

Progress Report Scanning Cover Sheet

5U10HD027856-20

PI Name: **POINDEXTER, BRENDA**
Org: **INDIANA UNIV-PURDUE UNIV AT
INDIANAPOLIS**
Start Date: **04/01/2010**
Snap: **N/A (NEEDS TO BE BOOKMARKED)**
Appl ID: **7799034**
Rec'd
Date: **02/02/2010**

Department of Health and Human Services
Public Health Services

Review Group	Type 5	Activity U10	Grant Number HD027856-19 20
Total Project Period			
From: 04/01/2006		Through: 03/31/2011	
Requested Budget Period			
From: 04/01/2010		Through: 03/31/2011	

Grant Progress Report

1. TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Research Network	
2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code) Brenda B. Poindexter, MD, MS Neonatal/Perinatal Medicine Department of Pediatrics 699 West Drive, RR 208 Indianapolis, IN 46202-5119	2b. E-MAIL ADDRESS bpoindex@iupui.edu
	2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Pediatrics
	2d. MAJOR SUBDIVISION Neonatology
2e. Tel: 317-274-4768 Fax: 317-274-2065	
3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code) Indiana University Office of Research Administration 620 Union Drive, Room 518 Indianapolis, IN 46202-5167	3b. Tel: 317-278-3473 Fax: 317-274-8744
	3c. DUNS: 60-300-7902
4. ENTITY IDENTIFICATION NUMBER 1-35-6001673-A1	
6. HUMAN SUBJECTS <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
6a. Research Exempt <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	Jean Mercer, Director, Grant Services Office of Research Administration 620 Union Dr., Room 518, Indianapolis, IN 46202
If Exempt ("Yes" in 6a): Exemption No.	
If Not Exempt ("No" in 6a): IRB approval date See pg. 16	
6b. Federal Wide Assurance No. FWA00003566	Tel: 317-278-3473 Fax: 317-274-5932
6c. NIH-Defined Phase III Clinical Trial <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	E-MAIL: spon2@iupui.edu
7. VERTEBRATE ANIMALS <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	10. PROJECT/PERFORMANCE SITE(S)
7a. If "Yes," IACUC approval Date	Organizational Name: Riley Hospital for Children
7b. Animal Welfare Assurance No.	DUNS: Indiana University Hospital
8. COSTS REQUESTED FOR NEXT BUDGET PERIOD	Street 1: Methodist Hospital
8a. DIRECT \$ 236,840	Street 2: Wishard Memorial Hospital
8b. TOTAL \$	
9. INVENTIONS AND PATENTS <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	City: Indianapolis County: Marion
If "Yes, <input type="checkbox"/> Previously Reported <input type="checkbox"/> Not Previously Reported	State: IN Province:
	Country: USA Zip/Postal Code: 46202
	Congressional Districts: 7th
11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 13) John W. Talbott, Assistant Vice President for Research Administration	
TEL: 317-278-3473	FAX: 317-274-8744 E-MAIL: spon2@iupui.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 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 11. (In ink) <i>John W. Talbott</i>	DATE 1/28/10
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DETAILED BUDGET FOR NEXT BUDGET PERIOD – DIRECT COSTS ONLY	FROM 04/01/10	THROUGH 3/31/11	GRANT NUMBER HD027856-19
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List PERSONNEL (*Applicant organization only*)
 Use Cal, Acad, or Summer to Enter Months Devoted to Project
 Enter Dollar Amounts Requested (*omit cents*) for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnth	Acad. Mnth	Summer Mnth	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Poindexter, B. (IU)	PI	(b) (6)			9,000	3,125	12,125
Poindexter, B. (UPA)	PI				20,383	2,283	22,676
Dusick, Anna (IU)	Follow-Up PI				3,000	1,042	4,042
Dusick, Anna (UPA)	Follow-Up PI				4,800	540	5,340
Wilson, Leslie Dawn	Research Coord.				91,981	31,936	123,917
Herron, Dianne	Data Entry Mgr				33,440	11,610	45,050
Lemons, James	Alternate PI				0	0	0
Sokol, Greg	Alternate PI				0	0	0
Golichowski, Alan	Perinatal Collaborator				0	0	0
SUBTOTALS					162,604	50,546	213,150

CONSULTANT COSTS

EQUIPMENT (*Itemize*)

SUPPLIES (*Itemize by category*)

Project specific supplies for data collection as specified in protocols 5,253

TRAVEL

Travel to Washington, DC for PI and Coordinator (10 trips annually) 15,500

INPATIENT CARE COSTS

OUTPATIENT CARE COSTS

ALTERATIONS AND RENOVATIONS (*Itemize by category*)

OTHER EXPENSES (*Itemize by category*)

Printing, Duplicating, postage and Long distance telephone calls 3,185

SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD **\$ 237,088**

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	128,028

TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD (*Item 8a, Face Page*) **\$ 237,088**

Program Director/Principal Investigator (Last, First, Middle): **Poindexter, Brenda B.**

BUDGET JUSTIFICATION

GRANT NUMBER HD027856-19

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

Funding for time and effort for the principal investigator, Dr. Brenda B. Poindexter, remains unchanged at (b) (6). Funding for time and effort of the follow-up principal investigator, Dr. Anna Dusick, remains unchanged at (b) (6). No funding is requested for the time and effort of the alternate principal investigators, Drs. James Lemons, Greg Sokol and Alan Golichowski as the Perinatal Collaborator. Leslie Dawn Wilson is the full-time research coordinator for Indiana. Dianne Herron is the data entry manager.

CURRENT BUDGET PERIOD

FROM 04/01/10

THROUGH 03/31/11

Explain any estimated unobligated balance (including prior year carryover) that is greater than 25% of the current year's total budget. We do not anticipate an unobligated balance that is greater than 25% of the current year's total budget in the base grant award. Any unobligated balance on the capitated portion of the current budget will be submitted as a carryover request after the NIH grants management office calculates the capitation offset report.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
 Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Brenda Louise Bradley Poindexter, M.D., M.S.		POSITION TITLE Associate Professor of Clinical Pediatrics	
eRA COMMONS USER NAME (credential, e.g., agency login) (b) (6)			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Milligan College, Johnson City, TN	B.S.	1986	Biology
Medical College of Ohio, Toledo, OH	M.D.	1990	Medicine
Cincinnati Children's Hospital Medical Center	Residency	1993	Pediatrics
Indiana University School of Medicine	Fellowship	1997	Neonatology
Indiana University-Purdue University Indianapolis	M.S.	2004	Clinical Research

A. Personal Statement

Dr. Poindexter is the current PI for the Neonatal Research Network and directs clinical research for the Division of Neonatal-Perinatal Medicine at Indiana University. She has a MS in Clinical Research and is nationally recognized for her expertise in the area of neonatal nutrition and metabolism.

B. Positions and Honors

1997-1998 Lecturer, Department of Pediatrics, Indiana Univ. School of Medicine, Indianapolis, Indiana
 1998-2006 Assistant Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana
 2006-present Associate Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana

Other Experience and Professional Memberships

1998 Fellow, American Academy of Pediatrics
 1999-present Nutritional Support Team, Clarian Health Partners, Indianapolis, Indiana
 1999-present Member, Institutional Review Board, Indiana University-Purdue University Indianapolis
 2001 Member, Society for Pediatric Research
 2002 Member, Midwest Society for Pediatric Research
 2003-present Council Member, Midwest Society for Pediatric Research
 2004-present Institutional Review Board Executive Committee, Indiana Univ.-Purdue Univ. Indianapolis
 2005-present Annual Scholar's Day Committee, Department of Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana
 2005-present Director of Clinical Research, Section of Neonatal-Perinatal Medicine, Indiana University School of Medicine, Indianapolis, Indiana
 2006-present Principal Investigator, NICHD Neonatal Research Network
 2007-present Vice-Chair, Protocol Review Committee, NICHD Neonatal Research Network
 2007-2008 Co-Chair, Newborn Committee, Clarian North Medical Center
 2009-present Vice Chair, Institutional Review Board, Indiana University-Purdue University Indianapolis

Honors

1990 Alpha Omega Alpha
 1990 Marian C. Regent Award in Pediatrics, Medical College of Ohio
 1990 American Medical Women's Association Award
 1996 National Research Service Award, National Institutes of Health
 1996 Fellow's Clinical Research Award, Society for Pediatric Research
 1996 Frederick M. Kenny Memorial Trainee Investigator Award, Midwest Society for Pediatric Research
 2006 President, Midwest Society for Pediatric Research

C. Selected Peer-reviewed Publications

1. **Poindexter BB**, Karn CA, Ahlrichs JA, Wang J, Leitch CA, Liechty EA, Denne SC: Amino acids suppress proteolysis independent of insulin throughout the neonatal period. *American Journal of Physiology* 272:E592-599, 1997.
2. **Poindexter BB**, Karn CA, Denne SC: Exogenous insulin suppresses proteolysis and endogenous glucose production in extremely low birth weight infants. *J Pediatrics* 132:948-53, 1998.
3. **Poindexter BB**, Karn CA, Leitch CA, Liechty EA, Denne SC: Amino acids do not suppress proteolysis in premature neonates. *American Journal of Physiology* 281:E472-478, 2001.
4. **Poindexter BB**, Ehrenkranz RA, Stoll BJ, Koch MA, Wright LL, Oh W, Papile LA, Bauer CR, Carlo WA, Donovan EF, Fanaroff AA, Korones SB, Lupton AR, Shankaran S, Stevenson DK, Tyson JE, Lemons JA: The effect of parenteral glutamine supplementation on plasma amino acid and ammonia concentrations in extremely low birth weight infants. *American Journal of Clinical Nutrition* 77:737-743, 2003.
5. Dusick AM, **Poindexter BB**, Ehrenkranz RA, Lemons JA: Growth Failure in the Preterm Infant: Can We Catch Up? *Seminars in Perinatology*, 27(4):302-310, 2003.
6. **Poindexter BB**, Ehrenkranz RA, Stoll BJ, Koch MA, Wright LL, Oh W, Papile LA, Bauer CR, Carlo WA, Donovan EF, Fanaroff AA, Korones SB, Lupton AR, Shankaran S, Stevenson DK, Tyson JE, Lemons JA: Parenteral glutamine supplementation does not reduce the risk of mortality or late-onset sepsis in extremely low birth weight infants. *Pediatrics*, 113(5):1209-1215, 2004.
7. Oh W, **Poindexter BB**, Perritt R, Lemons JA, Bauer CR, Ehrenkranz RA, Stoll BJ, Poole K, Wright LL: Association between fluid intake and weight loss during the first ten days of life and risk of bronchopulmonary dysplasia in extremely low birth weight infants. *J Pediatr*, 147(6):786-90, 2005.
8. **Poindexter BB**, Langer JC, Dusick AM, Ehrenkranz RA: Early provision of parenteral amino acids in extremely low-birth-weight infants – Relationship with growth and neurodevelopmental outcome. *J Pediatr*, 148(3):300-305, 2006.
9. Vohr BR, **Poindexter BB**, Dusick AM, McKinley LT, Wright LL, Langer JC, Poole WK: Effects of human milk in the neonatal intensive care unit on the developmental outcome and growth of extremely low birth weight infants at 18 months of age. *Pediatrics*, 118(1):e115-23, 2006.
10. Heller CD, O'Shea M, Yao Q, Langer L, Ehrenkranz RA, Phelps DL, Poole WK, Stoll BJ, Duara S, Oh W, Lemons J, **Poindexter B** for the NICHD Neonatal Research Network: Human Milk Intake and Retinopathy of Prematurity in Extremely Low Birth Weight Infants. *Pediatrics*, 120(1):1-9, 2007.
11. Vohr BR, **Poindexter BB**, Dusick AM, McKinley LT, Higgins RD, Langer JC, Poole WK: Persistent beneficial effects of breast milk ingested in the neonatal intensive care unit on outcomes of ELBW infants at 30 months of age. *Pediatrics*, 2007 Oct; 120(4):e953-9.
12. Denne SC, **Poindexter BB**: Evidence supporting early nutritional support with parenteral amino acid infusion. *Semin Perinatol*, 31(2):56-60, 2007.
13. Meinen-Derr J, **Poindexter B**, Wraga L, Morrow AL, Stoll B, Donovan EF: Role of human milk in extremely low birth weight infants' risk of necrotizing enterocolitis or death. *J Perinatology*, 29(1):57-62, 2009.
14. Morris B, Oh W, Tyson J, Stevenson D, Phelps D, O'Shea TM, McDavid G, Perritt R, VanMeurs K, Vohr B, Grisby C, Yao Q, Pedroza C, Das A, Poole WK, Carlo W, Duara S, Lupton A, Salhab W, Shankaran S, **Poindexter B**, Fanaroff A, Walsh M, Rasmussen M, Stoll B, Cotton CM, Donovan E, Ehrenkranz R, Guillet R, Higgins R, and Follow-up Investigators for the NICHD Neonatal Research Network: A Multi-center Randomized Trial of Aggressive versus Conservative Phototherapy for Extremely Low Birth Weight Infants. *N Engl J Med*, 2008 Oct 30;359(18):1885-96.
15. Agostoni C, Buonocore G, Carnielli VP, De Curtis M, Darmaun D, Decsi T, Domellof M, Embleton ND, Fusch C, Genzel-Boroviczeny O, Goulet O, Kalhan SC, Kolacek S, Koletzko B, Lapillonne A, Mihatsch W, Moreno L, Neu J, **Poindexter B**, Puntis J, Putet G, Rigo J, Riskin A, Salle B, Sauer P, Shamir R, Szajewska H, Thureen P, Turck D, van Goudoever JB, Ziegler E: Enteral nutrient supply for preterm infants – Commentary from the ESPGHAN Committee on Nutrition. *JPGN*, 2010;50:85-91.

D. Research Support

List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). *Begin with the projects that are most relevant to the research proposed in the application.* Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

ACTIVE

NIH 2U10HD27856-17 (Poindexter, PI) 4/01/06-3/31/11 (b) (6) Calendar
NICHD Cooperative Multicenter Neonatal Research Network \$163,910

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Principal Investigator

NIH RO1HL054062 (Tepper, PI) 7/01/06-6/30/10 (b) (6) Calendar
Growth of Airways and Lung Parenchyma in Normal Infants \$275,000

The major goal of this project is to determine the relationship between parenchymal tissue and alveolar volume with normal lung growth early in life and to determine the pulmonary sequelae of premature birth and assess the effectiveness of early treatment strategies upon the pulmonary sequelae.

Role: Collaborator

NIH-NHLBI - RO1 (Abman,S., PI) 4/01/08-03/31/13 (b) (6) Calendar
"Genetic Basis of Bronchopulmonary Dysplasia" \$194,054

The major goals of this study are to examine the effect of different SNPs in endothelial cells on the development of bronchopulmonary dysplasia in human patients.

Role: Co-investigator

NIH NCT00621192 (PI: Benjamin) 11/01/08 – 10/31/10 (b) (6) Calendar
"Multiple dose Pharmacokinetic Study of Meropenem

In Young Infants with Intra-Abdominal Infections"

Role: Co-investigator

NIH RO1NS053865 (Ment, PI; Yale University) 4/01/08-3/31/13 (b) (6) Calendar
"Gene Targets for IVH" \$18,996

The major goals of this study are to identify the genetic associations with grade II-IV IVH in VLBW infants in order to evaluate the relative contribution of genetic and environmental susceptibility to IVH.

Role: Co-investigator

NIH 1R01HD057956-01 (Benjamin, PI, Duke University) 07/6/09-06/30/10 (b) (6) Calendar
"Fluconazole Prophylaxis for the Prevention of

Candidiasis in Infants <750 Grams Birth Weight"

The major goals for this study are to determine whether fluconazole prophylaxis will decrease death or candidiasis in infants at highest risk for invasive candida infections.

Role: Co-Investigator

NIH 3UL1RR024128-04S5 (Benjamin, PI, Duke University) 02/01/10 – 01/31/11 (b) (6) Calendar
"Pharmacokinetics and Safety of Piperacillin-

Tazobactam in Neonates"

The major goal is to evaluate the safety, tolerability and pharmacokinetics of piperacillin-tazobactam in neonates with suspected systemic infection

Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Anna Dusick, M.D.		POSITION TITLE	
eRA COMMONS USER NAME (credential, e.g., agency login)		Associate Professor of Clinical Pediatrics Section of Developmental Pediatrics	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Mount Mary College	B.S.	05/77	Occupational Therapy
Chicago Medical School	M.D.	05/86	Medicine
University of Chicago, Wyler Children's Hospital	Resident	06/89	Pediatrics
University of Chicago, Pritzker School of Medicine	Fellow	06/90	Neonatology
University of Chicago, Pritzker School of Medicine	Fellow	06/92	Chronic Disease

A. Personal Statement

The goal of this research is to participate in the Neonatal Research Network (NRN) of the NICHD. Indiana University has been part of this network of researchers since 1992. While initial clinical and observational cohort studies focused on neonatal morbidity and mortality, we developed a longer term outcome protocol in 1994. I am Follow-Up Principal Investigator for the NRN studies (currently 4 studies) at Indiana University as well as a member of the Follow-Up PI sub-committee for the NRN. I have worked with the NRN on the follow-up protocol development committee and standardizing our neurologic examiners both at my center, and for the network as a whole. Our 18-22 month outcome protocol has been adapted, or used in its original form for all short term outcome used in clinical trials of the NRN. Additionally, I am project director, and clinical director of the Newborn Follow-up Program, serving 4 neonatal intensive care units covered by the Indiana University School of medicine faculty. The Newborn Follow-Up program cared for 901 infants and young children in FY 2009. We are a multidisciplinary team assisting the primary care physician with expertise in care of medically fragile infants, including feeding, growth, neurodevelopment and coordination of care. It is the clinical program for our outcome research. NRN research assistants facilitate the completion of the 18-22 month visit in this clinical setting. In summary, I am experienced in clinical outcome research and direct a large clinical program to serve the population of neonatal intensive care graduates. Our program can continue to work with Dr. Brenda Poindexter, PI for our center and support the clinical trials and observational studies of the NRN at Indiana University.

B. Positions and Honors

Positions and Employment

1992-1998	Clinical Assistant Professor of Pediatrics, Indiana University School of Medicine, Indianapolis, IN
1997-	Adjunct Assistant Professor, Department of Speech and Hearing Sciences, College of Arts and Sciences, Indiana University, Indianapolis, IN
1998-	Associate Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, IN

Other Experience and Professional Memberships

1989- Member, American Academy of Pediatrics
1994-2001 Member, American Academy of Cerebral Palsy and Developmental Medicine
1995- Medical Director Newborn Follow-Up Program, Riley Hospital, Indianapolis, IN
1997-2004 Board Member, Make-A-Wish Foundation of Indiana
1998-2006 Board Member, Interagency Coordinating Council for Infants & Toddlers Part C IDEA, State of Indiana
2002- Member, Society for Pediatric Research.
2003- Member, American Academy of Cerebral Palsy and Developmental Medicine
2008-2009 ad hoc Reviewer, Canadian Institute of Health
2009- CDC consultant for Division of Birth Defects and Developmental Disabilities in Response to H1N1
2009- Member, Institutional Review Board (02), Indiana University School of Medicine

Honors

1976 Pi Theta Epsilon Honor Society
1977 Delta Epsilon Sigma Honor Society
1997 Anne Mary McNally Scholarship Award
1997 Adjunct Assistant Professor of Speech and Hearing Sciences, Indiana University
2005 Red Shoes Award for Clinical Service at Riley Hospital for Children
2006 American Academy of Pediatrics Special Award for Service for the District, for Board participation in the Indiana Coordinating Council on Infants and Toddlers

C. Selected Peer-reviewed Publications (Selected from 24 publications)

Most relevant to the current application

1. Vohr BR, Wright LL, **Dusick A**, Mele L et al. Neurodevelopmental and Functional Outcomes of Extremely Low Birth weight Infants in the National Institute of Child Health and Human Development Neonatal Research Network, 1993-1994. *Pediatr* 105(6): 1216-1226, 2000. PMID: 10835060
2. **Dusick AM**, Poindexter BP, Ehrenkranz RA, Lemons JA: Growth Failure in the Preterm Infant: Can We Catch Up? *Semin Perinatol* 27(4): 302-310, 2003. PMID: 14510321
3. Vohr BR, Wright LL, **Dusick AM**, Perritt R, et al. Center Differences and Outcomes of Extremely Low Birth Weight Infants. *Pediatrics* 113 (4): 781-789, 2004. PMID: 15060228
4. Ohls RK, Ehrenkranz RA, Sas A, **Dusick AM**, et al. Neurodevelopmental Outcome and Growth at 18 to 22 Months Corrected Age in Extremely Low Birth Weight Infants Treated With Early Erythropoietin and Iron. *Pediatrics* 114(5):1287-1291, 2004. PMID: 15520109
5. Ehrenkranz RA, **Dusick AM**, Vohr BR, Wright LL, Wraga LA, Poole WK. Growth in the neonatal intensive care unit influences neurodevelopmental and growth outcomes of extremely low birth weight infants. *Pediatrics* 2006 Apr; 117(4):1253-61. PMID: 16585322
6. Poindexter BB, Langer JC, **Dusick AM**, Ehrenkranz RA; National Institute of Child Health and Human Development Neonatal Research Network. Early provision of parenteral amino acids in extremely low birth weight infants: relation to growth and neurodevelopmental outcome. *J Pediatr*. 2006 Mar; 148(3):300-305. PMID: 16615955
7. Vohr BR, Poindexter BB, **Dusick AM**, McKinley LT, Wright LL, Langer JC, Poole WK; NICHD Neonatal Research Network. Beneficial effects of breast milk in the neonatal intensive care unit on the developmental Outcome of extremely low birth weight infants at 18 months of age. *Pediatr*. 2006 Jul; 118(1) e115-23. PMID: 16818526
8. Hintz SR, Van Meurs KP, Perritt R, Poole WK, Das A, Stevenson DK, Ehrenkranz RA, Lemons JA, Vohr BR, Heyne R, Childers DO, Peralta-Carcelen M, **Dusick A**, Johnson YR, Morris B, Dillard R, Vaucher Y, Steichen J, Adams-Chapman I, Konduri G, Myers GJ, de Ungria M, Tyson JE, Higgins RD; NICHD Neonatal Research Network. Neurodevelopmental outcomes of premature infants with severe respiratory

BIOGRAPHICAL SKETCH

NAME James A. Lemons, MD	POSITION TITLE Professor of Pediatrics
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Princeton University, Princeton, NJ	B.A.	1965	
Northwestern Univ. Medical School, Chicago, IL	M.D.	1969	Medicine
Univ. of Michigan Medical School, Ann Arbor, MI	Intern	1970	Pediatrics
Univ. of Michigan Medical School, Ann Arbor, MI	Resident	1972	Pediatrics
Univ. of Michigan Medical School, Ann Arbor, MI	Fellow	1973	Reproductive Endo.
Univ. of Colorado Medical School, Denver, CO	Fellow	1975	Neonatal-Perinatal Med.

A. Personal Statement

Dr. Lemons has extensive experience in clinical and basic research; having published more than 250 peer-reviewed manuscripts, as well as serving as senior editor for Guidelines for Perinatal Care. He also served as PI for Indiana University on the Neonatal Research Network from 1990-2006.

B. Positions and Honors

Positions and Employment

1987-2009 Director, Section of Neonatal-Perinatal Medicine, Department of Pediatrics, Indiana University School of Medicine
 1988-present Hugh McK. Landon Professor of Pediatrics, Indiana University School of Medicine
 2003-2009 Associate, Faculty of Indiana University Graduate School

Other Experience and Professional Memberships

1988-1994 Executive Committee, American Academy of Pediatrics Section on Perinatal Pediatrics
 1991-2006 Principal Investigator, NICHD Neonatal Research Network, National Institutes of Health
 1992-1994 Chair, Executive Committee, Section on Perinatal Pediatrics of the American Academy of Pediatrics
 1993-1999 Member, Neonatal-Perinatal Medicine Sub-Board of the American Board of Pediatrics
 1994-present Professor of Pediatrics, Moi University, Faculty of Health Sciences Eldoret, Kenya
 1997-2001 Chair, Committee on Fetus and Newborn of American Academy of Pediatrics
 1999-present Pregnancy Labeling Subcommittee of the Reproductive Health Drugs Advisory Committee, FDA
 1999-2005 Task Force for Newborn Hearing Screening and Detection, American Academy of Pediatrics
 2000-2003 Chair, Technical Action Group, Council on Committees, American Academy of Pediatrics
 2000-2005 Joint Committee on Infant Hearing, American Academy of Pediatrics
 2001-2006 Member, NIH NICHD Network Steering Committee
 2006 Chair, NIH Global Network for Women's & Children's Health Research Study Section

Honors

1968 Alpha Omega Alpha
 1975 Sigma Xi
 1988 Edwin L. Gresham Award for Perinatal Service, American Academy of Pediatrics
 1999 March of Dimes Health Leadership Award
 1994 The Best Doctors in America
 2002-2005 Inclusion In *America's Top Doctors (2nd Edition)* National Physician Guide
 2002 Teaching Excellence Recognition Award, Indiana University
 2005 Physician of the Year, March of Dimes, Indiana Chapter
 2008 Indiana Business Journal, Health Care Heroes Physician Award, Finalist

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

- C. Selected peer-reviewed publications (in chronological order)***(Publications selected from more than 250 peer-reviewed publications)*
1. Hintz SR, Bann CM, Ambalavanan N, Cotten CM, Das A, Higgins RD; Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Predicting time to hospital discharge for extremely preterm infants. *Pediatrics*. 2010 Jan;125(1):e146-54. Epub 2009 Dec 14. PMID: 20008430
 2. Lptook AR, Shankaran S, Ambalavanan N, Carlo WA, McDonald SA, Higgins RD, Das A; Hypothermia Subcommittee of the NICHD Neonatal Research Network. Outcome of term infants using apgar scores at 10 minutes following hypoxic-ischemic encephalopathy. *Pediatrics*. 2009 Dec;124(6):1619-26. PMID: 19948631
 3. Bhandari V, Finer NN, Ehrenkranz RA, Saha S, Das A, Walsh MC, Engle WA, VanMeurs KP; Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Synchronized nasal intermittent positive-pressure ventilation and neonatal outcomes. *Pediatrics*. 2009 Aug;124(2):517-26. Epub 2009 Jul 27. PMID: 19651577
 4. Peralta-Carcelen M, Moses M, Adams-Chapman I, Gantz M, Vohr BR; NICHD Neonatal Research Network; National Institutes of Health. Stability of neuromotor outcomes at 18 and 30 months of age after extremely low birth weight status. *Pediatrics*. 2009 May;123(5):e887-95. PMID: 19403482
 5. Ambalavanan N, Carlo WA, D'Angio CT, McDonald SA, Das A, Schendel D, Thorsen P, Higgins RD; Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Cytokines associated with bronchopulmonary dysplasia or death in extremely low birth weight infants. *Pediatrics*. 2009 Apr;123(4):1132-41. PMID: 19336372
 6. Wilson-Costello D, Walsh MC, Langer JC, Guillet R, Lptook AR, Stoll BJ, Shankaran S, Finer NN, Van Meurs KP, Engle WA, Das A; Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Impact of postnatal corticosteroid use on neurodevelopment at 18 to 22 months' adjusted age: effects of dose, timing, and risk of bronchopulmonary dysplasia in extremely low birth weight infants. *Pediatrics*. 2009 Mar;123(3):e430-7. Epub 2009 Feb 9. PMID: 19204058
 7. Cotten CM, Taylor S, Stoll B, Goldberg RN, Hansen NI, Sánchez PJ, Ambalavanan N, Benjamin DK Jr; NICHD Neonatal Research Network. Prolonged duration of initial empirical antibiotic treatment is associated with increased rates of necrotizing enterocolitis and death for extremely low birth weight infants. *Pediatrics*. 2009 Jan;123(1):58-66. PMID: 19117861
 8. Vohr BR, Tyson JE, Wright LL, Perritt RL, Li L, Poole WK; NICHD Neonatal Research Network. Maternal age, multiple birth, and extremely low birth weight infants. *J Pediatr*. 2009 Apr;154(4):498-503.e2. Epub 2008 Dec 25. PMID: 19111322
 9. Chock VY, Van Meurs KP, Hintz SR, Ehrenkranz RA, Lemons JA, Kendrick DE, Stevenson DK; NICHD Neonatal Research Network. Inhaled nitric oxide for preterm premature rupture of membranes, oligohydramnios, and pulmonary hypoplasia. *Am J Perinatol*. 2009 Apr;26(4):317-22. Epub 2008 Dec 9. PMID: 19067285
 10. Morris BH, Oh W, Tyson JE, Stevenson DK, Phelps DL, O'Shea TM, McDavid GE, Perritt RL, Van Meurs KP, Vohr BR, Grisby C, Yao Q, Pedroza C, Das A, Poole WK, Carlo WA, Duara S, Lptook AR, Salhab WA, Shankaran S, Poindexter BB, Fanaroff AA, Walsh MC, Rasmussen MR, Stoll BJ, Cotten CM, Donovan EF, Ehrenkranz RA, Guillet R, Higgins RD; NICHD Neonatal Research Network. Aggressive vs. conservative phototherapy for infants with extremely low birth weight. *N Engl J Med*. 2008 Oct 30;359(18):1885-96. PMID: 18971491
 11. Shankaran S, Pappas A, Lptook AR, McDonald SA, Ehrenkranz RA, Tyson JE, Walsh M, Goldberg RN, Higgins RD, Das A; NICHD Neonatal Research Network. Outcomes of safety and effectiveness in a multicenter randomized, controlled trial of whole-body hypothermia for neonatal hypoxic-ischemic encephalopathy. *Pediatrics*. 2008 Oct;122(4):e791-8. PMID: 18829776
 12. Lptook A, Tyson J, Shankaran S, McDonald S, Ehrenkranz R, Fanaroff A, Donovan E, Goldberg R, O'Shea TM, Higgins RD, Poole WK; National Institute of Child Health and Human Development Neonatal Research Network. Elevated temperature after hypoxic-ischemic encephalopathy: risk factor for adverse outcomes. *Pediatrics*. 2008 Sep;122(3):491-9. PMID: 18762517

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

13. Cole CR, Hansen NI, Higgins RD, Ziegler TR, Stoll BJ; Eunice Kennedy Shriver NICHD Neonatal Research Network. Very low birth weight preterm infants with surgical short bowel syndrome: incidence, morbidity and mortality, and growth outcomes at 18 to 22 months.
14. Pediatrics. 2008 Sep;122(3):e573-82. PMID: 18762491
15. Hintz SR, Kendrick DE, Vohr BR, Poole WK, Higgins RD; National Institute of Child Health and Human Development (NICHD) Neonatal Research Network. Community supports after surviving extremely low-birth-weight, extremely preterm birth: special outpatient services in early childhood. Arch Pediatr Adolesc Med. 2008 Aug;162(8):748-55. PMID: 18678807

D. Research Support

Ongoing Research Support

NIH 2U10HD27856-16 (Poindexter, PI) 4/1/91-3/31/11

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Co-Principal Investigator

Completed Research Support

6T79 MC 00010-12

1978–2009

U.S. Dept. of Health and Human Services

Maternal and Child Health Bureau Neonatal Nutrition Training Grant

Leadership Education Excellence in Pediatric Nutrition Program

The major goal of this project is to provide support for a minimum of four predoctoral fellowships to assist dietitians/ nutritionists in developing the clinical nutrition skills necessary for quality care of high-risk infants.

Role: Co-Principal Investigator

RFA-90- HD-01

2002 – 2006

NIH

Cooperative Multicenter Network of Neonatal Intensive Care Units

Role: Principal Investigator

1U10EY12471-01S1

6/30/00-9/29/04

National Eye Institute

Early Treatment for Retinopathy of Prematurity

The major goal of this project is to investigate the value of treating retinopathy of prematurity earlier than usual, at a selected prethreshold level instead of at the threshold level.

Role: Principal Investigator

M01-RR-750-19

1994 – 1999

NIH

Neonatal Scatterbed, General Clinical Research Center

Role: Co-Principal Investigator

RFA-90-HD-01

1991 – 2001

NIH

Cooperative Multicenter Network of Neonatal Intensive Care Units

Role: Principal Investigator

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

M01-RR-750-19 1989 – 1994

NIH

Neonatal Scatterbed, General Clinical Research Center

Role: Principal Investigator

PHS-R01-14820 (Competitive Renewal) 1987 - 1992

NIH

Fetal Amino Acid Metabolism and Gluconeogenesis

Role: Principal Investigator

PHS-R01-14820 (Competitive Renewal) 1985 - 1987

NIH

Fetal Amino Acid Metabolism and Gluconeogenesis

Role: Principal Investigator

PHS-R01-14820 1981 - 1984

NIH

Fetal Amino Acid Metabolism and Gluconeogenesis

Role: Principal Investigator

PHS-R01-HD-12476 1979 -1980

NIH

Composition of Breast Milk in Relation to Gestational Age

Role: Principal Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
 Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Gregory M. Sokol, M.D.	POSITION TITLE Associate Professor of Clinical Pediatrics		
eRA COMMONS USER NAME (credential, e.g., agency login) (b) (6)			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Washington & Jefferson College, Washington, PA	BA	05/81	Chemistry
National Institutes of Health's Foundation for Advanced Ed in the Sciences, Bethesda, MD	Non-Degree	05/82	Neurobiology and Neurochemistry
University of Pittsburgh School of Medicine, Pittsburgh, PA	M.D.	06/86	Medicine
Eastern Virginia Graduate School of Medicine, Norfolk, VA	Intern/Res	06/89	Pediatrics
Indiana University School of Medicine, Indianapolis, IN	Fellowship	06/92	Neonatal-Perinatal Med

Please refer to the application instructions in order to complete sections A, B, C, and D of the Biographical Sketch.

A. Personal Statement

The major goal of the NIH-sponsored Neonatal Network is to cooperatively conduct multicenter clinical trials and observational studies in neonatal medicine. My prime interest and clinical expertise in neonatal medicine is the fetal circulation and its transition, be it through adaptation or mal-adaptation into the neonatal circulation. A second interest is the pursuit of objective evidence from which clinical practice can be based. These interests / background enabled me to assume leadership roles in the development and conduct of several of the Network-sponsored inhaled nitric oxide clinical trials. In addition to these leadership roles, I participated in many collaborative secondary projects including the neurodevelopmental follow up of these studies. Based on my clinical expertise, experiences and collaborations, I believe I am well prepared to continue an active role as an alternate principle investigator for the NICHD Cooperative Multicenter Neonatal Research Network.

B. Positions and Honors

Positions and Employment

1992-1999 Assistant Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, IN
 1999-present Associate Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, IN

Other Experience and Professional Memberships

1992-present Physician Coordinator for the Neonatal Inhaled Nitric Oxide Therapy Program at James Whitcomb Riley Hospital for Children.
 1992-present Fellow American Academy of Pediatrics
 1992-present Indiana Neonatal Society
 1992-present Perinatal Section of the American Academy of Pediatrics
 1992-present Neonatal Resuscitation Program Regional Trainer, #1218480.

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

- 1993-2000 Protocol development subcommittee, Executive committee & Principal Investigator at Indiana University for the "Neonatal Inhaled Nitric Oxide Study" (NINOS) sponsored by the NICHD Neonatal Research Network & Canadian Inhaled Nitric Oxide Study Group
- 1996-present Indiana Chapter of AAP, Chairman Perinatal Committee
- 1996-2006 Protocol development subcommittee, Executive committee & Principal Investigator at Indiana University for the "Early inhaled nitric oxide study in term and near-term infants with respiratory failure," sponsored by the NICHD Neonatal Research Network & Canadian Inhaled Nitric Oxide Study Group.
- 1998-present: Alternate Principal Investigator at Indiana University Medical Center for the National Institute of Child Health & Human Development's Cooperative Neonatal Research Network Steering Committee.
- 2000-2007: Principal Investigator at Indiana University Medical Center for the "Inhaled nitric oxide for preterm infants with severe respiratory failure," sponsored by the NICHD Neonatal Research Network.
- 2003-present: Member - Society for Pediatric Research
- 2004-2007: Protocol development subcommittee & Principal Investigator at Indiana University for the "Inhaled PGE in term and near-term infants with respiratory failure," sponsored by the NICHD Neonatal Research Network.
- 2007-present: Institutional Review Board – Alternate, Indiana University-Purdue University in Indianapolis.

C. Selected peer-reviewed publications (in chronological order)

1. **Sokol, G.M.**, Liechty, E.A., and Boyle, D.W.: Comparison of steady-state diffusion and transit time ultrasonic measurements of umbilical blood flow in the chronic fetal sheep preparation. *Am J Obstet Gynecol* 1996;174:1456-60.
2. The Neonatal Inhaled Nitric Oxide Group. Inhaled nitric oxide in full-term and nearly full-term infants with hypoxic respiratory failure. *N Engl J Med* 1997;336:597-604.
3. The Neonatal Inhaled Nitric Oxide Group. Inhaled nitric oxide and hypoxic respiratory failure in infants with congenital diaphragmatic hernia. *Pediatrics* 1997;99:838-845.
4. **Sokol, G.M.**, Van Meurs, K.P., Thorn W.J., Rivera, O., Chu, P., Wright, L., Sams, R.L. Nitrogen dioxide formation during inhaled nitric oxide therapy. *Clinical Chemistry* 1999;45(3):382-387.
5. The Neonatal Inhaled Nitric Oxide Group. Inhaled nitric oxide in term and near term infants: Neurodevelopmental follow-up of the neonatal inhaled nitric oxide study group (NINOS). *J Pediatr* 2000;136:611-617.
6. **Sokol, G.M.**, Fineberg, N.S., Wright, L.L., Ehrenkranz, R.A. Changes in arterial oxygen tension when weaning neonates from inhaled nitric oxide. *Pediatric Pulmonology* 2001;32:14-19.
7. Konduri, G.G., Solimano, A., **Sokol, G.M.**, Singer, J., Ehrenkranz, R.A., et al. A Randomized trial of early versus standard inhaled nitric oxide therapy in term and near term newborn infants with hypoxic respiratory failure. *Pediatrics* 2004;113:559-564.
8. Van Meurs, K.P., Wright, L.L., Ehrenkranz, R.A., Lemons, J.A., et al. Inhaled nitric oxide for premature infants with severe respiratory failure. *N Engl J Med* 2005;353:13-22.
9. Konduri, G.G., Vohr, B., Robertson, C., **Sokol, G.M.**, et al. Early inhaled nitric oxide therapy for term and near-term newborn infants with hypoxic respiratory failure: neurodevelopmental follow-up. *J Pediatr* 2007;150:235-40.
10. Hintz, S.R., Van Meurs K.P., Perritt R, et al. Neurodevelopmental outcomes of premature infants with severe respiratory failure enrolled in a randomized controlled trial of inhaled nitric oxide. *J Pediatr* 2007;151:16-22.

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

D. Research Support

Ongoing Research Support

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Alternate Principal Investigator

Completed Research Support

NIH U10HD27856-10 (Lemons, PI) 4/01/01-3/31/06

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Alternate Principal Investigator

IU #41-861-09 (Sokol, PI) 10/1/93 - 6/30/98

Riley Memorial Association #93-A16

The major objective of this project was to design and assemble an inhaled nitric oxide delivery and monitoring system that could be used in clinical trials.

Role: Principal Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
 Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Alan M. Golichowski, M.D., Ph.D.	POSITION TITLE Professor of Obstetrics and Gynecology		
eRA COMMONS USER NAME (credential, e.g., agency login)			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
University of Notre Dame, South Bend, IN	B.A.	1963-1967	
The Johns Hopkins University, Baltimore, MD		1967-1968	Chemical Biology
Indiana University, Bloomington, IN	Ph.D.	1968-1976	Biological Chemistry
Indiana University School of Medicine	M.D.	1971-1974	Medicine
Indiana University School of Medicine	Resident	1974-1977	Obstetrics/Gynecology
Indiana University School of Medicine	Fellow	1977-1979	Obstetrics/Gynecology

A. Personal Statement

Dr. Golichowski is the director of the Maternal Fetal Medicine program at Indiana University and has served as the perinatal collaborator since Indiana joined the Network in 1991. His primary area of research interest relates to the care of women with diabetes.

