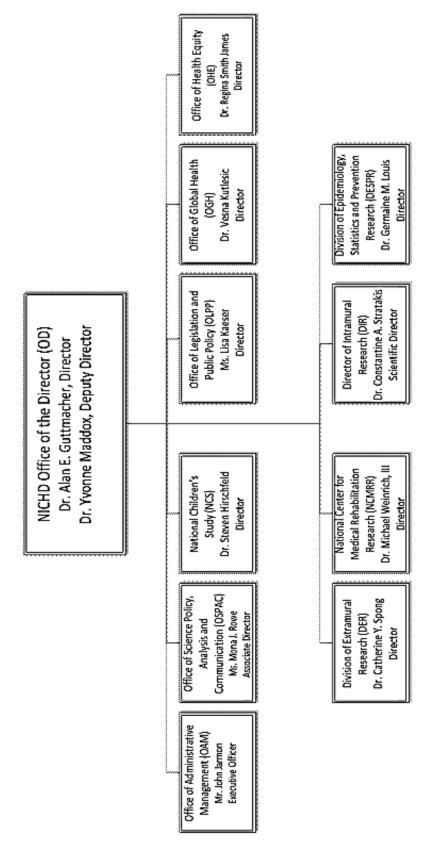
### DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 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, \$1,339,360,000.

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

(Dollars in Thousands)

Source of Funding	FY 2012 Actual	FY 2013 CR	FY 2014 PB
Appropriation	1,323,900	1,329,485	1,339,360
Rescission	(2,502)	0	0
Subtotal, adjusted appropriation	1,321,398	1,329,485	1,339,360
Secretary's Transfer for Alzheimer's disease (AD)	(871)	0	0
Secretary's Transfer for AIDS authorized by PL 112-74, Section 206	(376)	0	0
Comparative Transfers to NLM for NCBI and Public Access	(1,207)	(1,563)	0
Subtotal, adjusted budget authority	1,318,943	1,327,922	1,339,360
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	1,318,943	1,327,922	1,339,360
Unobligated balance lapsing	0	0	0
Total obligations	1,318,943	1,327,922	1,339,360

<sup>&</sup>lt;sup>1</sup> Excludes the following amounts for reimbursable activities carried out by this account:

FY 2012 - \$35,849 FY 2013 - \$37,000 FY 2014 - \$37,000

# **Budget Mechanism - Total** <sup>1</sup> (Dollars in Thousands)

	FY	2012	FY 2013		FY	2014		
MECHANISM	Actual		CR		PB		Change	vs. FY 2012
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants								
Research Projects								
Noncompeting	1,097	\$495,272	1,118	\$511,684	1,115	\$524,007	18	\$28,735
Administrative Supplements	(51)	7,672	(37)	4,000	(37)	4,000	-(14)	-3,672
Competing:								
Renewal	73	45,496	69	42,767	69	43,025	-4	-2,471
New	369	124,276	347	116,904	345	116,058	-24	-8,218
Supplements	1	694	3	572	0	0	-1	-694
Subtotal, Competing	443	\$170,466	419	\$160,243	414	\$159,083	-29	-\$11,383
Subtotal, RPGs	1,540	\$673,410	1,537	\$675,927	1,529	\$687,090	-11	\$13,680
SBIR/STTR	87	31,459	85	32,784	89	34,609	2	3,150
Research Project Grants	1,627	\$704,869	1,622	\$708,711	1,618	\$721,699	-9	\$16,830
Research Centers								
Specialized/Comprehensive	45	66,357	48	62,535	50	62,506	5	-3,851
Biotechnology	4	4,424	4	4,465		4,494	0	70
Comparative Medicine	0	1,169	0	1,169	0	1,169	0	0
Research Centers	49	\$71,950	52	\$68,169	54	\$68,169	5	-\$3,781
		+,,,		+ ,		+ ,		72,700
Other Research								
Research Careers	287	48.004	315	52,650	262	46,811	-25	-1,193
Cooperative Clinical Research	75	48,816		48,625		50,574	9	1,758
Other	149	23,990		25,885		24,279	9	289
Other Research	511	\$120,810	554	\$127,160	504	\$121,664	-7	\$854
Total Research Grants	2,187	\$897,629	2,228	\$904,040	2,176	\$911,532	-11	\$13,903
Ruth L. Kirschstein Training Awards	FTTPs		FTTPs		FTTPs		EVENT-	
Individual	83	3,932	83	4,200		4,200	FTTPs -1	268
Institutional	622	29,393	618	30,000	591	30,000	-31	607
Total Research Training	705	\$33,325	701	\$34,200	673	\$34,200	-31	\$875
Total Research Training	703	\$55,525	701	\$34,200	073	\$34,200	-32	\$673
Research & Development Contracts	99	135,047	99	135,158	100	137,221	1	2,174
SBIR/STTR (non-add)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	+(0)
	FTEs		FTEs		FTEs		FTEs	
Intramural Research	368	187,792	368	188.976		190.374	0	2,582
Research Management and Support	238	65,150	264	65,548		66,033	26	883
Construction	238	05,150	207	05,548	207	00,033	20	003
Buildings and Facilities		0		0		0		0
Total NICHD	606	\$1,318,943	632	\$1.327.922	632	\$1,339,360	26	\$20,417

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

### Major Changes in the Fiscal Year 2014 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 2014 President's Budget for NICHD, which is an increase of \$20.4 million above the FY 2012 level, for a total of \$1,339.4 million.

Research Project Grants (RPGs) (+\$16.830 million, total \$721.699 million): NICHD will support a total of 1,618 Research Project Grant (RPG) awards in FY 2014. Non-competing RPGs will increase by 18 awards and the amount to support the costs associated with the commitments of prior year competing awards will increase by \$28.735 million compared to the FY 2012 level. Competing RPGs will decrease by 29 grants compared to the FY 2012 level of 443 awards and the amount to support the costs associated with new competing awards will decline by \$11.383 million compared to the FY 2012 level. SBIR/STTR grants will increase by \$3.150 million compared to the FY 2012 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 3.2 percent.

