DEPARTMENT OF HEALTH AND HUMAN SERVICES

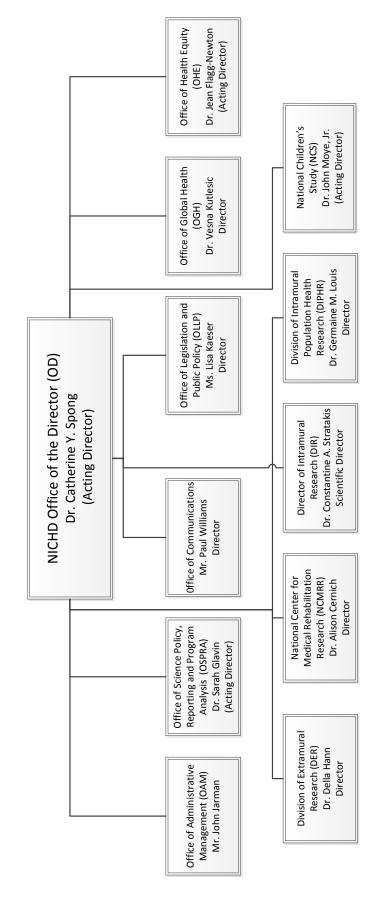
NATIONAL INSTITUTES OF HEALTH

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

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NOTE: The FY 2017 Enacted funding amounts cited throughout this chapter reflect the effects of OAR HIV/AIDS Transfers.

National Institute of Child Health and Human Development **Eunice Kennedy Shriver**



NATIONAL INSTITUTES OF HEALTH

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

For carrying out section 301 and title IV of the PHS Act with respect to child health and human development, [\$1,339,802,000]\$1,316,607,000.

Amounts Available for Obligation¹

(Dollars in Thousands)

Source of Funding	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
Appropriation	\$1,286,571	\$1,339,802	\$1,338,348
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	(0)	(0)	(0)
Other Mandatory financing	(0)	(0)	(21,741)
Rescission	0	0	0
Sequestration	0	0	0
FY 2015 First Secretary's Transfer	0	0	0
FY 2015 Second Secretary's Transfer	0	0	0
Subtotal, adjusted appropriation	\$1,286,571	\$1,339,802	\$1,338,348
OAR HIV/AIDS Transfers	298	-1,454	0
National Children's Study Transfers	0	0	0
Subtotal, adjusted budget authority	\$1,286,869	\$1,338,348	\$1,338,348
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$1,286,869	\$1,338,348	\$1,338,348
Unobligated balance lapsing	-72	0	0
Total obligations	\$1,286,797	\$1,338,348	\$1,338,348

 $^{^1}$ Excludes the following amounts for reimbursable activities carried out by this account: FY 2015 - \$30,135 $\,$ FY 2016 - \$32,000 $\,$ FY 2017 - \$32,000

NATIONAL INSTITUTES OF HEALTH **NICHD**

Budget Mechanism - Total¹ (Dollars in Thousands)

MECHANISM	FY 201		15 Actual FY 2016 Enacted		FY 2017 President's Budget ³			2017 +/- 2016
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	1,056	\$510,952	1,025	\$500,651	1,040	\$512,925	15	\$12,274
Administrative Supplements	(32)	2,544	(25)	3,000	(25)	3,000	_	_
Competing:	-	=	_	=	=	=	_	_
Renewal	34	27,341	41	33,721	37	30,898	-4	-2,823
New	363	122,128	434	148,410	390	135,987	-44	-12,423
Supplements		<u>-</u>	-	<u> </u>	=	<u>-</u>		
Subtotal, Competing	397	\$149,469	475	\$182,131	427	\$166,885	-48	\$15,246
Subtotal, RPGs	1,453	\$662,964	1,500	\$685,782	1,467	\$682,810	-33	-\$2,972
SBIR/STTR	76	33,344	85	36,440	90	38,335	5	1,895
Research Project Grants	1,529	\$696,308	1,585	\$722,222	1,557	\$721,145	-28	-\$1,077
Research Centers:	47	ec2 017	47	DC4 CD5	4.6	Ø60 120	1	04.555
Specialized/Comprehensive	47	\$62,917	47	\$64,685	46	\$60,130	-1	-\$4,555
Clinical Research	3	2 226	-	6 070	4	6 070	-	-
Biotechnology	3	3,226 1,239	4	6,970	4	6,970 510	-	-
Comparative Medicine	-	1,239	-	510	-	310	-	-
Research Centers in Minority Institutions Research Centers	50	\$67,381	51	\$72,165	50	\$67,610	-1	-\$4,555
	30	\$07,381	31	\$72,103	30	\$67,610	-1	-\$4,333
Other Research: Research Careers	241	\$40,412	242	\$42,619	208	\$39,219	-34	-\$3,400
Cancer Education		\$40,412	242	\$42,019	208	\$39,219	-34	-\$3,400
Cooperative Clinical Research	76	39,616	64	41,326	64	41,326	-	-
Biomedical Research Support	70	37,010	04	41,320	04	41,320	-	-
Minority Biomedical Research Support	-	-	-	-	-	-	-	-
Other	140	25,270	156	33,752	156	33,752	-	-
Other Research	457	\$105,298	462	\$117,697	428	\$114,297	-34	-\$3,400
Total Research Grants	2,036	\$868,988	2,098	\$912,084	2,035	\$903,052	-63	-\$9,032
Ruth L Kirchstein Training Awards:	<u>FTTPs</u>	_	FTTPs		FTTPs	_	FTTPs	_
Individual Awards	92	\$4,172	114	\$5,228	136	\$6,215	22	\$987
Institutional Awards	523	26,881	489	25,609	461	24,622	-28	-987
Total Research Training	615	\$31,053	603	\$30,837	597	\$30,837	-6	_
Research & Develop. Contracts	98	\$131,561	99	\$133,827	99	\$137,627	_	\$3,800
$(SBIR/STTR) (non-add)^2$	(1)	(283)	(3)	(290)	(3)	(290)	-	=
Intramural Research	309	\$186,317	312	\$190,932	312	\$194,751	-	\$3,819
Res. Management & Support	240	68,950	242	70,668	242	72,081	-	1,413
Res. Management & Support (SBIR Admin) (non-add) ²	-	(373)	-	(400)	-	-	-	(-400)
Office of the Director - Appropriation ²	-	-	-	-	-	-	-	-
Office of the Director - Appropriation								
ORIP/SEPA (non-add) ²	-	=	-	=	=	=	-	-
Common Fund (non-add) ²	-	-	-	-	-	-	-	=
Common I and (non dad)	-	-	=	-	-	-	-	-
Buildings and Facilities	_	_	_	_	-	_	_	_
Appropriation	_		_				_	
Type 1 Diabetes								
Program Evaluation Financing	-	-	_	_	-	_	_	_
Cancer Initiative Mandatory Financing	_	_	_	_	=	_	_	_
Other Mandatory Financing		=		_		-21,741		-21,741
Subtotal, Labor/HHS Budget Authority		\$1,286,869		\$1,338,348	_	\$1,316,607		-\$21,741
Interior Appropriation for Superfund Res.						-		
Total, NIH Discretionary B.A.		\$1,286,869		\$1,338,348		\$1,316,607		-\$21,741
Type 1 Diabetes		=		=		=		
Proposed Law Funding		_		_		_		
Cancer Initiative Mandatory Financing	 -	_		_	-			
Other Mandatory Financing	-	d1 201 011		ф1 220 24C	_	21,741		21,741
Total, NIH Budget Authority		\$1,286,869		\$1,338,348		\$1,338,348		
Program Evaluation Financing Total Program Level	-	¢1 207 070		¢1 229 240		¢1 220 240		
Total, Program Level	<u> </u>	\$1,286,869		\$1,338,348		\$1,338,348		

¹ All Subtotal and Total numbers may not add due to rounding. ² All numbers in italics and brackets are non-add.

