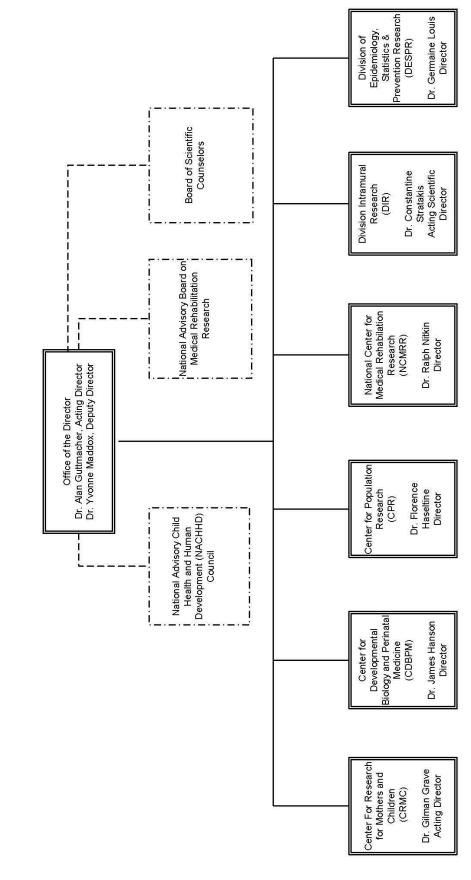
## DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH

Eunice Kennedy Shriver National Institute of Child Health and Human Development

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National Institute of Child Health and Human Development Eunice Kennedy Shriver



#### NATIONAL INSTITUTES OF HEALTH Eunice Kennedy Shriver

#### **National Institute of Child Health and Human Development**

For carrying out section 301 and title IV of the Public Health Service Act with respect to child health and human development [\$1,329,528,000] **\$1,368,894,000** (Department of Health and Human Services Appropriations Act, 2010).

#### National Institutes of Health Eunice Kennedy Shriver National Institute of Child Health and Human Development

#### Amounts Available for Obligation 1/

0	FY 2009	FY 2010	FY 2011
Source of Funding	Actual	Estimate	PB
Appropriation	\$1,294,894,000	\$1,329,528,000	\$1,368,894,000
Type 1 Diabetes	0	0	0
Rescission	0	0	0
Supplemental	0	0	0
Subtotal, adjusted appropriation	1,294,894,000	1,329,528,000	1,368,894,000
Real transfer under Director's one-percent transfer authority (GEI)	-1,942,000	0	0
Real transfer to the Global Fund to fight HIV/AIDS, Malaria and Tuberculosis	0	0	0
Comparative transfer to NLM	-375,000	-501,000	0
Comparative transfer under Director's one- percent transfer authority (GEI)	1,942,000	0	0
Comparative transfer to the Global Fund to fight HIV/AIDS, Malaria and Tuberculosis	0	0	0
Comparative transfer from DHHS for Autism	0	0	0
Subtotal, adjusted budget authority	1,294,519,000	1,329,027,000	1,368,894,000
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	1,294,519,000	1,329,027,000	1,368,894,000
Unobligated balance lapsing	-23,000	0	0
Total obligations	1,294,496,000	1,329,027,000	1,368,894,000

<sup>1/</sup> Excludes the following amounts for reimbursable activities carried out by this account: FY 2009 - \$27,300,000 FY 2010 - \$30,150,000 FY 2011 - \$30,150,000 Excludes \$1,144,839 in FY 2010 and \$1,144,839 in FY 2011 for royalties.

#### NATIONAL INSTITUTES OF HEALTH National Institute of Child Health and Human Development

(Dollars in Thousands)

Budget Mechanism - Total

			Budg	get Mechani	sm - Total							
	F١	/2009	FY 2009 F	Recovery	FY 201	0 Recovery	F١	/2010	F١	/2011		
MECHANISM	P	ctual	Act A	ctual	Act E	stimated	Es	timate		PB	CI	hange
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:												
Noncompeting	1,242	\$508,879			273	\$91,212	1,172	\$497,965	1,218	\$524,106	46	\$26,141
Administrative supplements	(58)	9,648	(254)	38,833	(371)	47,183	(41)	9,552	(37)	7,052	4	-2,500
Competing:												
Renewal	68	36,096	30	15,886			110	60,857	109	61,557	1	700
New	346	104,597	264	81,213	1	921	349	101,073	352	103,676	3	2,603
Supplements	2	248					2	253	2	253	0	0
Subtotal, competing	416	140,941	294	97,099	1	921	461	162,183	463	165,486	2	3,303
Subtotal, RPGs	1,658	659,468	294	135,932	274	139,316	1,633	669,700	1,681	696,644	48	26,944
SBIR/STTR	86	29,721	4	749	13	3,371	86	30,538	83	31,528	3	990
Subtotal, RPGs	1,744	689,189	298	136,681	287	142,687	1,719	700,238	1,764	728,172	45	27,934
Research Centers:												
Specialized/comprehensive	51	69,220		8,461		4,240	55	70,258	55	70,908	0	650
Clinical research	0	0					0	0	0	0	0	0
Biotechnology	0	238					0	241	0	241	0	0
Comparative medicine	0	300					0	304	0	304	0	0
Research Centers in Minority Institutions	0	0					0	0	0	0	0	0
Subtotal, Centers	51	69,758	0	8,461	0	4,240	55	70,803	55	71,453	0	650
Other Research:												
Research careers	290	49,112		7		282	290	55,803	280	54,313	(10)	-1,490
Cancer education	0	0					0	0	0	0	0	0
Cooperative clinical research	61	46,252		6,555			62	48,404	62	49,130	0	726
Biomedical research support	0	0					0	0	0	0	0	0
Minority biomedical research support	0	0					0	0	0	0	0	2
Other	132	24,511		2,186		1,680	134	24,879	134	24,879	0	0
Subtotal, Other Research	483	119,875	0	8,748	0	1,962	486	129,086	476	128,322	(10)	-764
Total Research Grants	2,278	878,822	298	153,890	287	148,889	2,260	900,127	2,295	927,947	35	27,820
December Training	CTTD.		CTTD <sub>*</sub>		ETTD:		CTTD-		CTTD.			
Research Training:	FTTPs	2.504	<u>FTTPs</u>	0	FTTPs		FTTPs	2.047	FTTPs	0.004	0	04.4
Individual awards	81 740	3,581		0			82 747	3,617	82 747	3,831 34,933	0	214
Institutional awards Total, Training	821	32,657 36,238	0	0	0	0	829	32,984 36,601	829	38,764	0	1,949 2,163
Total, Training	021	30,230	U	U	U	U	029	30,001	029	30,704	U	2,103
Research & development contracts	98	150,542		0		20,000	126	158,280	126	159,529	0	1,249
(SBIR/STTR)	(0)	(0)				,	(0)	(0)	(0)	(0)	(0)	(0)
		,					. ,		'			
	<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>		FTEs		<u>FTEs</u>	
Intramural research	378	166,305		0		1,637	390	170,311	404	175,761	14	5,450
Research management and support	237	62,612		878		2,149	244	63,708	259	66,893	15	3,185
Construction		0						0		0		0
Buildings and Facilities		0						0		0		0
Total, NICHD	615	1,294,519		154,768		172,675	634	1,329,027	663	1,368,894	29	39,867