B. Positions and Honors

Positions and Employment

- 1977-1996 Associate Professor, Department of OB/GYN and Director, Maternal-Fetal Medicine Division, Department of Obstetrics and Gynecology, Indiana University School of Medicine, Indianapolis, IN
- 1979-present Director, Maternal Fetal Medicine Fellowship Program, Indiana University School of Medicine, Indianapolis, IN
- 1996-present Professor, Department of OB/GYN and Director, Maternal-Fetal Medicine Division, Department of Obstetrics and Gynecology, Indiana University School of Medicine, Indianapolis, IN
- 1996-present William H. & Sallie E. Coleman Professor, Department of Obstetrics & Gynecology, Indiana University School of Medicine, Indianapolis, IN
- 1997-present Vice-Chairman, Department of Obstetrics & Gynecology, Indiana University School of Medicine, Indianapolis, IN

Other Experience and Professional Memberships

- 1986-present IUMC Committee on Protection of Human Subjects, Indiana University School of Medicine
- 1993-1995 Medical Student Admissions Committee, Indiana University School of Medicine
- 1991-present Pediatric Care Review Committee, Indiana University Hospital
- 1986-present Physician's Capital Review Committee, Indiana University Hospital
- 1994-present Information Systems Committee, Department of Obstetrics and Gynecology, Indiana University Hospital
- 1988-present Resident Education Committee, Indiana University Hospital
- 1988-present Executive Committee, Indiana University Hospital

C. Selected Peer-reviewed Publications

- 1: Xiao X, Miravalle L, Yuan J, McGeehan J, Dong Z, Wyza R, MacLennan GT, Golichowski AM, Kneale G, King N, Kong Q, Spina S, Vidal R, Ghetti B, Roos K, Gambetti P, Zou WQ. Failure to detect the presence of prions in the uterine and gestational tissues from a Gravida with Creutzfeldt-Jakob disease. *Am J Pathol.* 2009 May;174(5):1602-8. Epub 2009 Apr 6. PubMed PMID: 19349373; PubMed Central PMCID: PMC2671249.
- 2: Haas DM, Imperiale TF, Kirkpatrick PR, Klein RW, Zollinger TW, Golichowski AM. Tocolytic therapy: a meta-analysis and decision analysis. *Obstet Gynecol.* 2009 Mar;113(3):585-94. PubMed PMID: 19300321.

D. Research Support

List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). *Begin with the projects that are most relevant to the research proposed in the application.* Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

For New and Competing Applications (PHS 398) – DO NOT SUBMIT UNLESS REQUESTED
For Non-competing Progress Reports (PHS 2590) – Submit only Active Support for Key Personnel

PHS 398/2590 OTHER SUPPORT

Provide active support for all key personnel. **Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included.

There is no "form page" for other support. Information on other support should be provided in the *format* shown below, using continuation pages as necessary. **Include the principal investigator's name at the top and number consecutively with the rest of the application.** The sample below is intended to provide guidance regarding the type and extent of information requested.

For instructions and information pertaining to the use of and policy for other support, see Other Support in the PHS 398 Part III, Policies, Assurances, Definitions, and Other Information.

Note effort devoted to projects must now be measured using person months. Indicate calendar, academic, and/or summer months associated with each project.

POINDEXTER, BRENDA

ACTIVE

NIH 2U10HD27856-17 (Poindexter, PI) 4/01/06-3/31/11 (b) (6) Calendar
NICHD Cooperative Multicenter Neonatal Research Network \$163,910

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Principal Investigator

NIH RO1HL054062 (Tepper, PI) 7/01/06-6/30/10 (b) (6) Calendar
Growth of Airways and Lung Parenchyma in Normal Infants \$275,000

The major goal of this project is to determine the relationship between parenchymal tissue and alveolar volume with normal lung growth early in life and to determine the pulmonary sequelae of premature birth and assess the effectiveness of early treatment strategies upon the pulmonary sequelae.

Role: Collaborator

NIH-NHLBI - RO1 (Abman, S., PI) 4/01/08-03/31/13 (b) (6) Calendar
"Genetic Basis of Bronchopulmonary Dysplasia" \$194,054

The major goals of this study are to examine the effect of different SNPs in endothelial cells on the development of bronchopulmonary dysplasia in human patients.

Role: Co-investigator

NIH NCT00621192 (PI: Benjamin) 11/01/08 – 10/31/10 (b) (6) Calendar
"Multiple dose Pharmacokinetic Study of Meropenem

In Young Infants with Intra-Abdominal Infections"

Role: Co-investigator

NIH RO1NS053865 (Ment, PI; Yale University) 4/01/08-3/31/13 (b) (6) Calendar
"Gene Targets for IVH" \$18,996

The major goals of this study are to identify the genetic associations with grade II-IV IVH in VLBW infants in order to evaluate the relative contribution of genetic and environmental susceptibility to IVH.

Role: Co-investigator

Principal Investigator/Program Director: Poindexter, Brenda B.
(Last, first, middle)

NIH 1R01HD057956-01 (Benjamin, PI, Duke University) 07/6/09-06/30/10 (b) (6) Calendar
"Fluconazole Prophylaxis for the Prevention of \$205,000
Candidiasis in Infants <750 Grams Birth Weight"

The major goals for this study are to determine whether fluconazole prophylaxis will decrease death or candidiasis in infants at highest risk for invasive candida infections.

Role: Co-Investigator

NIH 3UL1RR024128-04S5 (Benjamin, PI, Duke University) 02/01/10 – 01/31/11 (b) (6) Calendar
"Pharmacokinetics and Safety of Piperacillin- \$131,000
Tazobactam in Neonates"

The major goal is to evaluate the safety, tolerability and pharmacokinetics of piperacillin-tazobactam in neonates with suspected systemic infection

Role: Co-Investigator

DUSICK, ANNA

ACTIVE

UIO HD027856 – 13 NIH/NICHD (Poindexter) 4/1/06 – 3/31/11 (b) (6) Calendar
\$163,910

Cooperative Multicenter Neonatal Research Network: 18 Month Follow-Up Study of High Risk Infants,
Role: PI for outcome studies with 4 separate outcome protocols for the Neonatal Research Network at IU

MCH/Indiana State Department of Health (Dusick) 10/1/09-9/30/10 (b) (6) Calendar
Federal I.D. # 35-600-1673 \$130,000

Title: Comprehensive Developmental Pediatric Care for Infants and Children with Special Health Care Needs

Role: PI and Clinical Director of the Newborn Follow-Up Program

LEMONS, JAMES A.

ACTIVE

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11 (b) (6) Calendar
NICHD Cooperative Multicenter Neonatal Research Network \$163,910

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Alternate Principal Investigator

SOKOL, G.

ACTIVE

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11 (b) (6) Calendar
NICHD Cooperative Multicenter Neonatal \$163,910
Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

NIH 3UL1RR024128-04S5 (Benjamin, PI, Duke University) 02/01/10 – 01/31/11 ?? Calendar
"Pharmacokinetics and Safety of Piperacillin- \$131,000
Tazobactam in Neonates"

The major goal is to evaluate the safety, tolerability and pharmacokinetics of piperacillin-tazobactam in neonates with suspected systemic infection

Role: Co-Investigator

Principal Investigator/Program Director: Poindexter, Brenda B.
(Last, first, middle)

United Biosource Corporation
IK-3001-BPD-301/Inhaled Nitric Oxide
Role: Principal Investigator

12/1/09-11/30/10
\$430,400

?? Calendar

GOLICHOWSKI, A.
ACTIVE

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11
NICHD Cooperative Multicenter Neonatal Research Network \$163,910

 Calendar

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Program Director/Principal Investigator (Last, First, Middle): **Poindexter, Brenda B.**

PROGRESS REPORT SUMMARY	GRANT NUMBER HD027856-19	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Brenda B. Poindexter, MD, MS	FROM 04/01/10	THROUGH 03/31/11
APPLICANT ORGANIZATION Indiana University		
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	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
C. Select Agent Research	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
D. Multiple PD/PI Leadership Plan	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
E. Human Embryonic Stem Cell Line(s) Used	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> 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 reporting actual and targeted/planned enrollment for each active study in the Neonatal Research Network at the Indiana Site are attached (see pages 34 - 44).

PROGRESS REPORT:

A. SPECIFIC AIMS

The NICHD Neonatal Research Network is a cooperative group of 16 academic centers whose principal aim is to perform multicenter randomized clinical trials to evaluate the safety and efficacy of treatment and management strategies for newborn infants, particularly those related to very low birth weight, prematurity, and common neonatal medical problems. The Steering Committee has worked diligently over the years, as the Network has grown, to create an organizational structure that permits timely evaluation of important clinical questions in the rapidly changing field of neonatology. The generic database and the follow-up study enable investigators to obtain information on a large cohort of premature infants regarding short- and long-term morbidities, differences in outcomes between centers and between different populations of infants, and variations in clinical practice related to outcomes. Indiana has been a member of the Neonatal Research Network since 1991 and continues to make substantial contributions to the Neonatal Research Network because of the large patient population, strong faculty, basic and clinical research experience, state-of-the-art clinical and research facilities, and excellent research support staff.

Program Director/Principal Investigator (Last, First, Middle): Poindexter, Brenda B.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD027856-19	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Brenda B. Poindexter, MD, MS	FROM 04/01/10	THROUGH 03/31/11

B. STUDIES AND RESULTS:

This year marked the 19th year of participation in the NICHD Neonatal Research Network for Indiana University. The following studies are currently active; IRB protocol numbers and the dates of the most recent approval are listed below. Unless otherwise noted, all approvals are for 12 months.

NRN IRB APPROVALS

<u>PROTOCOL NAME</u>	<u>PROTOCOL NUMBER</u>	<u>MOST RECENT DATE OF APPROVAL</u>	<u>APPROVED THROUGH</u>
Survey of Morbidity and Mortality Among Very Low Birth Weight Infants	9612-02	11-17-09	11-17-10
NICHD GDB Follow up of Very Low Birth Weight Infants	9412-30	01-27-09	01-27-10
A Randomized Trial of Aggressive or Conservative Phototherapy Treatment for Extremely Low birth Weight Infants	0204-22	09-17-09	09-17-10
Early Diagnosis of Nosocomial Candidiasis	0401-55	06-19-09	06-19-10
Neurodiagnostic Evaluations That Assist in the Prediction of Adverse Outcome Following Acute Perinatal Encephalopathy	0401-53	09-11-09	09-11-10

Program Director/Principal Investigator (Last, First, Middle): **Poindexter, Brenda B.**

PROGRESS REPORT SUMMARY	GRANT NUMBER HD027856-19	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Brenda B. Poindexter, MD, MS	FROM 04/01/10	THROUGH 03/31/11

<u>PROTOCOL NAME</u>	<u>PROTOCOL NUMBER</u>	<u>MOST RECENT DATE OF APPROVAL</u>	<u>APPROVED THROUGH</u>
Association of Apolipoprotein E (Apo E) Genotype with Brain Injury and Neurodevelopmental Outcome in Infants with Hypoxic Ischemic Encephalopathy	0410-30	06-16-09	06-16-10
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	0412-26	07-16-09	07-16-10
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	0412-26 placed in SUPPORT	07-16-09	07-16-10
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	0412-26 placed in SUPPORT	07-16-09	07-16-10
Breathing Outcomes (SUPPORT Study Secondary)	0412-26 placed in SUPPORT	07-16-09	07-16-10
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	0412-26 placed in SUPPORT	07-16-09	07-16-10
Extended follow-up at 6-7 years of age of patients enrolled in the Neuroimaging and Neurodevelopmental Outcome Secondary to SUPPORT	PENDING		

Program Director/Principal Investigator (Last, First, Middle): Poindexter, Brenda B.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD027856-19	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Brenda B. Poindexter, MD, MS	FROM 04/01/10	THROUGH 03/31/11

<u>PROTOCOL NAME</u>	<u>PROTOCOL NUMBER</u>	<u>MOST RECENT DATE OF APPROVAL</u>	<u>APPROVED THROUGH</u>
Long Term Follow Up of Children in the Randomized Controlled Trial of Induced Hypothermia for Hypoxic-Ischemic Encephalopathy	0612-08	08-18-09	08-18-10
Blood Inositol Status Among Neonates in 2005	0506-75	04-03-09	04-03-10
Single Dose Intravenous Inositol Pharmacokinetics in Preterm Infants	0609-36	08-06-09	08-06-10
Multiple Dose Intravenous Inositol Pharmacokinetics in Preterm Infants	0912-11	12-23-09	12-23-10
Early Onset Sepsis – An NICHD/CDC Surveillance Study	0610-88	01-22-09	01-22-10
6-24 hour hypothermia	9907-19	closed	
Hypotension in term and late preterm infants: an observational study	0904-51	05-01-09	05-01-10
A Multi-center Randomized Trial of Laparotomy vs. Drainage as the Initial Surgical Therapy for ELBW Infants with Necrotizing Enterocolitis (NEC) or Isolated Intestinal Perforation (IP): Outcomes at 18-22 months Adjusted Age	0910-22	12-08-09	12-08-10

Program Director/Principal Investigator (Last, First, Middle): Poindexter, Brenda B.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD027856-19	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Brenda B. Poindexter, MD, MS	FROM 04/01/10	THROUGH 03/31/11

Observational Studies:

The Generic Database (GDB) has provided for the collection of comprehensive data on very low-birth-weight (VLBW) infants which are used to monitor trends in morbidity and mortality associated with prematurity, to conduct observational studies, and to generate hypotheses for randomized clinical trials. Beginning in January of 2008, enrollment criteria for GDB was limited to inborn infants.

The Early Onset Sepsis (EOS) Surveillance Study is co-funded by the CDC. The objective is to determine the incidence of early-onset sepsis and the pathogens responsible for EOS since the implementation of universal screening and prophylaxis of group B streptococcus in pregnant women. This important study extends data collection to newborns of all birthweights. A total of 12 infants from Indiana were enrolled in this study in 2009 (72 total since the study began). The enrollment was extended through December 31, 2009. Data lock is scheduled for April 30, 2010.

The Hydrocortisone Treatment of Hypotension in Term and late preterm Infants was an observational time limited study. 1000 infants or a minimum of 50 infants per center were enrolled from April 2009 to December 15, 2009. The objective was to collect information on current incidence, management and short term outcomes of hypotension in infants > 34 weeks gestation to provide the framework for design of an RCT of hydrocortisone for the treatment of hypotension. Indiana enrolled 69 patients.

The Network Follow-Up study evaluates neurodevelopmental outcomes of premature infants born at less than or equal to 26 week gestational age or if they are in a randomized trial at 18 months corrected age. In addition to providing important information to the neonatal community, neurodevelopmental outcomes are increasingly becoming one of the primary or secondary outcome measures of many of the Network clinical trials. Indiana has consistently maintained an excellent rate of follow-up for this important longitudinal study. 93% of eligible infants in the SUPPORT study completed the 18-month follow-up study visit.

Clinical Trials:

The Extended Follow-up of the Hypothermia Trial Subjects study is ongoing. Neurodevelopmental assessments between 6 to 7 years of age are planned when study participants enter the follow-up window.

The Association of Apolipoprotein E (apo E) genotype with brain injury and neurodevelopmental outcome in infants with hypoxic ischemic encephalopathy study is ongoing: 3 infants have been enrolled in the study at Indiana.

The Evaluation of Systemic Hypothermia Initiated after 6 Hours of Age in Infants \geq 36 weeks gestation with Hypoxic-Ischemic Encephalopathy: A Bayesian Evaluation study has just recently been initiated. We have enrolled 2 patients in 2009 and 1 now in 2010. We are evaluating whether induced hypothermia with body cooling initiated between 6-24 hours of age and continued for 96 hours in infants > 36 weeks gestation with hypoxic-ischemic encephalopathy will reduce the incidence of death or disability of 18 months of age.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

The Extended Follow-up of the Hypothermia Trial Subjects study is ongoing. Neurodevelopmental assessments between 6 to 7 years of age are planned when study participants enter the follow-up window.

The Association of Apolipoprotein E (apo E) genotype with brain injury and neurodevelopmental outcome in infants with hypoxic ischemic encephalopathy study is ongoing: 3 infants have been enrolled in the study at Indiana.

A Multi-center Randomized Trial of Laparotomy vs. Drainage as the Initial Surgical Therapy for ELBW Infants with Necrotizing Enterocolitis (NEC) or Isolated intestinal Perforation (IP): Outcomes at 18-22 months Adjusted Age has began enrollment January 5, 2010. It is slated to continue enrollment through 01/2014. This study is to assess, whether the initial surgical treatment of ELBW infants who have NEC or IP should be a laparotomy or percutaneous drain.

The Phase II Randomized, Double-Masked, Placebo-Controlled, Safety, Pharmacokinetic, and Dose-Ranging Study of Multiple Doses of Inositol in Premature Infants trial began enrollment January 5, 2010. The objective is to evaluate the safety and multi-dose pharmacokinetics and dose ranging of intravenous followed by enteral myo-inositol (inositol) given at three dosage levels in extremely preterm neonates. This pilot will help characterize the population available for a Phase III RCT of Inositol administration. Inositol supplementation is based on the premise that achieving and maintaining inositol concentrations similar to those occurring in utero will reduce the rates of ROP, death, and BPD.

Completed Studies:

During this past year, several studies have been completed and are now closed to enrollment. The studies remain open with the IUPUI/Clarian IRB due to the fact that data analysis and manuscript preparation for these studies is ongoing.

The Surfactant Positive Airway Pressure and Pulse Oximetry (SUPPORT) trial's enrollment was completed February 27, 2009. The study's accrual goal of 1310 infants has been met. The objectives of the SUPPORT trial are 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 to determine whether management of infants with a lower SpO₂ range (85-89%) compared to a higher SpO₂ range (91-95%) will result in increased survival without the occurrence of threshold retinopathy of prematurity. In addition to the main trial, Indiana enrolled subjects in the following secondary studies: antenatal, growth, MRI neuroimaging and neurodevelopmental outcome, and the breathing outcomes study.

Genomics Studies:

A protocol entitled, "Association of Genetic Polymorphisms of Vascular Endothelial Growth Factor (VEGF), Endothelial Nitric Oxide Synthase (eNOS), and Extracellular Superoxide Dismutase (EC-SOD) with Bronchopulmonary Dysplasia" has been approved by the Network genomics subcommittee as well as the NRN Steering Committee. This protocol was written by Dr. Rebecca Rose, a neonatology fellow at Indiana University who is mentored by Dr. Poindexter and will utilize samples collected in the NRN retrospective DNA repository. In this case-control study we will analyze the relationship between BPD and specific polymorphisms of VEGF, eNOS and EC-SOD. Identification of such a relationship could provide a biomarker that would potentially identify infants more likely to develop BPD so that more aggressive treatment could be initiated. In addition, the elucidation of the pathways and genetic variants increasing the risk for BPD could result in the development of novel therapies for this common morbidity associated with premature birth.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

Trials in Design:

The following studies are being actively planned by the Neonatal Research Network:

- Probiotics for the Prevention of Necrotizing Enterocolitis
- Single-Dose Vitamin E for prevention of mortality and Morbidity in Extremely Preterm Infants: Pilot Study –protocol is developed and MOP is currently being developed. This pilot study will be conducted to evaluate feasibility and effectiveness of a single dose of vitamin E given intragastrically soon after birth in achieving plasma a-tocopherol levels between 1 and 3 mg/dl in extremely premature infants. This study is in anticipation of a subsequent randomized clinical trial to examine the impact of a single intragastric dose of vitamin E at birth on the incidence of intraventricular and intracerebral hemorrhage and survival without neurodevelopmental impairment in preterm infants.
- Trial of Donor Breast Milk vs Formula
- Concept: Dilemmas Initiating Enteral Feedings in High Risk Infants
- Regional Oximetry in Hypotensive Extremely Preterm Infants
- Transfusion and Brain Injury Trial
- Omegaven™ in the Treatment of Parenteral Nutrition Induced Liver Injury
- iPGE, pilot #2
- Hydrocortisone to facilitate extubation in infants at high risk for BPD
- Hypothyroxinemia of Prematurity

Subcommittee Membership:

Dr. Poindexter is currently an active member of the following Network subcommittees:

- Protocol review (Vice-Chair)
- Concurrent
- Early Onset Sepsis Surveillance
- Inositol
- Probiotics
- Surgical management of Necrotizing Enterocolitis – laparotomy vs. drain
- Optimizing Cooling

C. SIGNIFICANCE

Each of the Neonatal Research Network studies contribute to the evidence needed to support and/or change clinical practice in the field of Neonatology. Indiana University contributed to the following Year 19 publications and abstracts:

2009 Publications

1. Ambalavanan N, Carlo WA, D'Angio CT, McDonald SA, Das A, Schendel D, Thorsen P, Higgins RD; Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Cytokines associated with bronchopulmonary dysplasia or death in extremely low birth weight infants. *Pediatrics*. 2009 Apr;123(4):1132-41. PMID: 19336372. NIHMSID: 154397
2. Bassler D; Stoll BJ; Schmidt B; Asztalos EV; Roberts RS; Robertson CMT; Sauve RS; for the Trial of Indomethacin Prophylaxis in Preterms Investigators. Using a Count of Neonatal Morbidities to Predict Poor Outcome in Extremely Low-Birth-Weight Infants: The Added Role of Neonatal Infection. *Pediatrics*. 2009 Jan;123(1):313-318. PMID: 19117897

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

3. Bhandari V; Finer NN; Ehrenkranz RA; Saha S; Das A; Walsh MC; Engle WA; Van Meurs KP on behalf of the NICHD Neonatal Research Network. Synchronized Nasal Intermittent Positive Pressure Ventilation and Neonatal Outcomes. Pediatrics. 2009 Aug;124(2):786-9. PMID: 19651577
4. Cotten CM; Taylor S; Stoll B; Goldberg RN; Hansen NI; Sanchez P; Ambalavanan N; Benjamin DK on behalf of the NICHD Neonatal Research Network. Prolonged Initial Empirical Antibiotics for Early Onset Sepsis are Associated with Increased Necrotizing Enterocolitis and Mortality in Extremely Low Birthweight Infants. Pediatrics. 2009 Jan;123(1):58-66. PMID: 19117861. PMCID: PMC2760222
5. da Costa D, et al. Validation of the Functional Status II questionnaire in the assessment of extremely-low-birthweight infants. Dev Med Child Neurol. 2009 Apr 21. PMID: 19459909
6. Gargus RA; Vohr BR; High PC; Higgins RD; Tyson JE; Wrage LA; Poole WK. Unimpaired Outcome in Extremely Low Birth Weight Infants at 18-22 Months. Pediatrics. 2009 Jul;124(1):112-21. PMID: 19564290
7. Higgins RD; Shankaran S. Hypothermia for hypoxic ischemic encephalopathy in infants \geq 36 weeks. Early Hum Dev. 2009 Oct;85(10 Suppl):S49-52. Epub 2009 Sep 17. PMID: 19762176. NIHMSID: 146148
8. Laptook AR, Shankaran S, Ambalavanan N, Carlo WA, McDonald SA, Higgins RD, Das A; Hypothermia Subcommittee of the NICHD Neonatal Research Network. Outcome of term infants using apgar scores at 10 minutes following hypoxic-ischemic encephalopathy. Pediatrics. 2009 Dec;124(6):1619-26. PMID: 19948631
9. Lasky RE, Parikh NA, Williams AL, Padhye NS, Shankaran S. Changes in PQRST Intervals and Heart Rate variability Associated with Rewarming in Two Newborns undergoing Hypothermia Therapy. Neonatology. 2009 Mar 2;96(2):93-95. [Epub ahead of print]. PMID: 19252411
10. Madan J; Kendrick D; Hagadorn JI; Frantz III ID for the NICHD Neonatal Research Network. Patent ductus arteriosus therapy: impact on neonatal and 18-month outcome. Pediatrics. 2009 Feb;123(2):674-81. PMID: 19171637. PMCID: PMC2752886
11. Meinzen-Derr J; Poindexter B; Wrage L; Morrow AL; Stoll B; Donovan EF for the NICHD Neonatal Research Network. Role of human milk in extremely low birth weight infants' risk of necrotizing enterocolitis or death. J Perinatol. 2009 Jan;29(1):57-62. Epub 2008 Aug 21. PMID: 18716628. PMCID: PMC2801431. NIHMSID: 164921
12. Parikh NA, Lasky RE, Garza CN, Bonfante-Mejia E, Shankaran S, Tyson JE. Volumetric and anatomical MRI for hypoxic-ischemic encephalopathy: relationship to hypothermia therapy and neurosensory impairments. J Perinatol. 2009 Feb;29(2):143-9. Epub 2008 Nov 20. PMID: 19020525. PMCID: PMC2740332
13. Peralta-Carcelen M; Moses M; Adams-Chapman I; Gantz M; Vohr BR. Stability of Neuromotor Findings in Extremely Low Birth Weight Children at 18 and at 30 months of age. Pediatrics. 2009 May;123(5):e887-95. PMID: 19403482
14. Shankaran S. Neonatal encephalopathy: treatment with hypothermia. J Neurotrauma. 2009 Mar;26(3):437-43. PMID: 19281415. NIHMSID: 170793
15. Sood BG, Madan A, Saha S, Schendel D, Thorsen P, Skogstrand K, Hougaard D, Shankaran S, Carlo W; On behalf of the NICHD Neonatal Research Network. Perinatal Systemic Inflammatory Response Syndrome and Retinopathy of Prematurity. Pediatr Res. 2009 Dec 21. [Epub ahead of print]. PMID: 20032809
16. Stark AR, Tyson JE, Hibberd PL. Variation among institutional review boards in evaluating the design of a multicenter randomized trial. J Perinatol. 2009 Oct 1. [Epub ahead of print]. PMID: 19798046
17. Vohr, BR, Tyson JE, Wright, LL, Perritt, R, Li, L and Poole, WK. Maternal Age, Multiple Birth, and Extremely Low Birth Weight Infants. J Pediatr. 2009 Apr;154(4):498-503.e2. Epub 2008 Dec 25. PMID: 19111322
18. Wadhawan R, Oh W, Perritt RL, McDonald SA, Das A, Poole WK, Vohr BR, Higgins RD. Twin gestation and neurodevelopmental outcome in extremely low birth weight infants. Pediatrics. 2009 Feb;123(2):e220-7. Epub 2009 Jan 12. PMID: 19139085

Program Director/Principal Investigator (Last, first, middle): Poindexter, Brenda B.

19. Wilson-Costello D, Walsh MC, Langer JC, Guillet R, Lupton AR, Stoll BJ, Shankaran S, Finer NN, Van Meurs KP, Engle WA, Das A; Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Impact of postnatal corticosteroid use on neurodevelopment at 18 to 22 months' adjusted age: effects of dose, timing, and risk of bronchopulmonary dysplasia in extremely low birth weight infants. Pediatrics. 2009 Mar;123(3):e430-7. Epub 2009 Feb 9. PMID: 19204058

2010 Publications

1. Hintz SR, Bann CM, Ambalavanan N, Cotten CM, Das A, Higgins RD; Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Predicting Hospital Discharge for Extremely Preterm Infants. Pediatrics. 2010 Jan;125(1):e146-54. Epub 2009 Dec 14. PMID: 20008430
2. Natarajan G, Shankaran S, McDonald SA, Das A, Stoll BJ, Higgins RD, Thorsen P, Skogstrand K, Hougaard DM, Carlo WA; for the NICHD Neonatal Research Network. Circulating beta chemokine and MMP 9 as markers of oxidative injury in extremely low birth weight infants. Pediatr Res. 2010 Jan;67(1):77-82.2009 Sep 14. [Epub ahead of print]. PMID: 19755933

2009 Abstracts

1. Wadhawan, R., Oh, W., Saha, S., Das, A., Bell, E., Lupton, A., Shankaran, S., Stoll, B., Walsh, M., Higgins, R., and the NICHD Neonatal Research Network. Antecedents of Spontaneous Intestinal Perforation in Extremely Low Birth Weight Infants. (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009)
2. Adams-Chapman, I., Bann, C., Stoll, B., Vaucher, Y., for the NICHD Neonatal Research Network. Dysfunctional Feeding Patterns among ELBW Infants and Neurodevelopmental Outcome in Early Childhood. (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009)
3. Dimmitt, R., Schendel, D., Carlo, W., for the NICHD Neonatal Research Network (MRN). Early Postnatal Cytokine Concentrations and the Risk of Necrotizing Enterocolitis (NEC) in Extremely Low Birth Weight (ELBW) Infants. (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009)
4. Shankaran, S., Lupton, A., Tyson, J., Ehrenkranz, R., Bann, C., Das, A., Higgins, R., and NICHD Neonatal Research Network. Evolution of Encephalopathy with Whole Body Hypothermia for Neonatal Hypoxic-Ischemic Encephalopathy (HIE). (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009)
5. Stoll B., Hansen, N., for the NICHD/CDC Neonatal Sepsis Surveillance Study. GBS and E. coli Continue To Put Newborns at Risk for Early-Onset Sepsis (EOS): A Surveillance Study of \approx 200,000 Live Births (LB). (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009)
6. Walsh, M., Langer, J., Finer, N., Shankaran, S., Ambalavanan, N., for the NICHD Neonatal Research Network. Hypercarbia Is Associated with Increased Risk of Intraventricular Hemorrhage (IVH) in ELBW in First Week. (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009)
7. Murray, T., D'Angio, C., the NICHD Neonatal Research Network. Immunogenicity of Hemophilus influenzae Type B Protein Conjugate Vaccines by Birth Weight in Very Low Birthweight Infants. (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009)
8. Cole, C., Hansen, N., Higgins, R., Bell, E., Lupton, A., Hale, E., Shankaran, S., Stoll, B., the Neonatal Research Network (NRN). Infections in Low-Birth Weight Infants with Surgical Short Bowel Syndrome. (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009)
9. Hintz, S., Yao, Q., Das, A., Poole, W., D.K. Stevenson, the Phototherapy Subcommittee of the NICHD Neonatal Research Network (NRN). Is Phototherapy Associated with Adverse Outcomes in Extremely Low Birth Weight (ELBW) Infants? (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009)

Program Director/Principal Investigator (Last, first, middle): Poindexter, Brenda B.

10. Stoll, B., Hansen, N., for the NICHD Neonatal Research Network. Neonatal Morbidity and Mortality among Extremely Low Gestation (ELG) Infants from the NICHD Neonatal Research Network (NRN). (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009)
11. Hintz, S., Kendrick, D., for the NICHD Neonatal Research Network. Neurodevelopmental Outcomes Are Not Improving for <25 Week EGA Infants. (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009).
12. Ambalavanan, N., GDB Subcommittee for the NICHD Neonatal Research Network (NRN). Outcome Trajectories in Extremely Low Birth Weight (ELBW) Infants. (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009).
13. Laughon, M., Langer, J., Wilson, D., Walsh, M., the NICHD Neonatal Research Network. Predictive Models for Bronchopulmonary Dysplasia by Postnatal Day in Premature Infants. (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009).
14. Davis, A., Van Meurs, K., Li, L., Hintz, S., for the NICHD Neonatal Research Network Generic Database and Follow Up Subcommittees. Seizures in Extremely Low Birth Weight (ELBW) Infants: Association with Morbidities, Neurodevelopmental Outcome, and Death. (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009).
15. Ambalavanan, N., Hougaard, D., Skogstrand, K., Schendel, D., Thorsen, P., The Cytokine Subcommittee. Serum Cytokines and Post-Hemorrhagic Ventricular Dilation (PHVD) in Extremely Low Birth Weight (ELBW) Infants. (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009).
16. Shankaran, S., Laptook, A., Higgins, R., Tyson, J., Ehrenkranz, R., Sant'Anna, G., McDonald, S., NICHD Neonatal Research Network. Temperature Profile of Neonates Undergoing Whole Body Hypothermia for Hypoxic-Ischemic Encephalopathy (HIE). (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009).
17. Sant'Anna, G., Laptook, A., McDonald, S., Shankaran, S., on Behalf of Hypothermia Sub-Committee, Neonatal Research Network. The Effects of Barbiturates on Temperature Profile of HIE Infants Undergoing Whole Body Hypothermia. (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009).
18. Natarajan, G., Shankaran, S., McDonald, S., Das, A., Ehrenkranz, R., Goldberg, R., Stoll, B., Tyson, J., Higgins, R., Schendel, D., Thorsen, P., Hougaard, D., Skogstrand, K., Carlo, W., NICHD Neonatal Research Network. Transforming Growth Factor β (TGF β): Potential Marker of Patent Ductus Arteriosus in Extremely Low Birth Weight Infants? (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009).
19. Wadhawan, R., Oh, W., Wrage, L., Das, A., Bell, E., Laptook, A., Shankaran, S., Stoll, B., Walsh, M., Higgins, R., NICHD Neonatal Research Network. Triplet or Higher Order Extremely Low Birth Weight (ELBW) Birth Is Associated with an Increased Risk of Death or Neuro-Developmental Impairment at 18-22 Months Corrected Age as Compared to ELBW Twins and Singletons. (Presented, to the Pediatric Academic Societies, Baltimore, Maryland, May 2-5, 2009).

In summary, Indiana University has continued to be a productive member of the Neonatal Research Network, contributing significantly to all trials. We look forward to contributing to the improvement of neonatal outcomes through our participation in this important Network.

Program Director/Principal Investigator (Last, first, middle): **Poindexter, Brenda B.**

GRANT NUMBER
HD027856-19

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).

Budget Period	Anticipated Amount	Source(s)
N/A	\$0	N/A

2. ASSURANCES/CERTIFICATIONS (See instructions.)

In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398, and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after the Progress Report (Form Page 5).

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.

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: 5-14-04 No Facilities and Administrative Costs Requested.

No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base \$ 237,088 x Rate applied 54.00 % = F&A costs \$ 128,028

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

Salary and wages base Modified total direct cost base Other base (Explain)

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

Explanation (Attach separate sheet, if necessary.):

Program Director/Principal Investigator (Last, First, Middle): Poindexter, Brenda B.

ALL PERSONNEL REPORT

GRANT NUMBER
HD027856-19

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

Always list the PD/PI(s). In addition, list all other personnel who participated in the project during the current budget period for at least one person month or more, regardless of the source of compensation (a person month equals approximately 160 hours or 8.3% of annualized effort). Use Cal (calendar), Acad, or Summer to enter months devoted to project.

Commons ID	Name	Degree(s)	SSN (last 4 digits)	Role on Project (e.g. PD/PI, Res. Assoc.)	DoB (MM /YY)	Cal	Acad	Summer
(b) (6)	Brenda Poindexter	MD, MS	(b) (6)	PI	(b) (6)	(b) (6)		
	Anna Dusick	MD		Follow-Up PI				
	James Lemons	MD		Alternate PI				
	Greg Sokol	MD		Alternate PI				
	Leslie Dawn Wilson	RN, BSN		Research Coord				
	Dianne Herron	RN		Data Entry Mgr				
	Alan Golichowski	MD, PhD		Perinatal Collaborator				

Program Director/Principal Investigator (Last, First, Middle): Poindexter, Brenda B.

Targeted/Planned Enrollment Table

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

Study Title: Multidose study of Inositol in Premature infants

Total Planned Enrollment: 15

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Females	Males	Total
Hispanic or Latino	1		1
Not Hispanic or Latino	7	7	14
Ethnic Category: Total of All Subjects *	8	7	15
Racial Categories			
American Indian/Alaska Native			
Asian	1	0	1
Native Hawaiian or Other Pacific Islander			
Black or African American	2	2	4
White	5	5	10
Racial Categories: Total of All Subjects *	8	7	15

* 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): Poindexter, Brenda B.

Targeted/Planned Enrollment Table

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

Evaluation of Systemic Hypothermia Initiated After 6 Hours of Age in Infants >/- 36 Weeks
Study Title: gestation with Hypoxic-Ischemic Encephalopathy: A Bayesian Evaluation

Total Planned Enrollment: 12

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Females	Males	Total
Hispanic or Latino	1		1
Not Hispanic or Latino	5	6	11
Ethnic Category: Total of All Subjects *	6	6	12
Racial Categories			
American Indian/Alaska Native			
Asian	0	1	1
Native Hawaiian or Other Pacific Islander			
Black or African American	2	2	4
White	4	3	7
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."

Program Director/Principal Investigator (Last, First, Middle): Poindexter, Brenda B.

Targeted/Planned Enrollment Table

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

Study Title: Surgical management of Necrotizing Enterocolitis

Total Planned Enrollment: 30

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Females	Males	Total
Hispanic or Latino	1	1	2
Not Hispanic or Latino	14	14	28
Ethnic Category: Total of All Subjects *	15	15	30
Racial Categories			
American Indian/Alaska Native			
Asian	1	1	2
Native Hawaiian or Other Pacific Islander			
Black or African American	4	4	8
White	10	10	20
Racial Categories: Total of All Subjects *	15	15	30

* 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): Poindexter, Brenda B.

Inclusion Enrollment Report

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

Study Title: Generic Database - survey of Morbidity and Mortality Among VLBW Infants 401-1500 g
Total Enrollment: 135 **Protocol Number:** 9612-02
Grant Number: HD027856-19

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	7	13	0	20 **
Not Hispanic or Latino	59	56	0	115
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	66	69	0	135 *
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	28	26	0	54
White	36	42	1	78
More Than One Race	1	0	0	1
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	66	69	0	135 *
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	7	13	0	20
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	7	13	0	20 **

* These totals must agree.

** These totals must agree.

Program Director/Principal Investigator (Last, First, Middle): Poindexter, Brenda B.

Inclusion Enrollment Report

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

Study Title: Early Onset Sepsis - A NICHD/CDD Surveillance Study
Total Enrollment: 12 **Protocol Number:** 0601-88
Grant Number: HD027856-19

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	3	2	0	5 **
Not Hispanic or Latino	2	5	0	7
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	5	7	0	12 *
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	0	2	0	2
White	4	5	0	9
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	5	7	0	12 *
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	3	2	0	5
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	3	2	0	5 **

* These totals must agree.

** These totals must agree.

Program Director/Principal Investigator (Last, First, Middle): Poindexter, Brenda B.

Inclusion Enrollment Report

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

Study Title: SUPPORT
 Total Enrollment: 6 Protocol Number: 0412-26
 Grant Number: HD027856-19

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	1	5	0	6
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	1	5	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	0	2	0	2
White	1	3	0	4
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	1	5	0	6 *
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.

Program Director/Principal Investigator (Last, First, Middle): Poindexter, Brenda B.

Inclusion Enrollment Report

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

Study Title: Term Hypotension Study

Total Enrollment: 69 Protocol Number: 0904-51

Grant Number: HD027856-19

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	1	5	0	6 **
Not Hispanic or Latino	22	40	0	62
Unknown (individuals not reporting ethnicity)	1	0	0	1
Ethnic Category: Total of All Subjects*	24	45	0	69 *
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	3	7	0	10
White	19	36	0	55
More Than One Race	0	1	0	1
Unknown or Not Reported	2	0	0	2
Racial Categories: Total of All Subjects*	24	45	0	69 *
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	1	4	0	5
More Than One Race	0	1	0	1
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	1	5	0	6 **

* These totals must agree.

** These totals must agree.

Program Director/Principal Investigator (Last, First, Middle): Poindexter, Brenda B.

Inclusion Enrollment Report

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

Study Title: Follow-Up of Premature Infants with Birthweight Less than 1000 Grams at 18 (+4) Months of Age and/or 30 (+,-2) months of Age (Corrected for Gestation)

Total Enrollment: 51 **Protocol Number:** 0914-30

Grant Number: HD027856-19

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	2	4	0	6 **
Not Hispanic or Latino	22	23	0	45
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	24	27	0	51 *
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	8	10	0	18
White	16	16	0	32
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	24	27	0	51 *

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	1	0	1
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 Hispanics or Latinos**	2	4	0	6 **

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

Program Director/Principal Investigator (Last, First, Middle): Poindexter, Brenda B.