Research and Development contracts (+\$2.174 million, total \$137.221 million): NICHD will expand support for existing research activities, including epidemiological research, and continue to pursue a wide range of research activities including contraception, newborn screening, AIDS research, pharmaceutical safety for children, and participation in cross-cutting NIH projects related to genetics and neurology.

<u>AIDS Research (+\$7.999 million, total \$152.923 million):</u> 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.

### NATIONAL INSTITUTES OF HEALTH

### National Institute of Child Health and Human Development Summary of Changes

(Dollars in Thousands)

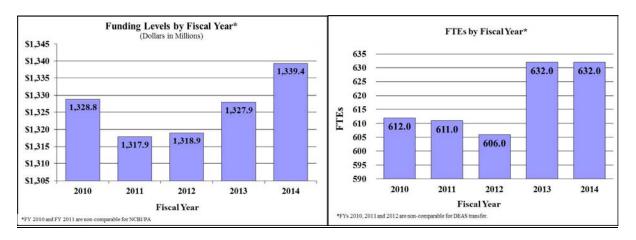
FY 2012 Actual				\$1,318,943
FY 2014 President's Budget				\$1,339,360
Net change				\$20,417
	2	2014		
	Preside	nt's Budget	Change from F	Y 2012
		Budget		Budget
CHANGES	FTEs	Authority	FTEs	Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of March				
2013 pay increase & benefits		\$67,497		\$184
b. January FY 2014 pay increase & benefits		67,497		491
c. One more day of pay		67,497		256
d. Differences attributable to change in FTE		67,497		0
e. Payment for centrally furnished services		32,398		580
f. Increased cost of laboratory supplies, materials,				
other expenses, and non-recurring costs		90,479		176
Subtotal				\$1,687
Research Management and Support:				
a. Annualization of March				
2013 pay increase & benefits		\$32,813		\$104
b. January FY 2014 pay increase & benefits		32,813		243
c. One more day of pay		32,813		124
d. Differences attributable to change in FTE		32,813		0
e. Payment for centrally furnished services		9,321		174
f. Increased cost of laboratory supplies, materials,		·		
other expenses, and non-recurring costs		23,899		7
Subtotal				\$652
Subtotal, Built-in				\$2,339

### **Summary of Changes--continued**

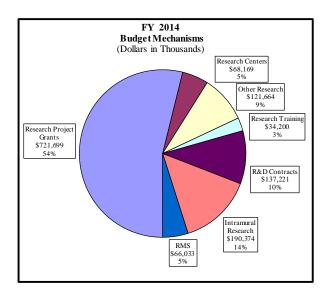
		2014		
	Preside	ent's Budget	Change fi	rom FY 2012
CHANGES	No.	Amount	No.	Amount
B. Program:				
Research Project Grants:				
a. Noncompeting	1,115	\$528,007	18	\$25,063
b. Competing	414	159,083	-29	-11,383
c. SBIR/STTR	89	34,609	2	3,150
Total	1,618	\$721,699	-9	\$16,830
2. Research Centers	54	\$68,169	5	-\$3,781
3. Other Research	504	121,664	-7	854
4. Research Training	673	34,200	-32	875
5. Research and development contracts	100	137,221	1	2,174
Subtotal, Extramural		\$1,082,953		\$16,952
	<u>FTEs</u>		<u>FTEs</u>	
6. Intramural Research	368	\$190,374	0	\$895
7. Research Management and Support	264	66,033	26	231
8. Construction		0		0
Buildings and Facilities		0		0
Subtotal, program	632	\$1,339,360	26	\$18,078
Total changes				\$20,417

### Fiscal Year 2014 Budget Graphs

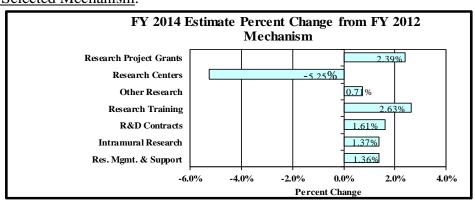
### History of Budget Authority and FTEs:



### Distribution by Mechanism:



### Change by Selected Mechanism:



#### NATIONAL INSTITUTES OF HEALTH

### National Institute of Child Health and Human Development

### Budget Authority by Activity <sup>1,2</sup> (Dollars in Thousands)

		Y 2012 Actual	F	Y 2013 CR	F	Y 2014 PB	Chang	ge vs. 2012
	P	Ctuai		CK		гь	FI	2012
Extramural Research  Detail:	FTEs	<u>Amount</u>	FTEs	<u>Amount</u>	FTEs	Amount	FTEs	<u>Amount</u>
Reproductive Health, Pregnancy, and Perinatology		\$305,118		\$307,235		\$309,970		\$4,852
Pediatric Health		257,881		259,671		261,982		\$4,101
Intellectual and Developmental Disabilities		125,336		126,205		127,329		\$1,993
Demography and Behavior		301,335		303,426		306,127		\$4,792
Rehabilitation		76,331		76,861		77,545		\$1,214
Subtotal, Extramural		\$1,066,001		\$1,073,398		\$1,082,953		\$16,952
Intramural Research	368	\$187,792	368	\$188,976	368	\$190,374	0	\$2,582
Research Management & Support	238	\$65,150	264	\$65,548	264	\$66,033	26	\$883
TOTAL	606	\$1,318,943	632	\$1,327,922	632	\$1,339,360	26	\$20,417

Includes FTEs whose payroll obligations are supported by the NIH Common Fund.
 Includes Transfers and Comparable Adjustments as detailed in the "Amounts Available for Obligation" table.

