal Screening and Consent in a Research Network Model	6/14/06	6/8/07
102005-005	Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial	10/3/06	10/2/07

Not responsive. Not related to SUPPORT.

Pages 12 through 17 redacted for the following reasons: Not responsive. Not related to SUPPORT. Principal Investigator/Program Director (Last, First, Middle):

Sánchez, Pablo J.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Study Title: Weight Infants (SUPPORT) Growth Secondary Included

Total Planned Enrollment: 30

Ethnic Category	Sex/Gender			
	Females	Males	Total	
Hispanic or Latino	8	11	19	
Not Hispanic or Latino	4	7	11	
Ethnic Category: Total of All Subjects *	12	18	30	
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander	1.1			
Black or African American	3	5	8	
White	9	13	22	
Racial Categories: Total of All Subjects *	12	18	30	

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Principal Investigator/Program Director (Last, First, Middle): Sanchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

	The Surfactant Positive Airwa	y Pressure and Pulse Oximetry Trial in Extremely Low Birth
Study Title:	Weight Infants (SUPPORT) G	arowth Secondary Included
Total Enrollment:	14	Protocol Number: 3a
Grant Number:	5-U10-HD 040689-06	

		S	ex/Gender		
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	4	5		9	**
Not Hispanic or Latino	2	3		5	
Unknown (individuals not reporting ethnicity)					
Ethnic Category: Total of All Subjects*	6	8		14	*
Racial Categories					
American Indian/Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American	1	2		3	
White	5	6		11	
More Than One Race					
Unknown or Not Reported					. 1
Racial Categories: Total of All Subjects*	6	8		14	*
PART B. HISPANIC ENROLLMENT REPORT: Numb Racial Categories	er of Hispanic Females	es or Latinos Males	s Enrolled to Date Unknown or Not Reported	(Cumulativ Total	ve)
American Indian or Alaska Native				_	_
Asian					
Native Hawaiian or Other Pacific Islander					
			·		
Black or African American	4	5		9	
Black or African American White	4	5		9	
Native Hawaiian or Other Pacific Islander Black or African American White More Than One Race Unknown or Not Reported	4	5		9	

* These totals must agree.

** These totals must agree.

Inclusion Enrollment Report Format Page

Principal Investigator/Program Director (Last, First, Middle): Sánchez, Pablo J.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial Follow-up Study of Pulmonary Outcomes

Total Planned Enrollment: 26

Ethnic Cotogony	Sex/Gender				
Ethnic Category	Females	Males	Total		
Hispanic or Latino	7	10	17		
Not Hispanic or Latino	3	6	9		
Ethnic Category: Total of All Subjects *	10	16	26		
Racial Categories					
American Indian/Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American	2	4	6		
White	8	12	20		
Racial Categories: Total of All Subjects *	10	16	26		

Pages 21 through 23 redacted for the following reasons: Not responsive. Not related to SUPPORT. Principal Investigator/Program Director (Last, First, Middle):

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial

Total Planned Enrollment: 30 / year

Ethnia Catagony	Sex/Gender				
Ethnic Category	Females	Males	Total		
Hispanic or Latino	8	14	22		
Not Hispanic or Latino	3	5	8		
Ethnic Category: Total of All Subjects *	11	19	30		
Racial Categories					
American Indian/Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American	2	4	6		
White	9	15	24		
Racial Categories: Total of All Subjects *	11	19	30		

Principal Investigator/Program Director (Last, First, Middle): Sanchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Neuroimaging and Neurodev	elopmental Outcome: A Secondary to the SUPPORT Trial
Total Enrollment:	8	Protocol Number: 3d
Grant Number:	5-U10-HD 040689-06	

	Sex/Gender				
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	1	4		5 *	
Not Hispanic or Latino	1	2		3	
Unknown (individuals not reporting ethnicity)					
Ethnic Category: Total of All Subjects*	2	6		8 *	
Racial Categories					
American Indian/Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American	0	1		1	
White	2	5		7	
More Than One Race					
Unknown or Not Reported					
Racial Categories: Total of All Subjects*	2	6		8 *	
PART B. HISPANIC ENROLLMENT REPORT: N	lumber of Hispanic	s or Latino	s Enrolled to Date	(Cumulative)	
Racial Categories	Females	Males	Unknown or Not Reported	Total	
American Indian or Alaska Native					
Prototo v					

 Asian
 Image: Constraint of the symbol
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 Native Hawaiian or Other Pacific Islander
 Image: Constraint of the symbol
 Image: Constraint of the symbol

 Black or African American
 Image: Constraint of the symbol
 Image: Constraint of the symbol
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 White
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 White
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* These totals must agree.

** These totals must agree.

PHS 398/2590 (Rev. 09/04, Reissued 4/2006)

Pages 26 through 38 redacted for the following reasons:

Progress Report Scanning Cover Sheet

5U10HD040689-08

PI Name:SANCHEZ, PABLOOrg:UNIVERSITY OF TEXAS SW MED
CTR/DALLASStart Date:04/01/2008Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7392228Rec'd
Date:02/13/2008

Grant P	of Health and Huma blic Health Services		Review Group ZHD1DSRA10	Туре	Activity	Grant Number	
Grant P				5	U10	HD 040689-08	3
					<u> </u>		-
	Grant Progress Report		From: 4/1/2006		Thr	rough: 3/31/2011	
	rogress i	кероп	Requested Budget P	eriod		**************************************	······
1. TITLE OF PROJECT			From: 4/01/2008		Thr	rough: 3/31/2009	
1. TITLE OF PROJECT NICHD Cooperat	tive Multicente	r Neonatal Rese	earch Network				
2a. PROGRAM DIRECTOR (Name and address, str			2b, E-MAIL ADDRES pablo.sanche	-	outhwest	ero odu	
Pablo J. Sanchez			2c. DEPARTMENT, S				NT
University of Tex		m Medical Ctr	Pediatrics				
Dept. of Pediatrics 5323 Harry Hines Blvd. Dallas, TX 75390-9063		2d. MAJOR SUBDIVI				·····	
		School of Me					
		2e. Tel: 214-648-	3753	Fax	x: 214-648-248	1	
3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)		3b. Tel: 214-648-	3753	Fax	x: 214-648-248	1	
University of Texas Southwestern Medical		3c. DUNS: 80-077	-1545				
Center at Dallas	o Dive			1040			3] 2 2008
5323 Harry Hines Blvd. Dallas, TX 75390-9105			4. ENTITY IDENTIFI 1756002868/		NUMBER		
6. HUMAN SUBJECTS		es	5. NAME, TITLE ANI	DADDRE	SS OF ADM	INISTRATIVE OFFI	CIAL
	6a. Research If Exempt ("Yes" In If Not Exempt ("No" ir Exempt 6a): 6a):				nts Manag		
No Yes Exemption No. IRB approval date			UT Southweste 5323 Harry Hir			er	
		see pg #12	Dallas, TX 75				
6b. Federal Wide Assurance No. FWA 00005087		Tel: 214-648-449	4	Fax	د 214-648-4474	1	
6c. NIH-Defined Phase III Clinical Trial No	Yes		E-MAIL: grants.mgt@utsouthwestern.edu				
7. VERTEBRATE ANIMAL	.S 🛛 No 🗌	Yes	10. PROJECT/PERFC	RMANCE	SITE(S)		····
7a. If "Yes," IACUC approv	val Date		Organizational Name: University of Texas Southwestern Med				
7b. Animal Welfare Assurar	nce No.		DUNS: 80-077-1545 Street 1: 5323 Harry Hines Blvd.				
8. COSTS REQUESTED F	FOR NEXT BUDGE	T PERIOD					
8a. DIRECT \$173,685	85. TOTAL	\$272,685	Street 2:				
9. INVENTIONS AND PAT		Yes	city: Dallas	· · · · · · · · · · · · · · · · · · ·	Cou	unty: Dallas	
lf "Yes, 🔲 Previously R	Reported		state: Texas		Pro	vince:	
	sly Reported		Country: USA		Zip/	Postal Code: 753	90
			Congressional District	s: TX-30			
11. NAME AND TITLE OF Perrie M. Adams, Ph		3 FOR APPLICANT O	RGANIZATION (Item	13)			
-		011.010	4 4 77 4		-MAIL:		•
TEL: 214-648-4494		FAX: 214-648-	4474			gt@utsouthwe	estern.edu
12. Corrections to Page 1 Fa	ace Page					<u></u>	
			NOTLINE	X16 6 101 100			
13. APPLICANT ORGANIZA statements herein are true,	complete and accurat	e to the best of my knowle	edge, and accept the / 11	SNATURI	ר UF UFFIC יו		DATE
obligation to comply with Puresult of this application. I a	am aware that any fals	e, fictitious, or fraudulent		du .	12.1	Dhing	2/12/08
may subject me to criminal, PHS 2590 (Rev. 11/07)	, civil, or administrative		Face Page	MUL	vn s		Form Page 1

Pages 3 through 8 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle):		Sanchez, Pablo J.		
		GRANT NUMBER 5-U10-HD 040689-08		
PROGRESS REPORT SU	MMART			
		PERIOD COVERED BY TH		
PROGRAM DIRECTOR / PRINCIPAL INVE	STIGATOR	FROM	JTHROUGH	
Pablo J. Sanchez		04/01/07	03/31/08	
APPLICANT ORGANIZATION University of Texas Southwestern M	edical Center at [Dallas		
TITLE OF PROJECT (Repeat title shown in Cooperative Multicenter Network of		e Care Units		
A. Human Subjects (Complete Item 6 on the	Face Page)			
Involvement of Human Subjects	🔀 No Change	e Since Previous Submission	Change	
B. Vertebrate Animals (Complete Item 7 on t	he Face Page)			
Use of Vertebrate Animals	🔀 No Change	e Since Previous Submission	Change	
C. Select Agent Research	No Change	e Since Previous Submission	Change	
D. Multiple PI Leadership Plan	No Change	Since Previous Submission	Change	
SEE DHS 2500 INSTRUCTIONS				

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The UT Southwestern Dallas (UTSW) site participated in the following Neonatal Research Network (NRN) studies during 2007. These studies are enthusiastically supported by members of the Neonatology Division, as well as by the Pediatric Department, Parkland Memorial Hospital (PMH) and Children's Medical Center Dallas (CMCD). A list of IRB approvals and patient enrollment tables are provided with this grant.

Not responsive. Not related to SUPPORT.

3. The Surractant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT). This study evaluates whether early use of nasal CPAP and a permissive ventilatory strategy in infants <28 wk of gestation results in a 10% increased survival without BPD, assesses the use of a lower oxygen saturation range on retinopathy of prematurity and survival, and whether these practices result in decreased mortality and neurodevelopmental impairment at 18-22 months corrected age. In 2007, we enrolled 22 infants, and all are part of the Growth assessment and Breathing Outcomes substudies. In additon, 14 of 15 (93%) infants were enrolled in the MRI secondary study which will correlate neuroimaging with neurodevelopmental outcome. We also have enrolled 49 mothers in the Antenatal Consent substudy.

Pages 10 through 12 redacted for the following reasons: Not responsive. Not related to SUPPORT.

CENTER 04

Grant # 5-U10-HD 040689-06 Principal Investigator: Pablo J. Sánchez, MD

Protocol #	Protocol Name	Approval Date	Expiration Date
Not responsive. Not related to	SUPPORT.		
012005-019	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT) with Growth and Breathing Outcomes Substudies	3/29/07	3/18/08
042006-061	Antenatal Screening and Consent in a Research Network Model	6/15/07	5/09/08
102005-005	Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial	10/3/07	09/09/08
Not responsive. Not related			

Pages 14 through 19 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low				
Study Title:	Weight Infants (SUPPORT) Growth	secondary included			
Total Enrollment:	36	Protocol Number: 012005 - 019			
Grant Number:	5-U10-HD 040689-08				

		S	ex/Gender		
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	11	17		28	**
Not Hispanic or Latino	5	3		8	
Unknown (individuals not reporting ethnicity)					
Ethnic Category: Total of All Subjects*	16	20		36	*
Racial Categories					
American Indian/Alaska Native					
Asian	1			1	
Native Hawaiian or Other Pacific Islander					
Black or African American	3	2		5	
White	12	18		30	
More Than One Race					
Unknown or Not Reported					
Racial Categories: Total of All Subjects*	16	20		36	*
PART B. HISPANIC ENROLLMENT REPORT: N	umber of Hispanio	es or Latino		te (Cumulativ	/e)
Racial Categories	Females	Males	Unknown or Not Reported	Total	
American Indian or Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					

Racial Categories: Total of Hispanics or Latinos**

More Than One Race

Unknown or Not Reported

White

* These totals must agree.

** These totals must agree.

11

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**

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Study Title: Weight Infants (SUPPORT) Growth secondary included

Total Planned Enrollment: 25 / year

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Sex/Gender				
	Females	Males	Total		
Hispanic or Latino	7	12	19		
Not Hispanic or Latino	4	2	6		
Ethnic Category: Total of All Subjects *	11	14	25		
Racial Categories					
American Indian/Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander			<u> </u>		
Black or African American	2	1	3		
White	9	13	22		
Racial Categories: Total of All Subjects *	11	14	25		

Program Director/Principal Investigator (Last, First, Middle): Sanchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	NICHD SUPPORT Trial Follow-up Study of Pulmonary Outcomes					
Total Enrollment:	14	Protocol Number: 012005 - 019				
Grant Number:	5-U10-HD 040689-08					

		S	ex/Gender		
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	4	4		8	**
Not Hispanic or Latino	3	3		6	
Unknown (individuals not reporting ethnicity)					
Ethnic Category: Total of All Subjects*	7	7		14	*
Racial Categories					
American Indian/Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American	2	2		4	
White	5	5		10	
More Than One Race					
Unknown or Not Reported					
Racial Categories: Total of All Subjects*	7	7		14	*

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	4	4		8
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	4	4		8 **

* These totals must agree. ** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial Follow-on Study of Pulmonary Outcomes

Total Planned Enrollment: 17 / year

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Sex/Gender				
	Females	Males	Total		
Hispanic or Latino	5	5	10		
Not Hispanic or Latino	3	4	7		
Ethnic Category: Total of All Subjects *	8	9	17		
Racial Categories					
American Indian/Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American	2	2	4		
White	6	7	13		
Racial Categories: Total of All Subjects *	8	9	17		

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Antenatal Screening and Consent	Consent in a Research Network Model			
Total Enrollment:	89	Protocol Number: 042006 - 061			
Grant Number:	5-U10-HD 040689-08	_			

	Sex/Gender				
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	46			46	**
Not Hispanic or Latino	19			19	
Unknown (individuals not reporting ethnicity)	24			24	
Ethnic Category: Total of All Subjects*	89			89	*
Racial Categories					, -
American Indian/Alaska Native					
Asian	2			2	
Native Hawaiian or Other Pacific Islander					
Black or African American	13			13	
White	50			50	
More Than One Race					
Unknown or Not Reported	24			24	
Racial Categories: Total of All Subjects*	89			89	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American		τ, τι _Α τικός - το - τ.		
White	46			46
More Than One Race	-			
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	46			46 **

* These totals must agree.

** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Antenatal Screening and Consent in a Research Network Model

Total Planned Enrollment: 60 / year

TARGETED/PLANNED ENROL	LMENT: Number of Subjec	ts			
Ethnic Category	Sex/Gender				
	Females	Males	Total		
Hispanic or Latino	27		27		
Not Hispanic or Latino	33		33		
Ethnic Category: Total of All Subjects *	60		60		
Racial Categories					
American Indian/Alaska Native					
Asian	1		1		
Native Hawaiian or Other Pacific Islander					
Black or African American	9		9		
White	50	· · · · · · · · · · · · · · · · · · ·	50		
Racial Categories: Total of All Subjects *	60		60		

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial					
Total Enrollment:	25	Protocol Number: 102005 - 005				
Grant Number:	5-U10-HD 040689-08					

	Sex/Gender				
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	7	11		18	**
Not Hispanic or Latino	5	2		7	
Unknown (individuals not reporting ethnicity)					
Ethnic Category: Total of All Subjects*	12	13		25	*
Racial Categories					
American Indian/Alaska Native					
Asian	1			1	
Native Hawaiian or Other Pacific Islander					
Black or African American	3	1		4	
White	8	12		20	
More Than One Race					
Unknown or Not Reported		1			
Racial Categories: Total of All Subjects*	12	13		25	*

B. RISPANIC ENRULLMEN 11 URI: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	7	11		18
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	7	11		18 **

* These totals must agree. ** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial

Total Planned Enrollment: 25 / year

TARGETED/PLANNED ENROL	LMENT: Number of Subject	sts			
Ethnic Category	Sex/Gender				
Etrinic Category	Females	Males	Total		
Hispanic or Latino	7	13	20		
Not Hispanic or Latino	2	3	5		
Ethnic Category: Total of All Subjects *	9	16	25		
Racial Categories					
American Indian/Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American	2	3	5		
White	7	13	20		
Racial Categories: Total of All Subjects *	9	16	25		

Pages 28 through 41 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD040689-09

PI Name:SANCHEZ, PABLOOrg:UNIVERSITY OF TEXAS SW MED
CTR/DALLASStart Date:04/01/2009Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7612127Rec'd
Date:02/06/2009