³ Includes mandatory financing.

Major Changes in the Fiscal Year 2017 President's Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanisms and activity detail and these highlights will not sum to the total change for the FY 2017 President's Budget for NICHD, which is the same as the FY 2016 Enacted level, for a total of \$1,338,348,000.

Research Project Grants (RPGs) (-\$1.077 million, total \$721.145 million):

NICHD will support a total of 1557 Research Project Grant (RPG) awards in FY 2017. Non-competing RPGs will increase by 15 awards and the amount to support the costs associated with the commitments of prior year competing awards will increase by \$12.274 million compared to the FY 2016 Enacted level. Competing RPGs will decrease by 48 grants compared to the FY 2016 Enacted level of 475 awards and the amount to support the costs associated with new competing awards will decrease by \$15.246 million compared to the FY 2016 Enacted level. In addition, awards under the Small Business Research programs will increase by five awards and \$1.895 million compared to the FY 2016 Enacted level.

Research Centers (-\$4.555 million, total \$67.610 million):

NICHD will support a total of 50 Research Centers awards in FY 2017, one less than the FY 2016 Enacted level. The decrease of \$4.555 million reflects the natural ending of a grant program that is not being renewed in FY 2017.

Other Research (-\$3.400 million, total \$114.297 million):

NICHD will support a total of 428 awards in the Other Research areas in FY 2017, a decrease of 34 awards compared with the FY 2016 Enacted level of 462 awards. The decrease of \$3.400 million is due to the natural ending of awards, which are not planned for renewal.

Research and Development Contracts (+\$3.800 million, total \$137.627 million):

NICHD will continue to support existing research activities, including epidemiological research, pursue a wide range of research activities including contraception, newborn screening, AIDS research, and participate in cross-cutting NIH projects.

Summary of Changes

(Dollars in Thousands)

FY 2016 Enacted				\$1,338,348		
FY 2017 President's Budget				\$1,338,348		
Net change				\$0		
		017 President's Change from Budget ¹		FY 2017 President's Budget¹ Chan		om FY 2016
CHANGES	FTEs	Budget Authority	FTEs	Budget Authority		
A. Built-in:						
1. Intramural Research:						
a. Annualization of January 2016 pay increase & benefits	-	\$58,554	-	\$245		
b. January FY 2017 pay increase & benefits	-	58,554	-	886		
c. Two less days of pay	-	58,554	-	-544		
d. Differences attributable to change in FTE	-	58,554	-	0		
e. Payment for centrally furnished services	-	31,615	-	771		
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs	-	104,582	-	2,461		
Subtotal	-	-	-	\$3,819		
2. Research Management and Support:						
a. Annualization of January 2016 pay increase & benefits	-	\$34,490	-	\$146		
b. January FY 2017 pay increase & benefits	-	34,490	-	468		
c. Two less days of pay	-	34,490	-	-261		
d. Differences attributable to change in FTE	-	34,490	-	0		
e. Payment for centrally furnished services	-	1,251	-	31		
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs	-	36,340	-	1,029		
Subtotal	-	-	-	\$1,413		
Subtotal, Built-in	-	-	-	\$5,232		

Summary of Changes - Continued

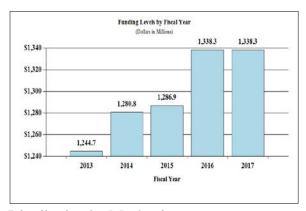
(Dollars in Thousands)

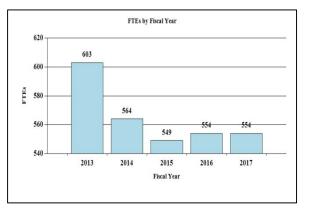
		7 President's Budget¹	Change from FY 2016		
CHANGES	No.	Amount	No.	Amount	
B. Program:					
1. Research Project Grants:					
a. Noncompeting	1,040	\$515,925	15	\$12,274	
b. Competing	427	166,885	-48	-15,246	
c. SBIR/STTR	90	38,335	5	1,895	
Subtotal, RPGs	1,557	\$721,145	-28	-\$1,077	
2. Research Centers	50	\$67,610	-1	-\$4,555	
3. Other Research	428	114,297	-34	-3,400	
4. Research Training	597	30,837	-6	0	
5. Research and development contracts	99	137,627	0	3,800	
Subtotal, Extramural	-	\$1,071,516	-	-\$5,232	
	<u>FTEs</u>	-	<u>FTEs</u>	-	
6. Intramural Research	312	\$194,751	0	\$0	
7. Research Management and Support	242	72,081	0	0	
8. Construction	-	0	-	0	
Buildings and Facilities	-	0	-	0	
Subtotal, Program	554	\$1,338,348	0	-\$5,232	
Total changes	-	-	-	\$0	

¹ Includes mandatory financing.

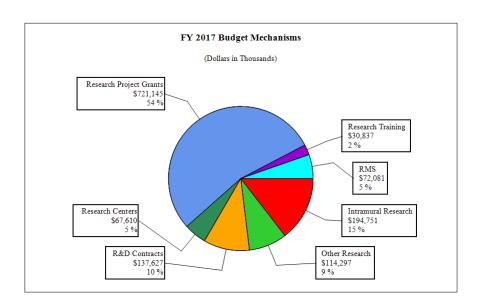
Fiscal Year 2017 Budget Graphs

History of Budget Authority and FTEs:

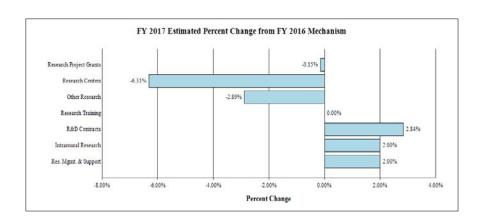




Distribution by Mechanism



Change by Selected Mechanism



Budget Authority by Activity¹ (Dollars in Thousands)

	FY 2015 Actual		FY 2016 Enacted		FY 2017 President's Budget ²		FY 2017 +/- FY2016	
Extramural Research	FTE	Amount	FTE	Amount	FTE	Amount	FTE	Amount
Detail								
Reproductive Health, Pregnancy, and Perinatology	-	\$287,048	-	\$299,610	_	\$298,154	-	-\$1,456
Pediatric Health	_	294,218	_	307,094	_	305,601	_	-1,492
Intellectual and Developmental Disabilities	-	115,485	-	120,538	-	119,953	-	-586
Demography and Behavior	_	263,378	_	274,905	ı	273,569	ı	-1,336
Rehabilitation	_	71,474	_	74,601		74,239	-	-362
Subtotal, Extramural	_	\$1,031,602	_	\$1,076,748	ı	\$1,071,516	ı	-\$5,232
Intramural Research	309	\$186,317	312	\$190,932	312	\$194,751	0	\$3,819
Research Management & Support	240	\$68,950	242	\$70,668	242	\$72,081	0	\$1,413
TOTAL	549	\$1,286,869	554	\$1,338,348	554	\$1,338,348	0	\$0

¹ Includes FTEs whose payroll obligations are supported by the NIH Common Fund. ² Includes mandatory financing.

