DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Eunice Kennedy Shriver National Institute of Child Health and Human Development

FY 2013 Budget	Page No.
Organization Chart	2
Appropriation Language	3
Amounts Available for Obligation	4
Budget Mechanism Table	5
Major Changes in Budget Request	6
Summary of Changes	7
Budget Graphs	9
Budget Authority by Activity	10
Authorizing Legislation	11
Appropriations History	12
Justification of Budget Request	13
Budget Authority by Object Class	22
Salaries and Expenses	23
Detail of Full-Time Equivalent Employment (FTE)	24
Detail of Positions.	25

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NATIONAL INSTITUTES OF HEALTH

Eunice Kennedy Shriver National Institute of Child Health and Human Development

For carrying out section 301 and title IV of the PHS Act with respect to child health and human development, [\$1,323,900,000] \$1,320,600,000. (Department of Health and Human Services Appropriations Act, 2012.)

Amounts Available for Obligation ¹

(Dollars in Thousands)

Source of Funding	FY 2011 Actual	FY 2012 Enacted	FY 2013 PB
Appropriation	1,329,528	1,323,900	1,320,600
Type 1 Diabetes	0	0	0
Rescission	(11,674)	(2,502)	0
Supplemental	0	0	0
Subtotal, adjusted appropriation	1,317,854	1,321,398	1,320,600
Real transfer under Secretary's transfer authority	0	(376)	0
Comparative Transfers to NCATS for Therapeutics and Rare and Neglected Diseases (TRND) Comparative Transfers to NLM for NCBI and Public	(1,085)	0	0
Access	(1,131)	(1,197)	0
Subtotal, adjusted budget authority	1,315,638	1,319,825	1,320,600
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	1,315,638	1,319,825	1,320,600
Unobligated balance lapsing	0	0	0
Total obligations	1,315,638	1,319,825	1,320,600

¹ Excludes the following amounts for reimbursable activities carried out by this account:

FY 2011 - \$35,717 FY 2012 - \$36,000 FY 2013 - \$36,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Child Health and Human Development

Budget Mechanism - Total ^{1/} (Dollars in Thousands)

	FY 2011		FY	2012	FY	7 2013			
MECHANISM	Actual		Enacted			PB	Change vs. FY 2012		
	No.	Amount	No.	Amount	No.	Amount	No.	Amount	
Research Grants									
Research Projects									
Noncompeting	1,178	\$499,011	1,099	\$506,444	1,058	\$507,764	(41)	\$1,320	
Administrative Supplements	41	3,343	37	4,000	37	4,000	0	0	
Competing:									
Renewal	71	55,206	71	51,167	71	50,644	0	(523)	
New	320	106,418	320	98,631	320	97,601	0	(1,030)	
Subtotal, Competing	391	\$161,624	391	\$149,798	391	\$148,245	0	(\$1,553)	
Subtotal, RPGs	1,569	\$663,978	1,490	\$660,242	1,449	\$660,009	(41)	(\$233)	
SBIR/STTR	82	\$30,094	80	\$31,505	80	\$32,513	0	\$1,008	
Research Project Grants	1,651	\$694,072	1,570	\$691,747	1,529	\$692,522	(41)	\$775	
Research Centers									
Specialized/Comprehensive	53	\$72,066	50	\$71,060	50	\$71,060	0	\$0	
Biotechnology	3	3,887	3	3,910	3	3,910	0	0	
Comparative Medicine	0	1,172	0	1,169	0	1,169	0	0	
Research Centers	56	\$77,125	53	\$76,139	53	\$76,139	0	\$0	
Orthon Browning									
Other Research Research Careers	284	\$44.542	278	\$49,014	278	¢40.014		\$0	
	102	\$44,543 51,371	100	52,712	100	\$49,014 52,712	0	90	
Cooperative Clinical Research Other	102	,	147		147	22,363	0	0	
Other Research		21,447	525	22,363			0	\$0	
	520	\$117,361		\$124,089	525	\$124,089			
Total Research Grants	2,227	\$888,558	2,148	\$891,975	2,107	\$892,750	(41)	\$775	
Research Training	FTTPs		FTTPs		FTTPs				
Individual Awards	100	\$4,585	99	\$4,576	95	\$4,576	(4)	\$0	
Institutional Awards	652	29,486	634	29,430	623	29,430	(11)	0	
Total Research Training	752	\$34,071	733	\$34,006	718	\$34,006	(15)	\$0	
Research & Development Contracts	100	\$138,538	98	\$139,410	98	\$139,410	0	\$0	
SBIR/STTR	0	\$136,336	98	\$139,410	98	\$139,410	0	\$0 \$0	
SBINSTIK		\$0	U	\$0	0	\$0	0	\$0	
	<u>FTEs</u>		FTEs		<u>FTEs</u>		<u>FTEs</u>		
Intramural Research	369	\$189,256	369	\$189,327	365	\$189,327	(4)	\$0	
Research Management and Support	242	65,215	242	65,107	240	65,107	(2)	0	
Total, NICHD	611	\$1,315,638	611	\$1,319,825	605	\$1,320,600	(6)	\$775	

 $^{1/\,\}mbox{All}$ items in italics are "non-adds"; items in parenthesis are subtractions

Major Changes in the Fiscal Year 2013 President's Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. The FY2013 President's Budget request is \$1,320.600 million, an increase of \$0.775 million over the FY 2012 Enacted level.