Department of Health and Human Bervices Public Health Services Type Public Health Services <thtype Public Health Services Type Pub</thtype 	Form Approved Throu	gh 11/30/2010					0	MB No. 0925-0001
Grant Progress Report From: 4/1/2006 Through: 3/31/2011 1. TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Research Network 2a. PROGRAM DIRECTOR: PRINCIPAL INVESTIGATOR (home and address, struct, b): state. Bp code) Data Cooperative Multicenter Neonatal Research Network 2a. PROGRAM DIRECTOR: PRINCIPAL INVESTIGATOR (home and address, struct, b): state. Bp code) Data Cooperative Multicenter Neonatal Research Network 2a. State State Structure S	Departmo							¥Ő Ŷ
Grant Progress Keport Imagested Budget Period From: Hill 2009 Through: 3/31/2010 1. TITLE OF PROJECT Nichel Docoperative Multicenter Neonatal Research Network 20. (Name and address, steet, city, state, zp code) Pablo J. Sanchez, MD Pablo J. Sanchez, MD Debt. Sanchez, MD University of Texas Southwestern Medical Ctr Pediatrics S323 Harry Hines Blvd. Za MAIOR Subprysion Dailas, TX 75390-9005 Te: 214-648-3753 3a. APPLICANT ORGANIZATION Za MAIOR Subprysion Sa. PARCIANT HIME SERVED Za Maio				Total Project Period				
I. TITLE OF PROJECT Prom:: 4/01/2009 Through: 3/31/2010 I. TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Research Network 2a. PROGRAM DIRECTORY PRINCIPAL INVESTIGATOR (Name and address, street, 0/y, state, 2P code) 2b. E-MAIL ADDRESS pablo.sanchez@ultsouthwestern.adu 2b. EAMIL ADDRESS 2b. EAMIL ADDRESS Pablo J. Sanchez, MD 2b. EAMIL ADDRESS University of Texas Southwstern Medical Ctr 2b. EMAIL ADDRESS 2a. APPLICANT ORGANIZATION 3b. Tel: 214-648-3753 3a. APPLICANT ORGANIZATION 3b. Tel: 214-648-3753 3b. New and address, street, 0/y, state, 2p code) 3b. Tel: 214-648-3753 2a. Tel: 214-648-3753 Fax: 214-648-2481 3b. New Trobal Southwestern Medical Center at Dallas 3b. Tel: 214-648-3753 5 S233 Harry Hines Blvd. 3c. Tel: 214-648-3753 2b. Research IVE Exempt (Yes' in 1682 2c. Research IVE Exempt (Yes' in 1682	Grant	Drogroee	Ponort			Th	rough: 3/31/201	1
1. TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Research Network 2a. PROGRAM DIRECTORY PRINCIPAL INVESTIGATOR (March 2608): Area (P) code) Pablo J. Sanchez, MD Pablo J. Sanchez, MD Dept. of Pediatrics S323 Harry Hines Blvd. Dailas, TX 75300-9063 a. APPLICANT ORGANIZATION (Nome and address, afreq. (c), table, zip code) University of Texas Southwestern Medical Center at Dailas TT: Z14-648-3753 Fax: 214-648-2481 a. APPLICANT ORGANIZATION (Name and address, afreq. (c), table, zip code) University of Texas Southwestern Medical Center at Dailas Center at Dailas S323 Harry Hines Blvd. Dailas, TX 75300-9105 I. If Not Exempt (Yes' in Ba: Research If Exempt (Yes' in Ba: Exempt (Yes' in Ba: Exempt (Yes' in Ba: Research Medical Center Sa2 Harry Hines Blvd. Ba: Research Mide Assurance No. File approval date See pg #11 Bb: Federal Wide Assurance No. File approval date See pg #11 Bb: Federal Wide Assurance No. Yes Command Time (Mark) No Yes No Yes No Yes No Yes No Yes No Yes	Grand	riogiess	Kepon	Requested Budget F	Period			
NICHD Cooperative Multicenter Neonatal Research Network 2a PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, strete, 127, state, 25 code) 2b E-MAIL ADDRESS pablo, sanchez@ulsouthwestern.edu 2b EARLY ADDRESS Pablo, Sanchez@ulsouthwestern.edu 2c DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Device Type, Lof Pediatrics 2c DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Dailas, TX 75390-9063 2c. Tel: 214-648-3753 3a. APPLICANT ORGANIZATION (Name and address, steel, city, state, 2p code) 3b. Tel: 214-648-3753 University of Texas Southwestern Medical Center at Dailas 5c. Dours: 80-077-1545 5323 Harry Hines Blvd. 5e. Pg Ø G ZUD9 Dailas, TX 75390-9105 75390-9105 7 Ves If Bampt (Yes' in Int Bapproval date See Pg #11 San Research Mark assurance No. FWA 00005087 6e. Indent Trial No 7. VERTEBRATE ANIMALS No 7. VERTEBRATE ANIMALS No 7. VERTEBRATE ANIMALS No 8. DRECTOR FX53,360 (b. Torta, £397,775 9. INVENTIONS AND PATENTS No Yes 9. INVENTIONS AND PATENTS No Yes 9. INVENTIONS AND PATENTS No Yes 9. INVENTION		<u></u>		From: 4/01/2009		Th	rough: 3/31/2010	2
(Name and address, street, city, state, zip code) pablo J. Sanchez, MD Pablo J. Sanchez, MD Department, SERVICE, LABORATORY, OR ECUIVALENT Depiler of Pediatrics Sanchez, MD S323 Harry Hines Blvd. School of Medicine Dailas, TX 75390-9063 Ze. Tel: 214-648-3753 Sa. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code) B. Tel: 214-648-3753 University of Texas Southwestern Medical Center at Dailas FEE 0 & ZUDS S323 Harry Hines Blvd. B. Entity IDENTIFICATION NUMBER Dailas, TX 75390-9105 T756002668A4 6. HUMAN SUBJECTS No No Yes 6. Reamption No. Exemption No. Barge p#111 Tick approval date see pp #111 To. Laborad (Yes' in Brage pproval date see pp #111 Southwestern.edu Cincat Trial No Yes Sa. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL Dan Alexander, Director, Office of Grants Management UT Southwestern Medical Center Sa. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL Dallas, TX 75390-9105 Tel: 214-648-4494 Fax: 214-648-4474 Exemption No. Cinicat Trial No Yes 7. KertEgrach Animal Weffare Assurance	NICHD Coop	erative Multicente						
Pablo J. Sanchez, MD Ze_DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT University of Texas Southwstern Medical Ctr Pediatrics S323 Harry Hines Bivd. Ze_department, SERVICE, LABORATORY, OR EQUIVALENT Dallas, TX 75390-9063 Ze_tz 214-648-3753 3a. APPLICANT ORGANIZATION School of Medicine 2a. APPLICANT ORGANIZATION School of Medicine Center at Dallas School of Medical Stars Stars and the set of the se								
University of Texas Southwstern Medical Ctr Pediatrics Dept: of Pediatrics 2d MAJOR SUBDIVISION S323 Harry Hines Blvd. School of Medicine Dallas, TX 75390-9063 2e. Tei: 214-648-3753 Fax: 214-648-2481 3a. APPLICANT ORGANIZATION (Name and address, siteel, city, state, zip code) university of Texas Southwestern Medical Center at Dallas 5a. Tei: 214-648-3753 Fax: 214-648-2481 3b. Tei: 214-648-3753 Fax: 214-648-2481 3b. Tei: 214-648-3753 Fax: 214-648-2481 3c. DUNS: 80-077-1545 FEB 0 & Z009 20.000 FEB 0 & Z009 5323 Harry Hines Blvd. Dallas, TX 75390-9105 5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL Ba. Research If Exempt (Yes' in Ba. Pederal Wide Assurance No. If Not Exempt (Yes' in Ba. Pederal Wide Assurance No. FWA 000005087 6e. Research If Exempt (Yes' in Ba. Pederal Wide Assurance No. FWA 000005087 Tei: 214-648-4494 Fax: 214-848-4474 6e. Nithead Team No. Yes 10. PROJECT/PERFORMANCE SITE(S) 0rganizational Name: University of Texas Southwestern Medical Center 7. Animal Wefare Assurance No. DUNS: 80-077-1545 Steel 1: 5323 Harry Hines Blvd. 8. COSTS REQUESTED FOR NEXT BUDGET PERIOD Street 1: 5323 Harry Hines Blvd. State: Texas			(code)		-			CHIE
S323 Harry Hines Blvd. School of Medicine 3a. APPLICANT ORGANIZATION School of Medicine 3a. APPLICANT ORGANIZATION School of Medicine 3a. APPLICANT ORGANIZATION School of Medicine Center at Dallas Fax: 214-648-3753 S323 Harry Hines Blvd. Jb. Tel: 214-648-3753 Dallas, TX 75390-9105 Sa. Research If Evernpt (Yes' in file Approval data See pg #11 Sa. Research If Evernpt (Yes' in file Approval data See pg #11 Sb. Federal Wide Assurance No. FWA 00005087 Federal Wide Assurance No. FWA 00005087 T. VERTEBRATE ANIMALS IN No Yes State: 124-648-4494 Federal Wide Assurance No. FWA 00005087 T. VERTEBRATE ANIMALS IN No Yes 10 PROJECT/PERFORMANCE SITE(S) Organizational Name: University of Texas Southwestern Medical Center State: 15323 Harry Hines Bivd. B. ORECT \$253,360 Jb. Torta \$397,775 Sireel 1: \$323 Harry Hines Bivd. Sireel 1: \$323 Harry Hines Bivd. B. ORECT \$253,360 Jb. Torta \$397,775 Sireel 2: Organizational Name: University of Texas Southwestern Med DUNS: 80-077-1545 Country: Dallas I'r Yes, MCUC Approval Date Country: USA Zep/Postal Code: 75390 Country: Dallas Corrections ND PATENTS No No	University of	Texas Southwste	ern Medical Ctr		SERVICE	LABURAT	JRY, OR EQUIVAL	EN I
Dallas, TX 75390-9063 26. Tel: 214-648-3753 Fax: 214-648-2481 3a. APPLICANT ORGANIZATION (Name and address, street, city, site, zp code) 3b. Tel: 214-648-3753 Fax: 214-648-2481 University of Texas Southwestern Medical Center at Dallas 3c. DUNS: 80-077-1545 FEB 0 G. Z009 S323 Harry Hines Blvd. Dallas, TX 75390-9105 1756002868A4 2. DUNS: 80-077-1545 6. HUMAN SUBJECTS No Yes 5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL Dan Alexander, Director, Office of Grants Management UT Southwestern Medical Center 5323 Harry Hines Blvd. Dallas, TX<75390-9105	-							
3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zp code) University of Texas Southwestern Medical Center at Dallas S323 Harry Hines Blvd. Dallas, TX 75390-9105 3b. Tel: 214-648-3753 Fax: 214-648-2481 3c. Dallas, TX 75390-9105 4. ENTITY IDENTIFICATION NUMBER 1756002868A4 5. NAME, TTLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL Dan Alexander, Director, Office of Grants Management Bal, Research Exempt ("Yes" in [Exempt ("Yes" in [Gai]: No Yes 5. NAME, TTLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL Dan Alexander, Director, Office of Grants Management UT Southwestern Medical Center 5323 Harry Hines Blvd. Dallas, TX 75390-9105 6b. HU-Dafined Phase III Cinclas Trial No Yes 5. 7. VERTEBRATE ANIMALS No Yes 10. PROJECT/PERFORMANCE SITE(S) Organizational Name: University of Texas Southwestern Med DUNS: 80-077-1545 8. COSTS REQUESTED FOR NEXT BUDGET PERIOD Sizeel 1: 5323 Harry Hines Blvd. 9. INVENTIONS AND PATENTS No Yes 11. Yes, Previously Reported Curry: USA Zup/Postal Code: 75390 11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 13) Period State: Texas Perviously Reported FAX: 214-648-4474 E-MAIL: grants.mgt@utsouthwestern.edu 11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 13) Perviously Reported State: Texas Province: Curry: USA Zup/Postal Code: 7								
Name and address, street, city, state, zip code) The Z 14-000-0130 The Z 14-000-0130 University of Texas Southwestern Medical Center at Dallas Southwestern Medical Center at Dallas FEB 0 6 Z009 S323 Harry Hines Blvd. If Exempt (No*in 63) FEB 0 6 Z009 A. Entitry IDENTIFICATION NUMBER Dallas, TX 75390-9105 If Exempt (Yes* in 63) If No Exempt (No*in 63) No Exempt (No*in 63) Dan. Alexander, Director, Office of Grants Management Exempt Bar No If Exempt (Yes* in 63) If No Exempt (No*in 63) Dan. Alexander, Director, Office of Grants Management Exempt Bar No If Reampt (No*in 63) Southwestern Medical Center Southwestern Medical Center Size 1 + 04-05/900 Size 1 + 04-04-04-04 Fax: 214-648-4474 Exemption No. Exemption No. If Reampt (No*in 63) Dallas, TX 75390-9105 Dallas, TX 75390-9105 Sb. Federal Wide Assurance No. FWA 000005087 Tel: 214-648-4494 Fax: 214-648-4474 E-MaiL: grants.mgt@utsouthwestern.edu Dinersity of Texas Southwestern Medical Center TV ext referat A NIMALS IN No I Yes 10. PROJECT/PERFORMANCE SITE(S) Organizational Name: University of Texas Southwestern Medical Center State: Texas Signature in 630 Bistreferat Signature in 630 Sisreef 1: 53				2e. Tel: 214-648-	3753	Fa	x: 214-648-24	81
Center at Dallas 5323 Harry Hines Blvd. Dallas, TX 75390-9105 6. HUMAN SUBJECTS No So. Research If Exempt (Yes" in [If Not Exempt (Yos" in [6a): Bail: If Exempt (Yes" in [If Not Exempt (Yos" in [6a): Bail: Exemption No. Bail: Fee pg #11 Dallas: Tt * 214-648-4494 Fax: 214-648-4494 Fax: 214-648-4474 E-MAIL: grants.mgt@utsouthwestern.edu Clinear Hines Blvd. Dallas To VERTEBRATE ANIMALS No Yes Invest 'IACUC approval Date 7. VERTEBRATE ANIMALS No 8. COSTS REQUESTE FOR NEXT BUDGET PERIOD Street 1: 5323 Harry Hines Blvd.	(Name and address	s, street, city, state, zip		3b. Tel: 214-648	-3753	Fa	x: 214-648-24	81
5323 Harry Hines Blvd. Dallas, TX 75390-9105 4. ENTITY IDENTIFICATION NUMBER 1756002868A4 FEB 0 G 2009 6. HUMAN SUBJECTS No Yes 5. NAME: ITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL Dan Alexander, Director, Office of Grants Management Ba: perproval date see pg #11 Dan Alexander, Director, Office of Grants Management US Southwestern Medical Center 5323 Harry Hines Blvd. Dallas, TX 75390-9105 6b. Federal Wide Assurance No. FWA 00005087 Tel: 214-648-4494 Fax: 214-648-4474 6c. NIH-Defined Phase III Clinical Trial No Yes Pres 7. VERTEBRATE ANIMALS No Yes 10. PROJECT/PERFORMANCE SITE(S) Organizational Name: University of Texas Southwestern Med DuNS: 80-077-1545 8. COSTS REQUESTED FOR NEXT BUDGET PERIOD Street 1: 5323 Harry Hines Blvd. 8. DIRECT \$253,360 ab. TOTAL \$397,775 9. INVENTIONS AND PATENTS No Yes	•		tern Medical	3c. DUNS: 80-07	7-1545			
Dallas, TX 75390-9105 - ENITE OLDENTIFICATION NUMBER 17756002868A4 - ENITE OLDENTIFICATION NUMBER 6. HUMAN SUBJECTS No Yes 6. HUMAN SUBJECTS No Yes 6. HUMAN SUBJECTS No Yes 6. Research If Exempt ('Yes' in Bit Not Exempt ('No' in Bit Bapproval date See pg #11 Dan Alexander, Director, Office of Grants Management UT Southwestern Medical Center 5. Federal Wide Assurance No. FWA 00005087 Tel: 214-648-4494 Fax: 214-648-4474 6c. NIH-Defined Phase III E-MAIL: grants.mgt@utsouthwestern.edu Clinical Trial No 7. VERTEBRATE ANIMALS No Yes 10. PROJECT/PERFORMANCE SITE(S) 7. J. Yes, "IACUC approval Date Organizational Name: University of Texas Southwestern Med 7. Animal Welfare Assurance No. DUNS: 80-077-1545 8. ORECT \$253,360 Bb. TOTAL \$397,775 Street 1: 5323 Harry Hines Blvd, 8a. DIRECT \$253,360 Bb. TOTAL \$397,775 Street 2: 9. INVENTIONS AND PATENTS No Yes City: Dallas If 'Yes, Previously Reported State: Texas Province: County: USA Zip/Postal Code: 75390 Congressional Di							FEE	<u>3 0 6 2009</u>
Ba. Research If Exempt (Yes' in ba) If Not Exempt ('No' in ba) Dan Alexander, Director, Office of Grants Management UT Southwestern Medical Center 5323 Harry Hines Bivd. Dallas, TX 75390-9105 Bb. Federal Wide Assurance No. FWA 00005087 Tel: 214-648-4494 Fax: 214-648-4474 Bc. NIH-Defined Phase III E-MAIL: grants.mgt@utsouthwestern.edu Interesting (State State S						NUMBER		
Exempt Gal: Fib approval date see pg #11 Gal: Fib approval date see pg #11 Mo Yes Yes Value Signature No. Gal: Signature No.	6. HUMAN SUBJECT	S 🗌 NO 🛛				ESS OF AD	INISTRATIVE OF	FICIAL
No Yes Exemption No. Inst approval date see pg #11 Of SouthWestern Medical Center S23 Harry Hines Blvd. Dallas, TX 75390-9105 6b. Federal Wide Assurance No. FWA 00005087 Tel: 214-648-4494 Fax: 214-648-4474 6c. NHH-Defined Phase III Clinical Trial No Yes Tel: 214-648-4494 Fax: 214-648-4474 7. VERTEBRATE ANIMALS No Yes 10. PROJECT/PERFORMANCE SITE(S) Organizational Name: University of Texas Southwestern Med 7. VERTEBRATE ANIMALS No Yes 10. PROJECT/PERFORMANCE SITE(S) 7. VERTEBRATE ANIMALS No Yes 10. PROJECT/PERFORMANCE SITE(S) 7. Alf Yes, 'IACUC approval Date Organizational Name: University of Texas Southwestern Med 7. DANS AND PATENTS No Yes 8. DIRECT \$253,360 ab. TOTAL \$397,775 Street 1: 5323 Harry Hines Blvd. 8a. DIRECT \$253,360 ab. TOTAL \$397,775 Street 2: 9. INVENTIONS AND PATENTS No Yes 11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 13) Perviously Reported 12. Corrections to Page 1 Face Page Fax: 214-648-4474 E-MAIL: grants.mgt@utsouthwestern.edu 12. Corrections to Page 1 Face Page 13. APPLICANT ORGANIZATION CERTIFICAT								agement
see pg #11 Oblias, TX 75390-9105 6b. Federal Wide Assurance No. FWA 00005087 7et: 214-648-4494 Fax: 214-648-4474 Clinical Trial No Yes 7. VERTEBRATE ANIMALS No Yes 10. PROJECT/PERFORMANCE SITE(S) Organizational Name: University of Texas Southwestern Med DUNS: 80-077-1545 Ours: 8. COSTS REQUESTED FOR NEXT BUDGET PERIOD Street 1: 5323 Harry Hines Blvd. 8. DIRECT \$253,360 ab. TOTAL \$397,775 Street 2: 9. INVENTIONS AND PATENTS No Yes City: Dallas If 'Yes, ' Previously Reported State: Texas Province: Country: USA zip/P					-		er	
6b. Federal Wide Assurance No. FWA 00005087 Tel: 214-648-4494 Fax: 214-648-4474 6c. NIH-Defined Phase III Clinical Trial No Yes 10. PROJECT/PERFORMANCE SITE(S) 7. VERTEBRATE ANIMALS No Yes 10. PROJECT/PERFORMANCE SITE(S) organizational Name: University of Texas Southwestern Med 7. VERTEBRATE ANIMALS No Yes 10. PROJECT/PERFORMANCE SITE(S) 7. Animal Welfare Assurance No. DUNS: 80-077-1545 Storet 1: 5323 Harry Hines Blvd. 8. DIRECT \$253,360 ab. TOTAL \$397,775 Street 2: Street 2: 9. INVENTIONS AND PATENTS No Yes City: Dallas County: Dallas If 'Yes, Previously Reported State: Texas Province: County: USA Zip/Postal Code: 75390 Congressional Districts: TX-030 Congressional Districts: TX-030 11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 13) Perrie M. Adarns, PhD FAX: 214-648-4474<			see pg #11					
6c. NIH-Defined Phase III E-MAIL: grants.mgt@utsouthwestern.edu Clinical Trial No Yes 7. VERTEBRATE ANIMALS No Yes 8. COSTS REQUESTED FOR NEXT BUDGET PERIOD Street 1: 5323 Harry Hines Blvd, 8a. DIRECT \$253,360 db. TOTAL \$397,775 Street 2: 9. INVENTIONS AND PATENTS No Yes City: Dallas If 'Yes, Previously Reported State: Texas Province: Country: USA Zip/Postal Code: 75390 Congressional Districts: TX-030 11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 13) Perine M. Adams, PhD FAX: 214-648-4474	6b Federal Wide Ass	urance No. FWA 0	0005087	4			x 214-648-44	74
7. VERTEBRATE ANIMALS No Yes 10. PROJECT/PERFORMANCE SITE(S) 7. A. If "Yes," IACUC approval Date Organizational Name: University of Texas Southwestern Med 7. A. If "Yes," IACUC approval Date DUNS: 80-077-1545 8. COSTS REQUESTED FOR NEXT BUDGET PERIOD Street 1: 5323 Harry Hines Blvd. 8a. DIRECT \$253,360 ab. TOTAL \$397,775 Street 2: 9. INVENTIONS AND PATENTS No Yes If "Yes, Previously Reported State: Texas If "Yes, Previously Reported State: Texas Not Previously Reported State: Texas Previously Reported Country: USA Zip/Postal Code: 75390 Contry: USA Zip/Postal Code: 75390 TEL: 214-648-4494 FAX: 214-648-4474 It with the blic health Services turns and conditions if a grant is awarded as a result of this application. Law aware that any false, fictitous, or traudulent statements or claims may subject me to complete and accurate to the bash of my knowledge, and accept the adjugation to complete most and conditions to traudulent statements or claims or traudulent statements or claims may subject me to complete and accurate to the bash of my knowledge, and accept the adjugation. Law aware that any false, fictitous, or traudulent statements or claims or taken to complete moto complete and accurate to the bash of my knowledge, and accept the adjugation. Law aware that any false, fi	6c. NIH-Defined Phase	e I			-			
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8a. DIRECT \$253,360 Bb. TOTAL \$397,775 Street 2: 9. INVENTIONS AND PATENTS No Yes City: Dallas If "Yes, Previously Reported State: Texas Province: Not Previously Reported State: Texas Province: Not Previously Reported Country: USA Zip/Postal Code: 75390 Congressional Districts: TX-030 11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 13) Perrie M. Adams, PhD TEL: 214-648-4494 FAX: 214-648-4474 E-MAIL: grants.mgt@utsouthwestern.edu 12. Corrections to Page 1 Face Page 13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the obligation to complete and accurate to the best of my knowledge, and accept the obligation to complete and accurate to the best of my knowledge, and accept the obligation. I am aware that any false, fictious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penallies.			SET PERIOD			nes Blvd	·	<u> </u>
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11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 13) Perrie M. Adams, PhD TEL: 214-648-4494 FAX: 214-648-4474 E-MAIL: grants.mgt@utsouthwestern.edu 12. Corrections to Page 1 Face Page 13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services torms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	Not Pre	eviously Reported		Country: USA		Zi	p/Postal Code: 75	390
Perrie M. Adams, PhD TEL: 214-648-4494 FAX: 214-648-4474 E-MAIL: grants.mgt@utsouthwestern.edu 12. Corrections to Page 1 Face Page 13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. S/GNATURE OF OFFICIAL NAMED IN 1. (<i>n ink</i>) DATE 2/4/09				Congressional Distric	ts: TX-0	030		<u></u>
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13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the obligation to complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictificuum, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	10. Corrections to Des			······································		grants.r	ngt@utsouth	western.edu
statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	12. Corrections to Pag	je i race Page						
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	PHS 2590 (Rev. 11/07)		Face Page	/			Form Page 1

Pages 3 through 8 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle	^{):} Sanchez, Pablo J.	
PROGRESS REPORT SUMMARY	GRANT NUMBER 5-U10-HD 040689-08	····
	PERIOD COVERED BY TH	IS REPORT
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	FROM	THROUGH
Pablo J. Sanchez	04/01/08	03/31/09
APPLICANT ORGANIZATION University of Texas Southwestern Medical Center a	t Dallas	
TITLE OF PROJECT (Repeat title shown in Item 1 on first page Cooperative Multicenter Network of Neonatal Intens		
A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects No Cha	nge Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals No Cha	nge Since Previous Submission	Change
C. Select Agent Research 🛛 🕅 No Cha	nge Since Previous Submission	Change
D. Multiple PI Leadership Plan 🛛 No Cha	nge Since Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS. WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. U Targeted/Planned Enrollment Format Page.	-	

The UT Southwestern Dallas (UTSW) site participated in the following Neonatal Research Network (NRN) studies during 2008. These studies are enthusiastically supported by members of the Neonatology Division, as well as by the Pediatric Department, Parkland Memorial Hospital (PMH) and Children's Medical Center Dallas (CMCD). A list of IRB approvals and patient enrollment tables are provided with this grant.

3. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT). This study evaluates whether early use of nasal CPAP and a permissive ventilatory strategy in infants <28 wk of gestation results in a 10% increased survival without BPD, assesses the use of a lower oxygen saturation range on retinopathy of prematurity and survival, and whether these practices result in decreased mortality and neurodevelopmental impairment at 18-22 months corrected age. In 2008, we enrolled 21 infants, and all are part of the Growth assessment and Breathing Outcomes substudies. In addition, 17 (100%) infants were enrolled in the MRI secondary study, which will correlate neuroimaging with neurodevelopmental outcome. We also have enrolled 102 mothers in the Antenatal Consent substudy.

Pages 10 through 12 redacted for the following reasons: Not responsive. Not related to SUPPORT.

CENTER 04

Grant # 5-U10-HD 040689-09 Principal Investigator: Pablo J. Sánchez, MD

Protocol #	Protocol Name	Approval Date	Expiration Date
Not responsive. Not related to S	UPPORT.		
012005-019	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT) with Growth and Breathing Outcomes Substudies	01/19/09	01/18/10
042006-061	Antenatal Screening and Consent in a Research Network Model	03/25/08	03/24/09
102005-005	Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial	08/15/08	08/10/09

Not responsive. Not related to SUPPORT.

Pages 14 through 19 redacted for the following reasons: Not responsive. Not related to SUPPORT. Program Director/Principal Investigator (Last, First, Middle): Sánchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

Total Enrollment: 21 Protocol Number: 012005-019

Grant Number:

Study Title:

5-U10-HD 040689-08

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race Sex/Gender Unknown or Ethnic Category Females Males Not Reported Total ** Hispanic or Latino 5 9 14 Not Hispanic or Latino 1 7 6 Unknown (individuals not reporting ethnicity) * Ethnic Category: Total of All Subjects* 21 6 15 **Racial Categories** American Indian/Alaska Native Asian 0 0 0 Native Hawaiian or Other Pacific Islander Black or African American 1 5 6 White 5 10 15 More Than One Race Unknown or Not Reported * Racial Categories: Total of All Subjects* 6 15 21 ÷., . . PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative) Unknown or Females Males Total **Racial Categories** Not Reported American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White 5 9 14 More Than One Race Unknown or Not Reported ** Racial Categories: Total of Hispanics or Latinos** 9 5 14

* These totals must agree.

** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth **Study Title:** Weight Infants (SUPPORT)

Total Planned Enrollment: 7

TARGETED/PLANNED ENROLLMENT: Number of Subjects						
Ethnic Category		Sex/Gender				
	Females	Males	Total			
Hispanic or Latino	3	3	6			
Not Hispanic or Latino	0	1	1			
Ethnic Category: Total of All Subjects *	3	4	7			
Racial Categories						
American Indian/Alaska Native						
Asian						
Native Hawaiian or Other Pacific Islander						
Black or African American	0	1	1			
White	3	3	6			
Racial Categories: Total of All Subjects *	3	4	7			

Program Director/Principal Investigator (Last, First, Middle): Sánchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial			
Total Enrollment:	17	Protocol Number:	102005-005	
Grant Number:	5-U10-HD 040689-08	-		

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race Sex/Gender Unknown or Ethnic Category Females Males Not Reported Total ** Hispanic or Latino 7 11 4 Not Hispanic or Latino 1 5 6 Unknown (individuals not reporting ethnicity) 0 0 * Ethnic Category: Total of All Subjects* 5 12 17 **Racial Categories** American Indian/Alaska Native Asian 0 0 0 Native Hawaiian or Other Pacific Islander Black or African American 1 4 5 White 4 8 12 More Than One Race Unknown or Not Reported * Racial Categories: Total of All Subjects* 5 12 17 · · PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander		,		
Black or African American				
White	4	7		11
More Than One Race				
Unknown or Not Reported				<u> </u>
Racial Categories: Total of Hispanics or Latinos**	4	7		11 **

* These totals must agree.

** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial

Total Planned Enrollment: 7

TARGETED/PLANNED ENROLLMENT: Number of Subjects						
Ethnic Category	Sex/Gender					
	Females	Males	Total			
Hispanic or Latino	3	3	6			
Not Hispanic or Latino	0	1	1			
Ethnic Category: Total of All Subjects *	3	4	7			
Racial Categories						
American Indian/Alaska Native						
Asian						
Native Hawaiian or Other Pacific Islander						
Black or African American	0	1	1			
White	3	3	6			
Racial Categories: Total of All Subjects *	3	4	7			

Program Director/Principal Investigator (Last, First, Middle): Sánchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Antenatal Screening and Consent i	n a Research Netw	ork Model
Total Enroliment:	102	Protocol Number:	042006-061
Grant Number;	5-U10-HD 040689-08	-	

PART A. TOTAL ENROLLMENT REPORT: Numi by Et	ber of Subjects En thnicity and Race	rolled to D	ate (Cumulative)				
		Sex/Gender					
Ethnic Category	Females	Males	Unknown or Not Reported	Total			
Hispanic or Latino	55			55	**		
Not Hispanic or Latino	18			18			
Unknown (individuals not reporting ethnicity)	29			29			
Ethnic Category: Total of All Subjects*	102			102	*		
Racial Categories							
American Indian/Alaska Native							
Asian	2			2			
Native Hawaiian or Other Pacific Islander							
Black or African American	14			14			
White	57			57			
More Than One Race							
Unknown or Not Reported	29			29			
Racial Categories: Total of All Subjects*	102			102	*		
PART B. HISPANIC ENROLLMENT REPORT: N	umber of Hispanic Females	cs or Latino	os Enrolled to Date Unknown or Not Reported	(Cumulati	ve)		
American Indian or Alaska Native							
Asian		<u> </u>					
Native Hawaiian or Other Pacific Islander							
Black or African American				<u> </u>			
White	55			55			
			····				

Racial Categories: Total of Hispanics or Latinos**

* These totals must agree.

Unknown or Not Reported

** These totals must agree.

55

55 **

Pages 25 through 39 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD040689-10

PI Name:SANCHEZ, PABLOOrg:UNIVERSITY OF TEXAS SW MED
CTR/DALLASStart Date:04/01/2010Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7840384Rec'd
Date:02/01/2010

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Department of Health and Human Services Public Health Services		Review Group ZHD1DSRA10	Type 5	Activity U10	Grant Number HD 040689-10			
				Total Project Period		1		
Grant	Prog	ress I	Report	From: 5/1/2001 Requested Budget F	Period	Th	rough: 3/31/2011	
				From: 4/01/2010	From: 4/01/2010 Through: 3/31/2011			
1. TITLE OF PROJEC NIHD Cooper	-	lticenter	Neonatal Rese	arch Network			<u> </u>	
2a. PROGRAM DIREC (Name and addres	s, street, city	y, state, zip		2b. E-MAIL ADDRES	-	outhwest	ern.edu	
Pablo J. Sand UT Southwes	tern Med	lical Cen	ter	2c. DEPARTMENT, S Pediatrics	SERVICE,	LABORAT	DRY, OR EQUIVALENT	
-	5323 Harry Hines Boulevard Dalls, TX 75390-9063			2d. MAJOR SUBDIVISION School of Medicine				
				2e. Tel: 214-648-			x: 214-648-2481	
3a. APPLICANT ORG (Name and address			code)	3b. Tel: 214-648	-8604	Fa	x: 214-648-2481	
UT Southwes 5323 Harry H	UT Southwestern Medical Center 5323 Harry Hines Boulevard Dallas, TX 75390-9105		3c. DUNS: 80-07	7-1545	,	FEB 0 1 2010		
			4. ENTITY IDENTIF 1756002868		NUMBER			
6. HUMAN SUBJECT	S 🗌 No		/es	5. NAME, TITLE AN		SS OF AD	MINISTRATIVE OFFICIAL	
6a. Research Exempt ∑ No ☐ Yes	lf Exempt (6a): Exemption		If Not Exempt ("No" 6a): IRB approval date See page #12	UT Southwestern Medical Center				
6b. Federal Wide Ass	urance No.	FWA 0	0005087	Tel: 214-648-44	94	Fa	ax: 214-648-4474	
6c. NIH-Defined Phase Clinical Trial	e III o 🛛 Yes			E-MAIL: grants.m	ngt@uts	outhwes	tern.edu	
7. VERTEBRATE AN	IMALS 🛛] No [Yes	10. PROJECT/PERF	ORMANC	E SITE(S)		
7a. If "Yes," IACUC a	pproval Date	9		Organizational Name	Organizational Name: UT Southwestern Medical Center			
7b. Animal Welfare As	surance No			DUNS: 80-077-1	545			
8. COSTS REQUES	TED FOR N	EXT BUDG	ET PERIOD	Street 1: 5323 H	Street 1: 5323 Harry Hines Boulevard			
8a. DIRECT \$262,2	40	8b. TOTAL	_ \$411,718	Street 2:				
9. INVENTIONS AND	PATENTS	🛛 No	Yes	city: Dallas		с	County: Dallas	
lf "Yes, 🔲 Previo				State: Texas		P	rovince:	
Not Pro	eviously Rep	ported		Country: USA	Country: USA		Zip/Postal Code: 75390	
				Congressional Distri	cts: TX-:	30		
				T ORGANIZATION (Iter ch Administration	n 13)			
TEL: 214-648-44	94		FAX: 214-64	18-4474		E-MAIL: gi	rants.mgt@utsouthwestem.edu	
12. Corrections to Pag	ge 1 Face Pa	age	1		·	1		
statements herein an obligation to comply result of this applicat may subject me to cr	e true, comple with Public He ion. I am awa iminal, civil, o	ete and accur alth Services are that any fa	rate to the best of my kr s terms and conditions i alse, fictitious, or fraudu	nowledge, and accept the if a grant is awarded as a ilent statements or claims	11. Nn ini	k)	M. Rece	
PHS 2590 (Rev. 06/09	り			Face Page	1 1	}	Form Page 1	

Face Page

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Pages 3 through 11 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Las	t, First, Middle):	Sanchez, Pablo J.		
·····		GRANT NUMBER		
PROGRESS REPORT SUMM	ARY	5-U10-HD 040689-09)	
		PERIOD COVERED BY T	HIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGA	ATOR	FROM	THROU	JGH
Pablo J. Sanchez		04/01/2009	03/31	/2010
APPLICANT ORGANIZATION	·. ·····			<u> </u>
University of Texas Southwestern Medica	al Center at	Dallas		
TITLE OF PROJECT (Repeat title shown in Item '	1 on first page)			······
Ccooperative Multicenter Network of Nec	onatal Intens	ive Care		
A. Human Subjects (Complete Item 6 on the Face Pa	ige)			· · · · · · · · · · · · · · · · · · ·
Involvement of Human Subjects	No Chang	e Since Previous Submission		Change
B. Vertebrate Animals (Complete Item 7 on the Face	Page)			
Use of Vertebrate Animals	No Chang	e Since Previous Submission		Change
C. Select Agent Research	No Chang	e Since Previous Submission		Change
D. Multiple PD/PI Leadership Plan	No Chang	e Since Previous Submission		Change
E. Human Embryonic Stem Cell Line(s) Used	No Chang	e Since Previous Submission		Change
SEE PHS 2590 INSTRUCTIONS				

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The UT Southwestern Dallas (UTSW) site participated in the following Neonatal Research Network (NRN) studies during 2009. These studies are enthusiastically supported by members of the Neonatology Division, as well as by the Pediatric Department, Parkland Memorial Hospital (PMH) and Children's Medical Center Dallas (CMCD). A list of IRB approvals and patient enrollment tables are provided with this grant.