Authorizing Legislation

	PHS Act/Other Citation	U.S. Code Citation	2016 Amount Authorized	FY 2016 Enacted	2017 Amount Authorized	FY 2017 President's Budget
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Institute of Child Health and Human Development	Section 401(a)	42§281	Indefinite	\$1,338,348,000	Indefinite	\$1,338,348,000
Total, Budget Authority				\$1,338,348,000		\$1,338,348,000

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2007	\$1,257,418,000	\$1,257,418,000	\$1,264,500,000	\$1,254,707,000
Rescission	-	-	-	\$0
2008	\$1,264,946,000	\$1,273,863,000	\$1,282,231,000	\$1,254,708,000
Rescission	-	-	-	\$22,309,000
Supplemental	-	-	-	\$6,673,000
2009	\$1,255,920,000	\$1,299,059,000	\$1,290,873,000	\$1,294,894,000
Rescission	-	-	-	\$0
2010	\$1,313,674,000	\$1,341,120,000	\$1,316,822,000	\$1,329,528,000
Rescission	-	-	-	\$0
2011	\$1,368,894,000	-	\$1,366,750,000	\$1,329,528,000
Rescission	-	-	-	\$11,674,048
2012	\$1,352,189,000	\$1,352,189,000	\$1,303,016,000	\$1,323,900,000
Rescission	-	-	-	\$2,502,171
2013	\$1,320,600,000	-	\$1,324,603,000	\$1,321,397,829
Rescission	-	-	-	\$2,642,796
Sequestration	-	-	-	(\$66,325,085)
2014	\$1,339,360,000	-	\$1,330,459,000	\$1,282,595,000
Rescission	-	-	-	\$0
2015	\$1,283,487,000	-	-	\$1,286,571,000
Rescission	-	-	-	\$0
2016	\$1,318,061,000	\$1,305,586,000	\$1,345,355,000	\$1,339,802,000
Rescission	-	-	-	\$0
20171	\$1,338,348,000	-	-	_

¹ Includes mandatory financing.

Justification of Budget Request

Eunice Kennedy Shriver National Institute of Child Health and Human Development

Authorizing Legislation: Section 301 and Title IV of the Public Health Service Act, as amended.

Budget Authority (BA):

	FY 2015	FY 2016	FY 2017	FY 2017 + / -
	Actual	Enacted	Budget Request	FY 2016
BA	\$1,286,689,000	\$1,338,348,000	\$1,338,348,000	\$0
FTE	549	554	554	0

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Director's Overview

Eunice Kennedy Shriver National Institute of Child Health and Human Development's (NICHD's) broad research portfolio is uniquely focused on human health and development, from before birth through adulthood. In scientific domains including developmental biology, reproductive health, pediatrics, population sciences, and medical rehabilitation, NICHD supports research that helps us better understand how health and disease develop over time, to reduce or even prevent illness and disability in current and future generations.

Science itself has a developmental trajectory. Basic research on complex physiological and behavioral phenomena forms the foundation for translational science, rigorous clinical trials, and later improvements in public health. After decades of progress in medical research, the scientific community is now positioned to take advantage of precision medicine – an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person. While the concept of precision medicine is not new, scientific advances and new technologies are making individualized prevention and treatment strategies far more possible than they were even a decade ago. Populations of primary interest to NICHD – children, pregnant women, and persons with disabilities – have too often and for too long been prescribed drugs, devices, and other treatments that were designed for and tested in other groups that are physiologically different from them. Special populations have a great deal to gain from precision medicine approaches that will address their individual specific needs.

NICHD continues to invest in the future of health by supporting basic science and fundamental research for developing future leading-edge technologies. The Institute's continuing efforts to understand the pivotal role of the human placenta will provide an unprecedented amount of information on how placental function affects maternal, fetal, and lifelong health. An initial 19 awards have been made to launch this effort. Already, the first "lab on a chip" model of the human placenta is available to help researchers conduct experiments more quickly and inexpensively. Working with other NIH Institutes and Centers (ICs) and the Common Fund of the NIH Office of the Director, in FY 2017 NICHD will extend its investment in basic and

translational sciences related to birth defects. Structural or functional anomalies affect about three percent of births and are the leading cause of infant death in the United States. Through intramural and extramural programs, NICHD supports collaborative teams of basic and clinical scientists studying the developmental biology, epidemiology, and genetics of structural birth defects. New FY 2017 initiatives in structural birth defects research will catalyze the development of new research teams and support data analysis that uses and complements the genomic sequencing data developed under the Common Fund's Gabriella Miller Kids First Pediatric Research program. Other basic research initiatives planned for FY 2017 include support for new efforts to assess the role of mitochondrial function in reproductive health, exploratory projects in biophysical aspects of embryonic development, and support for teambased projects to help young scientists apply bioengineering research to medical rehabilitation.

NICHD continues to find creative and effective ways to capitalize on previous investments. Building on previous advances in bioengineering, pharmacokinetics, and genetics, NICHD-supported researchers were able to adapt robotics technology to create powered prosthetics for amputees; discover a new, potentially more effective treatment for a rare inherited disease; and prevent severely disabling conditions through newborn screening, to name only a few examples. In FY 2017, a new translational initiative is planned to build on 3D printing technologies to create customizable, implantable medical devices for children. NICHD is also planning to work with National Science Foundation (NSF) on a joint program to fund promising new technologies in medical rehabilitation.

Through its clinical research networks, the Institute supports research in real-world settings – including pediatric and neonatal intensive care units – to ensure that new treatments are safe and effective. NICHD-supported clinical networks conduct research on treatments for pregnant women, premature infants, and critically ill children. Equally important, network studies have also shown that although some interventions may be new, they may not be more effective in improving health outcomes. For example, a recent NICHD-supported clinical trial showed that the standard treatment worked better than a proposed alternative for unexplained infertility.

NICHD continues to work with outside partners to help ensure that research results reach the public and health practitioners. Since the onset of the Safe to SleepTM (formerly Back to SleepTM) campaign, many more parents have adopted safe sleep practices, and the rates of sleep-associated infant deaths have decreased by nearly threefold in 20 years. In FY 2016 and FY 2017, the National Child and Maternal Health Education Program – an NICHD-led coalition of more than 30 of the Nation's most prominent maternal and child health care organizations – is bringing together a range of partners to provide parents, caregivers, and providers with critical information on postpartum depression and related conditions.

For NICHD, it is not enough to support innovative science and develop new interventions. We must ensure that all individuals can benefit from these revolutionary scientific developments. Pregnant women, children, persons with disabilities, and individuals with multiple chronic health conditions have important physiological and social differences that must be considered in developing new treatments and ensuring that these treatments work as planned. For example, although it has been increasingly recognized that one size does not fit all, information guiding drug treatment for children is still largely extrapolated from drug studies conducted in adults.

Research on the effects of new and existing drugs in children has been limited by technical difficulties, ethical constraints, legal risks, and financial disincentives. However, scientists are now in an excellent position to reap returns from recent advances in genetics, pharmacogenomics, and basic developmental biology, as well as apply the latest technologies and bioinformatics tools. In FY 2017, NICHD plans to energize translational research in pediatric and obstetric pharmacology, including developing safety and outcome measures to help address rising concerns about the use of pain medication in children and pregnant women. A new initiative is also planned to address Multiple Organ Dysfunction syndrome (MODS) – a poorly-understood, dangerous condition in which multiple body organs or organ systems fail simultaneously. A leading cause of death in pediatric intensive care units, MODS can be triggered by a wide range of disease processes, most notably sepsis and multiple trauma. Until recently, MODS appeared to be a nearly unsurmountable challenge for researchers. However, new tools and precision medicine strategies offer hope for progress.

This recent expansion of scientific opportunities is a welcome development, but it comes with the recognition that thoughtful prioritization and careful stewardship are essential. NICHD has implemented a data-driven approach to portfolio analysis, program evaluation, and performance assessment, which will help the Institute make funding choices, focusing on areas that hold the most promise to improve the health of children, individuals with disabilities, families, and communities.

