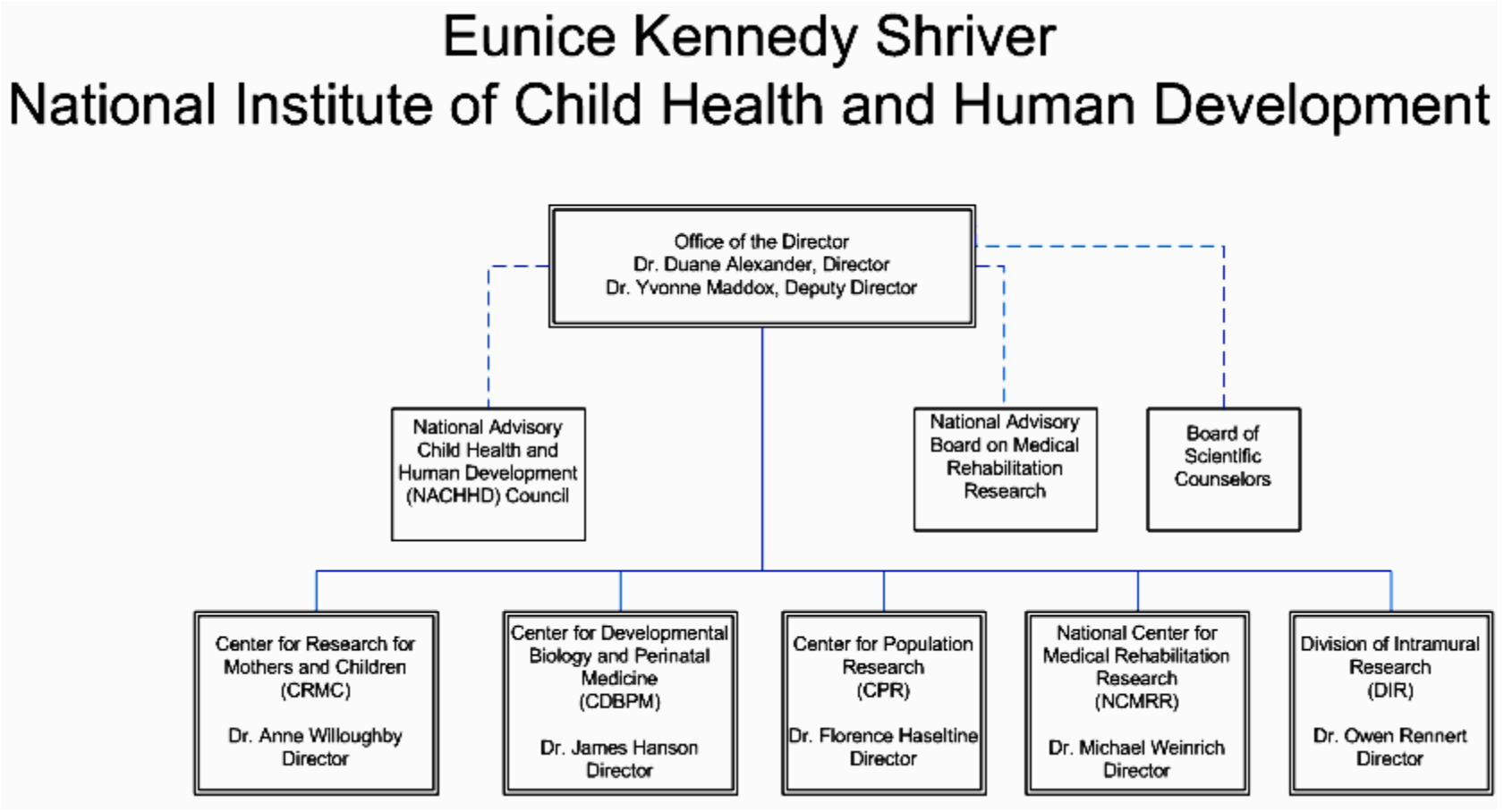
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Eunice Kennedy Shriver National Institute of Child Health and Human Development

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

For carrying out section 301 and title IV of the Public Health Service Act with respect to child health and human development ~~$1,277,017,000~~ ***$1,255,920,000*** (Department of Health and Human Services Appropriations Act, 2008).