Inclusion Enrollment Report

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

Study Title: Physiologic Definition Study
 Total Enrollment: 10 Protocol Number: 0412-26
 Grant Number: HD027856-19

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	1	0	0	1 **
Not Hispanic or Latino	3	6	0	9
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	4	6	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	1	4	0	5
White	3	2	0	5
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	4	6	0	10 *

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	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.

Program Director/Principal Investigator (Last, First, Middle): Poindexter, Brenda B.

Inclusion Enrollment Report

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

Study Title: Late Hypothermia
 Total Enrollment: 2 Protocol Number: 0802-23
 Grant Number: HD027856-19

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	0	2	0	2
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	0	2	0	2 *
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	2	0	2
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	0	2	0	2 *
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.

Program Director/Principal Investigator (Last, First, Middle): Poindexter, Brenda B.

Inclusion Enrollment Report

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

Study Title: NICHD SUPPORT Trial-Breathing Outcomes
 Total Enrollment: 15 Protocol Number: 0606-4
 Grant Number: HD027856-19

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	8	7	0	15
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	8	7	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	3	2	0	5
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 All Subjects*	8	7	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.
 ** These totals must agree.

Progress Report Scanning Cover Sheet

5U10HD027856-19

PI Name: **POINDEXTER, BRENDA**
Org: **INDIANA UNIV-PURDUE UNIV AT
INDIANAPOLIS**
Start Date: **04/01/2009**
Snap: **N/A (NEEDS TO BE BOOKMARKED)**
Appl ID: **7614359**
Rec'd
Date: **02/03/2009**

Form Approved Through 09/30/2007

OMB No. 0925-0001

Department of Health and Human Services Public Health Services <h2 style="margin: 0;">Grant Progress Report</h2>	Review Group	Type X5	Activity U10	Grant Number HD027856-48 16
	Total Project Period			
	From: 04/01/2006		Through: 03/31/2011	
	Requested Budget Period			
From: 04/01/2009				Through: 03/31/2010

1. TITLE OF PROJECT NICHD Cooperative Multicenter Neonatal Research Network	
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code) Brenda Poindexter, MD, MS Neonatal/Perinatal Medicine Department of Pediatrics 699 West Drive, RR 208 Indianapolis, IN 46202-5119	3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code) The Trustees of Indiana University Office of Research Administration 620 Union Drive, Room 518 Indianapolis, IN 46202-5167
2b. E-MAIL ADDRESS bpoindex@iupui.edu	4. ENTITY IDENTIFICATION NUMBER 1-35-6001673-A1
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Department of Pediatrics	5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL Executive Director Indiana University Office of Research Administration 620 Union Drive, Room 518 Indianapolis, IN 46202-5167
2d. MAJOR SUBDIVISION School of Medicine	E-MAIL: spon2@iupui.edu

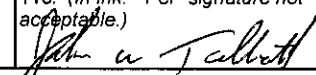
FEB 03 2009

6. HUMAN SUBJECTS		7. VERTEBRATE ANIMALS	
<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	6a. Research Exempt <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	7a. If "Yes," IACUC approval Date
If Exempt ("Yes" in 6a): Exemption No.	6b. Human Subjects Assurance No. FWA00003566	7b. Animal Welfare Assurance No.	
If Not Exempt ("No" in 6a): IRB approval date See p. 16	6c. NIH-Defined Phase III Clinical Trial <input type="checkbox"/> No <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Full IRB or <input type="checkbox"/> Expedited Review		

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD		9. INVENTIONS AND PATENTS	
8a. DIRECT \$ 208,316	8b. TOTAL \$: 348,823	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If "Yes,"	<input type="checkbox"/> Previously Reported <input type="checkbox"/> Not Previously Reported

10. PERFORMANCE SITE(S) (Organizations and addresses) Riley Hospital for Children Indiana University Hospital Methodist Hospital Wishard Memorial Hospital All located in Indianapolis, Indiana	11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a)	TEL 317-274-4920 FAX 317-274-2065
	11b. ADMINISTRATIVE OFFICIAL NAME (Item 5) W.S. Johnson	TEL 317-278-3473 FAX 317-274-5932
	11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14) NAME John W. Talbott TITLE Assistant VP for Research Administration TEL 317-278-3473 FAX 317-274-5932 E-MAIL spon2@iupui.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 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 1/30/09
--	---	------------------------

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

DETAILED BUDGET FOR NEXT BUDGET PERIOD - DIRECT COSTS ONLY		FROM 04/01/09			THROUGH 03/31/09		GRANT NUMBER HD027856-18	
PERSONNEL (Applicant organization only)		Months Devoted to Project			DOLLAR AMOUNT REQUESTED (omit cents)			
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	SALARY REQUESTED	FRINGE BENEFITS	TOTALS	
Brenda Poindexter	Principal Investigator	12			9,000	3,092	12,092	
Anna Dusick	Follow-Up PI	12			3,000	1,031	4,031	
Leslie Dawn Wilson	Research Coordinator	12			91,981	31,595	123,576	
Dianne Herron	Data Entry Mgr.	12			33,440	11,487	44,927	
James Lemons	Alternate PI	12			0	0	0	
Greg Sokol	Alternate PI	12			0	0	0	
Alan Golichowski	Perinatal Collaborator	12			0	0	0	
SUBTOTALS					137,421	47,205	184,626	
CONSULTANT COSTS								
EQUIPMENT (Itemize)								
SUPPLIES (Itemize by category)								
Project specific supplies for data collection as specified in protocols								
5,100								
TRAVEL								
Travel to Washington, DC for PI and Coordinator (10 trips annually)								
15,500								
PATIENT CARE COSTS								
INPATIENT								
OUTPATIENT								
ALTERATIONS AND RENOVATIONS (Itemize by category)								
OTHER EXPENSES (Itemize by category)								
Printing, duplicating, postage, and long-distance telephone calls								
3,090								
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD							\$ 208,316	
CONSORTIUM/CONTRACTUAL COSTS		DIRECT COSTS			UPA Subcontract			
					28,016			
		FACILITIES AND ADMINISTRATIVE COSTS			112,491			
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD (Item 8a, Face Page)							\$ 348,823	

Principal Investigator/Program Director (Last, First, Middle): **Poindexter, Brenda B.**

BUDGET JUSTIFICATION	GRANT NUMBER HD027856-18
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Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

Funding for time and effort for the principal investigator, Dr. Brenda Poindexter, remains unchanged at (b) (6). Funding for time and effort of the follow-up principal investigator, Dr. Anna Dusick, remains unchanged at (b) (6). No funding is requested for the time and effort of the alternate principal investigators, Drs. James Lemons and Greg Sokol. Leslie Dawn Wilson is the full-time research coordinator for Indiana. Dianne Herron is the data entry manager

CURRENT BUDGET PERIOD	FROM 04-01-09	THROUGH 03/31/10
------------------------------	-------------------------	----------------------------

Explain any estimated unobligated balance (including prior year carryover) that is greater than 25% of the current year's total budget. We do not anticipate an unobligated balance that is greater than 25% of the current year's total budget in the base grant award. Any unobligated balance on the capitated portion of the current budget will be submitted as a carryover request after the NIH grants management office calculates the capitation offset report.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Brenda Louise Bradley Poindexter, M.D., M.S.		POSITION TITLE Associate Professor of Clinical Pediatrics	
eRA COMMONS USER NAME (b) (6)			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Milligan College, Johnson City, TN	B.S.	1986	Biology
Medical College of Ohio, Toledo, OH	M.D.	1990	Medicine
Cincinnati Children's Hospital Medical Center	Residency	1993	Pediatrics
Indiana University School of Medicine	Fellowship	1997	Neonatology
Indiana University-Purdue University Indianapolis	M.S.	2004	Clinical Research

A. Positions and Honors

Positions and Employment

- 1997-1998 Lecturer, Department of Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana
- 1998-2006 Assistant Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana
- 2006-present Associate Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana

Other Experience and Professional Memberships

- 1998 Fellow, American Academy of Pediatrics
- 1999-present Nutritional Support Team, Clarian Health Partners, Indianapolis, Indiana
- 1999-present Member, Institutional Review Board, Indiana University-Purdue University Indianapolis
- 2001 Member, Society for Pediatric Research
- 2002 Member, Midwest Society for Pediatric Research
- 2003-present Council Member, Midwest Society for Pediatric Research
- 2004-present Institutional Review Board Executive Committee, Indiana University-Purdue University Indianapolis
- 2005-present Annual Scholar's Day Committee, Department of Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana
- 2005-present Director of Clinical Research, Section of Neonatal-Perinatal Medicine, Indiana University School of Medicine, Indianapolis, Indiana
- 2006-present Principal Investigator, NICHD Neonatal Research Network
- 2007-present Vice-Chair, Protocol Review Committee, NICHD Neonatal Research Network
- 2007-present Co-Chair, Newborn Committee, Clarian North Medical Center

Honors

- 1990 Alpha Omega Alpha
- 1990 Marian C. Regent Award in Pediatrics, Medical College of Ohio
- 1990 American Medical Women's Association Award
- 1996 National Research Service Award, National Institutes of Health
- 1996 Fellow's Clinical Research Award, Society for Pediatric Research
- 1996 Frederick M. Kenny Memorial Trainee Investigator Award, Midwest Society for Pediatric Research
- 2006 President, Midwest Society for Pediatric Research

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

Selected peer-reviewed publications (in chronological order)

1. Agostoni C, Buonocore G, Carnielli VP, De Curtis M, Darmaun D, Decsi T, Domellof M, Embleton ND, Fusch C, Genzel-Boroviczeny O, Goulet O, Kalhan SC, Kolacek S, Koletzko B, Lapillonne A, Mihatsch W, Moreno L, Neu J, **Poindexter B**, Puntis J, Putet G, Rigo J, Riskin A, Salle B, Sauer P, Shamir R, Szajewska H, Thureen P, Turck D, van Goudoever JB, Ziegler E: Enteral nutrient supply for preterm infants – A comment of the ESPGHAN Committee on Nutrition. 2008.
2. Adams-Chapman I; Hansen N; Higgins RD; Stoll BJ for the **NICHD Neonatal Research Network***. Neurodevelopmental Outcome of ELBW infants with posthemorrhagic hydrocephalus requiring shunt insertion. *Pediatrics*. 2008 May;121(5):e1167-77.
3. Cole CR; Hansen NI; Higgins RD; Ziegler TR; Stoll BJ for the **NICHD Neonatal Research Network***. Very Low Birthweight Preterm Infants with Surgical Short Bowel Syndrome: Incidence, Morbidity and Mortality and Growth Outcomes at 18-22 months. *Pediatrics*. 2008 Sep;122(3):e573-82.
4. Hintz SR; Kendrick DE; Vohr BR; Poole WK; Higgins RD for the **NICHD Neonatal Research Network***. Community supports after surviving extremely low birth weight, extremely preterm birth: Special outpatient services in early childhood. *Arch Pediatr Adolesc Med*. 2008 Aug;162(8):748-55.
5. Laptook AR; Tyson J; Shankaran S; McDonald S; Ehrenkranz R; Fanaroff A; Donovan E; Goldberg R; O'Shea TM; Higgins RD; Poole WK and the **NICHD Neonatal Research Network***. Elevated Temperature after Hypoxic-Ischemic Encephalopathy: A Risk Factor for Adverse Outcome. *Pediatrics*. 2008 Sep;122(3):491-9
6. Lee BH, Stoll BJ, McDonald SA, Higgins RD; **National Institute of Child Health and Human Development Neonatal Research Network***. Neurodevelopmental outcomes of extremely low birth weight infants exposed prenatally to dexamethasone versus betamethasone. *Pediatrics*. 2008 Feb;121(2):289-96.
7. Malcolm WF, Gantz M, Martin RJ, Goldstein RF, Goldberg RN, Cotten CM; **National Institute of Child Health and Human Development Neonatal Research Network***. Use of medications for gastroesophageal reflux at discharge among extremely low birth weight infants. *Pediatrics*. 2008 Jan;121(1):22-7.
8. Mietzsch U, Parikh NA, Williams AL, Shankaran S, Lasky RE. Effects of hypoxic-ischemic encephalopathy and whole-body hypothermia on neonatal auditory function: a pilot study. *Am J Perinatol*. 2008 Aug;25(7):435-41.
9. Morris BH, Oh W, Tyson JE, Stevenson DK, Phelps DL, O'Shea TM, McDavid GE, Perritt RL, Van Meurs KP, Vohr BR, Grisby C, Yao Q, Pedroza C, Das A, Poole WK, Carlo WA, Duara S, Laptook AR, Salhab WA, Shankaran S, Poindexter BB, Fanaroff AA, Walsh MC, Rasmussen MR, Stoll BJ, Cotten CM, Donovan EF, Ehrenkranz RA, Guillet R, Higgins RD; **NICHD Neonatal Research Network***. Aggressive vs. conservative phototherapy for infants with extremely low birth weight. *N Engl J Med*. 2008 Oct 30;359(18):1885-96.
10. Namasivayam A; Van Meurs KP; Perritt R; Carlo WA; Ehrenkranz RA; Stevenson DK; Lemons JA; Poole WK; Higgins RD for the **NICHD Neonatal Research Network***. Predictors of death or bronchopulmonary dysplasia in preterm infants with respiratory failure. *J Perinatol*. 2008 Jun;28(6):420-6. Epub 2008 Mar 13
11. Oh W; Perritt R, Shankaran S, Merritts M, Donovan EF, Ehrenkranz RA, O'Shea TM, Tyson JE, Laptook AR, Das A, Higgins RD. Association between Urinary Lactate to Creatinine Ratio and Neurodevelopmental Outcome in Full Term Infants with Hypoxic Ischemic Encephalopathy. *J Pediatr*. 2008 Sep;153(3):375-8. Epub 2008 May 9
12. Parikh NA, Lasky RE, Garza CN, Bonfante-Mejia E, Shankaran S, Tyson JE. Volumetric and anatomical MRI for hypoxic-ischemic encephalopathy: relationship to hypothermia therapy and neurosensory impairments. *J Perinatol*. 2008 Nov 20. [Epub ahead of print]
13. Shankaran S; Pappas A; Laptook AR; McDonald SA; Ehrenkranz RA; Tyson JE; Walsh MC; Goldberg RN; Higgins RD; Das A; for the **NICHD Neonatal Research Network***. Outcomes of Safety and Effectiveness in a Multicenter Randomized Controlled Trial of Whole Body Hypothermia for Neonatal Hypoxic Ischemic Encephalopathy. *Pediatrics*. 2008 Oct;122(4):e791-8.
14. Stephens, BE, Bann, CM, Poole, WK, Vohr, BR, for the **NICHD Neonatal Research Network***. Neurodevelopmental Impairment – Predictors of Its Impact on the Families of ELBW infants at 18 Months. *Infant Mental Health J*. 2008 Nov-Dec; 29(6): 570-587

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

15. Tyson JE; Parikh NA; Langer J; Green C; Higgins RD for the **National Institute of Child Health and Human Development Neonatal Research Network***. Intensive Care for Extremely Premature Newborns: Moving Beyond Gestational Age Thresholds. *N Engl J Med.* 2008 Apr 17;358(16):1672-81. *Members of the NICHD Neonatal Research Network are listed in the Appendix; BB Poindexter - Principal Investigator for Indiana University.
16. Vohr, BR, Wright, LL, Perritt, R and Poole, WK. Maternal Age, Multiple Birth, and Extremely Low Birth Weight Infants. *J Pediatr.* 2008 Dec 24. [Epub ahead of print]
17. Bassler D; Stoll BJ; Schmidt B; Asztalos EV; Roberts RS; Robertson CMT; Sauve RS; for the Trial of Indomethacin Prophylaxis in Preterms Investigators. Using a Count of Neonatal Morbidities to Predict Poor Outcome in Extremely Low-Birth-Weight Infants: The Added Role of Neonatal Infection. *Pediatrics.* 2009 Jan;123(1):313-318
18. Cotten CM; Taylor S; Stoll B; Goldberg RN; Hansen NI; Sanchez P; Ambalavanan N; Benjamin DK on behalf of the **NICHD Neonatal Research Network***. Prolonged Initial Empirical Antibiotics for Early Onset Sepsis are Associated with Increased Necrotizing Enterocolitis and Mortality in Extremely Low Birthweight Infants. *Pediatrics.* 2009 Jan;123(1):58-66.
19. Meinen-Derr J; Poindexter B; Wrage L; Morrow AL; Stoll B; Donovan EF for the NICHD Neonatal Research Network. Role of human milk in extremely low birth weight infants' risk of necrotizing enterocolitis or death. *J Perinatol.* 2009 Jan;29(1):57-62. Epub 2008 Aug 21

***Members of the NICHD Neonatal Research Network are listed in the Appendix; BB Poindexter - Principal Investigator for Indiana University.**

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Anna Dusick, M.D.		POSITION TITLE Associate Professor of Clinical Pediatrics	
eRA COMMONS USER NAME			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Mount Mary College	B.S.	1977	Occupational Therapy
Chicago Medical School	M.D.	1986	Medicine
University of Chicago, Wyler Children's Hospital	Resident	1989	Pediatrics
University of Chicago, Pritzker School of Medicine	Fellow	1990	Neonatology
University of Chicago, Pritzker School of Medicine	Fellow	1992	Chronic Disease

A. Positions and Honors.

Positions and Employment

- 1992 - 1998 Clinical Assistant Professor of Pediatrics, Indiana University School of Medicine, Indianapolis, IN
- 1998 - Present Assoc. Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, IN

Other Experience and Professional Memberships

- 1995 to present Medical Director Newborn Follow-Up Program, Riley Hospital, Indianapolis, IN.
- 1997-2004 Board Member, Make-A-Wish Foundation of Indiana.
- 1998-2006 Board Member, Interagency Coordinating Council for Infants & Toddlers. Part C IDEA, State of Indiana.
- 2003 Member, Society for Pediatric Research.

Honors

- 1976 Pi Theta Epsilon Honor Society
- 1977 Delta Epsilon Sigma Honor Society
- 1977 Anne Mary McNally Scholarship Award
- 1997 Adjunct Assistant Professor of Speech and Hearing Sciences, Indiana University

B. Selected peer-reviewed publications (in chronological order). Do not include publications submitted or in preparation.

- Browne SP, Tebbett IR, Moore CM, Dusick AM, Covert RF: Analysis of meconium for cocaine in neonates. *Journal of Chromatology: Biomedical Applications* 575:158-161, 1992.
- Dusick AM, Covert RF, Schreiber MD, Yee GT, Browne SP, Moore CM, Tebbett IR: Risk of Intracranial hemorrhage and other adverse outcomes after cocaine. Exposure in a Cohort of 323 very low birth weight babies. *J Pediatr* 122: 438-45, 1993.
- Browne S, Moore C, Negrusz A, Tebbett I, Covert R, Dusick AM: Detection of cocaine, norcocaine and cocaethylene in the meconium of premature neonates. *J Forensic Sci*, 39: 1515-19, 1994.
- Dusick AM: Medical outcomes in Preterm Infants. *Seminar Perinatal* 21(3): 164-177, 1997.
- Wheeler PG, Medina S, Dusick AM, Bull M, Andreoli SP, Edwards-Brown M, Weaver D: Livedo reticularis, developmental delay and stroke-like episode in a 7-year-old male. *Clinical Dysmorphology* 1998, 7:69-74.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

6. Vohr BR, Wright LL, Dusick AM, Mele L et al. Neurodevelopmental and Functional Outcomes of Extremely Low Birthweight Infants in the National Institute of Child Health and Human Development Neonatal Research Network, 1993-1994. *Pediatr* 105(6): 1216-1226,2000
7. Barlow, S.M., Dusick, A., Finan, D.S., Biswas, A., Coltart, S., & Flaherty, K.J. (2000). Neurophysiological monitoring of the orofacial system in premature and term infants. *Journal Medical Speech-Language Pathology*, 8(4), 221-238.
9. Barlow SM, Dusick AM, Finan DS, Coltart S, Biswas A: Mechanically evoked perioral reflexes in Premature and term human infants. *Brain Research* 899: 251-254, 2001.
10. Dusick AM, Poindexter BP, Ehrenkranz RA, Lemons JA: Growth Failure in the Preterm Infant: Can We Catch Up? *Semin Perinatol* 27(4), 302-310, 2003
11. Dusick AM: Investigation and Management of Dysphagia Seminars in Pediatric Neurology 10(4),255-264,2003
12. Vohr BR, Wright LL, Dusick AM, Perritt R, etal. Center Differences and Outcomes of Extremely Low Birth Weight Infants. *Pediatrics* 113 (4): 781-789, 2004.
13. Ohls RK, Ehrenkranz RA, Sas A, Dusick AM, etal. Neurodevelopmental Outcome and Growth at 18 to 22 Months Corrected Age in Extremely Low Birth Weight Infants Treated With Early Erythropoietin and Iron. *Pediatrics* 114(5):1287-1291, 2004
14. Ehrenkranz RA, Dusick AM, Vohr BR, Wright LL, Wraga LA, Poole WK. Growth in the neonatal intensive care unit influences neurodevelopmental and growth outcomes of extremely low birth weight infants. *Pediatrics* 2006 Apr;117 (4):1253-61.
15. Vohr BR, Poindexter BB, Dusick AM, McKinley LT, Wright LL, Langer JC, Poole WK; NICHD Neonatal Research Network. Beneficial effects of breast milk in the neonatal intensive care unit on the developmental outcome of extremely low birth weight infants at 18 months of age. *Pediatrics* 2006 Jul;118(1): e115-23.
16. Poindexter BB, Langer JC, Dusick AM, Ehrenkranz RA for the National Institute of Child Health and Human Development Neonatal Research Network. Early Provision of Parenteral Amino Acids in Extremely Low Birth Infants: Relation to Growth and Neurodevelopmental Outcome. *Pediatrics* 2006;118(3):300-313.
17. Hintz SR, Van Meurs KP, Perritt R, Poole WK, Das A, Stevenson DK, Ehrenkranz RA, Lemons JA, Vohr BR, Heyne R, Childers DO, Peralta-Carcelen M, Dusick A, Johnson YR, Morris B, Dillard R, Vaucher Y, Steichen J, Adams-Chapman I, Konduri G, Myers GJ, de Ungria M, Tyson JE, Higgins RD; NICHD Neonatal Research Network. Neurodevelopmental outcomes of premature infants with severe respiratory failure enrolled in a randomized controlled trial of inhaled nitric oxide. *J Pediatr*. 2007 Jul;151(1):16-22, 22.e1-3.
18. Vohr BR, Poindexter BB, Dusick AM, McKinley LT, Higgins RD, Langer JC, Poole WK; National Institute of Child Health and Human Development National Research Network. Persistent beneficial effects of breast milk ingested in the neonatal intensive care unit on outcomes of extremely low birth weight infants at 30 months of age. *Pediatrics* 2007 Oct;120(4):e953-9

C. Research Support. List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and your role (e.g. PI, Co-Investigator, Consultant) in the research project. Do not list award amounts or percent effort in projects.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME James A. Lemons, M.D.		POSITION TITLE Professor of Pediatrics	
eRA COMMONS USER NAME			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Princeton University, Princeton, NJ	B.A.	1965	
Northwestern Univ. Medical School, Chicago, IL	M.D.	1969	Medicine
Univ. of Michigan Medical School, Ann Arbor, MI	Intern	1970	Pediatrics
Univ. of Michigan Medical School, Ann Arbor, MI	Resident	1972	Pediatrics
Univ. of Michigan Medical School, Ann Arbor, MI	Fellow	1973	Reproductive Endo.
Univ. of Colorado Medical School, Denver, CO	Fellow	1975	Neonatal-Perinatal Med.

A. Positions and Honors

Positions and Employment

- 1987-present Director, Section of Neonatal-Perinatal Medicine, Department of Pediatrics, Indiana University School of Medicine
 1988 present Hugh McK. Landon Professor of Pediatrics, Indiana University School of Medicine
 2003-present Associate, Faculty of Indiana University Graduate School

Other Experience and Professional Memberships

- 1988-1994 Executive Committee, American Academy of Pediatrics Section on Perinatal Pediatrics
 1991-2006 Principal Investigator, NICHD Neonatal Research Network, National Institutes of Health
 1992-1994 Chair, Executive Committee, Section on Perinatal Pediatrics of the American Academy of Pediatrics
 1993-1999 Member, Neonatal-Perinatal Medicine Sub-Board of the American Board of Pediatrics
 1994-present Professor of Pediatrics, Moi University, Faculty of Health Sciences Eldoret, Kenya
 1997-2001 Chair, Committee on Fetus and Newborn of American Academy of Pediatrics
 1999-present Pregnancy Labeling Subcommittee of the Reproductive Health Drugs Advisory Committee, FDA
 1999-2005 Task Force for Newborn Hearing Screening and Detection, American Academy of Pediatrics
 2000-2003 Chair, Technical Action Group, Council on Committees, American Academy of Pediatrics
 2000-2005 Joint Committee on Infant Hearing, American Academy of Pediatrics
 2006-present Chair, NIH Global Network for Women's and Children's Health Research Study Group

Honors

- 1968 Alpha Omega Alpha
 1975 Sigma Xi
 1988 Edwin L. Gresham Award for Perinatal Service, American Academy of Pediatrics
 1999 March of Dimes Health Leadership Award
 1994 The Best Doctors in America
 2002-2005 Inclusion In *America's Top Doctors (2nd Edition)* National Physician Guide
 2002 Teaching Excellence Recognition Award, Indiana University
 2005 Physician of the Year, March of Dimes, Indiana Chapter

B. Selected peer-reviewed publications (in chronological order) (Publications selected from more than 250 peer-reviewed publications)

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

1. Ward R, **Lemons J**, Molteni R. Cisapride: A survey of the frequency of use and adverse events in premature newborns. *Pediatrics*. 103(2):469-472, 1999.
2. Stevenson D.K., Verter J., Fanaroff A., Oh W., Herenkranz R.A., Shankaran S., Donovan E.F., Wright L., **Lemons J.A.**, Tyson J.E., Korones S.B., Baur C.R., Stoll B.J., Papile L-A. Sex differences in very low birthweight outcomes: The newborn male disadvantage. *Arch Dis Child*. 83:F182-F185, Nov 2000.
3. Walsh-Sukys MC, Fanaroff AA, Bauer CR, Korones SB, Stevenson DK, Tyson JE, Verter J, Wright LL, Stoll BJ, **Lemons JA**, Papile LA, Donovan EF, Shankaran S, Oh W, Ehrenkranz RA for the NICHD Neonatal Research Network. Persistent pulmonary hypertension of the newborn (PPHN) in the era before nitric oxide: practice variation and outcomes. *Pediatrics*. 105:14-20, 2000.
4. Reis B.B., Hall R.T., Schanler R.J., Berseth C.L., Chan G., Ernst J.A., **Lemons J.**, Adamkin D., Braggs G., O'Connor D. Enhanced Growth of Preterm Infants Fed a New Powdered Human Milk Fortifier: A Randomized Controlled Trial. *Pediatrics* 106(3);581-588, Sept 2000.
5. **Lemons JA**, Bauer CR, Oh W, Korones SB, Papile L-A, Stoll BJ, Verter J, Temprosa M, Wright LL, Ehrenkranz RA, Fanaroff AA, Stark A, Waldemar C, Tyson JE, Donovan EF, Shankaran S, Stevenson DK. Very Low Birth Weight Outcomes of the National Institute of Child Health and Human Development Neonatal Research Network, January 1995 through December 1996. *Pediatrics*. 107(1): 1-8, Jan 2001.
6. Vohr BR, Oh W, Stewart EJ, Bentkover JD, Gabbard S, **Lemons J**, Papile L-A, Pye R. A Comparison of Costs and Referral Rates of Three Universal Newborn Hearing Screening Protocols. *J Pediatr*. 139:238-44. Aug 2001.
7. Ohls RK, Ehrenkranz RA, Wright LL, **Lemons JA**, Korones SB, Stoll BJ, Stark AR, Shankaran S, Donovan EF, Close NC, Das A. Effects of Early Erythropoietin Therapy on the Transfusion Requirements of Preterm Infants Below 1250 Grams Birth Weight: A Multicenter, Randomized, Controlled Trial. *Pediatrics* 108(4):934-942, Oct 2001.
8. **Lemons J**, Fanaroff A, Stewart EJ, Bentkover JD, Murray G, Diefendorf A. Newborn Hearing Screening: Costs of Establishing a Program. *J Perinatol*. 22:120-124, 2002.
9. Farrell PA, Weiner GM, **Lemons JA**. SIDS, ALTE, Apnea, and the Use of Home Monitoring. *Pediatr in Rev*. 23:3-9, 2002.
10. Shankaran S, Fanaroff AA, Wright LL, Stevenson DK, Donovan EF, Ehrenkranz RA, Langer JC, Korones SB, Stoll, BJ, Tyson JE, Bauer CR, **Lemons, JA**, Oh W, Papile L-A. Risk factors for early death among extremely low-birth-weight infants. *Am J Obstet Gynecol* 186:796-802, 2002.
11. Stoll BJ, Hansen N, Fanaroff AA, Wright LL, Waldemar AC, Ehrenkranz RA, **Lemons JA**, Donovan EF, Stark AR, Tyson JE, Oh W, Bauer CR, Korones SB, Shankaran S, Laptook AR, Stevenson DK, Papile L-A, Poole WK. Late-Onset Sepsis in Very Low Birth Weight Neonates: The Experience of the NICHD Neonatal Research Network. *Pediatrics*.110:285-291, Aug 2002.
12. American Academy of Pediatrics & The American College of Obstetricians and Gynecologists. Guidelines for Perinatal Care, 5th Edition. **Lemons J** (ed). Oct 2002.
13. American Academy of Pediatrics & The American College of Obstetricians and Gynecologists. Neonatal Encephalopathy and Cerebral Palsy; Defining the Pathogenesis and Pathophysiology. **Lemons J** (ed). 2002.
14. Dusick A, Poindexter BB, Ehrenkranz RA, **Lemons JA**. Growth Failure in the Preterm Infant: Can We Catch Up? *Sem Perinatol*. 27:302-310, Aug 2003.
15. Stoll BJ, Hansen N, Fanaroff AA, Wright LL, Carlo WA, Ehrenkranz RA, **Lemons JA**, Donovan EF, Stark AR, Tyson JE, Oh W, Bauer CR, Korones SB, Shankaran S, Laptook AR, Stevenson DK, Papile L, Poole WK. To Tap or Not to Tap: High Likelihood of Meningitis Without Sepsis Among Very Low Birth Weight Infants. *Pediatrics* 113:1181-1186, May 2004.
16. Poindexter BB, Ehrenkranz RA, Stoll BJ, Wright LL, Poole WK, Oh W, Bauer CR, Papile L-A, Tyson JE, Waldemar AC, Laptook AR, Narendran V, Stevenson DK, Fanaroff AA, Korones SB, Shankaran S, Finer NN, **Lemons JA**. Parenteral Glutamine Supplementation Does Not Reduce the Risk of Mortality or Late-Onset Sepsis in Extremely Low Birth Weight Infants. *Pediatr* 113:1209-1215, May 2004.
17. Stoll BJ, Hansen N, Farnaroff AA, **Lemons JA** for the National Institute of Child Health and Human Development Neonatal Research Network. Enterobacter Sakazakii is a Rare Cause of Neonatal Septicemia or Meningitis in VLBW Infants. *J Pediatr* 144:821-823, Jun 2004.

Principal Investigator/Program Director (Last, First, Middle): **Poindexter, Brenda B.**

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Gregory M. Sokol, M.D.		POSITION TITLE Associate Professor of Clinical Pediatrics	
eRA COMMONS USER NAME (b) (6)			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Washington & Jefferson College, Washington, PA	BA	1977-1981	Chemistry
National Institutes of Health's Foundation for Advanced Ed in the Sciences, Bethesda, MD	Non-Degree	1981-1982	Neurobiology and Neurochemistry
University of Pittsburgh School of Medicine, Pittsburgh, PA	M.D.	1982-1986	Medicine
Eastern Virginia Graduate School of Medicine, Norfolk, VA	Intern/Res	1986-1989	Pediatrics
Indiana University School of Medicine, Indianapolis, IN	Fellowship	1989-1992	Neonatal-Perinatal Med

B. Positions and Honors

Positions and Employment

- 1992-1999 Assistant Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, IN
- 1999-present Associate Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, IN

Other Experience and Professional Memberships

- 1992-present Physician Coordinator for the Neonatal Inhaled Nitric Oxide Therapy Program at James Whitcomb Riley Hospital for Children.
- 1992-present Fellow American Academy of Pediatrics
- 1992-present Indiana Neonatal Society
- 1992-present Perinatal Section of the American Academy of Pediatrics
- 1992-present Neonatal Resuscitation Program Regional Trainer, #1218480.
- 1993-2000 Protocol development subcommittee, Executive committee & Principal Investigator at Indiana University for the "Neonatal Inhaled Nitric Oxide Study" (NINOS) sponsored by the NICHD Neonatal Research Network & Canadian Inhaled Nitric Oxide Study Group
- 1996-present Indiana Chapter of AAP, Chairman Perinatal Committee
- 1996-2006 Protocol development subcommittee, Executive committee & Principal Investigator at Indiana University for the "Early inhaled nitric oxide study in term and near-term infants with respiratory failure," sponsored by the NICHD Neonatal Research Network & Canadian Inhaled Nitric Oxide Study Group.
- 1998-present: Alternate Principal Investigator at Indiana University Medical Center for the National Institute of Child Health & Human Development's Cooperative Neonatal Research Network Steering Committee.
- 2000-2007: Principal Investigator at Indiana University Medical Center for the "Inhaled nitric oxide for preterm infants with severe respiratory failure," sponsored by the NICHD Neonatal Research Network.
- 2003-present: Member - Society for Pediatric Research

Principal Investigator/Program Director (Last, First, Middle): **Poindexter, Brenda B.**

2004-2007: Protocol development subcommittee & Principal Investigator at Indiana University for the "Inhaled PGE in term and near-term infants with respiratory failure," sponsored by the NICHD Neonatal Research Network.

2007-present: Institutional Review Board – Alternate, Indiana University-Purdue University in Indianapolis.

C. Selected peer-reviewed publications (in chronological order)

1. **Sokol, G.M.**, Liechty, E.A., and Boyle, D.W.: Comparison of steady-state diffusion and transit time ultrasonic measurements of umbilical blood flow in the chronic fetal sheep preparation. *Am J Obstet Gynecol* 1996;174:1456-60.
2. The Neonatal Inhaled Nitric Oxide Group. Inhaled nitric oxide in full-term and nearly full-term infants with hypoxic respiratory failure. *N Engl J Med* 1997;336:597-604.
3. The Neonatal Inhaled Nitric Oxide Group. Inhaled nitric oxide and hypoxic respiratory failure in infants with congenital diaphragmatic hernia. *Pediatrics* 1997;99:838-845.
4. **Sokol, G.M.**, Van Meurs, K.P., Thorn W.J., Rivera, O., Chu, P., Wright, L., Sams, R.L. Nitrogen dioxide formation during inhaled nitric oxide therapy. *Clinical Chemistry* 1999;45(3):382-387.
5. The Neonatal Inhaled Nitric Oxide Group. Inhaled nitric oxide in term and near term infants: Neurodevelopmental follow-up of the neonatal inhaled nitric oxide study group (NINOS). *J Pediatr* 2000;136:611-617.
6. **Sokol, G.M.**, Fineberg, N.S., Wright, L.L., Ehrenkranz, R.A. Changes in arterial oxygen tension when weaning neonates from inhaled nitric oxide. *Pediatric Pulmonology* 2001;32:14-19.
7. Konduri, G.G., Solimano, A., **Sokol, G.M.**, Singer, J., Ehrenkranz, R.A., et al. A Randomized trial of early versus standard inhaled nitric oxide therapy in term and near term newborn infants with hypoxic respiratory failure. *Pediatrics* 2004;113:559-564.
8. Van Meurs, K.P., Wright, L.L., Ehrenkranz, R.A., Lemons, J.A., et al. Inhaled nitric oxide for premature infants with severe respiratory failure. *N Engl J Med* 2005;353:13-22.
9. Konduri, G.G., Vohr, B., Robertson, C., **Sokol, G.M.**, et al. Early inhaled nitric oxide therapy for term and near-term newborn infants with hypoxic respiratory failure: neurodevelopmental follow-up. *J Pediatr* 2007;150:235-40.
10. Hintz, S.R., Van Meurs K.P., Perritt R, et al. Neurodevelopmental outcomes of premature infants with severe respiratory failure enrolled in a randomized controlled trial of inhaled nitric oxide. *J Pediatr* 2007;151:16-22.

**For New and Competing Applications (PHS 398) – DO NOT SUBMIT UNLESS REQUESTED
For Non-competing Progress Reports (PHS 2590) – Submit only Active Support for Key Personnel**

PHS 398/2590 OTHER SUPPORT

Provide active support for all key personnel. Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included.

There is no "form page" for other support. Information on other support should be provided in the format shown below, using continuation pages as necessary. **Include the principal investigator's name at the top and number consecutively with the rest of the application.** The sample below is intended to provide guidance regarding the type and extent of information requested.

For instructions and information pertaining to the use of and policy for other support, see Other Support in the PHS 398 Part III, Policies, Assurances, Definitions, and Other Information.

Note effort devoted to projects must now be measured using person months. Indicate calendar, academic, and/or summer months associated with each project.

POINDEXTER, BRENDA

ACTIVE

NIH 2U10HD27856-17 (Poindexter, PI) 4/01/06-3/31/11 (b) (6) Calendar
NICHD Cooperative Multicenter Neonatal Research Network \$163,910

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Principal Investigator

NIH RO1HL054062 (Tepper, PI) 7/01/06-6/30/10 (b) (6) Calendar
Growth of Airways and Lung Parenchyma in Normal Infants \$275,000

The major goal of this project is to determine the relationship between parenchymal tissue and alveolar volume with normal lung growth early in life and to determine the pulmonary sequelae of premature birth and assess the effectiveness of early treatment strategies upon the pulmonary sequelae.

Role: Collaborator

NIH RO1NR08111 (Ellett, PI) 9/01/04-8/30/09 (b) (6) Calendar
Gastric Tube Placement in Young Children

The major goals of this study are to test three methods of predicting the insertion distance for placing gastric tubes in young children and then three non-radiographic methods of determining the internal location of the tubes once placed.

Role: Co-investigator

NIH-NHLBI - RO1 (Abman, S., PI) 4/01/08-03/31/13 (b) (6) Calendar
"Genetic Basis of Bronchopulmonary Dysplasia"

The major goals of this study are to examine the effect of different SNPs in endothelial cells on the development of bronchopulmonary dysplasia in human patients.

Role: Co-investigator

NIH NCT00621192 (PI: Benjamin) 11/01/08 – 10/31/10 (b) (6) Calendar
Meropenem Substudies/Duke Univ.
"Intestinal Meropenem Metabolism and Disposition in Young Infants (<91 days) with Suspected or Complicated Intra-abdominal Infections"
Appendix 6 - Scavenge Sampling Methods for Meropenem pharmacokinetic and genomic analysis in infants.

Principal Investigator/Program Director: Poindexter, Brenda B.
(Last, first, middle)

Role: Co-investigator

DUSICK, ANNA
ACTIVE

UIO HD027856 – 13 NIH/NICHD (Poindexter) 4/1/06 – 3/31/11 (b) (6) Calendar
\$163,910

Cooperative Multicenter Neonatal Research Network: 18 Month Follow-Up Study of High Risk Infants,
Role: PI for outcome studies with separate outcome protocols for the Neonatal Research Network at IU

MCH/Indiana State Department of Health (Dusick) 10/1/06 – 7/30/08 (b) (6) Calendar
Federal I.D. # 35-600-1673 \$298,027

Title: Comprehensive Developmental Pediatric Care for Infants and Children with Special Health Care
Needs

Role: PI and Clinical Director of the Newborn Follow-Up Program

LEMONS, JAMES A.
ACTIVE

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11 (b) (6) Calendar
NICHD Cooperative Multicenter Neonatal Research Network \$163,910

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal
intensive care programs in the United States to conduct multicenter clinical trials and observational studies
in neonatal medicine.