### **Authorizing Legislation**

	PHS Act/ Other Citation	U.S. Code Citation	2013 Amount Authorized	FY 2013 CR	2014 Amount Authorized	FY 2014 PB
Research and Investigation	Section 301	42§241	Indefinite	\$1,327,922,000	Indefinite	- \$1,339,360,000
National Institute of Child Health and Human Development	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				\$1,327,922,000		\$1,339,360,000

### Appropriations History

Fiscal	Budget Estimate to			
Year	Congress	House Allowance	Senate Allowance	Appropriation
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				-
2008	\$1,264,946,000	\$1,273,863,000	\$1,282,231,000	\$1,254,708,000
Rescission Supplemental				(\$22,309,000) \$6,673,000
2009	\$1,255,920,000	\$1,299,059,000	\$1,290,873,000	\$1,294,894,000
Rescission				-
2010	\$1,313,674,000	\$1,341,120,000	\$1,316,822,000	\$1,329,528,000
Rescission				-
2011	\$1,368,894,000	-	\$1,366,750,000	\$1,329,528,000
Rescission				(\$11,674,048)
2012	\$1,352,189,000	\$1,352,189,000	\$1,303,016,000	\$1,323,900,000
Rescission				(\$2,502,171)
2013	\$1,320,600,000	-	\$1,324,603,000	-
Rescission				-
2014	\$1,339,360,000	-	-	-

### **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 2014	
	FY 2012	FY 2013	President's	FY 2014 + / -
	Actual	CR	Budget	FY 2012
BA	\$1,318,943,000	\$1,327,922,000	\$1,339,360,000	+\$20,417,000
FTE	606	632	632	+26

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

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

In 2012, NICHD celebrated 50 years of scientific achievements. Our anniversary theme, "Research for a Lifetime," highlighted the far-ranging impact of our mission: to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, that all children have the chance to achieve their full potential for healthy and productive lives; and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation. NICHD research is uniquely positioned to advance understanding of the basic mechanisms that transform cells into healthy and effectively-functioning individuals as our translational studies help improve the lifelong health and well-being of women, children, and individuals with disabilities.

Informed by our Scientific Vision for the next decade, NICHD will continue to identify promising opportunities, build collaborations that leverage resources, and target research gaps that are critical public health issues.

- Promising Opportunities In addition to its recent scientific visioning process, NICHD convened two separate Blue Ribbon Panels, one to assess rehabilitation research at the NIH (focused on the National Center for Medical Rehabilitation Research at NICHD) and the other to provide new perspectives on the science of NICHD's Division of Intramural Research (DIR). Based on emerging needs and opportunities, the Institute also will implement a high priority initiative to improve our ability to understand, diagnose, prevent, and treat concussions, or mild traumatic brain injuries. This initiative addresses injuries that are difficult to detect with current technologies and can occur from infancy through adulthood. Another high priority initiative will support research that addresses the major health risks posed by household air pollution. Developing evidence-based interventions could reduce the up to 2 million deaths that occur globally from this exposure each year and decrease other major health problems such as premature birth and childhood and adult breathing problems for mothers and children in the U.S. and around the world.
- *Strengthening Internal Collaborations* These and other future initiatives will be developed within the newly reorganized extramural research program. NICHD restructured its

- extramural branches in 2012 to better leverage the multidisciplinary expertise of our scientists, encourage joint program planning and execution, and streamline operations. The Blue Ribbon Panel for the DIR will also provide insights on ways to organize intramural resources to maximize efficiencies and enhance the cross-fertilization of scientific ideas.
- Strengthening External Collaborations NICHD continues to promote collaborations that can yield the most innovative and far-reaching advances. Through a trans-federal partnership with academia, researchers working on BrainGate2 (a brain-computer interface system) demonstrated that paralyzed individuals could reach and grasp an object by controlling a robotic arm simply by using their thoughts. NICHD also works closely with the Bill and Melinda Gates Foundation and the March of Dimes to prevent preterm birth and stillbirths. By jointly funding research and sponsoring activities, these collaborative efforts address vital research questions and bring needed attention to the significant impact that these conditions have on millions of infants and their families each year.
- Addressing Critical Research Gaps Our scientific visioning process highlighted important research gaps that NICHD is uniquely positioned to address. This includes contraceptive development. NICHD will not only continue to support the development of new male contraceptive methods that are reversible and acceptable, but will also pursue non-hormonal contraceptive approaches for females, including the development of agents with fewer side effects than current products on the market. The visioning process also highlighted the need to better understand how experiences and exposures in childhood affect health throughout the life span. Under the NICHD's leadership, the National Children's Study (NCS) offers unprecedented opportunities for examining a broad range of environmental and biological factors that affect child health and development, as well as the earliest beginnings of many diseases or conditions that may not manifest themselves until adulthood. The NCS will follow approximately 100,000 children from across the United States from before birth to 21 years, providing a strong scientific foundation for improving the health and well-being of children for many generations to come.

NICHD will continue to build other aspects of our research programs and support diverse efforts to foster a new generation of researchers and physician scientists.

- Investments in basic science help make tomorrow's discoveries possible. Through the collaborative Autism Centers of Excellence program, researchers identified differences in brain structure as early as six months of age in children who were later diagnosed with autism spectrum disorders, the earliest that such structural changes have been recorded. Using gene analysis technology, other NICHD-supported researchers identified two novel genes associated with common childhood obesity. Although earlier studies identified genes associated with obesity in extremely obese youth and in adults, this study was important in identifying genes associated with the less severe, early onset, more common form of obesity.
- Building on basic science, translational research is essential for developing interventions to improve public health. We know this can work: according to the Centers for Disease Control and Prevention, the U.S. preterm birth rate recently dropped for the fifth year in a row, slipping from a peak of 12.8 per 1,000 births in 2006 to 11.7 in 2011. Progress can be linked to NICHD-supported and other research focused on treatments to prevent preterm birth, combined with efforts to transmit and help the clinical community adopt appropriate interventions. Similarly, recognizing NICHD's successful clinical research programs, the Society for Clinical Trials selected our Management of Myelomeningocele Study (MOMS),

- as its "Trial of the Year" in 2012. This study showed that surgery to repair spina bifida while the fetus is still in the womb can yield better overall outcomes than standard postnatal treatment. To advance our understanding and treatment of disorders that appear in the newborn period, NICHD recently launched a new translational research program, with the National Human Genome Research Institute, to determine how neonatal genome sequence information might improve the clinical care of infants and children.
- Inspiring and supporting the next generation of researchers is vital to maintaining a scientific workforce to support our multidisciplinary mission. Committed to promoting the success of new and early stage investigators, NICHD established a different and higher payline for these investigators. When combined with other programs, the policy helps to build a pipeline of future innovators of science. Maintaining this pipeline, however, also requires inspiration to motivate youth. Longtime NICHD grantee, Teresa K. Woodruff, Ph.D., received a Presidential Award for Excellence in Science, Mathematics, and Engineering Mentoring for a Chicago program that encourages high school girls to pursue science careers. NICHD also proudly recognizes that our own employees serve as role models for future researchers and the next generation of scientific staff. Lynne Mofenson, M.D., received the Federal Employee of the Year Award from the Partnership for Public Service for her pivotal role in preventing the AIDS epidemic in children. When she began her work, the rate of mother-to-child HIV transmission in the United States reached 25 percent. Today, based on the research she championed, the number of maternallytransmitted HIV cases in the United States has plummeted to an annual total of less than 100. Her persistence and dedication shows that, step by step, individually and together, NICHD and our partners can move science forward to improve the health of millions – for a lifetime.