**BA by Program** (Dollars in thousands)

	FY 2007	FY 2008	FY 2009		FY 2009	60	FY 2010	010	Ŧ	FY 2011		
		Actual					Estimate		_	B	Change	ge
Extramural Research Detail:	FTEs Amount	FTEs Amount	FTEs Am	Amount	FTEs Ar	<u>Amount</u>	FTEs /	Amount	FTES	Amount	FTEs Amount	monut
Center for Developmental Biology and Perinatal Medicine	\$303,541	\$306,972		\$320,406	\$3	\$320,952	↔	\$330,330		\$341,098		10,768
Center for Research for Mothers and Children	338,085	341,006		348,367	က	348,898		358,279		367,221		8,942
Center for Population Research	319,096	305,339		326,569	က	327,107		335,900		344,285		8,385
National Certer for Medical Rehabilitation Research	76,520	84,890		08,670		68,645		70,499		73,636		3,137
Subtotal, Extramural	1,037,242	1,038,207	1,06	1,064,012	1,0	1,065,602	7	1,095,008		1,126,240		31,232
Intramural research			378 16	166,305	378 16	166,305	390	170,311	404	175,761	14	5,450
Res. management & support			237 (	62,612	237 (	62,612	244	63,708	259	66,893	15	3,185
TOTAL	0 1,037,242	0 1,038,207	615 1,292,929		615 1,294,519	94,519	634 1,	634 1,329,027	663 1	663 1,368,894	29	39,867

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

#### Major Changes in the Fiscal Year 2011 Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail and these highlights will not sum to the total change for the FY2011 budget request for NICHD, which is a \$39.9 million increase over the FY 2010 Estimate, for a total of \$1,368,894,000.

Research Project Grants (RPGs) (+\$26.9 million, total \$696.6 million): The NIH Budget policy for RPGs in FY 2011 is to provide a 2.0% inflationary increase in noncompeting awards and a 2.0% increase in average cost for competing RPGs. The NICHD will support a total of 1,681 Research Project Grant (RPG) awards in 2011. Non-competing RPGs will increase by 46 awards for \$26.1 million to support the costs associated with the increased commitments of FY2010 competing awards.

Research Careers (-\$1.5 million, total \$54.3 million): While the number of career awards does not decrease, the NICHD is evaluating a core career program to provide cost effective mentorship opportunities and maximize research training.

Research Training (+2.2 million, total \$38.8 million): The Research Training budget will increase by \$2.2 million due to a 6% stipend increase. The number of Full Time Training Positions (FTTPs) will remain the same at 82 Individual awards and 747 Institutional slots.

Research and development (R&D) contracts (+\$1.2 million, total \$159.5 million): This additional funding is to expand the Therapeutics for Rare and Neglected Diseases (TRND) program to encourage and speed the development of new drugs for rare and neglected diseases.

Intramural research (+\$5.5 million, total \$175.8 million): The NIH Budget policy for Intramural research in FY 2011 is to provide a 3.2% increase over the FY 2010 estimate. The number of Full-Time Equivalents (FTEs) will increase by 14. Continuing priorities for the intramural program will include investigations in human development and its genetics, genomics, and epigenetics.

Research management and support (RMS) (+3.2 million, total \$66.9 million): The NIH Budget policy for RMS in FY 2011 is to provide a 5.0% increase over the FY 2010 estimate. The number of Full-Time Equivalents (FTEs) will increase by 15. NICHD RMS activities provide enhanced administrative efforts in records management, information technology, and public communications.

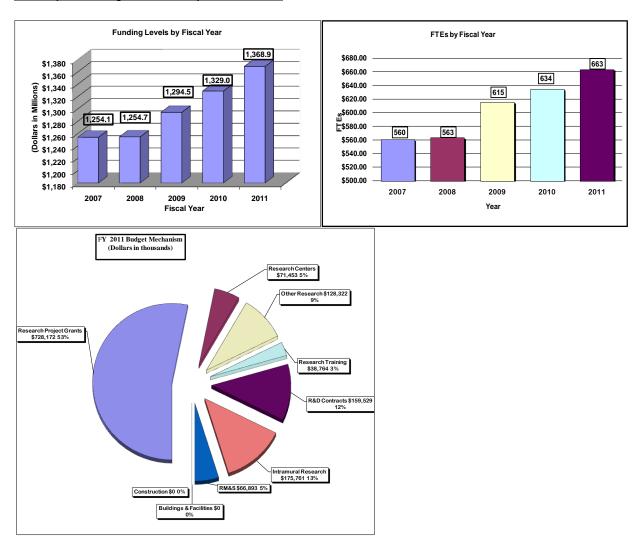
FY 2010 estimate				\$1,329,027,000
FY 2011 estimated budget authority				1,368,894,000
Net change				39,867,000
	20	10 Current		
	Esti	mate Base	Change	e from Base
		Budget		Budget
CHANGES	FTEs	Authority	FTEs	Authority
A. Built-in:				
Intramural research:				
a. Annualization of January				
2010 pay increase		\$68,776,000		\$416,000
b. January FY 2011 pay increase		68,776,000		722,000
c. Zero less days of pay (n/a for 2011)		68,776,000		0
<ul><li>d. Payment for centrally furnished services</li><li>e. Increased cost of laboratory supplies,</li></ul>		27,738,000		555,000
materials, and other expenses		73,797,000		1,254,000
materials, and other expenses		73,737,000		1,204,000
Subtotal				2,947,000
Research management and support:				
a. Annualization of January				
2010 pay increase		\$35,918,000		\$217,000
b. January FY 2011 pay increase		35,918,000		377,000
c. Zero less days of pay (n/a for 2011)		35,918,000		0
d. Payment for centrally furnished services		8,485,000		170,000
e. Increased cost of laboratory supplies,				
materials, and other expenses		19,305,000		340,000
Subtotal				1,104,000
Subtotal, Built-in				4,051,000