Not responsive. Not related to SUPPORT.

3. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT). This study evaluated whether early use of nasal CPAP and a permissive ventilatory strategy in infants <28 wk of gestation results in a 10% increased survival without BPD, assessed the use of a lower oxygen saturation range on retinopathy of prematurity and survival, and whether these practices result in decreased mortality and neurodevelopmental impairment at 18-22 months corrected age. In 2009, we enrolled 6 infants before enrollment was completed in 2/09 (total 73). Enrolled infants were eligible for the Growth assessment (n=61) and Breathing Outcomes substudies (n=63). In addition, 45 infants were enrolled in the MRI secondary study, which will correlate neuroimaging with neurodevelopmental outcome. We also enrolled 102 mothers in the Antenatal Consent substudy.

Page 13 redacted for the following reason: Not responsive. Not related to SUPPORT.

CENTER 04

Grant # 5-U10-HD 040689-09 Principal Investigator: Pablo J. Sánchez, MD

Protocol #	Protocol Name	Approval Date	Expiration Date	
Not responsive. Not relate	d to SUPPORT.			
012005-019	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT Study)	12/21/09	12/20/10	
042006-061	Antenatal Screening and Consent in a Research Network Model (SUPPORT Study secondary)	02/26/09	02/25/10	
102005-005	Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT	07/17/09	07/16/10	
102005-005	Breathing Outcomes (SUPPORT Study Secondary)	07/17/09	07/16/10	
102005-005	Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	07/17/09	07/16/10	
	Extended follow-up at 6-7 years of age of patients enrolled in the Neuroimaging and Neurodevelopmental Outcome Secondary to SUPPORT			

Not responsive. Not related to SUPPORT.

Pages 15 through 21 redacted for the following reasons: Not responsive. Not related to SUPPORT. Program Director/Principal Investigator (Last, First, Middle): Sánchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	The Surfactant Positive Airway Pr Infants (SUPPORT)	essure and Pulse Oximetry Trial in Extremely Low Birth Weight
Total Enrollment:	73	Protocol Number: 012005-019
Grant Number:	5-U10-HD 040689-09	

	mber of Subjects E Ethnicity and Race		late (Cumulative)	<u></u>
Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	22	33		55 **
Not Hispanic or Latino	7	11		18
Unknown (individuals not reporting ethnicity)		······	1	
Ethnic Category: Total of All Subjects*	29	44		73 *
Racial Categories	<u></u>	ing de faile in an		
American Indian/Alaska Native				
Asian	1	0		1
Native Hawaiian or Other Pacific Islander				
Black or African American	5	8		13
White	23	36		59
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	29	44		73 *
PART B. HISPANIC ENROLLMENT REPORT: N	lumber of Hispanic	cs or Latino	s Enrolled to Date	(Cumulative)
Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	22	33		55
More Than One Race				·····

Racial Categories: Total of Hispanics or Latinos**

Unknown or Not Reported

* These totals must agree.

** These totals must agree.

22

33

**

55

Program Director/Principal Investigator (Last, First, Middle): Sánchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth

Study Title: Weight Infants - Follow-Up

Total Enrollment: 16

Protocol Number: 12005-019

Grant Number: 5-U10-HD 040689-09

	ity and Race		<u>.</u>	- <u></u>		
	Sex/Gender					
Ethnic Category	Females	Males	Unknown or Not Reported	Total		
Hispanic or Latino	5	6		11	**	
Not Hispanic or Latino	3	2		5		
Unknown (individuals not reporting ethnicity)						
Ethnic Category: Total of All Subjects*	8	8		16	*	
Racial Categories						
American Indian/Alaska Native						
Asian	2			2		
Native Hawaiian or Other Pacific Islander						
Black or African American	1	1		2		
White	5	5		10		
More Than One Race		2		2		
Unknown or Not Reported		<u>.</u>				
Racial Categories: Total of All Subjects*	8	8		16	*	
	i da se se se de la serie d La serie de la s					
PART B. HISPANIC ENROLLMENT REPORT: Numb	er of Hispani	cs or Lating	os Enrolled to Date	∍ (Cumula	tive)	
Racial Categories	Females	Males	Unknown or Not Reported	Tota	1	
American Indian or Alaska Native						
Asian						
Native Hawaiian or Other Pacific Islander						
Black or African American						
White	5	4		9		
More Than One Race		2		2		
Unknown or Not Reported						
	I					

* These totals must agree. ** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Study Title: Weight Infants – Follow-Up

Total Planned Enrollment: 16

Ethnic Category	Sex/Gender			
ispanic or Latino ot Hispanic or Latino thnic Category: Total of All Subjects * Racial Categories merican Indian/Alaska Native sian	Females	Males	Total	
Hispanic or Latino	8	5	13	
Not Hispanic or Latino	2	1	3	
Ethnic Category: Total of All Subjects *	10	6	16	
Racial Categories				
American Indian/Alaska Native				
Asian	1	<u> </u>	1	
Native Hawaiian or Other Pacific Islander				
Black or African American	1	1	2	
White	8	5	13	
Racial Categories: Total of All Subjects *	10	6	16	

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Sánchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Antenatal Screening and Consent in a Research Network Model				
Total Enrollment:	102	Protocol Number: 042006-061			
Grant Number:	5-U10-HD 040689-09				

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total	
Hispanic or Latino	55			55	**
Not Hispanic or Latino	18			18	
Unknown (individuals not reporting ethnicity)	29			29	
Ethnic Category: Total of All Subjects*	102	· · · · · · ·		102	*
Racial Categories		<u>, , , , , , , , , , , , , , , , , , , </u>			
American Indian/Alaska Native		· ·			
Asian	2	<u></u>		2	
Native Hawaiian or Other Pacific Islander					
Black or African American	14			14	
White	57			57	
More Than One Race					
Unknown or Not Reported	29			29	
Racial Categories: Total of All Subjects*	102			102	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	55			55
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	55			55 **

* These totals must agree.

** These totals must agree.

Program Director/Principal Investigator (Last, First, Middle): Sánchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Neuroimaging and Neurodevelo	pmental Outcome: A Secondary to the SUPPORT Trial
Total Enrollment:	45	Protocol Number: 102005-005
Grant Number:	5-U10-HD 040689-09	

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total	
Hispanic or Latino	13	18		31	**
Not Hispanic or Latino	7	7		14	
Unknown (individuals not reporting ethnicity)	0	0		0	
Ethnic Category: Total of All Subjects*	20	25		45	*
Racial Categories					
American Indian/Alaska Native				<u></u>	
Asian	1	0		1	
Native Hawaiian or Other Pacific Islander					
Black or African American	5	5		10	
White	14	20		34	
More Than One Race					
Unknown or Not Reported					
Racial Categories: Total of All Subjects*	20	25		45	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	13	18		31
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	13	18		31 **

* These totals must agree.

** These totals must agree.

Pages 27 through 41 redacted for the following reasons: Not responsive. Not related to SUPPORT. Progress Report Scanning Cover Sheet

5U10HD053089-02

PI Name:WATTERBERG, KRISTIOrg:UNIVERSITY OF NEW MEXICO
ALBUQUERQUEStart Date:04/01/2007Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7218087Rec'd
Date:01/29/2007

Form Approved Through 09/30/2007	Revio	w Group	Туре	Activity	OMB No. 0925-000 Grant Number	
Department of Health and Human Services Public Health Services	Kevie	W Gloup	5	LUIO	HD053089 X -02	
	Total Project Period					
Creat Drawnood Danart	From:	04/01/200	6	Thr	ough: 03/31/2011	
Grant Progress Report	Requ	ested Budget F	Period			
	From:	04/01/200	7	Thr	rough: 03/31/2008	
 TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Res 	earch	Network				
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR		PLICANTOR	GANIZATI	ON		
(Name and address, street, city, state, zip code)		me and addres				
Kristi Watterberg, MD Dept. Pediatrics/Division Neonatology				A REAL OF A DECK OF	alth Sciences Center SC09-5220	
MSC10 5590	and the second sec	Jniversity of			5005-5220	
1 University of New Mexico, Albuquerque, NM		ouquerque			t —	
				_		
2b. E-MAIL ADDRESS kwatterberg@salud.unm.edu		TITY IDENTIF	ICATION	NUMBER		
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT	5. TIT	TLE AND ADD	RESS OF	ADMINISTR	ATIVE OFFICIAL	
Pediatrics		anager, Pre				
2d. MAJOR SUBDIVISION 01-School of Medicine					s, MSC09 5220 🖉 🔊	
		Albuquerque, NM 87131-0001				
		Juqueique,	14101 07	101-000	2007	
	E-MAI	L: HSC-Pr	eaward(@salud.un	m.edu	
6. HUMAN SUBJECTS	7.	VERTEBRAT	E ANIMA	LS		
No 6a. Research Exempt 6b. Human Subjects Assurance	No.	⊠ No]Yes		78	a. If "Yes," IACUC approval Date	
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III		7b. Animal Welfare Assurance No.				
Exemption No. Clinical Trial No Ye	es	A3350-0	1			
If Not Exempt ("No" in 6a): IRB approval date 03/07/06	w					
. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INV	ENTIONS ANI	PATEN	TS		
8a. DIRECT \$158,107 8b. TOTAL \$237,161	N	o 🗌 Yes	If "Yes,"		ously Reported reviously Reported	
0. PERFORMANCE SITE(S) (Organizations and addresses)	and the second second second	RINCIPAL IN			505-272-1080	
University of New Mexico Health Sciences Ctr. Department of Pediatrics	OR PR	ROGRAM DIRE	CTOR (It	em 2a) FAX	505-272-1539	
MSC10 5590	11b. A	DMINISTRATI	E OFFIC	IAL TEL	505.272.6264	
1 University of New Mexico Albuquergue, NM 87131-0001		NAME (Item 5) FAX 505.272.0159				
Albaquerque, Nin 07101-0001	11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14) NAME Rena Vinyard				NING FOR APPLICANT	
	TITLE Manager, PreAward Administration					
	TEL	505.272.0			FAX 505.272.0159	
	E-MAIL					
	L-IVIAIL	- HSC-Pre	award	@salud.u	nm.edu	

13. APPLICANT ORGANIZATION CERTIFICATION statements herein are true, complete and accurate to the obligation to comply with Public Health Services terms result of this application. I am aware that any false, fict may subject me to criminal, civil, or administrative pena	he best of my knowledge, and accept the	SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Per" signature not acceptable.)	DATE 1.24.07
PHS 2590 (Rev. 04/06)	Face Page	0	Form Page 1

Pages 3 through 13 redacted for the following reasons: Not responsive. Not related to SUPPORT. Watterberg, Kristi L.

PROGRESS REPORT SU	MMARY	GRANT NUMBER 1 U10 HD053089 01	
		PERIOD COVERED BY THI	S REPORT
PRINCIPAL INVESTIGATOR OR PROGRAM	M DIRECTOR	FROM	THROUGH
Kristi watterberg, MD		04/01/07	03/31/2008
APPLICANT ORGANIZATION University of New Mexico, Health Sc TITLE OF PROJECT (Repeat title shown in	<u> </u>	e)	
NICHD Cooperative Multicenter Nec		,	
A. Human Subjects (Complete Item 6 on the	Face Page)		
Involvement of Human Subjects	🔀 🛛 No Cha	inge Since Previous Submission	Change
B. Vertebrate Animals (Complete Item 7 on the second s	the Face Page)		
Use of Vertebrate Animals	🔀 🛛 No Cha	ange Since Previous Submission	Change
C. Select Agent Research	No Cha	ange Since Previous Submission	Change
D. Multiple PI Leadership Plan	No Cha	ande Since Previous Submission	Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

In our first year of membership in the NICHD Neonatal Research Network, the University of New Mexico has worked to promote the network's primary objective of "advancing the field of Neonatal-Perinatal medicine through a network of academic centers that perform rigorous, multicenter clinical protocols to investigate the safety and efficacy of treatment and management strategies for newborn infants." Specifically, our center has:

- 1. Achieved IRB approval of ongoing NRN studies, including:
 - Not responsive. Not related to SUPPORT.
 - infants (SUPPORT trial), including breathing outcomes and growth ancillaries.
 f. Antenatal screening and consent in a research network model a secondary protocol for the SUPPORT trial

2.	Not responsive. Not related to SUPPORT.
3.	
4.	

Pages 15 through 19 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD053089-03

PI Name:WATTERBERG, KRISTIOrg:UNIVERSITY OF NEW MEXICO
ALBUQUERQUEStart Date:04/01/2008Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7392218Rec'd
Date:01/25/2008

Form Approved Through 09/30/2007					OMB No. 09	25-0001
Department of Health and Human Services Public Health Services	Review	Group	Type 5	Activity UIO	Grant Number ≱ U10 HD053089 Ø2	50
	Total Pr	oject Period	<u> </u>	·		
Creat Dreaman Devert	From: 04/01/2006 Through: 03/31/2011					
Grant Progress Report	Reques	ted Budget P	eriod			
		04/01/2008	3	Th	rough: 03/31/2009	
1. TITLE OF PROJECT	oroh N	otwork				
NICHD Cooperative Multicenter Neonatal Rese 2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code) Kristi Watterberg, MD Dept. Pediatrics/Division Neonatology MSC 10 5590 1 University of New Mexico, Albuquerque, NM	3. APP (Nam Univ Fina 1 Ur	LICANT ORG e and addres /ersity of I	s, street, New Me vices D f New	city, state, z exico, He Division, M Mexico	ealth Sciences Center MSC09-5220	JAI
2b. E-MAIL ADDRESS		ITY IDENTIF	CATION	NUMBER		2
kwatterberg@salud.unm.edu 2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Pediatrics 2d. MAJOR SUBDIVISION 01-School of Medicine	5. TITL Asso UNN 1 Ur	E AND ADDF ociate Dir M HSC, Fi niversity o uquerque,	ector, I nancia f New NM 87	⁻ inancial I Service Mexico		5 2008
6. HUMAN SUBJECTS	ـــــــــــــــــــــــــــــــــــــ	VERTEBRAT	E ANIMA	LS		
No 6a. Research Exempt 6b. Human Subjects Assurance Yes No Yes FWA 00003255 If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III		No Yes Animal Welfa	ire Assur		7a. If "Yes," IACUC approva	l Date
Exemption No.	·	A3350-0				
If Not Exempt ("No" in 6a): IRB approval date 02/08/07	N					
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVE		PATEN	TS		
8a. DIRECT \$162,618 8b. TOTAL \$243,927	No No	Yes	lf "Yes,"		viously Reported Previously Reported	
10. PERFORMANCE SITE(S) (Organizations and addresses) University of New Mexico Health Sciences Ctr Department of Pediatrics	OR PRC	RINCIPAL INV OGRAM DIRE Vatterberg,	CTOR (It			
MSC10 5590	NAME (E OFFIC	DIAL TE	L 505.272.6264	
1 University of New Mexico Albuquerque, NM 87131-0001	Rena \	/inyard		FA	x 505.272.0159	
		RGANIZATIO	N (Item 1		GNING FOR APPLICANT	
	TITLE	Rena Vir	•	otor Eine	noial Suc/USC Dro Au	ard
	TEL	Associat 505.272.6		JUI, FINA	incial Svs/HSC PreAw ^{FAX} 505.272.0159	aiu
	E-MAIL			Bealing		
12 Corrections to Page 1 Face Page		HSC-Pre	award	พรลเนน.		

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATI	ON AND ACCEPTANCE: I certify that the	SIGNATURE OF OFFICIAL NA	MED IN	DATE	
statements herein are true, complete and accurate		11c. (In ink. "Per" signature no	ot		
obligation to comply with Public Health Services ten result of this application. I am aware that any false,		acceptable.)	. 1	1.	
may subject me to criminal, civil, or administrative p		Tena Uni	fard	1.22.0	え
PHS 2590 (Rev. 04/06)	Face Page		· ·	Form Page	7
		U	,		

Pages 3 through 6 redacted for the following reasons: Not responsive. Not related to SUPPORT.

^{):} Watterberg, Kristi L.		
GRANT NUMBER 1 U10 HD053089 02		
PERIOD COVERED BY TH	HIS REPORT	
FROM	THROUGH	
04/01/07	03/31/08	
e) Network		
ge Since Previous Submission	Change	
nge Since Previous Submission	Change	
ge Since Previous Submission	Change	
ge Since Previous Submission	Change	
	GRANT NUMBER 1 U10 HD053089 02 PERIOD COVERED BY TH FROM 04/01/07 Perious Submission Perious Submissio	

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

In our second year of membership in the NICHD Neonatal Research Network, the University of New Mexico has continued to work to promote the network's primary objective of "advancing the filed of Neonatal-Perinatal medicine through a network of academic centers that perform rigorous, multicenter clinical protocols to investigate the safety and efficacy of treatment and management strategies for newborn infants." Specifically, our center has:

 Achieved and maintained IRB approval of ongoing NRN studies (dates of latest approval listed below), including: Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

e. The Surfactant positive airway pressure and pulse oximetry trial in extremely low birth weight infants (SUPPORT trial), including breathing outcomes and growth ancillaries.

f. Antenatal screening and consent in a research network model – a secondary protocol for the SUPPORT trial

g. Neuroimaging and neurodevelopmental outcome (SUPPORT secondary)

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

•

-

Name	IRB Number	Most recent Approval Date	Expiration date
Not responsive. Not related to SUPPORT.			-
SUPPORT (including Breathing Outcomes & Growth)	06-283	7/24/07	8/14/08
Neuroimaging SUPPORT secondary	07-092	5/8/07	5/7/08
Antenatal Consent SUPPORT secondary	07-004	12/20/07	1/15/09
Not responsive. Not related to SUPPORT.			

Pages 9 through 12 redacted for the following reasons: Not responsive. Not related to SUPPORT. Principal Investigator/Program Director (Last, First, Middle): Wa

Watterberg. Kristi L.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The surfactant positive airway pressure and pulse oximetry trial in ELBW infants

 Total Enrollment:
 10
 Protocol Number:
 06-283 (UNM IRB)

Grant Number:

U10 HD053089 02

	Sex/Gender					
Ethnic Category	Females	Males	Unknown or Not Reported	Total		
Hispanic or Latino	2	2		4 **		
Not Hispanic or Latino	3	3		6		
Unknown (individuals not reporting ethnicity)		-				
Ethnic Category: Total of All Subjects*	5	5		10 *		
Racial Categories						
American Indian/Alaska Native	1	2		3		
Asian		-				
Native Hawaiian or Other Pacific Islander		-				
Black or African American	T					
White	4	3		7		
More Than One Race		-				
Unknown or Not Reported		-				
Racial Categories: Total of All Subjects*	5	5		10 *		

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				* <u>*****</u> *********
White	2	2		4
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	2	2		4 **

* These totals must agree.

** These totals must agree.

Pages 14 through 15 redacted for the following reasons: Not responsive. Not related to SUPPORT. Progress Report Scanning Cover Sheet

5U10HD053089-04

PI Name:WATTERBERG, KRISTIOrg:UNIVERSITY OF NEW MEXICOStart Date:04/01/2009Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7614361Rec'd Date:01/28/2009

http://type5.era.nih.gov/ice_type_five/printcoversheet.cfm

1/28/2009

Form Approved Through 11/30/2010					OMB No. 0925-00
Department of Health and Human Public Health Services	Services	Review Group	Туре	Activity UIO	Grant Number ゆU10 HD053089- 03
		Total Project Period	1		
Grant Progress R	eport	From: 04/01/200		Thr	ough: 03/31/2011
		Requested Budget		The	ough: 03/31/2010
1. TITLE OF PROJECT	. <u></u>	From: 04/01/200			ougn: 03/31/2010
NICHD Cooperative Multicenter					
2a. PROGRAM DIRECTOR / PRINCIPAL INVE (Name and address, street, city, state, zip co		2b. E-MAIL ADDRES	-	unm edu	
Kristi Watterberg, MD		-			RY, OR EQUIVALENT
Dept. Pediatrics/Division of Neo. MSC10 5590	natology	Pediatrics			
1 University of New Mexico, Albuquerque, NM 87131-0001		2d. MAJOR SUBDIV Neonatology			
07101-0001		2e. Tel: 505.272	.6753	Fax	c 505.272.1539
3a. APPLICANT ORGANIZATION	de)	3b. Tel: 505.272	.6264	Fax	c 505.272.0159
(Name and address, street, city, state, zip code) University of New Mexico, Health Sciences Center Financial Services; MSC 09-5520 1 University of New Mexico, Albuquerque NM 87131-0001		3c. DUNS: 86885	53094		IAN 2 8 21
		4. ENTITY IDENTIF 85-6000-642		NUMBER	JAN 2 3 L
		5. NAME, TITLE AN		SS OF ADM	INISTRATIVE OFFICIAL
6a. Research If Exempt ("Yes" in If Not Exempt ("No" ir 6a):					
No Yes Exemption No.	a): RB approval date)2/07/08	Associate Di	irector, I	-inancial	Services/HSC Preaward
6b. Federal Wide Assurance No. FWA000	3255	Tel: 505.272.62	64	Fax	c 505.272.0159
6c. NIH-Defined Phase III Clinical Trial 🔲 No 🔀 Yes		E-MAIL: HSC-Pro	eaward(@salud.u	nm.edu
7. VERTEBRATE ANIMALS No	Yes	10. PROJECT/PERFORMANCE SITE(S)			
7a. If "Yes," IACUC approval Date		Organizational Name: University of New Mexico HSC			
7b. Animal Welfare Assurance No.		DUNS: 868853094			
8. COSTS REQUESTED FOR NEXT BUDGET	PERIOD	Street 1: MSC09	5220		
8a. DIRECT \$314,739 8b. TOTAL \$	472,109	Street 2: 1 Unive	ersity of	New Mex	ico
9. INVENTIONS AND PATENTS \Box No	Yes	city: Albuquerq	ue	Cou	unty: Bernalillo
lf "Yes, 🔲 Previously Reported		State: NM		Pro	vince:
Not Previously Reported		Country: USA		Zip	/Postal Code: 87131-0001
		Congressional Districts: NM-001			
11. NAME AND TITLE OF OFFICIAL SIGNING Rena Vineyard, Associate Director			•		
TEL: 505.272.6264	FAX: 505.272.		r	E-MAIL: HS	C-Preaward(see above)
12. Corrections to Page 1 Face Page	<u></u>		,, <u>I</u>		
13. APPLICANT ORGANIZATION CERTIFICAT statements herein are true, complete and accurate obligation to comply with Public Health Services te result of this application. I am aware that any false	to the best of my know rms and conditions if a g , fictitious, or fraudulent	ledge, and accept the grant is awarded as a	11. (Ip ink))	CIAL NAMED IN DATE
may subject me to criminal, civil, or administrative					

Pages 3 through 8 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle	^{e):} Watterberg, Kristi L			
· · · · · · · · · · · · · · · · · · ·	GRANT NUMBER			
PROGRESS REPORT SUMMARY	1 U10 HD053089 03 PERIOD COVERED BY THIS REPORT			
I				
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	FROM	THROUGH		
Watterberg, Kristi L	04/01/2008	03/31/2009		
APPLICANT ORGANIZATION				
University of New Mexico Health Sciences Center				
TITLE OF PROJECT (Repeat title shown in Item 1 on first pag	16)			
NICHD Cooperative Multicenter Neonatal Research				
A. Human Subjects (Complete Item 6 on the Face Page)				
Involvement of Human Subjects No Cha	ange Since Previous Submission	Change		
B. Vertebrate Animals (Complete Item 7 on the Face Page)				
Use of Vertebrate Animals No Cha	ange Since Previous Submission	Change		
	ange Since Previous Submission	Change		
C. Select Agent Research No Cha	inge ennee i retriete easimeenen			
	ange Since Previous Submission	Change		

Targeted/Planned Enrollment Format Page.

