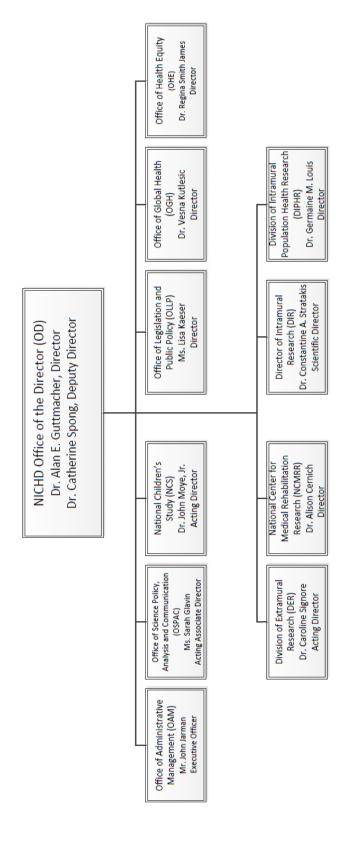
### DEPARTMENT OF HEALTH AND HUMAN SERVICES

### NATIONAL INSTITUTES OF HEALTH

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

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Eunice Kennedy Shriver
National Institute of Child Health and Human Development



### 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, [\$1,286,571,000]\$1,318,061,000.

### Amounts Available for Obligation<sup>1</sup>

Source of Funding	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget
Appropriation	\$1,282,595	\$1,286,571	\$1,318,061
Type 1 Diabetes	0	0	0
Rescission	0	0	0
Sequestration	0	0	0
FY 2014 First Secretary's Transfer	-3,220	0	0
FY 2014 Second Secretary's Transfer	-252	0	0
Subtotal, adjusted appropriation	\$1,279,123	\$1,286,571	\$1,318,061
OAR HIV/AIDS Transfers	0	298	0
National Children's Study Transfers	4,215	0	0
Subtotal, adjusted budget authority	\$1,283,338	\$1,286,869	\$1,318,061
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$1,283,338	\$1,286,869	\$1,318,061
Unobligated balance lapsing	-25	0	0
Total obligations	\$1,283,314	\$1,286,869	\$1,318,061

<sup>&</sup>lt;sup>1</sup> Excludes the following amounts for reimbursable activities carried out by this account: FY 2014 - \$28,754 FY 2015 - \$28,701 FY 2016 - \$25,415

### Budget Mechanism - Total<sup>1</sup>

MECHANISM	CHANISM FY 2014 Actual FY 2015 Enacted FY 2016 Preside			FY	FY 2016 +/-			
WECHAIUSW	1 1 201	Actual	11 201	3 Enacted	Budget		FY	Y 2015
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	1,045	\$487,719	1,062	\$508,978	1,000	\$487,516	-62	-\$21,462
Administrative Supplements	(35)	2,698	(25)	3,000	(25)	3,000	(0)	0
Competing:								
Renewal	36	34,181	33	27,821	44	36,242	11	8,421
New	374	131,512	341	107,041	443	139,452	102	32,411
Supplements	411	125	1	102	100	133	0	31
Subtotal, Competing	411	\$165,818	375	\$134,964	488	\$175,827	113	\$40,863
Subtotal, RPGs	1,456	\$656,235	1,437	\$646,942	1,488	\$666,343	51	\$19,401
SBIR/STTR	78	32,458	83	33,265	1.576	36,390	5	3,125
Research Project Grants	1,534	\$688,693	1,520	\$680,207	1,576	\$702,733	56	\$22,526
Research Centers:								
Specialized/Comprehensive	49	\$62,327	62	\$76,174	73	\$81,299	11	\$5,125
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	4	4,369	2	2,927	1	540	-1	-2,387
Comparative Medicine	0	1,185	0	0	0	0	0	0
Research Centers in Minority	0	0	0	1,060	0	310	0	-750
Institutions	-		U	· ·	-		_	
Research Centers	53	\$67,880	64	\$80,161	74	\$82,149	10	\$1,988
Other Research:								
Other Research: Research Careers	250	\$43,766	236	\$42,406	222	\$42,216	-14	-\$190
Cancer Education	0	0	0	542,400	0	542,210	0	-\$190
Cooperative Clinical Research	86	46,793	77	41,032	72	43,107	-5	2,075
Biomedical Research Support	0	0	0	0	0	0	0	2,073
Minority Biomedical Research								
Support	0	0	0	0	0	0	0	0
Other	150	23,743	142	20,608	132	15,744	-10	-4,864
Other Research	486	\$114,302	455	\$104,046	426	\$101,067	-29	-\$2,979
Total Research Grants	2,073	\$870,875	2,039	\$864,414	2,076	\$885,949	37	\$21,535
Ruth L Kirchstein Training Awards:	<u>FTTPs</u>	<b>#</b> 4 2 2 2	<u>FTTPs</u>	<b></b>	<u>FTTPs</u>	<b>\$5.054</b>	<u>FTTPs</u>	0.40
Individual Awards	91	\$4,393	100	\$4,832	106	\$5,074	6	\$242
Institutional Awards	563	26,363	556	27,187	550	27,187	-6	0
Total Research Training	654	\$30,756	656	\$32,019	656	\$32,261	0	\$242
Research & Develop. Contracts	98	\$132,176	100	\$135,382	100	\$139,120	0	\$3,738
(SBIR/STTR) (non-add)	(1)	(88)	(1)		(0)	(0)	(-1)	
Intramural Research	321	184,315	222	186,147	323	188,939		2,792
Res. Management & Support	243	65,217	323 244	68,907	323 244	71,792	0	_
Res. Management & Support				· ·				
(SBIR Admin) (non-add)	(0)	(392)	(0)	(435)	(0)	(0)	(0)	(-435)
Construction		0		0		0		0
Buildings and Facilities		0		0		0	-	0
Total, NICHD	564	\$1,283,338	567	\$1,286,869	567	\$1,318,061	0	\$31,192

<sup>&</sup>lt;sup>1</sup>All items in italics and brackets are non-add entries.