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

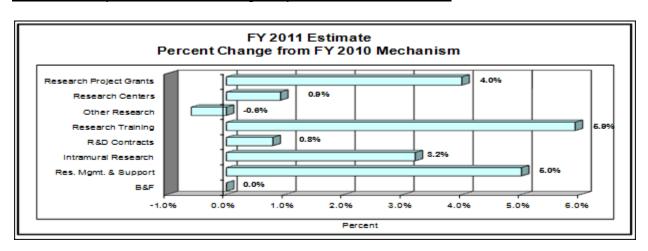
	20	010 Current		
	Es	timate Base	Chang	e from Base
CHANGES	No.	Amount	No.	Amount
B. Program:				
Research project grants:				
a. Noncompeting	1,172	\$507,517,000	46	\$23,641,000
b. Competing	461	162,183,000	2	3,303,000
c. SBIR/STTR	86	30,538,000	(3)	990,000
Total	1,719	700,238,000	45	27,934,000
2. Research centers	55	70,803,000	0	650,000
3. Other research	486	129,086,000	(10)	(764,000)
4. Research training	829	36,601,000	0	2,163,000
5. Research and development contracts	126	158,280,000	0	1,249,000
Subtotal, extramural				31,232,000
	<u>FTEs</u>		<u>FTEs</u>	
6. Intramural research	390	170,311,000	14	2,503,000
7. Research management and support	244	63,708,000	15	2,081,000
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program		1,329,027,000		35,816,000
Total changes	634		29	39,867,000

#### FY 2011 Budget Graphs

#### History of Budget Authority and FTEs:



#### Distribution by Mechanism: Changes by Selected Mechanism:



# Justification 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 2011	
	FY 2009 Appropriation	FY 2010 Appropriation	President's Budget	FY 2011 +/- FY 2010
BA	\$1,294,519,000	\$1,329,027,000	\$1,368,894,000	+\$39,867,000
FTE	615	634	663	+29

This document provides justification for the Fiscal Year (FY) 2011 activities of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), including HIV/AIDS activities. Details of the FY 2011 HIV/AIDS activities are in the "Office of AIDS Research (OAR)" Section of the Overview. Details on the Common Fund are located in the Overview, Volume One. 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 wanted; that women suffer no harmful effects from reproductive processes; that all children can achieve their full potential for healthy and productive lives, free from disease or disability; and that medical rehabilitation can optimize the health, productivity, and independence of all people. Scientifically, the NICHD supports a broad research portfolio, uniquely focused on understanding human health and development from before birth until adulthood. The NICHD provides a home to targeted research in women's health and reproductive sciences research, pediatric research, the science of early childhood learning, demographic and behavioral research on child and family well-being and medical rehabilitation. Thus, NICHD research spans from that needed to understand the molecular substrates of early health to research needed to understand the health impacts of economic and demographic changes on families.

**Recent Progress -** A central goal for the NICHD is to develop the basic knowledge needed to prevent diseases at the earliest possible stage. For example, NICHD-supported researchers pioneered a sophisticated technique with the potential to prevent a class of more than 40 hereditary disorders, known as mitochondrial diseases, from

being passed from mother to child. Other researchers discovered how the prion protein causes cellular damage in mad cow disease and related neurological illnesses, and tested new ways to manipulate the protein to prevent such damage. With findings that have implications for treating such diseases as leukemia, researchers deciphered key developmental events governing whether the stem cells that produce red and white blood cells remain anchored to the bone marrow, or migrate into the circulatory system. The NICHD also co-funded researchers who developed an innovative treatment in a canine version of Duchenne muscular dystrophy, a paralyzing and ultimately fatal muscle disease. The treatment involves a molecular "patch," comprised of DNA-like molecules, which is used to cover up mutant regions in a specific gene. Exciting new advances in the reproductive sciences also offer hope for parents. Researchers completed a critical first step in a procedure that would enable women with cancer to preserve their eggs so that they can choose to have children in the future.

**Future Directions** - The NICHD will invest wisely in the strongest science, ensuring that our priorities fill critical knowledge gaps and exploit emerging opportunities, while addressing urgent public health needs. A planned NICHD initiative, utilizing the newest high-throughput genomic technologies, will leverage the research resources developed by the NIH Roadmap to support additional studies in developmental epigenetics. Epigenetic actions on gene expression may critically influence early development from before birth and at key stages throughout childhood, serving as a mediator between genetics and the environment. Thus epigenetic research will lead to a better understanding of birth defects, developmental disabilities, obesity, and other conditions.

To translate scientific knowledge into new and better treatments, the NICHD will continue to examine how medication during pregnancy and delivery affects the mother and the fetus. Researchers will examine why children respond differently than adults to certain drug therapies, and apply this knowledge to improve safety, efficacy, and dosage in children. Such studies will include cutting-edge research in pharmacogenomics, linking different pharmacological outcomes to genetic differences in individuals and laying the foundation for future research in personalized medicine.