In our third year of membership in the NICHD Neonatal Research Network, the University of New Mexico has continued to work as an integral part of the network to achieve the primary objective of "advancing the field of Neonatal-Perinatal medicine through rigorous, multicenter clinical protocols." The specific aims of the Neonatal Research Network have not changed this year. This year, our center:

Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Watterberg, Kristi L.

	PROTOCOL	MOST RECENT	APPROVED
IRB APPROVED PROTOCOLS: NAME t responsive. Not related to SUPPORT.	NUMBER	APPROVAL	THROUGH
۲he Surfactant Positive Airway Pressure & Pulse		8/5/08	
Dximetry Trial in Extremely Low Birth Weight	06-283	(DSMC report	8/14/09
Dximetry Trial in Extremely Low Birth Weight	06-283		8/14/09
Oximetry Trial in Extremely Low Birth Weight nfants (SUPPORT Study) Antenatal Screening & Consent in a Research	06-283 07-004	(DSMC report	8/14/09 1/15/10
Dximetry Trial in Extremely Low Birth Weight nfants (SUPPORT Study) Antenatal Screening & Consent in a Research		(DSMC report 11/19/08)	
Oximetry Trial in Extremely Low Birth Weight nfants (SUPPORT Study) Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary) Neuroimaging and Neurodevelopmental		(DSMC report 11/19/08)	
Oximetry Trial in Extremely Low Birth Weight nfants (SUPPORT Study) Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary) Neuroimaging and Neurodevelopmental	07-004	(DSMC report 11/19/08) 12/20/08	1/15/10
Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study) Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary) Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT Breathing Outcomes (SUPPORT Study	07-004	(DSMC report 11/19/08) 12/20/08	1/15/10
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study) Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary) Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT Breathing Outcomes (SUPPORT Study Secondary) Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation	07-004	(DSMC report 11/19/08) 12/20/08 4/22/08	1/15/10 5/7/09

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Not responsive. Not related to SUPPORT.

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Pages 11 through 12 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in ELBW				
Total Enrollment:	17	Protocol Number: 06-283 (UNM IRB number)			
Grant Number:	1 U10 HD053089 03				

PART A. TOTAL ENROLLMENT REPORT: Number by Ethnic	of Subjects E city and Race	nrolled to Da	ate (Cumulative))
	Sex/Gender			
Ethnic Category	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	4	3		7 **
Not Hispanic or Latino	7	3		10
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	11	6		17 *
Racial Categories	·····		an an an an an an an an an an an an an a	<u></u>
American Indian/Alaska Native	2	2		4
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	9	4		13
More Than One Race				
Unknown or Not Reported				· ·
Racial Categories: Total of All Subjects*	11	6		17 *
	a di shine. Manazarta		YA MARINE I	
PART B. HISPANIC ENROLLMENT REPORT: Numb	er of Hispani	cs or Latinos	Enrolled to Da	te (Cumulative)
Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	4	3		7
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	4	3		7 **

* These totals must agree.

** These totals must agree.

Pages 14 through 17 redacted for the following reasons: Not responsive. Not related to SUPPORT. Progress Report Scanning Cover Sheet

5U10HD053089-05

PI Name:	WATTERBERG, KRISTI
Org:	UNIVERSITY OF NEW MEXICO
Start Date:	04/01/2010
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	7799869
Rec'd Date:	01/25/2010

Form Approved Throu	igh 11/30/20	010					OMB No. 0925-0001	
Department of Health and Human Services Public Health Services			Review Group	Туре	Activity	Grant Number		
			ZHD1DSRA10 Total Project Period	5	<u>U10</u>	1U10 HD053089 64 05		
			From: 04/01/2006 Through: 03/31/2011					
Grant Progress Report I. TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Rese		Requested Budget Period						
		From: 04/01/2010)	Thr	ough: 03/31/2011			
				2b. E-MAIL ADDRES	s			
(Name and address, street, city, state, zip code)			kwatterberg@salud.unm.edu					
			2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT					
MSC10 5590			eonatology	Pediatrics				
		exico, A	lbuquerque, NM	2d. MAJOR SUBDIVI		ø		
87131-0001				School of Medicine. 2e. Tel: 505-272-0180 Fax: 505-272-1539				
3a. APPLICANT ORG								
(Name and address	s, street, city	y, state, zip		3b. Tel: 505-272-	6264	Fax	: 505-272-0159	
University of I Center Finand				3c. DUNS: 86885	3094		LIAN 2 5 2010	
		•	Ibuquerque NM	4. ENTITY IDENTIFI	CATION			
87131-0001				85-6000-642	CATION	NUMBER		
6. HUMAN SUBJECT	S N	。 🛛	Yes	5. NAME, TITLE AN	D ADDRE	SS OF ADM	NISTRATIVE OFFICIAL	
6a. Research	If Exempt ("Yes" in	If Not Exempt ("No" in	Rena Vinyard	1			
Exempt	6a): Exemption	No.	6a): IRB approval date	Associate Director, Financial Services/HSC Preaward				
	}		02/07/09					
6b. Federal Wide Ass	urance No.	FWA00	10 4690	Tel: 505-272-626	64	Fax	505-272-0159	
6c. NIH-Defined Phase III Clinical Trial 🔲 No 🖾 Yes			E-MAIL: HSC-Preaward@salud.unm.edu					
7. VERTEBRATE AN	IMALS 🛛] No [Yes	10. PROJECT/PERFORMANCE SITE(S) Organizational Name: University of New Mexico HSC				
7a. If "Yes," IACUC a	oproval Date	e						
7b. Animal Welfare As	surance No			DUNS: 868853094				
8. COSTS REQUES	TED FOR N	EXT BUDG	ET PERIOD	Street 1: MSC09 5520				
8a. DIRECT \$161,19	97	8b. TOTAL	\$241,796	Street 2: 1 University of New Mexico				
9. INVENTIONS AND	PATENTS	No No	Yes	City: Albuquerque County: Berna		nty: Bernalillo		
If "Yes, 🔲 Previously Reported		State: NM			vince:			
Not Previously Reported			Country: USA Zip/Postal Code: 87131-0001			Postal Code: 87131-0001		
			Congressional Districts: NM-001					
			NG FOR APPLICANT O					
TEL: 505-272-620	54		FAX: 505-272-	0159	E	E-MAIL: HS	C-Preaward (see above)	
12. Corrections to Pag	e 1 Face Pa	ige			l.		<u></u>	
statements herein are obligation to compty w result of this application	true, comple with Public He on, 1 am awa	te and accurate alth Services re that any fa	ATION AND ACCEPTA ate to the best of my knowl terms and conditions if a g ilse, fictitious, or fraudulent ve penalties	edge, and accept the 1 arant is awarded as a	IGNATUR) •	IAL NAMED IN DATE	
may subject me to criminal, civil, or administrative penalties.			Face Page		<u> </u>	Form Page 1		

Pages 3 through 8 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle):	۷
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Watterberg, Kristi L

	•		
PROGRESS REPORT SUMMARY	GRANT NUMBER 1 U10 HD053089 04 PERIOD COVERED BY THIS REPORT		
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Watterberg, Kristi L	FROM 4/1/2009	THROUGH 3/31/2010	
APPLICANT ORGANIZATION University of New Mexico Health Sciences Center			
TITLE OF PROJECT (Repeat title shown in Item 1 on first pa NICHD Cooperative Multicenter Neonatal Researc	•		

A. Human Subjects (Complete Item 6 on the Face	e Page)		
Involvement of Human Subjects	No Change Since Previous Submission	Change	
B. Vertebrate Animals (Complete Item 7 on the F	ace Page)		
Use of Vertebrate Animals	No Change Since Previous Submission	Change	
C. Select Agent Research	No Change Since Previous Submission	Change	
D. Multiple PD/PI Leadership Plan	No Change Since Previous Submission	Change	
E. Human Embryonic Stem Cell Line(s) Used	No Change Since Previous Submission	Change	

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims: The University of New Mexico has had an extremely productive year as a participating site within the NICHD Neonatal Research Network, working to achieve the network's primary objective of "advancing the field of Neonatal-Perinatal medicine through rigorous, multicenter clinical protocols." The specific aims of the Neonatal Research Network have not changed this year, while numerous studies have been instituted, conducted and completed (protocols with IRB approval at UNM are attached to this report.)

B: Studies and results:

Not responsive. Not related to SUPPORT.

5. Developed forms and began data collection for the SUPPORT Neuroimaging ancillary study "Evaluation of early working memory in extremely preterm infants" (<u>UNM personnel: Lowe (co-PI), Duncan (co-PI) and Watterberg (co-investigator and sponsor as NRN PI at UNM</u>). This study will evaluate the ability of measures of working memory in children at 18 – 22 months corrected age to predict executive function at 6 – 7 years of age.

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

<u>D. Plans</u>: We will continue to participate fully in the activities and meetings of the NRN, maintaining IRB approval for all network protocols. We specifically anticipate:

Not responsive. Not related to SUPPORT.

4. Continuing the SUPPORT Neuroimaging ancillary study of working memory in extremely preterm infants (B.5, Lowe and Duncan, co-PIs);

Not responsive. Not related to SUPPORT.

Neonatal Research Network with IRB approval at the University of New Mexico

IRB APPROVED PROTOCOLS: NAME	PROTOCOL NUMBER	<u>MOST RECENT</u> <u>DATE OF</u> <u>APPROVAL</u>	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight	06-283	8/4/2009	8/14/2010
Infants (SUPPORT Study) (NCT00233324)	00-203	0/4/2009	0/14/2010
Antenatal Screening & Consent in a Research	07-004	Closure requested	1/15/2010
Network Model (SUPPORT Study secondary)			
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	07-092	5/5/2009	5/7/2010
Breathing Outcomes (SUPPORT Study Secondary)	06-283	8/4/2009	8/14/2010
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	06-283	8/4/2009	8/14/2010
Extended follow-up at 6-7 years of age of patients enrolled in the Neuroimaging and	Not yet		
Neurodevelopmental Outcome Secondary to SUPPORT Not responsive. Not related to SUPPORT.	submitted		

Pages 12 through 19 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth

Study Title:	Weight Infants	
Total Enrollment:	21	Protocol Number: 06-283 (UNM IRB)
Grant Number:	1 U10 HD053089 03	

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race					
Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total	
Hispanic or Latino	5	5	0	10	**
Not Hispanic or Latino	7	4	0	11	
Unknown (individuals not reporting ethnicity)	0	0	0	0	-
Ethnic Category: Total of All Subjects*	12	9	0	21	*
Racial Categories					
American Indian/Alaska Native	2	2	0	4	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	0	0	0	0	
White	10	7	0	17	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	12	9	0	21	*
		the first second and a second s			-

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	5	5	0	10
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	5	5	0	10 **

* These totals must agree.

** These totals must agree.

Pages 21 through 26 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Neonatal Research Network with IRB approval at the University of New Mexico

IRB APPROVED PROTOCOLS: NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	<u>APPROVED</u> <u>THROUGH</u>
Not responsive. Not related to SUPPORT.			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study) (NCT00233324)	06-283	8/4/2009	8/14/2010
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	07-004	Closure requested	1/15/2010
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	07-092	5/5/2009	5/7/2010
Breathing Outcomes (SUPPORT Study Secondary)	06-283	8/4/2009	8/14/2010
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	06-283	8/4/2009	8/14/2010
Extended follow-up at 6-7 years of age of patients enrolled in the Neuroimaging and Neurodevelopmental Outcome Secondary to SUPPORT	Not yet submitted		

revised Page 10

Page 28 redacted for the following reason: Not responsive. Not related to SUPPORT. Progress Report Scanning Cover Sheet

5U10HD053089-02

PI Name:WATTERBERG, KRISTIOrg:UNIVERSITY OF NEW MEXICO
ALBUQUERQUEStart Date:04/01/2007Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7218087Rec'd
Date:01/29/2007

Form Approved Through 09/30/2007	Revio	w Group	Туре	Activity	OMB No. 0925-000 Grant Number
Department of Health and Human Services Public Health Services		W Gloup	5	LUIO	HD053089 X -02
		Project Period		1.00	
		04/01/200	6	Thr	ough: 03/31/2011
Grant Progress Report	Requ	ested Budget F	Period		
	From:	04/01/200	7	Thr	rough: 03/31/2008
 TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Res 	earch	Network			
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR		PLICANTOR	GANIZATI	ON	
(Name and address, street, city, state, zip code)		me and addres			
Kristi Watterberg, MD Dept. Pediatrics/Division Neonatology				A REAL OF A DECK OF	alth Sciences Center SC09-5220
MSC10 5590	and the second sec	Jniversity of			5005-5220
1 University of New Mexico, Albuquerque, NM		ouquerque			t —
				_	
2b. E-MAIL ADDRESS kwatterberg@salud.unm.edu		TITY IDENTIF	ICATION	NUMBER	
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT	5. TIT	TLE AND ADD	RESS OF	ADMINISTR	ATIVE OFFICIAL
Pediatrics		anager, Pre			
2d. MAJOR SUBDIVISION 01-School of Medicine					s, MSC09 5220 🖉 🔊
		Albuquerque NM 87131-0001			
		Juqueique,	14101 07	101-000	2007
	E-MAI	L: HSC-Pr	eaward(@salud.un	m.edu
6. HUMAN SUBJECTS	7.	VERTEBRAT	E ANIMA	LS	
No 6a. Research Exempt 6b. Human Subjects Assurance	No.	⊠ No]Yes		78	a. If "Yes," IACUC approval Date
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III		7b. Animal Welfare Assurance No.			
Exemption No. Clinical Trial No Ye	es	A3350-0	1		
If Not Exempt ("No" in 6a): IRB approval date 03/07/06	w				
. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INV	ENTIONS ANI	PATEN	TS	
8a. DIRECT \$158,107 8b. TOTAL \$237,161	N	o 🗌 Yes	If "Yes,"		ously Reported reviously Reported
0. PERFORMANCE SITE(S) (Organizations and addresses)	and the second second second	RINCIPAL IN			505-272-1080
University of New Mexico Health Sciences Ctr. Department of Pediatrics MSC10 5590 1 University of New Mexico Albuquerque, NM 87131-0001		OR PROGRAM DIRECTOR (Item 2a) FAX 505-272-1539			505-272-1539
		DMINISTRATI	E OFFIC	IAL TEL	505.272.6264
		(Item 5) Vinyard		FAX	505.272.0159
		IAME AND TIT RGANIZATIO Rena Vi	N (Item 1	FICIAL SIGI 4)	NING FOR APPLICANT
		riona ri		ward Adm	ninistration
	TITLE	505.272.0			FAX 505.272.0159
	E-MAIL				
	L-IVIAIL	- HSC-Pre	award	@salud.u	nm.edu

13. APPLICANT ORGANIZATION CERTIFICATION statements herein are true, complete and accurate to the obligation to comply with Public Health Services terms result of this application. I am aware that any false, fict may subject me to criminal, civil, or administrative pena	he best of my knowledge, and accept the	SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Per" signature not acceptable.)	DATE 1.24.07
PHS 2590 (Rev. 04/06)	Face Page	0	Form Page 1

Pages 3 through 13 redacted for the following reasons: Not responsive. Not related to SUPPORT. Watterberg, Kristi L.

PROGRESS REPORT SU	MMARY	GRANT NUMBER 1 U10 HD053089 01			
		PERIOD COVERED BY THIS REPORT			
PRINCIPAL INVESTIGATOR OR PROGRAM	M DIRECTOR	FROM	THROUGH		
Kristi watterberg, MD		04/01/07	03/31/2008		
APPLICANT ORGANIZATION University of New Mexico, Health Sc TITLE OF PROJECT (Repeat title shown in	<u> </u>	e)			
NICHD Cooperative Multicenter Nec		,			
A. Human Subjects (Complete Item 6 on the	Face Page)				
Involvement of Human Subjects	🔀 🛛 No Cha	inge Since Previous Submission	Change		
B. Vertebrate Animals (Complete Item 7 on the second s	the Face Page)				
Use of Vertebrate Animals	🔀 🛛 No Cha	ange Since Previous Submission	Change		
C. Select Agent Research	No Cha	ange Since Previous Submission	Change		
D. Multiple PI Leadership Plan	No Cha	ande Since Previous Submission	Change		

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

In our first year of membership in the NICHD Neonatal Research Network, the University of New Mexico has worked to promote the network's primary objective of "advancing the field of Neonatal-Perinatal medicine through a network of academic centers that perform rigorous, multicenter clinical protocols to investigate the safety and efficacy of treatment and management strategies for newborn infants." Specifically, our center has:

- 1. Achieved IRB approval of ongoing NRN studies, including:
 - Not responsive. Not related to SUPPORT.
 - infants (SUPPORT trial), including breathing outcomes and growth ancillaries.
 f. Antenatal screening and consent in a research network model a secondary protocol for the SUPPORT trial

2.	Not responsive. Not related to SUPPORT.
3.	
4.	

Pages 15 through 19 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD053089-03

PI Name:WATTERBERG, KRISTIOrg:UNIVERSITY OF NEW MEXICO
ALBUQUERQUEStart Date:04/01/2008Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7392218Rec'd
Date:01/25/2008

Form Approved Through 09/30/2007					OMB No. 09	25-0001
Department of Health and Human Services Public Health Services	Review	Group	Type 5	Activity UIO	Grant Number ≱ U10 HD053089 Ø2	50
	Total Pr	oject Period	<u> </u>	·		
Grant Progress Report		04/01/2006	3	Th	rough: 03/31/2011	
		ted Budget P	eriod			
		04/01/2008	3	Th	rough: 03/31/2009	
1. TITLE OF PROJECT	oroh N	otwork				
NICHD Cooperative Multicenter Neonatal Rese 2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code) Kristi Watterberg, MD Dept. Pediatrics/Division Neonatology MSC 10 5590 1 University of New Mexico, Albuquerque, NM	3. APP (Nam Univ Fina 1 Ur	LICANT ORG e and addres /ersity of I	s, street, New Me vices D f New	city, state, z exico, He Division, M Mexico	ealth Sciences Center MSC09-5220	JAI
2b. E-MAIL ADDRESS		ITY IDENTIF	CATION	NUMBER		2
kwatterberg@salud.unm.edu 2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Pediatrics 2d. MAJOR SUBDIVISION 01-School of Medicine		E AND ADDF ociate Dir M HSC, Fi niversity o uquerque,	ector, I nancia f New NM 87	⁻ inancial I Service Mexico		5 2008
6. HUMAN SUBJECTS	ـــــــــــــــــــــــــــــــــــــ	VERTEBRAT	E ANIMA	LS		
No 6a. Research Exempt 6b. Human Subjects Assurance Yes No Yes FWA 00003255 If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III		No Yes Animal Welfa	ire Assur		7a. If "Yes," IACUC approva	l Date
Exemption No.	·	A3350-0				
If Not Exempt ("No" in 6a): IRB approval date 02/08/07	N					
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVE		PATEN	TS		
8a. DIRECT \$162,618 8b. TOTAL \$243,927	No No	Yes	lf "Yes,"		viously Reported Previously Reported	
10. PERFORMANCE SITE(S) (Organizations and addresses) University of New Mexico Health Sciences Ctr Department of Pediatrics		RINCIPAL INV OGRAM DIRE Vatterberg,	CTOR (It			
MSC10 5590	NAME (E OFFIC	DIAL TE	L 505.272.6264	
1 University of New Mexico Albuquerque, NM 87131-0001		/inyard		FA	x 505.272.0159	
		RGANIZATIO	N (Item 1		GNING FOR APPLICANT	
	NAME	Rena Vir	•	otor Eine	noial Suc/USC Dro Au	ard
	TEL	Associat 505.272.6		JUI, FINA	incial Svs/HSC PreAw ^{FAX} 505.272.0159	aiu
	E-MAIL			Bealing		
12 Corrections to Page 1 Face Page		HSC-Pre	award	พรลเนน.		

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATI	ON AND ACCEPTANCE: I certify that the	SIGNATURE OF OFFICIAL NA	MED IN	DATE	
statements herein are true, complete and accurate		11c. (In ink. "Per" signature no	ot		
obligation to comply with Public Health Services ten result of this application. I am aware that any false,		acceptable.)	. 1	1.	
may subject me to criminal, civil, or administrative p		Tena Uni	fars	1.22.0	え
PHS 2590 (Rev. 04/06)	Face Page			Form Page	7
		U	,		

Pages 3 through 6 redacted for the following reasons: Not responsive. Not related to SUPPORT.

[:] Watterberg, Kristi L.		
GRANT NUMBER 1 U10 HD053089 02		
PERIOD COVERED BY TH	HIS REPORT	
FROM	THROUGH	
04/01/07	03/31/08	
e) Network		
ge Since Previous Submission	Change	
nge Since Previous Submission	Change	
ge Since Previous Submission	Change	
ge Since Previous Submission	Change	
	GRANT NUMBER 1 U10 HD053089 02 PERIOD COVERED BY TH FROM 04/01/07 Perious Submission Perious Submissio	

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

In our second year of membership in the NICHD Neonatal Research Network, the University of New Mexico has continued to work to promote the network's primary objective of "advancing the filed of Neonatal-Perinatal medicine through a network of academic centers that perform rigorous, multicenter clinical protocols to investigate the safety and efficacy of treatment and management strategies for newborn infants." Specifically, our center has:

 Achieved and maintained IRB approval of ongoing NRN studies (dates of latest approval listed below), including: Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

e. The Surfactant positive airway pressure and pulse oximetry trial in extremely low birth weight infants (SUPPORT trial), including breathing outcomes and growth ancillaries.

f. Antenatal screening and consent in a research network model – a secondary protocol for the SUPPORT trial

g. Neuroimaging and neurodevelopmental outcome (SUPPORT secondary)

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

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-

Name	IRB Number	Most recent Approval Date	Expiration date
Not responsive. Not related to SUPPORT.			-
SUPPORT (including Breathing Outcomes & Growth)	06-283	7/24/07	8/14/08
Neuroimaging SUPPORT secondary	07-092	5/8/07	5/7/08
Antenatal Consent SUPPORT secondary	07-004	12/20/07	1/15/09
Not responsive. Not related to SUPPORT.			

Pages 9 through 12 redacted for the following reasons: Not responsive. Not related to SUPPORT. Principal Investigator/Program Director (Last, First, Middle): Wa

Watterberg. Kristi L.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The surfactant positive airway pressure and pulse oximetry trial in ELBW infants

 Total Enrollment:
 10
 Protocol Number:
 06-283 (UNM IRB)

Grant Number:

U10 HD053089 02

	Sex/Gender				
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	2	2		4 **	
Not Hispanic or Latino	3	3		6	
Unknown (individuals not reporting ethnicity)		-			
Ethnic Category: Total of All Subjects*	5	5		10 *	
Racial Categories					
American Indian/Alaska Native	1	2		3	
Asian		-			
Native Hawaiian or Other Pacific Islander		-			
Black or African American	T				
White	4	3		7	
More Than One Race		-			
Unknown or Not Reported		-			
Racial Categories: Total of All Subjects*	5	5		10 *	

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				* <u>*****</u> *********
White	2	2		4
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	2	2		4 **

* These totals must agree.

** These totals must agree.

Pages 14 through 15 redacted for the following reasons: Not responsive. Not related to SUPPORT. Progress Report Scanning Cover Sheet

5U10HD053089-04

PI Name:WATTERBERG, KRISTIOrg:UNIVERSITY OF NEW MEXICOStart Date:04/01/2009Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7614361Rec'd Date:01/28/2009

http://type5.era.nih.gov/ice_type_five/printcoversheet.cfm

1/28/2009

Form Approved Through 11/30/2010					OMB No. 0925-00
Department of Health and Human Public Health Services	Services	Review Group	Туре	Activity UIO	Grant Number ゆU10 HD053089- 03
		Total Project Period	1		
Grant Progress R	eport	From: 04/01/200		Thr	ough: 03/31/2011
		Requested Budget		The	ough: 03/31/2010
1. TITLE OF PROJECT	. <u></u>	From: 04/01/200			ougn: 03/31/2010
NICHD Cooperative Multicenter					
2a. PROGRAM DIRECTOR / PRINCIPAL INVE (Name and address, street, city, state, zip co		2b. E-MAIL ADDRES	-	unm edu	
Kristi Watterberg, MD		-			RY, OR EQUIVALENT
Dept. Pediatrics/Division of Neo.	natology	Pediatrics			
MSC10 5590 1 University of New Mexico, Albuquerque, NM 87131-0001		2d. MAJOR SUBDIV Neonatology			
07101-0001		2e. Tel: 505.272	.6753	Fax	c 505.272.1539
3a. APPLICANT ORGANIZATION	de)	3b. Tel: 505.272	.6264	Fax	c 505.272.0159
(Name and address, street, city, state, zip code) University of New Mexico, Health Sciences Center Financial Services; MSC 09-5520 1 University of New Mexico, Albuquerque NM 87131-0001		3c. DUNS: 86885	53094		. 40 N & D 71
		4. ENTITY IDENTIFICATION NUMBER 85-6000-642			
		5. NAME, TITLE AN		SS OF ADM	INISTRATIVE OFFICIAL
	Not Exempt ("No" in	Rena Vinyar	ď		
Exempt 6a): 6a): No Yes Exemption No. IRB approval date 02/07/08		Associate Di	irector, I	-inancial	Services/HSC Preaward
6b. Federal Wide Assurance No. FWA000	3255	Tel: 505.272.62	64	Fax	c 505.272.0159
6c. NIH-Defined Phase III Clinical Trial 🔲 No 🔀 Yes		E-MAIL: HSC-Pro	eaward(@salud.u	nm.edu
7. VERTEBRATE ANIMALS No	Yes	10. PROJECT/PERF	ORMANC	E SITE(S)	
7a. If "Yes," IACUC approval Date		Organizational Name	: Unive	rsity of Ne	ew Mexico HSC
7b. Animal Welfare Assurance No.		DUNS: 868853094			
8. COSTS REQUESTED FOR NEXT BUDGET	PERIOD	Street 1: MSC09 5220			
8a. DIRECT \$314,739 8b. TOTAL \$	472,109	Street 2: 1 Unive	ersity of	New Mex	ico
9. INVENTIONS AND PATENTS \Box No	Yes	city: Albuquerq	ue	Cou	unty: Bernalillo
lf "Yes, 🔲 Previously Reported		State: NM		Pro	vince:
Not Previously Reported		Country: USA		Zip	/Postal Code: 87131-0001
		Congressional Districts: NM-001			
11. NAME AND TITLE OF OFFICIAL SIGNING Rena Vineyard, Associate Director			•		
TEL: 505.272.6264	FAX: 505.272.		r	E-MAIL: HS	C-Preaward(see above)
12. Corrections to Page 1 Face Page	<u></u>		,, <u>I</u>		
13. APPLICANT ORGANIZATION CERTIFICAT statements herein are true, complete and accurate obligation to comply with Public Health Services te result of this application. I am aware that any false	to the best of my know rms and conditions if a g , fictitious, or fraudulent	ledge, and accept the grant is awarded as a	11. (Ip ink))	CIAL NAMED IN DATE
may subject me to criminal, civil, or administrative					

Pages 3 through 8 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle	^{e):} Watterberg, Kristi L			
· · · · · · · · · · · · · · · · · · ·	GRANT NUMBER			
PROGRESS REPORT SUMMARY	1 U10 HD05 3089 03			
1	PERIOD COVERED BY TH	IS REPORT		
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	FROM	THROUGH		
Watterberg, Kristi L	04/01/2008	03/31/2009		
APPLICANT ORGANIZATION				
University of New Mexico Health Sciences Center				
TITLE OF PROJECT (Repeat title shown in Item 1 on first pag	le)			
NICHD Cooperative Multicenter Neonatal Research				
A. Human Subjects (Complete Item 6 on the Face Page)				
Involvement of Human Subjects 🛛 🛛 No Cha	ange Since Previous Submission	Change		
B. Vertebrate Animals (Complete Item 7 on the Face Page)				
Use of Vertebrate Animals No Cha	ange Since Previous Submission	Change		
	ange Since Previous Submission	Change		
C. Select Agent Research No Cha	3			
	ange Since Previous Submission	Change		

Targeted/Planned Enrollment Format Page.