#### Major Changes in the Fiscal Year 2016 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 2016 President's Budget for NICHD, which is an increase of \$31.192 million above the FY 2015 level, for a total of \$1,318.061 million

#### Research Project Grants (RPGs) (+\$22.526 million, total \$702.733 million):

NICHD will support a total of 1,576 Research Project Grant (RPG) awards in FY 2016. Non-competing RPGs will decrease by 62 awards and the amount to support the costs associated with the commitments of prior year competing awards will decrease by \$21.462 million compared to the FY 2015 level. Competing RPGs will increase by 113 grants compared to the FY 2015 level of 375 awards and the amount to support the costs associated with new competing awards will increase by \$40.863 million compared to the FY 2015 level. The increase in Competing RPGs includes funds for the BRAIN initiative and the Precision Medicine Initiative.

#### Research Centers (+\$1.988 million, total \$82.149 million):

NICHD will support a total of 74 Research Centers awards in FY 2016, an increase of 10 grants compared with the FY 2105 level of 64 awards. The increase of \$1.988 million is based upon the utilization of new mechanisms within Research Centers for existing research programs, as well as the funding of the Precision Medicine initiative and child abuse and neglect research.

#### Other Research (-\$2.979 million, total \$101.067 million):

NICHD will support a total of 426 awards in the Other Research areas in FY 2016, a decrease of 29 awards compared with the FY 2015 level of 455 awards. The decrease of \$2.979 million is due to the utilization of new mechanisms in the Research Centers mechanism for existing programs which had previously been funded in Other Research.

#### Research and Development Contracts (+\$3.738 million, total \$139.120 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 a new effort related to research on the human placenta, and participate in crosscutting NIH projects.

#### Research Management and Support (+\$2.885 million, total \$71.792 million):

In addition to supporting a 1.3 percent pay increase for staff, and corresponding increases in benefit costs, NICHD will use funds to support staff formerly assigned to the National Children's Study (NCS) who will be reassigned to other NICHD scientific priorities, as the activities of the NCS are concluded.

#### AIDS Research (+\$5.053 million, total \$147.069 million):

NICHD will expand its work to investigate ways to prevent the transmission of HIV, including through drug therapies, and the impact of the disease on HIV-infected populations, aligning research with the overall NIH AIDS research priorities.

## **Summary of Changes**

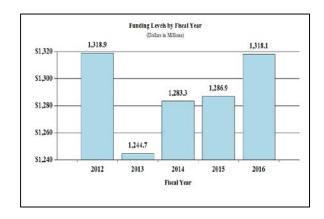
FY 2015 Enacted		\$1,286,869
FY 2016 President's Budget		\$1,318,061
Net change		\$31,192
	FY 2016 President's Budget	Change from FY 2015
CHANGES	Budget FTEs Authority	Budget FTEs Authority
A. Built-in:		
1. Intramural Research:		
a. Annualization of January 2015 pay increase & benefits	\$63,296	\$195
b. January FY 2016 pay increase & benefits	63,296	414
c. One more day of pay (n/a for 2015)	63,296	209
d. Differences attributable to change in FTE	63,296	0
e. Payment for centrally furnished services	31,894	778
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs	93,749	1,714
Subtotal		\$3,310
2. Research Management and Support:		
a. Annualization of January 2015 pay increase & benefits	\$34,900	\$103
b. January FY 2016 pay increase & benefits	34,900	218
c. One more day of pay (n/a for 2015)	34,900	110
d. Differences attributable to change in FTE	34,900	0
e. Payment for centrally furnished services	9,722	234
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs	27,170	495
Subtotal		\$1,161
Subtotal, Built-in		\$4,471

## **Summary of Changes - Continued**

	FY 2016 Pre	sident's Budget	Change from FY 2015		
CHANGES	No.	Amount	No.	Amount	
B. Program:					
Research Project Grants:					
a. Noncompeting	1,000	\$490,516	-62	-\$21,462	
b. Competing	488	175,827	113	40,863	
c. SBIR/STTR	88	36,390	5	3,125	
Subtotal, RPGs	1,576	\$702,733	56	\$22,526	
2. Research Centers	74	\$82,149	10	\$1,988	
3. Other Research	426	101,067	-29	-2,979	
4. Research Training	656	32,261	0	242	
5. Research and development contracts	100	139,120	0	3,738	
Subtotal, Extramural		\$1,057,330		\$25,515	
	<u>FTEs</u>		<u>FTEs</u>		
6. Intramural Research	323	\$188,939	0	-\$518	
7. Research Management and Support	244	71,792	0	1,724	
8. Construction		0		0	
Buildings and Facilities		0		0	
Subtotal, Program	567	\$1,318,061	0	\$26,721	
Total changes				\$31,192	