Research Project Grants (RPGs) (+\$0.775 million, total \$692.522 million): NIH budget policy for RPGs in FY 2013 discontinues inflationary allowances and reduces the average cost of noncompeting and competing RPGs by one percent below the FY 2012 level. The NICHD will support a total of 1,529 Research Project Grant (RPG) awards in 2013. Non-competing RPGs will decrease by 41 awards while increasing the amount to support the costs associated with the commitments of prior year competing awards by \$1.320 million compared to the FY 2012 Enacted level. Competing RPGs will remain at the FY 2012 level of 391 awards, while the amount to support the costs associated with those awards will decline by \$1.553 million compared to the FY 2012 Enacted level, due to the declining average cost. SBIR/STTR grants will increase by \$1.008 million compared to the FY 2012 Enacted level to reflect the provisions of P.L. 112-81, the National Defense Authorization Act for Fiscal Year 2012, which increased the SBIR/STTR set-aside percentage to 2.95%.

NATIONAL INSTITUTES OF HEALTH

National Institute of Child Health and Human Development Summary of Changes

(Dollars in Thousands)

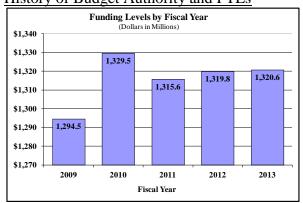
FY 2012 Enacted				\$1,319,825
FY 2013 Estimate				1,320,600
Net change				\$775
	2	2013		
	Es	timate	Change fr	om FY 2012
		Budget		Budget
CHANGES	FTEs	Authority	FTEs	Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January				
2012 pay increase & benefits		\$68,160		\$7
b. January FY 2013 pay increase & benefits		68,160		\$219
c. One more day of pay		68,160		\$259
d. Annualization of PY net hires		68,160		\$0
e. Payment for centrally furnished services		31,368		\$0
f. Increased cost of laboratory supplies, materials,				
other expenses, and non-recurring costs		89,799		\$0
Subtotal				\$485
2. Research Management and Support:				
a. Annualization of January				
2012 pay increase & benefits		\$32,582		\$2
b. January FY 2013 pay increase & benefits		32,582		\$100
c. One more day of pay		32,582		\$124
d. Annualization of PY net hires		32,582		\$0
e. Payment for centrally furnished services		8,092		\$0
f. Increased cost of laboratory supplies, materials,				
other expenses, and non-recurring costs		24,433		\$0
Subtotal		1		\$226
Subtotal, Built-in				\$711

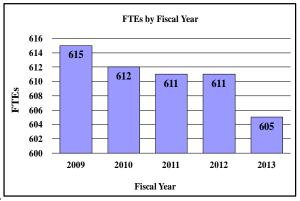
Summary of Changes--continued

		2013		
		Estimate	Change	from FY 2012
CHANGES	No.	Amount	No.	Amount
B. Program:				
Research Project Grants:				
a. Noncompeting	1,058	\$511,764	(41)	\$1,320
b. Competing	391	148,245	0	(1,553)
c. SBIR/STTR	80	32,513	0	1,008
Total	1,529	\$692,522	(41)	\$775
2. Research Centers	53	\$76,139	0	\$0
3. Other Research	525	124,089	0	0
4. Research Training	718	34,006	(15)	0
5. Research and development contracts	98	139,410	0	0
Subtotal, Extramural		\$1,066,166		\$775
	<u>FTEs</u>		<u>FTEs</u>	
6. Intramural Research	365	\$189,327	(4)	(\$485)
7. Research Management and Support	240	65,107	(2)	(226)
8. Construction		0		0
Buildings and Facilities		0		0
Subtotal, program	605	\$1,320,600	(6)	\$64
Total changes				\$775

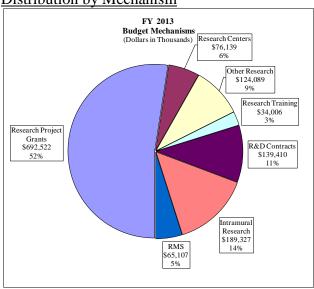
Fiscal Year 2013 Budget Graphs

History of Budget Authority and FTEs

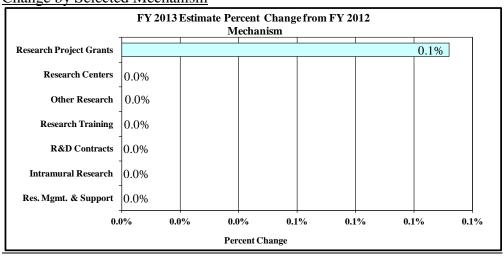




Distribution by Mechanism



Change by Selected Mechanism



NATIONAL INSTITUTES OF HEALTH

National Institute of Child Health and Human Development Budget Authority by Activity

(Dollars in thousands)

		Y 2011 Actual		Y 2012 nacted	FY 2013 PB		Change vs. FY 2012 Enacted	
Extramural Research Detail:	FTEs	<u>Amount</u>	FTEs	<u>Amount</u>	FTEs	<u>Amount</u>	<u>FTEs</u>	Amount
Center for Developmental Biology and		\$311,038		\$312,999		\$313,226		227
Perinatal Medicine Center for Population Research		301,374		303,460		303,681		221
Center for Research for Mothers and Children		376,705		377,815		378,091		276
National Center for Medical Rehabilitation Research		72,050		71,117		71,168		51
Subtotal, Extramural		\$1,061,167		\$1,065,391		\$1,066,166		\$775
Intramural Research	369	\$189,256	369	\$189,327	365	\$189,327	(4)	\$0
Research Management & Support	242	\$65,215	242	\$65,107	240	\$65,107	(2)	\$0
TOTAL	611	\$1,315,638	611	\$1,319,825	605	\$1,320,600	(6)	\$775

^{1.} Includes FTEs which are reimbursed from the NIH Common Fund for Medical Research.