In our third year of membership in the NICHD Neonatal Research Network, the University of New Mexico has continued to work as an integral part of the network to achieve the primary objective of "advancing the field of Neonatal-Perinatal medicine through rigorous, multicenter clinical protocols." The specific aims of the Neonatal Research Network have not changed this year. This year, our center:

Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Watterberg, Kristi L.

	PROTOCOL	MOST RECENT	APPROVED
IRB APPROVED PROTOCOLS: NAME of responsive. Not related to SUPPORT.	NUMBER	APPROVAL	THROUGH
The Surfactant Positive Airway Pressure & Pulse		8/5/08	
Dximetry Trial in Extremely Low Birth Weight	06-283	(DSMC report	8/14/09
Oximetry Trial in Extremely Low Birth Weight	06-283		8/14/09
Dximetry Trial in Extremely Low Birth Weight nfants (SUPPORT Study) Antenatal Screening & Consent in a Research	06-283 07-004	(DSMC report	8/14/09 1/15/10
Oximetry Trial in Extremely Low Birth Weight nfants (SUPPORT Study) Antenatal Screening & Consent in a Research		(DSMC report 11/19/08)	
Oximetry Trial in Extremely Low Birth Weight nfants (SUPPORT Study) Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary) Neuroimaging and Neurodevelopmental		(DSMC report 11/19/08)	
Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study) Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary) Neuroimaging and Neurodevelopmental	07-004	(DSMC report 11/19/08) 12/20/08	1/15/10
Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study) Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary) Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT Breathing Outcomes (SUPPORT Study	07-004	(DSMC report 11/19/08) 12/20/08	1/15/10
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study) Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary) Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT Breathing Outcomes (SUPPORT Study Secondary) Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation	07-004 07-092	(DSMC report 11/19/08) 12/20/08 4/22/08	1/15/10 5/7/09

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Not responsive. Not related to SUPPORT.

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Pages 11 through 12 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in ELBW			
Total Enrollment:	17	Protocol Number: 06-283 (UNM IRB number)		
Grant Number:	1 U10 HD053089 03			

PART A. TOTAL ENROLLMENT REPORT: Number by Ethnic	of Subjects E city and Race	nrolled to Da	ate (Cumulative))
		S	ex/Gender	
Ethnic Category	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	4	3		7 **
Not Hispanic or Latino	7	3		10
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	11	6		17 *
Racial Categories	·····		an an an an an an an an an an an an an a	<u></u>
American Indian/Alaska Native	2	2		4
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	9	4		13
More Than One Race				
Unknown or Not Reported				· ·
Racial Categories: Total of All Subjects*	11	6		17 *
	a di shine. Manazarta		YA MARINE I	
PART B. HISPANIC ENROLLMENT REPORT: Numb	er of Hispani	cs or Latinos	Enrolled to Da	te (Cumulative)
Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	4	3		7
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	4	3		7 **

* These totals must agree.

** These totals must agree.

Pages 14 through 17 redacted for the following reasons: Not responsive. Not related to SUPPORT. Progress Report Scanning Cover Sheet

5U10HD053089-05

PI Name:	WATTERBERG, KRISTI
Org:	UNIVERSITY OF NEW MEXICO
Start Date:	04/01/2010
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	7799869
Rec'd Date:	01/25/2010

Form Approved Throu	igh 11/30/20	010					OMB No. 0925-0001	
Department of Health and Human Services			Review Group	Туре	Activity	Grant Number		
Public Health Services				ZHD1DSRA10 Total Project Period	5	<u>U10</u>	1U10 HD053089 64 05	
Grant Progress Report			From: 04/01/200					
			From: 04/01/2006 Through: 03/31/2011 Requested Budget Period					
			From: 04/01/2010)	Thr	ough: 03/31/2011		
1. TITLE OF PROJE		Aulticont	er Neonatal Rese					
				2b. E-MAIL ADDRES	s			
2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)			kwatterberg@salud.unm.edu					
Kristi Watterberg, MD Dept. Pediatrics/Division of Neonatology				2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT				
MSC10 5590			eonatology	Pediatrics				
		exico, A	lbuquerque, NM	2d. MAJOR SUBDIVI School of M		ø		
87131-0001							. 505. 272-1530	
3a. APPLICANT ORG				2e. Tel: 505-272-0180 Fax: 505-272-1539				
(Name and address	s, street, city	y, state, zip		3b. Tel: 505-272-	6264	Fax	: 505-272-0159	
University of I Center Finand				3c. DUNS: 86885	3094		LIAN 2 5 2010	
		•	Ibuquerque NM	4. ENTITY IDENTIFI	CATION			
87131-0001				85-6000-642	CATION	NUMBER		
6. HUMAN SUBJECT	S N	。 🛛	Yes	5. NAME, TITLE AN	D ADDRE	SS OF ADM	NISTRATIVE OFFICIAL	
6a. Research	If Exempt ("Yes" in	If Not Exempt ("No" in	Rena Vinyaro	1			
Exempt	6a): Exemption	No.	6a): IRB approval date	Associate Dir	ector, F	Financial \$	Services/HSC Preaward	
	}		02/07/09					
6b. Federal Wide Ass	urance No.	FWA00	10 4690	Tel: 505-272-626	64	Fax	505-272-0159	
6c. NIH-Defined Phase III Clinical Trial 🔲 No 🔀 Yes			E-MAIL: HSC-Preaward@salud.unm.edu					
7. VERTEBRATE AN	IMALS 🛛] No [Yes	10. PROJECT/PERFC	RMANC	E SITE(S)		
7a. If "Yes," IACUC a	oproval Date	e		Organizational Name: University of New Mexico HSC				
7b. Animal Welfare As	surance No			DUNS: 868853094				
8. COSTS REQUES	TED FOR N	EXT BUDG	ET PERIOD	Street 1: MSC09 5520				
8a. DIRECT \$161,19	97	8b. TOTAL	\$241,796	Street 2: 1 University of New Mexico				
9. INVENTIONS AND	PATENTS	No No	Yes	city: Albuquerque		Cou	County: Bernalillo	
	isly Reporte			State: NM			vince:	
Not Previously Reported			Country: USA Zip/Postal Code: 87131-0		Postal Code: 87131-0001			
				Congressional District	s: NM-(001		
			NG FOR APPLICANT O					
TEL: 505-272-620	54		FAX: 505-272-	0159	E	E-MAIL: HS	C-Preaward (see above)	
12. Corrections to Pag	e 1 Face Pa	ige			l.		<u></u>	
statements herein are obligation to comply w	true, comple with Public He on, 1 am awa	te and accurate alth Services re that any fa	ATION AND ACCEPTA ate to the best of my knowl terms and conditions if a g ilse, fictitious, or fraudulent ve penalties	edge, and accept the 1 arant is awarded as a	IGNATUR) •	IAL NAMED IN DATE	
PHS 2590 (Rev. 11/07)				Face Page		<u> </u>	Form Page 1	

Pages 3 through 8 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle):	۷
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Watterberg, Kristi L

	•		
PROGRESS REPORT SUMMARY	GRANT NUMBER 1 U10 HD053089	04	
	PERIOD COVERED E	BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Watterberg, Kristi L	FROM 4/1/2009	THROUGH 3/31/2010	
APPLICANT ORGANIZATION University of New Mexico Health Sciences Center			
TITLE OF PROJECT (Repeat title shown in Item 1 on first pa NICHD Cooperative Multicenter Neonatal Researc	•		

A. Human Subjects (Complete Item 6 on the Face	e Page)		
Involvement of Human Subjects	No Change Since Previous Submission	Change	
B. Vertebrate Animals (Complete Item 7 on the F	ace Page)		
Use of Vertebrate Animals	No Change Since Previous Submission	Change	
C. Select Agent Research	No Change Since Previous Submission	Change	
D. Multiple PD/PI Leadership Plan	No Change Since Previous Submission	Change	
E. Human Embryonic Stem Cell Line(s) Used	No Change Since Previous Submission	Change	

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims: The University of New Mexico has had an extremely productive year as a participating site within the NICHD Neonatal Research Network, working to achieve the network's primary objective of "advancing the field of Neonatal-Perinatal medicine through rigorous, multicenter clinical protocols." The specific aims of the Neonatal Research Network have not changed this year, while numerous studies have been instituted, conducted and completed (protocols with IRB approval at UNM are attached to this report.)

B: Studies and results:

Not responsive. Not related to SUPPORT.

5. Developed forms and began data collection for the SUPPORT Neuroimaging ancillary study "Evaluation of early working memory in extremely preterm infants" (<u>UNM personnel: Lowe (co-PI), Duncan (co-PI) and Watterberg (co-investigator and sponsor as NRN PI at UNM</u>). This study will evaluate the ability of measures of working memory in children at 18 – 22 months corrected age to predict executive function at 6 – 7 years of age.

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

<u>D. Plans</u>: We will continue to participate fully in the activities and meetings of the NRN, maintaining IRB approval for all network protocols. We specifically anticipate:

Not responsive. Not related to SUPPORT.

4. Continuing the SUPPORT Neuroimaging ancillary study of working memory in extremely preterm infants (B.5, Lowe and Duncan, co-PIs);

Not responsive. Not related to SUPPORT.

Neonatal Research Network with IRB approval at the University of New Mexico

IRB APPROVED PROTOCOLS: NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			
		-	
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight	06-283	8/4/2009	8/14/2010
Infants (SUPPORT Study) (NCT00233324)	00-283	0/4/2009	0/14/2010
Antenatal Screening & Consent in a Research	07-004	Closure requested	1/15/2010
Network Model (SUPPORT Study secondary)			
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	07-092	5/5/2009	5/7/2010
Breathing Outcomes (SUPPORT Study Secondary)	06-283	8/4/2009	8/14/2010
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	06-283	8/4/2009	8/14/2010
Extended follow-up at 6-7 years of age of patients enrolled in the Neuroimaging and Neurodevelopmental Outcome Secondary to	Not yet submitted		
SUPPORT Not responsive. Not related to SUPPORT.		<u> </u>	

Pages 12 through 19 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth

Study Title:	Weight Infants				
Total Enrollment:	21	Protocol Number: 06-283 (UNM IRB)			
Grant Number:	1 U10 HD053089 03				

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race					
Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total	
Hispanic or Latino	5	5	0	10	**
Not Hispanic or Latino	7	4	0	11	
Unknown (individuals not reporting ethnicity)	0	0	0	0	-
Ethnic Category: Total of All Subjects*	12	9	0	21	*
Racial Categories					
American Indian/Alaska Native	2	2	0	4	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	0	0	0	0	
White	10	7	0	17	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	12	9	0	21	*
		the first second and a second s			-

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	5	5	0	10
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	5	5	0	10 **

* These totals must agree.

** These totals must agree.

Pages 21 through 26 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Neonatal Research Network with IRB approval at the University of New Mexico

IRB APPROVED PROTOCOLS: NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	<u>APPROVED</u> <u>THROUGH</u>
Not responsive. Not related to SUPPORT.			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study) (NCT00233324)	06-283	8/4/2009	8/14/2010
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	07-004	Closure requested	1/15/2010
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	07-092	5/5/2009	5/7/2010
Breathing Outcomes (SUPPORT Study Secondary)	06-283	8/4/2009	8/14/2010
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	06-283	8/4/2009	8/14/2010
Extended follow-up at 6-7 years of age of patients enrolled in the Neuroimaging and Neurodevelopmental Outcome Secondary to SUPPORT	Not yet submitted		

revised Page 10

Page 28 redacted for the following reason: Not responsive. Not related to SUPPORT. Progress Report Scanning Cover Sheet

5U10HD053109-02

PI Name: Org: Start Date: Snap: Appl ID: Rec'd Date: BELL, EDWARD UNIVERSITY OF IOWA 04/01/2007 N/A (NEEDS TO BE BOOKMARKED) 7220065 02/06/2007

Form Approved Through 09/30/2007					OMB No. 0925-0001
Department of Health and Human Services		w Group	Туре	Activity U10	Grant Number HD053109_02
Public Health Services		1DSRA10 Project Period	5		
			•		02/21/2011
Grant Progress Report	From: 04/05/2006 Through: 03/31/2011 Requested Budget Period				
1. TITLE OF PROJECT	IFIOIII.	04/01/2007	;		ough: 03/31/2008
NICHD Cooperative Multicenter Neonatal Rese		<i>i i i i i i i i i i</i>			
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)		PLICANT ORG			n code)
Edward F. Bell, MD		e University			,
Department of Pediatrics	low	/a City, IA	52242		
University of Iowa					
200 Hawkins Drive, 8811 JPP Iowa City, IA 52242					
2b. E-MAIL ADDRESS		TITY IDENTIFI			
edward-bell@uiowa.edu		2-6004-813-		NUMBER	
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT	1				
Pediatrics	1	ila Fisher F	-	•) h
2d. MAJOR SUBDIVISION Roy J. and Lucille A. Carver College of		sistant Vice			
Medicine	Division of Sponsored Programs 2 Gilmore Hall Iowa City, IA 52242				
	E-MAIL	ih@uio	wa.edu		
6. HUMAN SUBJECTS		VERTEBRAT	E ANIMA	LS	
No 6a. Research Exempt 6b. Human Subjects Assurance FWA00003007	^{No.} 🛛	No		7	a. If "Yes," IACUC approval Date
		Yes			
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III	·	. Animal Welfa	re Assura	ance No.	
Exemption No. Clinical Trial No Ye	5				
If Not Exempt ("No" in 6a): IRB approval date 06/07/06					
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD 8a. DIRECT \$177,419 8b. TOTAL \$261,693	1	ENTIONS AND			iously Reported
80. DIRECT \$177,419 80. TOTAL \$201,093			li tes,		Previously Reported
10. PERFORMANCE SITE(S) (Organizations and addresses)		RINCIPAL INV			_ 319-356-4006
University of Iowa, Iowa City, IA 52242	OR PR	OGRAM DIRE	CTOR (It	em 2a) FAX	< 319-356-4685
		DMINISTRATI	/E OFFIC		
		(Item 5) Fisher Reig	hlev		
				FAX	INING FOR APPLICANT
1	0	RGANIZATIO	N (Item 1		
	NAME	Meredith	Hay		
	TITLE	Vice Pre	sident	for Resea	arch
	TEL	319-335-2	2123		FAX 319-335-2130
	E-MAIL	└ nih@uio [,]	wa.edu	ı	
12. Corrections to Page 1 Face Page					

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

PHS 2590 (Rev. 04/06)

Form Page 1

Ζ

Pages 3 through 18 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Mi	ddle): Bell, Edward F.	Bell, Edward F.			
PROGRESS REPORT SUMMARY	GRANT NUMBER HD053109				
	PERIOD COVERED BY TH	IS REPORT			
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Bell, Edward F.	FROM 04/05/2006	THROUGH 03/31/2007			
APPLICANT ORGANIZATION University of Iowa					
A. Human Subjects (Complete Item 6 on the Face Page) Involvement of Human Subjects		Change			
A. Human Subjects (Complete Item 6 on the Face Page) Involvement of Human Subjects (Complete Item 7 on the Face Page) B. Vertebrate Animals (Complete Item 7 on the Face Page)	arch Network	Change			
NICHD Cooperative Multicenter Neonatal Resea A. Human Subjects (Complete Item 6 on the Face Page) Involvement of Human Subjects Solution B. Vertebrate Animals (Complete Item 7 on the Face Page) Use of Vertebrate Animals Solution	Change Since Previous Submission				

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

The <u>primary aim</u> of the University of Iowa Neonatal Research Network center is to participate in all aspects of the work of the Network. We recognize that many crucial questions in neonatal medicine can only be addressed by large multicenter clinical trials. We believe it is our responsibility to offer our participation in such trials in order to provide clear answers more quickly than is possible with single-center trials. We have considerable expertise and resources to contribute to this effort, and our rural population base that fills a gap in previous Network efforts and distinguishes itself by high enrollment rates in clinical trials involving neonates.

Not responsive. Not related to SUPPORT.

B. Studies and Results

The table below summarizes the University of Iowa IRB approval process and subject recruitment for the first 9 ½ months of the first year of funding (04-01-06 to 01-15-07).

Study Name	IRB Number	Approval Date	Expiration Date	Subjects Consented	Subjects Enrolled	Subjects Completed
Not responsive. Not relate	ed to SUPPORT.					
SUPPORT	200605740	6/29/06	6/22/07	7	6	All active

Not responsive. Not related to SUPPORT.

Pages 21 through 24 redacted for the following reasons: Not responsive. Not related to SUPPORT. Progress Report Scanning Cover Sheet

5U10HD053109-03

PI Name: Org: Start Date: Snap: Appl ID: Rec'd Date: BELL, EDWARD UNIVERSITY OF IOWA 04/01/2008 N/A (NEEDS TO BE BOOKMARKED) 7413379 02/05/2008

,

Form Approved Through 09/30/2007	OMB No. 0925-000					
Department of Health and Human Services Public Health Services	Review Group Type Activity Grant Number 45 U10 HD053109–03					
	Total Project Period					
Grant Brograss Bapart	From: 04/05/2006 Through: 03/31/2011					
Grant Progress Report	Requested Budget Period					
	From: 04/01/2008 Through: 03/31/2009					
1. TITLE OF PROJECT						
NICHD Cooperative Multicenter Neonatal Re 2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR						
(Name and address, street, city, state, zip code)	3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)					
Edward F. Bell, MD	The University of Iowa					
Department of Pediatrics	Iowa City, IA 52242					
University of Iowa	FEB 0 5 2008					
200 Hawkins Drive, 8811 JPP						
Iowa City, IA 52242						
2b. E-MAIL ADDRESS edward-bell@uiowa.edu	4. ENTITY IDENTIFICATION NUMBER					
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALEN	1-42-6004-813-A1 T 5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL					
Pediatrics	Twila Fisher Reighley					
2d. MAJOR SUBDIVISION	Assistant Vice President for Research					
Roy J. and Lucille A. Carver College of	Division of Sponsored Programs					
Medicine	2 Gilmore Hall					
	Iowa City, IA 52242					
	E-MAIL: nih@uiowa.edu					
6. HUMAN SUBJECTS	7. VERTEBRATE ANIMALS					
No 6a. Research Exempt 6b. Human Subjects Assurar	ance No. No 7a. If "Yes," IACUC approval Date					
\bigvee_{Yes} No \bigvee_{Yes} FWA00003007	T Yes					
If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III	7b. Animal Welfare Assurance No.					
	Yes					
If Not Exempt ("No" in 6a):						
IRB approval date 4/13/07 1 🛛 Expedited Re	eview					
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	9. INVENTIONS AND PATENTS					
8a. DIRECT \$177,217 8b. TOTAL \$261,395	No 🗌 Yes If "Yes," 🔲 Previously Reported					
	Not Previously Reported					
10. PERFORMANCE SITE(S) (Organizations and addresses)	11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a)					
	FAX 319-356-4685					
	11b. ADMINISTRATIVE OFFICIAL TEL 319-335-2123					
	NAME (Item 5) Twila Fisher Reighley FAX 319-335-2130					
	11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)					
	NAME Meredith Hay					
	TITLE Vice President for Research					
	TEL 319-335-2123 FAX 319-335-2130					
	E-MAIL nih@uiowa.edu					
12. Corrections to Dago 1 Eaco Bago						

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACC statements herein are true, complete and accurate to the best of my obligation to comply with Public Health Services terms and condition result of this application. I am aware that any false, fictilious, or frau may subject me to criminal, civil, or administrative penalties.	y knowledge, and accept the ns if a grant is awarded as a	11c. (In ink.	"Per" signatu		108
PHS 2590 (Rev. 04/06)	Face Page			Form	Page 1

M/Lynn Hudachek Acting for Meredith Hay Pages 3 through 4 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last	, First, Middle)	Bell, Edward F.			
PROGRESS REPORT SUMMARY		GRANT NUMBER HD053109			
		PERIOD COVERED BY T	HIS REPORT		
PRINCIPAL INVESTIGATOR OR PROGRAM DIR	ECTOR	FROM	THROUGH		
Bell, Edward F.		04/01/2007	03/31/2008		
APPLICANT ORGANIZATION University of Iowa					
TITLE OF PROJECT (Repeat title shown in Item 1 NICHD Cooperative Multicenter Neonata					
A. Human Subjects (Complete Item 6 on the Face I	Page)				
Involvement of Human Subjects	🛛 No Chan	ge Since Previous Submission	Change		
B. Vertebrate Animals (Complete Item 7 on the Fac	e Page)				
Use of Vertebrate Animals	🛛 No Chan	ge Since Previous Submission	Change		
C. Select Agent Research	No Chan	ge Since Previous Submission	Change		
D. Multiple PI Leadership Plan	No Chan	ge Since Previous Submission	Change		
SEE PHS 2590 INSTRUCTIONS					

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

The <u>primary aim</u> of the University of Iowa Neonatal Research Network center is to participate in all aspects of the work of the Network. We recognize that many crucial questions in neonatal medicine can only be addressed by large multicenter clinical trials. We believe it is our responsibility to offer our participation in such trials in order to provide clear answers more quickly than is possible with single-center trials. We have considerable expertise and resources to contribute to this effort. Moreover, our rural population base fills a gap in previous Network efforts.

B. Studies and Results

The table below summarizes the University of Iowa IRB approval process and subject recruitment for the first 21 months of our Network participation (04-01-06 to 12-31-07).

Study Name	IRB Number	Most Recent Approval	Expiration	Subjects Consented	Subjects Enrolled	Subjects Completed
Not responsive. Not related to	SUPPORT.					
SUPPORT	200605740	8/31/07	6/3/08	16	16	all active
Antenatal Consent (bundled with SUPPORT)	200605740	8/31/07	6/3/08	-	-	-
Neuroimaging (bundled with SUPPORT)	200605740	8/31/07	6/3/08	16	16	11
Breathing Outcomes (bundled with SUPPORT)	200605740	8/31/07	6/3/08	16	16	all active
Postnatal Growth (bundled with SUPPORT)	200605740	8/31/07	6/3/08	16	16	11
Not responsive. Not related	to SUPPORT.				<u> </u>	<u> </u>
=						-
2						-
2						-

Pages 7 through 11 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Support Protocol			
Total Enrollment:	13	Protocol Number:	200605740	
Grant Number:	HD053109			

		Sex/Gender						
Ethnic Category	Females	Males	Unknown or Not Reported	Total				
Hispanic or Latino	0	0		0	**			
Not Hispanic or Latino	1	12		13				
Unknown (individuals not reporting ethnicity)	0	0		0				
Ethnic Category: Total of All Subjects*	1	12		13	*			
Racial Categories		1111						
American Indian/Alaska Native	0	0		0				
Asian	0	0		0				
Native Hawaiian or Other Pacific Islander	0	0		0				
Black or African American	0	4		4				
White	1	8		9				
More Than One Race	0	0		0				
Unknown or Not Reported	0	0		0				
Racial Categories: Total of All Subjects*	1	12		13	*			

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander		· · · · · · · · · · · · · · · ·		<u></u>
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	0	0		0 **

* These totals must agree.