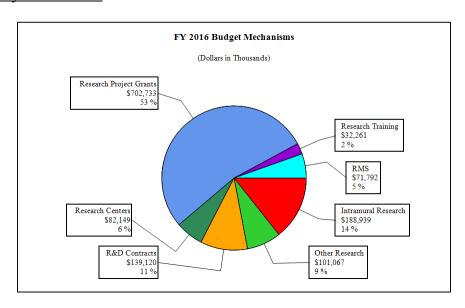
## Fiscal Year 2016 Budget Graphs

#### History of Budget Authority and FTEs:

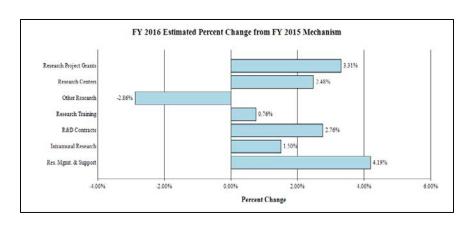




#### Distribution by Mechanism:



### Change by Selected Mechanism



### Budget Authority by Activity<sup>1</sup>

	FY 2014 Actual		FY 2015 Enacted		FY 2016 President's Budget		FY 2016 +/- FY2015	
Extramural Research	<u>FTE</u>	Amount	<u>FTE</u>	Amount	<u>FTE</u>	<u>Amount</u>	<b>FTE</b>	Amount
<u>Detail</u>								
Reproductive Health, Pregnancy, and Perinatology		\$292,945		\$292,720		\$299,958		\$7,238
Pediatric Health		298,768		297,340		304,693		7,353
Intellectual and Developmental Disabilities		119,148		119,057		122,001		2,944
Demography and Behavior		252,466		252,272		258,511		6,238
Rehabilitation		70,480		70,426		72,168		1,742
Subtotal, Extramural		\$1,033,807		\$1,031,815		\$1,057,330		\$25,515
Intramural Research	321	\$184,315	323	\$186,147	323	\$188,939	0	\$2,792
Research Management & Support	243	\$65,217	244	\$68,907	244	\$71,792	0	\$2,885
TOTAL	564	\$1,283,338	567	\$1,286,869	567	\$1,318,061	0	\$31,192

<sup>&</sup>lt;sup>1</sup>Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

## **Authorizing Legislation**

	PHS Act/ Other Citation	U.S. Code Citation	2015 Amount Authorized	FY 2015 Enacted	2016 Amount Authorized	FY 2016 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	\$1,286,869,000	Indefinite	\$1,318,061,000
Total, Budget Authority				\$1,286,869,000		\$1,318,061,000

## **Appropriations History**

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2006 Rescission	\$1,277,544,000	\$1,277,544,000	\$1,310,989,000	\$1,277,544,000 (\$12,775,000)
2007 Rescission	\$1,257,418,000	\$1,257,418,000	\$1,264,500,000	\$1,254,707,000 \$0
2008 Rescission Supplemental	\$1,264,946,000	\$1,273,863,000	\$1,282,231,000	\$1,254,708,000 (\$22,309,000) \$6,673,000
2009 Rescission	\$1,255,920,000	\$1,299,059,000	\$1,290,873,000	\$1,294,894,000 \$0
2010 Rescission	\$1,313,674,000	\$1,341,120,000	\$1,316,822,000	\$1,329,528,000 \$0
2011 Rescission	\$1,368,894,000		\$1,366,750,000	\$1,329,528,000 (\$11,674,048)
2012 Rescission	\$1,352,189,000	\$1,352,189,000	\$1,303,016,000	\$1,323,900,000 (\$2,502,171)
2013 Rescission Sequestration	\$1,320,600,000		\$1,324,603,000	\$1,321,397,829 (\$2,642,796) (\$66,325,085)
2014 Rescission	\$1,339,360,000		\$1,330,459,000	\$1,282,595,000 \$0
2015 Rescission	\$1,283,487,000			\$1,286,571,000 \$0
2016	\$1,318,061,000			

#### **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 2016	
	FY 2014	FY 2015	President's	FY 2016 +/
	Actual	Enacted	Budget	- FY 2015
BA	\$1,283,338,335	\$1,286,869,000	\$1,318,061,000	+31,192,000
FTE	564	567	567	0

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

#### **Director's Overview**

The National Institute of Child Health and Human Development's (NICHD's) mission focuses on understanding human development – that is, all the mechanisms by which a single cell becomes an individual – to improve the health and well-being of children, women, those with disabilities, families, and communities. NICHD's endeavors span the developmental spectrum, from early origins of adult disease, developmental biology, and pregnancy to pediatric and adolescent development, intellectual and developmental disabilities, and rehabilitation. NICHD's science also follows a developmental trajectory, translating basic research findings into more complex clinical approaches and technologies.

Pursuit of NICHD's far-ranging mission puts us on less-traveled paths, often – as Emerson said – going where there is no path, and leaving a trail. With these new trails come new questions, new beginnings, and other paths.

Entering FY 2016, the Institute is blazing new trails by supporting research that is directly relevant and unique to NICHD's mission. For instance, extraordinary scientific advances now enable clinicians to help tiny, premature babies survive and thrive. In tandem with these successes, however, emerge new questions. What accounts for the gender and racial disparities in birth outcomes for the tiniest of infants? What tools and biomarkers will better predict gestational age and fetal growth in pregnancy? What innovative therapies can maximize long-term outcomes to help these infants thrive? How can clinicians caring for these infants better support families who often face daunting situations? NICHD will launch a new initiative to answer these and other critical questions.

Nearly 70 percent of white and more than 80 percent of black women have at least one uterine fibroid by the time they reach 50 years of age, with nearly one-third developing severe symptoms such as pain, heavy bleeding, or miscarriage during their lifetimes. The U.S. economic burden of fibroid tumors is estimated to be as high as \$34 billion a year. Yet, scientists know little about the genomics and epigenomics that underlie uterine fibroids and other common gynecologic conditions, such as endometriosis and pelvic floor disorders. A new NICHD initiative will

support multidisciplinary research with the aim of generating novel insights into the genetic origins of these conditions, with the potential for developing new treatments.

Existing trails also can serve as starting points to hasten arrival at new destinations. By finding creative means of repurposing scientific evidence, NICHD aims to advance human health – faster, better, more efficiently, and more effectively. In FY 2016, NICHD will accelerate efforts to harness the power of large existing data sets. For example, NICHD will capitalize on previous research investments with a new initiative to support scientists in analyzing data and biospecimens collected from previous large-scale traumatic brain injury (TBI) studies. These activities will enhance researchers' ability to define biomarkers for TBI, which in turn, can assist clinicians in determining which patients are likely to benefit from various treatments.