 $^{2. \} Includes \ Real \ Transfers \ and \ Comparable \ Adjustments \ as \ detailed \ in the \ "Amounts \ Available \ for \ Obligation" \ table.$

Authorizing Legislation

	PHS Act/ Other Citation		2012 Amount Authorized	FY 2012 Enacted	2013 Amount Authorized	t FY 2013 PB
Research and Investigation	Section 301	42§241	Indefinite	-\$1,319,825,000	Indefinite	- \$1,320,600,000
National Institute of Child Health and Human Development	Section 401(a)	42§281	Indefinite	.,,	Indefinite	
Total, Budget Authority				\$1,319,825,000		\$1,320,600,000

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2004	\$1,245,371,000	\$1,245,371,000	\$1,251,185,000	\$1,250,585,000
Rescission	\$1, 2 10,0 / 1,000	\$1, 2 10,0 11,0 00	ψ1, 2 ε1,1εε,εε	(\$8,224,000)
				(1-)
2005	\$1,280,915,000	\$1,280,515,000	\$1,288,900,000	\$1,280,915,000
Rescission				(\$10,594,000)
2006	\$1,277,544,000	\$1,277,544,000	\$1,310,989,000	\$1,277,544,000
Rescission				(\$12,775,000)
				, , , , , ,
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	; -,ee - ,100,000	+ -,ee - ,100,000	+1,000,010,000	(\$2,502,171)
				(\$2,502,171)
2013	\$1,320,600,000			

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:

			FY 2013	FY 2013
	FY 2011	FY 2012	President's	+/-
	Actual	Enacted	Budget	FY 2012
BA	\$1,315,638,000	\$1,319,825,000	\$1,320,600,000	+\$775,000
FTE	611	611	605	-6

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

Director's Overview

Institute Mission: The NICHD mission is to ensure that every child is born healthy and planned; that women suffer no harmful effects from reproductive processes; that all children can achieve their full potential for healthy and productive lives; and that medical rehabilitation can optimize the health, productivity, and independence of all people. NICHD supports a broad research portfolio, uniquely focused on understanding human health and development from before birth through adulthood. NICHD provides a home to targeted research in developmental biology; women's health; the reproductive sciences; child health and development; cognition and early learning; demography and population dynamics; behavioral studies related to child health and family well-being; and medical rehabilitation.

Over the last year, NICHD has made significant progress in advancing science and improving health, in part by leveraging its resources through strategic partnerships with other government entities, nonprofit organizations, and the private sector.

- The NICHD program, Helping Babies Breathe, won the 2011 Global Development Alliance Excellence Award for its inspiring partnerships with the U.S. Agency for International Development, Laerdal Medical, the Norwegian Agency for Development Cooperation, the American Academy of Pediatrics, and Save the Children. Launched in 2010, this training program in newborn resuscitation is aimed at reducing neonatal mortality in resource-limited settings. The partnership has mobilized \$13.3 million in contributions, yielding \$6 for every U.S. dollar invested. Introduced in 27 countries, the program has trained over 18,000 health providers and reduced asphyxia-related neonatal mortality by over 50 percent in a pilot study.
- With support from the Bill and Melinda Gates Foundation, PepsiCo, and other partners, NICHD created the Biomarkers of Nutrition for Development (BOND) Program to identify valid biomarkers to assess nutrient exposure, status, function, and effect. New BOND studies will harness the power of nutrition to improve health, especially in lower-income countries.

• Findings from the landmark Management of Myelomeningocele (MOMS) Study showed the benefits of prenatal surgery for babies with a severe form of spina bifida. NICHD engaged in discussions with a wide range of partners to determine how to implement these findings to improve health outcomes for mothers and babies throughout the nation. NICHD convened experts to advance research in other areas across NIH, including the Down Syndrome Consortium; the Blue Ribbon Panel on Medical Rehabilitation Research; and a summit of scientists, clinicians, and advocates to develop a vulvodynia research plan for NIH.

Moving forward, NICHD will continue to focus its activities on the most promising scientific opportunities of the future. NICHD's scientific visioning process, to identify the most important scientific opportunities of the next decade across the Institute's broad mission, is key to this effort. The process engages hundreds of researchers, clinicians, and policy experts, catalyzing discussions about future directions in the scientific areas embodied by the NICHD mission. The emerging priorities and bold ideas will help drive future initiatives and collaborations.