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**

Reproductive Health, Pregnancy, and Perinatology – NICHD's efforts in reproductive health, pregnancy, and perinatology support a comprehensive array of research and research training in topics ranging from contraception, gynecologic disorders, and fertility and infertility to pregnancy and care of the newborn. Basic, clinical, and translational research in contraception includes efforts to create more safe, effective, reversible, and acceptable options for both women and men. The program also supports studies on the mechanisms underlying conditions and disorders that may impair either male or female fertility. For example, researchers recently reported that elevated levels of cadmium in the blood of women, and lead in the blood of men, were associated with delays in achieving conception.

Over the past year, researchers concluded a clinical trial comparing an oral medication for urinary incontinence with Botox injections to the bladder. Findings showed that both interventions were similarly effective, with each having different but still notable side effects and limitations. Other gynecological research showed that reservatrol, a compound made from plants with anti-inflammatory and antioxidant properties, can reduce the proportion of experimental mice developing endometriosis, a painful condition in women in which a specific type of uterine cell grows outside the uterus. Another team of scientists found that treatment with vitamin D

reduced the size of uterine fibroids in laboratory rats predisposed to developing these benign tumors. NICHD's newly-established Gynecologic Health and Disease branch will expand our vital research portfolio in these and other gynecologic disorders.

Pregnancy-related research spans from preconception care through pregnancy, fetal growth, and labor and delivery, and includes maternal and neonatal health. The program supports research on reducing rates of preterm birth and treating high-risk pregnancies complicated by obesity, infections, and other conditions such as preeclampsia (a dangerous increase in a pregnant woman's blood pressure). This program also focuses on research to improve the safety and efficacy of pharmaceutical therapies during pregnancy, when standard adult doses of medications may be inappropriate for the developing fetus or for the pregnant woman. For example, scientists found that the recommended adult dose of the influenza drug oseltamivir (Tamiflu®) does not adequately prevent or treat flu in pregnant women – a population who are more likely to get sicker and die if they develop an influenza infection. Scientists also showed that women who developed gestational diabetes, or diabetes during pregnancy, could greatly reduce their risk of developing type 2 diabetes by solely modifying their diets.

Budget Policy: The FY 2014 President's Budget estimate for this program is \$309.970 million, an increase of \$4.852 million, or 1.6 percent above the FY 2012 level. The program will continue to maintain its investment in an essential research network specifically designed to support clinical studies in obstetric and fetal pharmacology. Efforts to expand options for both male and female contraception will also continue. New initiatives are expected to help researchers better understand the mechanisms that lead to spontaneous preterm birth and preeclampsia. Building on insights from the NICHD Scientific Vision, another new effort aims to develop non-invasive technologies and techniques to shed light on the normal and abnormal characteristics of the placenta. Programmatic efforts will also continue to encourage research on vulvodynia, a chronic pain disorder that affects millions of women in the U.S. each year.

Pediatric Health -- The pediatric health program supports a comprehensive array of research and research training efforts. It includes studies of the fundamental biological processes that control both healthy and atypical child development, studies in pediatric pharmacology, pediatric HIV and associated infections, nutrition science, pediatric endocrinology, and pediatric trauma and critical illness. The program's basic studies in developmental biology may ultimately allow scientists to understand processes that keep embryonic and fetal development on track, as well as those factors that cause early development to go awry. Continued emphasis on the need to expand limited knowledge about the safety, efficacy, and appropriate doses of pharmaceuticals for children reflects the program's commitment to expand the number of drugs licensed for pediatric use. Consistent with this goal and NICHD's responsibilities under the Best Pharmaceuticals for Children Act, program staff collaborate closely with the FDA to improve labeling of drugs for use in children.

Domestic and international research focused on better understanding the epidemiology, diagnosis, clinical manifestations, disease process, transmission, and prevention of HIV infection comprises another critical pediatric research area. Targeting pregnant women, infants, children, and adolescents, this program has expanded its purview to include research to better understand similar processes and the impact of other infectious diseases on these populations. In activities

to further the health of women and children world-wide, NICHD has joined seven other NIH Institutes and Centers (ICs), the U.S. Department of State, the U.S. Agency for International Development, the Environmental Protection Agency, private companies, and foundations in the Global Alliance for Clean Cookstoves. The collaborative goal of the Alliance is to address the harmful household air pollution emitted by smoky, inefficient stoves used widely in resource-poor regions.

NICHD's research in pediatric health includes studies on pediatric endocrinology and nutrition to help scientists and clinicians better understand the interactive roles of nutrients and hormones in growth and development, and the role of nutrition throughout the life cycle. For example, in collaboration with the HHS Office of Disease Prevention and Health Promotion and the United States Department of Agriculture, NICHD is leading an effort to ensure that Dietary Guidelines for Americans include appropriate recommendations for infants from birth through age two, a crucial population whom the guidelines do not currently reference. Additional program interests include lactation and breastfeeding, childhood obesity, and antecedents of bone health and early origins of osteoporosis. Addressing another critical research gap, a newly-created extramural branch will concentrate on childhood trauma and critical illness, including studies pertaining to the complex physiological, behavioral, environmental, and psychosocial influences responsible for injury, the leading cause of death in children in the United States.