Enhanced technologies also can contribute to advancing the health of more people, more quickly, in more settings. In FY 2016, NICHD will engage the bioengineering community in developing and tailoring simple platforms, or "labs-on–a-chip," to allow clinicians to measure and monitor important biological functions and responses (such as cardiac function, liver enzymes, and bilirubin) quickly and non-invasively. This technology could replace more invasive and less effective ways of monitoring millions of newborn infants, pregnant women, and lactating mothers in the United States and internationally, particularly those receiving care for acute, chronic, and pregnancy-related conditions.

However research tools need not be complex or sophisticated to achieve significant advances. Simple, standardized assessments that can accurately measure neurodevelopmental features not only speed research, but also enable clinicians in resource-limited settings to monitor the impact of interventions. For instance, worldwide estimates place the number of infants and children with HIV at about 2.3 million, and the number of infants born too early at 15 million. Many of these infants and children are exposed to a wide range of therapies throughout their care. Yet, researchers have few easy, systematic, and cost-effective ways to assess neurodevelopmental outcomes for any of these infants or children, particularly methods that are appropriate or valid for use in different cultural and low-resource settings. NICHD will make small business innovation and technology grants available to companies that bring creative insights to the issue and make such assessments a reality.

Blazing new scientific trails means being willing to take risks and collaborating to help others reach destinations that can only be imagined. The NICHD intramural program embodied this concept when it offered to host and provide resources to Dr. Eric Betzig, now at the Howard Hughes Medical Institute, who recently won the 2014 Nobel Prize in Chemistry "for the development of super-resolved fluorescence microscopy." NICHD intramural scientists offered Dr. Betzig, then a postdoctoral fellow, space in their lab and other resources so that he and a colleague, Harold Hasse, could overcome the resolution limitations of light microscopes. The two scientists moved forward to create a fully operational microscope capable of producing super-resolution images of a single molecule for the first time. Called photoactivated localization microscopy (PALM), the new technique provided 10 times the resolution of conventional light microscopy, created a new field of nanoscopy, and is now allowing scientists to peer into the inner workings of the body with revolutionary clarity.

Similarly, NICHD is embarking upon one of its most ambitious paths yet – to reveal the inner workings of humans' least understood organ. The Human Placenta Project aims to cross

technological frontiers to understand the pivotal role of the placenta in both supporting the healthy development of new life and influencing health across the span of that new life. The ability to reveal the placenta's workings, in real-time, could provide an unmatched opportunity to define and measure optimal function during pregnancy, develop and evaluate non-invasive markers that predict adverse outcomes, and eventually identify and evaluate interventions to improve outcomes. This initiative, like the whole of NICHD research, focuses on unlocking some of life's earliest biological mysteries and generating the knowledge needed to improve health across generations.

In FY 2016, NICHD will also support broad NIH scientific efforts:

- Precision Medicine Initiative: NIH proposes to launch a national research cohort of one million or more Americans to propel our understanding of health and disease and set the foundation for a new way of doing research through engaged participants and open, responsible data sharing. Participants who voluntarily choose to join this effort will be able to share their genomic data, biological specimens, and behavioral data, and, if they choose, link it to their electronic health records (EHRs), taking advantage of the latest in social media and mobile applications, and with appropriate privacy protections in place. Bona fide researchers from across the country will have access to data voluntarily provided, thereby crowdsourcing rich data to the brightest minds in biomedical research. The cohort will be built largely by linking existing cohorts together taking advantage of infrastructure, data security and expertise already in place. NIH will help to connect these existing cohorts, but the current sponsors of the cohorts will maintain their ownership and management. Research on this scale promises to lead to new prevention strategies, novel therapeutics and medical devices, and improvements in how we prescribe drugs on an *individual and personalized basis*. NICHD is requesting \$4.5 million in its budget to support this priority.
- <u>BRAIN Initiative</u>: In FY 2014 NIH launched the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative as a large-scale effort to equip researchers with fundamental insights necessary for treating a wide variety of devastating brain disorders like Alzheimer's, schizophrenia, autism, epilepsy, and traumatic brain injury. NIH is requesting a total of \$70 million in new funding for this Presidential initiative. NICHD is requesting \$2.25 million in its budget to support this priority.

#### **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, and pregnancy and care of the newborn. Contraception research encompasses discovery of potential and new pharmaceutical targets, non-pharmaceutical devices, and other methods to increase safe, effective, and acceptable contraceptive options for both women and men. Program research on male and female fertility and infertility addresses not only interventions, but also the underlying mechanisms, including environmental causes, that enhance or impair the capacity to conceive. In this context, researchers recently assessed whether exposure to common chemicals, often used in plastics manufacturing, could affect the ability to conceive. They found that women whose male partners had high urine concentrations of three common chemicals took longer to become pregnant than women whose male partners did not. However, female urinary concentrations of

the same three substances were not associated with a delay in pregnancy. The program's pregnancy-related research spans preconception care, pregnancy, fetal growth, labor and delivery, and maternal and neonatal health. Studies to reduce rates of high-risk pregnancies and preterm birth, as well as complications, such as preeclampsia and other conditions, are also supported.

<u>Budget Policy</u> – The FY 2016 President's Budget request for this program is \$299.958 million, an increase of \$7.238 million, or 2.5 percent above the FY 2015 Enacted level. In FY 2016, 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. New initiatives will support development of innovative methods and technologies to assess the structure, function, and development of the human placenta (see below for details). Another initiative will support multidisciplinary research that can generate novel insights into the genetic origins of gynecologic conditions, with the intention of developing new treatments.