NICHD priorities complement those of NIH, and are premised on the knowledge that building extraordinary scientific opportunities for the future starts with **investments in basic research**. Recently, NICHD researchers converted stem cells from the lining of the human uterus into insulin-producing cells, transplanting them into mice to control the animals' diabetes, a finding that may lead to more effective diabetes treatments. Other NICHD-supported researchers developed a novel animal model for autism by modifying genes in mice to mimic human mutations associated with autism; the animal model will enable future studies on the causes of autism and the development of new interventions. Another study identified a molecular trigger to create the myelin that insulates nerve fibers and aids neural functioning. That discovery may allow scientists, one day, to speed myelin formation and help repair injured neurons.

Accelerating discovery through technology opens new paths to improve health. NICHD collaborative studies on x-ray and neutron diffraction on membranes exposed to anesthetics refined our understanding of how anesthesia works at the molecular level. These data could help researchers design better anesthetics and increase understanding of the membrane-protein interactions that are crucial to cellular function and survival. Recent advances also showed how gene regulatory networks control the formation of the basic body plan in an invertebrate model organism, the sea urchin. Now, improved genomic sequencing and digital imaging may permit researchers to extend these studies to vertebrates, eventually allowing scientists to map how the networks regulate the development of any cell type, any tissue, at any point in time. Such knowledge may shed new light on ways to prevent or ameliorate birth defects.

NICHD's efforts to **advance translational sciences** also promise new treatments for major health concerns. Building on previous NICHD-funded research, scientists found that administering progesterone, a naturally occurring hormone, to pregnant women with a short cervix can reduce preterm birth and the infants' risk of developing respiratory distress syndrome. Researchers also discovered that a drug already approved to treat HIV/AIDS, tenofovir, when formulated as a vaginal gel, reduces the risk of herpes infections in women by disabling a key DNA enzyme in the herpes virus. Such discoveries, which lead to new uses for previously-approved drugs, have the potential to save many years and dollars in drug testing and approval.

NICHD research also holds promise for developing novel, long-acting contraceptives for women, without negative side effects, and for creating innovative models that reveal the genetic and molecular pathways underlying drug toxicity in the developing human. These models will help generate improved therapeutics for pregnant women and children.

Future progress, however, cannot be made without **new investigators and new ideas.** NICHD has long supported the nation's leading scientists. Recently, two NICHD-supported researchers were honored with the National Medal of Science, one for pioneering work in understanding the genetic basis of human biology and disease, the other for work that includes transforming mature cells into stem cells that can then be used to treat disease. For the fourth year in a row, NICHD also supported a researcher who won the Presidential Early Career Award for Scientists and Engineers; this year for work to develop biomarkers to optimize the dosing for certain drugs to treat children with cancer. Most importantly, the NICHD vision reaffirms the need to continue supporting the next generation of scientists, by encouraging the use of creative incentives, new mentoring approaches, social media, and creative transdisciplinary training programs.

In 2013, NICHD will complete its 50th birthday commemoration. This is an occasion not so much to applaud how far we have come, but to celebrate the promise of a healthier future for all women, children, families, and persons with disabilities, in communities at home and around the world.

Funds are included in R&D contracts to support trans-NIH initiatives, such as the Basic Behavioral and Social Sciences Opportunity Network (OppNet).

Program Descriptions and Accomplishments

Center for Developmental Biology and Perinatal Medicine:

The Center for Developmental Biology and Perinatal Medicine supports research to advance basic and clinical knowledge about maternal health and child development, including studies of normal developmental processes and the origins and expression of congenital and developmental disorders. Center studies focus on factors that affect maternal and fetal health. For example, the Center-supported Management of Myelomeningocele (MOMS) study showed that performing specialized surgery in the womb, rather than waiting until after birth, can reduce complications of spina bifida. Center-supported research has highlighted the increased risk for early term and late preterm births, as well as for triplets born with low birth weight. The Center's projects also include studies to help prevent such conditions as cerebral palsy, stillbirth, and sudden infant death syndrome. The Center supports research on the genetic and epigenetic (changes in genetic activity not related to changes in DNA sequence) mechanisms that may adversely affect health and development. Multidisciplinary research to understand fetal development and the biology and genetics of birth defects are also current priorities, along with



Findings from the landmark MOMS Study showed the benefits of prenatal surgery for babies with a severe form of spina bifida. The study involved correcting the spinal protrusion, shown above, which relieves pressure on the brain and spinal cord.

translational research to inform newborn screening programs on a national scale. Research center and network programs provide the infrastructure for basic and clinical research on preterm birth, neonatal health, autism spectrum disorders, Fragile X syndrome, Down syndrome, and other intellectual and developmental disabilities. For example, NICHD-supported scientists have recently tied a specific genetic variation to alterations in the brain's connective wiring among youth with autism spectrum disorders.

<u>Budget Policy</u>: The FY 2013 President's Budget request for this program is \$313.226 million, an increase of \$0.227 million or 0.07 percent, over the FY 2012 Enacted level. Continuing investments in research resources will provide investigators with the infrastructure needed to conduct basic and translational research in intellectual and developmental disabilities. The Center will continue to set a high priority on support for scientists working to identify developmental mechanisms of birth defects. A new collaborative effort with multiple NIH ICs will streamline efforts to increase scientists' access to tissue samples to conduct basic and translational research. The Center will also maintain ongoing investigations into the causes of, and potential treatments and prevention strategies for, autism spectrum disorders. The Center will also continue its research to determine the effectiveness and safety of existing and evolving treatments, particularly for high-risk pregnant women and for infants born too early and too small.