** These totals must agree.

Pages 13 through 15 redacted for the following reasons: Not responsive. Not related to SUPPORT. Progress Report Scanning Cover Sheet

5U10HD053109-04

PI Name:	BELL, EDWARD
Org:	UNIVERSITY OF IOWA
Start Date:	04/01/2009
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	7617726
Rec'd Date:	02/05/2009

Form Approved Through 11/30/2010				OMB No. 0925-000	
Department of Health and Human Services Public Health Services	Review Group	Type ¥5	Activity U10	Grant Number HD053109-04	
	Total Project Perio	od			
Grant Brogross Boport	From: 04/05/20	006	Tł	rough: 03/31/2011	
Grant Progress Report	Requested Budge	t Period			
	From: 04/01/20	009	Tł	nrough: 03/31/2010	
1. TITLE OF PROJECT					
NICHD Cooperative Multicenter Neonatal Re	search Network				
2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)	2b. E-MAIL ADDR		1		
Edward F. Bell, MD	edward-be	•			
University of Iowa	Departmen			ORY, OR EQUIVALENT	
200 Hawkins Drive, 8811 JPP	-				
Iowa City, IA 52242	2d. MAJOR SUBD			College of Medicine	
				-	
	2e. Tei: 319.35	6.4006	F	ax: 319.356.4685	
3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)	3b. Tel: 319.33	5.2123	F	ax: 319.335.2130	
The University of Iowa Iowa City, IA 52242	3c. DUNS: 062	761671			
		4. ENTITY IDENTIFICATION NUMBER 1-42-6004-813-A1			
6. HUMAN SUBJECTS 🗌 No 🛛 Yes				MINISTRATIVE OFFICIAL	
6a. Research f Exempt ("Yes" in f Not Exempt ("No					
Exempt 6a): 6a):	Assistant Vice President for Research		Pacaarch		
No Yes Exemption No. IRB approval date					
11/24/08		Sponsor	leuriogi	FEB 05	
6b. Federal Wide Assurance No. FWA00003007	Tel: 319.335.2	2123	F	ax: 319.335.2130	
6c. NIH-Defined Phase III Clinical Trial 🛛 No 🗌 Yes	E-MAIL: nih@u	iowa.edu	L		
7. VERTEBRATE ANIMALS No Yes	10. PROJECT/PE	RFORMAN	CE SITE(S)		
7a. If "Yes," IACUC approval Date	Organizational Name: applicant				
7b. Animal Welfare Assurance No.	DUNS: 062761671				
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	Street 1: 2 Gilmore Hall				
a pipeor a181.022					
8a. DIRECT \$181,023 8b. TOTAL \$267,009	Street 2:				
9. INVENTIONS AND PATENTS 🛛 No 🗌 Yes	city: Iowa City	/	c	ounty: Johnson	
lf "Yes, 🔲 Previously Reported	State: 1A		P	rovince:	
Not Previously Reported	Country: USA		z	ip/Postal Code: 52242	
	Congressional Dis	tricts:	u		
11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICAN		om 121	· · · ·		
Jordan Cohen, Vice President for Research	it organization (/i	em 13)			
TEL: 319-335-2123 FAX: 319-33	35-2130		E-MAIL: N	ih@uiowa.edu	
12. Corrections to Page 1 Face Page				······································	
13. APPLICANT ORGANIZATION CERTIFICATION AND ACCE				FICIAL NAMED IN DATE	
statements herein are true, complete and accurate to the best of my k obligation to comply with Public Health Services terms and conditions	nowledge, and accept the				
result of this application. I am aware that any false, fictitious, or fraudu may subject me to criminal, civil, or administrative penalties.		<i>[(1)]</i>	HMNN	Ullachik 2121	
PHS 2590 (Rev. 11/07)	Face Page	<u></u>	~///	Form Page	
	-		, , , , , , , , , , , , , , , , , , ,		
				Hudachek	
			Acting f	or Jordan Cohen	

Pages 3 through 4 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): B		Bell, Edward F.				
PROGRESS REPORT SUMMARY		GRANT NUMBER HD053109				
		PERIOD COVERED BY THIS REPORT				
PROGRAM DIRECTOR / PRINCIPAL INVESTIGA	TOR	FROM	THROUGH			
Bell, Edward F.	II, Edward F. 04/01/2008		03/31/2009			
APPLICANT ORGANIZATION University of Iowa						
TITLE OF PROJECT (Repeat title shown in Item 7 NICHD Cooperative Multicenter Neonata		Network				
A. Human Subjects (Complete Item 6 on the Face	Page)					
Involvement of Human Subjects	No Change	e Since Previous Submission	Change			
B. Vertebrate Animals (Complete Item 7 on the Fa	ce Page)					
Use of Vertebrate Animats	No Change	e Since Previous Submission	Change			
C. Select Agent Research	No Change	e Since Previous Submission	Change			
D. Multiple PD/PI Leadership Plan	No Change	e Since Previous Submission	Change			
SEE PHS 2590 INSTRUCTIONS.						

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

The primary aim of the University of Iowa Neonatal Research Network center is to participate in all aspects of the work of the Network. We recognize that many crucial questions in neonatal medicine can only be addressed by large multicenter clinical trials. We believe it is our responsibility to offer our participation in such trials in order to provide clear answers more quickly than is possible with single-center trials. We have considerable expertise and resources to contribute to this effort. Moreover, our rural population base fills a gap in previous Network efforts.

Not responsive. Not related to SUPPORT.

B. Studies and Results

The table below summarizes the University of Iowa IRB approval process and subject recruitment for the first 33 months of our Network participation (04-01-06 to 12-31-08).

Protocol Name	Protocol Number	Most Recent Approval	Approved Through	Subjects Consented	Subjects Enrolled
Not responsive. Not related to SUPPORT.					
-					
-					
_					
SUPPORT	200605740	11/24/08	5/19/09	30	28
Antenatal Screening & Consent (SUPPORT secondary)	Bundled with above			50	50
Neuroimaging (SUPPORT secondary)	Bundled with above			30	26
Breathing Outcomes (SUPPORT secondary)	Bundled with above			30	24
Postnatal Growth (SUPPORT	Bundled with above			30	26

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Pages 8 through 11 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Support Protocol			
Total Enrollment:	11	Protocol Number:	200605740	
Grant Number:	HD053109			

		S	ex/Gender	
Ethnic Category	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	4	7	0	11
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	4	7	0	11 *
Racial Categories			_	
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	1	2	0	3
White	3	4	0	7
More Than One Race	0	1	0	1
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	4	7	0	11 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

. .

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.

** These totals must agree.

Pages 13 through 17 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD053109-05

PI Name:	BELL, EDWARD
Org:	UNIVERSITY OF IOWA
Start Date:	04/01/2010
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	7802145
Rec'd Date:	02/01/2010

	Review Group	Type	Activity	Grant Number	925-0001
Department of Health and Human Services Public Health Services		Type X.S	U10	HD053109-05	
	Total Project Period	ł			
Grant Brograss Bonart	From: 04/05/2006 Through: 03/31/2011				
Grant Progress Report	Requested Budget	Period			
	From: 04/01/20	10	Thr	ough: 03/31/2011	
. TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Resea	arch Network				
	2b. E-MAIL ADDRE				
(Name and address, street, city, state, zip code) Edward F. Bell, MD	edward-bell	-			
University of Iowa	Department			RY, OR EQUIVALENT	
200 Hawkins Drive 8811 JPP	2d. MAJOR SUBDIV				
Iowa City, IA 52242			Carver	College of Medicine	
	2e. Tel: 319.356			c 319.356.4685	
	3b. Tel: 319.335			c 319.335.2130	<u></u>
(Name and address, street, city, state, zip code)		52123	Fa	K 0 19.000,2 100	
The University of IOwa	3c. DUNS: 0627	51671			FE
Iowa City, IA 52242			<u></u>		EB
	4. ENTITY IDENTI		NUMBER		0
	1-42-6004-8	· · · ·			
				IINISTRATIVE OFFICIAL	2010
a. Research If Exempt ("Yes" in If Not Exempt ("No" in Exempt 6a): 6a):	Twila Fisher Reighley Assistant Vice President for Research				
No Yes Exemption No. IRB approval date		-			
3/2/09	Division of S	sponsor	ed Progra	ims	
b. Federal Wide Assurance No. FWA00003007	Tel: 319.335.21	23	Fa	c 319.335.2130	
Sc. NIH-Defined Phase III Clinical Trial X No Yes	E-MAIL: nih@uid	owa.edu			
	10. PROJECT/PER	FORMANC	E SITE(S)		
7a. If "Yes," IACUC approval Date	Organizational Name: applicant				
	DUNS: 062761671				
COSTS REQUESTED FOR NEXT BUDGET PERIOD	Street 1: 2 Gilmore Hall				
	Street 2:		unty: Johnson		
	City: Iowa City				
If "Yes, Previously Reported Not Previously Reported	State: IA			ovince:	
	Country: USA			/Postal Code: 52242	
	Congressional Distr		02		
11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT O Jordan Cohen, Vice President for Research	RGANIZATION (Ite	m 13)			
TEL: 319.335.2123 FAX: 319.335.	2130		E-MAIL: NI	h@uiowa.edu	
12. Corrections to Page 1 Face Page			I		
		SIGNATU			
13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTA statements herein are true, complete and accurate to the best of my knowl obligation to comply with Public Health Services terms and conditions if a g result of this application. Lam overage that any false, fitting or fraudulant	ledge, and accept the grant is awarded as a	11. (In ini	Λ	1/ 1 Able	11.
statements herein are true, complete and accurate to the best of my knowl obligation to comply with Public Health Services terms and conditions if a g result of this application. I am aware that any false, fictitious, or fraudulent may subject me to criminal, civil, or administrative penalties.	ledge, and accept the grant is awarded as a t statements or claims	11. (In in	lim	Hudachak	1/20
statements herein are true, complete and accurate to the best of my knowl obligation to comply with Public Health Services terms and conditions if a g result of this application. I am aware that any false, fictitious, or fraudulent may subject me to criminal, civil, or administrative penalties.	ledge, and accept the grant is awarded as a	11. (In in)	lynn	Hudachek For	//2 (m Page 1

Pages 3 through 4 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle):	Bell, Edward F.				
	GRANT NUMBER				
PROGRESS REPORT SUMMARY	HD053109				
	PERIOD COVERED BY TH	IIS REPORT			
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	FROM	THROUGH			
Bell, Edward F.	04/01/2009	03/31/2010			
APPLICANT ORGANIZATION		L			
University of Iowa					
TITLE OF PROJECT (Repeat title shown in Item 1 on first page))				
NICHD Cooperative Multicenter Neonatal Research	Network				
A. Human Subjects (Complete Item 6 on the Face Page)					
Involvement of Human Subjects No Chang	ge Since Previous Submission	Change			
B. Vertebrate Animals (Complete Item 7 on the Face Page)					
Use of Vertebrate Animals No Chang	ge Since Previous Submission	Change			
C. Select Agent Research No Chang	ge Since Previous Submission	Change			
D. Multiple PD/PI Leadership Plan 🛛 🛛 🔀 No Chang	ge Since Previous Submission	Change			
E. Human Embryonic Stem Cell Line(s) Used No Chang	ge Since Previous Submission	Change			
SEE PHS 2590 INSTRUCTIONS.					

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

The <u>primary aim</u> of the University of Iowa Neonatal Research Network center is to participate in all aspects of the work of the Network. We recognize that many crucial questions in neonatal medicine can only be addressed by large multicenter clinical trials. We believe it is our responsibility to offer our participation in such trials in order to provide clear answers more quickly than is possible with single-center trials. We have considerable expertise and resources to contribute to this effort. Moreover, our rural population base fills a gap in previous Network efforts.

Not responsive. Not related to SUPPORT.	
	er
	the

B. Studies and Results

The table below summarizes the University of Iowa IRB approval process and subject recruitment for the first 33 months of our Network participation (04-01-06 to 12-31-09).

Protocol Name	Protocol Number	Most Recent Approval	Approved Through	Subjects Consented	Subjects Enrolled
t responsive. Not related to SUPPORT.	<u> </u>	L	L <u></u>		JL
SUPPORT	200605740	5/11/09	5/11/10	31	29[b1]
Antenatal Screening & Consent (SUPPORT secondary)	Bundled with above			50	50
Neuroimaging (SUPPORT secondary)	Bundled with above			31	29
Breathing Outcomes (SUPPORT secondary)	Bundled with above			31	24
Postnatal Growth (SUPPORT secondary)	Bundled with above			31	29
t responsive. Not related to SUPPORT.	· · · · · · · · · · · · · · · · · · ·			<u> </u>	1

Pages 7 through 17 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	Support Study		
Total Enrollment:	1	Protocol Number: 200605740	
Grant Number:	HD053109		

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino	1			1
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	1			1 *
Racial Categories				
American Indian/Alaska Native				
Asian				······
Native Hawaiian or Other Pacific Islander		· · · ·		
Black or African American				
White	1			1
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	1			1 *
میں اور ایک از ایک ایک میں ایک میں ایک میں ایک ایک میں ایک ایک میں ایک میں ایک میں ایک میں ایک میں ایک میں ایک میں		ele der siet.		

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**				**

* These totals must agree.

** These totals must agree.

Page 19 redacted for the following reason: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD053119-02

PI Name:FRANTZ, IVANOrg:NEW ENGLAND MEDICAL CENTER
HOSPITALSStart Date:04/01/2007Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7218093Rec'd
Date:02/02/2007

Form Approved Through 09/30/2007	OMB No. 0925-0001					
Department of Health and Human Services Public Health Services	Review GroupTypeActivityGrant NumberZHD1DSRA105U105 U10 HD053119-02					
	Total Project Period					
Grant Prograss Poport	From: 04/01/2006 Through: 03/31/2011					
Grant Progress Report	Requested Budget Period					
	From: 04/01/2007 Through: 03/31/2008					
1. TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Res	search Network					
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code) Ivan D. Frantz, III, MD Tufts-New England Medical Center Department of Pediatrics 750 Washington Street Boston, MA 02111	3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code) New England Medical Center Hospitals, Inc. Office of Grants and Contracts 750 Washington Street, #817 Boston, MA 02111					
2b. E-MAIL ADDRESS IFrantz@tufts-nemc.org	4. ENTITY IDENTIFICATION NUMBER 1043400617A1					
 2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Pediatrics 2d. MAJOR SUBDIVISION Newborn Medicine 	 TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL Robert P. Bloomberg Director, Grants and Contracts New England Medical Center Hospitals, Inc. 750 Washington Street, #817 Boston, MA 02111 					
	E-MAIL: RBloomberg@tufts-nemc.org					
6. HUMAN SUBJECTS No 6a. Research Exempt 6b. Human Subjects Assurance Yes 6b. Human Subjects Assurance Yes 6b. Human Subjects Assurance FWA00004449 If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III Exemption No. Clinical Trial No Yes If Not Exempt ("No" in 6a): Exemption In Comparison of the full IRB or	7. VERTEBRATE ANIMALS No 7a. If "Yes," IACUC approval Date Yes 7b. Animal Welfare Assurance No. A3775-01					
IRB approval date 04/01/2006	ew					
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD 8a. DIRECT \$156,291 8b. TOTAL \$252,033	9. INVENTIONS AND PATENTS					
 PERFORMANCE SITE(S) (Organizations and addresses) New England Medical Center Hospitals, Inc. 750 Washington Street 	11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a)TEL(617) 636-5322Ivan D. Frantz, III, MDFAX(617) 636-1456					
Boston, MA 02111	11b. ADMINISTRATIVE OFFICIAL NAME (Item 5)TEL(617) 636-1142Robert P. BloombergFAX(617) 636-8568					
	11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14) NAME Robert P. Bloomberg					
	TITLE Director, Grants and Contracts					
	TEL (617) 636-1142 FAX (617) 636-8568					

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEP statements herein are true, complete and accurate to the best of my kno obligation to comply with Public Health Services terms and conditions if result of this application. I am aware that any false, fictitious, or fraudule may subject me to criminal, civil, or administrative penalfies.	owledge, and accept the a grant is awarded as a	SIGNATURE OF OFFICIAL NAMED IN 11c (In ink. "Ber" signature not acceptable.)	DATE 1/29/07
PHS 2590 (Rev. 04/06)	Face Page	0	/Form Page 1

Pages 3 through 8 redacted for the following reasons: Not responsive Principal Investigator/Program Director (Last, First, Middle):

Frantz III, Ivan D

	Tranz III, Wall D.		
PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD053119-02 PERIOD COVERED BY THIS REPORT		
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Ivan D. Frantz, III, MD	FROM 04/01/2006	THROUGH 03/30/2007	
APPLICANT ORGANIZATION New England Medical Center Hospitals, Inc.			
TITLE OF PROJECT (Repeat title shown in Item 1 on first pag NICHD Cooperative Multicenter Neonatal Research			
A. Human Subjects (Complete Item 6 on the Face Page)		an, ,	

Involvement of Human Subjects	No Change Since Previous Submission	Change	
B. Vertebrate Animals (Complete Item 7 on t	he Face Page)		
Use of Vertebrate Animals	No Change Since Previous Submission	Change	
C. Select Agent Research	No Change Since Previous Submission	Change	
D. Multiple PI Leadership Plan	No Change Since Previous Submission	Change	

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

Not responsive	

B. Studies and Results

Not responsive

Protocol	Approval Date	First Subject Enrolled	Number Enrolled
Not responsive			
Support	8/7/2006	10/1/2006	8
Support Growth	8/7/2006	10/1/2006	8
Support Respiratory	8/7/2006	10/1/2006	8
Support MRI	8/7/2006	10/1/2006	8

Not responsive

Support Consent

8/7/2006

10/1/2006

31

PROGRESS REPORT (continued)

	We projected slightly over 8 subjects to date for SUPPORT, and have enrolled
8. Not responsive	
Not responsive	

Dr. Frantz and the coordinators have given numerous inservice sessions to nurses, physicians and respiratory therapists at T-NEMC about the Network in general and all of the active protocols, with particular emphasis on Support.

Not responsive

C. Significance

Not responsive

D. Plans

During the next year we will continue to recruit subjects into ongoing clinical trials. We expect to complete

E. Publications

Not responsive

F. Project-Generated Resources

N/A

Pages 11 through 13 redacted for the following reasons: Not responsive Principal Investigator/Program Director (Last, First, Middle): Frantz III, Ivan D.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	The Surfactant Positive Airway Pressure Pulse Oximetry Randomized Trial (SUPPORT)		
	in Extremely Low Birth Weight Infants		
Total Enrollment:	8	Protocol Number: # 7856	

Grant Number:

1 U10 HD053119-01

		S	Sex/Gender		
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	0	1	0	1	**
Not Hispanic or Latino	5	2	0	7	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	5	3	0	8	*
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	1	0	0	1	
White	4	3	0	7	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	5	3	0	8	*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total	
American Indian or Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	0	0	0	0	
White	0	1	0	1	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of Hispanics or Latinos**	0	1	0	1 **	

* These totals must agree.

** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Total Planned Enrollment: 32

Etherie Osterner	Sex/Gender					
Ethnic Category	Females	Males	Total			
Hispanic or Latino	2	2	4			
Not Hispanic or Latino	14	16	32			
Ethnic Category: Total of All Subjects *	16	18	32			
Racial Categories						
American Indian/Alaska Native	0	0	0			
Asian	1	1	2			
Native Hawaiian or Other Pacific Islander	0	0	0			
Black or African American	1	3	4			
White	12	14	26			
Racial Categories: Total of All Subjects *	16	18	32			

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

.

Study Title: The Surfactant Positive Airway Pressure Pulse Oximetry Randomized Trial (SUPPORT) in Extremely Low Birth Weight Infants

Pages 16 through 25 redacted for the following reasons: Not responsive Tufts-New England Medical Center

1796 Boston Dispensary 1894 Floating Hospital for Infants and Children 1933 P-att Diagnostic Clinic 1948 New England Medical Center Hospital 1953 Rehitolistation Institute



Frantz III, Ivan D.

Tufts University

1893 School of Medicine 1899 School of Dental Medicine 1979 School of Veterinary Medicine 1980 Sachler School of Graduate Biometical Sciences

Institutional Review Board Tel: 617-636-7312 Fax. 617-606-6394

750 Washington Street Tufts-NEMC #817 Boston, MA 02111

David P. Chelmow, MD Chair

Edward L. Decker, PharmD Vice-Chair

Judith A. Frazier, RN, MEd Vice-Chair

Nicholas G. Guerina, MD, PhD Vice-Chair

7856 IRB ≓:

Ivan D. Frantz, MD

044 H-PED

Tufts-NEMC

The Surfactant Positive Airway Pressure and Pulse Oximetry Protocol Title: Trial (SUPPORT) in Extremely Low Birth Weight Infants

07/11/2006 Date of IRB Review: 08/07/2006 Date of IRB Approval:

Protocols: (Main Study protocol and 5 Secondary Study protocols)

This approval includes approval of modified living arrangement codes in Appendix C of the Follow-Up Manual of Operations for Forms SF01 and SF03, Question B1 and revised form SF04A.

Main Study:

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants [Version Dated: 28 March 2005]

Secondary Studies:

- Neuroimaging and Neurodevelopmental Outcome: A Secondary to Surfactant Positive Airway Pressure and Pulse Oximetry Trial [Version Dated: 17 June 2005]
- NICHD Support Trial: Breathing Outcomes Study Protocol [Version Dated: 6 December 2005]
- Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study [Version Dated: 26 January 2006]
- Follow-Up Study 18 Month Follow-Up Visit of Extremely Low Birth Weight Survivors [Version Dated: 7 February ٠ 2006]
- Antenatal Screening and Consent in a Research Network Model

The IRB made the following findings (no actions required):

- 1. Because the study involves neonates, state laws governing research involving the fetus or newborn are applicable. The study procedures have the potential to preserve the subject's health, and the research is therefore approvable under Massachusetts General Laws Chapter 112 Section 12J.
- 2. In accordance with 45 CFR 46.405, the IRB found that this research involves greater than minimal risk; but, it presents the prospect of direct benefit to the individual subjects. Accordingly, the IRB-RED found that: (1) the risks are justified by the potential benefit to the subjects, (2) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and (3) adequate provisions are made for soliciting permission of the parent or guardian.
- 3. In accordance with 45 CFR 46.408, the IRB also found that the signature of one parent, or guardian, will be required to execute the ICF.
- 4. In accordance with 45 CFR 46.116 (d), the IRB granted a waiver of consent for the Antenatal Screening and Consent in a Research Network Model sub-study, noting that this sub-study 1) does not affect the rights or welfare of the subject, 2) is minimal risk, and 3) is a necessary component of the study.
- 5. In accordance with the Health Insurance Portability and Accountability Act (HIPAA), the IRB granted a waiver of research authorization for the Antenatal Screening and Consent in a Research Network Model sub-study.

- as submitted

25

<u>__X</u>

NOTICE OF STUDT APPROVAL

Frantz III, Ivan D.

NOTICE OF STUDY APPROVAL Ivan D. Frantz, MD IRB #: 7856 Page 2 of 2

PLEASE NOTE: *FOR ANY FUNDED STUDY*: THIS RESEARCH MUST NOT BE INITIATED WITHOUT AUTHORIZATION FROM EITHER THE CLINICAL TRIALS OFFICE OR THE GRANTS AND CONTRACTS OFFICE.

Informed Consent Form (ICF): [Version Dated: 7/28/06]

- approved as revised, dated copy enclosed <u>X</u>

Other Approved Documents:

Parent newsletter [No Version Dated; Received 31 July 2006] Breathing Outcomes Calendar Packet for Parents [No Version Dated; Received 31 July 2006]

- approved as revised, dated copy enclosed

Human Protection Form for Funding Agency:

- not required .

Regulations regarding your research protocol:

- 1. The approval is valid for one (1) year from the date of review (unless otherwise stipulated by the IRB).
- 2. Unanticipated or serious adverse reactions/side effects encountered in this study must be promptly reported to the IRB within five (5) days. *Deaths are reportable immediately.*

X

- 3. Any changes or modifications in the study protocol or consent form must be reviewed and approved by the IRB prior to implementation.
- 4. You may not use the ICF or any other study document until it has been approved and validated by the IRB.
- 5. If you are subject to HIPAA, the Security Rule applies to your research. If you create, receive, store, or transmit electronic PHI you must meet institutional Security Rule standards. For more information, please contact your HIPAA Privacy Officer for Research.

THIS NOTICE MUST BE RETAINED WITH YOUR RESEARCH FILES.