Role: Alternate Principal Investigator

SOKOL, G.
ACTIVE

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11 (b) (6) Calendar
NICHD Cooperative Multicenter Neonatal Research Network \$163,910

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal
intensive care programs in the United States to conduct multicenter clinical trials and observational studies
in neonatal medicine.

GOLICHOWSKI, A.
ACTIVE

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11 (b) (6) Calendar
NICHD Cooperative Multicenter Neonatal Research Network \$163,910

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal
intensive care programs in the United States to conduct multicenter clinical trials and observational studies
in neonatal medicine.

Principal Investigator/Program Director (Last, First, Middle): **Poindexter, Brenda Louise Bradley**

PROGRESS REPORT SUMMARY	GRANT NUMBER HD027856-18	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Brenda Poindexter, MD, MS	FROM 04/01/09	THROUGH 03/31/10
APPLICANT ORGANIZATION Indiana University		
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	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
C. Select Agent Research	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
D. Multiple PI Leadership Plan	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> 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 reporting actual and targeted/planned enrollment for each active study in the Neonatal Research Network at the Indiana site are attached (see pages 26-41).

PROGRESS REPORT:

A. SPECIFIC AIMS

The NICHD Neonatal Research Network is a cooperative group of 16 academic centers whose principal aim is to perform multicenter randomized clinical trials to evaluate the safety and efficacy of treatment and management strategies for newborn infants, particularly those related to very low birth weight, prematurity, and common neonatal medical problems. The Steering Committee has worked diligently over the years, as the Network has grown, to create an organizational structure that permits timely evaluation of important clinical questions in the rapidly changing field of neonatology. The generic database and the follow-up study enable investigators to obtain information on a large cohort of premature infants regarding short- and long-term morbidities, differences in outcomes between centers and between different populations of infants, and variations in clinical practice related to outcomes. Indiana has been a member of the Neonatal Research Network since 1991 and continues to make substantial contributions to the Neonatal Research Network because of the large patient population, strong faculty, basic and clinical research experience, state-of-the-art clinical and research facilities, and excellent research support staff.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

B. STUDIES AND RESULTS:

This year marked the 18th year of participation in the NICHD Neonatal Research Network for Indiana University. The following studies are currently active; IRB protocol numbers and the dates of the most recent approval are listed below. Unless otherwise noted, all approvals are for 12 months.

NRN IRB APPROVALS

<u>PROTOCOL NAME</u>	<u>PROTOCOL NUMBER</u>	<u>MOST RECENT DATE OF APPROVAL</u>	<u>APPROVED THROUGH</u>
Survey of Morbidity and Mortality Among Very Low Birth Weight Infants	9612-02	01/14/09	01/14/10
NICHD GDB Follow up of Very Low Birth Weight Infants	9412-30	02/07/08	02/07/09
A Randomized Trial of Aggressive or Conservative Phototherapy Treatment for Extremely Low birth Weight Infants	0204-22	10/18/07	10/03/09
Early Diagnosis of Nosocomial Candidiasis	0401-55	07/08/08	08/08/09
Neurodiagnostic Evaluations That Assist in the Prediction of Adverse Outcome Following Acute Perinatal Encephalopathy	0401-53	09/23/08	09/23/09

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

Poindexter, Brenda Louise Bradley

<u>PROTOCOL NAME</u>	<u>PROTOCOL NUMBER</u>	<u>MOST RECENT DATE OF APPROVAL</u>	<u>APPROVED THROUGH</u>
Association of Apolipoprotein E (Apo E) Genotype with Brain Injury and Neurodevelopmental Outcome in Infants with Hypoxic Ischemic Encephalopathy	0410-30	07/25/08	07/25/09
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	0412-26	08/27/08	08/27/09
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	0412-26	08/27/08	08/27/09
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	0412-26	08/27/08	08/27/09
Breathing Outcomes (SUPPORT Study Secondary)	0412-26	08/27/08	08/27/09
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	0412-26	08/27/08	08/27/09

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

Poindexter, Brenda Louise Bradley

<u>PROTOCOL NAME</u>	<u>PROTOCOL NUMBER</u>	<u>MOST RECENT DATE OF APPROVAL</u>	<u>APPROVED THROUGH</u>
Long Term Follow Up of Children in the Randomized Controlled Trial of Induced Hypothermia for Hypoxic-Ischemic Encephalopathy	0612-08	10/21/08	10/21/09
Blood Inositol Status Among Neonates in 2005	0506-75	03/13/08	03/13/09
Single Dose Intravenous Inositol Pharmacokinetics in Preterm Infants	0609-36	08/13/08	08/13/09
Multiple Dose Intravenous Inositol Pharmacokinetics in Preterm Infants	Not submitted		
Early Onset Sepsis – An NICHD/CDC Surveillance Study	0601-88	01/22/09	01/22/10
PCV-7	N/A		
IPGE for Hypoxemic respiratory failure	N/A		
6-24 hour hypothermia	0802-23	04/04/08	04/04/09

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

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

Observational Studies:

The Generic Database (GDB) has provided for the collection of comprehensive data on very low-birth-weight (VLBW) infants which are used to monitor trends in morbidity and mortality associated with prematurity, to conduct observational studies, and to generate hypotheses for randomized clinical trials. Beginning in January of 2008, enrollment criteria for GDB was limited to inborn infants.

The Early Onset Sepsis (EOS) Surveillance Study is co-funded by the CDC. The objective is to determine the incidence of early-onset sepsis and the pathogens responsible for EOS since the implementation of universal screening and prophylaxis of group B streptococcus in pregnant women. This important study extends data collection to newborns of all birthweights. A total of 6 infants from Indiana were enrolled in this study in 2008 (44 total since the study began).

The Network Follow-Up study evaluates neurodevelopmental outcomes of premature infants born at less than or equal to 26 week gestational age or if they are in a randomized trial less than 1000 grams at 18 months corrected age. In addition to providing important information to the neonatal community, neurodevelopmental outcomes are increasingly becoming one of the primary or secondary outcome measures of many of the Network clinical trials. Indiana has consistently maintained an excellent rate of follow-up for this important longitudinal study, with 85% of eligible ELBW infants completing the 18-month follow-up study visit in 2008.

Clinical Trials:

The Surfactant Positive Airway Pressure and Pulse Oximetry (SUPPORT) trial is ongoing and nearing completion. The objectives of the SUPPORT trial are 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 to determine whether management of infants with a lower SpO₂ range (85-89%) compared to a higher SpO₂ range (91-95%) will result in increased survival without the occurrence of threshold retinopathy of prematurity. In addition to the main trial, Indiana is actively enrolling subjects in the following secondary studies: growth, MRI neuroimaging and neurodevelopmental outcome, and the breathing outcomes study.

The Phase II Randomized, Double Blind, Placebo Controlled, Safety and Pharmacokinetic Study of a Single Dose of Inositol in Premature Infants study recently completed enrollment. Pending analysis of the results, a dose will be determine for Inositol multidose randomized clinical trial. Dr. Poindexter serves as a member of the Inositol subcommittee and Leslie Dawn Wilson has played an instrumental role in developing the toxicity tables that will be used to define adverse events in the multidose study.

The Extended Follow-up of the Hypothermia Trial Subjects study is ongoing. Neurodevelopmental assessments between 6 to 7 years of age are planned when study participants enter the follow-up window.

The Association of Apolipoprotein E (apo E) genotype with brain injury and neurodevelopmental outcome in infants with hypoxic ischemic encephalopathy study is ongoing: 3 infants have been enrolled in the study at Indiana.

The Evaluation of Systemic Hypothermia Initiated after 6 Hours of Age in Infants \geq 36 weeks gestation with Hypoxic-Ischemic Encephalopathy: A Bayesian Evaluation study has just recently been initiated. We are currently screening for enrollment in the study at Indiana University.

Completed Studies:

During the past year, several studies have been completed and are now closed to enrollment. The studies remain open with the IUPUI/Clarian IRB due to the fact that data analysis and manuscript preparation for these studies is ongoing. :

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

Genomics Studies:

A protocol entitled, "Association of Genetic Polymorphisms of Vascular Endothelial Growth Factor (VEGF), Endothelial Nitric Oxide Synthase (eNOS), and Extracellular Superoxide Dismutase (EC-SOD) with Bronchopulmonary Dysplasia" has been approved by the Network genomics subcommittee as well as the NRN Steering Committee. This protocol was written by Dr. Rebecca Rose, a neonatology fellow at Indiana University who is mentored by Dr. Poindexter and will utilize samples collected in the NRN retrospective DNA repository. In this case-control study we will analyze the relationship between BPD and specific polymorphisms of VEGF, eNOS and EC-SOD. Identification of such a relationship could provide a biomarker that would potentially identify infants more likely to develop BPD so that more aggressive treatment could be initiated. In addition, the elucidation of the pathways and genetic variants increasing the risk for BPD could result in the development of novel therapies for this common morbidity associated with premature birth.

Trials in Design:

The following studies are being actively planned by the Neonatal Research Network:

- Multidose study of Inositol in Premature infants
- Probiotics for the Prevention of Necrotizing Enterocolitis
- Surgical management of Necrotizing Enterocolitis
- Trial of Donor Breast Milk vs Formula
- Concept: Dilemmas Initiating Enteral Feedings in High Risk Infants

Subcommittee Membership:

Dr. Poindexter is currently an active member of the following Network subcommittees:

- Protocol review (Vice-Chair)
- Early Onset Sepsis Surveillance
- Inositol
- Probiotics
- Surgical management of Necrotizing Enterocolitis – laparotomy vs. drain

C. SIGNIFICANCE

Each of the Neonatal Research Network studies contribute to the evidence needed to support and/or change clinical practice in the field of Neonatology. Indiana University contributed to the following Year 18 publications and abstracts:

2008 Publications:

1. Adams-Chapman I; Hansen N; Higgins RD; Stoll BJ for the NICHD Neonatal Research Network. Neurodevelopmental Outcome of ELBW infants with posthemorrhagic hydrocephalus requiring shunt insertion. *Pediatrics*. 2008 May;121(5):e1167-77.
2. Alfaleh K, Smyth JA, Roberts RS, Solimano A, Asztalos EV, Schmidt B; Trial of Indomethacin Prophylaxis in Preterms Investigators. Prevention and 18-month outcomes of serious pulmonary hemorrhage in extremely low birth weight infants: results from the trial of indomethacin prophylaxis in preterms. *Pediatrics*. 2008 Feb;121(2):e233-8.
3. Ambalavanan N, Van Meurs KP, Perritt R, Carlo WA, Ehrenkranz RA, Stevenson DK, Lemons JA, Poole WK, Higgins RD. Predictors of death or bronchopulmonary dysplasia in preterm infants with respiratory failure. *J Perinatol*. 2008 Jun;28(6):420-6. Epub 2008 Mar 13
4. Chock VY; Van Meurs KP; Hintz SR; Ehrenkranz RA; Lemons JA; Kendrick DE; Stevenson DK. Inhaled nitric oxide for preterm premature rupture of membranes, oligohydramnios, and pulmonary hypoplasia. *Am J Perinatol*. 2008 Dec 9. [Epub ahead of print]
5. Cole CR; Hansen NI; Higgins RD; Ziegler TR; Stoll BJ for the NICHD Neonatal Research Network. Very Low Birthweight Preterm Infants with Surgical Short Bowel Syndrome: Incidence, Morbidity and Mortality and Growth Outcomes at 18-22 months. *Pediatrics*. 2008 Sep;122(3):e573-82.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

6. Hintz SR; Kendrick DE; Vohr BR; Poole WK; Higgins RD for the NICHD Neonatal Research Network. Community supports after surviving extremely low birth weight, extremely preterm birth: Special outpatient services in early childhood. *Arch Pediatr Adolesc Med.* 2008 Aug;162(8):748-55.
7. Laptook AR; Tyson J; Shankaran S; McDonald S; Ehrenkranz R; Fanaroff A; Donovan E; Goldberg R; O'Shea TM; Higgins RD; Poole WK and the NICHD Neonatal Research Network. Elevated Temperature after Hypoxic-Ischemic Encephalopathy: A Risk Factor for Adverse Outcome. *Pediatrics.* 2008 Sep;122(3):491-9
8. Lee BH, Stoll BJ, McDonald SA, Higgins RD; National Institute of Child Health and Human Development Neonatal Research Network. Neurodevelopmental outcomes of extremely low birth weight infants exposed prenatally to dexamethasone versus betamethasone. *Pediatrics.* 2008 Feb;121(2):289-96.
9. Malcolm WF, Gantz M, Martin RJ, Goldstein RF, Goldberg RN, Cotten CM; National Institute of Child Health and Human Development Neonatal Research Network. Use of medications for gastroesophageal reflux at discharge among extremely low birth weight infants. *Pediatrics.* 2008 Jan;121(1):22-7.
10. Mietzsch U, Parikh NA, Williams AL, Shankaran S, Lasky RE. Effects of hypoxic-ischemic encephalopathy and whole-body hypothermia on neonatal auditory function: a pilot study. *Am J Perinatol.* 2008 Aug;25(7):435-41.
11. Morris BH, Oh W, Tyson JE, Stevenson DK, Phelps DL, O'Shea TM, McDavid GE, Perritt RL, Van Meurs KP, Vohr BR, Grisby C, Yao Q, Pedroza C, Das A, Poole WK, Carlo WA, Duara S, Laptook AR, Salhab WA, Shankaran S, Poindexter BB, Fanaroff AA, Walsh MC, Rasmussen MR, Stoll BJ, Cotten CM, Donovan EF, Ehrenkranz RA, Guillet R, Higgins RD; NICHD Neonatal Research Network. Aggressive vs. conservative phototherapy for infants with extremely low birth weight. *N Engl J Med.* 2008 Oct 30;359(18):1885-96.
12. Namasivayam A; Van Meurs KP; Perritt R; Carlo WA; Ehrenkranz RA; Stevenson DK; Lemons JA; Poole WK; Higgins RD for the NICHD Neonatal Research Network. Predictors of death or bronchopulmonary dysplasia in preterm infants with respiratory failure. *J Perinatol.* 2008 Jun;28(6):420-6. Epub 2008 Mar 13
13. Oh W; Perritt R, Shankaran S, Merritts M, Donovan EF, Ehrenkranz RA, O'Shea TM, Tyson JE, Laptook AR, Das A, Higgins RD. Association between Urinary Lactate to Creatinine Ratio and Neurodevelopmental Outcome in Full Term Infants with Hypoxic Ischemic Encephalopathy. *J Pediatr.* 2008 Sep;153(3):375-8. Epub 2008 May 9
14. Parikh NA, Lasky RE, Garza CN, Bonfante-Mejia E, Shankaran S, Tyson JE. Volumetric and anatomical MRI for hypoxic-ischemic encephalopathy: relationship to hypothermia therapy and neurosensory impairments. *J Perinatol.* 2008 Nov 20. [Epub ahead of print]
15. Shankaran S; Pappas A; Laptook AR; McDonald SA; Ehrenkranz RA; Tyson JE; Walsh MC; Goldberg RN; Higgins RD; Das A; for the NICHD Neonatal Research Network. Outcomes of Safety and Effectiveness in a Multicenter Randomized Controlled Trial of Whole Body Hypothermia for Neonatal Hypoxic Ischemic Encephalopathy. *Pediatrics.* 2008 Oct;122(4):e791-8.
16. Stephens, BE, Bann, CM, Poole, WK, Vohr, BR, for the NICHD Neonatal Research Network. Neurodevelopmental Impairment – Predictors of Its Impact on the Families of ELBW infants at 18 Months. *Infant Mental Hlth J.* 2008 Nov-Dec; 29(6): 570-587
17. Tyson JE; Parikh NA; Langer J; Green C; Higgins RD for the National Institute of Child Health and Human Development Neonatal Research Network. Intensive Care for Extremely Premature Newborns: Moving Beyond Gestational Age Thresholds. *N Engl J Med.* 2008 Apr 17;358(16):1672-81.
18. Vohr, BR, Wright, LL, Perritt, R and Poole, WK. Maternal Age, Multiple Birth, and Extremely Low Birth Weight Infants. *J Pediatr.* 2008 Dec 24. [Epub ahead of print]

2009 Publications:

1. Bassler D; Stoll BJ; Schmidt B; Asztalos EV; Roberts RS; Robertson CMT; Sauve RS; for the Trial of Indomethacin Prophylaxis in Preterms Investigators. Using a Count of Neonatal Morbidities to Predict Poor Outcome in Extremely Low-Birth-Weight Infants: The Added Role of Neonatal Infection. *Pediatrics.* 2009 Jan;123(1):313-318

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

2. Cotten CM; Taylor S; Stoll B; Goldberg RN; Hansen NI; Sanchez P; Ambalavanan N; Benjamin DK on behalf of the NICHD Neonatal Research Network. Prolonged Initial Empirical Antibiotics for Early Onset Sepsis are Associated with Increased Necrotizing Enterocolitis and Mortality in Extremely Low Birthweight Infants. *Pediatrics*. 2009 Jan;123(1):58-66.
3. Meinzen-Derr J; Poindexter B; Wrage L; Morrow AL; Stoll B; Donovan EF for the NICHD Neonatal Research Network. Role of human milk in extremely low birth weight infants' risk of necrotizing enterocolitis or death. *J Perinatol*. 2009 Jan;29(1):57-62. Epub 2008 Aug 21

2008 Abstracts:

1. 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)
2. Ang, J., Asmar, B., D'Angio, C., Whitney, C. For The Neonatal Research Network (NRN), National Institute of Child Health and Human Development (NICHD). Nasopharyngeal (NP) Carriage of *Streptococcus pneumoniae* (SP) in Very Low Birth Weight (VLBW) Infants After Administration of Heptavalent Pneumococcal Conjugate Vaccine (PCV-7). (Presented, to the Society for Pediatric Research, Honolulu, Hawaii, May 2-6, 2008)
3. Bell, E., Hansen, N., Morriss, Jr., F., and the NICHD Neonatal Research Network. Impact of Timing of Birth and Resident Work-Hour Restrictions on Neonatal Mortality in Very-Low-Birth-Weight Infants. (Presented, to the Society for Pediatric Research, Honolulu, Hawaii, May 2-6, 2008)
4. Benjamin, Jr., D., Stoll, B., Goldberg, R., Walsh, T., and the NICHD Neonatal Research Network. Neonatal Candidiasis: Epidemiology, Clinical Judgment, and Outcomes. (Presented, to the Society for Pediatric Research, Honolulu, Hawaii, May 2-6, 2008)
5. D'Angio, C., Carlo, W., and the NICHD Neonatal Research Network. Blood Cytokine Profiles in Distinct Patterns of Bronchopulmonary Dysplasia (BPD) in Extremely Low Birth Weight Infants. (Presented, to the Society for Pediatric Research, Honolulu, Hawaii, May 2-6, 2008)
6. D'Angio, C., and the NICHD Neonatal Network. Pneumococcal Conjugate Vaccine (PCV-7) Immunogenicity in Very-Low-Birth-Weight, Premature Infants. (Presented, to the Society for Pediatric Research, Honolulu, Hawaii, May 2-6, 2008)
7. Denson, L., McDonald, S., Ehrenkranz, R., and the NICHD Neonatal Research Network. Early Elevation in Circulating Interleukin-6 (IL-6) Is Associated with Reduced Growth Velocity at Hospital Discharge in Extremely Low Birth Weight (ELBW) Infants. (Presented, to the Society for Pediatric Research, Honolulu, Hawaii, May 2-6, 2008)
8. Hintz, S., and the NICHD Neonatal Research Network. Predicting Early and Late Hospital Discharge in Extremely Preterm Infants. (Presented, to the Society for Pediatric Research, Honolulu, Hawaii, May 2-6, 2008)
9. Laptook, A., Shankaran, S. and the Hypothermia Sub-Committee of the NICHD Neonatal Research Network (NRN). Apgar Scores at 10Min and Outcome in Term Infants with Hypoxic-Ischemic Encephalopathy (HIE). (Presented, to the Society for Pediatric Research, Honolulu, Hawaii, May 2-6, 2008)
10. Lenfestey, R., Madan, J., and the NICHD Neonatal Research Network. No Differential Gender Effects of Early Indomethacin in Extremely Preterm Infants. (Presented, to the Society for Pediatric Research, Honolulu, Hawaii, May 2-6, 2008)
11. Natarajan, G., Carlo, W., For Cytokine SubCommittee, NICHD Neonatal Research Network. Matrix Metalloproteinases and Chemokines: Potential Markers of Oxidative Injury in Preterm Infants? (Presented, to the Society for Pediatric Research, Honolulu, Hawaii, May 2-6, 2008)
12. Schelonka, R., Carlo, W., for the NICHD Neonatal Research Network. T Cell Cytokines and the Risk of Blood Stream Infection in Extremely Low Birth Weight Infants. (Presented, to the Society for Pediatric Research, Honolulu, Hawaii, May 2-6, 2008)
13. Sood, B., Madan, A., Carlo, W. Fetal Inflammatory Response Syndrome and Retinopathy of Prematurity: Is There a Relationship? (Presented, to the Society for Pediatric Research, Honolulu, Hawaii, May 2-6, 2008)

Principal Investigator/Program Director (Last, First, Middle): **Poindexter, Brenda Louise Bradley**

In summary, Indiana University has continued to be a productive member of the Neonatal Research Network, contributing significantly to all trials. We look forward to contributing to the improvement of neonatal outcomes through our participation in this important Network.

Poindexter, Brenda Louise Bradley

GRANT NUMBER

HD027856-18

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).

Budget Period	Anticipated Amount	Source(s)
N/A	N/A	N/A

2. ASSURANCES/CERTIFICATIONS (See instructions.)

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

- Debarment and Suspension
- Drug-Free Workplace (applicable to new [Type 1] or revised [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 Agents

3. FACILITIES AND ADMINISTRATION (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.

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 date 06/04/008 No Facilities and Administration Costs Requested

No DHHS Agreement, but rate established with Date

CALCULATION*

Entire proposed budget period: Amount of base \$ 208,316 x Rate applied 54.00 % = F&A costs \$ 112,491

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

- Salary and wages base Modified total direct cost base Other base (Explain)
- Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary.):

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda B.

KEY PERSONNEL REPORT

GRANT NUMBER
HD027856-18

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

All Key Personnel for the Current Budget Period (do not include Other Significant Contributors)

Name	Degree(s)	SSN (last 4 digits)	Role on Project (e.g. PI, Res. Assoc.)	Date of Birth (MM/DD/YY)	Months Devoted to Project		
					Cal	Acad	Summer
Brenda Poindexter	MD, MS	(b) (6)	PI	(b) (6)	(b) (6)		
Anna Dusick	MD		Follow-Up PI				
James Lemons	MD		Alternate PI				
Greg Sokol	MD		Alternate PI				
Leslie Dawn Wilson	RN, BSN		Research Coord.				
Dianne Herron	RN		Data Entry Manager				
Alan Golichowski	MD, PhD		Perinatal Collaborator				

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Targeted/Planned Enrollment Table

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

Study Title: Multidose study of Inositol in Premature infants

Total Planned Enrollment: 15

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	1		1
Not Hispanic or Latino	7	7	14
Ethnic Category: Total of All Subjects *	8	7	15
Racial Categories			
American Indian/Alaska Native			
Asian	1	0	1
Native Hawaiian or Other Pacific Islander			
Black or African American	2	1	3
White	5	5	10
Racial Categories: Total of All Subjects *	8	6	14

* 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): Poindexter, Brenda Louise Bradley

Targeted/Planned Enrollment Table

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

Evaluation of Systemic Hypothermia Initiated after 6 Hours of Age in Infants \geq 36 weeks

Study Title: gestation with Hypoxic-Ischemic Encephalopathy: A Bayesian Evaluation

Total Planned Enrollment: 12

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	1		1
Not Hispanic or Latino	5	6	11
Ethnic Category: Total of All Subjects *	6	6	12
Racial Categories			
American Indian/Alaska Native			
Asian	0	1	1
Native Hawaiian or Other Pacific Islander			
Black or African American	2	2	4
White	4	2	6
Racial Categories: Total of All Subjects *	6	5	11

* 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): Poindexter, Brenda Louise Bradley

Targeted/Planned Enrollment Table

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

Study Title: Surgical management of Necrotizing Enterocolitis

Total Planned Enrollment: 30

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	1	1	2
Not Hispanic or Latino	14	14	28
Ethnic Category: Total of All Subjects *	15	15	30
Racial Categories			
American Indian/Alaska Native			
Asian	1	1	2
Native Hawaiian or Other Pacific Islander			
Black or African American	4	3	7
White	9	10	19
Racial Categories: Total of All Subjects *	14	14	28

* 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): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Generic Database - Survey of Morbidity and Mortality Among VLBW Infants 401-1500 g
 Total Enrollment: 130 Protocol Number: 9612-02
 Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	10	6	0	16 **
Not Hispanic or Latino	47	66	1	114
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	57	72	1	130 *
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	21	25	0	46
White	35	46	1	82
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	57	72	1	130 *
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	10	6	0	16
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	10	6	0	16 **

* These totals must agree.

** These totals must agree.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Early Diagnosis of Nosocomial Candidiasis
 Total Enrollment: 0 Protocol Number: 0401-55
 Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			
	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	0	0	0
Ethnic Category: Total of All Subjects*	0	0	0	0 *
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	0	0	0	0
Racial Categories: Total of All Subjects*	0	0	0	0 *
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): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Neurodiagnostic Evaluations that assist in the Prediction of Adverse Outcome
 Total Enrollment: 0 Protocol Number: 0401-53
 Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	0	0	0	0 *
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	0	0	0	0
Racial Categories: Total of All Subjects*	0	0	0	0 *
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): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Early Onset Sepsis - A NICHD/CDC Surveillance Study
 Total Enrollment: 16 Protocol Number: 0601-88
 Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	4	2	0	6 **
Not Hispanic or Latino	5	5	0	10
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	9	7	0	16 *
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	2	0	5
White	6	5	0	11
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	9	7	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	4	2	0	6
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	4	2	0	6 **

* These totals must agree.

** These totals must agree.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: SUPPORT
 Total Enrollment: 14 Protocol Number: 0412-26
 Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	7	7	0	14
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	7	7	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	3	2	0	5
White	4	5	0	9
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	7	7	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.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: A Randomized Trial of Aggressive or Conservative Phototherapy for Extremely Low Birth Weight Infants

Total Enrollment: 0 **Protocol Number:** 0204-22

Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	0	0	0	0 *
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	0	0	0	0
Racial Categories: Total of All Subjects*	0	0	0	0 *
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): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Follow-Up of Premature Infants With Birthweight Less Than 1000 Grams at 18 (+4) Months of Age and/or 30 (+,-2) Months of Age (Corrected for Gestation)

Total Enrollment: 50 Protocol Number: 0914-30

Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	1	2	0	3 **
Not Hispanic or Latino	26	21	0	47
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	27	23	0	50 *
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	12	6	0	18
White	15	16	0	31
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	27	23	0	50 *
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	2	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**	1	2	0	3 **

* These totals must agree.

** These totals must agree.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

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 SUPPORT

Total Enrollment: 15 **Protocol Number:** 0609-37

Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	8	7	0	15
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	8	7	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	3	2	0	5
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 All Subjects*	8	7	0	15 *
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): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Association of Apolipoprotein E (apo E) genotype with brain injury and neurodevelopmental outcome in infants with hypoxic ischemic encephalopathy
Total Enrollment: 3 **Protocol Number:** 0410-30
Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	2	1	0	3
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	2	1	0	3 *
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	2	1	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	1	0	3 *
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): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: NICHD SUPPORT Trial-Breathing Outcomes

Total Enrollment: 15

Protocol Number: 0606-41

Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	8	7	0	15
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	8	7	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	3	2	0	5
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 All Subjects*	8	7	0	15 *
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): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Extended Follow-up of the Hypothermia Trial Subjects
 Total Enrollment: 0 Protocol Number: 0612-08
 Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	0	0	0	0
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	0	0	0	0
Racial Categories: Total of All Subjects*	0	0	0	0 *
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): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Phase II Randomized, Double Blind, Placebo Controlled, Safety and Pharmacokinetic Study of a Single Dose of Inositol in Premature Infants
Total Enrollment: 0 **Protocol Number:** 0609-36
Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	0	0	0	0 *
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	0	0	0	0
Racial Categories: Total of All Subjects*	0	0	0	0 *
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): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Blood Inositol Status Among Neonates in 2005
 Total Enrollment: 0 Protocol Number: 0506-75
 Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	0	0	0	0 *
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	0	0	0	0
Racial Categories: Total of All Subjects*	0	0	0	0 *
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.



INDIANA UNIVERSITY

DEPARTMENT OF PEDIATRICS

School of Medicine

January 30, 2009

Division of Extramural Activities Support, OER
National Institute of Health
6705 Rockledge Drive, Room 2207, MSC 7987
Rockville, MD 20817

RE: NIH Grant Progress Report – HD027856-18

Enclosed please find our grant progress report for the HD027856-18 NICHD Cooperative Multicenter Neonatal Research Network grant.

We apologize for the unavoidable delay due to adverse weather conditions. Our University was closed due to weather and the sign-off could not be completed at the scheduled time.

Please feel free to contact me with any questions or if we can provide additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Brenda B. Poindexter".

Brenda B. Poindexter, M.D., M.S.
Associate Professor of Clinical Pediatrics
Section of Neonatal-Perinatal Medicine
Riley Hospital for Children

Progress Report Scanning Cover Sheet

5U10HD027856-18

PI Name: **POINDEXTER, BRENDA**
Org: **INDIANA UNIV-PURDUE UNIV AT
INDIANAPOLIS**
Start Date: **04/01/2008**
Snap: **N/A (NEEDS TO BE BOOKMARKED)**
Appl ID: **7392223**
Rec'd
Date: **02/04/2008**

Department of Health and Human Services
Public Health Services

Review Group	Type 25	Activity U10	Grant Number HD027856- 7 18
Total Project Period			
From: 04/01/2006		Through: 03/31/2011	
Requested Budget Period			
From: 04/01/2008		Through: 03/31/2009	

Grant Progress Report

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR
(Name and address, street, city, state, zip code)
**Brenda Poindexter, MD, MS
Neonatal/Perinatal Medicine
Department of Pediatrics
699 West Drive, RR 208
Indianapolis, IN 46202-5119**

3. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code)
**The Trustees of Indiana University
Sponsored Research Services
620 Union Drive, Room 618
Indianapolis, IN 46202-5167**

FEB 04 2008

2b. E-MAIL ADDRESS
bpoindex@iupui.edu

4. ENTITY IDENTIFICATION NUMBER
1-35-6001673-A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Department of Pediatrics

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
**Executive Director
Indiana University
Sponsored Research Services
620 Union Drive, Room 618
Indianapolis, IN 46202-5167
E-MAIL: spon2@iupui.edu**

2d. MAJOR SUBDIVISION

School of Medicine

6. HUMAN SUBJECTS

No Yes

6a. Research Exempt No Yes

6b. Human Subjects Assurance No. **FWA00003566**

If Exempt ("Yes" in 6a):
Exemption No.

6c. NIH-Defined Phase III
Clinical Trial No Yes

If Not Exempt ("No" in 6a):
IRB approval date **See p. 18**

Full IRB **or**
 Expedited Review

7. VERTEBRATE ANIMALS

No Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT **\$223,879**

8b. TOTAL **\$298,211**

9. INVENTIONS AND PATENTS

No Yes If "Yes," Previously Reported Not Previously Reported

10. PERFORMANCE SITE(S) (*Organizations and addresses*)

**Riley Hospital for Children
Indiana University Hospital
Methodist Hospital
Wishard Memorial Hospital**

All located in Indianapolis, Indiana

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (*Item 2a*)
TEL **317-274-4920**
FAX **317-274-2065**

11b. ADMINISTRATIVE OFFICIAL NAME (*Item 5*)
W.S. Johnson
TEL **317-278-3473**
FAX **317-274-8744**

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (*Item 14*)
NAME **John W. Talbott**
TITLE **Interim Assistant VP for Research Administration**
TEL **317-278-3473** | FAX **317-274-8744**
E-MAIL **spon2@iupui.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 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.*)
John W. Talbott

DATE
1/31/08

DETAILED BUDGET FOR NEXT BUDGET PERIOD – DIRECT COSTS ONLY		FROM 04/01/08			THROUGH 03/31/08		GRANT NUMBER HD027856-17	
PERSONNEL (Applicant organization only)		Months Devoted to Project			DOLLAR AMOUNT REQUESTED (omit cents)			
NAME	ROLE ON PROJECT	Cal. Mnth	Acad. Mnth	Summer Mnth	SALARY REQUESTED	FRINGE BENEFITS	TOTALS	
Brenda Poindexter	Principal Investigator	(b)			9,000	3,000	12,000	
Anna Dusick	Follow-Up PI	(6)			3,000	1,000	4,000	
Leslie Dawn Wilson	Research Coordinator				90,177	30,056	120,233	
Dianne Herron	Data Entry Mgr.				31,976	4,940	36,916	
James Lemons	Alternate PI							
Greg Sokol	Alternate PI							
Alan Golichowski	Perintal Collaborator							
SUBTOTALS →					134,153	38,996	173,149	
CONSULTANT COSTS								
EQUIPMENT (Itemize)								
SUPPLIES (Itemize by category)								
Project specific supplies for data collection as specified in protocols								
5,100								
TRAVEL								
Travel to Washington, DC for PI and Coordinator (10 trips annually)								
15,500								
PATIENT CARE COSTS		INPATIENT						
		OUTPATIENT						
ALTERATIONS AND RENOVATIONS (Itemize by category)								
OTHER EXPENSES (Itemize by category)								
Printing, duplicating, postage, and long-distance telephone calls								
3,090								
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD							\$ 196,839	
CONSORTIUM/CONTRACTUAL COSTS		DIRECT COSTS						
		FACILITIES AND ADMINISTRATIVE COSTS						
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD (Item 8a, Face Page)							\$ 223,879	

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

BUDGET JUSTIFICATION**GRANT NUMBER**HD027856-17

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

Funding for time and effort for the principal investigator, Dr. Brenda Poindexter, remains unchanged at (b) (6). Funding for time and effort of the follow-up principal investigator, Dr. Anna Dusick, remains unchanged at (b) (6). No funding is requested for the time and effort of the alternate principal investigators, Drs. James Lemons and Greg Sokol. Leslie Dawn Wilson is the full-time research coordinator for Indiana. Dianne Herron is the data entry manager.

CURRENT BUDGET PERIODFROM
4/1/08THROUGH
3/31/09

Explain any estimated unobligated balance (including prior year carryover) that is greater than 25% of the current year's total budget.

We do not anticipate an unobligated balance that is greater than 25% of the current year's total budget in the base grant award. However, we do anticipate that there will be an unobligated balance in excess of 25% on the capitated portion of the current budget period due to the fact that enrollment in several studies has not yet begun, yet these studies have been funded by the grant. The final amount of carryover request will be submitted after the NIH grants management office calculates the capitation offset report.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Brenda Louise Bradley Poindexter, M.D., M.S.		POSITION TITLE Associate Professor of Clinical Pediatrics	
eRA COMMONS USER NAME (b) (6)			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Milligan College, Johnson City, TN	B.S.	1986	Biology
Medical College of Ohio, Toledo, OH	M.D.	1990	Medicine
Cincinnati Children's Hospital Medical Center	Residency	1993	Pediatrics
Indiana University School of Medicine	Fellowship	1997	Neonatology
Indiana University-Purdue University Indianapolis	M.S.	2004	Clinical Research

A. Positions and Honors

Positions and Employment

- 1997-1998 Lecturer, Department of Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana
- 1998-2006 Assistant Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana
- 2006-present Associate Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana

Other Experience and Professional Memberships

- 1998 Fellow, American Academy of Pediatrics
- 1999-present Nutritional Support Team, Clarian Health Partners, Indianapolis, Indiana
- 1999-present Member, Institutional Review Board, Indiana University-Purdue University Indianapolis
- 2001 Member, Society for Pediatric Research
- 2002 Member, Midwest Society for Pediatric Research
- 2003-present Council Member, Midwest Society for Pediatric Research
- 2004-present Institutional Review Board Executive Committee, Indiana University-Purdue University Indianapolis
- 2005-present Annual Scholar's Day Committee, Department of Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana
- 2005-present Director of Clinical Research, Section of Neonatal-Perinatal Medicine, Indiana University School of Medicine, Indianapolis, Indiana
- 2006-present Principal Investigator, NICHD Neonatal Research Network
- 2007-present Vice-Chair, Protocol Review Committee, NICHD Neonatal Research Network
- 2007-present Co-Chair, Newborn Committee, Clarian North Medical Center

Honors

- 1990 Alpha Omega Alpha
- 1990 Marian C. Regent Award in Pediatrics, Medical College of Ohio
- 1990 American Medical Women's Association Award
- 1996 National Research Service Award, National Institutes of Health
- 1996 Fellow's Clinical Research Award, Society for Pediatric Research
- 1996 Frederick M. Kenny Memorial Trainee Investigator Award, Midwest Society for Pediatric Research
- 2006 President, Midwest Society for Pediatric Research

B. Selected peer-reviewed publications (in chronological order)

1. **Poindexter BB**, Karn CA, Ahlrichs JA, Wang J, Leitch CA, Liechty EA, Denne SC: Amino acids suppress proteolysis independent of insulin throughout the neonatal period. *American Journal of Physiology* 272:E592-599, 1997.
2. Denne SC, Clark SE, **Poindexter BB**, Leitch CA, Ernst JA, Lemons PK, Lemons JA, Hertz DE, Liechty EA: Nutrition and Metabolism in the High-Risk Neonate - in "Neonatal-Perinatal Medicine: Diseases of the fetus and infant", Avroy A. Fanaroff and Richard J. Martin (eds), Sixth edition, Mosby Year Book, p. 562-621, 1997.
3. **Poindexter BB**, Karn CA, Denne SC: Exogenous insulin suppresses proteolysis and endogenous glucose production in extremely low birth weight infants. *J Pediatrics* 132:948-53, 1998.
4. **Poindexter BB**, Karn CA, Leitch CA, Liechty EA, Denne SC: Amino acids do not suppress proteolysis in premature neonates. *American Journal of Physiology* 281:E472-478, 2001.
5. Denne SC, **Poindexter BB**, Leitch CA, Ernst JA, Lemons PK, Lemons JA: Parenteral and Enteral Nutrition - in "Neonatal-Perinatal Medicine: Diseases of the fetus and infant", Avroy A. Fanaroff and Richard J. Martin (eds), Seventh edition, Mosby Year Book, p. 578-617, 2001.
6. **Poindexter BB**, Ehrenkranz RA, Stoll BJ, Koch MA, Wright LL, Oh W, Papile LA, Bauer CR, Carlo WA, Donovan EF, Fanaroff AA, Korones SB, Lupton AR, Shankaran S, Stevenson DK, Tyson JE, Lemons JA: The effect of parenteral glutamine supplementation on plasma amino acid and ammonia concentrations in extremely low birth weight infants. *American Journal of Clinical Nutrition* 77:737-743, 2003.
7. Dusick AM, **Poindexter BB**, Ehrenkranz RA, Lemons JA: Growth Failure in the Preterm Infant: Can We Catch Up? *Seminars in Perinatology*, 27(4):302-310, 2003.
8. **Poindexter BB**, Denne SC: Parenteral Nutrition - in "Avery's Diseases of the Newborn", H. William Taeusch, Roberta A. Ballard, and Christine A. Gleason (eds), Eighth edition, Elsevier, p. 1061-1070, 2004.
9. **Poindexter BB**, Ehrenkranz RA, Stoll BJ, Koch MA, Wright LL, Oh W, Papile LA, Bauer CR, Carlo WA, Donovan EF, Fanaroff AA, Korones SB, Lupton AR, Shankaran S, Stevenson DK, Tyson JE, Lemons JA: Parenteral glutamine supplementation does not reduce the risk of mortality or late-onset sepsis in extremely low birth weight infants. *Pediatrics*, 113(5):1209-1215, 2004.
10. **Poindexter BB**: Infant Nutrition – in "Care of the Newborn – A Handbook for Primary Care", David E. Hertz (ed), Lippincott Williams & Wilkins, 2005.
11. **Poindexter BB**, Denne SC: Differences Between Metabolism and Feeding of Preterm and Term Infants – in "Principles of Perinatal-Neonatal Metabolism", William Hay and Patti Thureen (eds), Second edition.
12. **Poindexter BB**, Leitch CA, Denne SC: Parenteral Nutrition - in "Neonatal-Perinatal Medicine: Diseases of the fetus and infant", Avroy A. Fanaroff and Richard J. Martin (eds), Eighth edition, Mosby Year Book, p. 679-693, 2005.
13. Oh W, **Poindexter BB**, Perrit R, Lemons JA, Bauer CR, Ehrenkranz RA, Stoll BJ, Poole K, Wright LL: Association between fluid intake and weight loss during the first ten days of life and risk of bronchopulmonary dysplasia in extremely low birth weight infants. *J Pediatr*, 147(6):786-90, 2005.
14. **Poindexter BB**, Langer JC, Dusick AM, Ehrenkranz RA: Early provision of parenteral amino acids in extremely low-birth-weight infants – Relationship with growth and neurodevelopmental outcome. *J Pediatr*, 148(3):300-305, 2006.
15. Vohr BR, **Poindexter BB**, Dusick AM, McKinley LT, Wright LL, Langer JC, Poole WK: Effects of human milk in the neonatal intensive care unit on the developmental outcome and growth of extremely low birth weight infants at 18 months of age. *Pediatrics*, 118(1):e115-23, 2006.
16. Denne SC, **Poindexter BB**: Evidence supporting early nutritional support with parenteral amino acid infusion. *Semin Perinatol*, 31(2):56-60, 2007.
17. Heller CD, O'Shea M, Yao Q, Langer L, Ehrenkranz RA, Phelps DL, Poole WK, Stoll BJ, Duara S, Oh W, Lemons J, **Poindexter B** for the NICHD Neonatal Research Network: Human Milk Intake and Retinopathy of Prematurity in Extremely Low Birth Weight Infants. *Pediatrics*, 120(1):1-9, 2007.