Program Portrait: Extramural Research in Developmental Biology and Genetics

FY 2012 Level: \$65.594 million FY 2013 Level: \$65.594 million Change: \$0 million

Developmental biology is undergoing exciting changes due to rapid advances in technology and genomics that allow researchers to visualize activities in living cells and reveal the molecular, biophysical, and biochemical process that can transform the union of two cells into a fully functional organism. For NICHD, this knowledge is used to understand the causes of birth defects and discover means to treat or prevent them from occurring. According to the Centers for Disease Control and Prevention, about one in every 33 American infants is born with a birth defect; birth defects account for more than one of every five infant deaths and can negatively affect lifelong health and functioning.

Many extramural researchers are investigating how early embryos develop, including the genesis of organs, limbs, and biological systems such as the immune system. Recently, a long-standing grantee won the International Prize for Biology for his pioneering research revealing the delicately balanced process of how gene networks regulate embryo development, activating the appropriate genes at just the appropriate times. This knowledge is key to understanding the factors that contribute to birth defects. Currently, researchers are trying to understand how embryonic cells migrate to form the the neural crest, which gives rise to such neural systems as those that control heart rate and breathing. Using new techologies, another grantee substituted a teflon window for part of the shell of a chicken egg. Then, by labeling cells of the neural crest with green fluorescent protein, the researchers tracked the migrating cells as they gave rise to the autonomic nervous system in the developing embryo. Eventually a wide array of research, which merges genomics, bioinformatics, and sophisticated computer modeling, will allow scientists to understand the complex systems that regulate— and the environmental factors that influence— human development. This understanding will provide targets for new drugs, genetic interventions to prevent birth defects, and the basis for designing stem cell therapies.

The program also supports a unique initiative to encourage the next generation of developmental biologists. This effort targets undergraduate institutions, supporting basic course work and student research projects. The intiative has successfully encouraged undergraduate students to pursue graduate study in developmental biology. Just as the development of a healthy organism must start early, the ability for the field to thrive lies in our ability to capture the imagination of researchers early in their educational careers.

Center for Population Research: The Center for Population Research focuses on reproductive health and biology, including human fertility, infertility, and reproductive disorders, as well as population research and behavioral science. To meet the diverse contraceptive needs of both women and men throughout their reproductive lives and to prevent sexually transmitted infections (STIs), the Center supports research on the safety, effectiveness, and acceptability of a variety of contraceptive measures. The Center also supports behavioral and social science research on issues related to the spread of STIs and health risk behaviors. Center research projects seek to understand the consequences of changes in population composition, size, and distribution; the factors that affect family formation, functioning, and stability; and the influence of families on child health and development. For example, researchers supported by the Center recently developed a new statistical technique to better forecast changes in fertility rates, allowing policy makers to plan more reliably for population changes. Center studies in the reproductive sciences range from basic research to those that advance the treatment of infertility and reproductive disorders such as endometriosis and vulvodynia. For example, Centersupported researchers recently identified a specific protein essential for embryo implantation. This finding may contribute to the understanding of endometriosis, endometrial cancer, and some forms of unexplained female infertility.

Program Portrait: Contraceptive Development Research Program

FY 2012 Level: \$26.321 million FY 2013 Level: \$26.321 million Change: \$0 million

Even though a range of contraceptive methods is currently available, nearly half of all pregnancies in the U.S. are unintended. Dissatisfaction with current methods and, for some populations, significant risk of adverse effects make it difficult for many couples to find safe, effective, reversible, and acceptable contraceptive methods that meet their needs.

Through the Contraceptive Development Research Centers, scientists work together to discover and develop promising new leads that may be developed into clinically useful contraceptive products. The centers also serve as a national resource for career development of young scientists electing to pursue research in contraceptive research. Promising agents are prepared into compounds by the Chemical Synthesis and Peptide Synthesis Facilities. In addition, the Biological Testing Facility supports studies on the biological activity, pharmacology, and toxicology of promising compounds. Through the Contraceptive Clinical Trials Network, researchers conduct trials to evaluate new or existing contraceptive methods. Together, these components create an effective program for developing and improving hormonal and non-hormonal contraceptive methods for women and men.

Discovering and making widely available effective methods to regulate male fertility would benefit both men's and women's health. However, a range of side effects and low efficacy are key hurdles in developing acceptable male contraceptives. NICHD-supported research is starting to overcome these difficulties: a recent study showed that a certain pharmacological approach may lead to the development of an effective, non-steroidal, birth control pill for men without some of the potential side effects on the cardiovascular system and prostate gland, among others. The approach involves blocking a certain molecule to prevent the creation of sperm, and further animal studies have shown that this approach could be readily reversible. Through this and other innovative approaches, the Contraceptive Development Research program aims to develop contraceptive methods that meet the needs of women and men throughout their reproductive lives.