The NICHD will take strategic advantage of existing resources and infrastructure to ensure that scientific research improves health care. Scientists will assess the newest treatment approaches, but researchers will also evaluate the safety and efficacy of more established treatments for which safety and efficacy data are currently inadequate. The NICHD will invest in the development of new medical devices specifically for fragile infants in neonatal intensive care units, rather than relying on miniaturized versions of instruments designed for adults. NICHD researchers will work to identify the earliest developmental paths leading to obesity. We will address the understudied area of maternal obesity and its immediate and long-term impact on women and their children. Rehabilitation research priorities include better understanding of the immediate and long-term outcomes of critical care treatment of children and of autonomic dysreflexia, a grave and little-studied complication of spinal cord injury that often occurs unexpectedly.

The NICHD will continue efforts to promote women's and children's health around the globe, including studies to improve birth outcomes, to reduce maternal-fetal transmission of HIV, and to address interactions between iron deficiency and malaria.

Reinvigorating the U.S. biomedical research community will be essential in the next decade. The NICHD will build on successful training and career development programs to recruit and mentor the next generation of scientists. The Institute's focus on developmental processes, in both the child and the adult, will continue to provide the basic scientific and clinical insights needed to improve care for a wide range of conditions affecting many populations.

Overall Budget Policy - The NICHD continues to place high priority on investigatorinitiated projects, new investigator research, and crucial infrastructure programs. In FY 2011, the NICHD will support new investigators on R01 equivalent awards at success rates equivalent to those of established investigators submitting new R01 equivalent applications. The Institute has established robust networks that provide expertise in conducting clinical research involving children, pregnant women, and individuals with disabling conditions. These programs target critical public health issues such as prematurity, poor birth outcomes, intellectual and developmental disabilities, and a range of reproductive health concerns. Similar focus is placed on improving rehabilitative outcomes and using emerging high-throughput technologies to develop new generations of drugs for infants, children, and pregnant women. Systematic science planning and program evaluation allow the Institute to balance its portfolio carefully, taking advantage of emerging scientific opportunities while meeting public health needs. Funds are included in R&D contracts to support several trans-NIH initiatives, such as the Therapies for Rare and Neglected Diseases program (TRND), the Basic Behavioral and Social Sciences Opportunity Network (OppNet), and support for a new synchrotron at the Brookhaven National Laboratory, as well as increased support for other HHS agencies through the program evaluation set-aside. Intramural Research and Research Management and Support receive modest increases. The FY 2011 President's budget request for the National Children's Study can be found in the NIH Office of the Director Congressional Justification.

### Program Descriptions <u>Center for Developmental Biology and Perinatal Medicine</u>

<u>Program Description</u>: The Center supports research to advance basic and clinical knowledge about maternal health and child development, encompassing the origins and expression of congenital and genetic disorders. This research addresses conditions such as autism spectrum disorders (ASDs), Fragile X syndrome (FXS), Down syndrome, and their associated intellectual and developmental disabilities. Center studies focus on factors that affect maternal and fetal health during pregnancy, including the causes and consequences of fetal growth restriction, preterm birth, and stillbirth. The Center's research portfolio also includes conditions that emerge early in life, including respiratory distress syndrome and Sudden Infant Death Syndrome (SIDS). To address these major public health issues, the Center is interested in the epigenetic

processes associated with embryonic development that may contribute to pregnancy outcomes and neurodevelopmental disorders. Research in the biomechanics of embryonic development and projects that integrate basic, translational, and clinical approaches to better understand the developmental biology and genetic bases of congenital human malformations are also current Center priorities. The Center's well-established Intellectual and Developmental Disabilities (IDD) research centers, and the newer Autism Centers of Excellence (ACE), provide fundamental infrastructure resources for basic and clinical research on ASDs, FXS, Down syndrome and other more rare IDDs.

Budget Policy: The FY 2011 budget request for this program is \$341.098 million, an increase of \$10.768 million, or 3.3 percent over the FY 2010 estimate. The Center has planned several initiatives to integrate the latest advances in genetics with the rapidly changing science of developmental biology. One planned effort includes translating the basic knowledge gained from functional genomics into innovative and more effective ways, at the molecular and genetic levels, to diagnose, treat, and prevent structural birth defects. Another planned initiative would study the natural history of disorders recently identifiable through newborn screening, to help researchers better understand when targeted, age-appropriate interventions are warranted. The Center will continue to support research networks to compare the effectiveness and safety of existing and evolving treatments, particularly for high-risk pregnant women and for infants born too early and too small. Expanded efforts will also continue to support small business in developing safe and effective instruments for use in neonatal intensive care nurseries. The Center's well-established Intellectual and Developmental Disabilities (IDD) research centers program will continue to provide critical infrastructure resources for basic and clinical research on ASDs, FXS, Down syndrome, and other, rarer IDDs.

#### **Program Portrait: Newborn Screening and Birth Defects**

FY 2010 level: \$24.478 million FY 2011 level: \$25.835 million Change: +\$1.357 million

The institute's efforts on newborn screening began shortly after its founding, in 1962, when a test for phenylketonuria (PKU) had become available. The disorder results from an inability to process the amino acid phenylalanine, and if untreated, results in severe intellectual and developmental disabilities. Because of NICHD research, newborns in the U.S. are now routinely screened for PKU at birth and if positive, special diets can be started early – saving children from lifelong disability, and the country significant health care costs.

As with PKU, the earliest identification of serious, often fatal, inborn conditions in children, and the prompt treatment of those affected, can prevent or at least mitigate serious health problems. Today, most states screen newborn infants for 29 conditions for which treatment is available. In 2007, more than 4.2 million U.S. infants underwent newborn screening; of these, more than 11,000 were diagnosed with hearing or metabolic disorders and were referred for treatment. NICHD research now seeks to increase the number of conditions that can be identified at birth.

Recognizing the importance of these efforts, Congress enacted the Newborn Screening Saves Lives Act, which also names the Institute's established newborn screening program for Hunter Kelly, a boy whose family has advocated for more research and screening. The Hunter Kelley research program is developing and enhancing cutting-edge technologies to help identify multiple disorders from a simple procedure, such as analyzing a single bloodspot. Equally important, the program is developing new treatments for screenable disorders for which currently no treatments exist.