C. Research Support

Ongoing Research Support

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Principal Investigator

NIH RO1HL054062 (Tepper, PI) 7/01/06-6/30/10

Growth of Airways and Lung Parenchyma in Normal Infants

The major goal of this project is to determine the relationship between parenchymal tissue and alveolar volume with normal lung growth early in life and to determine the pulmonary sequelae of premature birth and assess the effectiveness of early treatment strategies upon the pulmonary sequelae.

Role: Collaborator

NIH RO1NR08111 (Ellett, PI) 9/01/04-8/30/09

Gastric Tube Placement in Young Children

The major goals of this study are to test three methods of predicting the insertion distance for placing gastric tubes in young children and then three non-radiographic methods of determining the internal location of the tubes once placed.

Role: Co-investigator

NIH-NHLBI - RO1 (Abman,S., PI) 4/01/08-03/31/13

“Genetic Basis of Bronchopulmonary Dysplasia”

The major goals of this study are to examine the effect of different SNPs in endothelial cells on the development of bronchopulmonary dysplasia in human patients.

Role: Co-investigator

Completed Research Support

NIH U10HD27856-10 (Lemons, PI) 4/01/01-3/31/06

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Alternate Principal Investigator

NIH MO1-RR00750 (Poindexter, PI) 5/1/97-6/30/02

NIH Clinical Associate Physician Award

Glutamine Metabolism in Human Neonates

The major goal of this project is to examine pathways of glutamine metabolism in neonates and to determine how stressors such as prematurity and surgery alter these pathways.

Role: Principal Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
 Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Anna Dusick, M.D.	POSITION TITLE Associate Professor of Clinical Pediatrics		
eRA COMMONS USER NAME			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Mount Mary College	B.S.	1977	Occupational Therapy
Chicago Medical School	M.D.	1986	Medicine
University of Chicago, Wyler Children's Hospital	Resident	1989	Pediatrics
University of Chicago, Pritzker School of Medicine	Fellow	1990	Neonatology
University of Chicago, Pritzker School of Medicine	Fellow	1992	Chronic Disease

A. Positions and Honors.

Positions and Employment

- 1992 - 1998 Clinical Assistant Professor of Pediatrics, Indiana University School of Medicine, Indianapolis, IN
- 1998 – Present Assoc. Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, IN

Other Experience and Professional Memberships

- 1995 to present Medical Director Newborn Follow-Up Program, Riley Hospital, Indianapolis, IN.
- 1997-2004 Board Member, Make-A-Wish Foundation of Indiana.
- 1998-2006 Board Member, Interagency Coordinating Council for Infants & Toddlers. Part C IDEA, State of Indiana.
- 2003 Member, Society for Pediatric Research.

Honors

- 1976 Pi Theta Epsilon Honor Society
- 1977 Delta Epsilon Sigma Honor Society
- 1977 Anne Mary McNally Scholarship Award
- 1997 Adjunct Assistant Professor of Speech and Hearing Sciences, Indiana University

B. Selected peer-reviewed publications (in chronological order). Do not include publications submitted or in preparation.

1. Browne SP, Tebbett IR, Moore CM, Dusick AM, Covert RF: Analysis of meconium for cocaine in neonates. *Journal of Chromatography: Biomedical Applications* 575:158-161, 1992.
2. Dusick AM, Covert RF, Schreiber MD, Yee GT, Browne SP, Moore CM, Tebbett IR: Risk of Intracranial hemorrhage and other adverse outcomes after cocaine. Exposure in a Cohort of 323 very low birth weight babies. *J Pediatr* 122: 438-45, 1993.
3. Browne S, Moore C, Negrusz A, Tebbett I, Covert R, Dusick AM: Detection of cocaine, norcocaine and cocaethylene in the meconium of premature neonates. *J Forensic Sci*, 39: 1515-19, 1994.
4. Dusick AM: Medical outcomes In Preterm Infants. *Seminar Perinatal* 21(3): 164-177, 1997.
5. Wheeler PG, Medina S, Dusick AM, Bull M, Andreoli SP, Edwards-Brown M, Weaver D: Livedo reticularis, developmental delay and stroke-like episode in a 7-year-old male. *Clinical Dysmorphology* 1998, 7:69-74.

6. Vohr BR, Wright LL, Dusick AM, Mele L et al. Neurodevelopmental and Functional Outcomes of Extremely Low Birthweight Infants in the National Institute of Child Health and Human Development Neonatal Research Network, 1993-1994. *Pediatr* 105(6): 1216-1226,2000
7. Barlow, S.M., Dusick, A., Finan, D.S., Biswas, A., Coltart, S., & Flaherty, K.J. (2000). Neurophysiological monitoring of the orofacial system in premature and term infants. *Journal Medical Speech-Language Pathology*, 8(4), 221-238.
9. Barlow SM, Dusick AM, Finan DS, Coltart S, Biswas A: Mechanically evoked perioral reflexes in Premature and term human infants. *Brain Research* 899: 251-254, 2001.
10. Dusick AM, Poindexter BP, Ehrenkranz RA, Lemons JA: Growth Failure in the Preterm Infant:Can We Catch Up? *Seminar Perinatol* 27(4), 302-310, 2003
11. Dusick AM: Investigation and Management of Dysphagia Seminars in *Pediatric Neurology* 10(4),255-264,2003
12. Vohr BR, Wright LL, Dusick AM, Perritt R, etal. Center Differences and Outcomes of Extremely Low Birth Weight Infants. *Pediatrics* 113 (4): 781-789, 2004.
13. Ohls RK, Ehrenkranz RA, Sas A, Dusick AM, etal. Neurodevelopmental Outcome and Growth at 18 to 22 Months Corrected Age in Extremely Low Birth Weight Infants Treated With Early Erythropoietin and Iron. *Pediatrics* 114(5):1287-1291, 2004
14. Ehrenkranz RA, Dusick AM, Vohr BR, Wright LL, Wrage LA, Poole WK. Growth in the neonatal intensive care unit influences neurodevelopmental and growth outcomes of extremely low birth weight infants. *Pediatrics* 2006 Apr;117 (4):1253-61.
15. Vohr BR, Poindexter BB, Dusick AM, McKinley LT, Wright LL, Langer JC, Poole WK; NICHD Neonatal Research Network. Beneficial effects of breast milk in the neonatal intensive care unit on the developmental outcome of extremely low birth weight infants at 18 months of age. *Pediatrics* 2006 Jul;118(1): e115-23.
16. Poindexter BB, Langer JC, Dusick AM, Ehrenkranz RA for the National Institute of Child Health and Human Development Neonatal Research Network. Early Provision of Parenteral Amino Acids in Extremely Low Birth Infants: Relation to Growth and Neurodevelopmental Outcome. *Pediatrics* 2006;118(3):300-313.
17. Hintz SR, Van Meurs KP, Perritt R, Poole WK, Das A, Stevenson DK, Ehrenkranz RA, Lemons JA, Vohr BR, Heyne R, Childers DO, Peralta-Carcelen M, Dusick A, Johnson YR, Morris B, Dillard R, Vaucher Y, Steichen J, Adams-Chapman I, Konduri G, Myers GJ, de Ungria M, Tyson JE, Higgins RD; NICHD Neonatal Research Network. Neurodevelopmental outcomes of premature infants with severe respiratory failure enrolled in a randomized controlled trial of inhaled nitric oxide. *J Pediatr*. 2007 Jul;151(1):16-22, 22.e1-3.
18. Vohr BR, Poindexter BB, Dusick AM, McKinley LT, Higgins RD, Langer JC, Poole WK; National Institute of Child Health and Human Development National Research Network. Persistent beneficial effects of breast milk ingested in the neonatal intensive care unit on outcomes of extremely low birth weight infants at 30 months of age. *Pediatrics* 2007 Oct;120(4):e953-9

C. Research Support. List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and your role (e.g. PI, Co-Investigator, Consultant) in the research project. Do not list award amounts or percent effort in projects.

Ongoing Research Support

UIO HD027856 - 13

NIH/NICHD

4/1/06 – 3/31/11

Cooperative Multicenter Neonatal Research Network: 18 Month Follow-Up Study of High Risk Infants, Role: PI for outcome studies with separate outcome protocols for the Neonatal Research Network at IU

MCH/Indiana State Department of Health

Federal I.D. # 35-600-1673

10/1/06 – 7/30/08

Title: Comprehensive Developmental Pediatric Care for Infants and Children with Special Health Care Needs

Role: PI and Clinical Director of the Newborn Follow-Up Program

Completed Research Support

3 M01 RRO0750 – 24S1

NIH M01 7/1/96 – 6/30/99

Mechanically Evoked Reflexes and Functional Oromotor Skill Acquisition in Preterm Infants

Role: Principle Investigator

RR – 99 – 008

NIH M01 7/1/00 – 6/2/02

Mechanically Evoked Reflexes and Functional Oromotor Skill Acquisition in Preterm Infants

Role: Principle Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME James A. Lemons, M.D.	POSITION TITLE Professor of Pediatrics		
eRA COMMONS USER NAME			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Princeton University, Princeton, NJ	B.A.	1965	
Northwestern Univ. Medical School, Chicago, IL	M.D.	1969	Medicine
Univ. of Michigan Medical School, Ann Arbor, MI	Intern	1970	Pediatrics
Univ. of Michigan Medical School, Ann Arbor, MI	Resident	1972	Pediatrics
Univ. of Michigan Medical School, Ann Arbor, MI	Fellow	1973	Reproductive Endo.
Univ. of Colorado Medical School, Denver, CO	Fellow	1975	Neonatal-Perinatal Med.

A. Positions and Honors

Positions and Employment

- 1987-present Director, Section of Neonatal-Perinatal Medicine, Department of Pediatrics, Indiana University School of Medicine
- 1988 present Hugh McK. Landon Professor of Pediatrics, Indiana University School of Medicine
- 2003-present Associate, Faculty of Indiana University Graduate School

Other Experience and Professional Memberships

- 1988-1994 Executive Committee, American Academy of Pediatrics Section on Perinatal Pediatrics
- 1991-2006 Principal Investigator, NICHD Neonatal Research Network, National Institutes of Health
- 1992-1994 Chair, Executive Committee, Section on Perinatal Pediatrics of the American Academy of Pediatrics
- 1993-1999 Member, Neonatal-Perinatal Medicine Sub-Board of the American Board of Pediatrics
- 1994-present Professor of Pediatrics, Moi University, Faculty of Health Sciences Eldoret, Kenya
- 1997-2001 Chair, Committee on Fetus and Newborn of American Academy of Pediatrics
- 1999-present Pregnancy Labeling Subcommittee of the Reproductive Health Drugs Advisory Committee, FDA
- 1999-2005 Task Force for Newborn Hearing Screening and Detection, American Academy of Pediatrics
- 2000-2003 Chair, Technical Action Group, Council on Committees, American Academy of Pediatrics
- 2000-2005 Joint Committee on Infant Hearing, American Academy of Pediatrics
- 2006-present Chair, NIH Global Network for Women's and Children's Health Research Study Group

Honors

- 1968 Alpha Omega Alpha
- 1975 Sigma Xi
- 1988 Edwin L. Gresham Award for Perinatal Service, American Academy of Pediatrics
- 1999 March of Dimes Health Leadership Award
- 1994 The Best Doctors in America
- 2002-2005 Inclusion In *America's Top Doctors (2nd Edition)* National Physician Guide
- 2002 Teaching Excellence Recognition Award, Indiana University
- 2005 Physician of the Year, March of Dimes, Indiana Chapter

B. Selected peer-reviewed publications (in chronological order) (Publications selected from more than 250 peer-reviewed publications)

1. Ward R, **Lemons J**, Molteni R. Cisapride: A survey of the frequency of use and adverse events in premature newborns. *Pediatrics*. 103(2):469-472, 1999.
2. Stevenson D.K., Verter J., Fanaroff A., Oh W., Herenkranz R.A., Shankaran S., Donovan E.F., Wright L., **Lemons J.A.**, Tyson J.E., Korones S.B., Baur C.R., Stoll B.J., Papile L-A. Sex differences in very low birthweight outcomes: The newborn male disadvantage. *Arch Dis Child*. 83:F182-F185, Nov 2000.
3. Walsh-Sukys MC, Fanaroff AA, Bauer CR, Korones SB, Stevenson DK, Tyson JE, Verter J, Wright LL, Stoll BJ, **Lemons JA**, Papile LA, Donovan EF, Shankaran S, Oh W, Ehrenkranz RA for the NICHD Neonatal Research Network. Persistent pulmonary hypertension of the newborn (PPHN) in the era before nitric oxide: practice variation and outcomes. *Pediatrics*. 105:14-20, 2000.
4. Reis B.B., Hall R.T., Schanler R.J., Berseth C.L., Chan G., Ernst J.A., **Lemons J.**, Adamkin D., Braggs G., O'Connor D. Enhanced Growth of Preterm Infants Fed a New Powdered Human Milk Fortifier: A Randomized Controlled Trial.. *Pediatrics* 106(3);581-588, Sept 2000.
5. **Lemons JA**, Bauer CR, Oh W, Korones SB, Papile L-A, Stoll BJ, Verter J, Temprosa M, Wright LL, Ehrenkranz RA, Fanaroff AA, Stark A, Waldemar C, Tyson JE, Donovan EF, Shankaran S, Stevenson DK. Very Low Birth Weight Outcomes of the National Institute of Child Health and Human Development Neonatal Research Network, January 1995 through December 1996. *Pediatrics*. 107(1): 1-8, Jan 2001.
6. Vohr BR, Oh W, Stewart EJ, Bentkover JD, Gabbard S, **Lemons J**, Papile L-A, Pye R. A Comparison of Costs and Referral Rates of Three Universal Newborn Hearing Screening Protocols. *J Pediatr*.139:238-44. Aug 2001.
7. Ohls RK, Ehrenkranz RA, Wright LL, **Lemons JA**, Korones SB, Stoll BJ, Stark AR, Shankaran S, Donovan EF, Close NC, Das A. Effects of Early Erythropoietin Therapy on the Transfusion Requirements of Preterm Infants Below 1250 Grams Birth Weight: A Multicenter, Randomized, Controlled Trial. *Pediatrics* 108(4):934-942, Oct 2001.
8. **Lemons J**, Fanaroff A, Stewart EJ, Bentkover JD, Murray G, Diefendorf A. Newborn Hearing Screening: Costs of Establishing a Program. *J Perinatol*. 22:120-124, 2002.
9. Farrell PA, Weiner GM, **Lemons JA**. SIDS, ALTE, Apnea, and the Use of Home Monitoring. *Pediatr in Rev*. 23:3-9, 2002.
10. Shankaran S, Fanaroff AA, Wright LL, Stevenson DK, Donovan EF, Ehrenkranz RA, Langer JC, Korones SB, Stoll, BJ, Tyson JE, Bauer CR, **Lemons, JA**, Oh W, Papile L-A. Risk factors for early death among extremely low-birth-weight infants. *Am J Obstet Gynecol* 186:796-802, 2002.
11. Stoll BJ, Hansen N, Fanaroff AA, Wright LL, Waldemar AC, Ehrenkranz RA, **Lemons JA**, Donovan EF, Stark AR, Tyson JE, Oh W, Bauer CR, Korones SB, Shankaran S, Laptook AR, Stevenson DK, Papile L-A, Poole WK. Late-Onset Sepsis in Very Low Birth Weight Neonates: The Experience of the NICHD Neonatal Research Network. *Pediatrics*.110:285-291, Aug 2002.
12. American Academy of Pediatrics & The American College of Obstetricians and Gynecologists. Guidelines for Perinatal Care, 5th Edition. **Lemons J** (ed). Oct 2002.
13. American Academy of Pediatrics & The American College of Obstetricians and Gynecologists. Neonatal Encephalopathy and Cerebral Palsy; Defining the Pathogenesis and Pathophysiology. **Lemons J** (ed). 2002.
14. Dusick A, Poindexter BB, Ehrenkranz RA, **Lemons JA**. Growth Failure in the Preterm Infant: Can We Catch Up? *Sem Perinatol*. 27:302-310, Aug 2003.
15. Stoll BJ, Hansen N, Fanaroff AA, Wright LL, Carlo WA, Ehrenkranz RA, **Lemons JA**, Donovan EF, Stark AR, Tyson JE, Oh W, Bauer CR, Korones SB, Shankaran S, Laptook AR, Stevenson DK, Papile L, Poole WK. To Tap or Not to Tap: High Likelihood of Meningitis Without Sepsis Among Very Low Birth Weight Infants. *Pediatrics* 113:1181-1186, May 2004.
16. Poindexter BB, Ehrenkranz RA, Stoll BJ, Wright LL, Poole WK, Oh W, Bauer CR, Papile L-A, Tyson JE, Waldemar AC, Laptook AR, Narendran V, Stevenson DK, Fanaroff AA, Korones SB, Shankaran S, Finer NN, **Lemons JA**. Parenteral Glutamine Supplementation Does Not Reduce the Risk of Mortality or Late-Onset Sepsis in Extremely Low Birth Weight Infants. *Pediatr* 113:1209-1215, May 2004.
17. Stoll BJ, Hansen N, Farnaroff AA, **Lemons JA** for the National Institute of Child Health and Human Development Neonatal Research Network. Enterobacter Sakazakii is a Rare Cause of Neonatal Septicemia or Meningitis in VLBW Infants. *J Pediatr* 144:821-823, Jun 2004.

C. Research Support

Ongoing Research Support

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Alternate Principal Investigator

6T79 MC 00010-12 1978–2008

U.S. Dept. of Health and Human Services

Maternal and Child Health Bureau Neonatal Nutrition Training Grant

Leadership Education Excellence in Pediatric Nutrition Program

The major goal of this project is to provide support for a minimum of four predoctoral fellowships to assist dietitians/ nutritionists in developing the clinical nutrition skills necessary for quality care of high-risk infants.

Role: Co-principal Investigator

Completed Research Support

NIH U10HD27856-10 (Lemons, PI) 4/01/01-3/31/06

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Principal Investigator

1U10EY12471-01S1 6/30/00-9/29/04

National Eye Institute

Early Treatment for Retinopathy of Prematurity

The major goal of this project is to investigate the value of treating retinopathy of prematurity earlier than usual, at a selected prethreshold level instead of at the threshold level.

Role: Principal Investigator

NIH M01-RR-750-19 1989 – 1999

NIH

Neonatal Scatterbed, General Clinical Research Center

Role: Co-Principal Investigator

NIH R01-14820 1981 - 1992

Fetal Amino Acid Metabolism and Gluconeogenesis

Role: Principal Investigator

NIH R01-HD-12476 1979 -1980

Composition of Breast Milk in Relation to Gestational Age

Role: Principal Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Gregory M. Sokol, M.D.		POSITION TITLE Associate Professor of Clinical Pediatrics	
eRA COMMONS USER NAME (b) (6)			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Washington & Jefferson College, Washington, PA	BA	1977-1981	Chemistry
National Institutes of Health's Foundation for Advanced Ed in the Sciences, Bethesda, MD	Non-Degree	1981-1982	Neurobiology and Neurochemistry
University of Pittsburgh School of Medicine, Pittsburgh, PA	M.D.	1982-1986	Medicine
Eastern Virginia Graduate School of Medicine, Norfolk, VA	Intern/Res	1986-1989	Pediatrics
Indiana University School of Medicine, Indianapolis, IN	Fellowship	1989-1992	Neonatal-Perinatal Med

D. Positions and Honors

Positions and Employment

- 1992-1999 Assistant Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, IN
- 1999-present Associate Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, IN

Other Experience and Professional Memberships

- 1992-present Physician Coordinator for the Neonatal Inhaled Nitric Oxide Therapy Program at James Whitcomb Riley Hospital for Children.
- 1992-present Fellow American Academy of Pediatrics
- 1992-present Indiana Neonatal Society
- 1992-present Perinatal Section of the American Academy of Pediatrics
- 1992-present Neonatal Resuscitation Program Regional Trainer, #1218480.
- 1993-2000 Protocol development subcommittee, Executive committee & Principal Investigator at Indiana University for the "Neonatal Inhaled Nitric Oxide Study" (NINOS) sponsored by the NICHD Neonatal Research Network & Canadian Inhaled Nitric Oxide Study Group
- 1996-present Indiana Chapter of AAP, Chairman Perinatal Committee
- 1996-2006 Protocol development subcommittee, Executive committee & Principal Investigator at Indiana University for the "Early inhaled nitric oxide study in term and near-term infants with respiratory failure," sponsored by the NICHD Neonatal Research Network & Canadian Inhaled Nitric Oxide Study Group.
- 1998-present: Alternate Principal Investigator at Indiana University Medical Center for the National Institute of Child Health & Human Development's Cooperative Neonatal Research Network Steering Committee.
- 2000-2007: Principal Investigator at Indiana University Medical Center for the "Inhaled nitric oxide for preterm infants with severe respiratory failure," sponsored by the NICHD Neonatal Research Network.
- 2003-present: Member - Society for Pediatric Research

- 2004-2007: Protocol development subcommittee & Principal Investigator at Indiana University for the "Inhaled PGE in term and near-term infants with respiratory failure," sponsored by the NICHD Neonatal Research Network.
- 2007-present: Institutional Review Board – Alternate, Indiana University-Purdue University in Indianapolis.

E. Selected peer-reviewed publications (in chronological order)

1. **Sokol, G.M.**, Liechty, E.A., and Boyle, D.W.: Comparison of steady-state diffusion and transit time ultrasonic measurements of umbilical blood flow in the chronic fetal sheep preparation. *Am J Obstet Gynecol* 1996;174:1456-60.
2. The Neonatal Inhaled Nitric Oxide Group. Inhaled nitric oxide in full-term and nearly full-term infants with hypoxic respiratory failure. *N Engl J Med* 1997;336:597-604.
3. The Neonatal Inhaled Nitric Oxide Group. Inhaled nitric oxide and hypoxic respiratory failure in infants with congenital diaphragmatic hernia. *Pediatrics* 1997;99:838-845.
4. **Sokol, G.M.**, Van Meurs, K.P., Thorn W.J., Rivera, O., Chu, P., Wright, L., Sams, R.L. Nitrogen dioxide formation during inhaled nitric oxide therapy. *Clinical Chemistry* 1999;45(3):382-387.
5. The Neonatal Inhaled Nitric Oxide Group. Inhaled nitric oxide in term and near term infants: Neurodevelopmental follow-up of the neonatal inhaled nitric oxide study group (NINOS). *J Pediatr* 2000;136:611-617.
6. **Sokol, G.M.**, Fineberg, N.S., Wright, L.L., Ehrenkranz, R.A. Changes in arterial oxygen tension when weaning neonates from inhaled nitric oxide. *Pediatric Pulmonology* 2001;32:14-19.
7. Konduri, G.G., Solimano, A., **Sokol, G.M.**, Singer, J., Ehrenkranz, R.A., et al. A Randomized trial of early versus standard inhaled nitric oxide therapy in term and near term newborn infants with hypoxic respiratory failure. *Pediatrics* 2004;113:559-564.
8. Van Meurs, K.P., Wright, L.L., Ehrenkranz, R.A., Lemons, J.A., et al. Inhaled nitric oxide for premature infants with severe respiratory failure. *N Engl J Med* 2005;353:13-22.
9. Konduri, G.G., Vohr, B., Robertson, C., **Sokol, G.M.**, et al. Early inhaled nitric oxide therapy for term and near-term newborn infants with hypoxic respiratory failure: neurodevelopmental follow-up. *J Pediatr* 2007;150:235-40.
10. Hintz, S.R., Van Meurs K.P., Perritt R, et al. Neurodevelopmental outcomes of premature infants with severe respiratory failure enrolled in a randomized controlled trial of inhaled nitric oxide. *J Pediatr* 2007;151:16-22.

F. Research Support

Ongoing Research Support

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Alternate Principal Investigator

Completed Research Support

NIH U10HD27856-10 (Lemons, PI) 4/01/01-3/31/06

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Alternate Principal Investigator

Poindexter, Brenda B.

**For New and Competing Applications (PHS 398) – DO NOT SUBMIT UNLESS REQUESTED
For Non-competing Progress Reports (PHS 2590) – Submit only Active Support for Key Personnel**

PHS 398/2590 OTHER SUPPORT

Provide active support for all key personnel. **Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included.

There is no "form page" for other support. Information on other support should be provided in the *format* shown below, using continuation pages as necessary. **Include the principal investigator's name at the top and number consecutively with the rest of the application.** The sample below is intended to provide guidance regarding the type and extent of information requested.

For instructions and information pertaining to the use of and policy for other support, see Other Support in the PHS 398 Part III, Policies, Assurances, Definitions, and Other Information.

Note effort devoted to projects must now be measured using person months. Indicate calendar, academic, and/or summer months associated with each project.

POINDEXTER, BRENDA

ACTIVE

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11 (b) (6) Calendar
NICHD Cooperative Multicenter Neonatal Research Network \$163,910

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Principal Investigator

NIH RO1HL054062 (Tepper, PI) 7/01/06-6/30/10 (b) (6) Calendar
Growth of Airways and Lung Parenchyma in Normal Infants \$275,000

The major goal of this project is to determine the relationship between parenchymal tissue and alveolar volume with normal lung growth early in life and to determine the pulmonary sequelae of premature birth and assess the effectiveness of early treatment strategies upon the pulmonary sequelae.

Role: Collaborator

NIH RO1NR08111 (Ellett, PI) 9/01/04-8/30/09
Gastric Tube Placement in Young Children

The major goals of this study are to test three methods of predicting the insertion distance for placing gastric tubes in young children and then three non-radiographic methods of determining the internal location of the tubes once placed.

Role: Co-investigator

NIH-NHLBI - RO1 (Abman,S., PI) 4/01/08-03/31/13
"Genetic Basis of Bronchopulmonary Dysplasia"

The major goals of this study are to examine the effect of different SNPs in endothelial cells on the development of bronchopulmonary dysplasia in human patients.

Role: Co-investigator

DUSICK, ANNA

ACTIVE

UIO HD027856 – 13 NIH/NICHD (Poindexter) 4/1/06 – 3/31/11 (b) (6) Calendar
\$163,910

Cooperative Multicenter Neonatal Research Network: 18 Month Follow-Up Study of High Risk Infants,

Poindexter, Brenda B.

Role: PI for outcome studies with separate outcome protocols for the Neonatal Research Network at IU

MCH/Indiana State Department of Health (Dusick) 10/1/06 – 7/30/08 (b) (6) Calendar
Federal I.D. # 35-600-1673 \$298,027
Title: Comprehensive Developmental Pediatric Care for Infants and Children with Special Health Care Needs
Role: PI and Clinical Director of the Newborn Follow-Up Program

LEMONS, JAMES A.

ACTIVE

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11 (b) (6) Calendar
NICHD Cooperative Multicenter Neonatal Research Network \$163,910
The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.
Role: Alternate Principal Investigator

6T79 MC 00010-12 (Lemons) 1978–2008 (b) (6) Calendar
U.S. Dept. of Health and Human Services
Maternal and Child Health Bureau Neonatal Nutrition Training Grant
Leadership Education Excellence in Pediatric Nutrition Program
The major goal of this project is to provide support for a minimum of four predoctoral fellowships to assist dietitians/ nutritionists in developing the clinical nutrition skills necessary for quality care of high-risk infants.
Role: Co-principal Investigator

SOKOL, G.

ACTIVE

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11 (b) (6) Calendar
NICHD Cooperative Multicenter Neonatal Research Network \$163,910
The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

GOLICHOWSKI, A.

ACTIVE

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11 (b) (6) Calendar
NICHD Cooperative Multicenter Neonatal Research Network \$163,910

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD027856-17	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Brenda Poindexter, MD, MS	FROM 04/01/08	THROUGH 03/31/09
APPLICANT ORGANIZATION Indiana University		
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	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
C. Select Agent Research	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
D. Multiple PI Leadership Plan	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> 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 reporting actual and targeted/planned enrollment for each active study in the Neonatal Research Network at the Indiana site are attached (see pages 25-40).

PROGRESS REPORT:

A. SPECIFIC AIMS

The NICHD Neonatal Research Network is a cooperative group of 16 academic centers whose principal aim is to perform multicenter randomized clinical trials to evaluate the safety and efficacy of treatment and management strategies for newborn infants, particularly those related to very low birth weight, prematurity, and common neonatal medical problems. The Steering Committee has worked diligently over the years, as the Network has grown, to create an organizational structure that permits timely evaluation of important clinical questions in the rapidly changing field of neonatology. The generic database and the follow-up study enable investigators to obtain information on a large cohort of premature infants regarding short- and long-term morbidities, differences in outcomes between centers and between different populations of infants, and variations in clinical practice related to outcomes.

Since 1991, Indiana has made substantial contributions to the Neonatal Research Network because of the large patient population, strong faculty, basic and clinical research experience, state-of-the-art clinical and research facilities, and excellent research support staff. At the time of the competitive renewal in April, 2006, Dr. Brenda Poindexter assumed the role of Principal Investigator for the Indiana site. Drs. James Lemons and Greg Sokol remain actively involved in all aspects of Network activities at Indiana as the alternate PIs and Dr. Anna Dusick continues in her role as follow-up PI.

B. STUDIES AND RESULTS:

This year marked the 17th year of participation in the NICHD Neonatal Research Network for Indiana University. The following studies are currently active; IRB protocol numbers and the dates of the most recent approval are listed below. Unless otherwise noted, all approvals are for 12 months.

Protocol #	Protocol Name	Approval Dt
9612-02	Generic Database-Survey of Morbidity and Mortality Among Very Low Birth Weight Infants 401-1500 Grams	01/15/08
0601-88	Early Onset Sepsis - A NICHD/CDC Surveillance Study	03/06/07
9412-30	Follow-Up of Premature Infants With Birthweight Less Than 1000 Grams at 18 (+4) Months of Age and/or 30 (+,- 2) Months of Age (Corrected for Gestation)	03/15/07
0412-26	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	10/03/07
0609-37	Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT	08/22/07
0606-41	NICHD SUPPORT Trial-Breathing Outcomes	06/07/07
0609-36	Phase II Randomized, Double Blind, Placebo Controlled, Safety and Pharmacokinetic Study of a Single Dose of Inositol in Premature Infants	08/22/07
0612-08	Extended Follow-up of the Hypothermia Trial Subjects	11/13/07
0410-30	Association of Apolipoprotein E (apo E) genotype with brain injury and neurodevelopmental outcome in infants with hypoxic ischemic encephalopathy	07/25/07
0204-22	A Randomized Trial of Aggressive or Conservative Phototherapy for Extremely Low Birth Weight Infants	10/18/07
0401-53	Neurodiagnostic Evaluations That Assist in the Predication of Adverse Outcome Following Acute Perinatal Asphyxia	10/16/07
0401-55	Early Diagnosis of Nosocomial Candidiasis	08/23/07
0506-75	Blood Inositol Status Among Neonates in 2005	05/07/07

Observational Studies:

The Generic Database (GDB) has provided for the collection of comprehensive data on very low-birth-weight (VLBW) infants which are used to monitor trends in morbidity and mortality associated with prematurity, to conduct observational studies, and to generate hypotheses for randomized clinical trials. The Indiana Network site enrolled 286 infants in the GDB in 2007 (8.1% of the total infants enrolled in all Network centers).

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

The Early Onset Sepsis (EOS) Surveillance Study is co-funded by the CDC. The objective is to determine the incidence of early-onset sepsis and the pathogens responsible for EOS since the implementation of universal screening and prophylaxis of group B streptococcus in pregnant women. This important study extends data collection to newborns of all birthweights. A total of 24 infants from Indiana were enrolled in this study in 2007 (38 total since the study began). A secondary study to evaluate neurodevelopment at 18 months in infants with early onset sepsis and/or meningitis identified through the EOS Surveillance study is currently under consideration.

The Network Follow-Up study evaluates neurodevelopmental outcomes of premature infants with birthweight less than 1000 grams at 18 months corrected age. In addition to providing important information to the neonatal community, neurodevelopmental outcomes are increasingly becoming one of the primary or secondary outcome measures of many of the Network clinical trials. Indiana has consistently maintained an excellent rate of follow-up for this important longitudinal study, with 83% of eligible ELBW infants completing the 18-month follow-up study visit in 2007.

Clinical Trials:

The Surfactant Positive Airway Pressure and Pulse Oximetry (SUPPORT) trial is ongoing. The objectives of the SUPPORT trial are 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 to determine whether management of infants with a lower SpO₂ range (85-89%) compared to a higher SpO₂ range (91-95%) will result in increased survival without the occurrence of threshold retinopathy of prematurity. In addition to the main trial, Indiana is actively enrolling subjects in the following secondary studies: growth, MRI neuroimaging and neurodevelopmental outcome, and the breathing outcomes study. In 2007, a total of 31 infants were randomized in the SUPPORT trial at Indiana (55 total since the trial began in 2005).

The Phase II Randomized, Double Blind, Placebo Controlled, Safety and Pharmacokinetic Study of a Single Dose of Inositol in Premature Infants study recently completed enrollment. Indiana enrolled a total of 5 infants in this important pilot study. Pending analysis of the results, a dose will be determined for Inositol multidose randomized clinical trial. Dr. Poindexter serves as a member of the Inositol subcommittee and Leslie Dawn Wilson has played an instrumental role in developing the toxicity tables that will be used to define adverse events in the multidose study.

The Extended Follow-up of the Hypothermia Trial Subjects study is ongoing. Neurodevelopmental assessments between 6 to 7 years of age are planned when study participants enter the follow-up window.

The Association of Apolipoprotein E (apo E) genotype with brain injury and neurodevelopmental outcome in infants with hypoxic ischemic encephalopathy study is ongoing: 3 infants have been enrolled in the study at Indiana.

Completed Studies:

During the past year, several studies have been completed and are now closed to enrollment. The studies remain open with the IUPUI/Clarian IRB due to the fact that data analysis and manuscript preparation for these studies is ongoing. Studies now closed to enrollment include the following 4 studies:

- A Randomized Trial of Aggressive or Conservative Phototherapy for Extremely Low Birth Weight Infants
- Neurodiagnostic Evaluations that assist in the Prediction of Adverse Outcome following Acute Perinatal Asphyxia

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

- Early Diagnosis of Nosocomial Candidiasis
- Blood Inositol Status Among Neonates in 2005

Genomics Studies:

A protocol entitled, "Association of Genetic Polymorphisms of Vascular Endothelial Growth Factor (VEGF), Endothelial Nitric Oxide Synthase (eNOS), and Extracellular Superoxide Dismutase (EC-SOD) with Bronchopulmonary Dysplasia" has been approved by the Network genomics subcommittee as well as the NRN Steering Committee. This protocol was written by Dr. Rebecca Rose, a neonatology fellow at Indiana University who is mentored by Dr. Poindexter and will utilize samples collected in the NRN retrospective DNA repository. In this case-control study we will analyze the relationship between BPD and specific polymorphisms of *VEGF*, *eNOS* and *EC-SOD*. Identification of such a relationship could provide a biomarker that would potentially identify infants more likely to develop BPD so that more aggressive treatment could be initiated. In addition, the elucidation of the pathways and genetic variants increasing the risk for BPD could result in the development of novel therapies for this common morbidity associated with premature birth.

Trials in Design:

The following studies are being actively planned by the Neonatal Research Network:

- Multidose study of Inositol in Premature infants
- Probiotics for the Prevention of Necrotizing Enterocolitis
- Evaluation of Systemic Hypothermia Initiated after 6 Hours of Age in Infants \geq 36 weeks gestation with Hypoxic-Ischemic Encephalopathy: A Bayesian Evaluation
- Surgical management of Necrotizing Enterocolitis

Subcommittee Membership:

Dr. Poindexter is currently an active member of the following Network subcommittees:

- Protocol review (Vice-Chair)
- Early Onset Sepsis Surveillance
- Inositol
- Probiotics
- Surgical management of Necrotizing Enterocolitis – laparotomy vs. drain

C. SIGNIFICANCE

Each of the Neonatal Research Network studies contribute to the evidence needed to support and/or change clinical practice in the field of Neonatology. Indiana University contributed to the following Year 17 publications and abstracts:

2007 Publications:

1. Ahlfors, CE, Vreman, HJ, Wong, RJ, Bender, J, Oh, W, Morris, BH, Stevenson, DK and the Phototherapy Subcommittee on behalf of the NICHD Research Network. Effects of sample dilution, peroxidase concentration, and chloride ion on the measurement of unbound bilirubin in premature newborns. *Clin Biochem.* 2007 Feb;40(3-4):261-7.
2. Bender, J, Cashore, WJ, Oh, W. Ontogeny of Bilirubin Binding Capacity and the Effect of Clinical Status in Very Low Birth Weight Infants. *Pediatrics* 2007 Nov;120(5):1067-73.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

3. Broitman, E, Ambalavanan, N, Higgins, R, Vohr, B, Abhik Das, A, Brinda Bhaskar, B Murray, K, Susan Hintz, SR, Carlo, CA for the National Institute of Child Health and Human Development Neonatal Research Network. Clinical data predict neurodevelopmental outcome better than head ultrasound in extremely low birth weight infants. *J Pediatr.* 2007 Nov;151(5):500-5.
4. Clyman RI, Saha S, Jobe A, Oh W. Indomethacin prophylaxis for preterm infants: the impact of 2 multicentered randomized controlled trials on clinical practice. *Pediatrics* 2007 Jan;150(1):46-50.e2
5. Fanaroff AA, Stoll BJ, Wright LL, Carlo WA, Ehrenkranz RA, Stark A, Bauer CR, Donovan EF, Korones SB, Laptook A, Lemons JA, Oh W, Papile L, Shankaran S, Stevenson DK, Tyson JE, Poole WK. Trends in neonatal morbidity and mortality for very low birthweight infants. *Am J OB GYN* 2007 Feb;196(2):147.e1-8.
6. Heller, CD, Yao, Q, Langer, L, Ehrenkranz, RA, Phelps, DL, Poole, WK, Stoll, BJ, Duara, S, Oh, W, Lemons, J, Poindexter, B, For the NICHD Neonatal Research Network. Human Milk Intake and Retinopathy of Prematurity in Extremely Low Birth Weight Infants. *Pediatrics* 2007 Jul;120(1):1-9.
7. Hintz SR, Van Meurs KP, Perritt R, Poole WK, Das A, Stevenson DK, Ehrenkranz RA, Lemons JA, Vohr BR, Heyne R, Childers DO, Peralta-Carcelen M, Dusick A, Johnson YR, Morris B, Dillard R, Vaucher Y, Steichen J, Adams-Chapman I, Konduri G, Myers GJ, de Ungria M, Tyson JE, Higgins RD; NICHD Neonatal Research Network. Neurodevelopmental outcomes of premature infants with severe respiratory failure enrolled in a randomized controlled trial of inhaled nitric oxide. *J Pediatr.* 2007 Jul;151(1):16-22, 22.e1-3
8. Konduri, GG., Vohr, B, Robertson, C, Sokol, GM, Solimano, Singer, AJ, Ehrenkranz, RA, Singhal, N, Wright, LL, Van Meurs, K, Stork, E, Kirpalani, H, Peliowski, A, for the Neonatal Inhaled Nitric Oxide Study Group. Early Inhaled Nitric Oxide Therapy for Term and Near Term Newborn Infants with Hypoxic Respiratory Failure: Neurodevelopmental Follow-up. *The Journal of Pediatrics* 2007 Mar;150(3):235-40, 240.e1
9. Laptook AR, Salhab W, Bhaskar B. Admission temperature of low birth weight infants: predictors and associated morbidities. *The Journal of Pediatrics* 2007 Mar;119(3):e643-9.
10. Wadhawan, R, Fanaroff, AA, Perritt, R, Duara, S, Stoll, BJ, Goldberg, R, Laptook, A, Poole, WK, Wright, LL and Oh, W. Early postnatal weight loss is associated with decreased risk of bronchopulmonary dysplasia or death in very low birth weight infants. *J Perinatol.* 2007 Jun;27(6):359-64.
11. Walsh, MC, Laptook, AR, Kazzi, SN, Engle, WA, Yao, Q, Rasmussen, M, Buchter, S, Heldt, G, Rhine, W, Higgins, RD, for the NICHD Neonatal Research Network. A Cluster Randomized Trial of Benchmarking and Multimodal Quality Improvement To Improve Survival Free of Bronchopulmonary Dysplasia in Infants < 1250 grams Birthweight. *Pediatrics.* 2007 May;119(5):876-90.