Budget Policy: The FY 2014 President's Budget estimate for this program is \$261.982 million, an increase of \$4.101 million, or 1.6 percent above the FY 2012 level. This will support our ongoing investments in basic developmental biology research, pediatric pharmacology, and infectious diseases such as HIV and tuberculosis in pediatric populations. NICHD will recompete the Pediatric Critical Care Research Network to further research needed to optimize care for conditions commonly treated within pediatric intensive care units. The program will also support a new follow-up study to the Upstate New York Infant Development Screening Program, which has investigated whether children conceived via infertility treatments face long-term adverse effects on their growth, motor, and social development. This new study will allow researchers to focus on the potential long-term cardiovascular and metabolic health effects in the same group of children, six to eight years later. Another effort will bring together multidisciplinary investigators to fill critical gaps in our understanding of how bone and muscle tissue typically grow and interact as children develop.

Program Portrait: Biomarkers of Nutrition for Development Program

**FY 2012 Level:** \$3.986 million\* **FY 2014 Level:** \$4.049 million\* **Change:** +\$.063 million

Nutrition is an integral component of all aspects of human health. Global maternal and child under-nutrition results in 3.5 million deaths per year and accounts for 35 percent of the disease burden in children under age five. Deficiencies in micronutrients—sometimes known as the "hidden hunger"—affect approximately 2 billion underweight *and* overweight individuals in the United States and throughout the world. Understanding the role of nutrition in health and disease prevention requires reliable biomarkers to measure accurately the types, levels, and effects of nutrients in individuals and populations. Given the focus of the research involved, NICHD assumed a leadership role in establishing the Biomarkers of Nutrition for Development (BOND) Program. BOND aims to harmonize how scientists determine the best biomarkers to use in research, clinical care, program development, monitoring, and evaluation. The program also represents a unique public/private collaboration, with worldwide

partners including the Bill and Melinda Gates Foundation, PepsiCo, the World Health Organization, the International Life Sciences Institute, EURRECA (EURopean micronutrient RECommendations Aligned), the Micronutrient Genomics Project, and the NIH's Division of Nutrition Research Coordination and Office of Dietary Supplements, as well as dozens of additional collaborating organizations.

The BOND initiative features state-of-the-art scientific approaches to discover and develop new biomarkers. The program also provides training and advice to allow individuals with varying levels of nutritional expertise to incorporate biomarkers successfully into their research and other activities. BOND's ultimate goal is to allow researchers, public health advocates, and governments to develop better nutrition surveys, enhance nutrition-related policies, and implement more effective food/nutrient programs to improve public health.

\*These figures reflect NICHD appropriated funds only and do not include funding support provided by collaborating partners from both public and private organizations.

**Intellectual and Developmental Disabilities** – The program in intellectual and developmental disabilities (IDDs) supports research and research training to advance knowledge of such common and rare disorders as Down, Fragile X and Rett syndromes; inborn errors of metabolism; and autism spectrum disorders (ASD). Scientists supported by this program seek to understand the complex processes through which such disorders alter cognitive, emotional, social, and physical development not only in infants and children, but also throughout the lifespan. Recent research findings on shortened telomeres (end regions of chromosomes) in older individuals with Down syndrome suggest that telomere length could serve as a biomarker for early stages of dementia in these individuals. Other studies show that identifying IDDs and beginning therapies as early as possible increases a child's chance for better health outcomes. Accordingly, the IDD research program targets newborn screening and the earliest diagnosis, treatment, and management of IDDs. For instance, the program supported a rigorous clinical trial of the Early Start Denver Model, which provides a comprehensive behavioral intervention for toddlers with ASD. The results showed that young children undergoing comprehensive treatment had a greater increase in IQ and more sustained growth in adaptive behaviors, such as getting dressed and brushing teeth, compared to children who received other conventional therapies. The Institute's IDD program collaborates closely with other NIH ICs in multiple endeavors, including the NIH Down Syndrome Working Group, the trans-NIH Fragile X Research Coordinating Group, and the Autism Centers of Excellence. Recently, NICHD led the establishment of a public-private Down Syndrome Consortium. The NIH Down Syndrome Working Group is working with eight national organizations, whose missions focus on Down syndrome, to establish a contact registry for families and update the NIH Down syndrome research plan.

<u>Budget Policy:</u> The FY 2014 President's Budget estimate for this program is \$127.329 million, an increase of \$1.993 million, or 1.6 percent above the FY 2012 level. Through the Intellectual and Developmental Disabilities Research centers, the program will continue to invest in the critical infrastructure needed to conduct basic and translational research in a wide array of intellectual and developmental disabilities. The IDD program will also continue to set a high priority on initiatives involving newborn screening. Through multiple collaborations, the program will continue to support the NIH Rare Disease Clinical Research Consortia and the Wellstone Centers for Research on Muscular Dystrophy. Another NICHD collaborative initiative will explore which factors may increase the risk for, or serve to protect, preterm infants from developing ASD.

Demography and Behavior – The program in demography and behavior supports research and research training in population dynamics to increase understanding of population structure and change in such areas as fertility, family demography and functioning, urbanization, and migration, and their implications for health. For example, a landmark study shows that providing specialized housing vouchers, which enabled low-income women and children to move from impoverished neighborhoods to those with relatively few poor residents, reduced extreme obesity and diabetes in this cohort over time. The study was a major collaboration among NICHD, other NIH Institutes, the Department of Housing and Urban Development and other federal agencies, and major private foundations. The program's longitudinal population studies, such as the National Longitudinal Study of Adolescent Health, yield data that are widely used by the scientific community to enhance understanding of how parental education influences children's health, and how various aspects of work affect family well-being. In addition, the demography and behavior program seeks to better understand how social and community risk factors may influence family formation, functioning, and stability, and child health and behavior.

In addition, the program supports studies on a wide range of cognitive and behavioral developmental topics – from understanding trajectories of typical cognitive, affective, and social development to studies of language, attention, reasoning, problem-solving, and other aspects of learning. For example, researchers recently reported that children who grow up learning to speak two languages may be slightly slower to build vocabulary than those who speak only one language; however, children who switch back and forth between languages show a greater ability to pay attention, plan, organize, and strategize. The program also targets research on the neurobiological and genetic bases of behavioral development and learning, risk-taking behaviors, and learning disabilities. Finally, the program seeks to understand the impact of violence against women and of child abuse on the health and development of children and youth.