Program Descriptions and Accomplishments and Budget Policy

Reproductive Health, Pregnancy, and Perinatology: The program in reproductive health, pregnancy and perinatology supports basic, clinical, and translational research on an array of topics, including contraception, fertility and infertility, gynecologic disorders, pregnancy, and care of the newborn.

Program research on contraception encompasses discovery of potential new pharmaceutical targets, non-pharmaceutical devices, and other methods to increase the variety of safe, effective, and acceptable contraceptive options for both women and men. Program research on male and female fertility and infertility includes basic research on underlying mechanisms that impair the capacity to conceive, including environmental causes, as well as clinical trials to increase and refine infertility treatment options. Recently, investigators compared the effects of drugs used to treat unexplained infertility. By comparing the effects of these agents in a large (900) cohort of women, researchers concluded that clomiphene (a standard treatment) was the most appropriate for stimulating ovulation. Its rate of live births (23.3 percent) was higher than that of letrozole (an alternative drug), although slightly lower than the rate for another hormone treatment. However, clomiphene also produced the lowest rate of risky pregnancies with multiple fetuses. Researchers also found that for all three treatments they studied, there were no statistical differences in rates of birth defects or complications with pregnancy or birth.

The program's pregnancy-related research spans preconception care, pregnancy, labor and delivery, and maternal and neonatal health. Recently, investigators tackled the perplexing question of whether maternal antidepressant use during pregnancy raises the risk of the rare, potentially fatal condition, persistent pulmonary hypertension (PPHN), in their newborn infants.

Previously, some studies found significant PPHN risk associated with maternal antidepressant use, but others had found no association. Scientists analyzed a large body of medical records data for pregnant women in 46 States over a decade. After controlling for other relevant factors, the researchers found a slightly elevated risk of PPHN associated with maternal use of one type of antidepressant, selective serotonin reuptake inhibitors (SSRIs), but not with other types of antidepressants. The risk was statistically significant, but lower than found in previous studies.

In another project, an analysis of brain scans of preterm infants found that "early" scans, performed soon after birth, were useful in detecting bleeding in the brain and other urgent medical problems, but less useful than later scans in checking for brain structure abnormalities that might be associated with developmental delay or disability. The study compared early scans of nearly 500 extremely preterm infants (born 13 to 16 weeks before their due date) with later scans near their original due date. The results of the study suggest that scans near the due date are useful to alert physicians, parents and care providers to possible brain-related concerns in these infants.

Similarly, a follow-up study to an earlier NICHD effort provided more detailed information that clinicians can use to make important decisions about appropriate care for individuals with spina bifida. In 2011, scientists conducted a clinical trial to assess whether it was better for infants with myelomeningocele, the most serious form of spina bifida, to undergo corrective surgery while still in the womb or to wait and have the surgery after birth. The researchers discovered that infants who had undergone the surgery prenatally were twice as likely to walk independently. However, as with any surgery, the procedure presented risks. For example, babies who underwent surgery in the uterus were more likely to be born preterm than were those who had the surgery after birth. To identify which infants were the best candidates for fetal surgery, researchers followed up with the mothers and infants who had participated in the trial. When the pregnant women were first enrolled, the researchers took magnetic resonance imaging scans of the fetuses' brains. Irrespective of whether they were later placed in the prenatal or postnatal surgery group, children with the largest ventricles were more likely to require a shunt than those with smaller ventricles. The researchers concluded that fetuses with ventricles smaller than 10 mm are the ideal candidates for fetal surgery, while there appears to be no benefit, in relation to shunting, for fetuses with ventricles 15 mm or larger.

NICHD also supports studies to reduce rates of high-risk pregnancies and preterm births complicated by preeclampsia and other conditions. A generation ago, infants born before the 28th week of pregnancy were very unlikely to survive. Thanks to medical advances, many funded by NICHD, these infants are surviving in greater numbers today and escaping serious chronic illness. Researchers reviewed the birth records of more than 35,000 premature infants born from 1993 to 2012 in 26 U.S. hospitals. They found that infants born at 23 and 24 weeks survived in greater numbers over the 20-year period. Of those born at 24 weeks, for example, only 52 percent survived in 1993 while 65 percent survived in 2012. In addition, a higher number of premature infants survived without major illnesses. For infants born at 27 weeks, for example, survival without major illness increased from 29 percent in 1993 to 47 percent in 2012.

Equally important, sometimes NICHD research shows when new technology does not offer a significant improvement. For many years, physicians have monitored the fetal heart rate during

labor to alert them to potential birth complications. Researchers tested a new technology that tracks the electrical activity of the fetal heart, to determine if it offered any advantages over conventional methods. They assigned more than 11,000 pregnant women to one of two groups when they went into labor after the 36th week of pregnancy. Physicians delivering women in the first group received readings from both the new technology and the traditional fetal heart rate monitors. In the second group, attending physicians saw only the fetal heart rate readings. The researchers measured a wide variety of outcomes such as fetal and newborn death, seizures, the need for a ventilator after birth, or high levels of acid in the blood. They also tracked cesarean delivery, the use of forceps or vacuum to assist with vaginal delivery, infection of the membranes enclosing the amniotic fluid, and the need for a blood transfusion. The readings on all of these outcomes were similar despite the technology used, demonstrating no significant improvement gained by using the newer technologies.

<u>Budget Policy:</u> The FY 2017 budget request for this program is \$298.154 million, a decrease of \$1.456 million or 0.5 percent compared to the FY 2016 Enacted level. The program will continue to maintain its investments in highly productive research networks to address maternal, fetal, and neonatal health and to improve treatments for the millions of women with pelvic floor disorders. One new initiative will support studies to assess the structure, function, and development of the human placenta, capitalizing on existing datasets and emerging technology. Another new initiative, in basic research, will focus on the role of mitochondrial function in infertility and reproductive health.

Program Portrait: Infertility

FY 2016 Level: \$60.8 million FY 2017 Level: \$60.5 million Change: -\$0.3 million

Nearly 15 percent of couples experience infertility, defined as the inability to achieve pregnancy after 12 months or more of regular, unprotected sexual intercourse (or after six months if the woman is older than 35). Many different medical conditions and other factors contribute to infertility in men and women, and an individual case may have a single cause, several causes, or in some cases no identifiable cause. In men, the most common issues that lead to infertility are problems that affect how the testicles work, hormone imbalances, or blockages in the male reproductive organs. Low sperm counts and poor sperm morphology (shape and structure) are key signs of male infertility. In about 50 percent of cases, the cause of male infertility cannot be determined. In women, a number of medical conditions, including polycystic ovarian syndrome (PCOS), problems in the menstrual cycle, aging, and lifestyle factors affect fertility.

Scientists are working to identify factors involved in unexplained infertility. For example, in a recent NICHD-funded study, researchers analyzed sperm from men in nearly 500 couples to see if there were differences in the quantity and quality of sperm among men who had different work environments and health conditions. They found that men whose jobs included heavy lifting or exertion, and men who took multiple medications, had fewer sperm than other men. Additionally, men who had high blood pressure had a lower percentage of normally shaped sperm. NICHD-supported epidemiological research has identified a series of environmental factors that affect fertility in men and women, including exposure to certain chemical compounds and heavy metals.

NICHD also supports clinical studies on infertility treatment. Over the past two years, NICHD-funded scientists conducted several related studies to compare a standard infertility drug with alternative drugs. In women with unexplained fertility, one of the standard medications worked better, with higher pregnancy rates and fewer multiple births. In women with PCOS, however, women who took an alternative drug had a higher birth rate. With advances in treatment and prevention, more couples will be able to realize their dream of having children.