2007 Abstracts:

1. Ambalavanan, N. for the NICHD Neonatal Research Network. Cytokines Associated with BPD/Death in Extremely Low Birth Weight Infants: A Role for T-Lymphocytes? (Presented, to the Society for Pediatric Research, Toronto, Canada, May 5-8, 2007)
2. Bhandari, V., Finer, N.N., Ehrenkranz, R.A. for the NICHD Neonatal Research Network. Use of Nasal Ventilation (NV) Is Associated with Significantly Decreased Bronchopulmonary Dyplasia (BPD) and/or Death in Babies of 500-750 Grams Birth Weight (BW). (Presented, to the Society for Pediatric Research, Toronto, Canada, May 5-8, 2007)
3. Carlo, W.A., Schendel, D., Thorsen, P. for the NICHD Neonatal Research Network. Inflammatory Cytokines and Neurodevelopmental Outcomes in Extremely Low Birth Weight Infants. (Presented, to the Society for Pediatric Research, Toronto, Canada, May 5-8, 2007)
4. Cotten, C.M. for the NICHD Neonatal Research Network. Duration of Initial Antibiotic Course in Extremely Low Birthweight Infants: Association with Necrotizing Enterocolitis and Death. (Presented, to the Society for Pediatric Research, Toronto, Canada, May 5-8, 2007)

Principal Investigator/Program Director (Last, First, Middle): **Poindexter, Brenda Louise Bradley**

5. Ehrenkranz, R.A. for the NICDH Neonatal Research Network. Early Nutritional Support for ELBW Infants: Influence of Severity of Illness. (Presented, to the Society for Pediatric Research, Toronto, Canada, May 5-8, 2007) Gaskins, R.B., LaGasse, L.L., Liu, J., Lester, B.M., Shankaran, S., Bada, H., Bauer, C.R., Das, A., & Higgins,
6. Kwon, J.M., Guillet R. for the NICHD Neonatal Research Network. Clinical Neonatal Seizures Have No Independent Effect on Outcomes in the NRN Systemic Hypothermia Trial (Presented, to the Society for Pediatric Research, Toronto, Canada, May 5-8, 2007)
7. Madan, J., Frantz, I.D. for the NICHD Neonatal Research Network. PDA Treatment and NDI/Death, NEC and BPD. (Presented, to the Society for Pediatric Research, Toronto, Canada, May 5-8, 2007)
8. Oh, W. for the NICHD Neonatal Research Network. Urinary Lactate to Creatinine Ratio (ULCR) in Full Term Infants with Hypoxic Ischemic Encephalopathy: (HIE): Predictor of Neuro-Developmental Outcome Following Whole Body Cooling. (Presented, to the Society for Pediatric Research, Toronto, Canada, May 5-8, 2007)
9. Pappas, A., Shankaran, S. for the NICHD Neonatal Research Network. Early Hypocarbica Following Hypoxic-Ischemic Encephalopathy (HIE) Is Associated with an Increased Risk of Poor Outcome. (Presented, to the Society for Pediatric Research, Toronto, Canada, May 5-8, 2007)
10. Phelps, D. Ward, R. for the NICHD Network Research Network. Inositol Blood Levels in Preterm and Term Neonates. (Presented, to the Society for Pediatric Research, Toronto, Canada, May 5-8, 2007)
11. Shankaran, S. for the Neonatal Research Network. NICHD Neonatal Research Network Cumulative Index of Exposure to Hypocarbica and Hyperoxia as Risk Factors for Poor Neurodevelopmental Outcome in Low Birth Weight (LBW) Infants. (Presented, to the Society for Pediatric Research, Toronto, Canada, May 5-8, 2007)
12. Shankaran, S. for the Neonatal Research Network. Secondary Safety Outcomes in a Multicenter Randomized Controlled Trial of Whole Body Hypothermia for Neonatal Hypoxic Ischemic Encephalopathy. (Presented, to the Society for Pediatric Research, Toronto, Canada, May 5-8, 2007)

In summary, Indiana University has continued to be a productive member of the Neonatal Research Network, contributing significantly to all trials. We look forward to contributing to the improvement of neonatal outcomes through our participation in this important Network.

GRANT NUMBER
HD027856-17

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).

Budget Period	Anticipated Amount	Source(s)
NA	\$0	NA

2. ASSURANCES/CERTIFICATIONS (See instructions.)

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

• 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.

3. FACILITIES AND ADMINISTRATIVE (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.

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: 5-14-04 No Facilities and Administrative Costs Requested.

No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base \$ 196,839 x Rate applied 51.50 % = F&A costs \$ 101,372

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

Salary and wages base Modified total direct cost base Other base (Explain)

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

Explanation (Attach separate sheet, if necessary.):

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

KEY PERSONNEL REPORT

GRANT NUMBER
HD027856-17

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

All Key Personnel for the Current Budget Period (do not include Other Significant Contributors)

Name	Degree(s)	SSN (last 4 digits)	Role on Project (e.g. PI, Res. Assoc.)	Date of Birth (MM/DD/YY)	Months Devoted to Project		
					Cal	Acad	Sum
Brenda Poindexter	MD, MS	(b) (6)	PI	(b) (6)	(b) (6)		
Anna Dusick	MD	████	Follow-Up PI	████	████		
James Lemons	MD	████	Alternate PI	████	████		
Greg Sokol	MD	████	Alternate PI	████	████		
Leslie Dawn Wilson	RN, BSN	████	Research Coord.	████	████		
Dianne Herron	RN	████	Data Entry Manager	████	████		
Alan Golichowski	MD, PhD	████	Perinatal Collaborator	████	████		

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Targeted/Planned Enrollment Table

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

Study Title: Multidose study of Inositol in Premature infants

Total Planned Enrollment: 15

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	1		1
Not Hispanic or Latino	7	7	14
Ethnic Category: Total of All Subjects *	8	7	15
Racial Categories			
American Indian/Alaska Native			
Asian	1	0	1
Native Hawaiian or Other Pacific Islander			
Black or African American	2	1	3
White	5	5	10
Racial Categories: Total of All Subjects *	8	6	14

* 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): Poindexter, Brenda Louise Bradley

Targeted/Planned Enrollment Table

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

Evaluation of Systemic Hypothermia Initiated after 6 Hours of Age in Infants \geq 36 weeks
Study Title: gestation with Hypoxic-Ischemic Encephalopathy: A Bayesian Evaluation

Total Planned Enrollment: 12

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	1		1
Not Hispanic or Latino	5	6	11
Ethnic Category: Total of All Subjects *	6	6	12
Racial Categories			
American Indian/Alaska Native			
Asian	0	1	1
Native Hawaiian or Other Pacific Islander			
Black or African American	2	2	4
White	4	2	6
Racial Categories: Total of All Subjects *	6	5	11

* 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): Poindexter, Brenda Louise Bradley

Targeted/Planned Enrollment Table

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

Study Title: Surgical management of Necrotizing Enterocolitis

Total Planned Enrollment: 30

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	1	1	2
Not Hispanic or Latino	14	14	28
Ethnic Category: Total of All Subjects *	15	15	30
Racial Categories			
American Indian/Alaska Native			
Asian	1	1	2
Native Hawaiian or Other Pacific Islander			
Black or African American	4	3	7
White	9	10	19
Racial Categories: Total of All Subjects *	14	14	28

* 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): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Generic Database - Survey of Morbidity and Mortality Among VLBW Infants 401-1500 g
Total Enrollment: 316 **Protocol Number:** 9612-02
Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	12	17	0	29 **
Not Hispanic or Latino	139	148	0	287
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	151	165	0	316 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	1	5	0	6
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	48	54	0	102
White	101	106	0	207
More Than One Race	1	0	0	1
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	151	165	0	316 *
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	12	17	0	29
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	12	17	0	29 **

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

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Early Diagnosis of Nosocomial Candidiasis
Total Enrollment: 36 **Protocol Number:** 0401-55
Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	2	0	0	2 **
Not Hispanic or Latino	18	16	0	34
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	20	16	0	36 *
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	20	14	0	34
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	20	16	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	2	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**	2	0	0	2 **

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

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Neurodiagnostic Evaluations that assist in the Prediction of Adverse Outcome
Total Enrollment: 8 **Protocol Number:** 0401-53
Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	3	5	0	8
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	3	5	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	1	0	2
White	2	4	0	6
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	3	5	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	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): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Early Onset Sepsis - A NICHD/CDC Surveillance Study
 Total Enrollment: 38 Protocol Number: 0601-88
 Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	3	0	3 **
Not Hispanic or Latino	20	15	0	35
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	20	18	0	38 *
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	7	0	16
White	10	11	0	21
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	20	18	0	38 *
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.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: SUPPORT
 Total Enrollment: 55 Protocol Number: 0412-26
 Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	1	1	0	2 **
Not Hispanic or Latino	26	27	0	53
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	27	28	0	55 *
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	7	0	11
White	23	21	0	44
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	27	28	0	55 *
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	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.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: A Randomized Trial of Aggressive or Conservative Phototherapy for Extremely Low Birth Weight Infants

Total Enrollment: 149 Protocol Number: 0204-22

Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	2	4	0	6 **
Not Hispanic or Latino	65	78	0	143
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	67	82	0	149 *
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	19	25	0	44
White	48	57	0	44
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	67	82	0	149 *
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	4	0	6
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	2	4	0	6 **

* These totals must agree.

** These totals must agree.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Follow-Up of Premature Infants With Birthweight Less Than 1000 Grams at 18 (+4) Months of Age and/or 30 (+,-2) Months of Age (Corrected for Gestation)

Total Enrollment: 945 **Protocol Number:** 0914-30

Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	19	19	0	38 **
Not Hispanic or Latino	457	450	0	907
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	476	469	0	945 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	2	3	0	5
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	135	111	0	246
White	339	355	0	694
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	476	469	0	945 *
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	19	19	0	38
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	19	19	0	38 **

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

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

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 SUPPORT
 Total Enrollment: 10 Protocol Number: 0609-37
 Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	5	5	0	10
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	5	5	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	2	0	2
White	5	3	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	5	0	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	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): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Association of Apolipoprotein E (apo E) genotype with brain injury and neurodevelopmental outcome in infants with hypoxic ischemic encephalopathy
Total Enrollment: 3 **Protocol Number:** 0410-30
Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	3	0	3
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	0	3	0	3 *
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	3	0	3
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	0	3	0	3 *
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): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: NICHD SUPPORT Trial-Breathing Outcomes
 Total Enrollment: 13 Protocol Number: 0606-41
 Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	9	4	0	13
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	9	4	0	13 *
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	8	4	0	12
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	9	4	0	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	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 **

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Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Extended Follow-up of the Hypothermia Trial Subjects
 Total Enrollment: 0 Protocol Number: 0612-08
 Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	0	0	0	0
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	0	0	0	0
Racial Categories: Total of All Subjects*	0	0	0	0 *
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): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Phase II Randomized, Double Blind, Placebo Controlled, Safety and Pharmacokinetic Study of a Single Dose of Inositol in Premature Infants
Total Enrollment: 5 **Protocol Number:** 0609-36
Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	1	4	0	5
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	1	4	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	1	1	0	2
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 All Subjects*	1	4	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	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): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Blood Inositol Status Among Neonates in 2005
Total Enrollment: 7 **Protocol Number:** 0506-75
Grant Number: HD027856-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	1	6	0	7
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	1	6	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	0	0	0	0
White	1	6	0	7
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	1	6	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.

Progress Report Scanning Cover Sheet

5U10HD027856-17

PI Name: **POINDEXTER, BRENDA**
Org: **INDIANA UNIV-PURDUE UNIV AT
INDIANAPOLIS**
Start Date: **04/01/2007**
Snap: **N/A (NEEDS TO BE BOOKMARKED)**
AppI ID: **7219963**
Rec'd
Date: **02/05/2007**

Department of Health and Human Services
Public Health Services

Review Group	Type	Activity	Grant Number
	2.5	U10	HD027856-1817
Total Project Period			
From: 04/01/2006		Through: 03/31/2011	
Requested Budget Period:			
From: 04/01/2007		Through: 03/31/2008	

Grant Progress Report

1. TITLE OF PROJECT

NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR

(Name and address, street, city, state, zip code)

Brenda Poindexter, MD, MS
Neonatal/Perinatal Medicine
Department of Pediatrics
699 West Drive, RR208
Indianapolis, IN 46202-5119

3. APPLICANT ORGANIZATION

(Name and address, street, city, state, zip code)

The Trustees of Indiana University
Sponsored Research Services
620 Union Drive Room 618
Indianapolis IN 46202-5167

2b. E-MAIL ADDRESS

bpoindex@iupui.edu

4. ENTITY IDENTIFICATION NUMBER

1-35-6001673-A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT

Department of Pediatrics

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL

Executive Director

2d. MAJOR SUBDIVISION

School of Medicine

Indiana University

Sponsored Research Services
620 Union Drive, Room 618
Indianapolis, IN 46202-5167
E-MAIL: spon2@iupui.edu

6. HUMAN SUBJECTS

No

6a. Research Exempt

Yes

No Yes

6b. Human Subjects Assurance No.

FWA00003566

No

Yes

7a. If "Yes," IACUC approval Date

If Exempt ("Yes" in 6a):

Exemption No.

6c. NIH-Defined Phase III

Clinical Trial No Yes

7b. Animal Welfare Assurance No.

If Not Exempt ("No" in 6a):

IRB approval date see p 16-17

Full IRB or
 Expedited Review

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT \$

198,008

8b. TOTAL \$

286,715

9. INVENTIONS AND PATENTS

No

Yes If "Yes,"

Previously Reported

Not Previously Reported

10. PERFORMANCE SITE(S) (Organizations and addresses)

Riley Hospital for Children
Indiana University Hospital
Methodist Hospital
Wishard Memorial Hospital

All located in Indianapolis, Indiana

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a)

Brenda Poindexter, MD, MS

TEL (317) 274-4920

FAX (317) 274-2065

11b. ADMINISTRATIVE OFFICIAL NAME (Item 5)

W.S. Johnson

TEL (317) 278-3473

FAX (317) 274-8744

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)

NAME Janice C. Froehlich, Ph.D.

TITLE Interim Vice Chancellor for Research

TEL (317) 278-3473

FAX (317) 274-8744

E-MAIL spon2@iupui.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 Service 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.)

Janice C. Froehlich

DATE

1-31-07

FEB 05 2007

Poindexter, Brenda Louise Bradley

DETAILED BUDGET FOR NEXT BUDGET PERIOD -- DIRECT COSTS ONLY		FROM			THROUGH	GRANT NUMBER	
		04/01/07			03/31/08	HD027856-16	
PERSONNEL (Applicant organization only)		Months Devoted to Project			DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Sum. Mnths	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Brenda Poindexter	Principal Investigator	(b) (6)			9,000	2,921	11,921
Anna Dusick	Follow-Up PI				3,000	974	3,974
Leslie Dawn Wilson	Research Coordinator				87,550	28,410	115,960
To Be Named	Data Entry Manager				15,600	1,101	16,701
James Lemons	Alternate PI				0	0	0
Greg Sokol	Alternate PI				0	0	0
Alan Golichowski	Perinatal Collaborator				0	0	0
SUBTOTALS					115,150	33,406	148,556
CONSULTANT COSTS							0
EQUIPMENT (Itemize)							0
SUPPLIES (Itemize by category)							
Project specific supplies for data collection as specified in protocols						5,150	5,150
TRAVEL							
Travel to Washington, DC for PI and Coordinator (10 trips annually)						15,450	15,450
PATIENT CARE COSTS		INPATIENT				0	0
		OUTPATIENT				0	0
ALTERATIONS AND RENOVATIONS (Itemize by category)							0
OTHER EXPENSES (Itemize by category)							
Printing, duplicating, postage and long-distance telephone calls						3,090	3,090
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD							\$ 172,246
CONSORTIUM/CONTRACTUAL COSTS		DIRECT COSTS		UPA Subcontract		25,762	25,762
		FACILITIES AND ADMINISTRATION COSTS				0	0
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD (Item 8a, Face Page)							\$ 198,008

DETAILED BUDGET FOR NEXT BUDGET PERIOD -- DIRECT COSTS ONLY		FROM 04/01/07			THROUGH 03/31/08		GRANT NUMBER HD027856-16	
PERSONNEL (Applicant organization only)		Months Devoted to Project			DOLLAR AMOUNT REQUESTED (omit cents)			
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Sum. Mnths	SALARY REQUESTED	FRINGE BENEFITS	TOTALS	
Brenda Poindexter	Principal Investigator	(b) (6)			18,525	2,084	20,609	
Anna Dusick	Follow-Up PI	(b) (6)			4,632	521	5,153	
SUBTOTALS →					23,157	2,605	25,762	
CONSULTANT COSTS								0
EQUIPMENT (Itemize)								0
SUPPLIES (Itemize by category)								0
TRAVEL								0
PATIENT CARE COSTS		INPATIENT						0
		OUTPATIENT						0
ALTERATIONS AND RENOVATIONS (Itemize by category)								0
OTHER EXPENSES (Itemize by category)								0
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD							\$	25,762
CONSORTIUM/CONTRACTUAL COSTS		DIRECT COSTS			0	0		
		FACILITIES AND ADMINISTRATION COSTS			0	0		
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD (Item 8a, Face Page)							\$	25,762

BUDGET JUSTIFICATION

GRANT NUMBER
 HD027856-16

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

In the original application, funding was requested for (b) (6) of time and effort for the PI (Dr. Brenda Poindexter) and (b) (6) of time and effort for the alternate PI (Dr. James Lemons). As the PI spends considerably more than (b) (6) of her time in that role, we are requesting that funding for her time and effort be increased to (b) (6). To offset this request, no funding will be requested for the alternate PI. However, Dr. Lemons will continue to dedicate (b) (6) time and effort toward grant activities. Funding for time and effort of the follow-up PI (Dr. Anna Dusick) remains unchanged at (b) (6) FTE. Consequently, the total percent effort for faculty salary support at Indiana remains unchanged at (b) (6). As faculty in the Department of Pediatrics at Indiana University, the PI and Follow-up PI receive their salary support from two sources. The first source is from Indiana University as represented in the budget under Personnel. The second source is from a third party, non-profit corporation, University Pediatric Associates (UPA), whose mission is to support the instruction, research, and public service missions of Indiana University. This portion of salary compensation is represented in the budget under Consortium/Contractual Costs as a subcontract with UPA. It is certified that the two sources of income comprise a single compensation package for these faculty. Leslie Dawn Wilson was recently hired as the new full-time research coordinator for Indiana. The increase in salary requested for this position reflects that which was necessary to recruit her to the position given her level of expertise and experience. We are in the process of hiring a new data entry manager.

CURRENT BUDGET PERIOD	FROM	THROUGH
	04/01/2006	03/31/2007

Explain any estimated unobligated balance (including prior year carryover) that is greater than 25% of the current year's total budget.

There will be no carryover in the base grant award. However, we anticipate that there will be an unobligated balance in excess of 25% in the capitated portion of the current budget period. The final amount will be submitted in the Fall of 2007 when the NIH grants management office calculates the capitation offset report; the carryover request will be submitted at that time.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
 Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Brenda Louise Bradley Poindexter, M.D., M.S.	POSITION TITLE Associate Professor of Clinical Pediatrics		
eRA COMMONS USER NAME (b) (6)			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Milligan College, Johnson City, TN	B.S.	1986	Biology
Medical College of Ohio, Toledo, OH	M.D.	1990	Medicine
Cincinnati Children's Hospital Medical Center	Residency	1993	Pediatrics
Indiana University School of Medicine	Fellowship	1997	Neonatology
Indiana University-Purdue University	M.S.	2004	Clinical Research

A. Positions and Honors

Positions and Employment

1990-1993 Pediatric Internship and Residency, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio

1993-1994 Staff Physician, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio

1994-1997 Neonatal-Perinatal Medicine Fellowship, Indiana University School of Medicine, Indianapolis, Indiana

1997-1998 Lecturer, Department of Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana

1998-2006 Assistant Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana

2006-present Associate Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana

Other Experience and Professional Memberships

1998 Fellow, American Academy of Pediatrics

1999-present Nutritional Support Team, Clarian Health Partners, Indianapolis, Indiana

1999-present Member, Institutional Review Board, Indiana University-Purdue University Indianapolis

2000-2006 Alternate Principal Investigator, NICHD Neonatal Research Network

2001 Member, Society for Pediatric Research

2002 Member, Midwest Society for Pediatric Research

2003-present Council Member, Midwest Society for Pediatric Research

2004-present Institutional Review Board Executive Committee, Indiana University-Purdue University Indianapolis

2005-present Annual Scholar's Day Committee, Department of Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana

2005-present Director of Clinical Research, Section of Neonatal-Perinatal Medicine, Indiana University School of Medicine, Indianapolis, Indiana

2006-present Principal Investigator, NICHD Neonatal Research Network

Honors

1990 Alpha Omega Alpha

1990 Marian C. Regent Award in Pediatrics, Medical College of Ohio

1990 American Medical Women's Association Award

1996 National Research Service Award, National Institutes of Health

- 1996 Fellow's Clinical Research Award, Society for Pediatric Research
1996 Frederick M. Kenny Memorial Trainee Investigator Award, Midwest Society for Pediatric Research
2006 President, Midwest Society for Pediatric Research

B. Selected peer-reviewed publications (in chronological order)

1. **Poindexter BB**, Karn CA, Ahrichs JA, Wang J, Leitch CA, Liechty EA, Denne SC: Amino acids suppress proteolysis independent of insulin throughout the neonatal period. *American Journal of Physiology* 272:E592-599, 1997.
2. Denne SC, Clark SE, **Poindexter BB**, Leitch CA, Ernst JA, Lemons PK, Lemons JA, Hertz DE, Liechty EA: Nutrition and Metabolism in the High-Risk Neonate - in "Neonatal-Perinatal Medicine: Diseases of the fetus and infant", Avroy A. Fanaroff and Richard J. Martin (eds), Sixth edition, Mosby Year Book, p. 562-621, 1997.
3. **Poindexter BB**, Karn CA, Denne SC: Exogenous insulin suppresses proteolysis and endogenous glucose production in extremely low birth weight infants. *J Pediatrics* 132:948-53, 1998.
4. **Poindexter BB**, Karn CA, Leitch CA, Liechty EA, Denne SC: Amino acids do not suppress proteolysis in premature neonates. *American Journal of Physiology* 281:E472-478, 2001.
5. Denne SC, **Poindexter BB**, Leitch CA, Ernst JA, Lemons PK, Lemons JA: Parenteral and Enteral Nutrition - in "Neonatal-Perinatal Medicine: Diseases of the fetus and infant", Avroy A. Fanaroff and Richard J. Martin (eds), Seventh edition, Mosby Year Book, p. 578-617, 2001.
6. **Poindexter BB**, Ehrenkranz RA, Stoll BJ, Koch MA, Wright LL, Oh W, Papile LA, Bauer CR, Carlo WA, Donovan EF, Fanaroff AA, Korones SB, Lupton AR, Shankaran S, Stevenson DK, Tyson JE, Lemons JA: The effect of parenteral glutamine supplementation on plasma amino acid and ammonia concentrations in extremely low birth weight infants. *American Journal of Clinical Nutrition* 77:737-743, 2003.
7. Dusick AM, **Poindexter BB**, Ehrenkranz RA, Lemons JA: Growth Failure in the Preterm Infant: Can We Catch Up? *Seminars in Perinatology*, 27(4):302-310, 2003.
8. **Poindexter BB**, Denne SC: Parenteral Nutrition - in "Avery's Diseases of the Newborn", H. William Taeusch, Roberta A. Ballard, and Christine A. Gleason (eds), Eighth edition, Elsevier, p. 1061-1070, 2004.
9. **Poindexter BB**, Ehrenkranz RA, Stoll BJ, Koch MA, Wright LL, Oh W, Papile LA, Bauer CR, Carlo WA, Donovan EF, Fanaroff AA, Korones SB, Lupton AR, Shankaran S, Stevenson DK, Tyson JE, Lemons JA: Parenteral glutamine supplementation does not reduce the risk of mortality or late-onset sepsis in extremely low birth weight infants. *Pediatrics*, 113(5):1209-1215, 2004.
10. **Poindexter BB**: Infant Nutrition – in "Care of the Newborn – A Handbook for Primary Care", David E. Hertz (ed), Lippincott Williams & Wilkins, 2005.
11. **Poindexter BB**, Denne SC: Differences Between Metabolism and Feeding of Preterm and Term Infants – in "Principles of Perinatal-Neonatal Metabolism", William Hay and Patti Thureen (eds), Second edition, in press.
12. **Poindexter BB**, Leitch CA, Denne SC: Parenteral Nutrition - in "Neonatal-Perinatal Medicine: Diseases of the fetus and infant", Avroy A. Fanaroff and Richard J. Martin (eds), Eighth edition, Mosby Year Book, p. 679-693, 2005.
13. Oh W, **Poindexter BB**, Perrit R, Lemons JA, Bauer CR, Ehrenkranz RA, Stoll BJ, Poole K, Wright LL: Association between fluid intake and weight loss during the first ten days of life and risk of bronchopulmonary dysplasia in extremely low birth weight infants. *J Pediatr*, 147(6):786-90, 2005.
14. **Poindexter BB**, Langer JC, Dusick AM, Ehrenkranz RA: Early provision of parenteral amino acids in extremely low-birth-weight infants – Relationship with growth and neurodevelopmental outcome. *J Pediatr*, 148(3):300-305, 2006.
15. Vohr BR, **Poindexter BB**, Dusick AM, McKinley LT, Wright LL, Langer JC, Poole WK: Effects of human milk in the neonatal intensive care unit on the developmental outcome and growth of extremely low birth weight infants at 18 months of age. *Pediatrics*, 118(1):e115-23, 2006.

16. Heller CD, Yao Q, Langer L, Ehrenkranz RA, Phelps DL, Poole WK, Stoll BJ, Duara S, Oh W, Lemons J, **Poindexter B** for the NICHD Neonatal Research Network: Human Milk Intake and Retinopathy of Prematurity in Extremely Low Birth Weight Infants. Pediatrics, in press.

C. Research Support

Ongoing Research Support

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Principal Investigator

NIH RO1HL054062 (Tepper, PI) 7/01/06-6/30/10

Growth of Airways and Lung Parenchyma in Normal Infants

The major goal of this project is to determine the relationship between parenchymal tissue and alveolar volume with normal lung growth early in life and to determine the pulmonary sequelae of premature birth and assess the effectiveness of early treatment strategies upon the pulmonary sequelae.

Role: Collaborator

Completed Research Support

NIH U10HD27856-10 (Lemons, PI) 4/01/01-3/31/06

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Alternate Principal Investigator

NIH MO1-RR00750 (Poindexter, PI) 5/1/97-6/30/02

NIH Clinical Associate Physician Award

Glutamine Metabolism in Human Neonates

The major goal of this project is to examine pathways of glutamine metabolism in neonates and to determine how stressors such as prematurity and surgery alter these pathways.

Role: Principal Investigator

Clarian Health Partners (Poindexter, PI) 10/1/99-9/30/01

Values Fund for Research

Randomized Trial of Parenteral Glutamine for Surgically Stressed Infants

The major goal of this project is to conduct a randomized double-masked clinical trial of glutamine supplementation in surgically stressed neonates.

Role: Principal Investigator

NIH NICHD RO1 HD29153 (Denne, PI) 5/1/97-4/30/01

Mechanisms of Neonatal Protein Accretion

The major goal of this project is to examine the mechanisms of protein accretion in premature and term neonates.

Role: Co-investigator

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
 Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Anna M. Dusick, M.D.	POSITION TITLE Associate Professor of Clinical Pediatrics		
eRA COMMONS USER NAME			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Mount Mary College	B.S.	1977	Occupational Therapy
Chicago Medical School University of Chicago,	M.D.	1986	Medicine
Wyler Children's Hospital University of Chicago,	Resident	1989	Pediatrics
Pritzker School of Medicine University of Chicago,	Fellow	1990	Neonatology
Pritzker School of Medicine	Fellow	1992	Chronic Disease

A. Positions and Honors

Positions and Employment

- 1992-1998 Assistant Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, IN
- 1997 Adjunct Assistant Professor of Speech and Hearing Sciences, Indiana University
- 1998-present Associate Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, IN

Other Experience and Professional Memberships

- 1994 Follow-Up Principal Investigator, NICHD Neonatal Research Network
- 1995 Medical Director Newborn Follow-Up Program, Riley Hospital for Children, Indianapolis, IN.
- 1997 Board Member, Make-A-Wish Foundation of Indiana
- 1998 Board Member, Interagency Coordinating Council for Infants & Toddlers. Part C IDEA, State of Indiana
- 2001 Diplomat in Neurodevelopmental Disabilities, American Board of Pediatrics
- 2002 Invited Presenter, Growth and Neurodevelopment, NIH Conference on Follow-up
- 2002 Member, Society for Pediatric Research

Honors

- 1976 Pi Theta Epsilon Honor Society
- 1977 Delta Epsilon Sigma Honor Society
- 1977 Anne Mary McNally Scholarship Award

B. Selected peer-reviewed publications (in chronological order)

1. Browne SP, Tebbett IR, Moore CM, **Dusick AM**, Covert RF: Analysis of meconium for cocaine in neonates. *Journal of Chromatology: Biomedical Applications* 575:158-161, 1992.
2. **Dusick AM**, Covert RF, Schreiber MD, Yee GT, Browne SP, Moore CM, Tebbett IR: Risk of Intracranial hemorrhage and other adverse outcomes after cocaine exposure in a cohort of 323 very low birth weight infants. *J Pediatr* 122(3):438-45, 1993.
3. Browne S, Moore C, Negrusz A Tebbett I, Covert R, **Dusick AM**: Detection of cocaine, norcocaine and cocaethylene in the meconium of premature neonates. *J Forensic Sci*, 39:1515-19, 1994.

4. **Dusick AM:** Medical outcomes In Preterm Infants. Semin Perinatol 21(3):164-177, 1997.
5. Wheeler PG, Medina S, **Dusick AM**, Bull M, Andreoli SP, Edwards-Brown M, Weaver D: Livedo reticularis, developmental delay and stroke-like episode in a 7-year-old male. Clinical Dysmorphology 7:69-74, 1998.
6. Vohr BR, Wright LL, **Dusick AM**, Mele L et al.: Neurodevelopmental and Functional Outcomes of Extremely Low Birth Weight Infants in the National Institute of Child Health and Human Development Neonatal Research Network, 1993-1994. Pediatrics 105(6): 1216-1226, 2000.
7. Barlow, S.M., **Dusick, A.**, Finan, D.S., Biswas, A., Coltart, S., & Flaherty, K.J: Neurophysiological monitoring of the orofacial system in premature and term infants. Journal Medical Speech-idiom Pathology, 8(4):221-238, 2000.
8. Barlow SM, **Dusick AM**, Finan DS, Coltart S, Biswas A: Mechanically evoked perioral reflexes in Premature and term human infants. Brain Research 899:251-254, 2001.
9. **Dusick AM**, Poindexter BB, Ehrenkranz RA, Lemons JA: Growth Failure in the Preterm Infant: Can We Catch Up? Seminars in Perinatology, 27(4):302-310, 2003.
10. Vohr BR, Wright LL, **Dusick AM**, Perritt R, et al.: Center Differences and Outcomes of Extremely Low Birth Weight Infants. Pediatrics 113(4): 781-789, 2004.
11. Ohls RK, Ehrenkranz RA, Das A, **Dusick AM**, et al.: Neurodevelopmental Outcome and Growth at 18 to 22 Months Corrected Age in Extremely Low Birth Weight Infants Treated With Early Erythropoietin and Iron. Pediatrics 114(5):1287-1291, 2004.
12. Poindexter BB, Langer JC, **Dusick AM**, Ehrenkranz RA: Early provision of parenteral amino acids in extremely low-birth-weight infants – Relationship with growth and neurodevelopmental outcome. J Pediatr, 148(3):300-305, 2006.
13. Vohr BR, Poindexter BB, **Dusick AM**, McKinley LT, Wright LL, Langer JC, Poole WK: Effects of human milk in the neonatal intensive care unit on the developmental outcome and growth of extremely low birth weight infants at 18 months of age. Pediatrics, 118(1):e115-23, 2006.

C. Research Support

Ongoing Research Support

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Follow-Up Principal Investigator

Completed Research Support

NIH U10HD27856-10 4/01/01-3/31/06

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Follow-Up Principal Investigator

NIH MO1-RR-99-008 7/1/00-6/30/02

NIH Clinical Associate Physician Award

Mechanically Evoked Reflexes and Functional Oromotor Skill Acquisition in Preterm Infants

The major goal of this project is to examine mechanically evoked reflexes and functional oromotor skill acquisition in premature infants.

Role: Principal Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME James A. Lemons, M.D.		POSITION TITLE Professor of Pediatrics	
eRA COMMONS USER NAME			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Princeton University, Princeton, NJ	B.A.	1965	
Northwestern Univ. Medical School, Chicago, IL	M.D.	1969	Medicine
Univ. of Michigan Medical School, Ann Arbor, MI	Intern	1970	Pediatrics
Univ. of Michigan Medical School, Ann Arbor, MI	Resident	1972	Pediatrics
Univ. of Michigan Medical School, Ann Arbor, MI	Fellow	1973	Reproductive Endo.
Univ. of Colorado Medical School, Denver, CO	Fellow	1975	Neonatal-Perinatal Med.

A. Positions and Honors

Positions and Employment

- 1987-present Director, Section of Neonatal-Perinatal Medicine, Department of Pediatrics, Indiana University School of Medicine
 1988 present Hugh McK. Landon Professor of Pediatrics, Indiana University School of Medicine
 2003-present Associate, Faculty of Indiana University Graduate School

Other Experience and Professional Memberships

- 1988-1994 Executive Committee, American Academy of Pediatrics Section on Perinatal Pediatrics
 1991-2006 Principal Investigator, NICHD Neonatal Research Network, National Institutes of Health
 1992-1994 Chair, Executive Committee, Section on Perinatal Pediatrics of the American Academy of Pediatrics
 1993-1999 Member, Neonatal-Perinatal Medicine Sub-Board of the American Board of Pediatrics
 1994-present Professor of Pediatrics, Moi University, Faculty of Health Sciences Eldoret, Kenya
 1997-2001 Chair, Committee on Fetus and Newborn of American Academy of Pediatrics
 1999-present Pregnancy Labeling Subcommittee of the Reproductive Health Drugs Advisory Committee, FDA
 1999-2005 Task Force for Newborn Hearing Screening and Detection, American Academy of Pediatrics
 2000-2003 Chair, Technical Action Group, Council on Committees, American Academy of Pediatrics
 2000-2005 Joint Committee on Infant Hearing, American Academy of Pediatrics
 2006-present Chair, NIH Global Network for Women's and Children's Health Research Study Group

Honors

- 1968 Alpha Omega Alpha
 1975 Sigma Xi
 1988 Edwin L. Gresham Award for Perinatal Service, American Academy of Pediatrics
 1999 March of Dimes Health Leadership Award
 1994 The Best Doctors in America
 2002-2005 Inclusion In *America's Top Doctors (2nd Edition)* National Physician Guide
 2002 Teaching Excellence Recognition Award, Indiana University
 2005 Physician of the Year, March of Dimes, Indiana Chapter

B. Selected peer-reviewed publications (in chronological order) (Publications selected from more than 250 peer-reviewed publications)

1. Ward R, **Lemons J**, Molteni R. Cisapride: A survey of the frequency of use and adverse events in premature newborns. *Pediatrics*. 103(2):469-472, 1999.
2. Stevenson D.K., Verter J., Fanaroff A., Oh W., Herenkranz R.A., Shankaran S., Donovan E.F., Wright L., **Lemons J.A.**, Tyson J.E., Korones S.B., Baur C.R., Stoll B.J., Papile L-A. Sex differences in very low birthweight outcomes: The newborn male disadvantage. *Arch Dis Child*. 83:F182-F185, Nov 2000.
3. Walsh-Sukys MC, Fanaroff AA, Bauer CR, Korones SB, Stevenson DK, Tyson JE, Verter J, Wright LL, Stoll BJ, **Lemons JA**, Papile LA, Donovan EF, Shankaran S, Oh W, Ehrenkranz RA for the NICHD Neonatal Research Network. Persistent pulmonary hypertension of the newborn (PPHN) in the era before nitric oxide: practice variation and outcomes. *Pediatrics*. 105:14-20, 2000.
4. Reis B.B., Hall R.T., Schanler R.J., Berseth C.L., Chan G., Ernst J.A., **Lemons J.**, Adamkin D., Braggs G., O'Connor D. Enhanced Growth of Preterm Infants Fed a New Powdered Human Milk Fortifier: A Randomized Controlled Trial. *Pediatrics* 106(3);581-588, Sept 2000.
5. **Lemons JA**, Bauer CR, Oh W, Korones SB, Papile L-A, Stoll BJ, Verter J, Temprosa M, Wright LL, Ehrenkranz RA, Fanaroff AA, Stark A, Waldemar C, Tyson JE, Donovan EF, Shankaran S, Stevenson DK. Very Low Birth Weight Outcomes of the National Institute of Child Health and Human Development Neonatal Research Network, January 1995 through December 1996. *Pediatrics*. 107(1): 1-8, Jan 2001.
6. Vohr BR, Oh W, Stewart EJ, Bentkover JD, Gabbard S, **Lemons J**, Papile L-A, Pye R. A Comparison of Costs and Referral Rates of Three Universal Newborn Hearing Screening Protocols. *J Pediatr*.139:238-44. Aug 2001.
7. Ohls RK, Ehrenkranz RA, Wright LL, **Lemons JA**, Korones SB, Stoll BJ, Stark AR, Shankaran S, Donovan EF, Close NC, Das A. Effects of Early Erythropoietin Therapy on the Transfusion Requirements of Preterm Infants Below 1250 Grams Birth Weight: A Multicenter, Randomized, Controlled Trial. *Pediatrics* 108(4):934-942, Oct 2001.
8. **Lemons J**, Fanaroff A, Stewart EJ, Bentkover JD, Murray G, Diefendorf A. Newborn Hearing Screening: Costs of Establishing a Program. *J Perinatol*. 22:120-124, 2002.
9. Farrell PA, Weiner GM, **Lemons JA**. SIDS, ALTE, Apnea, and the Use of Home Monitoring. *Pediatr in Rev*. 23:3-9, 2002.
10. Shankaran S, Fanaroff AA, Wright LL, Stevenson DK, Donovan EF, Ehrenkranz RA, Langer JC, Korones SB, Stoll, BJ, Tyson JE, Bauer CR, **Lemons, JA**, Oh W, Papile L-A. Risk factors for early death among extremely low-birth-weight infants. *Am J Obstet Gynecol* 186:796-802, 2002.
11. Stoll BJ, Hansen N, Fanaroff AA, Wright LL, Waldemar AC, Ehrenkranz RA, **Lemons JA**, Donovan EF, Stark AR, Tyson JE, Oh W, Bauer CR, Korones SB, Shankaran S, Luptook AR, Stevenson DK, Papile L-A, Poole WK. Late-Onset Sepsis in Very Low Birth Weight Neonates: The Experience of the NICHD Neonatal Research Network. *Pediatrics*.110:285-291, Aug 2002.
12. American Academy of Pediatrics & The American College of Obstetricians and Gynecologists. Guidelines for Perinatal Care, 5th Edition. **Lemons J** (ed). Oct 2002.
13. American Academy of Pediatrics & The American College of Obstetricians and Gynecologists. Neonatal Encephalopathy and Cerebral Palsy; Defining the Pathogenesis and Pathophysiology. **Lemons J** (ed). 2002.
14. Dusick A, Poindexter BB, Ehrenkranz RA, **Lemons JA**. Growth Failure in the Preterm Infant: Can We Catch Up? *Sem Perinatol*. 27:302-310, Aug 2003.
15. Stoll BJ, Hansen N, Fanaroff AA, Wright LL, Carlo WA, Ehrenkranz RA, **Lemons JA**, Donovan EF, Stark AR, Tyson JE, Oh W, Bauer CR, Korones SB, Shankaran S, Luptook AR, Stevenson DK, Papile L, Poole WK. To Tap or Not to Tap: High Likelihood of Meningitis Without Sepsis Among Very Low Birth Weight Infants. *Pediatrics* 113:1181-1186, May 2004.
16. Poindexter BB, Ehrenkranz RA, Stoll BJ, Wright LL, Poole WK, Oh W, Bauer CR, Papile L-A, Tyson JE, Waldemar AC, Luptook AR, Narendran V, Stevenson DK, Fanaroff AA, Korones SB, Shankaran S, Finer NN, **Lemons JA**. Parenteral Glutamine Supplementation Does Not Reduce the Risk of Mortality or Late-Onset Sepsis in Extremely Low Birth Weight Infants. *Pediatr* 113:1209-1215, May 2004.
17. Stoll BJ, Hansen N, Farnaroff AA, **Lemons JA** for the National Institute of Child Health and Human Development Neonatal Research Network. Enterobacter Sakazakii is a Rare Cause of Neonatal Sepsis or Meningitis in VLBW Infants. *J Pediatr* 144:821-823, Jun 2004.