Date

/JMN

Signature of Chair Vice Chair

Pages 28 through 29 redacted for the following reasons: Not responsive **Progress Report Scanning Cover Sheet**

5U10HD053119-03

PI Name:FRANTZ, IVANOrg:NEW ENGLAND MEDICAL CENTER
HOSPITALSStart Date:04/01/2008Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7391718Rec'd
Date:01/31/2008

Form Approved Through	ah 11/30/2010		,		•	0	MB No. 0925-0001
Department of Health and Human Services Public Health Services			Review Group ZHD1DSRA10	Type 5	Activity U10	Grant Number 5 U10 HD053	· · · · · · · · · · · · · · · · · · ·
			Total Project Period	<u>. </u>	- I		
Grant Progress Report		From: 04/01/200 Requested Budget P		Thre	ough: 03/31/201	1	
			From: 04/01/200		T h		0
1. TITLE OF PROJECT				0		ough: 03/31/200	9
		er Neonatal Rese					
2a. PROGRAM DIREC (Name and addres	CTOR / PRINCIPAL IN s, street, city, state, zip		2b. E-MAIL ADDRES	-	.ora		
Ivan D. Franta	• •	antor	2c. DEPARTMENT, S	_	-	RY, OR EQUIVALI	ENT
Department o	gland Medical C	enter	Pediatrics				
750 Washing	ton Street		2d. MAJOR SUBDIVI	÷ · · · ·			
Boston, MA 0	2111		2e. Tel: (617) 636		Fax	c (617) 636-14	156
3a. APPLICANT ORG			3b. Tel: (617) 63			c (617) 636-85	
	s, street, city, state, zip			0-11-12	Fax		,00
-	Medical Center nts and Contracts	•	3c. DUNS: 07-953	3-2263		. 1	AN-R T STAR
	ton Street, #817		JAN 31 2008 4. ENTITY IDENTIFICATION NUMBER				
Boston, MA 0	2111		1043400617A1				
6. HUMAN SUBJECT			5. NAME, TITLE AN	ID ADDRE	ESS OF ADM	INISTRATIVE OFF	ICIAL
6a. Research Exempt	If Exempt ("Yes" in 6a):	If Not Exempt ("No" in 6a):	 Robert P. Bloomberg, Director, Grants and Contracts New England Medical Center Hospitals, Inc. 				
🛛 No 🗌 Yes	Exemption No.	IRB approval date 06/11/2007	· · · ·			, Boston, MA	
6b. Federal Wide Ass			_				
6c. NIH-Defined Phase		1004449	Tel: (617) 636-1			c (617) 636-85	00
Clinical Trial	5.7		E-MAIL: RBIOOM	berg@u	uns-nemo	y	
7. VERTEBRATE AN	IMALS 🛛 No [Yes	10. PROJECT/PERF	ORMANC	E SITE(S)		
7a. If "Yes," IACUC a	pproval Date		Organizational Name	: New E	ingland Me	edical Center H	ospitals, Inc.
7b. Animal Welfare As	surance No. A3775	01	DUNS: 07-953-2	263			·
8. COSTS REQUES	TED FOR NEXT BUDG	ET PERIOD	Street 1: 750 Washington Street, #817				<u></u>
8a. DIRECT \$156,0	88 86. TOTA	\$251,781	Street 2:			<u></u>	
9. INVENTIONS AND		Yes	City: Boston County: Suffo		unty: Suffolk		
lf "Yes, 🔲 Previo	usly Reported		State: MA		Pro	ovince:	[*] *******
	eviously Reported		Country: USA		Zip	/Postal Code: 02	111
			Congressional Districts: 9th				
11. NAME AND TITL	E OF OFFICIAL SIGN	NG FOR APPLICANT					
		Grants and Contra		,		•	
TEL: (617) 636-1	142	FAX: (617) 63	6-8568		E-MAIL: RE	Bloomberg@tuf	ts-nemc.org
12. Corrections to Pag	ge 1 Face Page						
	. <u>.</u>						
statements herein are	e true, complete and accu	CATION AND ACCEPT/ rate to the best of my know	ledge, and accept the	SIGNATUi 11ہر11 ink			DATE
result of this applicati	ion. I am aware that any f	s terms and conditions if a alse, fictitious, or fraudulen	grant is awarded as a	21.	10G		1 hatiz
may subject me to cri PHS 2590 (Rev. 11/07	iminal, civil, or administrat	ve penalties.	Face Page	1Care	1/2 2	mondas	Form Page 1

Pages 3 through 4 redacted for the following reasons: Not responsive

Program Director/Principal Investigate	or (Last, First, Middle):	Frantz III, Ivan D.			
	······································	GRANT NUMBER			
PROGRESS REPORT SU	PROGRESS REPORT SUMMARY				
		PERIOD COVERED BY TH	HIS REPORT		
PROGRAM DIRECTOR / PRINCIPAL INVE	STIGATOR	FROM	THROUGH		
Ivan D. Frantz, III, MD		04/01/2007	03/31/2008		
TITLE OF PROJECT (Repeat title shown in NICHD Cooperative Multicenter Nec	onatal Research I	Network			
A. Human Subjects (Complete Item 6 on the Face Page) Involvement of Human Subjects No Change		e Since Previous Submission	Change		
B. Vertebrate Animals (Complete Item 7 on	the Face Page)		•		
Use of Vertebrate Animals	No Chang	e Since Previous Submission	Change		
C. Select Agent Research	No Chang	e Since Previous Submission	Change		
D Multinle PLI eadershin Plan		e Since Previous Submission	Change		

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A.	nsive	
Not responsive	nsive	

B. Studies and Results

During the second year of funding enrollment has continued to proceed in all of the currently active studies at the rates predicted. The table below indicates enrollment to date.

2007 Cumulative Progress Report Enrollment Numbers

Protocol	Approval Date	First Subject Enrolled	# Enrolled Year 1	# Enrolled Year 2	Total Enrollment
Not responsive	Joan	Emoned			
Support	8/7/2006	10/1/2006	8	32	40
Support Growth	8/7/2006	10/1/2006	8	32	40
Support BO	8/7/2006	10/1/2006	8	32	40
Support MRI	8/7/2006	10/1/2006	8	32	40

Our number enrolled matches well with our projected enrollment as indicated in our application. For example the d^{Not responsive}

We projected 40 subjects to date for

SUPPORT, and have enrolled 40. We are pleased to have enrolled all of the Support infants in the Support secondary studies. We have successfully completed MRIs on all of the infants who have reached their study window. Not responsive

Dr. Frantz and the coordinators have given numerous inservice sessions to nurses, physicians and respiratory therapists at T-NEMC about the Network in general and all of the active protocols, with particular emphasis on Support.^{Not responsive}

C. Significance

Not responsive

Not responsive

Not responsive

D. Plans

E. Publications

F. Project-Generated Resources

N/A

Pages 7 through 10 redacted for the following reasons: Not responsive

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT

Total Planned Enrollment: 36/year

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Sex/Gender				
	Females	Males	Total		
Hispanic or Latino	3	9	12		
Not Hispanic or Latino	8	12	20		
Ethnic Category: Total of All Subjects *	11	21	. 32		
Racial Categories					
American Indian/Alaska Native	1	0	1		
Asian	2	1	3		
Native Hawaiian or Other Pacific Islander	. 0	0	0		
Black or African American	0	3	3		
White	8	17	25		
Racial Categories: Total of All Subjects *	11	21	32		

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

NRN IRB APPROVALS

Page 11

	PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
ot responsive			<u></u>	

	PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
	Not responsive			
	The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	# 7856	6/11/2007	6/11/2008
Page	Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	7856	6/11/2007	6/11/2008
12	Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	7856	6/11/2007	6/11/2008
	Breathing Outcomes (SUPPORT Study Secondary)	7856	6/11/2007	6/11/2008
	Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	7856	6/11/2007	6/11/2008

Frantz III, Ivan D.

	•	· · · · · · · · · · · · · · · · · · ·	
PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
			,

*** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.

Frantz III, Ivan D.

Pages 15 through 16 redacted for the following reasons: Not responsive **Progress Report Scanning Cover Sheet**

5U10HD053119-04

PI Name: Org: Start Date: Snap: Appl ID: Rec'd Date: FRANTZ, IVAN TUFTS MEDICAL CENTER 04/01/2009 N/A (NEEDS TO BE BOOKMARKED) 7614357 02/02/2009

Form Approved Through 11/30/2010				OMB No. 0925-0001
Department of Health and Human Services Public Health Services	Review Group ZHD1DSRA10	Type 5	Activity U10	Grant Number 5 U10 HD053119-04
	Total Project Period	<u> </u>		· · · · · · · · · · · · · · · · · · ·
Cropt Drogroop Bonort	From: 04/01/200	6	Thro	bugh: 03/31/2011
Grant Progress Report	Requested Budget P	Period		
	From: 04/01/200	9	Thro	bugh: 03/31/2010
1. TITLE OF PROJECT				·····
NICHD Cooperative Multicenter Neonatal Res				
2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)	2b. E-MAIL ADDRES	-	alcenter o	ra
Ivan D. Frantz, III, MD				RY, OR EQUIVALENT
Tufts Medical Center	Pediatrics		, 0.001011.0	
Department of Pediatrics	2d. MAJOR SUBDIVI	SION		
800 Washington Street	Newborn Me			
Boston, MA 02111	2e. Tel: (617) 636	6-5322	Fax	: (617) 636-1456
3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)	3b. Tel: (617) 63	6-1142	Fax	: (617) 636-8568
Tufts Medical Center	3c. DUNS: 07-953	2-2263		FEB 0 2 2009
Office of Grants and Contracts				LEB 0 Z 2003
800 Washington Street, #817 Boston, MA 02111	4. ENTITY IDENTIF 1043400617		NUMBER	
6. HUMAN SUBJECTS 🗌 No 🛛 Yes	5. NAME, TITLE AN	ID ADDRI	ESS OF ADM	INISTRATIVE OFFICIAL
6a. Research If Exempt ("Yes" in If Not Exempt ("No")	in Robert P. Blo	oomber	g, Directo	r, Grants and Contracts
Exempt 6a): 6a): No Yes Exemption No. IRB approval date	Tufts Medica		-	
06/11/2008	800 Washing	gton Str	reet, #817	, Boston, MA 02111
6b. Federal Wide Assurance No. FWA00004449	Tel: (617) 636-1	142	Fax	: (617) 636-8568
6c. NIH-Defined Phase III Clinical Trial 🔲 No 🔀 Yes	E-MAIL: RBloom	perg@t	uftsmedic	alcenter.org
7. VERTEBRATE ANIMALS X № Yes	10. PROJECT/PERF		E SITE(S)	
7. If "Yes," IACUC approval Date	Organizational Name		• •	enter
	-		Medical C	çintçi
7b. Animal Welfare Assurance No. A3775-01	DUNS: 07-953-2	263		
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	Street 1: 800 Wa	shingto	on Street,	#817
8a. DIRECT \$156,023 8b. TOTAL \$251,728	Street 2:			
9. INVENTIONS AND PATENTS 🛛 No 🗌 Yes	city: Boston		Col	unty: SUffolk
If "Yes, Previously Reported	State: MA		Pro	vince:
Not Previously Reported	Country: USA		Zip/	Postal Code: 02111
	Congressional Distric	ts: 9th	L _	
11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT John Gonsalves, Jr, Director, Research Adminis	•	13)	t.	
TEL: (617) 636-8105 FAX: (617) 6	36-1468		E-MAIL: JGc	onsalves@tuftsmedicalcenter.org
12. Corrections to Page 1 Face Page				
13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPT statements herein are true, complete and accurate to the best of my kno obligation to comply with Public Health Services terms and conditions if result of this application. I am aware that any false, fictitious, or fraudule may subject me to criminat, civil, or administrative penalties.	owledge, and accept the a grant is awarded as a		-	CIAL NAMED IN DATE
PHS 2590 (Rev. 11/07)	Face Page	-/ Y		Form Page 1
		\bigcup		
		-		

Pages 3 through 4 redacted for the following reasons: Not responsive

Program Director/Principal Investigator (Last, First, Middle):		^{er:} Frantz III, Ivan D.		
PROGRESS REPORT SUMMARY		GRANT NUMBER 5 U10 HD053119-04		
		PERIOD COVERED BY THI	S REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVE	STIGATOR	FROM	THROUGH	
Ivan D. Frantz, III, MD		04/01/2008	03/31/2009	
APPLICANT ORGANIZATION			ب _{ورد بو} ر بور	
Tufts Medical Center				
	onatal Research			
ITLE OF PROJECT (Repeat title shown in NICHD Cooperative Multicenter Net	onatal Research		Change	
TITLE OF PROJECT (Repeat title shown in NICHD Cooperative Multicenter Ner A. Human Subjects (Complete Item 6 on th	onatal Research Face Page) No Cha	h Network	Change	
TITLE OF PROJECT (Repeat title shown in NICHD Cooperative Multicenter Net A. Human Subjects (Complete Item 6 on the Involvement of Human Subjects	Dinatal Research Face Page) No Cha the Face Page)	h Network	Change	
TITLE OF PROJECT (Repeat title shown in NICHD Cooperative Multicenter New A. Human Subjects (Complete Item 6 on the Involvement of Human Subjects B. Vertebrate Animals (Complete Item 7 on	Dinatal Research Face Page) No Cha the Face Page) No Cha	h Network		

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

Not responsive		

B. Studies and Results

During the third year of funding enrollment has continued to proceed in all of the currently active studies at the rates predicted. The table below indicates enrollment to date.

2008 Cumulative Progress Report Enrollment Numbers

Protocol	Approval Date	First Subject Enrolled	# Enrolled Year 1	# Enrolled Year 2	# Enrolled Year 3	Total Enroliment
lot responsive						
Support	8/7/2006	10/1/2006	8	32	13	53
Support	8/7/2006	10/1/2006	8	32	13	53
Growth						
Support BO	8/7/2006	10/1/2006	8	32	13	53
Support MRI	8/7/2006	10/1/2006	8	32	13	53
Support	8/7/2006	10/1/2006	12	54	38	66
Consent						
lot responsive						

Our number enrolled matches well with our projected enrollment as indicated in our application. For example

We projected 20 subjects per year for SUPPORT, and have enrolled just under that number. We are pleased to have enrolled all of the Support infants in all of the Support secondary studies. We have successfully completed MRIs on all of the infants who have reached their study window. We Not responsive

Not responsive

C. Significance

Not responsive

D. Plans

Not responsive

In addition we expect to

begin enroliment in the	protocols. Support Follow-up will continue. We will
E. Publications	

F. Project-Generated Resources

N/A

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Pages 8 through 10 redacted for the following reasons: Not responsive

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT

Total Planned Enrollment: 30/year

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Females	Males	Total
Hispanic or Latino	2	6	8
Not Hispanic or Latino	2	3	5
Ethnic Category: Total of All Subjects *	4	9	13
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	1
White	3	9	12
Racial Categories: Total of All Subjects *	4	9	13

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Page 12 redacted for the following reason: Not responsive

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive		· · · · · · · · · · · · · · · · · · ·	

Frantz III, Ivan D.

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
lot responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry	# 7856	6/11/2008	5/12/2009
Trial in Extremely Low Birth Weight Infants (SUPPORT Study) Antenatal Screening & Consent in a Research Network Model	7856	6/11/2008	5/12/2009
(SUPPORT Study secondary) Neuroimaging and Neurodevelopmental Outcome: A	7856	6/11/2008	5/12/2009
Secondary Study to SUPPORT Breathing Outcomes (SUPPORT Study Secondary)	7856	6/11/2008	5/12/2009
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	7856	6/11/2008	5/12/2009

Frantz III, Ivan D.

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

*** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.

Pages 16 through 17 redacted for the following reasons: Not responsive

5U10HD053119-05

PI Name:	FRANTZ, IVAN
Org:	TUFTS MEDICAL CENTER
Start Date:	04/01/2010
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	7802116
Rec'd Date:	02/01/2010

Form Approved Through 06/30/2012					OMB No. 09	25-0001	
Department of Health and Hui Public Health Servin		Review Group ZHD1DSRA1	Type 5	Activity U10	Grant Number 5 U10 HD053119-	05	
		Total Project Period	~		00/04/0044		
Grant Progress	Report	From: 04/01/200		Thro	ough: 03/31/2011		
Chanter rogrood	Roport	Requested Budget P			02/24/2014		
		From: 04/01/201	0	Thro	ough: 03/31/2011		
1. TITLE OF PROJECT NICHD Cooperative Multicent	er Neonatal Resea	arch Network					
2a. PROGRAM DIRECTOR / PRINCIPAL I	NVESTIGATOR	2b. E-MAIL ADDRES			······································		
(Name and address, street, city, state, a	zip code)	IFrantz@tufts					
lvan D. Frantz, III, MD			SERVICE	, LABORATO	RY, OR EQUIVALENT		
Tufts Medical Center		Pediatrics				_ <u></u>	
Department of Pediatrics		2d. MAJOR SUBDIVI				-11	
800 Washington Street		Newborn Me		_		EB	
Boston, MA 02111-1552		^{2e. Tel:} (617) 636-	5322	Fax	^{::} (617) 636-1456		
3a. APPLICANT ORGANIZATION (Name and address, street, city, state, z	ip code)	^{3b. Tel:} (617) 636	-1142	Fax	" (617) 636-8568	ا الحصر	
Tufts Medical Center		^{3c.} DUNS: 079532	263			2010	
Office of Grants and Contract	S						
800 Washington Street, Box 8	317	4. ENTITY IDENTIFI		NUMBER			
Boston. MA 02111-1552		1043400617A	1				
6. HUMAN SUBJECTS 🗌 No 🛛	Yes	5. NAME, TITLE AN	D ADDRI	ESS OF ADM	INISTRATIVE OFFICIAL		
6a. Research If Exempt ("Yes" in	If Not Exempt ("No" in	Robert P Bloo	mbera	Director	Grants and Contract	s	
Exempt 6a):	6a): IRB approval date	Tufts Medical (-	,,			
	06/11/2008			et#817 F	Boston, MA 02111-1	552	
6b. Federal Wide Assurance No. FWA0	1	Tel: (617) 636-114			[:] (617) 636-8568		
6c. NIH-Defined Phase III	0004449		12		(017) 030-0300		
		E-MAIL: RBloomberg@ti	iftemor	licalcontor	ora		
	☐ Yes	10. PROJECT/PERFO					
7. VERTEBRATE ANIMALS _ No 7a. If "Yes," IACUC approval Date	L_I Yes	Organizational Name: Tufts Medical Center					
7b. Animal Welfare Assurance No. A377	/5-01	DUNS: 07-953-22					
8. COSTS REQUESTED FOR NEXT BUI		Street 1: 800 Washington Street					
8a. DIRECT \$ 159,152 8b. TOT	AL\$256,828	Street 2: Box 817					
	· · · · · · · · · · · · · · · · · · ·						
	o 🗌 Yes	City: Boston			unty: Suffolk		
If "Yes, I Previously Reported		State: MA			vince:		
		Country: USA		/2/p/	Postal Code: 021111552	۱ ۲	
		Congressional District	^{:s:} 9th	·····			
11. NAME AND TITLE OF OFFICIAL SIGN		RGANIZATION (Item	_	•···	······		
John Gonsalves, Jr, Director, F	Research Administr	ation	,				
TEL: (617) 636-8105	FAX: (617) 636	-1468		E-MAIL: JG	onsalves@tuftsmedi	calc	
12. Corrections to Page 1 Face Page							
13. APPLICANT ORGANIZATION CERTIF	ICATION AND ACCEPTA	NCE: I certify that the S	IGNATU		A DATE		
statements herein are true, complete and acc obligation to comply with Public Health Servic result of this application. I am aware that any	curate to the best of my know ces terms and conditions if a false, fictitious, or fraudulent	ledge, and accept the T grant is awarded as a			01/29/	2010	
may subject me to criminal, civil, or administr PHS 2590 (Rev. 06/09)	auve perialities.	Face Page	-IF		Form	n Page 1	
•		6				.	

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Pages 3 through 4 redacted for the following reasons: Not responsive Program Director/Principal Investigator (Last, First, Middle): Frantz, Ivan D.

PROGRESS REPORT SUMMARY			GRANT NUMBER 5 U10 HD053119-05				
		PEF	RIOD COVERED BY	THIS REPORT			
PROGRAM DIRECTOR / PRINCIPAL INVEST	IGATO	R FRO	OM	THROL	JGH		
Ivan D. Frantz, III, MD		04	/01/2009	03/31	/2010		
APPLICANT ORGANIZATION Tufts Medical Center				n			
TITLE OF PROJECT (Repeat title shown in Ite NICHD Cooperative Multicenter Neon	atal R		ork				
A. Human Subjects (Complete Item 6 on the Face	e Page)						
Involvement of Human Subjects	\mathbf{X}	No Change Since	e Previous Submission		Change		
B. Vertebrate Animals (Complete Item 7 on the F	محت ace Pag	e)		ليسيا			
Use of Vertebrate Animals	\times	No Change Since	e Previous Submission		Change		
C. Select Agent Research	\mathbf{X}	No Change Since	e Previous Submission		Change		
D. Multiple PD/PI Leadership Plan	\boxtimes	No Change Since	e Previous Submission		Change		
E. Human Embryonic Stem Cell Line(s) Used	\mathbf{X}	No Change Since Previous Submission Change					

SEE PHS 2590 INSTRUCTIONS.

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WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Please see attached Narrative (p. 5-9)

A. Specific Aims

B. Studies and Results

During the fourth year of funding enrollment has continued to proceed in all of the currently active studies at the rates predicted. Table I below indicates enrollment to date:

Table I:	2009 Cumulative	Progress R	Report Enrollment Numbers
----------	-----------------	-------------------	---------------------------

Protocol	Approval Date	First Subject Enrolled	# Enrolled Year 1	# Enrolled Year 2	# Enrolled Year 3	# Enrolled Year 4	Totai
Not responsive							
	0.7.0000	40/4/0000					
Support	8/7/2006	10/1/2006	8	32	11	6	57
Support Growth	8/7/2006	10/1/2006	8	32	11	6	57
Support BO	8/7/2006	10/1/2006	8	32	11	6	57
Support MRI	8/7/2006	10/1/2006	8	32	11	6	57
Support Consent	8/7/2006	10/1/2006	12	54	38	15	107
Not responsive							

Our number enrolled is well-matched to the enrollment projected in our application: we

while our projected annual enrollment of 20 subjects for SUPPORT was met exactly. Our enrollment of 61% of eligible infants is the second highest in the Network. We are pleased to report that all SUPPORT infants have been enrolled in all secondary SUPPORT studies, and that MRIs have been successfully completed on all infants who have reached their study window.

Not responsive

•

Since

beginning follow-up for our SUPPORT subjects in June 2008, 97% of those enrolled have been tested. One subject enrolled in both Not responsive and SUPPORT is unable to be tested because the family has entered the Witness Protection Program. Not responsive

Not responsive

Page 8 redacted for the following reason: Not responsive

C. Significance

Not responsive

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D. Plans

During the next year we will continue Not responsive

Support Follow-up will continue in the current

manner. Not responsive

E. Publications

TABLE II: NRN IRB APPROVALS 2009-2010

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	7856	4/17/2009	4/16/2010
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	7856	4/17/2009	4/16/2010
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	7856	4/17/2009	4/16/2010
Breathing Outcomes (SUPPORT Study Secondary)	7856	4/17/2009	4/16/2010
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	7856	4/17/2009	4/16/2010

*** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.

Pages 11 through 14 redacted for the following reasons: Not responsive Program Director/Principal Investigator (Last, First, Middle):

Frantz, Ivan D.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)

Total Planned Enrollment: 20/year

TARGETED/PLANNED ENROLLMENT: Number of Subjects						
Ethnic Category	Females	Males	Totai			
Hispanic or Latino	0	0	0			
Not Hispanic or Latino	3	3	6			
Ethnic Category: Total of All Subjects *	3	3	6			
Racial Categories						
American Indian/Alaska Native	0	0	0			
Asian	0	0	0			
Native Hawaiian or Other Pacific Islander	0	0	0			
Black or African American	0	0	0			
White	3	3	6			
Racial Categories: Total of All Subjects *	3	3	6			

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 16 through 18 redacted for the following reasons: Not responsive **Progress Report Scanning Cover Sheet**

5U10HD053124-02

PI Name:FAIX, ROGEROrg:UNIVERSITY OF UTAHStart Date:04/01/2007Snap:N/A (NEEDS TO BE BOOKMARKED)Appl ID:7219983Rec'd Date:01/31/2007

http://impacii.nih.gov/ice_type_five/printcoversheet.cfm

Form Approved Through 09/30/2007	7					OMB No. 0925-0001
Department of Health a Public Healt			v Group I DSR-	Type 5	Activity U10	Grant Number 5U10HD053124-02
		Total Project Period				
	ana Demant	From:	4/1/2006		Thr	ough: 3/31/2011
Grant Progr	ess Report	Reque	sted Budget P	eriod		
		From:	4/1/2007		Thr	ough: 3/31/2008
1. TITLE OF PROJECT						
NICHD Cooperative Mu						
2a. PRINCIPAL INVESTIGATOR O (Name and address, street, city,			PLICANT ORG			code)
Roger G. Faix, M.D.	state, zip code)		versity of I		sity, state, zij	
Department of Pediatric	s/Ped Admin		1 Federal			
P.O. Box 581289			t Lake City		102	
Williams Building- 295 (Chipeta Way					
Salt Lake City, UT 8415	58					
2b. E-MAIL ADDRESS			FITY IDENTIF		NUMBER	
roger.faix@hsc.utah.edu	and the second second second second second second second second second second second second second second second		6000525A1			
2c. DEPARTMENT, SERVICE, LAB	ORATORY, OR EQUIVALENT	1				ATIVE OFFICIAL
Pediatrics			ants and C		sonicer	
2d. MAJOR SUBDIVISION School of Medicine			versity of			
School of Medicine		School of Medicine 30 North 1900 East				
		00				
		E-MAIL	: ospawar	ds@osp	.utah.edu	
6. HUMAN SUBJECTS		1	VERTEBRAT		S	· · · · · · · · · · · · · · · · · · ·
No 6a. Research Exempt	6b. Human Subjects Assurance	No.] No		78	a. If "Yes," IACUC approval Date
	FWA00003745] Yes			·····
	6c. NIH-Defined Phase III		Animal Welfa		nce No.	JAN 3 1 2007
	Clinical Trial 🔲 No 🛛 Ye	S ·	A3031-0	1		2007
If Not Exempt ("No" in 6a): IRB approval date 4/14/2006	Full IRB <u>or</u>	N				
8. COSTS REQUESTED FOR NE	XT BUDGET PERIOD	9. INV	ENTIONS AND	D PATENT	S	·····
8a. DIRECT \$168,566	b. total \$252,007	No 🛛	Yes	If "Yes,"		ously Reported
		44- 5				reviously Reported
10. PERFORMANCE SITE(S) (Orga University of Utah Heal			RINCIPAL IN\ OGRAM DIRE			801-581-7052
50 N. Medical Drive, Sa				,	FAX	801-585-7395
			MINISTRATI	VE OFFIC	IAL TEL	801-585-6945
Primary Children's Medical Center,			(Item 5) ie Bernard			901 595 5740
100 N. Medical Drive						801-585-5749
Salt Lake City, UT 8411	13		RGANIZATIO			NING FOR AFFLICANT
		NAME	Brent K.	Brown		
LDS Hospital, 9 th and C		TITLE	Director.	Office	of Spons	ored Programs
Salt Lake City, UT 8414	ło	TEL	801-581-		•	FAX 801-585-5749
		E-MAIL			1	
12. Corrections to Page 1 Face Pag	Δ				p.utah.ed	iu
The sum of the sum of	0					

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the SIGNATURE OF OFFICIAL NAMED IN DATE 11c. (In ink. "Per" signature not acceptable.) statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a an 07 result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. Von PHS 2590 (Rev. 04/06) Form Page 1 Face Page

Pages 3 through 7 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Principal	Investigator/F	Program Di	irector (Last,	First, Mi	ddle): p	aix
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Faix, Roger Gordon

		•				
PROGRESS REPORT SUMMARY		GRANT NUMBER 5U10HD053124-02				
		PERIOD COVERED BY THIS REPORT				
PRINCIPAL INVESTIGATOR OR PROGRAM	M DIRECTOR	FROM	THROUGH			
Roger Faix, M.D.		4/1/2006	3/31/2007			
APPLICANT ORGANIZATION University of Utah	<u> </u>					
TITLE OF PROJECT (Repeat title shown in NICHD Cooperative Multicenter Neo						
A. Human Subjects (Complete Item 6 on the	Face Page)					
Involvement of Human Subjects	🔀 🛛 No Cha	nge Since Previous Submission	Change			
B. Vertebrate Animals (Complete Item 7 on t	he Face Page)					
Use of Vertebrate Animals	🔀 🛛 No Cha	nge Since Previous Submission	Change			
C. Select Agent Research	🛛 No Cha	No Change Since Previous Submission				
D. Multiple Pt Leadership Plan	No Change Since Previous Submission					

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific aims: The specific aim of our participation in the NICHD Cooperative Multicenter Neonatal Research Network have not changed. This is to foster rigorous clinical research on the care of newborn infants, particularly low birth weight infants, by assuring sufficient patients to answer important clinical questions in a timely, powerful and potentially generalizable manner.