#### Program Portrait: Unlocking the Secrets of the Placenta

FY 2015 Level: \$5.0 million FY 2016 Level: \$7.0 million Change: +\$2.0 million

The placenta is critical during pregnancy and can affect the lifelong health of mothers and their children. And yet, it is the least understood and studied of all human organs. NICHD supports a range of research projects to better understand the placenta and its role in health and disease, with the ultimate goal of developing effective interventions to improve outcomes for both mother and infant. Knowledge of the inner workings of placental cells and of the placenta's role in the transmission of nutrients is crucial to improving outcomes. Other efforts include examining the possible role of placental bacteria in preterm birth, and an NICHD small business innovation research grant to support the ground-breaking development of an artificial placenta that could be used to treat very premature infants soon after birth, improving their chances for a healthy start.

NICHD is supporting two new initiatives to push the frontiers of this research and accelerate its pace. The goal of the first initiative, the Human Placenta Project, is to develop innovative methods and technology to assess the placenta's typical structure, function, and development across pregnancy. Such knowledge will allow clinicians to better monitor pregnancies and detect placental problems at the outset, raising the possibility for earlier intervention. A complementary second initiative, the Placental Atlas Tool, is planned as an online central repository of all available molecular data on the placenta, including data that may be generated through the Human Placenta Project, with a goal of providing the means to expand knowledge rapidly and make it more readily available.

Unlocking the secrets of the placenta is no small undertaking, but the potential benefits are tremendous – for science and for health.

**Pediatric Health:** The pediatric health program supports a comprehensive array of basic and clinical research and research training on such topics as basic scientific investigations of biological processes that control healthy and atypical development; clinical studies in pediatric pharmacology, pediatric HIV, and associated infections; nutrition science; pediatric endocrinology; and pediatric trauma and critical illness. This program includes studies of congenital and developmental disorders to understand processes that influence normal and abnormal embryonic and fetal development. Research to expand relatively limited scientific knowledge about the safety, efficacy, and appropriate doses of pharmaceuticals for children is also part of this portfolio. As part of NICHD's responsibilities under the Better Pharmaceuticals for Children Act, the program collaborates with the Food and Drug Administration to improve labeling of drugs for use in children. Domestic and international research on HIV infection and

its effects in pregnant women and children is also an important aspect of this program, including recent work to determine why some infants developed resistance to nevirapine (NVP), an antiretroviral drug used to decrease rates of mother-to-child HIV transmission. Using data from a large study of NVP, scientists found that, among infants who became infected with HIV after 6 weeks of age, those who received extended NVP regimens were more likely to develop NVP resistance. Similarly, infants who were already infected with HIV were more likely to develop resistance when their HIV-positive breastfeeding mothers were treated with NVP. When considered with previous research findings, these latest results help inform guidelines for treating HIV-infected infants. Additional program research on nutrition and endocrinology aims to describe the interactions between nutrients and hormones in growth and development, and the role of nutrition throughout the life cycle, but especially in infancy, childhood, and adolescence. Other program interests include lactation and breastfeeding, childhood obesity, antecedents of bone health, as well as pediatric critical illness and trauma.

<u>Budget Policy</u> – The FY 2016 President's Budget request for this program is \$304.693 million, an increase of \$7.353 million, or 2.5 percent above the FY 2015 Enacted level. In FY 2016, the program will maintain its investments in research on pediatric pharmacology, pediatric critical care, and the implications of HIV and HIV treatment in adolescents. It will also continue to conduct innovative research in the neuroscience of reading, mathematics, and other learning disabilities. New initiatives will support efforts to better understand the origins and consequences of disorders of sexual development, advance knowledge of structural birth defects, develop new tools for assessing neurodevelopment in low-resource settings, and conduct multidisciplinary research and training on child abuse and neglect.

#### **Program Portrait: Rare Diseases**

FY 2015 Level: \$156.0 million FY 2016 Level: \$156.9 million Change: +\$0.9 million

Rare diseases pose a special paradox. Individual conditions affect relatively few people, but, because there are nearly 7,000 rare diseases, their combined impact extends to approximately 30 million Americans. Research on rare diseases often advances scientific knowledge for more common conditions because such diseases typically reflect the impact of a specific genetic defect or biological pathway. Research to better understand and treat rare diseases is also at the forefront of personalized medicine, applying genetic information to tailor medical care to an individual's needs.

Rare diseases can cause intellectual and developmental disability, metabolic dysfunction, and other problems, as well as death in early childhood. As a key contributor to the trans-NIH Rare Disease Clinical Research Network, NICHD supports and co-funds multidisciplinary research consortia that address groups of rare diseases: Rett Syndrome; Brittle Bone Disorders, including Osteogenesis Imperfecta; Developmental Synaptopathies; Urea Cycle Disorders; Mitochondrial Disorders; and Sterol and Isoprenoid Metabolism. NICHD's intramural and extramural activities aim to identify the underlying genetic and epigenetic causes of rare diseases and determine how these factors affect early development and progression of disease. In one recent example, NICHD-funded researchers identified the roles that specific genes play in the symptoms of such rare diseases as WAGR syndrome, isolated congenital asplenia, Kuskokwim syndrome, and pontocerebellar hypoplasia. Scientists also developed new insights into how the workings of certain proteins lead to symptoms of Rett syndrome, and how mutations in adrenal tissue lead to overproduction of cortisol for people with Cushing's syndrome. NICHD intramural scientists have described the genetic underpinnings of Menkes disease, a lethal disorder that prevents the brain and other parts of the body from getting enough copper. Researchers are now using these basic and translational research findings to develop and test new treatments for the disease. NICHD's multifaceted research on rare diseases has also helped scientists develop a promising new drug for urea cycle disorders. NICHD's successful approach to rare disease research illustrates that it is not the prevalence of disease that matters, but the combined strength of the Institute's science and commitment to conquer these conditions.