To complement its newborn screening efforts, the NICHD also supports research to identify the causes of birth defects and to find ways to prevent or treat them. Of the 4 million children born each year in the United States, about 120,000 have serious birth defects. After accidents, birth defects are the leading cause of death in children, and account for half of all pediatric hospitalizations. Based in part on NICHD research, the U.S. added folic acid to cereal grains in the 1990s, decreasing the risk of neural tube defects. The NICHD research program in birth defects seeks to identify the genes, environmental factors, and gene-environment interactions underlying birth defects. In uncovering these clues, researchers can also find ways to prevent such conditions as heart defects, cleft lip and palate, limb defects, and other skeletal defects like scoliosis and club foot. Through its combined research on newborn screening and the earliest causes of birth defects, the NICHD helps lead the NIH in prevention research.

#### Center for Research for Mothers and Children

<u>Program Description</u>: The Center supports an array of maternal and child health research, including studies on factors affecting growth and development; gestational diabetes; antecedents of adult diseases, obesity and overweight; growth retardation; and congenital and infectious diseases, including the treatment of HIV/AIDs in children, adolescents, and women. The Center also funds research that examines mechanisms of cognitive, social, emotional, and neurobiological development; the influences of genetics, environment, and life experiences on development; the causes and treatment of specific learning disabilities; and health promotion and disease prevention in children and adolescents. In compliance with the Best Pharmaceuticals for Children Act, the Center houses the primary federal research entity to study and compare safety and doses of pharmaceuticals for children, as well as a network to aid in testing the safety of pharmaceutical use in pregnant women.

Budget Policy: The FY 2011 budget request for this program is \$367.221 million, an increase of \$8.942 million, or 2.5 percent over the FY 2010 estimate. The Center plans to enhance its portfolio in pediatric pharmacology by supporting translational research in such understudied areas as understanding the metabolic effects of drugs in children and adolescents at the molecular level and how genetics influence the disposition and effectiveness of drugs in children. This would include developing new laboratory assays, age-appropriate outcome measures, and product delivery systems to speed the course of drug development for children. Emphasis would also be placed on developing complementary pediatric pharmacology training programs for clinicians and pharmacologists. The Adolescent Medicine Trials Network for AIDS will continue to conduct basic science and clinical research to find the most effective ways to prevent HIV infection and its complications, including a focus on behavioral, antimicrobial, and vaccine methods. Because minority youth account for about one-third of new HIV infections, these sustained efforts have significant implications for health disparities. Support will also continue for trans-disciplinary research in learning disabilities, with an expanded emphasis on understanding deficiencies in the development of reading, writing, comprehension, and listening and literacy skills in relationship to neurobiological, genetic, cognitive, behavioral, and environmental influences.

#### Portrait of a Program: Reducing Pregnancy Complications and Protecting Fragile Newborns

FY 2010 level: \$126.073 million FY 2011 level: \$127.923 million Change: +\$1.850 million

Preterm birth is a leading cause of infant mortality and surviving children can suffer serious illness and lasting disability. The U.S. saw the percentage of infants born at less than 37 weeks of gestation climb by 20 percent between 1990 and 2006. To address this growing problem, the NICHD supports basic, clinical, and multidisciplinary research to reduce pregnancy complications. Research in clinical settings promises to translate basic science into improved management of, and outcomes for, high-risk women and their often premature and low-birth weight infants. Recent advances underscore this progress:

- Preterm infants born to mothers receiving intravenous magnesium sulfate—a common treatment to delay labor—are less likely to develop cerebral palsy than are preterm infants whose mothers do not receive it.
- Newborns who were treated, often preventively, in the neonatal intensive care unit with a medication
  for non-symptomatic gastroesophogeal reflux or for gastritis associated with steroid treatments, were
  at increased risk of necrotizing enterocolitis (NEC), a devastating intestinal disorder. Such findings
  can help clinicians refine treatment practices and improve health outcomes.
- Whole-body cooling (hypothermia) of newborns who experienced acute oxygen shortage and brain damage (hypoxic-ischemic encephalopathy, HIE) during birth significantly improved their survival.

The NICHD works collaboratively to improve clinical practice, for instance, supporting the development of the Consensus Statement on Maternal Request Cesarean Delivery and the Institute of Medicine's reevaluation and issuance of updated pregnancy-weight gain guidelines. Future NICHD investments include developing devices for neonates and new comparative effectiveness trials, to continue to improve medical care for the most fragile of infants.

#### **Center for Population Research**

Program Description: The Center focuses on reproductive health and biology, including human infertility and reproductive disorders, as well as population research and the behavioral sciences. To meet the diverse contraceptive needs of women and men throughout their reproductive lives, and to support the prevention of sexually transmitted infections, the Center supports the development and testing of a variety of contraceptive methods to ensure that they are safe and effective, acceptable, and, preferably, reversible. The Center also supports behavioral and social science research to understand the consequences of changes in population size, composition and distribution, with a particular interest in factors that affect the formation, functioning, and stability of families, and how families influence child health and development. In the area of reproductive disorders, the Center's Pelvic Floor Disorders Network has already influenced clinical practice through comparative effectiveness research. Similarly, translational research studies to advance the treatment of reproductive disorders that impair fertility and compromise the quality of life are expected from the Center's productive cooperative program in reproduction and infertility. Other Center-supported studies target the epidemiological, behavioral, and environmental dynamics of HIV, to help public health officials develop effective evidence-based interventions to prevent the spread of HIV/AIDS.

Budget Policy: The FY 2011 budget request for this program is \$344.285 million, an increase of \$8.385 million, or 2.5 percent over the FY 2010 estimate. The Center will continue supporting its successful translational and clinical research programs targeting reproductive disorders that impair fertility and compromise the quality of life of millions of men and women. This work includes applying genomic and proteomic advances to study male reproduction, reproductive neuroendocrinology, and conditions that effect infertility, such as endometriosis and polycystic ovary disease. To inform physician practice, the Institute will continue to support comparative effectiveness and other clinical trials in a network aimed at improving the scope and efficacy of treatments for women with pelvic floor disorders. A new comparative effectiveness study is also planned that should inform obstetric and gynecologic practice as it relates to identifying the safest and most effective contraceptives for obese women. More than five million women of reproductive age are obese and at increased risk for high-risk pregnancies. The Center's robust Population Research Infrastructure Program continues to develop and strengthen complex, interdisciplinary approaches to understanding demographic, behavioral, and other determinants of human health. These advances inform the development of public health interventions in the U.S. and globally.