B. Studies and results: Since joining the Neonatal Research Network (NRN) in April, 2006, we have implemented 2 major NRN studies following IRB approval. The first^{Not responsive. Not related to SUPPORT.}

The other is the SUPPORT

study, a study of infants born between 24 0/7 and 27 6/7 weeks gestation who, after obatining parental consent antenatally, are randomized to treatment from birth with continuous positive airway pressure (CPAP) or intubation, exogenous surfactant and mechanical ventilation as well as randomized to one of two target oxygen saturation ranges with endpoints including death, bronchopulmonary dysplasia at 36 weeks gestation and neurodevelopmental status at 18-22 months of age. In addition, 3 secondary studies of the SUPPORT trial (MRI follow-up, breathing outcomes, antenatal consent,) were instituted as well, with consent imbedded into the form for the main trial. The SUPPORT trial and its secondary studies were implemented at the two sites with associated labor and delivery units (U of Utah and LDS Hospital) following approval by both IRBs.

To the present (1/26/2007), we have enrolled Not responsive. Not related to SUPPORT. 11 in the SUPPORT study, and in the secondary studies, Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Pages 9 through 10 redacted for the following reasons: Not responsive. Not related to SUPPORT. Principal Investigator/Program Director (Last, First, Middle): Faix, Roger Gordon

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	SUPPORT study
and a second of the	

Total Enrollment: 10 **Protocol Number:**

Grant Number:

5U10HD053124-02

	thnicity and Race	9	Sex/Gender	
Ethnic Category	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	2	0	0	2 **
Not Hispanic or Latino	1	7	0	8
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	3	7	0	10 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	3	7	0	10
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	3	7	0	10 *
PART B. HISPANIC ENROLLMENT REPORT: N	umber of Hispanic	s or Latino:		(Cumulative)
Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	2	0	0	2
TTT ING				-

* These totals must agree.

Unknown or Not Reported

** These totals must agree.

PHS 398/2590 (Rev. 09/04, Reissued 4/2006)

Racial Categories: Total of Hispanics or Latinos**

0

2

0

0

0

2

**

0

0

Pages 12 through 13 redacted for the following reasons: Not responsive. Not related to SUPPORT. **Progress Report Scanning Cover Sheet**

5U10HD053124-03

PI Name: Org: Start Date: Snap: Appl ID: Rec'd Date: FAIX, ROGER UNIVERSITY OF UTAH 04/01/2008 N/A (NEEDS TO BE BOOKMARKED) 7392211 02/04/2008

Department of Health and Human Services Public Health Services	Review Group	Type 5	Activity U10	Grant Number 5U10HD053124-03	
Fubic Health Services	Total Project Period	<u> </u>		0010112033124-00	
Grant Progress Report	From: 4/1/2006 Through: 3/31/2011 Requested Budget Period				
	From: 4/1/2008		т	hrough: 3/31/2009 🎞	
1. TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Rese		<u>,</u>			
2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	2b. E-MAIL ADDRES		·	O	
(Name and address, street, city, state, zip code)	roger.faix@h				
Roger G. Faix, M.D. Department of Pediatrics/Ped Admin P.O. Box 581289	2c. DEPARTMENT, S Pediatrics	SERVICE,	, LABORA1	TORY, OR EQUIVALENT	
Williams Building 295 Chipeta Way Salt Lake City, Utah 84108	2d. MAJOR SUBDIV				
	2e. Tel: 801-581-	7052	F	ax: 801-585-7395	
3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)	3b. Tel: 801-585	-6944	F	ax: 801-585-5749	
University of Utah 75 South 2000 East	3c. DUNS: 00909	5365			
Salt Lake City, UT 84112	4. ENTITY IDENTIF 1876000525		NUMBER		
6. HUMAN SUBJECTS 🔲 No 🛛 Yes	5. NAME, TITLE AN	ID ADDRE	ESS OF AD	MINISTRATIVE OFFICIAL	
6a. Research If Exempt ("Yes" in 6a): If Not Exempt ("No" in 6a): ☑ No □ Yes Exemption No. IRB approval date 4/14/06	Kristie Thom 75 South 200 Salt Lake Cit	00 E, R	oom 21		
6b. Federal Wide Assurance No.	- теі: 801-585-69	44	F	ax: 801-585-5749	
6c. NIH-Defined Phase III Clinical Trial No	E-MAIL: OSPAWAR	ds@os	p.utah.e	edu	
7. VERTEBRATE ANIMALS No Yes	10. PROJECT/PERFORMANCE SITE(S)				
7a. If "Yes," IACUC approval Date	Organizational Name: Applicant				
7b. Animal Welfare Assurance No.	DUNS: 009095365				
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	Street 1:				
8a. DIRECT \$192,252 8b. TOTAL \$287,417	Street 2:				
9. INVENTIONS AND PATENTS No Yes	City:		C	County:	
If "Yes, 🔲 Previously Reported	State:		F	Province:	
Not Previously Reported	Country:		Z	Zip/Postal Code:	
	Congressional Distric	cts: UT-(002		
11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT O Brent K. Brown, Director, Office of Sponsored Pro		n 13)			
TEL: 801-581-3003 FAX: 801-585	-5749		E-MAIL: (ospawards@osp.utah.edu	
12. Corrections to Page 1 Face Page					
13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPT, statements herein are true, complete and accurate to the best of my know obligation to comply with Public Health Services terms and conditions if a result of this application. I am aware that any false, fictitious, or frauduler may subject me to criminal, civil, or administrative penalties.	vledge, and accept the grant is awarded as a	signatu 11. (In inf		FICIAL NAMED IN DATE for BA Thompson 1/31/08	

Form Page 1

Pages 3 through 5 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle):		Faix, Roger G.		
PROGRESS REPORT SUMMARY		GRANT NUMBER 5U10HD053124-02		
		PERIOD COVERED BY THIS REPORT		
PROGRAM DIRECTOR / PRINCIPAL INVEST	STIGATOR	FROM	THROUGH	
Roger G. Faix, M.D.		04/01/2007	3/31/2008	
APPLICANT ORGANIZATION University of Utah				
TITLE OF PROJECT (Repeat title shown in NICHD Cooperative Multicenter Nec	• - •			
A. Human Subjects (Complete Item 6 on the	Face Page)		#* <u> </u>	
Involvement of Human Subjects 🛛 🛛 No Change Si		e Since Previous Submission	Change	
B. Vertebrate Animals (Complete Item 7 on t	he Face Page)			
Use of Vertebrate Animals	🔀 No Chang	e Since Previous Submission	Change	
C. Select Agent Research	No Change Since Previous Submission		Change	
D. Multiple PI Leadership Plan	No Chang	e Since Previous Submission	Change	
SEE PHS 2590 INSTRUCTIONS				

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific aims: The specific aim of our participation in the NICHD Cooperative Multicenter Neonatal Research Network have not changed. This is to foster rigorous clinical research on the care of newborn infants, particularly low birth weight infants, by assuring sufficient patients to answer important clinical questions in a timely, powerful and potentially generalizable manner.

B. Studies and results: Since joining the Neonatal Research Network (NRN) in April, 2006, we have implemented 10 NRN studies (including several secondary studies) following IRB approval. These studies and recruitment are listed below. In addition, one of our 3 participating NICUs moved physically to a new hospital (from LDS Hospital to the new Intermountain Medical Center [IMC]). This necessitated considerable paperwork, as well as assuring that appropriate resources and services were available at the new facility and that new staff were educated and oriented to the ongoing NRN studies that had also been re-located.

The SUPPORT study includes infants born between 24 0/7 and 27 6/7 weeks gestation who, after obtaining parental consent antenatally, are randomized to treatment from birth with continuous positive airway pressure (CPAP) or intubation, exogenous surfactant and mechanical ventilation as well as randomized to one of two target oxygen saturation ranges. Endpoints include death, bronchopulmonary dysplasia (BPD) at 36 weeks gestation, retinopathy of prematurity (ROP), and neurodevelopmental status at 18-22 months of age. In addition, 4 secondary studies of the SUPPORT trial (MRI, follow-up, breathing outcomes, antenatal

Program Director/Principal Investigator (Last, First, Middle): Faix, Roger Gordon

Consent, and SUPPORT Follow-up) have progressed. We have completed our contribution to the antenatal consent study with provision of data from 56 subjects. The SUPPORT trial and secondaries have been implemented at the two sites with associated labor and delivery units (U of Utah and now IMC) following approval by both IRBs.

Not responsive. Not related to SUPPORT.

Pages 8 through 16 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial

Total Planned Enrollment: 20

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Sex/Gender				
	Females	Males	Total		
Hispanic or Latino	2	2	4		
Not Hispanic or Latino	6	10	16		
Ethnic Category: Total of All Subjects *	8	8 12 20			
Racial Categories					
American Indian/Alaska Native	1	1	2		
Asian	1	1	2		
Native Hawaiian or Other Pacific Islander	1	1	2		
Black or African American	0	0	0		
White	5	9	14		
Racial Categories: Total of All Subjects *	8	12	20		

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 18 through 23 redacted for the following reasons: Not responsive. Not related to SUPPORT. Progress Report Scanning Cover Sheet

5U10HD053124-04

PI Name: Org: Start Date: Snap: Appl ID: Rec'd Date: FAIX, ROGER UNIVERSITY OF UTAH 04/01/2009 N/A (NEEDS TO BE BOOKMARKED) 7614363 01/29/2009

http://type5.era.nih.gov/ice_type_five/printcoversheet.cfm

Form Approved Through	gh 11/30/2010					OME	3 No. 0925-0001
Departme	ent of Health and Huma Public Health Services		Review Group ZHD1DSRA10	Type 5	Activity U10	Grant Number 5 U10 HD0531	24-04
			Total Project Period				
Grant	Progress I	Report	From: 04/01/200 Requested Budget F		Thi	rough: 03/31/2011	
			From: 04/01/200	9	Th	rough: 03/31/2010	
1. TITLE OF PROJEC	• ·	ter Neonatal Res	earch Network				
	CTOR / PRINCIPAL IN s, street, city, state, zip		2b. E-MAIL ADDRES				
Roger G. Faix		,	· · ·			ORY, OR EQUIVALEN	<u></u>
Department o PO BOX 5812	of Pediatrics/Ped 289	Admin	Pediatrics		,		
	, 295 Chipeta Wa	ау	2d. MAJOR SUBDIV School of Me				
Salt Lake City	/, Utah 84108		2e. Tel: 801-581-	7052	Fa	x: 801-585-7395	
3a. APPLICANT ORG	ANIZATION s, street, city, state, zip	code)	3b. Tel: 801-585	-6944	Fa	x: 801-585-5749	- <u></u> -
University of U 75 South 200	Utah 0 East, Room 21		3c. DUNS: 00909	5365		Jan 2	9 2009 9
Salt Lake City	y, Utah 84112		4. ENTITY IDENTIF 1876000525		NUMBER		
6. HUMAN SUBJECT	'S 🗌 No 🖾	Yes	5. NAME, TITLE AN		ESS OF ADM	MINISTRATIVE OFFIC	CIAL
6a. Research Exempt ⊠ No	lf Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date See Page 2	 ⁱⁿ Kristie Thompson, Grant and Contract Officer 75 South 2000 East, Room 211 Salt Lake City, Utah 84112 			r	
6b. Federal Wide Ass	surance No. FWA00	003745	Tel: 801-585-69	44	Fa	ax: 801-585-5749)
6c. NIH-Defined Phase Clinical Trial			E-MAIL: kristie.thompson@osp.utah.edu				
7. VERTEBRATE AN	IMALS 🛛 NO	Yes	10. PROJECT/PERF	ORMANO	CE SITE(S)		
7a. If "Yes," IACUC a	pproval Date		Organizational Name: Applicant (plus - see page 2)				
7b. Animal Welfare As	surance No.		DUNS: 009095365				
8. COSTS REQUES	TED FOR NEXT BUDG	GET PERIOD	Street 1:				
8a. DIRECT \$302,7	15 85. ТОТАІ	_ \$452,559	Street 2:				
9. INVENTIONS AND	PATENTS No	Yes	City:		Co	ounty:	
	usly Reported		State:		Pr	ovince:	
L) Not Pre	eviously Reported		Country:		Zij	p/Postal Code:	
			Congressional Distri	cts: UT-	002		
		NG FOR APPLICANT C of Sponsored Pro		n 13)			
TEL: 801-581-30	03	FAX: 801-585	-5749		E-MAIL: OS	spawards@osp.	utah.edu
12. Corrections to Pag Additional per	ge 1 Face Page rformance sites.	See page 2.					
statements herein an obligation to comply result of this applicati may subject me to cr	e true, complete and accur with Public Health Service ion. I am aware that any fa iminal, civil, or administrati		ledge, and accept the grant is awarded as a t statements or claims	11. (In in		for BB	DATE 1/27/09
PHS 2590 (Rev. 11/07)		Face Page			1	Form Page 1

IRB Approvals:

Not responsive. Not related to SUPPORT.

IRB_00017893 The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Exremely Low Birth Weight Infants (SUPPORT Trial)

Not responsive. Not related to SUPPORT.

Pages 4 through 8 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last,	First, Middle):	Faix, Roger G.		
PROGRESS REPORT SUMMARY		GRANT NUMBER 5U10HD053124-02		
		PERIOD COVERED BY T	HIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGA	TOR	FROM	THROUGH	
Roger G. Faix, M.D.		4/1/2008	3/31/2009	
APPLICANT ORGANIZATION University of Utah				
TITLE OF PROJECT (Repeat title shown in Item 1 NICHD Cooperative Multicenter Neonatal				
A. Human Subjects (Complete Item 6 on the Face P	age)			
Involvement of Human Subjects	Involvement of Human Subjects No Change Since Previous Submission			
B. Vertebrate Animals (Complete Item 7 on the Face	e Page)			
Use of Vertebrate Animals	No Chan	ge Since Previous Submission	Change	
C. Select Agent Research	No Chan	ge Since Previous Submission	Change	
D. Multiple PD/PI Leadership Plan	No Chan	ge Since Previous Submission	Change	

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific aims: The specific aim of our participation in the NICHD Cooperative Multicenter Neonatal Research Network has not changed. This is to foster rigorous clinical research on the care of newborn infants, particularly low birth weight infants, by assuring sufficient patients with appropriate long-term followup to answer important clinical questions in a timely, powerful and potentially generalizable manner. B. Studies and results: Since joining the Neonatal Research Network (NRN) in April, 2006, we have implemented 10 NRN studies (including several secondary studies) following IRB approval. These studies and recruitment are listed below. In addition, one of our 3 participating NICUs moved physically to a new hospital (from LDS Hospital to the new Intermountain Medical Center [IMC]), effective 10/29/2007. This has necessitated considerable paperwork, assuring that appropriate resources and services were available at the new facilitity and that new staff were educated and oriented to the ongoing NRN studies that had also been re-located, and conducting all necessary interactions with a new IRB.

The SUPPORT study includes infants born between 24 0/7 and 27 6/7 weeks gestation who, after obtaining

parental consent antenatally, are randomized to treatment from birth with continuous positive airway pressure (CPAP) or intubation, surfactant and mechanical ventilation as well as randomized to one of two target oxygen saturation ranges. Endpoints include death, bronchopulmonary dysplasia (BPD) at 36 weeks gestation, retinopathy of prematurity (ROP), and neurodevelopmental status at 18-22 months of age. In addition, 4 secondary studies of the SUPPORT trial (MRI, Breathing Outcomes, Antenatal Consent, and SUPPORT Follow-up) have progressed. We previously completed our contribution to the antenatal consent study with provision of data from 56 subjects. The SUPPORT trial and secondary studies remain underway at the two sites with associated labor and delivery units (U of Utah and now IMC) with ongoing approval and annual review by both IRBs.

Pages 11 through 16 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial					
Total Enrollment:	20 Protocol Number:					
Grant Number:	5 U10 HD053124-03					

	Sex/Gender				
Ethnic Category	Females	Males	Unknown or Not Reported	Total	
Hispanic or Latino	3	0	0	3 **	
Not Hispanic or Latino	6	11	0	17	
Unknown (individuals not reporting ethnicity)	0	0	0	0	
Ethnic Category: Total of All Subjects*	9	11	0	20 *	
Racial Categories					
American Indian/Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	0	1	0	1	
White	9	10	0	19	
More Than One Race	0	0	0	0	
Unknown or Not Reported	0	0	0	0	
Racial Categories: Total of All Subjects*	9	11	0	20 *	

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	3	0	0	3
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	3	0.	0	3 **

* These totals must agree.

** These totals must agree.

Pages 18 through 19 redacted for the following reasons: Not responsive. Not related to SUPPORT.

5U10HD053124-05

PI Name:	FAIX, ROGER
Org:	UNIVERSITY OF UTAH
Start Date:	04/01/2010
Snap:	N/A (NEEDS TO BE BOOKMARKED)
Appl ID:	7799160
Rec'd Date:	01/29/2010

Form Approved Through 06/30/20	012					OMB No. 0925-0001
Department of Healt Public Hea	h and Human alth Services	n Services	Review Group ZHD1DSRA10	Type 5	Activity U10	Grant Number 5 U10 HD053124-05
			Total Project Period			•
Grant Prog	ross F	Penort	From: 04/01/200		TI	nrough: 03/31/2011
Graint Prog	1633 P	report	Requested Budget I	Period		
			From: 04/01/201	0	TI	nrough: 03/31/2011
1. TITLE OF PROJECT NICHD Cooperative N						
2a. PROGRAM DIRECTOR / PRI (Name and address, street, ci			2b. E-MAIL ADDRES Roger.Faix@		ah.edu	
Roger G. Faix, M.D. Department of Pediati PO BOX 581289	rics/Ped A	Admin	2c. DEPARTMENT, Pediatrics	SERVICE	E, LABORAT	ORY, OR EQUIVALENT
Williams Bldg, 295 Ch Salt Lake City, Utah 3		у	2d. MAJOR SUBDIV School of Me			
	51100		2e. Tel: (801) 58	1-7052	F	ax: (801) 585-7085
3a. APPLICANT ORGANIZATION (Name and address, street, cit		ode)	3b. Tel: 801-585	-6944	F	ax: 801-585-5749
(Name and address, street, city, state, zip code) University of Utah 75 South 2000 East, Room 211		3c. DUNS: 00909	5365			
Salt Lake City, Utah 8	84112		4. ENTITY IDENTIF 1876000525		INUMBER	9 201
6. HUMAN SUBJECTS	0 X	es	5. NAME, TITLE AN	ND ADDR	ESS OF AD	MINISTRATIVE OFFICIAL
6a. Research Exempt 6a): ☐ No ☐ Yes Exemption	P P	lf Not Exempt ("No" in 6a): IRB approval date	Kristie Thomps 75 South 20 Salt Lake Cit	00 Eas	t, Room :	
6b. Federal Wide Assurance No.	FWA000	003745	Tel: 801-585-69	44	F	ax: 801-585-5749
6c. NIH-Defined Phase III Clinical Trial No Yes		E-MAIL: kristie.thompson@osp.utah.edu				
7. VERTEBRATE ANIMALS	No 🗌	Yes	10. PROJECT/PERF	ORMAN	CE SITE(S)	
7a. If "Yes," IACUC approval Dat	e		Organizational Name: Applicant (plus - see page 2)			
7b. Animal Welfare Assurance No) .		DUNS: 009095365			
8. COSTS REQUESTED FOR N	EXT BUDGE	ET PERIOD	Street 1: University of Utah Hospital (NICU)			
8a. DIRECT \$304,106	8b. TOTAL	\$454,638	Street 2: 30 North 1900 East			
9. INVENTIONS AND PATENTS	No [Yes	City: Salt Lake (City	с	ounty: Salt Lake
If "Yes, Previously Report Not Previously Re	ed		State: UT		P	rovince:
Not Previously Re	ported		Country: United	States	z	ip/Postal Code: 84112
		Congressional Distric	cts: UT-	002		
11. NAME AND TITLE OF OFFIC Brent K. Brown, Director				n 13)		
TEL: 801-581-3003		FAX: 801-585-	-5749		E-MAIL: O	spawards@osp.utah.edu
12. Corrections to Page 1 Face P Changed in address t		ance Site and a	dditional perform	nance	sites (see	e PAGE 2) and addresses.
13. APPLICANT ORGANIZATION statements herein are true, compl- obligation to comply with Public Her result of this application. I am awa may subject me to criminal, civil, c	ete and accurat ealth Services t are that any fais	te to the best of my knowl terms and conditions if a g se, fictitious, or fraudulent	ledge, and accept the grant is awarded as a	signati 11. (In in		TICIAL NAMED IN DATE for BB JLOMDFELL
PHS 2590 (Rev. 06/09)			Face Page	•		Form Page 1

Pages 3 through 5 redacted for the following reasons: Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Mid	^{dle):} Faix, Roger G.			
PROGRESS REPORT SUMMARY	GRANT NUMBER 5U10HD053124-02			
	PERIOD COVERED BY TH	IIS REPORT		
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	FROM	THROUGH		
Roger G. Faix, M.D.	4/1/2009	3/31/2010		
APPLICANT ORGANIZATION University of Utah	·····	• • • • • • • • • • • • • • • • • • • •		
TITLE OF PROJECT (Repeat title shown in Item 1 on first pa NICHD Cooperative Multicenter Neonatal Resear	•			
A. Human Subjects (Complete Item 6 on the Face Page)				
Involvement of Human Subjects 🛛 🛛 No C	hange Since Previous Submission	Change		
B. Vertebrate Animals (Complete Item 7 on the Face Page)				
Use of Vertebrate Animals No C	hange Since Previous Submission	Change		
C. Select Agent Research No C	hange Since Previous Submission	Change		
D. Multiple PD/PI Leadership Plan	hange Since Previous Submission	Change		
E. Human Embryonic Stem Cell Line(s) Used No C	hange Since Previous Submission	Change		

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific aims: The aim of our participation in the NICHD Cooperative Multicenter Neonatal Research Network (NRN) has not changed. This is to foster rigorous clinical research on the care of newborn infants, particularly low birth weight infants, by assuring sufficient patients with appropriate long-term follow-up to answer important clinical questions in a timely, powerful and generalizable manner.

B. Studies and results: Since joining the NRN in April, 2006, we have implemented 11 NRN studies and 5 secondary studies following IRB approval. These are discussed below. Ongoing studies are conducted at our 3 participating NICUs (University of Utah, Primary Children's and Intermountain Medical Centers).

Not responsive. Not related to SUPPORT.

The SUPPORT

study completed enrollment this year. Infants born between 24 0/7 and 27 6/7 weeks GA were randomized after antenatal parental consent to treatment from birth with continuous positive airway

pressure or intubation, surfactant and mechanical ventilation, and randomized to one of two target oxygen saturation ranges. Endpoints include death, bronchopulmonary dysplasia (BPD) at 36 weeks GA, retinopathy of prematurity, and neurodevelopmental status at 18-22 months. In addition, 4 secondary studies (MRI, Followup, Breathing Outcomes, and Antenatal Consent) completed enrollment with data collection, follow-up and analysis continuing. All SUPPORT-related studies continue to undergo annual IRB review. Pages 8 through 10 redacted for the following reasons: Not responsive. Not related to SUPPORT. Program Director/Principal Investigator (Last, First, Middle):

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The SUPPORT Triall

Total Planned Enrollment: 0

TARGETED/PLANNED ENROLLMENT: Number of Subjects					
Ethnic Category	Females	Males	Total		
Hispanic or Latino	0	0	0		
Not Hispanic or Latino	0	0	0		
Ethnic Category: Total of All Subjects *	0	0	0		
Racial Categories					
American Indian/Alaska Native	0	0	0		
Asian	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0		
Black or African American	0	0	0		
White	0	0	0		
Racial Categories: Total of All Subjects *	0	0	0		

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 12 through 17 redacted for the following reasons: Not responsive. Not related to SUPPORT. Program Director/Principal Investigator (Last, First, Middle): Faix, Roger Gordon

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:	The SUPPORT Trial		
Total Enrollment:	52	Protocol Number:	00017893
Grant Number:	5 U10 HD053124-03		

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race							
Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total			
Hispanic or Latino	8	0	0	8	**		
Not Hispanic or Latino	15	29	0	44			
Unknown (individuals not reporting ethnicity)	0	0	0	0			
Ethnic Category: Total of All Subjects*	23	29	0	52	*		
Racial Categories							
American Indian/Alaska Native	1	0	0	1			
Asian	0	0	0	0			
Native Hawaiian or Other Pacific Islander	0	0	0	0			
Black or African American	0	1	0	1			
White	21	28	0	49			
More Than One Race	0	0	0	0			
Unknown or Not Reported	1	0	0	1			
Racial Categories: Total of All Subjects*	23	29	0	52	*		

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	6	0	0	6
More Than One Race	0	0	0	0
Unknown or Not Reported	2	0	0	2
Racial Categories: Total of Hispanics or Latinos**	8	0	0	8 **

* These totals must agree.

** These totals must agree.

Pages 19 through 25 redacted for the following reasons: Not responsive. Not related to SUPPORT.