<u>Budget Policy</u>: The FY 2013 President's Budget request for this program is \$303.681 million, an increase of \$0.221 million, or 0.07 percent above the FY 2012 Enacted level. Research programs to foster the discovery, development, and clinical testing of new approaches to contraception for women and men are a primary focus of the Center's research. The Center will continue to maintain investments in population sciences and support health research in special populations, including lesbian, bisexual, gay, transgender, and intersex health. Continuing support for multidisciplinary approaches to understanding and developing effective interventions to treat or prevent infertility and other reproductive disorders is also a priority.

Center for Research for Mothers and Children: The Center for Research for Mothers and Children supports an array of maternal and child health research, including studies of growth and development, obesity and overweight, early origins of adult diseases, and congenital and infectious diseases (including the prevention and treatment of HIV/AIDS in children, adolescents, and women). The Center also funds research on mechanisms of neurobiological, cognitive, emotional, and social development; genetic and environmental influences on development; and causes of and treatments for specific learning disabilities. Recently, Centersupported scientists published research indicating that, regardless of IQ scores, children with dyslexia show similar patterns of brain activity. The results call into question the practice of classifying a child as dyslexic based on lag between reading ability and overall IQ scores. The Center has a strong international presence, conducting research that benefits women and children around the globe. For example, Center-supported scientists found that an inexpensive instructional program to teach routine newborn care skills to midwives in Zambia resulted in a substantial reduction in infant deaths. Collaborating with other NIH institutes, NICHD organized a groundbreaking workshop on indoor air pollution in the developing world. The workshop provided the foundation to create the Global Alliance for Clean Cookstoves Roadmap and led to two publications in Science, alerting the research community to the dangers of indoor air pollution, which affects more than half the world's population and leads to nearly two million deaths annually. The Center houses the primary federal research program for investigating the safety and efficacy of drugs used to treat children and pregnant women. This includes clinical networks implementing the Best Pharmaceuticals for Children Act, and other research to fill long-standing gaps in understanding pharmaceutical regimens appropriate for the distinct physiologies of children, pregnant women, and fetuses.

<u>Budget Policy</u>: The FY 2013 President's Budget request for this program is \$378.091 million, an increase of \$0.276 million, or 0.07 percent above the FY 2012 Enacted level. The Center will maintain its strong research emphasis on obstetric and pediatric pharmacology, child development and behavior, the biological basis of learning and learning disabilities, maternal and child HIV/AIDS, and childhood obesity. In collaboration with public and private partners, the Center will bring together experts in the field of nutrition to discover, develop, and distribute scientifically-based measures of nutritional status, and to provide science-based advice to researchers, clinicians, and policy makers on the role of food and nutrition in health promotion and disease prevention.

Program Portrait: Ensuring the Safety and Effectiveness of Drugs Used By Children

FY 2012 Level: \$15.605 million*
FY 2013 Level: \$15.605 million*
Change: \$0 million

Until fairly recently, over-the-counter and prescription drugs that were safe for adults were generally considered to be safe for children. However, in addition to being smaller, children's brains, bones, and metabolism differ from that in adults. Many of the drugs shown to be safe and effective for adults have never been tested in children and, in fact, behave very differently in children. To make sure that drugs used in children are safe and effective for children's specific needs, the Best Pharmaceuticals for Children Act (BPCA) established a trans-NIH effort, led by the NICHD, to prioritize therapies in need of study, sponsor pediatric clinical trials that are declined by industry, and submit data to the Food and Drug Administration (FDA) for pediatric labeling.

In its annual prioritization of pediatric therapeutic needs, NICHD consults with colleagues from across the NIH and experts in pediatrics, and with the FDA, to identify drugs that are used to treat children where further research is most urgently needed. For example, the lack of commercially available oral pediatric formulations is a continuing problem for children, parents, and pediatricians, and a consensus approach to the development of pediatric formulations is urgently needed. The NIH and the FDA joined together to produce an open-source, publicly available approach to pediatric oral formulations manufacturing. This project will assess available products, characterize their molecular structures, determine the best formulations technology for specific drug categories, and produce prototype batches of selected drug products (http://bpca.nichd.nih.gov/collaborativeefforts/initiatives/index.cfm).

Recognizing that the conduct of pediatric clinical trials requires an established infrastructure, NICHD established a new Pediatric Trials Network (PTN) in September 2010. Data collected from the PTN will help inform pediatric labeling, and will be used to develop publications and other materials that provide pediatricians and researchers with new information on medication disposition and response in children. Among the pediatric therapeutic areas expected to be studied are cardiovascular, infectious, and respiratory diseases; gastroenterology; pediatric oncology; and therapeutics for neonates.

* These figures reflect NICHD funds only and do not include approximately \$17.8 million in funding for BPCA activities provided by other ICs. These funds would bring the total to \$33.405 million in FY 12 and \$33.296 million in FY 2013.

National Center for Medical Rehabilitation Research: The National Center for Medical Rehabilitation Research enhances the health, productivity, independence, and quality-of-life of people with disabilities by supporting 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. The Center's activities include a special emphasis on research related to spinal cord injury, traumatic brain injury, and stroke, frequently in collaboration with other NIH ICs and other partners. Childhood disabilities and long-term outcomes of young survivors of neonatal oxygen deprivation, trauma, congenital anomalies, life-threatening infections, and septic shock are also areas of interest for the Center. As a complement to this research, the Center also supports development of equipment, devices, and treatments to improve mobility and to enhance the functional capabilities of individuals with disabling conditions. To foster creation and testing of new advanced technologies, such as sensors for prosthetic devices and virtual reality systems to enhance rehabilitative interventions, the Center makes frequent use of Small Business Innovation Research Awards.