Pediatric Health – Pediatric research ranges from basic scientific investigations of biological processes that control healthy and atypical development to clinical studies in pediatric pharmacology, pediatric HIV and associated infections, nutrition science, pediatric endocrinology, pediatric trauma and critical illness, and other aspects of pediatric medicine. For example, researchers recently reported a more precise way to predict the progression of chronic kidney disease (CKD) in children, together with delineation of multiple risk factors, including those that may be manageable so as to slow progression of CKD. By tracking children over four years, the investigators were able to delineate un-modifiable and modifiable risk factors for disease progression – factors not often investigated in pediatric CKD patients. Identifying modifiable risk factors is a crucial step towards developing and implementing interventions to slow the progression of CKD in children and adolescents, or even to prevent its onset. In another example, researchers found that structured debriefings of pediatric intensive care clinicians, after cardiopulmonary resuscitation (CPR), improved both CPR quality and patient survival rates. A third example addressed the issue of pediatricians being pressured by parents into prescribing antibiotics for children with acute viral respiratory tract infections (ARTI), even though antibiotics are ineffective against the viruses, and overuse contributes to antibiotic resistance in bacterial infections. It has been shown that the negative approach of informing parents that an antibiotic cannot cure their child's viral ARTI, but would contribute to bacterial antibiotic resistance, does not necessarily discourage antibiotic overuse. The researchers, working with a group of pediatric practitioners, tested a strategy in which parents received positive recommendations about how to treat viral ARTI symptoms, with explanations of why an antibiotic would be inappropriate for these infections. Trial results indicated that this communication strategy of combining positive and negative information reduced inappropriate antibiotic prescribing while also yielding high parental ratings for physicians.

NICHD studies congenital and developmental disorders to understand both the processes that keep embryonic and fetal development on track and the factors that can cause the developmental processes to go awry. Genetic analysis of a rare, puzzling multi-system disorder in three children, for example, led to identification of a new syndrome, called CHOPS. The acronym stands for the *cognitive* impairment, *heart* defects, *obesity*, *pulmonary* and *short* stature and skeletal symptoms that comprise the syndrome. This discovery sheds new light on key biological processes during human development and may eventually offer clues to treatment for both CHOPS Syndrome and Cornelia de Lange Syndrome, a condition that shares a number of features with CHOPS.

NICHD also is working to expand the relatively limited scientific knowledge base on the safety, efficacy and appropriate doses of pharmaceuticals for children, a majority of which are prescribed "off label." For example, sodium nitroprusside (SNP), a drug commonly used to keep critically ill patients' blood pressure at a safe level, has been used for many years in pediatric as well as adult intensive care units, but with only limited data on the safety and efficacy in children. Recently, NICHD supported a clinical trial of SNP in critically ill children, in which their blood pressure was measured minute by minute, and blood and urine tests were also used to monitor the children during and after the study. The researchers found that SNP was safe and effective for the children receiving it. As part of NICHD's responsibilities under the Better Pharmaceuticals for Children Act, the program collaborates with the Food and Drug

Administration (FDA) to improve labeling of drugs for use in children. The results of the SNP study supported FDA revised labeling of the drug for pediatric use.

Another area of emphasis comprises domestic and international research on the epidemiology, diagnosis, clinical manifestations, disease process, transmission, and prevention of HIV infection in pregnant women and children. Because of continuing concerns about possible adverse effects on fetal development of antiretroviral (ARV) treatment of pregnant women with HIV, scientists studied approximately 2,500 children who had been exposed in utero, but not infected by their mother's HIV. The mothers of about half of the children had been treated with ARV in the early months of their pregnancy. The researchers found an increased, but small, risk of birth defects associated with one ARV (Atazanavir), and the few health issues identified were mild and did not threaten the children's overall health. The study results affirmed that the benefits of ARVs in preventing maternal-to-child HIV transmission outweigh their risks to embryonic and fetal development. In another study, NICHD-supported researchers found that due to early treatment to prevent transmission of HIV, it is possible that between one-third and one-half of individuals in the United States who were infected with HIV around the time of birth may not have sufficient immunity to ward off measles, mumps, and rubella – even though they may have been vaccinated against these diseases. Individuals who were infected with HIV around the time of birth, and their health care professionals, should be made aware of the possible risks and may wish to consider if additional doses of the MMR vaccine are warranted.

<u>Budget Policy:</u> The FY 2017 budget request for this program is \$305.601 million, a decrease of \$1.492 million or 0.5 percent compared to the FY 2016 Enacted level. The program will maintain its investments in research on pediatric pharmacology, pediatric critical care, and the implications of HIV and HIV treatment in adolescents. New initiatives will support efforts to advance knowledge of structural birth defects; develop new safety and outcome measures to assess the use of pain medications in children and pregnant women; and conduct research to understand better how the HIV virus can persist in exposed infants.

Program Portrait: Birth defects

FY 2016 Level: \$87.3 million FY 2017 Level: \$86.8 million Change: -\$0.5 million

Birth defects are structural or functional abnormalities that can cause physical, intellectual and/or developmental disability (IDD), and other health problems. If not detected and treated quickly, some can be fatal or cause lifelong disabilities. Currently, birth defects are the leading cause of death for infants during the first year of life. NICHD is a leader in research on birth defects, their causes, their prevention and treatments, and their long-term health outcomes. High-priority research areas include identifying and describing the biochemical, molecular, biologic, genetic, and cellular mechanisms of both normal and abnormal early development; understanding disorders of limb, skeleton, and organ development; and discovering the basis for congenital disorders of the nervous system, including neural tube defects like spina bifida. For example, researchers recently identified 20 genetic variants associated with heterotaxy, a rare disorder that results in organs forming in abnormal positions in the body.

Because birth defects are complex, collaboration among basic scientists, clinicians, and researchers in genetics, intellectual and developmental disabilities, developmental biology, cardiology, and other areas is especially important. NICHD leads the trans-NIH Structural Birth Defects Working Group to ensure that birth defects research is carefully coordinated across the NIH and scientific developments are shared quickly and efficiently. In addition, NICHD is working with scientists in the extramural community and experts across the NIH to develop curated

phenotype, genetic, and genomic data that will help determine the biological basis of structural birth defects. These resources, made possible by the Gabriella Miller Kids First Pediatric Research program, will help scientists develop new methods to understand, prevent, and treat structural birth defects.

Intellectual and Developmental Disabilities – The IDD program supports basic, clinical, and translational research and research training to advance knowledge of origins of common and rare disorders such as Down syndrome (DS), Fragile X syndrome, Rett syndrome, inborn errors of metabolism, and autism spectrum disorders (ASD). The IDD program also supports research to understand the complex processes through which these disorders compromise cognitive, emotional, social, and physical development in infants and children and through the lifespan. In searching for the origins of ASD, for example, researchers recently analyzed medical records from the pregnancies of mothers of children diagnosed with autism spectrum disorder or developmental delay, and compared with maternal records for typically developing children. They found that children with ASD were twice as likely to have been born to mothers with preeclampsia – an unpredictable condition in pregnancy that affects many organs, such as the kidney, and includes high blood pressure.