<u>Budget Policy:</u> The FY 2014 President's Budget estimate for this program is \$306.127 million, an increase of \$4.792 million, or 1.6 percent above the FY 2012 level. Planned investments include continued support of infrastructure programs for population research. The program will continue to provide resources to ensure that population-based data are properly archived and made easily accessible to researchers nationwide and worldwide. The program will also maintain collaborations with the CDC and other federal agencies to support the National Survey of Family Growth, a nationally representative survey on family life, marriage and divorce, pregnancy, infertility, use of contraception, and men's and women's health.

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 persons with disabilities. The program supports a broad range of research, including studies 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 rehabilitation research related to spinal cord injury, traumatic brain injury, and stroke, in collaboration with ICs across the NIH and private sector partners. Complementing this research, the Center encourages researchers and businesses to develop equipment, devices, and treatments that improve mobility and enhance the functional capabilities of individuals with disabling conditions. NCMRR uses its collaborations to leverage research resources, engaging actively with the Department of Defense (DOD) and Department of

Veterans Affairs (VA). For instance, NCMRR works with these partners to support improved technology development that can improve functioning of both civilian and military individuals with prosthetic lower limbs. Recent research in this area includes comparison studies of prosthetic sockets and liners. The Center also supports a large-scale prospective study of rehabilitation services and outcomes for veterans. The multidisciplinary Blue Ribbon Panel that reviewed rehabilitation research across the NIH suggested that the field could benefit from expanding opportunities to coordinate research across the agency and with the DOD, VA, and other federal partners. NIH is actively considering these and other Panel recommendations.

Budget Policy: The FY 2014 President's Budget estimate for this program is \$77.545 million, an increase of \$1.214 million, or 1.6 percent above the FY 2012 level. This will help to support a new, comprehensive effort to accelerate research on the epidemiology, diagnosis, and treatment of concussion, or mild traumatic brain injury, across the life span. The initiative responds to increasing evidence that even seemingly insignificant concussions in childhood, adolescence, or adulthood may harm cognitive functioning over the life span. Bringing together experts in rehabilitation, child development and behavior, and intellectual and developmental disabilities, the initiative is designed to improve diagnostic criteria and help clinicians better understand and treat these injuries. The Center will also encourage scientists to find innovative ways to maximize how humans and technology can better interact to enhance rehabilitation. In a new initiative, NCMRR will challenge both scientists and entrepreneurs to use biomechanical modeling and state-of-the art materials to design novel braces and orthotics for children with disabling musculoskeletal conditions, such as cerebral palsy and spina bifida. Many of the currently available orthotics were designed decades ago, and are made from rigid metal and plastic that cannot "grow" with a child. Faced with devices that are ugly and uncomfortable, children often fail to use the orthotics, reducing their therapeutic benefits.

**Intramural Research** -- The Division of Intramural Research (DIR) conducts interdisciplinary research to answer basic biomedical research questions and to solve difficult clinical problems in human health and development. Research training, taking advantage of the mentoring of the program's senior scientists, is an essential element of this program. DIR research includes investigations into the genetics, genomics, and epigenetics that underlie disease processes and typical and atypical development. For example, intramural scientists recently discovered a genetic mutation that appears to increase the production of red blood cells in a rare form of cancer. The discovery could shed light on factors that hinder the growth of tumors and provide new ways to treat certain cancers. In its quest to understand the early origins of health and disease, the intramural research program emphasizes studies into the basic physics, chemistry, and biology of cells, their components, and the processes that govern and regulate their function. Recently, scientists used next-generation gene sequencing techniques to discover active DNA regions in rat brains once thought to be inert "dark matter." These areas appear to be uniquely active in the pineal gland, which controls the body's 24-hour cycle and is integral to maintaining health and development. The intramural program also emphasizes research that translates fundamental discoveries into clinical applications and new therapies. A recent clinical trial showed that when the anti-HIV drug, tenovir, is formulated as a vaginal gel, it can reduce the risk of herpes simplex virus (HSV) infections, as well as HIV infection, in women. Currently, an NICHD Blue Ribbon Panel is closely examining the DIR program; panel findings will provide the foundation for an updated long-range, intramural strategic plan.

Budget Policy: The FY 2014 President's Budget estimate for this program is \$190.374 million, an increase of \$2.582 million, or 1.4 percent above the FY 2012 level. NICHD is leading a trans-NIH initiative that will make the diverse and unique resources, expertise, and infrastructure of the NIH Clinical Center (CC) available to extramural researchers who wish to collaborate with intramural clinical investigators. The research program can help optimize the use of federal resources while advancing clinical studies that are intellectually challenging and high-risk/high-reward, with the potential for generating medical breakthroughs. The DIR will continue to emphasize research into the genetics, genomics, and epigenetics that underlie human development. "Bench-to-bedside" research will remain another critical focus, allowing novel basic scientific discoveries to be translated quickly into clinical protocols that can improve the treatment or prevention of disease.

Program Portrait: Developing Treatments for Childhood Obesity

**FY 2012 Level:** \$12.162 million **FY 2014 Level:** \$12.332 million **Change:** +\$0.170 million

The prevalence of overweight and obesity in U.S. children and adults has tripled during the past 40 years. This is particularly alarming since obesity-related diseases previously seen only in adults, such as type 2 diabetes, are now increasingly diagnosed in children. Moreover, people who develop these conditions as children often face an earlier onset of related complications such as kidney damage.

Easy access to high-calorie foods and limited exercise can lead to a significant rise in body weight. However, the physiological systems of high-risk individuals are often unable to control body fat well in the current high-calorie/low-activity environment. To address this widespread and complex problem, the Section on Growth and Obesity of the NICHD intramural program conducts an integrated program of basic, translational, and clinical research. Program scientists aim to identify the genetic, metabolic, and behavioral characteristics involved in energy balance during childhood, then use this knowledge to develop interventions that can help prevent and treat obesity and related disorders. Recently, the research group identified deletions in the brain-derived neurotrophic factor (BDNF) gene that result in pediatric obesity. Now, a clinical trial is underway, involving children with these deletions, to analyze energy intake and expenditure with the aim of developing more effective interventions. In another study, obese children with genetic variations in a gene known as MCR3 had no abnormalities in energy metabolism, but were found instead to have hyperphagia (excessive hunger and food intake), which warrants an entirely different treatment approach to regulate appetite.