#### Portrait of a Program: Female Reproductive Health Research

FY 2010: \$40.167 million FY 2011: \$40.200 million Change: \$.033 million

Pelvic floor disorders, uterine fibroids, vulvodynia, and other conditions that affect the female reproductive system can have profound impacts on the quality of life of millions of women. For example, research conducted by the NICHD Pelvic Floor Disorders Research Network recently demonstrated that nearly one-quarter of all U.S. women are afflicted with one or more pelvic floor disorders that cause physical discomfort and limit activity. These disorders—urinary incontinence, fecal incontinence, and pelvic organ prolapse—occur when the muscles and connective tissue within the pelvic cavity holding the bladder, uterus, bowel, and rectum weaken or are injured. The NICHD, in collaboration with the NIDDK and the Office of Research on Women's Health (ORWH), supports the Pelvic Floor Disorders Network to evaluate outcomes of different management strategies: surgical versus non-surgical, timing of interventions, and post-operative management. A recent network study revealed that a special two-step surgical procedure, compared to standard practice, reduced by half the incidence of urinary incontinence in women with pelvic organ prolapse. The Institute continues to support collaborative research on the physiology and pathophysiology of pelvic function, and will continue to support a range of comparative effectiveness trials that promise to improve the management of these conditions and the quality of life for millions of women each year. Other reproductive disorders, including uterine fibroids, also affect millions of women. Uterine fibroids are non-cancerous tumors in women of childbearing age. NICHD-supported studies have characterized the make-up of fibroid tissues and identified a multifunctional molecule (TGF-beta) that regulates several processes that lead to uterine fibroid growth. Researchers are now developing alternative treatment approaches based on this discovery. In addition, the Institute's intramural program is developing a fibroid tissue bank to promote research on fibroids by providing access to tissue samples for investigators throughout the world. The NICHD is also supporting research to identify the causes and ultimately develop treatments for vulvodynia, or chronic pain or discomfort of the lower pelvic or vulva area. NICHD-supported research estimates that as many as 16 percent of women suffer from chronic vulvar pain at some time in their lives. What causes vulvodynia is unknown and currently there is no cure, though treatments to relieve symptoms exist. To increase awareness about the condition, the NICHD collaborated with the ORWH and other organizations to launch the Vulvodynia Awareness Campaign, providing both resources for women with vulvodynia and information for scientists about the latest research on the disorder.

With new research in all of these areas, women can look forward to a time when they will no longer need to suffer so extensively – or at all -- from these chronic, life-disrupting conditions.

#### **National Center for Medical Rehabilitation Research**

Program Description: The Center aims to enhance the health, productivity, independence, and quality of life of people with disabilities by supporting a broad range of research. Research supported by this Center includes the underlying biology of injury and disability and the body's normal mechanisms of recovery and adaptation, with a special emphasis on spinal cord and traumatic brain injuries and stroke. Childhood disabilities and long-term outcomes of survivors of neonatal oxygen deprivation, trauma, congenital anomalies, infection, and septic shock are also targeted. The Center supports the development of equipment, devices, and treatments to improve mobility and enhance the functional capacities of individuals with disabling conditions. The Center is a leading user of the Small Business Innovation Research Awards to foster the creation and testing of such sophisticated technologies as sensors for prosthetic devices and virtual reality systems to enhance rehabilitative interventions.

Budget Policy: The FY 2011 budget request for this program is \$73.636 million, an increase of \$3.137 million, or 4.4 percent over the FY 2010 estimate. The Center intends to stimulate new research on autonomic dysreflexia, the poorly understood, potentially fatal complication of spinal cord injury (SCI). Developing protocols for emergency management and, potentially, prevention of this disorder in SCI patients could be relevant for such other serious medical conditions as multiple sclerosis and severe head or brain trauma. Partnering with the Department of Health and Human Services, the Center for Disease Control (CDC), and the National Institute of General Medical Sciences, the Center will also continue to manage a major study that follows children presenting in emergency rooms with critical pertussis to determine acute and long-term outcomes of the infection and its treatment.

#### **Division of Intramural Research**

<u>Program Description</u>: NICHD intramural researchers conduct interdisciplinary and interactive research to answer basic biomedical research questions and to solve difficult clinical problems in human development. This research includes investigations in genetics, genomics (the study of how genes function), and epigenetics (DNA-associated, heritable switches that can affect gene function) and how these factors influence healthy and atypical development. The intramural program also studies the basic biophysical mechanisms underlying cell and tissue function; the development, physiology, and pathophysiology of the mammalian central nervous system, including basic biobehavioral research; and the prevention and treatment of endocrine and reproductive disorders, including cancers, through innovative diagnostics, therapies, and vaccines. Intramural researchers also develop the innovative tools needed to conduct increasingly sophisticated biomedical research at the cellular and subcellular levels.

<u>Budget Policy</u>: The FY 2011 budget request for this program is \$175.761 million, an increase of \$5.450 million, or 3.2 percent over the FY 2010 estimate. Continuing priorities for the intramural program will include investigations in human development and its genetics, genomics, and epigenetics. Such studies are 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. Expanded studies will focus on the genetic causes of obesity and extended collaborations with other Institutes and Centers will target autism, cancer, and other conditions and disorders. The support of "scientific cores" to increase research efficiencies and of expanded training programs and opportunities for new researchers remains a high priority for the intramural research program. Another critical focus is "bench-to-bedside" research that allows novel basic scientific discoveries to be quickly translated into clinical treatments that can be evaluated for their effectiveness in preventing or mitigating disease.

#### **Research Management and Support (RMS)**

<u>Program Description</u>: Research Management and Support (RMS) activities include technical and administrative functions required for the Institute's research investments. The RMS budget also supports the Institute's international and special populations research activities and its outreach and public education activities, such as the Back-to-Sleep campaign to reduce the risk of SIDS. The NICHD regularly reviews administrative and programmatic functions to identify ways to streamline activities, save costs, and ensure that its programs are effective. The Institute is enhancing consistency of NICHD clinical research activities; improving business processes, such as records management; and finding new ways to improve efficiencies in the design and conduct of clinical research programs.