Budget Policy: The FY 2013 President's Budget request for this program is \$71.168 million, an increase of \$0.051 million, or 0.07 percent above the FY 2012 Enacted level. The Center will continue its support for rehabilitation research infrastructure, providing scientists with access to expertise such as computer simulations for understanding movement disorders, techniques for analyzing how genes influence the recovery process, and robots and sensors to help deliver and analyze treatments. In maintaining its diverse research portfolio covering the mechanisms that underlie severe disabling conditions and new ways to speed recovery, the Center will encourage scientists to find innovative approaches to understand and maximize how humans and technology can interact to enhance rehabilitation.

Division of Intramural Research: The Division of Intramural Research conducts interdisciplinary research to answer basic biomedical research questions and to solve difficult clinical problems in human health and development. This research includes investigations in genetics, genomics, and epigenetics, and studies of how these factors and processes influence typical and atypical development. The intramural program also studies 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. The Division places special emphasis on translational research to create new therapies. For example, intramural scientists found that gene therapy plus an injection of copper dramatically improves survival for mice with a condition that mimics Menkes disease, a rare and often fatal childhood disorder. Other focus areas of the NICHD intramural program include behavioral research; pediatric cancer; innovative diagnostics for endocrine, metabolic, and reproductive diseases; and vaccine development and use, particularly vaccines targeting diseases that affect children and pregnant women. Additional multidisciplinary research combines biostatistics, mathematics, genetics, statistics, and epidemiology to address critical health issues in human fertility, pregnancy outcomes, childhood growth and injuries, pediatric chronic disease, and communitybased interventions to promote health and prevent disease in children, adolescents, and their families. A new intramural "Developing Talent Program" is providing special mentoring, training, and networking opportunities for recent college graduates from groups traditionally underrepresented in science.

<u>Budget Policy</u>: The FY 2013 President's Budget request for this program is \$189.327 million, the same as the FY 2012 Enacted level. Continuing priorities for the intramural program include investigations of human development and its genetics, genomics, and epigenetics. Such research is key to understanding the basis for many critical developmental events, starting from before birth and continuing throughout childhood and adolescence, that can determine future health and well-being. Another critical focus is "bench-to-bedside" research that allows novel basic scientific discoveries to be translated quickly into clinical protocols, which can then be evaluated for effectiveness in preventing or mitigating disease.

Research Management and Support: Research Management and Support (RMS) activities include the technical and administrative functions required to support the Institute's research investments. Key functions include budget, contracts, grants management, peer review, and information technology. The RMS budget also supports NICHD's web presence, and outreach and health activities targeting special populations. NICHD regularly reviews administrative functions and scientific programs to identify ways to streamline activities, reduce costs, and

ensure program effectiveness. These and other assessments support NICHD's robust process to determine which future initiatives will best meet the Institute's mission and priorities.

<u>Budget Policy</u>: The FY 2013 President's Budget request for RMS is \$65.107 million, the same as the FY 2012 Enacted level. The NICHD RMS activities provide enhanced administrative efforts in information technology to help manage research investments more efficiently. This investment also includes efforts to manage and update Web content to disseminate more effectively the most current information to the public and to the many constituencies vested in the outcomes of NICHD research.

Budget Authority by Object (Dollars in Thousands)

	FY 2012	FY 2013	Increase or
	Enacted	PB	Decrease
Total compensable workyears:			
Full-time employment	611	605	(6)
Full-time equivalent of overtime and holiday hours	1	1	0
Assess FC select (* 1.11. a)	Φ17.C 7.10	0176710	Φ0.
Average ES salary (in dollars)	\$176,710	\$176,710	\$0
Average GM/GS grade	12.3	12.3	0.0
Average GM/GS salary (in dollars)	\$101,513	\$101,864	\$351
Average salary, grade established by act of	\$101,515	\$101,804	φ331
July 1, 1944 (42 U.S.C. 207) (in dollars)	\$113,723	\$115,429	\$1,706
Average salary of ungraded positions (in dollars)	129,951	130,438	487
Trotage summy of ungraded positions (in trotains)	127,731	150, 150	107
	FY 2012	FY 2013	Increase or
OBJECT CLASSES	Enacted	PB	Decrease
Personnel Compensation:			
11.1 Full-time permanent	\$35,856	\$35,960	\$104
11.3 Other than full-time permanent	26,365	26,651	286
11.5 Other personnel compensation	1,955	1,979	24
11.7 Military personnel	2,176	2,234	58
11.8 Special personnel services payments	12,372	12,501	129
Total, Personnel Compensation	\$78,724	\$79,325	\$601
12.0 Personnel benefits	\$19,283	\$19,431	\$148
12.2 Military personnel benefits	1,971	1,986	15
13.0 Benefits for former personnel	0	0	0
Subtotal, Pay Costs	\$99,978	\$100,742	\$764
21.0 Travel and transportation of persons	\$2,518	\$2,367	(\$151)
22.0 Transportation of things	241	232	(9)
23.1 Rental payments to GSA	0	0	0
23.2 Rental payments to others	90	89	(1)
23.3 Communications, utilities and			
miscellaneous charges	1,562	1,549	(13)
24.0 Printing and reproduction	501	424	(77)
25.1 Consulting services	1,425	1,435	10
25.2 Other services	16,856	16,898	42
25.3 Purchase of goods and services from	125 425	144.507	0.072
government accounts	135,435 4,173	144,507	9,072
25.4 Operation and maintenance of facilities 25.5 Research and development contracts	4,173 121,857	3,809 117,122	(364) (4,735)
25.6 Medical care	1,130	1,130	(4,733)
25.7 Operation and maintenance of equipment	2,520	2,540	20
25.8 Subsistence and support of persons	2,320	2,540	0
25.0 Subtotal, Other Contractual Services	\$283,396	\$287,441	\$4,045
26.0 Supplies and materials	\$9,893	\$9,898	\$5
31.0 Equipment	9,848	9,258	(590)
32.0 Land and structures	0	0	0
33.0 Investments and loans	0	0	0
41.0 Grants, subsidies and contributions	911,789	908,591	(3,198)
42.0 Insurance claims and indemnities	0	0	0
43.0 Interest and dividends	9	9	0
44.0 Refunds	0	0	0
Subtotal, Non-Pay Costs	\$1,219,847	\$1,219,858	\$11
Total Budget Authority by Object	\$1,319,825	\$1,320,600	\$775