In addition, the Section's comprehensive approach to the study of childhood obesity includes research on the psychology of behaviors such as binge-eating. Scientists are currently conducting a clinical protocol examining the effects of a targeted, interpersonal therapy intervention on body weight changes in adolescents who engage in binge-eating behaviors. Another study demonstrated that severely obese adolescents can lose weight when enrolled in a comprehensive weight management program that includes both behavioral interventions and the additive orlistat, which reduces fat absorption. Yet another study, in younger children, demonstrated that combining a behavioral intervention and the drug metformin (used to treat adult, insulin-resistant type 2 diabetes) could significantly improve weight loss and lower insulin resistance in severely obese, insulin-resistant children.

The laboratory's central premise is that effective strategies for preventing and treating childhood obesity require a commitment to addressing its causes and consequences at multiple levels – an approach designed to yield the most promising and comprehensive array of treatment strategies.

<u>Research Management and Support</u> – Research Management and Support (RMS) activities include administrative and technical functions that enable the Institute to support and enhance the research enterprise, while disseminating important research findings to improve public health. Key functions include budget, contracts, information technology, grants management,

peer review, program evaluation, science policy, and communications. The RMS budget supported the development of the Institute's Scientific Vision for the next decade; the reorganization of the NICHD Extramural program; revised and redesigned content for the Institute's website; and developed new media tools such as podcasts, Facebook, and YouTube to enhance the Institute's ability to share its research with scientists, clinicians, patients, parents, teachers, and advocacy organizations. This year, NICHD expanded its already successful efforts to prevent Sudden Infant Death Syndrome and other sleep-related causes of infant death in the new "Safe to Sleep" campaign, while increasing its outreach to American Indian and Native American communities. RMS funds are also critical in supporting systematic evaluations of NICHD's administrative and scientific programs, helping to identify ways to ensure program effectiveness and reduce costs.

Budget Policy: The FY 2014 President's Budget estimate for this program is \$66.033 million, an increase of \$0.883 million, or 1.4 percent above the FY 2012 level. NICHD will continue to implement policy guidance on efficiencies related to conferences, travel, publications, technology and other initiatives. It will also continue to minimize administrative costs throughout the Institute, including a thoughtful approach to space allocation as it relocates extramural program staff. RMS funds will support the acquisition and maintenance of information technology and the development of new technology applications for ongoing programs. Similarly, the Institute will continue to update Web content and usability, support several new program evaluations, and develop strategic approaches to expand the scientific portfolios in its new extramural branches. The apparent increase in estimated FY 2014 FTE compared to the FY 2012 actual FTE usage level is due to the effect of transferring positions previously funded from a centralized support operation (Division of Extramural Activities Support) to individual ICs as of year-end 2012. As a result of the DEAS transfer, estimated salaries and benefits for FY 2014 are proportionately higher than those identified for FY 2012 and previous years.

**Program Portrait: Toward Eliminating Sudden Infant Death** 

**FY 2012 Level:** \$2.290 million **FY 2014 Level:** \$2.326million **Change:** +\$0.036 million

Every year more than 2,000 families in the United States share an unthinkable tragedy – their seemingly healthy baby goes to sleep and never wakes up. The Back to Sleep Campaign – named for its recommendation to place healthy babies on their backs to sleep – has helped reduce the incidence of sudden infant death syndrome (SIDS). Since that campaign started in 1994, the percentage of infants placed on their backs to sleep has increased dramatically, and the overall SIDS rates have declined by more than 50 percent. However, SIDS is not the only cause of unexpected infant death.

In September of 2012, *Back* to Sleep became *Safe* to Sleep, marking the expansion of the campaign to reduce the risk of sudden unexpected infant death (SUID). SUID encompasses all unexpected infant deaths-- those due to SIDS as well as those from other causes. Many SUID cases are due to accidental suffocation, such as when an infant becomes trapped between a mattress and a wall, or when bedding material presses on or wraps around an infant's neck. In addition to placing infants on their backs to sleep, the Safe to Sleep Campaign emphasizes placing infants in their own safe sleep environment and not on an adult bed, not using any soft bedding with infants, breastfeeding infants when possible, avoiding overheating infants, and reducing other risks to infant health.

Safe to Sleep includes enhanced outreach and dissemination of culturally appropriate materials to African-American and American Indian/Alaska Native communities, which have higher rates of sudden infant death. NICHD has enlisted the aid of diverse spokespersons around the country for its Safe to Sleep Champions Initiative, which will

target areas of the country with the highest rates of sudden infant death. Safe to Sleep Champions include infant and family health advocates, community leaders, and pediatricians who will work with local media to draw attention to sleep-related causes of infant death.

### **Budget Authority by Object Class**

(Dollars in Thousands)