<u>Budget Policy</u>: The NICHD FY 2011 RMS budget request of \$66.893 million is an increase of \$3.185 million or 5.0% increase from the FY 2010 estimate. The FY 2011 NICHD RMS activities provide enhanced administrative efforts in records management, information technology, and public communications. Additional focus is being placed on enhancing communications through the National Child Health and Maternal Education Program and on management and update of website content to better disseminate the most current information to the public and the many constituencies that are vested in the outcomes of NICHD research.

#### **Recovery Act Implementation**

Recovery Act Funding: \$327.443 million

In FY 2009, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) received \$327.443 million under the Recovery Act. Of this amount, \$154.768 million was obligated in FY 2009 and \$172.675 million will be obligated in FY 2010. These funds support new research across the NICHD's mission, including perinatal and pediatric research, reproductive health, and medical rehabilitation. For example, the NICHD's ARRA funding will be used to develop the first U.S. national standard for normal fetal growth. To provide optimal prenatal and neonatal care, physicians need to be able to objectively and precisely assess normal and abnormal fetal growth. Currently the United States has no standard of optimal fetal growth. This study will provide data that is based on longitudinal ultrasound data and that includes a sufficient sample size representative of the U.S. population. Such a standard is urgently needed, especially given the high prevalence of maternal obesity and delayed childbearing in contemporary society. The project will employ technicians, nurses, laboratory staff, and data monitoring and analysis professionals across the country.

ARRA funding will enable the NICHD to support the rigorous clinical research that is needed to assess the safety and effectiveness of drugs currently used in children. Nearly 80 percent of prescription drugs lack scientific data on appropriate dosing, efficacy, and safety for neonates, infants, children, or adolescents, although physicians prescribe them "off label" for pediatric use. ARRA funding will support research on drug therapies currently used to treat children with conditions such as sickle cell anemia, asthma, spinal muscular atrophy, and pediatric hypertension, among others.

The NICHD has also used ARRA dollars to support new research in medical rehabilitation. Over two million people experience a stroke, traumatic brain injury, or spinal cord injury each year in the United States. Survivors of these and similar conditions often suffer from debilitating cognitive and/or mobility impairments that significantly lower quality of life. ARRA-funded grants are exploring basic mechanisms of cell regeneration and adaptation to enhance the ability to recover from injuries or disorders that destroy or severely impair tissue, developing new pharmacological treatments for tissue loss and/or dysfunction, and assessing new strategies for exercise, motor training, and stimulation therapies to improve mobility in patients with a variety of conditions. These projects have created or saved jobs for postdoctoral scientists, clinicians, and rehabilitation specialists.

**Budget Authority by Object** 

Budget Auti	nority by Object			1
	FY 2010	FY 2011	Increase or	Percent
	Estimate	PB	Decrease	Change
Total compensable workyears:				
Full-time employment	634	663	29	4.6
Full-time equivalent of overtime and holiday hours	2	2	0	0.0
Average ES colony	¢176 407	¢101 700	<b>የ</b> ፍ ኃርፍ	2.0
Average ES salary	\$176,497 12.1	\$181,792	\$5,295	3.0
Average GM/GS grade	12.1	12.1	0.0	0.0
Average GM/GS salary	\$99,217	\$100,090	\$873	0.9
Average salary, grade established by act of				
July 1, 1944 (42 U.S.C. 207)	\$89,700	\$90,642	\$942	1.1
Average salary of ungraded positions	133,775	135,138	1,363	1.0
	FY 2010	FY 2011	Increase or	Percent
OBJECT CLASSES	Estimate	Estimate	Decrease	Change
Personnel Compensation:				
11.1 Full-time permanent	\$39,541,000	\$42,181,000	\$2,640,000	6.7
11.3 Other than full-time permanent	26,254,000	27,741,000	1,487,000	5.7
11.5 Other personnel compensation	2,102,000	2,243,000	141,000	6.7
11.7 Military personnel	2,784,000	2,945,000	161,000	5.8
11.8 Special personnel services payments	12,871,000	13,548,000	677,000	5.3
Total, Personnel Compensation	83,552,000	88,658,000	5,106,000	6.1
12.0 Personnel benefits	18,981,000	20,156,000	1,175,000	6.2
12.2 Military personnel benefits	2,161,000	2,289,000	128,000	5.9
13.0 Benefits for former personnel	0	0	0	0.0
Subtotal, Pay Costs	104,694,000	111,103,000	6,409,000	6.1
21.0 Travel and transportation of persons	2,209,000	2,239,000	30,000	1.4
22.0 Transportation of things	299,000 0	303,000	4,000	1.3 0.0
23.1 Rental payments to GSA 23.2 Rental payments to others	75,000	76,000	0 1,000	1.3
23.3 Communications, utilities and	75,000	70,000	1,000	1.3
miscellaneous charges	1,680,000	1,698,000	18,000	1.1
24.0 Printing and reproduction	551,000	557,000	6,000	1.1
25.1 Consulting services	1,992,000	2,021,000	29,000	1.5
25.2 Other services	12,548,000	12,730,000	182,000	1.5
25.3 Purchase of goods and services from	, ,	, ,	,	
government accounts	138,129,000	141,429,000	3,300,000	2.4
25.4 Operation and maintenance of facilities	299,000	304,000	5,000	1.7
25.5 Research and development contracts	109,876,000	109,464,000	(412,000)	-0.4
25.6 Medical care	1,001,000	1,018,000	17,000	1.7
25.7 Operation and maintenance of equipment	2,378,000	2,416,000	38,000	1.6
25.8 Subsistence and support of persons	0	0	0	0.0
25.0 Subtotal, Other Contractual Services	266,223,000	269,382,000	3,159,000	1.2
26.0 Supplies and materials	10,731,000	10,907,000	176,000	1.6
31.0 Equipment	5,844,000	5,925,000	81,000	1.4
32.0 Land and structures	2,000	2,000	0	0.0
33.0 Investments and loans	0	000 700 000	0 000 000	0.0
41.0 Grants, subsidies and contributions	936,719,000	966,702,000	29,983,000	3.2
42.0 Insurance claims and indemnities	0	0	0	0.0
43.0 Interest and dividends 44.0 Refunds	0	0	0	0.0
Subtotal, Non-Pay Costs	1,224,333,000	1,257,791,000	33,458,000	0.0 <b>2.7</b>
-				
Total Budget Authority by Object	1,329,027,000	1,368,894,000	39,867,000	3.0