**Intellectual and Developmental Disabilities:** The program in intellectual and developmental disabilities (IDDs) supports basic, clinical, and translational research, and research training to advance knowledge on origins of common and rare IDDs, such as Down, Fragile X, and Rett syndromes, inborn errors of metabolism, and autism spectrum disorders (ASD). The program includes an additional emphasis on research to unravel the complex processes through which these disorders compromise cognitive, emotional, social, and physical development in infants and children and through the lifespan. Recent research supported by the program, using data from Sweden's universal health registry, found that most of the genetic risk for ASD came from genes common in the population, rather than from rare variants or spontaneous mutations in the genetic code. Other program advances and activities are based on the concept that it is best to detect and treat childhood illnesses as early as possible, particularly when so many IDDs start in infancy. Accordingly, the IDD program includes newborn screening studies and related research focused on diagnosing and treating a wide array of IDDs and other illnesses. This includes a recent effort in which scientists tested the reliability of a screening test for severe combined immunodeficiency (SCID), an inherited immune deficiency in newborns that affects the development and function of infection-fighting immune cells. Unless treated early, SCID is fatal usually within the first two years of life. By evaluating data from more than three million newborns across 10 States and the Navajo Nation, scientists found that screening detected 52 newborns with SCID, equivalent to 1 in 58,000 infants; previous estimates suggested SCID was less prevalent, affecting only 1 in 100,000 infants. Having a more accurate screening test allows physicians to diagnose and treat SCID infants promptly, before infections become overwhelming.

Budget Policy – The FY 2016 President's Budget request for this program is \$122.001 million, an increase of \$2.944 million, or 2.5 percent above the FY 2015 Enacted level. In FY 2016, 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. To strengthen this research, NICHD will support a new initiative fostering future generations of researchers from diverse disciplines to help them address the clinical needs of persons with IDDs.

**Demography and Behavior:** The program in demography and behavior aims to increase understanding of how population structure and change affect individual, family, and community health, including understanding infants' and children's health and development and how local communities and the larger society may influence these outcomes. The program's research examines factors that contribute to health risk behaviors and the spread of sexually transmitted infections, as well as factors that affect family formation, functioning, and stability. Consider the research on demographic and use patterns of young women who use, or fail to use, dual contraception to protect against sexually transmitted diseases and unplanned pregnancy: NICHD-supported researchers found that only one-fifth of young women used dual methods, and that those at highest risk for unplanned pregnancy were least likely to use them. A related study determined that although only 10 percent of women used the most effective types of reversible contraception, use of these methods has increased steadily over the last decade. This broad program also encompasses important topics in behavioral development, from work to understand 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, such as dyslexia. By exploiting emerging technologies, researchers are

examining the combined neurobiological and genetic bases of behavioral development and learning as well as identifying the biobehavioral mechanisms that underlie resiliency and risk-taking behaviors, especially during adolescence. Researchers recently found that teens with higher cortisol responses to stress tended to be safer drivers, had fewer crashes and near crashes, and seemed to improve at avoiding crashes over time.

<u>Budget Policy</u> – The FY 2016 President's Budget request for this program is \$258.510 million, an increase of \$6.238 million, or 2.5 percent above the FY 2015 Enacted level. In FY 2016, the 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 NIH's overall efforts to advance research training in large-scale data analysis, informatics, and biomedical computing.

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 examinations of the underlying biology of injury and disability and the body's mechanisms of recovery and adaptation. NCMRR's activities include a special emphasis on research related to spinal cord injury (SCI), traumatic brain injury (TBI), and stroke, frequently in collaboration with other NIH ICs and other partners. In this context, researchers found that a physical therapy intervention, which incorporated a type of electrical muscle stimulation, helped to preserve bone mineral density in people with SCI. Another important aspect of this program is NCMRR's support of the development of medical devices and equipment, and of treatments to improve mobility and enhance the functional capabilities of individuals with disabling conditions. Recently, NICHD-supported scientists tested a new type of prosthetic implant (in an animal model) and showed that the implants may be less prone to infection than those currently in use.

<u>Budget Policy</u> – The FY 2016 President's Budget request for this program is \$72.168 million, an increase of \$1.742 million, or 2.5 percent above the FY 2015 Enacted level. In FY 2016, 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. New initiatives will help improve assessment of individuals with TBI over time, with a focus on developing and improving ways to measure recovery over the longer term.

#### Program Portrait: Traumatic Brain Injury (TBI) and Concussion Research

FY 2015 Level: \$9.4 million FY 2016 Level: \$9.6 million Change: +\$0.2 million

TBI is a major cause of death and disability in the United States, affecting more than 2 million people each year and resulting in over 50,000 deaths. Media coverage highlighting the serious nature of sports-related concussions and of injuries sustained during combat has increased the attention of parents, children, schools, national sports organizations, the military, Congress, and the general public to this issue. NICHD long has supported TBI research to help scientists and clinicians better understand, prevent, and improve outcomes for those affected. These activities range from studies at the cellular level to tests of new interventions in clinic, hospital, or rehabilitation settings.

Several NICHD-supported scientists focus on sports-related brain injuries to understand the long-term neurological effects from repetitive head impacts, especially in children, adolescents, and young adults. This effort resulted in development and use of a sports-related head-impact system to measure blows to the head and subsequently test for changes in brain functioning. NICHD-supported researchers also are improving diagnosis of TBI; identifying a new, more accurate, blood serum marker for mild TBI; and developing new ways to promote recovery from the physical, emotional, and cognitive problems that TBI may cause. Of equal importance to the field, NICHD supports studies to assess rehabilitation methods, procedures, and therapies that can improve long-term outcomes and quality-of-life for TBI patients and their families. Conditions secondary to TBI, such as depression, suicidal ideation, and impaired mental functioning also are an important component of this program. With such support, researchers carefully designed a "gist reasoning" intervention, which taught adolescents with TBI how to process incoming information more strategically, rather than focusing solely on ways to improve their memory. The research showed that, even many months after injury, this cognitive intervention could help adolescents with TBI improve both their memory and reasoning ability, offering additional hope for improving and maintaining day-to-day functioning over time.