At present, clinicians use rigorously validated diagnostic tools to determine whether a patient has ASD, based on assessments of his or her social and other behaviors as well as other factors. At the same time, some researchers are exploring the potential of brain imaging and sophisticated data analysis to search for neural signs of atypical brain function that may help explain the distinctive social behaviors of ASD. In one study, investigators observed the brains of high-functioning adults with ASD and a control group, with functional magnetic resolution imaging (fMRI), while these individuals thought of a series of verbs, including "compliment," "insult," "adore," and "hate," that refer to interpersonal actions. The study found significant differences between the two groups in brain activation – differences that suggested that the individuals with ASD experienced themselves as observers, not participants in the social interactions described by certain verbs. The investigators suggested that the distinctive brain activation patterns they observed in individuals with ASD constitute a novel biological marker for atypical cognitive states corresponding to conceptions of social interactions in individuals with ASD.

Another project focuses on a known cognitive complication of DS at the other end of the life span. Alzheimer's-like dementia is known to affect as many as half of individuals with DS who survive to age 50, but standard dementia diagnostic techniques have not been successful with these individuals. Scientists have recently tested a novel imaging approach to compare brain activity in younger and older individuals with DS as they looked at the same pictures multiple times and at sequences of unfamiliar pictures, detecting memory problems in the older individuals. As with dementia without DS, early detection would be essential for any interventions that may be available or developed for aging individuals with DS.

NICHD recognizes that detecting illnesses in a child and beginning therapies early may increase the likelihood of better outcomes. Accordingly, IDD research encompasses studies of the newborn screening, as well as the earliest diagnosis, treatment, and management of IDDs and other conditions. For example, NICHD-funded researchers helped develop and test newborn screening for severe combined immunodeficiency (SCID), a rare group of genetic disorders of the immune systems. While a typically developing infant will recover quickly from a minor infection, an infant with SCID may have life-threatening consequences. Early hematopoietic cell

transplantation is effective in treating infants with SCID. In the overall U.S. population, SCID is estimated to occur in about 1 in 50,000 births. However, a much higher rate has been reported in the Navajo Nation. A comprehensive newborn screening program was implemented in the Navajo Nation in 2012. This confirmed that in the Navajo Nation, about 1 in 2,000 babies were born with one type of SCID, called SCID-A. This rate was nearly 30 times the rate of SCID-A found in the general U.S. population. Between February 2012 and July 2014, SCID-A was identified in several Navajo infants, and all of these babies were referred for early treatment. In another development, scientists discovered that a repurposed cancer drug may prove helpful in managing a rare, inherited disorder in which the cycle of biochemical reactions that produces urea, for excretion in urine, fails to function normally. The disorder, known as arginase deficiency, causes a form of cerebral palsy, mild to severe intellectual disability and other problems. If detected in newborn screening, it can be managed to a certain extent with a dietary approach, but such management is challenging and a new, more reliably effective approach is needed.

Another core component of the IDD program is a focus on understanding, describing, and managing comorbid conditions in individuals with intellectual disability. Although individuals with IDD have a higher prevalence of co-occurring mental health conditions, for example, little is known about what factors influence the risk of comorbid conditions, how comorbid conditions affect IDD treatment and management of symptoms, and how these multiple conditions manifest differently in individuals with IDD. Clinicians often experience difficulty in assessing and identifying mental health conditions in those with IDD; many individuals with IDD have language or sensory impairments that make traditional methods of mental health evaluation much more challenging. Recently, NICHD-supported researchers have documented high rates of co-occurring epilepsy and autism in children with cerebral palsy. A different group of scientists found that individuals with a type of disorder called RASopathies often have symptoms associated with autism. In an international study, researchers reviewed a large database with cases from many countries to assess the link between psychiatric disorders and a condition called 22q11.1 deletion syndrome. A rare genetic disorder, 22q11.1 deletion syndrome can involve a variety of symptoms, including intellectual disability. In this study, researchers were able to confirm that people with this syndrome also had a high prevalence of mental health disorders, such as schizophrenia and anxiety disorder. Moreover, the study showed that these conditions often emerged in childhood and had major impact on adolescent health.

<u>Budget Policy:</u> The FY 2017 budget request for this program is \$119.953 million, a decrease of \$0.586 million or 0.5 percent compared to the FY 2016 Enacted level. The program will continue its investments in the Intellectual and Developmental Disabilities Research Centers, an engine for basic and translational research in IDDs that supports crucial infrastructure and innovative projects for the field. NICHD will also continue its work with four other NIH ICs in support of the Autism Centers of Excellence. A new initiative is planned to build on research progress and develop new tools for assessment and treatment of mental disorders in individuals with IDD.

Program Portrait: Developing Research Resources through Crowdsourcing Techniques

FY 2016 Level: \$0.9 million FY 2017 Level: \$0.9 million Change: \$0.0 million

New techniques, such as crowdsourcing, offer the NIH creative opportunities for reaching the public to carry out its mission of improving health through discovery. In 2013, the NICHD launched DS-Connect®, a patient registry that now includes over 3,200 participants with DS. The registry collects voluntary subject- and family-entered demographic and medical information about people with DS, on a secure and confidential web platform. In addition, since the launch of a professional portal in December 2014, more than 100 professional accounts have been established, and a growing number of investigators are utilizing the data to recruit for and complete research projects on DS, such as tracking feeding behaviors in children with DS and studying the complication of hypothyroidism in infants with DS. The registry can facilitate linkages to other data repositories and to tissue and brain banks as they are developed, by using a secure Global Unique Identifier that protects personally identifiable information about participants with DS.

Building on the success of DS-Connect®, the NICHD will soon launch PregSource TM, a mobile app and website that focuses on gathering information about normative pregnancy. Pregnant and postpartum women will voluntarily answer questions about their pregnancies and health in real time. After completing an application process to ensure an appropriate research plan, approved researchers will examine this information (from which personal identifiers have been removed) to identify trends, similarities, and differences so that they can design specific research hypotheses for further study. The more women who participate in PregSource TM, the more reliable aggregated, patient-reported data will be. Ultimately, this information will help to fill the large gap in knowledge about medications used by pregnant women, and other issues commonly experienced during pregnancy. Although led by the NICHD, the development of PregSource TM has greatly benefited from a team of partners that includes seven NIH Institutes, 10 research advocacy organizations and professional societies, the CDC, and HRSA. The partners are providing extensive input and review of the questionnaires, populating the health information messages that will be sent to participants, and helping to create an extensive online resource library for participants' use.

Demography and Behavior – The program in demography and behavior supports research and research training in the characteristics and dynamics of populations and subpopulations, to increase understanding of the causes and consequences of population structure and change in such areas as fertility, family demography and functioning, urbanization, migration, and their implications for behavioral and social influences on health. The research interests of the demography and behavior program also include factors that contribute to the spread of sexually transmitted infections and health risks, influences on family formation, functioning, and stability, and families' effects on child health and behavior. In one NICHD-supported study, investigators found that when mothers' caregiving in the early years was appropriately responsive to the child's signals, their young adult children were more successful academically and socially in the first three decades of life, compared with others who had not received such care.

Some researchers supported by this program explore how children's peer relationships, group formation and social networks, as well as parental, school, and work factors influence health and healthy functioning. For example, results of recent research suggest that workplace interventions may have potential for helping to achieve the *Healthy People 2020* goal of increasing the number of adults who get sufficient sleep. Lack of sleep or poor quality of sleep can lead to poor concentration, workplace absenteeism, accidents, injuries and fatalities, and chronic disease, and it is estimated that about 30 percent of U.S. adults get less than an appropriate quantity and

quality of sleep. Scientists found that an intervention to alleviate conflict between demands of work and personal and family life measurably improved workers' sleep in the course of a year.

In addition, the demography and behavior program encompasses research in a wide range of developmental science areas, from trajectories of typical cognitive, affective, and social development to studies of language, attention, reasoning, problem-solving, and multiple mechanisms underlying typical learning and learning disabilities. Also included in this program are research in neurobiological and genetic bases of behavioral development and learning biobehavioral mechanisms involved in risk-taking behaviors, their prevention and resilience to risk, especially in adolescence.