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

Salaries and Expenses

Salaries	and Expenses			
	FY 2010	FY 2011	Increase or	Percent
OBJECT CLASSES	Estimate	PB	Decrease	Change
Personnel Compensation:				J
Full-time permanent (11.1)	\$39,541,000	\$42,181,000	\$2,640,000	6.7
Other than full-time permanent (11.3)	26,254,000	27,741,000	1,487,000	5.7
Other personnel compensation (11.5)	2,102,000	2,243,000	141,000	6.7
Military personnel (11.7)	2,784,000	2,945,000	161,000	5.8
Special personnel services payments (11.8)	12,871,000	13,548,000	677,000	5.3
Total Personnel Compensation (11.9)	83,552,000	88,658,000	5,106,000	6.1
Civilian personnel benefits (12.1)	18,981,000	20,156,000	1,175,000	6.2
Military personnel benefits (12.2)	2,161,000	2,289,000	128,000	5.9
Benefits to former personnel (13.0)	0	0	0	0.0
Subtotal, Pay Costs	104,694,000	111,103,000	6,409,000	6.1
Travel (21.0)	2,209,000	2,239,000	30,000	1.4
Transportation of things (22.0)	299,000	303,000	4,000	1.3
Rental payments to others (23.2)	75,000	76,000	1,000	1.3
Communications, utilities and				
miscellaneous charges (23.3)	1,680,000	1,698,000	18,000	1.1
Printing and reproduction (24.0)	551,000	557,000	6,000	1.1
Other Contractual Services:				
Advisory and assistance services (25.1)	1,992,000	2,021,000	29,000	1.5
Other services (25.2)	12,548,000	12,730,000	182,000	1.5
Purchases from government accounts (25.3)	90,986,000	92,629,000	1,643,000	1.8
Operation and maintenance of facilities (25.4)	299,000	304,000	5,000	1.7
Operation and maintenance of equipment (25.7)	2,378,000	2,416,000	38,000	1.6
Subsistence and support of persons (25.8)	0	0	0	0.0
Subtotal Other Contractual Services	108,203,000	110,100,000	1,897,000	1.8
Supplies and materials (26.0)	10,711,000	10,887,000	176,000	1.6
Subtotal, Non-Pay Costs	123,728,000	125,860,000	2,132,000	1.7
Total, Administrative Costs	228,422,000	236,963,000	8,541,000	3.7

Eunice Kennedy Shriver National Institute of Child Health and Human Development NATIONAL INSTITUTES OF HEALTH

		Authorizii	<b>Authorizing Legislation</b>			
	PHS Act/	U.S. Code	2010 Amount	FY2010	2011 Amount	FY 2011
	Other Citation	Citation	Authorized	Estimate	Authorized	PB
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
				* \$1,329,027,000		\$1,368,894,000
Eunice Kennedy Shriver	Section 402(a)	42§281	Indefinite		Indefinite	
National Institute of Child Health and Human Development						
Total, Budget Authority				1,329,027,000		1,368,894,000

**Appropriations History** 

Fiscal	Budget Estimate	House	Senate	
Year	to Congress	Allowance	Allowance	Appropriation
2002	1,096,650,000	1,088,208,000	1,123,692,000	1,113,605,000
Rescission				(1,931,000)
2003	1,196,093,000	1,196,093,000	1,213,817,000	1,213,817,000
Rescission				(7,890,000)
2004	1,245,371,000	1,245,371,000	1,251,185,000	1,250,585,000
Rescission				(8,224,000)
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			

<sup>1/</sup> Reflects enacted supplementals, rescissions, and reappropriations.

<sup>2/</sup> Excludes funds for HIV/AIDS research activities consolidated in the NIH Office of AIDS Research.

#### NATIONAL INSTITUTES OF HEALTH

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

**Details of Full-Time Equivalent Employment (FTEs)** 

Betaile of Fall Time Equivalent Emp		,	
OFFICE/DIVISION	FY 2009 Actual	FY 2010 Estimate	FY 2011 PB
Office of the Director	153	158	169
Center for Developmental Biology & Perinatal Medicine	21	21	22
Center for Population Research	22	24	24
Center for Research for Mothers & Children	32	32	35
National Center for Medical Rehabilitation Research	9	9	9
Division of Intramural Research	378	390	404
Total	615	634	663
Includes FTEs which are reimbursed from the NIH Roadmap	for Medical I	Research	
FTEs supported by funds from Cooperative Research and	(2)	(2)	(2)
Development Agreements	(0)	(0)	(0)
FISCAL YEAR	Avera	age GM/GS C	Grade
2007		11.7	
2008		11.8	
2009		12.1	
2010		12.1	
2011		12.1	

#### **New Positions Requested**

		FY 2011	
			Annual
	Grade	Number	Salary
Intramural:			
Medical Officer	GS-15	1	141,732
Investigator	AD	2	110,000
Administrative Officer	GS-12	1	85,746
Research Fellow	AD	4	70,000
Clinical Fellow	AD	4	58,687
Purchasing Agent	GS-7	2	48,340
Extramural:			
Director	AD	1	\$174,000
Medical Officer	GS-14	2	120,490
Web Manager	GS-14	1	120,490
Health Scientist Administrator	GS-14	1	120,490
Contract Specialist	GS-13	1	101,963
Health Scientist Administrator	GS-13	1	101,963
Program Officer	GS-13	4	101,963
Program Officer	GS-14	1	120,490
Budget Analyst	GS-12	1	85,746
Administrative Assistant	GS-9	1	59,125
Secretary	GS-8	1	53,532
Total Requested		29	\$1,674,757