C. Research Support

Ongoing Research Support

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Alternate Principal Investigator

6T79 MC 00010-12 1978-2008

U.S. Dept. of Health and Human Services

Maternal and Child Health Bureau Neonatal Nutrition Training Grant

Leadership Education Excellence in Pediatric Nutrition Program

The major goal of this project is to provide support for a minimum of four predoctoral fellowships to assist dietitians/ nutritionists in developing the clinical nutrition skills necessary for quality care of high-risk infants.

Role: Co-principal Investigator

Completed Research Support

NIH U10HD27856-10 (Lemons, PI) 4/01/01-3/31/06

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Principal Investigator

1U10EY12471-01S1 6/30/00-9/29/04

National Eye Institute

Early Treatment for Retinopathy of Prematurity

The major goal of this project is to investigate the value of treating retinopathy of prematurity earlier than usual, at a selected prethreshold level instead of at the threshold level.

Role: Principal Investigator

NIH M01-RR-750-19 1989 - 1999

NIH

Neonatal Scatterbed, General Clinical Research Center

Role: Co-Principal Investigator

NIH R01-14820 1981 - 1992

Fetal Amino Acid Metabolism and Gluconeogenesis

Role: Principal Investigator

NIH R01-HD-12476 1979 -1980

Composition of Breast Milk in Relation to Gestational Age

Role: Principal Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Gregory M. Sokol, M.D.	POSITION TITLE Associate Professor of Clinical Pediatrics		
eRA COMMONS USER NAME			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Washington & Jefferson College, Washington, PA	BA	1977-1981	Chemistry
National Institutes of Health's Foundation for Advanced Ed in the Sciences, Bethesda, MD	Non-Degree	1981-1982	Neurobiology and Neurochemistry
University of Pittsburgh School of Medicine, Pittsburgh, PA	M.D.	1982-1986	Medicine
Eastern Virginia Graduate School of Medicine, Norfolk, VA	Intern/Res	1986-1989	Pediatrics
Indiana University School of Medicine, Indianapolis, IN	Fellowship	1989-1992	Neonatal-Perinatal Med

A. Positions and Honors

Positions and Employment

- 1992-1999 Assistant Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, IN
- 1999-present Associate Professor of Clinical Pediatrics, Indiana University School of Medicine, Indianapolis, IN

Other Experience and Professional Memberships

- 1992-present Physician Coordinator for the Neonatal Inhaled Nitric Oxide Therapy Program at James Whitcomb Riley Hospital for Children.
- 1992-present Fellow American Academy of Pediatrics
- 1992-present Indiana Neonatal Society
- 1992-present Perinatal Section of the American Academy of Pediatrics
- 1992-present Neonatal Resuscitation Program Regional Trainer, #1218480.
- 1993-2000 Protocol development subcommittee, Executive committee & Principal Investigator at Indiana University for the "Neonatal Inhaled Nitric Oxide Study" (NINOS) sponsored by the NICHD Neonatal Research Network & Canadian Inhaled Nitric Oxide Study Group
- 1996-present Indiana Chapter of AAP, Chairman Perinatal Committee
- 1996-2006 Protocol development subcommittee, Executive committee & Principal Investigator at Indiana University for the "Early inhaled nitric oxide study in term and near-term infants with respiratory failure," sponsored by the NICHD Neonatal Research Network & Canadian Inhaled Nitric Oxide Study Group.
- 1998-present: Alternate Principal Investigator at Indiana University Medical Center for the National Institute of Child Health & Human Development's Cooperative Neonatal Research Network Steering Committee.
- 2000-present: Principal Investigator at Indiana University Medical Center for the "Inhaled nitric oxide for preterm infants with severe respiratory failure," sponsored by the NICHD Neonatal Research Network.

2004-present: Protocol development subcommittee & Principal Investigator at Indiana University for the "Inhaled PGE in term and near-term infants with respiratory failure," sponsored by the NICHD Neonatal Research Network.

B. Selected peer-reviewed publications (in chronological order)

1. **Sokol, G.M.**, Liechty, E.A., and Boyle, D.W.: Comparison of steady-state diffusion and transit time ultrasonic measurements of umbilical blood flow in the chronic fetal sheep preparation. *Am J Obstet Gynecol* 1996;174:1456-60.
2. The Neonatal Inhaled Nitric Oxide Group. Inhaled nitric oxide in full-term and nearly full-term infants with hypoxic respiratory failure. *N Engl J Med* 1997;336:597-604.
3. The Neonatal Inhaled Nitric Oxide Group. Inhaled nitric oxide and hypoxic respiratory failure in infants with congenital diaphragmatic hernia. *Pediatrics* 1997;99:838-845.
4. **Sokol, G.M.**, Van Meurs, K.P., Thorn W.J., Rivera, O., Chu, P., Wright, L., Sams, R.L. Nitrogen dioxide formation during inhaled nitric oxide therapy. *Clinical Chemistry* 1999;45(3):382-387.
5. The Neonatal Inhaled Nitric Oxide Group. Inhaled nitric oxide in term and near term infants: Neurodevelopmental follow-up of the neonatal inhaled nitric oxide study group (NINOS). *J Pediatr* 2000;136:611-617.
6. **Sokol, G.M.**, Fineberg, N.S., Wright, L.L., Ehrenkranz, R.A. Changes in arterial oxygen tension when weaning neonates from inhaled nitric oxide. *Pediatric Pulmonology* 2001;32:14-19.
7. Konduri, G.G., Solimano, A., **Sokol, G.M.**, Singer, J., Ehrenkranz, R.A., et al. A Randomized trial of early versus standard inhaled nitric oxide therapy in term and near term newborn infants with hypoxic respiratory failure. *Pediatrics* 2004;113:559-564.
8. Van Meurs, K.P., Wright, L.L., Ehrenkranz, R.A., Lemons, J.A., et al. Inhaled nitric oxide for premature infants with severe respiratory failure. *N Engl J Med* 2005;353:13-22.
9. Konduri, G.G., Vohr, B., Robertson, C., **Sokol, G.M.**, et al. Early inhaled nitric oxide therapy for term and near term newborn infants with hypoxic respiratory failure: Neurodevelopmental Follow-Up. (*J Pediatr* – in Press).

C. Research Support

Ongoing Research Support

NIH 2U10HD27856-16 (Poindexter, PI) 4/01/06-3/31/11

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Alternate Principal Investigator

Completed Research Support

NIH U10HD27856-10 (Lemons, PI) 4/01/01-3/31/06

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Role: Alternate Principal Investigator

PROGRESS REPORT SUMMARY	GRANT NUMBER HD027856-16	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Brenda Poindexter, M.D., M.S.	FROM 04/01/2006	THROUGH 03/31/2007
APPLICANT ORGANIZATION Indiana University		
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	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
C. Select Agent Research	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
D. Multiple PI Leadership Plan	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> 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 reporting actual and targeted/planned enrollment for each active study in the Neonatal Research Network at the Indiana site are attached (see pages 25-30).

PROGRESS REPORT:

A. SPECIFIC AIMS

The NICHD Neonatal Research Network is a cooperative group of 16 academic centers whose principal aim is to perform multicenter randomized clinical trials to evaluate the safety and efficacy of treatment and management strategies for newborn infants, particularly those related to very low birth weight, prematurity, and common neonatal medical problems. The Steering Committee has worked diligently over the years, as the Network has grown, to create an organizational structure that permits timely evaluation of important clinical questions in the rapidly changing field of neonatology. In addition to the randomized controlled trials, a generic database is maintained on all very low birth-weight infants cared for at each of the participating centers and comprehensive neurodevelopmental follow-up of the extremely premature infants (birth weight less than 1000 grams) at 18 months corrected age. The generic database and the follow-up study enable investigators to obtain information on a large cohort of premature infants regarding short- and long-term morbidities, differences in outcomes between centers and between different populations of infants, and variations in clinical practice related to outcomes.

Since 1991, Indiana has made substantial contributions to the Neonatal Research Network because of the large patient population, strong faculty, basic and clinical research experience, state-of-the-art clinical and research facilities, and excellent research support staff. At the time of the competitive renewal in April, 2006, Dr. Brenda Poindexter assumed the role of Principal Investigator for the Indiana site. Drs. James Lemons and Greg Sokol remain actively involved in all aspects of Network activities at Indiana as the alternate PIs and Dr. Anna Dusick continues in her role as follow-up PI.

B. STUDIES AND RESULTS

This past year marked Indiana's 16th year of participation in the NICHD Neonatal Research Network. The following studies are currently active at Indiana University; IRB protocol numbers and the date of the most recent approval are listed in the following table. Unless otherwise noted, all approvals are for 12 months.

IRB APPROVAL DATES:

STUDY TITLE	IRB PROTOCOL #	MOST RECENT APPROVAL DATE*
Generic Database-Survey of Morbidity and Mortality Among Very Low Birth Weight Infants 401-1500 Grams	9612-02	03/02/2006
Early Onset Sepsis - A NICHD/CDC Surveillance Study	0601-88	04/18/2006
Follow-up of Premature Infants with Birth Weight Less than 1000 Grams at 18 (\pm 4) Months of Age and/or 30 (\pm 2) Months of Age (Corrected for Gestation)	9412-30	05/31/2006
Study to determine if Inflammatory Cytokines are Associated with Perinatal Brain Injury and Long Term Neurodevelopmental Handicap	0006-33	10/24/2006 Completed
Inhaled Nitric Oxide for Preterm Infants with Severe Respiratory Failure	0004-22	11/06/2006 Closed to enrollment; data analysis only
Blood Inositol Status Among Neonates in 2005	0506-75	06/13/2006
NICHD SUPPORT Trial—Breathing Outcomes Study	0606-41	08/08/2006
Association of Apolipoprotein E (apoE) genotype with brain injury and neurodevelopmental outcome in infants with hypoxic ischemic encephalopathy	0410-30	08/08/2006
Neurodiagnostic Evaluations That Assist in the Prediction of Adverse Outcome Following Acute Perinatal Asphyxia	0401-53	9/19/2006 Closed to enrollment; research interaction (follow-up) continues
Early Diagnosis Of Nosocomial Candidiasis	0401-55	9/19/2006
Phase II Randomized, Double Blind, Placebo Controlled, Safety and Pharmacokinetic Study of a Single Dose of Inositol in Premature Infants	0609-36	10/24/2006
Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial	0609-37	10/24/2006

The <u>S</u> urfactant <u>P</u> ositive Airway Pressure and <u>P</u> ulse <u>O</u> ximetry <u>T</u> rial in Extremely Low Birth Weight Infants (includes Antenatal Consent and Growth Secondaries)	0412-26	10/25/2006
Development of an Anonymized Database Linked to Anonymized DNA Samples for Studies of Genomic Impact on Morbidity and Mortality Among High-Risk Infants	0403-74	10/30/2006 Completed
Inhaled Nitric Oxide for Preterm Infants with Severe Respiratory Failure	0004-22	11/06/2006 Closed to enrollment
A Randomized Trial of Aggressive or Conservative Phototherapy for Extremely Low Birth Weight Infants.	0204-22	11/14/2006 Closed to enrollment; research interaction (follow-up) continues
Extended Follow-Up of the Hypothermia Trial Subjects		Approval pending

The Generic Database provides for the collection of comprehensive data on all very low birth-weight (birth weight less than 1500 grams) infants throughout their hospitalization. Data from 4,515 VLBW infants have been entered since Indiana joined the Network in 1991. The Inclusion Enrollment Report reflects data from 234 infants entered thus far in 2006. These data are used to monitor trends in morbidity and mortality associated with prematurity, to conduct observational studies, and to generate hypotheses for randomized clinical trials.

The Follow-up of Premature Infants with Birth Weight Less than 1000 Grams at 18 (± 4) Months of Age and/or 30 (± 2) Months of Age (Corrected for Gestation) study continues to provide important outcome information to the neonatal community. Indiana has consistently maintained an excellent rate of follow-up for this important longitudinal study, with 88% of ELBW infants returning overall for follow-up at 18 months during 2006. In addition, one of the psychologists at Indiana was chosen this year as the gold-standard examiner for the Network for performance of the Bayley scales of infant development.

The early diagnosis of nosocomial Candidiasis study is an observational study that will test different methods of diagnosing fungal infections in the most premature neonates. The Inclusion Enrollment Report reflects data from 2 infants enrolled in 2006. We continue to actively screen and enroll infants in this study.

The observational study titled, "Neurodiagnostic Evaluations That Assist in the Prediction of Adverse Outcome Following Acute Perinatal Asphyxia" recently completed enrollment. This study will assess the predictive value of the aEEG in infants with hypoxic ischemic encephalopathy. The Inclusion Enrollment Report reflects data from 2 infants enrolled in 2006.

The Early Onset Sepsis study is a surveillance study co-funded by the NICHD and the CDC to determine the incidence of early onset sepsis and the pathogens responsible for EOS since the implementation of universal screening and prophylaxis of group B streptococcus in pregnant women. This important study extends data collection to newborns of all birthweights. The Inclusion Enrollment Report reflects data from 12 infants enrolled in 2006.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants is ongoing. 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. In addition to the main trial, Indiana is participating in 4 secondary studies including antenatal consent, growth, MRI neuroimaging and neurodevelopmental outcome, and a study of breathing outcomes at 12 months of age. The Inclusion Enrollment Report reflects data from 14 infants enrolled in 2006. Thus far in 2007, Indiana already has 8 subjects active in the SUPPORT trial.

The Randomized Trial of Aggressive or Conservative Phototherapy for Extremely Low Birth-Weight Infants (PHACT) was initiated in June 2002 and is now closed to enrollment. Indiana has achieved a 96% rate of follow-up at 18 months to assess the primary outcome measure in surviving infants. The results of this trial will be analyzed in the next month and the steering committee hopes to submit a late-breaker abstract describing the results to the 2007 Pediatric Academic Societies (PAS) Annual Meeting.

The Blood Inositol Status Among Neonates Study is one of several pilot studies that was performed in preparation for a large multicenter RCT that will evaluate the efficacy of an inositol supplement in reducing the incidence of ROP requiring surgical intervention in infants < 28 weeks gestation. One hundred thirty-eight scavenged blood samples were obtained between August 2005 and August 2006 for the purpose of determining current blood levels of inositol in preterm infants (compared with term infants), at birth and in the weeks following birth, as affected by type of parenteral and enteral nutritional intake. These results will be used to estimate the dose of inositol that will be used in the planned RCT. An abstract describing these data has been submitted to the 2007 PAS Annual Meeting. After the conclusion of the Serum Inositol Status in Neonates Study, the first of two pharmacokinetic trials was initiated. That trial will determine pharmacokinetics following a single dose of inositol; a multidose trial will follow. The Targeted/Planned Enrollment Table reflects the 10 subjects that Indiana plans to enroll in this phase II study. Dr. Poindexter is a member of the Inositol subcommittee.

Neurodevelopmental outcome assessments of the Hypothermia Trial survivors (Extended Follow-up for Hypothermia Trial Survivors) between 6 to 7 years of age are planned during the upcoming year (IRB approval pending) when study participants enter the follow-up window.

Dr. Poindexter is also an active member of the Probiotics subcommittee; this group is finalizing the study design for a randomized trial of probiotics to prevent necrotizing enterocolitis (NEC) in extremely premature neonates.

C. SIGNIFICANCE

Each of the trials above is contributing to the evidence needed to support and/or change clinical practice in the field of Neonatology. In addition to actively enrolling subjects into the observational and interventional trials, Dr. Poindexter is a member of the Network Protocol Review Committee. She was recently elected to serve as the Vice Chair of this committee. In addition, she provides review of Network manuscripts for the Publications subcommittee on an ad hoc basis.

Year 16 Publications and Abstracts in which infants at Indiana were included in the patient population or to which Dr. Poindexter contributed include:

2006 Publications:

Ahlfors, CE, Vreman, HJ, Wong, RJ, Bender, J, Oh, W, Morris, BH, Stevenson, DK and the Phototherapy Subcommittee on behalf of the NICHD Research Network. Effects of sample dilution, peroxidase concentration, and chloride ion on the measurement of unbound bilirubin in premature newborns. Clin Biochem. 2006 Sep 29.

Ambalavanan N, Baibergenova A, Carlo WA, Saigal S, Schmidt B, Thorpe KE; Trial of Indomethacin Prophylaxis in Preterms (TIPP) Investigators. Early prediction of poor outcome in extremely low birth weight infants by classification tree analysis. J Pediatr. 2006 Apr;148(4):438-444.

Ambalavanan N, Carlo WA, Shankaran S, Bann CM, Emrich SL, Higgins RD, Tyson JE, O'Shea TM, Laptook AR, Ehrenkranz RA, Donovan EF, Walsh MC, Goldberg RN, Das A; National Institute of Child Health and Human Development Neonatal Research Network. Predicting outcomes of neonates diagnosed with hypoxemic-ischemic encephalopathy. Pediatrics. 2006 Nov;118(5):2084-93.

Benjamin DK Jr, Stoll BJ, Fanaroff AA, McDonald SA, Oh W, Higgins R, Duara S, Poole K, Laptook A, Goldberg R. Neonatal Candidiasis Among Infants < 1000g Birthweight: Risk Factors, Mortality, and Neuro-Developmental Outcomes at 18-22 months. Pediatrics 2006 Jan;117(1):84-92.

Blakely ML, Tyson JE, Lally KP, McDonald S, Stoll BJ, Stevenson DK, Poole WK, Jobe AH, Wright LL, Higgins RD; NICHD Neonatal Research Network. Laparotomy versus peritoneal drainage for necrotizing enterocolitis or isolated intestinal perforation in extremely low birth weight infants: outcomes through 18 months adjusted age. Pediatrics. 2006 Apr;117(4):e680-7. Epub 2006 Mar 20.

Cotten CM, McDonald, SA, Stoll, BJ, Goldberg, RN, Poole, WK, Benjamin, DK on Behalf of the NICHD Neonatal Research Network. The association of third-generation cephalosporin use and invasive candidiasis in extremely low birth-weight infants. Pediatrics. 2006 Aug;118(2):717-22

Ehrenkranz RA, Dusick AM, Vohr BR, Wright LL, Wrage L, Poole WK. Growth in the neonatal intensive care unit influences neurodevelopmental and growth outcomes of extremely low birth weight infants. Pediatrics 2006 Apr;117(4):1253-61

Guillet R, Stoll BJ, Cotten, CM, Gantz, M, McDonald S, Poole WK, Phelps DI. Association of H2 Blocker Therapy and Higher Incidence of Necrotizing Enterocolitis in Very Low Birth Weight Infants. Pediatrics. 2006 Feb;117(2):e137-42. Epub 2006 Jan 3

Hintz SR, Kendrick DE, Vohr BR, Kenneth Poole W, Higgins RD, For The NICHD Neonatal Research Network. Gender differences in neurodevelopmental outcomes among extremely preterm, extremely-low-birthweight infants. Acta Paediatr. 2006 Oct;95(10):1239-48

Laptook, A. Pulse Oximetry in Very Low Birth Weight Infants: Can Oxygen Saturation Be Maintained in the Desired Range? J Pediatr 2006 Jun;26(6):337-41.

Lee, BH, Stoll, BJ, McDonald, SA, Higgins, RD for the NICHD Neonatal Network. Adverse neonatal outcomes associated with antenatal dexamethasone versus antenatal betamethasone. Pediatrics. 2006 May;117(5):1503-10.

Poindexter, BB, Langer, JC, Dusick, AM, Ehrenkranz, RA, for the Neonatal Research Network. Early Provision of Parenteral Amino Acids in Extremely Low-Birth-Weight Infants – Relationship with Growth and Neurodevelopmental Outcome. J Pediatr 2006 Mar;148(3):300-305.

Shankaran S, Das A, Bauer CR, Bada H, Lester B, Wright L, Higgins R, Poole K. Fetal origin of childhood disease: intrauterine growth restriction in term infants and risk for hypertension at 6 years of age. Arch Pediatr Adolesc Med. 2006 Sep;160(9):977-81.

Shankaran, S, Langer, JC, Kazzi, SN, Laptook, AR, Walsh, MC. Cumulative Index of Exposure to Hypocarbia and Hyperoxia as Risk Factors for Periventricular Leukomalacia (PVL) in Low Birth Weight (LBW) Infants. Pediatrics 2006 Oct;118(4):1654-9.

Vohr BR, Poindexter BB, Dusick AM, McKinley LT, Wright LL, Langer JC, Poole WK; NICHD Neonatal Research Network. Beneficial effects of breast milk in the neonatal intensive care unit on the developmental outcome of extremely low birth weight infants at 18 months of age. Pediatrics. 2006 Jul;118(1):e115-23.

Bender, J, Cashore, WJ, Oh, W. Ontogeny of Bilirubin Binding Capacity and the Effect of Clinical Status in Very Low Birth Weight Infants. Pediatrics (in press)

Heller, CD, Yao, Q, Langer, L, Ehrenkranz, RA, Phelps, DL, Poole, WK, Stoll, BJ, Duara, S, Oh, W, Lemons, J, Poindexter, B, For the NICHD Neonatal Research Network. Human Milk Intake and Retinopathy of Prematurity in Extremely Low Birth Weight Infants. Pediatrics (in press).

Konduri, GG., Vohr, B, Robertson, C, Sokol, GM, Solimano, Singer, AJ, Ehrenkranz, RA, Singhal, N, Wright, LL, Van Meurs, K, Stork, E, Kirpalani, H, Peliowski, A, for the Neonatal Inhaled Nitric Oxide Study Group. Early Inhaled Nitric Oxide Therapy for Term and Near Term Newborn Infants with Hypoxic Respiratory Failure: Neurodevelopmental Follow-up. J Pediatr (in press)

Walsh, MC, Laptook, AR, Kazzi, SN, Engle, WA, Yao, Q, Rasmussen, M, Buchter, S, Heldt, G, Rhine, W, Higgins, RD, for the NICHD Neonatal Research Network. A Cluster Randomized Trial of Benchmarking and Multimodal Quality Improvement To Improve Survival Free of Bronchopulmonary Dysplasia in Infants < 1250 grams Birthweight. Pediatrics (in press).

2006 Abstracts:

Adams-Chapman, I, for the NICHD Neonatal Research Network. Speech and Language Outcome at 30 Months Adjusted Age Among a Cohort of ELBW Infants. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Ambalavanan, N, Van Meurs, KP, for the NICHD Neonatal Research Network. Predictors of Death/BPD in Preterm Infants with Respiratory Failure. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Ambalavanan, N, Shankaran, S, for the NICHD Neonatal Research Network. Prediction of Prognosis in Neonatal Hypoxemic-Ischemic Encephalopathy (HIE) by Classification and Regression Tree (CART) Analysis. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Ambalavanan, N, Shankaran, S for the NICHD Neonatal Research Network. A scoring system for Neonatal Hypoxic-Ischemic Encephalopathy. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Bada, H, Das, A, Bauer, CR, Shankaran, S, Lester, B, LaGasse, L, Hammond, J, Higgins, R. Prenatal Cocaine Exposure and Trajectories of Childhood Behavior Problems Through Age 9 Years (Maternal Lifestyle Study). (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Buchter, S, for the NICHD Neonatal Research Network. The Composition of the Neonatal Team at Deliveries of <1250 Gram Babies—Who Makes the Most Difference? (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Chock, VY, Van Meurs, KP, for the NICHD Neonatal Research Network. Inhaled Nitric Oxide for Premature Prolonged Rupture of Membranes, Oligohydramnios, and Suspected Pulmonary Hypoplasia: PiNO Trial Results. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Fuller, MG, Vaucher, YE, for the NICHD Neonatal Research Network. Social Isolation as Measured by the Family Resource Scale Screening Tool Is Associated with Adverse Cognitive Outcome in the Extremely Low

Birthweight (ELBW) Population. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Gordon, PV, Aschner, JL, for the NICHD Neonatal Research Network. Can Inhaled Nitric Oxide (iNO) Alter the Natural History of Spontaneous Intestinal Perforations (SIP) in the ELBW Infant?: A Post Hoc Analysis of the NICHD Premie iNO Study. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Hintz, SR, Van Meurs, KP, for the NICHD Neonatal Research Network. Reliability and Accuracy of Cranial Ultrasound in the NICHD Randomized Controlled Trial of Inhaled Nitric Oxide for Premature Infants with Severe Respiratory Failure. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Hintz, SR, Van Meurs, KP, for the NICHD Neonatal Research Network. Neurodevelopmental Outcomes of the NICHD Randomized Controlled Trial of iNO for Premature Infants with Severe Respiratory Failure. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Laptook, AR, for the NICHD Neonatal Research Network. Adverse Outcome Increases with Elevated Temperature for Infants Provided Usual Care Following Hypoxia-Ischemic Encephalopathy (HIE). (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Lee, BH, Stoll, BJ, for the NICHD Neonatal Research Network. Neurodevelopmental (ND) Outcomes of Extremely Low Birth Weight (ELBW) Infants at 18-22 Months Associated with Antenatal Dexamethasone (Dex) Versus Betamethasone (Beta). (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Malcolm, WF, Cotton, CM, for the NICHD Neonatal Research Network. Anti-Reflux Medications (ARM) at NICU Discharge for Extremely Low Birthweight (ELBW) Infants. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Meinzen-Derr, J, Poindexter, B, for the NICHD Neonatal Research Network. Role of Human Milk (HM) in ELBW Risk of Necrotizing Enterocolitis (NEC) or Death. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Meinzen-Derr, J, Donovan, E, for the NICHD Neonatal Research Network. Using Prediction Models To Enhance Informed Consent for Prevention Trials. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Moore, J, LaGasse, L, Liu, J, High, P, Lester, B, Shankaran, S, Bada, H, Bauer, C, Higgins, C, Das, A. Risk Factors for Failure To Thrive (FTT) in Cocaine-Exposed Infants. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Morris, BH, for the NICHD Neonatal Research Network. Comparison of Phototherapy Devices Used in Extremely Low Birth Weight Infants. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Navarrete, C, Duara, S, for the NICHD Neonatal Research Network. Risk-Benefit Analysis of Prophylactic Indomethacin (P-INDO) Use in Extremely Low Birth Weight (ELBW) Infants: Does Post-Menstrual Age Make a Difference to Outcome?

Peralta-Carcelen, M for the NICHD Neonatal Research Network. Socio-Emotional and Competence Problems of Extreme Low Birth Weight Children. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Parikh, NA, Tyson, JE, for the NICHD Neonatal Research Network. Viability, Treatment, and Outcome at 18-22 Months for Extremely Premature Infants. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Salhab, WA, for the NICHD Neonatal Research Network. Delivery Room Cardiopulmonary Resuscitation and Outcome in Extremely Low Birth Weight (ELBW) Infants: A Cohort Analysis. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Sanchez, PJ, Cotten, CM, for the NICHD Neonatal Research Network. Antimicrobial Therapy for Necrotizing Enterocolitis (NEC): Practice Variations and Clinical Outcome. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Sokol, GM, Van Meurs, KP, for the NICHD Neonatal Research Network. Does Inhaled Nitric Oxide (iNO) Exhibit Dose Related Toxicity in the Premature Infant with Severe Respiratory Failure? (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Vaucher, YE, for the NICHD Neonatal Research Network. Does Neonatal Brain Injury Increase the Risk of Emotional and Behavior Problems in Extremely Low Birthweight (ELBW) Children? (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Wilson-Costello, D, Walsh, M, for the NICHD Neonatal Research Network. Impact of Postnatal Corticosteroid Dose and Timing in Extremely Low Birthweight Infants on Neurodevelopment at 18-22 Months. (Presented, to the Society for Pediatric Research, San Francisco, CA, April 29-May 2, 2006)

Brenda Louise Bradley Poindexter, MD, MS

GRANT NUMBER

U10 HD027856-16

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).

Budget Period	Anticipated Amount	Source(s)
N/A	N/A	N/A

2. ASSURANCES/CERTIFICATIONS (See instructions.)

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

- Debarment and Suspension
- Drug- Free Workplace (*applicable to new [Type 1] or revised [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 Agents
- STTR ONLY: Certification of Research Institution Participation.

3. FACILITIES AND ADMINISTRATION (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.

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: 05/14/04 No Facilities and Administration Costs Requested.

No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base \$ 172,246 x Rate applied 51.50 % = F&A costs \$ 88,707
Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

Salary and wages base Modified total direct cost base Other base (*Explain*)

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

Explanation (*Attach separate sheet, if necessary.*):

KEY PERSONNEL REPORT

GRANT NUMBER
 HD027856-16

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

All Key Personnel for the Current Budget Period (do not include Other Significant Contributors)

Name	Degree(s)	SSN (last 4 digits)	Role on Project (e.g. PI, Res. Assoc.)	Date of Birth (MM/DD/YY)	Months Devoted to Project		
					Cal	Acad	Summer
Brenda Poindexter	MD, MS	(b) (6)	PI	(b) (6)	(b) (6)		
Anna Dusick	MD		Follow-up PI				
James Lemons	MD		Alternate PI				
Greg Sokol	MD		Alternate PI				
Leslie Dawn Wilson	RN, BSN		Research Coordinator				
To be named			Data Entry				
Alan Golichowski	MD, PhD		Perinatal Collaborator				

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Generic Database-Survey of Morbidity and Mortality Among VLBW Infants 401-1500 g
 Total Enrollment: 234 Protocol Number: 9612-02
 Grant Number: HD027856-16

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	6	12		18 **
Not Hispanic or Latino	119	97		216
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	125	109		234 *
Racial Categories				
American Indian/Alaska Native	1	0		1
Asian	2	2		4
Native Hawaiian or Other Pacific Islander				
Black or African American	58	41		99
White	64	66		130
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	125	109		234 *
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	0	1		1
White	6	11		17
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or	6	12		18 **

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

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Early Diagnosis of Nosocomial Candidiasis
 Total Enrollment: 2 Protocol Number: 0401-55
 Grant Number: HD027856-16

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

* These totals must agree.

** These totals must agree.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Neurodiagnostic Evaluations that assist in the Prediction of Adverse Outcome
Total Enrollment: 2 **Protocol Number:** 0401-53
Grant Number: HD027856-16

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

* These totals must agree.

** These totals must agree.

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: Early Onset Sepsis - A NICHD/CDC Surveillance Study
Total Enrollment: 12 **Protocol Number:** 0601-88
Grant Number: HD027856-16

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	1		1 **
Not Hispanic or Latino	7	4		11
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	7	5		12 *
Racial Categories				
American Indian/Alaska Native				
Asian	1	0		1
Native Hawaiian or Other Pacific Islander				
Black or African American	4	3		7
White	2	2		4
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	7	5		12 *
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	0	1		1
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or	0	1		1 **

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

Principal Investigator/Program Director (Last, First, Middle): Poindexter, Brenda Louise Bradley

Inclusion Enrollment Report

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

Study Title: SUPPORT
Total Enrollment: 14 **Protocol Number:** 0412-26
Grant Number: HD027856-16

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino				**
Not Hispanic or Latino	8	6		14
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	8	6		14 *
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American	2	0		2
White	6	6		12
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	8	6		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				
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				**

* 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: Phase II Safety and Pharmacokinetic Study of a Single Dose of Inositol in Premature Infants

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			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	1	1	2
White	4	4	8
Racial Categories: Total of All Subjects *	5	5	10

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

For New and Competing Applications (PHS 398) – DO NOT SUBMIT UNLESS REQUESTED
For Non-competing Progress Reports (PHS 2590) – Submit only Active Support for Key Personnel

PHS 398/2590 OTHER SUPPORT

Provide active support for all key personnel. **Other Support** includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included.

There is no "form page" for other support. Information on other support should be provided in the *format* shown below, using continuation pages as necessary. **Include the principal investigator's name at the top and number consecutively with the rest of the application.** The sample below is intended to provide guidance regarding the type and extent of information requested.

For instructions and information pertaining to the use of and policy for other support, see Other Support in the PHS 398 Part III, Policies, Assurances, Definitions, and Other Information.

Note effort devoted to projects must now be measured using person months. Indicate calendar, academic, and/or summer months associated with each project.

POINDEXTER, B.L.B.

ACTIVE

2U10HD27856-16 (Poindexter) 4/01/06-3/31/11 (b) (6) calendar
NIH \$163,910

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

2RO1HL054062 (Tepper) 7/01/06-6/30/10 (b) (6) calendar
NIH \$275,000

Growth of Airways and Lung Parenchyma in Normal Infants

The major goal of this project is to determine the relationship between parenchymal tissue and alveolar volume with normal lung growth early in life and to determine the pulmonary sequelae of premature birth and assess the effectiveness of early treatment strategies upon the pulmonary sequelae.

OVERLAP

There is no scientific overlap between this grant and the Network grant, although some infants who have participated in Network studies may also be enrolled in Aim 2 of this RO1.

DUSICK, A.M.

ACTIVE

2U10HD27856-16 (Poindexter) 4/01/06-3/31/11 (b) (6) calendar
NIH \$163,910

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

ACTIVE

Indiana State Dept Health 10/01/06-6/30/07 (b) (6) calendar
State grant \$298,027

Comprehensive developmental Pediatric Core for Infants and Children with Special Health Care Needs

The major goal of this project is to ensure comprehensive specialty care for at-risk infants and children.

OVERLAP

There is no scientific overlap as this program is for clinical care only.

LEMONS, J.A.

ACTIVE

2U10HD27856-16 (Poindexter) 4/01/06-3/31/11 (b) (6) calendar
NIH \$163,910

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

ACTIVE

6T79 MC 00010-12 (Lemons) 1978 – 2008 (b) (6) calendar
U.S. Dept. of Health and Human Services

Maternal and Child Health Bureau Neonatal Nutrition Training Grant

Leadership Education Excellence in Pediatric Nutrition Program

The major goal of this project is to provide support for a minimum of four predoctoral fellowships to assist dietitians/nutritionists in developing the clinical nutrition skills necessary for quality care of high-risk infants.

OVERLAP

There is no overlap between this project and the application under consideration.

SOKOL, G.M.

ACTIVE

2U10HD27856-16 (Poindexter) 4/01/06-3/31/11 (b) (6) calendar
NIH \$163,910

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

GOLICHOWSKI, A.

ACTIVE

2U10HD27856-16 (Poindexter) 4/01/06-3/31/11 (b) (6) calendar
NIH \$163,910

NICHD Cooperative Multicenter Neonatal Research Network

The major goal of this project is to participate in a NIH-sponsored Network of 16 academic neonatal intensive care programs in the United States to conduct multicenter clinical trials and observational studies in neonatal medicine.

Progress Report Scanning Cover Sheet

5U10HD027856-15

PI Name: **LEMONS, JAMES**
Org: **INDIANA UNIV-PURDUE UNIV AT
INDIANAPOLIS**
Start Date: **04/01/2005**
Snap: **N/A (NEEDS TO BE BOOKMARKED)**
Appl ID: **6895907**
Rec'd
Date: **02/01/2005**

Department of Health and Human Services
 Public Health Services

Review Group (RA)	Type	Activity	Grant Number
	5	U10	HD27856-15
Total Project Period			
From: 04/04/1991		Through: 03/31/2006	
Requested Budget Period:			
From: 04/01/1991		Through: 03/31/2006	

Grant Progress Report

1. TITLE OF PROJECT

Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR

(Name and address, street, city, state, zip code)

James A. Lemons, MD
 Indiana University Medical Center
 Peds, Neonatal-Perinatal Medicine
 699 West Drive, RR 208
 Indianapolis IN 46202-5119

3. APPLICANT ORGANIZATION

(Name and address, street, city, state, zip code)

Indiana University
 Research and Sponsored Programs
 620 Union Drive Room 618
 Indianapolis IN 46202-5167

2b. E-MAIL ADDRESS

jlemons@iupui.edu

4. ENTITY IDENTIFICATION NUMBER

35-6001673

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT

Department of Pediatrics

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL

Assistant Vice President for Research

2d. MAJOR SUBDIVISION

School of Medicine

Indiana University

P.O. Box 1847
 Bloomington IN 47402

E-MAIL: spon2@iupui.edu

6. HUMAN SUBJECTS

No Yes

6a. Research Exempt No Yes

6b. Human Subjects Assurance No. FWA00003544

No Yes

7a. If "Yes," IACUC approval Date

If Exempt ("Yes" in 6a):

Exemption No.

6c. NIH-Defined Phase III

Clinical Trial No Yes

7b. Animal Welfare Assurance No.

If Not Exempt ("No" in 6a):

IRB approval date See page 4

Full IRB or Expedited Review

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT \$ 171,476

8b. TOTAL \$ 255,499

9. INVENTIONS AND PATENTS

No Yes If "Yes," Previously Reported Not Previously Reported

10. PERFORMANCE SITE(S) (Organizations and addresses)

Indiana University
 James Whitcomb Riley Hospital for Children
 702 Barnhill Drive
 Indianapolis IN 46202-5119

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) TEL (317) 274-4716

James A. Lemons, MD FAX (317) 274-2065

11b. ADMINISTRATIVE OFFICIAL NAME (Item 5) TEL (812) 855-3963

Steven A. Martin FAX (812) 855-9943

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)

NAME Mark L. Brenner, PhD
 TITLE Vice Chancellor for Research and Graduate Educ
 TEL (317) 274-8285 FAX (317) 274-8744
 E-MAIL spon2@iupui.edu

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that 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.