<u>Budget Policy:</u> The FY 2017 budget request for this program is \$273.569 million, a decrease of \$1.336 million or 0.5 percent compared to the FY 2016 Enacted level. NICHD will continue its investments in the Population Research Infrastructure Program, which provides essential infrastructure for the population sciences field, and its ongoing investment in understanding mathematical and science cognition and reasoning, including interventions to enhance student functioning in the math and sciences, and to prevent or address math learning disabilities. New initiatives will support research in contraceptive acceptability and use.

Rehabilitation – Through the National Center for Medical Rehabilitation Research (NCMRR), the rehabilitation program fosters research and research training to enhance the health, productivity, independence, and quality of life of people with disabilities. The program supports a broad range of research, including efforts to understand the underlying biology of injury and disability, and the body's mechanisms of recovery and adaptation. For example, a recent study found that outcomes for surgical reconstruction of a torn anterior cruciate ligament (ACL) – a common, painful knee injury – were significantly better for patients whose quadriceps muscles had been strengthened before the surgery with physical therapy, compared with patients with weaker pre-surgical quadriceps. Another NICHD-funded project developed tools to better measure the psychological and health outcomes of people living with spinal cord injury (SCI). By measuring individuals' psychological and physical quality of life (QOL), the new tools will enable clinicians better to manage the conditions of SCI survivors, while also enabling researchers to assess the impacts of possible new treatments for people living with SCI.

NCMRR also supports the development of medical devices and equipment to improve mobility and to enhance the functional capabilities of individuals with disabling conditions. In one project, bioengineering researchers developed and successfully tested a device that enables lower-limb amputees to use a powered prosthesis – a robotic leg – without complex fine-tuning of multiple control switches and sensors for multiple tasks (standing and walking, for instance). The investigators expect that further development will lead to devices enabling users of powered prosthetic legs to walk up inclined surfaces and stairs. This approach to prosthetics may eventually improve the mobility and quality of life not only for individuals after amputation, but also for survivors of SCI and stroke.

The rehabilitation program's activities include a special emphasis on research related to stroke, SCI, and traumatic brain injury (TBI), frequently in collaboration with other NIH ICs and other partners. Recently, a large study of more than 250 young patients (5 to 18 years old) in a

hospital pediatric sports clinic who had suffered a concussion found that these patients took significantly longer to recover and return to school full-time than has been reported before. While previous studies had estimated healing times after concussion of 14 to 28 days in a general pediatric population, the median time for resolution of patient health problems in this study was 64 days. Factors that could account for the longer recovery times were the severity of concussion, indicated by these patients' referral to the specialized clinic, and also loss of consciousness or dizziness at the time of the concussion, vision abnormalities at time of admission to the clinic, and a history of previous concussion or pre-injury anxiety and depression. The study's findings increased the relatively limited data on pediatric concussion, particularly for younger children.

<u>Budget Policy:</u> The FY 2017 budget request for this program is \$74.239 million, a decrease of \$0.362 million or 0.5 percent compared to the FY 2016 Enacted level. The program will continue its efforts to strengthen coordination and enhance medical rehabilitation research across the NIH. Within the NICHD, the NCMRR will continue to emphasize research training and career development, small business grants for assistive technology innovation, and orthotics and prosthetics research. A new initiative will provide support for team-based projects to help young scientists apply bioengineering research to medical rehabilitation. NICHD is also planning to work with NSF on a joint program to fund promising new technologies in medical rehabilitation.

Intramural Research – The Division of Intramural Research (DIR) conducts interdisciplinary research to answer basic biomedical research questions and to solve difficult clinical problems in human health and development. Research training with the program's senior scientists is an essential element of this program. DIR research includes investigations in genetics, genomics, and epigenetics, and how these factors and processes influence typical and atypical development and disease processes. Recently, intramural scientists created a sophisticated new technology that will enable searchers to study the functioning of the placenta, the temporary organ that encompasses the developing fetus during pregnancy and that helps nutrients and oxygen move to the fetus, while enabling waste products to be moved away. At the same time, the placenta tries to filter out harmful environmental exposures, such as bacteria, viruses, and certain medications, from reaching the developing fetus. The importance of these processes for healthy fetal development seems self-evident, but opportunities to study placental functioning have been quite limited. The new "placenta-on-a-chip" technology consists of a semi-permeable membrane between two tiny chambers, one filled with human maternal cells derived from a delivered placenta and the other filled with human fetal cells derived from an umbilical cord. The chip is expected to enable scientists to conduct experiments more efficiently, and at a lower cost, than studies with animals.

The intramural program emphasizes the importance of fundamental investigations into the physics, chemistry, and biology of cells, their component parts, and the processes that govern and regulate their function as the foundation of disease and health. Scientists in the NICHD intramural program also study the basic biophysical mechanisms that underlie cell biology and tissue function and how these factors influence development, specifically targeting the nervous, endocrine, and reproductive systems. Researchers in DIR have identified genetic causes of rare diseases, such as gigantism. In another example, in research on donated postmortem brain tissue from individuals with ASD and those without, intramural scientists were able to study

simultaneously three types of brain cells with critical functions that seem to go awry in individuals with ASD. They focused on neurons, responsible for communications between different regions of the brain, and astrocytes and microglial cells, which have important roles in establishing circuits in the developing brain. In analyzing the ASD tissue samples, the scientists found that all three cell types expressed abnormal levels of certain proteins in two areas of the brain: one associated with personality expression, decision-making and problem-solving, and one associated with motor control, attention and language. These results support the hypothesis that underlying the symptoms of ASD is a complex interplay between abnormal function at the cellular level and atypical brain circuitry.

The NICHD intramural program places special emphasis on translational research and also focuses on behavioral research; innovative diagnostics for endocrine, metabolic, and reproductive diseases; and the impact of pediatric cancer on child development. A clinical study of the antipsychotic drug loxapine found that it could help adolescents with severe ASD become less irritable and aggressive. They found that the adolescents who completed the study had only minor side effects, and their behaviors and irritability were much improved. In other pharmacology research, intramural scientists found that in laboratory conditions, the anti-herpes drug Acyclovir (ACV) also directly suppressed HIV in tissues co-infected with the herpes virus and HIV. They then conducted a small trial with individuals with HIV, treating half with an ACV derivative, Valacyclovir (valACV) which, like ACV, was known to be effective in treating herpes and HIV co-infection. They found that when the patients were taking valACV, their blood HIV levels declined significantly. The results are considered promising because they show that a common drug, already approved as safe and effective for another viral infection, may be used as a new medication for HIV therapy. New medicines are currently needed, as established HIV treatments are beginning to develop resistance and may not be as effective as they once were.

<u>Budget Policy</u>: The FY 2017 budget request for this mechanism is \$194.751 million, an increase of \$3.819 million or 2.0 percent compared to the FY 2016 Enacted level. The increase in funds will cover mandatory cost increases for staff and centralized NIH services, as well as increases in the costs of performing research. Following recommendations by a panel of national and outside experts, the DIR has taken many organizational steps to improve efficiencies and leverage resources. These endeavors will continue in FY 2017.