**Intramural Research:** The NICHD 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 senior scientists is an essential element of this program and its continued success. DIR research includes investigations in genetics, genomics, and epigenetics and on how these factors and processes influence typical and atypical development and disease processes. The 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. Building on previous basic research, program scientists recently used emerging knowledge of HIV proteins to design drugs that target the virus, fight off infection, and reduce the risk of drug resistance. Other scientists in the NICHD intramural program also study the basic biophysical mechanisms of cell biology and tissue function, while their colleagues examine how multiple factors influence development, specifically targeting the nervous, endocrine, and reproductive systems. Among program activities is a recent study in which NICHD intramural scientists found that hormone replacement therapy in young women with primary ovarian insufficiency increased bone mineral density, restoring it to normal levels. Translational research is also a hallmark of NICHD's wide-ranging intramural program, as are behavioral studies, and innovative diagnostics for endocrine, metabolic, and reproductive diseases. These efforts include studies on gene therapy for infants with neurometabolic diseases, one of a range of metabolic disorders that affect the central nervous system. Researchers found that injecting genetic material typically used to treat muscle and eye diseases into brain cells of fetal mice could help fight or prevent disease. Within 48 hours of injection, the new genetic material began to function, suggesting that gene therapy targeting specific parts of the brain

could improve treatment and provide hope for infants with sometimes devastating neurometabolic conditions.

Budget Policy – The FY 2016 President's Budget request for this mechanism is \$188.939 million, an increase of \$2.792 million, or 1.5 percent above the FY 2015 enacted level. In FY 2016, funding increases will support the increased personnel, centralized NIH and scientific costs to sustain the intramural research programs. Following recommendations by a panel of national and outside experts, the DIR has taken many organizational steps to improve efficiencies and leverage resources. Most notably, the program has set-aside funds to promote research collaborations and share resources across laboratories and the NIH. These endeavors will continue in FY 2016. The program will also continue to increase its contribution to an NIH-wide initiative that enables external researchers to collaborate with NIH clinical investigators, leveraging the diverse resources, expertise, and infrastructure of the NIH Clinical Center. Clinical studies that are considered intellectually challenging and risky, but that offer the potential of high reward with new breakthroughs in medicine are important to this effort. Unraveling the genetic, genomic, and epigenetic underpinnings of human development will remain a key program priority.

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, such as the Media Smart Youth® Teen Leaders Program, a new community service opportunity for teens and young adults interested in teaching youth about media's influence on health. NICHD also launched the Know Your Terms Initiative to raise awareness about the new definition of "term" in pregnancy. The effort educates consumers and health care providers about the new definition for "full-term" pregnancy, one that helps to communicate the importance of the last few weeks of pregnancy for infant development. The NICHD-led Safe to Sleep<sup>®</sup> campaign, formerly the Back to Sleep<sup>®</sup> campaign, also celebrates its 20th anniversary this year; activities to commemorate this milestone and to further spread campaign messages also are planned. To improve the functioning of research programs and identify opportunities for improvement, the Institute will develop new evaluation paradigms, including some to help identify and use more appropriate measures to assess key scientific and administrative operations.

Budget Policy – The FY 2016 President's Budget request for this mechanism is \$71.792 million, an increase of \$2.885 million, or 4.2 percent above the FY 2015 Enacted level. In FY 2016, funding increases will support the increased personnel and centralized NIH costs to sustain the support of extramural programs. In addition, resources will support staff formerly assigned to the National Children's Study who will be reassigned to other NICHD scientific priorities. The NICHD RMS activities will continue to focus on improving dissemination of NICHD science, including enhanced efforts to manage and update web content, find innovative ways to improve access to information for individuals with limited English proficiency, and to take advantage of new media opportunities for reaching new audiences. Staff continues to find new ways to conduct program analyses and evaluate our national research programs to ensure that the programs are being implemented effectively and efficiently, and that they continue to advance our scientific endeavors.

# Budget Authority by Object Class<sup>1</sup> (Dollars in Thousands)

		FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Total co	mpensable workyears:			
	Full-time employment	567	567	0
	Full-time equivalent of overtime and holiday hours	1	1	0
	Average ES salary	\$182	\$182	\$0
	Average GM/GS grade	12.2	12.2	0.0
	Average GM/GS salary	\$104	\$105	\$1
	Average salary, grade established by act of	\$124	\$125	\$1
	July 1, 1944 (42 U.S.C. 207)			
	Average salary of ungraded positions	\$120	\$122	\$1
	OBJECT CLASSES	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
	Personnel Compensation	_	_	_
11.1	Full-Time Permanent	\$36,463	\$37,903	\$1,440
11.3	Other Than Full-Time Permanent	22,834	23,150	316
11.5	Other Personnel Compensation	1,618	1,640	22
11.7	Military Personnel	1,503	1,524	21
11.8	Special Personnel Services Payments	12,728	12,904	176
11.9	<b>Subtotal Personnel Compensation</b>	\$75,146	\$77,121	\$1,975
12.1	Civilian Personnel Benefits	\$19,159	\$19,663	\$503
12.2	Military Personnel Benefits	1,393	1,413	19
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	\$95,698	\$98,196	\$2,498
21.0	Travel & Transportation of Persons	\$1,675	\$1,686	\$11
22.0	Transportation of Things	138	140	2
23.1	Rental Payments to GSA	0	0	0
23.2	Rental Payments to Others	33	33	1
23.3	Communications, Utilities & Misc. Charges	1,289	1,292	3 0
24.0 25.1	Printing & Reproduction	0 \$908	0 \$908	\$0 \$0
25.1	Consulting Services Other Services	16,885	17,155	270
	Purchase of goods and services from	·		
25.3	government accounts	137,002	146,600	9,598
25.4 25.5	Operation & Maintenance of Facilities R&D Contracts	\$1,226	\$1,226	\$0 15
25.5	Medical Care	127,085 1,077	127,069 1,104	-15 27
25.7		*	3,934	-210
	Operation & Maintenance of Equipment	4,144	3,934	-210 0
25.8 <b>25.0</b>	Subsistence & Support of Persons Subtotal Other Contractual Services	\$288,327	\$297,997	\$9,670
26.0	Supplies & Materials	\$8,193	\$8,198	\$ <b>5,070</b>
31.0	Equipment	9,207	9,263	55
32.0	Land and Structures	0,207	0,209	0
33.0	Investments & Loans		0	ő
41.0	Grants, Subsidies & Contributions	882,307	901,253	18,947
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	2	2	0
44.0	Refunds	$\overline{0}$	0	0
	Subtotal Non-Pay Costs	\$1,191,171	\$1,219,865	\$28,694
	Total Budget Authority by Object Class	\$1,286,869	\$1,318,061	\$31,192