	FY 2012 Actual	FY 2014 PB	Increase or Decrease
Total compensable workyears:			
Full-time employment	606	632	26
Full-time equivalent of overtime and holiday hours	1	1	0
Average ES salary (in whole dollars)	\$179,607	\$179,607	\$0
Average GM/GS grade	12.3	12.0	(0.3)
Average GM/GS salary (in whole dollars)	\$102,217	\$99,060	(\$3,157)
Average salary, grade established by act of			
July 1, 1944 (42 U.S.C. 207) (in whole dollars)	\$114,642	\$114,642	\$0
Average salary of ungraded positions (in whole dollars)	\$131,590	\$131,590	\$0
	EN/2012	EN 2014	T
OD TECT OF ACCEC	FY 2012	FY 2014	Increase or
OBJECT CLASSES	Actual	PB	Decrease
Personnel Compensation:	\$35,662	\$36,863	\$1,201
11.1 Full-time permanent 11.3 Other than full-time permanent	25,261	25,780	519
11.5 Other personnel compensation	1.514	1,569	55
11.7 Military personnel	2,064	2,115	51
11.8 Special personnel services payments	12,318	12,529	211
Total, Personnel Compensation	\$76,819	\$78,856	\$2,037
12.0 Personnel benefits	\$18,985	\$19,498	\$513
12.2 Military personnel benefits	1,906	1,956	50
13.0 Benefits for former personnel	0	0	0
Subtotal, Pay Costs	\$97,710	\$100,310	\$2,600
21.0 Travel and transportation of persons	\$2,158	\$2,029	(\$129)
22.0 Transportation of things	218	218	0
23.1 Rental payments to GSA	1	0	(1)
23.2 Rental payments to others	67	67	0
23.3 Communications, utilities and			
miscellaneous charges	1,531	1,531	(0)
24.0 Printing and reproduction	46	46	0
25.1 Consulting services	1,033	1,033	0
25.2 Other services	263	300	37
25.3 Purchase of goods and services from			
government accounts	148,429	156,449	8,020
25.4 Operation and maintenance of facilities	1,549	1,385	(164)
25.5 Research and development contracts	125,796	124,216	(1,580)
25.6 Medical care	810	809	(1)
25.7 Operation and maintenance of equipment	3,387	3,404	17
25.8 Subsistence and support of persons	9 \$281,267	\$287,596	\$6,329
25.0 Subtotal, Other Contractual Services 26.0 Supplies and materials	\$281,267	\$2 <b>87,596</b> \$9,671	(\$129)
31.0 Equipment	8,937	8,837	(100)
32.0 Land and structures	0,937	0,837	(100)
33.0 Investments and loans	0	0	0
41.0 Grants, subsidies and contributions	917,205	929,051	11,846
42.0 Insurance claims and indemnities	0	0	0
43.0 Interest and dividends	4	4	(0)
44.0 Refunds	0	0	0
Subtotal, Non-Pay Costs	\$1,221,233	\$1,239,050	\$17,817
Total Budget Authority by Object Class	\$1,318,943	\$1,339,360	\$20,417

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

### **Salaries and Expenses**

(Dollars in Thousands)

	FY 2012	FY 2014	Increase or
OBJECT CLASSES	Actual	PB	Decrease
Personnel Compensation:			
Full-time permanent (11.1)	\$35,662	\$36,863	\$1,201
Other than full-time permanent (11.3)	25,261	25,780	519
Other personnel compensation (11.5)	1,514	1,569	55
Military personnel (11.7)	2,064	2,115	51
Special personnel services payments (11.8)	12,318	12,529	211
<b>Total Personnel Compensation (11.9)</b>	\$76,819	\$78,856	\$2,037
Civilian personnel benefits (12.1)	\$18,985	\$19,498	\$513
Military personnel benefits (12.2)	1,906	1,956	50
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	\$97,710	\$100,310	\$2,600
Travel (21.0)	\$2,158	\$2,029	(\$129)
Transportation of things (22.0)	218	218	0
Rental payments to others (23.2)	67	67	0
Communications, utilities and			
miscellaneous charges (23.3)	1,531	1,531	0
Printing and reproduction (24.0)	46	46	0
Other Contractual Services:			
Advisory and assistance services (25.1)	1,033	1,033	0
Other services (25.2)	263	300	37
Purchases from government accounts (25.3)	113,067	114,547	1,480
Operation and maintenance of facilities (25.4)	549	548	(1)
Operation and maintenance of equipment (25.7)	3,387	3,404	17
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$118,299	\$119,832	\$1,533
Supplies and materials (26.0)	\$9,787	\$9,658	(\$129)
Subtotal, Non-Pay Costs	\$132,106	\$133,381	\$1,275
Total, Administrative Costs	\$229,816	\$233,691	\$3,875

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

	FY 2012 Actual			FY 2013 CR			FY 2014 PB		
OFFICE/DIVISION	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director									
Direct:	87	3	90	87	3	90	87	3	90
Reimbursable:	29	-	29	29	-	29	29	-	29
Total:	116	3	119	116	3	119	116	3	119
Division of Extramural Research									
Direct:	107	2	109	133	2	135	133	2	135
Reimbursable:	_	_	_	_	-	-	-	_	-
Total:	107	2	109	133	2	135	133	2	135
National Center for Medical Rehabilitation Research									
Direct:	10	_	10	10	-	10	10	_	10
Reimbursable:	_	_	-	_	-	-	-	_	-
Total:	10	-	10	10	-	10	10	-	10
Division of Intramural Programs									
Direct:	356	12	368	356	12	368	356	12	368
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	356	12	368	356	12	368	356	12	368
Total	589	17	606	615	17	632	615	17	632
Includes FTEs whose payroll obligations are supported by the NIH	507		000	015	- 7	002	010		052
Common Fund.									
FTEs supported by funds from Cooperative Research and									
Development Agreements.									
FISCAL YEAR				Av	erage GS Gra	ıde			
2010		12.1							
2011		12.1							
2012					12.3				
2013 2014					12.0 12.0				
2014					12.0				

### **Detail of Positions**

	FY 2012	FY 2013	FY 2014
GRADE	Actual	CR	PB
Total, ES Positions	3	3	3
Total, ES Salary	\$538,820	\$538,820	\$538,820
GM/GS-15	53	53	53
GM/GS-14	93	93	93
GM/GS-13	62	62	62
GS-12	63	63	63
GS-11	36	36	36
GS-10	4	4	4
GS-9	25	27	27
GS-8	17	25	25
GS-7	13	26	26
GS-6	1	2	2
GS-5	2	4	4
GS-4	1	1	1
GS-3	0	0	0
GS-2	1	1	1
GS-1	0	0	0
Subtotal	371	397	397
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	201	201	201
Total permanent positions	403	429	429
Total positions, end of year	592	638	638
Total full-time equiv (FTE) at YE	606	632	632
Average ES salary	\$179,607	\$179,607	\$179,607
Average GM/GS grade	12.3	12.0	12.0
Average GM/GS salary	\$102,217	\$99,060	\$99,060

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