SIGNATURE OF PI/PD NAMED IN 2d DATE

(In ink. "Per" signature not acceptable)

James A. Lemons 1/27/05

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Service 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. I agree to accept responsibility for the scientific conduct of the project.

SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Per" signature not acceptable.) DATE

Mark L. Brenner 1/31/05

2005 FEB - 1 PM 11:07

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

Lemons, James A.

DETAILED BUDGET FOR NEXT BUDGET PERIOD -- DIRECT COSTS ONI		FROM 04/01/05	THROUGH 03/31/06	GRANT NUMBER HD27856-15		
PERSONNEL (Applicant organization only)		TYPE APPT. (months)	% EFFORT ON PROJ.	DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT			SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Lemons, James	Principal Investigator	12	(b) (6)	27,686	8,674	36,360
Dusick, Anna	Co-PI, Followup Program	12	(b) (6)	3,183	997	4,180
Miller, Lucy	Res RN Coord	12	(b) (6)	58,511	18,331	76,842
Laughlin, Eileen	Data Manager	12	(b) (6)	23,175	7,261	30,436
				0	0	0
				0	0	0
				0	0	0
				0	0	0
SUBTOTALS				112,555	35,263	147,818
CONSULTANT COSTS						
				0	0	0
EQUIPMENT (Itemize)						
				0	0	0
				0	0	0
				0	0	0
SUPPLIES (Itemize by category)						
	Project-specific data collection materials as specified in protocols				6,578	
	Study participant expenses				0	
					0	
					0	
					0	6,578
TRAVEL						
	PI and study nurse travel to Washington, D.C. (10 trips annually)				14,322	14,322
PATIENT CARE COSTS						
	INPATIENT				0	0
	OUTPATIENT				0	0
ALTERATIONS AND RENOVATIONS (Itemize by category)						
					0	0
OTHER EXPENSES (Itemize by category)						
	Long distance phone calls	318	Postage		583	
	Printing/duplicating	1,857			0	2,758
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD					\$	171,476
CONSORTIUM/CONTRACTUAL COSTS						
	DIRECT COSTS				0	0
	FACILITIES AND ADMINISTRATION COSTS				0	0
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD (Item 8a, Face Page)					\$	171,476

BUDGET JUSTIFICATION**GRANT NUMBER**
HD27856-15

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

NICHD has provided for funding of the follow-up principal investigator at each center for (b) (6) effort. Anna Dusick, M.D. is the follow-up principal investigator at Indiana. She directs the High Risk Newborn Follow-up Program at our center, and is also a member of the Steering Committee for the follow-up program within the NICHD Neonatal Research Network. She spends considerably more than (b) (6) of her time in that role.

NICHD also has provided funding of the principal investigator at each Network center at the level of (b) (6) effort. Dr. Lemons spends at least (b) (6) of his effort on Network activities.

CURRENT BUDGET PERIOD

FROM

THROUGH

Explain any estimated unobligated balance (including prior year carryover) that is greater than 25% of the current year's total budget.

IRB APPROVAL DATES:

STUDY TITLE	IRB PROTOCOL #	MOST RECENT APPROVAL DATE
Generic Database-Survey of Morbidity and Mortality Among Very Low Birth Weight Infants 401-1500 Grams	9612-02	6/15/2004
Follow-up of Premature Infants with Birth Weight Less than 1000 Grams at 18 (+4) Months of Age (Corrected for Gestation)	9412-30	7/20/2004
Randomized Trial of Parenteral Glutamine Supplementation for Extremely Low Birth Weight Infants	9904-09	1/21/2003 *Study Completed
Randomized Controlled Trial of Induced Hypothermia for Hypoxic-Ischemic Encephalopathy in Term Newborns	9907-19	12/16/2004 *Study Completed
Study to determine if Inflammatory Cytokines are Associated with Perinatal Brain Injury and Long Term Neurodevelopmental Handicap	0006-33	3/24/2004 *Enrollment Completed
Randomized Controlled Trial of Benchmarking to Reduce Bronchopulmonary Dysplasia	0105-33	12/16/2004
Inhaled Nitric Oxide for Preterm Infants with Severe Respiratory Failure	0004-22	3/24/2004 *Enrollment Completed
A Randomized Trial of Aggressive or Conservative Phototherapy for Extremely Low Birth Weight Infants.	0204-22	2/17/2004
Neurodiagnostic Evaluations That Assist in the Prediction of Adverse Outcome Following Acute Perinatal Asphyxia	0401-53	12/14/2004
Early Diagnosis of Nosocomial Candidiasis	0401-55	12/14/2004
Association of Apolipoprotein E (apoE) genotype with brain injury and neurodevelopmental outcome in infants with hypoxic ischemic encephalopathy	0410-30	12/17/2004
The <u>S</u> urfactant <u>P</u> ositive Airway Pressure and <u>P</u> ulse <u>O</u> ximetry <u>T</u> rial in Extremely Low Birth Weight Infants	0412-26	12/16/2004 *Provisional Approval

PROGRESS REPORT SUMMARY	GRANT NUMBER HD27856-15	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR James A. Lemons, M.D.	FROM 4/1/04	THROUGH 3/31/05
APPLICANT ORGANIZATION Indiana University		
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	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> 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 principal aim of the NICHD Neonatal Research Network is to perform randomized controlled trials to evaluate the safety and efficacy of treatment and management strategies for newborn infants, particularly for very low birth-weight infants. The Steering Committee has worked diligently over the years, as the Network has grown, to create an organizational structure that permits timely evaluation of important clinical questions in the rapidly changing field of neonatology. In addition to the randomized controlled trials, comprehensive data are collected on all very low birth-weight infants cared for at each of the participating centers with follow-up of the most preterm infants (those weighing less than 1000 grams at birth) through approximately 2 years of corrected age. This generic database and follow-up cohort enable Steering Committee members to obtain information on a large cohort of preterm infants regarding short- and long-term morbidities, differences in outcomes between centers and between different populations of infants, and variations in clinical practice related to outcomes. Focused hypotheses are then generated for consideration for the prospective randomized trials.

b. Studies and Results.

This year has been a very productive one for both the Network and for Indiana. Specific studies and results are as follows:

The Generic Database provides for the collection of comprehensive data on all very low birth-weight infants throughout their hospitalization. During 2004, Indiana enrolled 271 infants weighing less than 1500 grams at birth into the GDB, comprising 8% of the Network GDB.

The Follow-up Program of the Network has been successful in achieving over 80% follow-up success rate. At Indiana, 85% of eligible extremely low birth-weight infants completed follow-up in 2004. Thus far, over 75% of infants eligible for 30 month follow-up have completed this study. In addition, all infants eligible for hypothermia follow-up completed study, as well as all infants in the Inhaled Nitric Oxide Study.

The Randomized Trial of Parenteral Glutamine Supplementation for Extremely Low Birth-Weight Infants was initiated in October 1999, with enrollment of 1430 ELBW infants completed in the fall of 2001. Follow-up of study infants is ongoing and will include 18-22 month as well as 30 month extended followup. Dr. Brenda Poindexter, Assistant Professor of Pediatrics at Indiana University, served as the principal investigator for this trial, with Dr. Lemons as co-principal investigator. The study was designed to evaluate if supplementation of early parenteral nutrition with glutamine will decrease the risk of death or late-onset

sepsis in this population. Results indicated that there was no effect of glutamine supplementation on the primary outcome. While overseeing this large trial, Dr. Poindexter also completed a Masters Degree in Clinical Research at Indiana University School of Medicine. She has gained wonderful experience, and has developed remarkable expertise in clinical trial design and management as a result of her experience with the Network and with her Masters Program. Dr. Poindexter completed the primary manuscript with the input of the subcommittee and other principal investigators, which was published in Pediatrics in May 2004. Dr. Poindexter also presented the impact of early parenteral amino acids on growth and developmental outcome at 18-22 months at the Society for Pediatric Research meeting.

There are numerous other secondary and ancillary studies that have been completed and are ongoing by a number of investigators within the Network. Of particular note is the attention now being given to nutrition and other clinical outcomes within the Network. With the potential impact of breast milk on chronic lung disease, retinopathy of prematurity, sepsis, NEC, growth and neurodevelopmental outcome are all focused questions which are utilizing the glutamine database to query. Dr. Poindexter has continued to work with RTI to formalize methodology for understanding and utilizing the nutrition data, particularly human milk data.

The Benchmarking Study, focused on decreasing chronic lung disease in the very low birth-weight population, was completed in 2004. Dr. William Engle at Indiana University is the principal investigator for this specific study. The Benchmark Team, led by Dr. Engle, Lucy Miller, RN and Richard Hooper, RRT, devoted a major portion of their time in overseeing this initiative at our center. Frequent meetings with the staff and faculty were undertaken, to monitor and maintain momentum to change 13 different practices thought to affect CLD. This study entailed enrollment of an additional 41 babies at Indiana in 2004. The study was effective in that 11 of the 13 practices achieved their goal, although at completion no change in the incidence of CLD occurred for the entire Network. Analysis of individual center data is still ongoing. Two manuscripts have been published/accepted for publication relative to this study.

The Randomized Trial of Aggressive or Conservative Phototherapy for Extremely Low Birth-Weight Infants was initiated in June 2002. Indiana enrolled 54 babies into this trial in 2004. Indiana is also participating in secondary studies for this protocol, including a free bilirubin study and a study of auditory brain stem response. The collection of free bilirubin samples was completed in late 2004. Followup is ongoing, as enrollment into the primary trial is anticipated to be completed in the Spring of 2005.

The Premie Inhaled Nitric Oxide Study was initiated in early 2001, with enrollments discontinued per DSMC in September 2003. Indiana enrolled 34 infants into this trial, representing 7.8% of total. Dr. Greg Sokol at Indiana University has assisted in overseeing the secondary trial at Indiana, evaluating echocardiographic changes during inhaled nitric oxide in the preterm population. The results of the trial were presented at the Society for Pediatric Research Meeting, and the final manuscript is under editorial review by NEJM. The trial demonstrated no benefit of INO in the ELBW population.

Enrollment into the Hypothermia Trial was completed in May 2003 with a total of 208 infants. Follow-up is completed. Results demonstrated a significant benefit on death/neurodevelopmental outcome for infants receiving hypothermia. Results were presented at Hot Topics in December, 2004 and will be presented again at the Society for Pediatric Research in 2005. The primary manuscript will be submitted to NEJM.

The study of the amplitude EEG and other neurodiagnostic evaluations that may assist in the prediction of adverse outcome following acute perinatal asphyxia is ongoing. Indiana enrolled two patients into this trial in 2004.

The study of Apolipoprotein E and its potential association with brain injury and neurodevelopmental outcome in infants with HIE is ongoing. Indiana contributed a total of 12 infants to this trial.

The study of different technologies to provide earlier and more accurate diagnosis of nosocomial Candidiasis is ongoing. Indiana enrolled 7 infants into this trial since its initiation in 2004.

The study to determine if inflammatory cytokines are associated with perinatal brain injury and long term neurodevelopmental impairment is still underway, with analysis of cytokines anticipated in 2005.

The Genomics Subcommittee, of which Dr. Lemons is a member, made a number of initiatives in 2004. Approval was obtained from the Steering Committee to establish a retrospective DNA repository, linked to an anonymized data base comprised of GDB, followup and cytokine data. The DNA samples will be obtained from blood spots initially obtained for the cytokine trial. DNA will be amplified and stored for future study. Two protocols have already been submitted and reviewed by the subcommittee for potential use of the DNA samples. We anticipate a substantial interest in the use of the DNA for studies in the future. The subcommittee also is studying the feasibility of establishing a prospective DNA repository for sample to be collected in concert with the SUPPORT trial, planned for initiation in early 2005.

c. Significance

Each of the trials above is contributing to the evidence needed to support and/or change clinical practice in Neonatology. The Hypothermia Trial is an example of the benefit of large randomized trials in assessing the potential benefit of new therapies. Further, these trials or databases are serving to generate additional hypotheses which will be addressed with observational or randomized trials of the future. The Benchmarking Trial is of particular note as it has been a new undertaking for the Network. This is an initiative that addresses quality improvement strategies which are of increasing priority to medicine in general, and neonatology in particular. The Network is giving direction and prioritization of quality improvement to the larger neonatal community through this trial.

The Glutamine Trial was one of the most effective and efficient clinical studies performed by the Network. It has yielded more secondary and ancillary studies than any other trial to date. It has also established renewed interest in the area of nutrition for the extremely preterm population.

The Steering Committee is beginning one of its most challenging studies, the SUPPORT Trial, in early 2005. This is a management trial(s), assessing the potential benefit of DR CPAP vs standard intubation with surfactant administration in the delivery room on the development of BPD. The second factorially designed study is high vs lower oxygen saturations and the potential effect on ROP. This is a difficult clinical study which entails fundamental changes in clinical practice by neonatologists in the delivery room setting. The pilot study has been successfully completed, and demonstrates the feasibility of the larger trial. The Steering Committee enthusiastically supported a request to perform the SUPPORT Trial using a data set and inclusion/exclusion criteria shared by several other international trial groups who are embarking on similar trials to assess high and lower oxygen saturations. Common equipment and uniform primary outcomes are also being used by the different trial groups. This will enable a prospective meta-analysis to be designed and performed.

A number of other trials are being considered and prioritized by the Steering Committee, including Inositol for prevention of ROP, NA and fluid restriction to prevent BPD, Phenobarbital for treatment of seizures in near term and term infants (assessment of safety and efficacy), and a potential randomized trial of drain vs laparotomy for NEC in ELBW infants.

Overall, this has been an exciting year for the Network as a whole. It has been the goal of many Steering Committee members, and particularly for Dr. Lemons, to engage young investigators into the Network. Drs. Poindexter and Sokol have developed exceptional experience and expertise in clinical research because of their involvement at the Network over the last several years. In addition, Dr. Anna Dusick, the follow-up principal investigator at Indiana, has been intimately involved in the leadership of the Network Follow-up Program. She and Dr. Betty Vohr continue to identifying potential clinical trials that can be performed primarily by the follow-up investigators. Neurodevelopmental outcome and growth outcome have become primary or secondary outcomes on almost every interventional trial designed by the Network.

Network Publications

2004

Boukydis CF, Bigsby R, Lester BM. Clinical use of the Neonatal Intensive Care Unit Network Neurobehavioral Scale. Pediatrics. 2004 Mar;113(3 Pt 2):679-89

Castro L, Yolton K, Haberman B, Roberto N, Hansen NS, Ambalavanan N, Vohr BR, Donovan EF. Bias in Reported Neurodevelopmental Outcomes Among Extremely Low Birth Weight Survivors. Pediatrics 2004; Aug; 114: 404-410.

Das A, W. Kenneth Poole WK, Bada HS. A Repeated Measures Approach for Simultaneous Modeling of Multiple Neurobehavioral Outcomes in Newborns Exposed to Cocaine in utero. Am J Epidemiology. 2004 May 1;159(9):891-9.

Finer NN, Carlo WA, Duara S, Fanaroff AA, Donovan EF, Wright LL, Kandefor S. Delivery Room Continuous Positive Airway Pressure/Positive End Expiratory Pressure (CPAP/PEEP) In Extremely Low Birth Weight (ELBW) Infants; A Feasibility Trial. Pediatrics 2004 Sep;114(3):651-7.

Konduri G, Solimano A, Sokol GM, Singer J, Ehrenkranz RA, Singhal N, Wright LL, VanMeurs K, Stork E, Kirpalani H, and Peliowski A for the Neonatal Inhaled Nitric Oxide Study Group. A randomized trial of early versus standard inhaled nitric oxide therapy in term and near-term newborn infants with hypoxic respiratory failure. Pediatrics, 2004 Mar (113): 559-564.

Lester BM, Tronick EZ, LaGasse L, Seifer R, Bauer CR, Shankaran S, Bada HS, Wright LL, Smeriglio VL, Lu J. Summary statistics of neonatal intensive care unit network neurobehavioral scale scores from the maternal lifestyle study: a quasinormative sample. Pediatrics. 2004 Mar;113(3 Pt 2):668-75

Lester BM, Tronick EZ, Brazelton TB. The Neonatal Intensive Care Unit Network Neurobehavioral Scale procedures. Pediatrics. 2004 Mar;113(3 Pt 2):641-67

Lester BM, Tronick EZ. History and description of the Neonatal Intensive Care Unit Network Neurobehavioral Scale. Pediatrics. 2004 Mar;113(3 Pt 2):634-40.

Messinger DS, Bauer CR, Das A, Seifer R, Lester BM, LaGasse LL, Wright LL, Shankaran S, Bada HS, Smeriglio VL, Langer JC, Poole WK. The Maternal Lifestyle Study (MLS): Cognitive, Motor, and Behavioral Outcomes of Cocaine Exposed and Opiate Exposed Infants Through Three Years of Age. Pediatrics 2004 Jun;113(6):1677-85

Ohls R, Ehrenkranz RA, Das A, Dusick AM, Yolton K, Sherwonit E, Delaney-Black V, Papile A, Simon NP, Steichen JL, Gronsmann Lee K. Neurodevelopmental Outcome and Growth at 18-22 Months Corrected Age in Extremely Low Birth Weight Infants Treated with Early Erythropoietin and Iron. Pediatrics 2004 Nov;114(5):1287-91.

Poindexter BB, Ehrenkranz RA, Stoll BJ, Wright LL, Poole WK, Oh W, Bauer CR, Papile L, Tyson JE, Carlo WA, Lupton AR, Narendran V, Stevenson DK, Fanaroff AA, Korones SB, Shankaran S, Finer NN, Lemons JA. Parenteral Glutamine Supplementation Does Not Reduce The Risk of Mortality or Late-Onset Sepsis in Extremely-Low-Birth-Weight Infants. Pediatrics 2004 May;113(5):1209-15.

Seifer, R, LaGasse, LL, Lester, B, Bauer, DR, Shankaran, S, Bada, HS, Wright, LL, Smeriglio, VL, Liu, J. Attachment Status in Children Prenatally Exposed to Cocaine and Other Substances. Child Development 2004 May-Jun;75(3):850-68.

Shankaran, S, Das, A, Bauer, CR, Bada, HS, Lester, B, Wright, LL, Smeriglio, V. Associations Between patterns of Maternal Substance Use and Infant Birth weight, Length and Head Circumference. Pediatrics 2004; August ;114: e226-e234.

Shankaran S, Johnson Y, Langer JC, Vohr BR, Fanaroff AA, Wright LL, Poole WK. Outcome of Extremely Low Birth Weight Infants at Highest Risk: Gestational Age ≤ 24 Weeks, Birth Weight ≤ 750 g and 1 Minute Apgar ≤ 3 . American Journal of Obstetrics and Gynecology 2004 191 1084-91.

Stoll BJ, Hansen N, Fanaroff AA, Lemons JA. Enterobacter Sakazakii is a Rare Cause of Neonatal Sepsis/Meningitis in VLBW Infants. Journal of Pediatrics 2004 Jun;144(6):821-3.

Stoll BJ, Hansen N, Adams-Chapman I, Fanaroff AA, Hintz SR, Vohr BR, Higgins RD. Neurodevelopmental and Growth Impairment Among Extremely Low Birth-weight Infants with Neonatal Infection. JAMA. 2004 Nov 17;292(19):2357-2365.

Stoll BJ, Hansen N, Fanaroff AA, Wright LL, Carlo WA, Ehrenkranz RA, Lemons JA, Donovan EF, Stark AR, Tyson JE, Oh W, Bauer CR, Korones SB, Shankaran S, Laptook AR, Stevenson DK, Papile L, Poole WK. To Tap or Not to Tap: High Likelihood of Meningitis Without Sepsis Among Very Low Birth Weight Infants. Pediatrics 2004 May;113(5):1181-6.

Tronick EZ, Olson K, Rosenberg R, Bohne L, Lu J, Lester BM. Normative neurobehavioral performance of healthy infants on the Neonatal Intensive Care Unit Network Neurobehavioral Scale. Pediatrics. 2004 Mar;113(3 Pt 2):676-8

Vohr BR, Wright LL, Dusick AM, Perritt R, Poole WK, Delaney –Black V, Yolton K, Broyles S, Tyson JE, Steichen JJ, Bauer CR, Fleisher BE, Papile LA, Wilson DC, Simon NP, Kaplan MD for the NICHD Neonatal Research Network. Center differences and outcomes of extremely-low-birth-weight infants. Pediatrics 2004 Apr;113(4):781-9.

Walsh MC, Yao Q, Gettner P, Hale E, Collins M, Hensman A, Everett R, Peters N, Miller N, Muran G, Auten K, Newman N, Rowan G, Grisby C, Arnell K, Miller L, Ball B, McDavid G. Impact of a Physiologic Definition on Bronchopulmonary Dysplasia Rates. Pediatrics 2004; 114: 1305-1311.

2005

Ambalavanan N, Carlo W, Bobashev G, Mathias E, Poole WK, Fanaroff AA, Stoll BJ, Ehrenkranz RA, Wright LL. Prediction of mortality in extremely low birth weight neonates by regression analysis and by neural networks. Pediatrics (in press).

Ambalavanan N, Tyson, JE, Kennedy, KA, Hansen, N, Vohr, BR, Wright, LL, Carlo, WA. Vitamin A Supplementation for Extremely Low Birth Weight Infants: Outcome at 18-22 Months. Pediatrics (in press)

Benjamin DK Jr, Stoll BJ, Fanaroff AA, McDonald SA, Oh W, Higgins R, Duara S, Poole K, Laptook A, Goldberg R. Neonatal Candidiasis Among Infants < 1000g Birthweight: Risk Factors, Mortality, and Neuro-Developmental Outcomes at 18-22 months. Pediatrics (in press).

Brunner SM, Messinger DS, Bauer CR. Cocaine Exposure and Mother-Toddler Social Play. Infant and Behavior (in press).

Hintz SR, Kendrick DE, Stoll BJ, Vohr BR, Fanaroff AA, Donovan EF, Poole WK, Blakely ML, Linda Wright LL. Neurodevelopmental and Growth Outcomes of Extremely Low Birth Weight Infants After Necrotizing Enterocolitis. Pediatrics (in press)

Hintz, SR, Poole, WK, Wright, LL, Fanaroff, AA, Kendrick, DE, Luptook, AR, Goldberg, RN, Duara, S, Stoll, BJ, Oh, W. Changes in Mortality and Morbidities Among Infants Born at Less Than 25 Weeks During the Post-Surfactant Era. Archives in Childhood Diseases (in press)

Hintz SR, Kendrick, DE, Vohr, BR, Poole, WK, Higgins, RD. Changes in Neurodevelopmental Outcomes at 18-22 Months Corrected Age Infants Less than 25 Weeks Born 1993-1999. Pediatrics (in press).

Luptook AR, O'Shea TM, Shankaran S, Bhaskar B. Birth Weight Infants with a Normal Head Ultrasound: Prevalence and Antecedents. Pediatrics (in press)

Loncar C, Lester BM, Seifer R, Lagasse LL, Bauer CR, Shankaran S, Bada HS, Wright LL, Smeriglio VL, Liu, J. Predictors of motor development in children prenatally exposed to cocaine. Neurotoxicol and Teratol (in press)

Tronick EZ, Messinger DS, Weinberg MK, Lester BM, LaGasse LL, Seifer R, Bauer CR, Shankaran S, Bada H, Wright LL, Smeriglio VL, Poole WL, Liu J. Cocaine Exposure Compromises Infant and Caregiver Social Emotional Behavior and Dyadic Interactive Features in the Face-to-Face Still-Face Paradigm. Dev Psych (in press)

Vohr, BR, Msall, ME, Wilson, D, Wright, LL, McDonald, S, Poole, WK. Spectrum of Gross Motor Function in Extremely Low Birthweight (ELBW) Children with Cerebral Palsy at 18 Months of Age. Pediatrics (in press)

Walsh, M, Engle, W, Luptook, A, Kazzi, SN, Buchter, S, Rasmussen M, Yao, Q. Oxygen Delivery by Nasal Cannula to Preterm Infants: Opportunities for Improvement. Pediatrics (in press)

Manuscripts Under Review

Bada HS, Abhik Das A, Bauer CR, Shankaran S, Lester BM, Gard CC, Wright LL, Smeriglio VL, LaGasse LL. Low Birth Weight, Prematurity And Intrauterine Growth Restriction: Disease Burden From Legal And Illegal Drug Use.

Bauer CR, Shankaran S, Bada HS, Lester BM, Wright LL, Langer JC, Krause-Steinrauf H, Smeriglio VL, Finnegan LP, Maza PL, Verter J. Illegal drug exposure during pregnancy and acute neonatal outcomes--The Maternal Lifestyle Study (MLS).

Cotten CM, Oh W, McDonald S, Fanaroff AA, Carlo WA, Duara S, Stoll BJ, Luptook AR, Poole WK, Wright LL, Goldberg RN. Risk-Adjusted Center Differences in Prolonged Hospital Stay Among Extremely-Low-Birth-Weight Infants.

Fanaroff AA, Stoll BJ, Wright LL, Carlo WA, Ehrenkranz RA, Stark A, Bauer CR, Donovan EF, Korones SB, Luptook A, Lemons JA, Oh W, Papile L, Shankaran S, Stevenson DK, Tyson JE, Poole WK. Very Low-Birth-Weight (VLBW) Outcomes of the NICHD Neonatal Research Network January 1997 through December 2000: A Plateau, Is Further Improvement Feasible?

Lemons JA, Stevenson DK, Poole WK, Bearden-Branch A, Bauer CR, Papile LA, Shankaran S, Tyson JE, Wright LL, Stark AR, Donovan EF, Carlo WA, Oh W, Stoll BJ, Fanaroff AA, Korones SB, Ehrenkranz RA. In utero magnesium exposure: Effects on extremely-low-birth-weight infants.

Morris, BH, Gard, CC, Kennedy K, for the NICHD Neonatal Research Network. Rehospitalization of Extremely Low Birth Weight (ELBW) Infants: Are there racial/ethnic disparities?

Stark, AR, Carlo, WA, Vohr, BR, Papile, L, Bauer, C, Donovan, E, Oh, W, Shankaran, S, Tyson, JE, Wright, LL, Saha, S, Poole, K. Neurodevelopmental outcome and growth at 18-22 months in infants treated with early dexamethasone.

Stark AR, Tyson JE, Hibberd PL. Variation among institutional review boards in evaluating the design of a multicenter randomized trial.

Van Meurs, KP, Wright, LL, Ehrenkranz, RA, Lemons, JA, Ball, MB, Poole, WK, Perritt, R, Higgins, RD, Oh, W, Hudak, ML, Laptook, AR, Shankaran, S, Finer, NN, Carlo, WA, Kennedy, KA, Fridriksson, JH, Steinhorn, RH, Sokol, GM, Konduri, GG, Aschner, JL, Stoll, BJ, D'Angio, CT, Stevenson, DK. Inhaled Nitric Oxide for Premature Infants with Severe Respiratory Failure.

Vohr, BR, Wright, LL, Poole, WK, McDonald, S. Neurodevelopmental Outcomes of Extremely Low Birth Weight Infants <32 weeks Gestation Between 1993 and 1998>.

Wadhawan, R, Fanaroff, AA, Perritt, R, Duara, S, Stoll, BJ, Goldberg, R, Laptook, A, Poole, WK, Wright, LL and Oh, W. Early postnatal weight loss is associated with decreased risk of bronchopulmonary dysplasia or death in very low birth weight infants.

Walsh MC, Morris BH, Wrage L, Vohr BR, Poole WK, Tyson JE, Wright LL, Ehrenkranz RA, Stoll BJ, Fanaroff AA. Mortality and 18-Month Neurodevelopmental Outcomes in Extremely Low Birthweight Neonates with Persistent Ventilator Dependence

Manuscripts in draft

Bauer CR, Steichen JJ, Vohr BR, Dusick A, Wright LL, Verter J, Mele L, The NICHD Neonatal Research Network Follow-up Study. Developmental resource utilization and health outcome in extremely-low-birth-weight (401-1000 gm) infants.

Blakley M, Stevenson DK, Stoll BJ, Jobe A, Poole WK, Tyson JE. Outcome of Extremely Low Birth Weight Premature Infants with Necrotizing Enterocolitis or Isolated Intestinal Perforation Treated With Initial Laparotomy or Peritoneal Drainage.

Ehrenkranz RA, Walsh MC, Vohr BR, Jobe AC, Wright LL, Fanaroff AA, Wrage LA, Poole WK. New Consensus Definition of Bronchopulmonary Dysplasia Predicts Pulmonary and Neurodevelopmental Outcomes in Early Infancy

Ehrenkranz RA, Dusick AM, Vohr BR, Wright LL, Wrage L, Poole WK. Outcomes in Early Infancy Early Growth in the NICU Influences Early Childhood Outcome of Extremely Low Birth Weight Infants

Guillet R, Stoll BJ, McDonald S, Poole WK, Phelps DI. Association of H2 Blocker Therapy and Lower Incidence of Necrotizing Enterocolitis in Very Low Birth Weight Infants.

Maza PL, Wright LL, Bauer CR, Shankaran S, Bada HS, Lester B, Krause-Steinrauf H, Smeriglio VL, Bowler A, Katsikiotis V. Maternal Lifestyles Study: Risk, residential stability and caretakers of drug-exposed and comparison infants at one-month corrected age.

Oh W, Poindexter BB, Perritts R, Lemons JA, Bauer CR, Ehrenkranz RA, Papile LA, Stoll BJ, Poole WK, Wright LL. High Parenteral Fluid Intake During the First Week of Life is Associated with Increased Risk of Bronchopulmonary Dysplasia in Extremely Low Birth Weight Infants.

Wright LL, Bauer CR, Shankaran S, Bada HS, Lester B, Katsikiotis V, Smeriglio VL, Finnegan LP, Maza PL, Krause-Steinrauf H. The Maternal Lifestyles Study: Health status of substance-exposed infants at one-month corrected age.

Abstracts

2004

Ambalavanan N, Tyson, JE, Kennedy, KA, Hansen, N, Vohr, BR, Wright, LL, Carlo, WA for the NICHD Neonatal Research Network Does Vitamin A Supplementation Affect Long-Term Neurodevelopment in Extremely Low Birth Weight (ELBW) Infants? (submitted to the Society for Pediatric Research, 2004)

Ambalavanan, N, Baibergenova, A, Carlo, WA, Saigal, S, Schmidt, B, Thorpe, KE, and the TIPP Investigators Early Prediction of Poor Outcome in Extremely Low Birth Weight (ELBW) Infants by Classification and Regression Tree Analysis. (submitted to the Society for Pediatric Research, 2004)

Broitman, E, Ambalavanan, N, Higgins, R, Das, A, Bhaskar, B, Murray, K, Vohr, BR, Shankaran, S, Hintz, S, Carlo, WA, for the NICHD Neonatal Research Network Cranial Ultrasound Closer to 36 Weeks but Not in the First 28 Days When Combined With Clinical Variables Is Predictive of Long-Term Neurodevelopmental Outcome. (submitted to the Society for Pediatric Research, 2004)

Bada, H, Bursi, C, Twomey, J, Langer, J and (MLS: Lester, BM, Shankaran, S, Bauer, CR, Poole, WK, Higgins, R, Smeriglio, V) Behavior Problems and Adaptive Skills of Children in Out-of-Home Placement Because of Prenatal Drug Exposure. (submitted to the Society for Pediatric Research, 2004)

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Lemons, James A.

GRANT NUMBER

U11 HD27856-15

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 is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)
N/A	N/A	N/A

2. ASSURANCES/CERTIFICATIONS (See instructions.)

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

- Debarment and Suspension
- Drug- Free Workplace (applicable to new [Type 1] or revised [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 Agents

3. FACILITIES AND ADMINISTRATION (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.

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 date 05/14/04 No Facilities and Administration Costs Requested
- No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base \$ 171,476 x Rate applied 49.00 % = F&A costs \$ 84,023
 Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

- Salary and wages base Modified total direct cost base Other base (Explain)
- Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary.):

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Inclusion Enrollment Report

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

Generic Database-Survey of Morbidity and Mortality Among Very Low Birth Weight Infants

Study Title: 401-1500 Grams

Total Enrollment: 271 **Protocol Number:** 9612-02

Grant Number: HD27856-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	8	10	0	18 **
Not Hispanic or Latino	113	138	0	251
Unknown (individuals not reporting ethnicity)	2	0	0	2
Ethnic Category: Total of All Subjects*	123	148	0	271 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	2	1	0	3
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	37	39	0	76
White	82	108	0	190
More Than One Race	0	0	0	0
Unknown or Not Reported	2	0	0	2
Racial Categories: Total of All Subjects*	123	148	0	271 *
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	10	0	18
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	8	10	0	18 **

* 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: Follow-up of Premature Infants with Birth Weight Less than 1000 Grams at 18 (+4) Months of Age (Corrected for Gestation)

Total Enrollment: 87 **Protocol Number:** 9412-30

Grant Number: HD27856-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	3	1	0	4 **
Not Hispanic or Latino	44	39	0	83
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	47	40	0	87 *
Racial Categories				
American Indian/Alaska Native	1	0	0	1
Asian	1	1	0	2
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	23	10	0	33
White	22	29	0	51
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	47	40	0	87 *
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	1	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**	3	1	0	4 **

* 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: Follow-up of Premature Infants with Birth Weight Less than 1000 Grams at 30 Months of Age (Corrected for Gestation)

Total Enrollment: 17 **Protocol Number:** 9412-30

Grant Number: HD27856-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	8	9	0	17
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	8	9	0	17 *
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	1	0	4
White	5	8	0	13
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	8	9	0	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	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: Randomized Controlled Trial of Induced Hypothermia for Hypoxic-Ischemic Encephalopathy in Term Newborns

Total Enrollment: 1 **Protocol Number:** 9907-19

Grant Number: HD27856-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
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	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*	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.

Inclusion Enrollment Report

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

Study Title: Study to determine if Inflammatory Cytokines are associated with Perinatal Brain Injury and Long Term Neurodevelopmental Handicap

Total Enrollment: 6 **Protocol Number:** 0006-33

Grant Number: HD27856-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	1	5	0	6
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	1	5	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	0	3	0	3
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*	1	5	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.

Inclusion Enrollment Report

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

Study Title: Randomized Controlled Trial of Benchmarking to Reduce Bronchopulmonary Dysplasia
Total Enrollment: 41 **Protocol Number:** 0105-33
Grant Number: HD27856-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	1	0	0	1 **
Not Hispanic or Latino	17	23	0	40
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	18	23	0	41 *
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	6	0	7
White	16	17	0	33
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	18	23	0	41 *
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.

Inclusion Enrollment Report

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

Study Title: Inhaled Nitric Oxide for Preterm Infants with Severe Respiratory Failure
Total Enrollment: 34 **Protocol Number:** 0004-22
Grant Number: HD27856-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	15	19	0	34
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	15	19	0	34 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	1	0	1
Black or African American	4	2	0	6
White	11	16	0	27
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	15	19	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	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: A Randomized Trial of Aggressive or Conservative Phototherapy for Extremely Low Birth Weight Infants

Total Enrollment: 54 **Protocol Number:** 0204-22

Grant Number: HD27856-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	2	0	2 **
Not Hispanic or Latino	25	27	0	52
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	25	29	0	54 *
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	7	6	0	13
White	18	23	0	41
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	25	29	0	54 *
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.

Inclusion Enrollment Report

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

Study Title: A Randomized Trial of Aggressive or Conservative Phototherapy for Extremely Low Birth Weight Infants - Follow-up

Total Enrollment: 20 **Protocol Number:** 0204-22

Grant Number: HD27856-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	1	0	0	1 **
Not Hispanic or Latino	11	8	0	19
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	12	8	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	6	3	0	9
White	6	5	0	11
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	12	8	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	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.

Inclusion Enrollment Report

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

Study Title: Neurodiagnostic Evaluations That Assist in the Prediction of Adverse Outcome Following Acute Perinatal Asphyxia

Total Enrollment: 2 **Protocol Number:** 0401-53

Grant Number: HD27856-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	1	1	0	2
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	1	1	0	2 *
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	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*	1	1	0	2 *
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: Early Diagnosis of Nosocomial Candidiasis
Total Enrollment: 7 **Protocol Number:** 0401-55
Grant Number: HD27856-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
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	0	0	0	0
White	5	2	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	2	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.

Targeted/Planned Enrollment Table

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

Generic Database - Survey of Morbidity and Mortality Among Very Low Birth Weight Infants

Study Title: 401-1500 Grams

Total Planned Enrollment: 280

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	7	8	15
Not Hispanic or Latino	130	135	265
Ethnic Category: Total of All Subjects *	137	143	280
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	35	45	80
White	95	105	200
Racial Categories: Total of All Subjects *	130	150	280

* 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.

Follow-up of Premature Infants with Birth Weight Less than 1000 Grams at 18 (+4) Months of
Study Title: Age (Corrected for Gestation)

Total Planned Enrollment: 100

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	2	2	4
Not Hispanic or Latino	53	43	96
Ethnic Category: Total of All Subjects *	55	45	100
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	20	25	45
White	23	32	55
Racial Categories: Total of All Subjects *	43	57	100

* 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.

Randomized Controlled Trial of Induced Hypothermia for Hypoxic-Ischemic Encephalopathy in
Study Title: Term Nowborns

Total Planned Enrollment: 0

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	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."

Targeted/Planned Enrollment Table

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

Study Title: Randomized Controlled Trial of Benchmarking to Reduce Bronchopulmonary Dysplasia

Total Planned Enrollment: 0

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	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."

Targeted/Planned Enrollment Table

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

A Randomized Trial of Aggressive or Conservative Phototherapy for Extremely Low Birth

Study Title: Weight Infants

Total Planned Enrollment: 50

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	3	2	5
Not Hispanic or Latino	21	24	45
Ethnic Category: Total of All Subjects *	24	26	50
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	4	10
White	19	21	40
Racial Categories: Total of All Subjects *	25	25	50

* 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.

Neurodiagnostic Evaluations That Assist in the Prediction of Adverse Outcome Following Acute

Study Title: Perinatal Asphyxia

Total Planned Enrollment: 4

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	1	1	2
Not Hispanic or Latino	1	1	2
Ethnic Category: Total of All Subjects *	2	2	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	1	2
White	1	1	2
Racial Categories: Total of All Subjects *	2	2	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: Early Diagnosis of Nosocomial Candidiasis

Total Planned Enrollment: 70

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	2	3	5
Not Hispanic or Latino	37	28	65
Ethnic Category: Total of All Subjects *	39	31	70
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	6	10
White	27	33	60
Racial Categories: Total of All Subjects *	31	39	70

* 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.

Association of Apolipoprotein E (apoE) genotype with brain injury and neurodevelopmental
Study Title: outcome in infants with hypoxic ischemic encephalopathy

Total Planned Enrollment: 4

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	2	4
Ethnic Category: Total of All Subjects *	2	2	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	0	0	0
White	2	2	4
Racial Categories: Total of All Subjects *	2	2	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.

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

Total Planned Enrollment: 100

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	5	5	10
Not Hispanic or Latino	45	45	90
Ethnic Category: Total of All Subjects *	50	50	100
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	10	20
White	40	40	80
Racial Categories: Total of All Subjects *	50	50	100

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

KEY PERSONNEL REPORT

GRANT NUMBER
 HD27856-15

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

All Key Personnel for the Current Budget Period (do not include Other Significant Contributors)

Name	Degree(s)	SSN (last 4 digits)	Role on Project (e.g. PI, Res. Assoc.)	Date of Birth (MM/DD/YY)	Annual % Effort
James A. Lemons	M.D.	(b) (6)	PI	(b) (6)	(b) (6)
Anna Dusick	M.D.	[REDACTED]	Co-PI, Follow-up	[REDACTED]	[REDACTED]
Lucy Miller	B.S.N.	[REDACTED]	Nurse Coord.	[REDACTED]	[REDACTED]
Elleen Laughlin		[REDACTED]	Data Analysis	[REDACTED]	[REDACTED]