### **Salaries and Expenses**

OBJECT CLASSES	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015	
Personnel Compensation				
Full-Time Permanent (11.1)	\$36,463	\$37,903	\$1,440	
Other Than Full-Time Permanent (11.3)	22,834	23,150	316	
Other Personnel Compensation (11.5)	1,618	1,640	22	
Military Personnel (11.7)	1,503	1,524	21	
Special Personnel Services Payments (11.8)	12,728	12,904	176	
Subtotal Personnel Compensation (11.9)	\$75,146	\$77,121	\$1,975	
Civilian Personnel Benefits (12.1)	\$19,159	\$19,663	\$503	
Military Personnel Benefits (12.2)	1,393	1,413	19	
Benefits to Former Personnel (13.0)	0	0	0	
Subtotal Pay Costs	\$95,698	\$98,196	\$2,498	
Travel & Transportation of Persons (21.0)	\$1,675	\$1,686	\$11	
Transportation of Things (22.0)	138	140	2	
Rental Payments to Others (23.2)	33	33	1	
Communications, Utilities & Misc. Charges (23.3)	1,289	1,292	3	
Printing & Reproduction (24.0)	0	0	0	
Other Contractual Services:				
Consultant Services (25.1)	0	0	0	
Other Services (25.2)	16,885	17,155	270	
Purchases from government accounts (25.3)	100,445	103,539	3,094	
Operation & Maintenance of Facilities (25.4)	1,226	1,226	0	
Operation & Maintenance of Equipment (25.7)	4,144	3,934	-210	
Subsistence & Support of Persons (25.8)	0	0	0	
Subtotal Other Contractual Services	\$122,701	\$125,855	\$3,154	
Supplies & Materials (26.0)	\$8,193	\$8,198	\$5	
Subtotal Non-Pay Costs	\$134,028	\$137,205	\$3,177	
Total Administrative Costs	\$229,726	\$235,401	\$5,674	

## **Detail of Full-Time Equivalent Employment (FTE)**

	FY	2014 Act	ual	F	Y 2015 Es	it.	F	Y 2016 Es	t.
OFFICE/DIVISION	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Extramural Research									
Direct:	125	1	126	129	1	130	136	1	137
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	125	1	126	129	1	130	136	1	137
Division of Intramural Programs									
Direct:	310	11	321	312	11	323	312	11	323
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	310	11	321	312	11	323	312	11	323
National Center for Medical Rehabilitation Research									
Direct:	7	=	7	8	-	8	8	-	8
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	7	-	7	8	-	8	8	-	8
Office of the Director	_								
Direct:	86	-	86	88	-	88	89	-	89
Reimbursable:	23	1	24	17	1	18	9	1	10
Total:	109	1	110	105	1	106	98	1	99
Total	551	13	564	554	13	567	554	13	567
Includes FTEs whose payroll oblig	ations are	supported	by the NI	H Commo	on Fund.				
FTEs supported by funds from									
Cooperative Research and	0	0	0	0	0	0	0	0	0
Development Agreements.									
FISCAL YEAR				Aver	age GS G	rade			
2012					12.3				
2013					12.0				
2014		12.2							
2015					12.2				
2016					12.2				

### Detail of Positions<sup>1</sup>

GRADE	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget
Total, ES Positions	2	2	2
Total, ES Salary	363,000	363,000	363,000
GM/GS-15	50	50	50
GM/GS-14	81	82	82
GM/GS-13	67	68	68
GS-12	64	64	64
GS-11	29	29	29
GS-10	2	2	2
GS-9	16	16	16
GS-8	22	22	22
GS-7	17	17	17
GS-6	3	3	3
GS-5	1	1	1
GS-4	1	1	1
GS-3	0	0	0
GS-2	1	1	1
GS-1	0	0	0
Subtotal	354	356	356
Grades established by Act of July 1, 1944	0	0	0
(42 U.S.C. 207)	O	U	O
Assistant Surgeon General	- 0	- 0	- 0
Director Grade	13	13	13
Senior Grade	0	0	0
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	13	13	13
Ungraded	209	210	210
Total permanent positions	382	382	382
Total positions, end of year	576	579	579
Total full-time equivalent (FTE)	-	-	-
employment, end of year	564	567	567
Average ES salary	181,500	181,500	181,500
Average GM/GS grade	12.2	12.2	12.2
Average GM/GS salary	102,987	104,050	105,090

<sup>&</sup>lt;sup>1</sup>Includes FTEs whose payroll obligations are supported by the NIH Common Fund.