Research Management and Support (RMS): RMS activities include administrative and technical functions that support and enhance the usability and effectiveness of the Institute's research investments. Key functions include public communications; budget, contracts, and grants management; peer review; and information technology. The RMS budget supports NICHD's health outreach activities, including those focused on special populations. For example, the NICHD-led Safe to Sleep® campaign, formerly the Back to Sleep® campaign, provides information to educate parents and caregivers about the importance of placing healthy babies on their backs to sleep, for naps and at night, to reduce the risk of Sudden Infant Death Syndrome (SIDS). The campaign also describes other ways to reduce the risk of sleep-related infant death. The NICHD's National Child and Maternal Health Education Program (NCMHEP) provides a forum for reviewing, translating, and disseminating new research in the field of maternal and child health through a coalition of the Nation's most prominent health care provider

associations, Federal agencies, nonprofit maternal and child health organizations, and other partners. NICHD conducted or supported several program reviews recently. For example, in 2015, NICHD conducted an internal review of its training and career development programs, and plans to implement many of this review's recommendations in 2016 and 2017.

<u>Budget Policy</u>: The FY 2017 budget request for this mechanism is \$72.081 million, an increase of \$1.413 million or 2.0 percent compared to the FY 2016 Enacted level. The increase in funds will cover mandatory cost increases for staff and centralized NIH services. The NICHD RMS activities will continue to focus on improving dissemination of NICHD science, including enhanced efforts to manage and update web content and to take advantage of new media opportunities for reaching new audiences. NICHD will continue to implement its data-driven approach to portfolio analysis, program evaluation, and performance assessment.

Budget Authority by Object Class¹

(Dollars in Thousands)

		FY 2016 Enacted	FY 2017 President's Budget ²	FY 2017 +/- FY 2016
Total co	ompensable workyears:			
	Full-time employment	554	554	0
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	\$183	\$183	\$0
	Average GM/GS grade	12.2	12.2	0.0
	Average GM/GS salary	\$107	\$108	\$2
	Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$125	\$127	\$2
	Average salary of ungraded positions	\$120	\$122	\$2
	OBJECT CLASSES	FY 2016 Enacted	FY 2017 President's Budget ²	FY 2017 +/- FY 2016
	Personnel Compensation			112010
11.1	Full-Time Permanent	\$32,743	\$32,993	\$249
11.3	Other Than Full-Time Permanent	22,514	22,685	171
11.5	Other Personnel Compensation	1.619	1.631	12
11.7	Military Personnel	1,561	1,573	12
11.8	Special Personnel Services Payments	12,834	12,932	98
11.9	Subtotal Personnel Compensation	\$71,270	\$71,813	\$543
12.1	Civilian Personnel Benefits	\$19,565	\$19,953	\$387
12.2	Military Personnel Benefits	1,269	1,278	10
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	\$92,104	\$93,044	\$940
21.0	Travel & Transportation of Persons	\$1,919	\$1,953	\$35
22.0	Transportation of Things	138	140	2
23.1	Rental Payments to GSA	1	1	0
23.2	Rental Payments to Others	16	16	0
23.3	Communications, Utilities & Misc. Charges	1,573	1,970	396
24.0	Printing & Reproduction	62	63	1
25.1	Consulting Services	\$700	\$713	\$13
25.2	Other Services	22,295	22,697	401
25.3	Purchase of goods and services from government accounts	138,533	147,478	8,945
25.4	Operation & Maintenance of Facilities	\$4,403	\$4,482	\$79
25.5	R&D Contracts	129,340	129,904	565
25.6	Medical Care	900	925	24
25.7	Operation & Maintenance of Equipment	3,123	3,179	56
25.8	Subsistence & Support of Persons	0	0	0
25.0	Subtotal Other Contractual Services	\$299,295	\$309,378	\$10,083
26.0	Supplies & Materials	\$9,020	\$9,182	\$162
31.0	Equipment	7,339	7,671	332
32.0	Land and Structures	0	0	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	926,878	914,926	-11,952
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	4	4	0
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	\$1,246,244	\$1,245,304	-\$940
	Total Budget Authority by Object Class	\$1,338,348	\$1,338,348	\$0

¹ Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

² Includes mandatory financing.

Salaries and Expenses (Dollars in Thousands)

OBJECT CLASSES	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Personnel Compensation			
Full-Time Permanent (11.1)	\$32,743	\$32,993	\$249
Other Than Full-Time Permanent (11.3)	22,514	22,685	171
Other Personnel Compensation (11.5)	1,619	1,631	12
Military Personnel (11.7)	1,561	1,573	12
Special Personnel Services Payments (11.8)	12,834	12,932	98
Subtotal Personnel Compensation (11.9)	\$71,270	\$71,813	\$543
Civilian Personnel Benefits (12.1)	\$19,565	\$19,953	\$387
Military Personnel Benefits (12.2)	1,269	1,278	10
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	\$92,104	\$93,044	\$940
Travel & Transportation of Persons (21.0)	\$1,919	\$1,953	\$35
Transportation of Things (22.0)	138	140	2
Rental Payments to Others (23.2)	16	16	0
Communications, Utilities & Misc. Charges (23.3)	1,573	1,970	396
Printing & Reproduction (24.0)	62	63	1
Other Contractual Services:			
Consultant Services (25.1)	700	713	13
Other Services (25.2)	22,295	22,697	401
Purchases from government accounts (25.3)	100,893	103,146	2,253
Operation & Maintenance of Facilities (25.4)	4,403	4,482	79
Operation & Maintenance of Equipment (25.7)	3,123	3,179	56
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$131,414	\$134,217	\$2,803
Supplies & Materials (26.0)	\$9,020	\$9,182	\$162
Subtotal Non-Pay Costs	\$144,141	\$147,541	\$3,400
Total Administrative Costs	\$236,246	\$240,585	\$4,340

Detail of Full-Time Equivalent Employment (FTE)

	FY 2015 Actual			F	Y 2016 Est.		FY 2017 Est.		
OFFICE/DIVISION	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Extramural Research									
Direct:	127	-	127	132	-	132	132	-	132
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	127	-	127	132	-	132	132	-	132
Division of Intramural Programs									
Direct:	298	11	309	301	11	312	301	11	312
Reimbursable:	-	-	-	-	-	-	-	_	_
Total:	298	11	309	301	11	312	301	11	312
National Center for Medical Rehabilitation Research									
Direct:	10	_	10	10	_	10	10	_	10
Reimbursable:	-	_	-	-	-	-	-	_	-
Total:	10	-	10	10	-	10	10	-	10
Office of the Director									
Direct:	79	2	81	82	2	84	82	2	84
Reimbursable:	21	1	22	16	-	16	16	_	16
Total:	100	3	103	98	2	100	98	2	100
Total	535	14	549	541	13	554	541	13	554
Includes FTEs whose payroll obliga									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0
FISCAL YEAR				Avera	age GS Gra	de			
20113					12.3				
20113					12.3				
2014		12.0							
2016		12.2							
2017					12.2				

Detail of Positions¹

GRADE	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	183,300	183,300	183,300
GM/GS-15	58	58	58
GM/GS-14	80	80	80
GM/GS-13	71	73	73
GS-12	66	69	69
GS-11	24	24	24
GS-10	2	2	2
GS-9	14	14	14
GS-8	20	20	20
GS-7	23	23	23
GS-6	4	4	4
GS-5	2	2	2
GS-4	3	3	3
GS-3	1	1	1
GS-2	0	0	0
GS-1	0	0	0
Subtotal	368	373	373
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	11	11	11
Senior Grade	2	2	2
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	13	13	13
Ungraded	191	191	191
Total permanent positions	374	374	374
Total positions, end of year	573	573	573
Total full-time equivalent (FTE) employment, end of year	549	554	554
Average ES salary	183,300	183,300	183,300
Average GM/GS grade	12.2	12.2	12.2
Average GM/GS salary	104,982	106,661	108,368

¹ Includes FTEs whose payroll obligations are supported by the NIH Common Fund.