Includes FTEs which are reimbursed from the NIH Common Fund for Medical Research

Salaries and Expenses (Dollars in Thousands)

	FY 2012	FY 2013	Increase or
OBJECT CLASSES	Enacted	PB	Decrease
Personnel Compensation:			
Full-time permanent (11.1)	\$35,856	\$35,960	\$104
Other than full-time permanent (11.3)	26,365	26,651	286
Other personnel compensation (11.5)	1,955	1,979	24
Military personnel (11.7)	2,176	2,234	58
Special personnel services payments (11.8)	12,372	12,501	129
Total Personnel Compensation (11.9)	\$78,724	\$79,325	\$601
Civilian personnel benefits (12.1)	\$19,283	\$19,431	\$148
Military personnel benefits (12.2)	1,971	1,986	15
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	\$99,978	\$100,742	\$764
Travel (21.0)	\$2,518	\$2,367	(\$151)
Transportation of things (22.0)	241	232	(9)
Rental payments to others (23.2)	90	89	(1)
Communications, utilities and			
miscellaneous charges (23.3)	1,562	1,549	(13)
Printing and reproduction (24.0)	501	424	(77)
Other Contractual Services:			
Advisory and assistance services (25.1)	1,425	1,435	10
Other services (25.2)	16,856	16,898	42
Purchases from government accounts (25.3)	92,988	92,988	0
Operation and maintenance of facilities (25.4)	233	233	0
Operation and maintenance of equipment (25.7)	2,520	2,540	20
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$114,022	\$114,094	\$72
Supplies and materials (26.0)	\$9,882	\$9,887	\$5
Subtotal, Non-Pay Costs	\$128,816	\$128,642	(\$174)
Total, Administrative Costs	\$228,794	\$229,384	\$590

$Details\ of\ Full-Time\ Equivalent\ Employment\ (FTEs)$

		FY 2011			FY 2012			FY 2013	
		Actual			Enacted			PB	
OFFICE/DIVISION	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director	158	2	160	159	2	161	158	2	160
Center for Developmental Biology and Perinatal Medicine	22	0	22	21	0	21	21	0	21
Center for Research for Mothers and Children	27	1	28	27	1	28	26	1	27
Center for Population Research	19	2	21	19	2	21	19	2	21
National Center for Medical Rehabilitation Research	11	0	11	11	0	11	11	0	11
Division of Intramural Research Programs	357	12	369	357	12	369	353	12	365
Total	594	17	611	594	17	611	588	17	605
Includes FTEs which are reimbursed from the NIH Commor	n Fund for Med	lical Research							
FTEs supported by funds from Cooperative Research and									
Development Agreements	0	0	0	0	0	0	0	0	0
FISCAL YEAR				Av	erage GS Gra	ade			
2009					12.1				
2010					12.2				
2011					12.3				
2012					12.3				
2013					12.3				

Detail of Positions

	FY 2011	FY 2012	FY 2013
GRADE	Actual	Enacted	PB
Total, ES Positions	4	4	4
Total, ES Salary	706,839	706,839	706,839
GM/GS-15	52	52	52
GM/GS-14	93	93	92
GM/GS-13	66	66	65
GS-12	64	64	63
GS-11	34	34	34
GS-10	5	5	5
GS-9	25	25	25
GS-8	14	14	14
GS-7	13	13	13
GS-6	4	4	4
GS-5	4	4	4
GS-4	1	1	1
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	375	375	372
Grades established by Act of			
July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	16	16	16
Senior Grade	1	1	1
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	17	17	17
Ungraded	215	215	212
Total permanent positions	404	404	398
Total positions, end of year	629	629	623
Total full-time equivalent (FTE)			
employment, end of year	611	611	605
Average ES salary	176,710	176,710	176,710
Average GM/GS grade	12.3	12.3	12.3
Average GM/GS salary	101,513	101,513 ₀	101,864

Includes FTEs which are reimbursed from the NIH Common Fund for Medical Research.