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

Amounts Available for Obligation 1/

Source of Funding	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Appropriation	$1,253,769,000	$1,277,017,000	$1,255,920,000
Pay cost add-on	938,000		
Rescission		-22,309,000	
Subtotal, adjusted appropriation	1,254,707,000	1,254,708,000	1,255,920,000
Real transfer under Director's one-percent transfer authority (GEI)	-1,942,000		
Comparative transfer to NIBIB	-88,000		
Comparative transfer to OD	-40,000		
Comparative transfer to NCRR	-431,000		
Comparative transfers to the Office of the Assistant Secretary for Admin. and Mgmt. and to the Office of the Assistant Secretary for Public Affairs	-4,000		
Comparative transfer under Director's one-percent transfer authority (GEI)	1,942,000		
Subtotal, adjusted budget authority	1,254,144,000	1,254,708,000	1,255,920,000
Unobligated balance, start of year			
Unobligated balance, end of year			
Subtotal, adjusted budget authority	1,254,144,000	1,254,708,000	1,255,920,000
Unobligated balance lapsing			
Total obligations	1,254,144,000	1,254,708,000	1,255,920,000

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

FY 2007 - $34,892,746; FY 2008 - $35,390,000; FY 2009 - $35,390,000

Excludes $1,523,510 in FY 2008 and $1,523,500 in FY 2009 for royalties.

NATIONAL INSTITUTES OF HEALTH

Eunice Kennedy Shriver National Institute of Child Health and Human Development

(Dollars in Thousands)

Budget Mechanism - Total

MECHANISM	FY 2007 Actual		FY 2008 Enacted		FY 2009 Estimate		Change	
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	1,180	$475,914	1,254	$517,369	1,191	$492,745	(63)	-$24,624
Administrative supplements	(55)	4,464	(55)	4,464	(55)	4,464	(0)	0
Competing:								
Renewal	124	63,193	91	46,231	105	53,294	14	7,063
New	409	108,746	299	79,557	345	91,711	46	12,154
Supplements	3	735	2	538	2	620	0	82
Subtotal, competing	536	172,674	392	126,326	452	145,625	60	19,299
Subtotal, RPGs	1,716	653,052	1,646	648,159	1,643	642,834	(3)	-5,325
SBIR/STTR	100	29,090	100	29,061	100	29,061	0	0
Subtotal, RPGs	1,816	682,142	1,746	677,220	1,743	671,895	(3)	-5,325
Research Centers:								
Specialized/comprehensive	50	65,505	50	63,505	50	63,505	0	0
Clinical research	0	0	0	0	0	0	0	0
Biotechnology	0	243	0	234	0	234	0	0
Comparative medicine	0	233	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Subtotal, Centers	50	65,981	50	63,739	50	63,739	0	0
Other Research:								
Research careers	294	49,104	294	49,535	294	49,535	0	0
Cancer education	0	0	0	0	0	0	0	0
Cooperative clinical research	96	39,243	96	41,232	96	41,232	0	0
Biomedical research support	0	0	0	0	0	0	0	0
Minority biomedical research support	0	0	0	0	0	0	0	0
Other	143	24,099	143	22,479	143	22,479	0	0
Subtotal, Other Research	533	112,446	533	113,246	533	113,246	0	0
Total Research Grants	2,399	860,569	2,329	854,205	2,326	848,880	(3)	-5,325
Research Training:			FTTPs		FTTPs			
Individual awards	103	4,652	103	4,652	103	4,682	0	30
Institutional awards	769	33,702	769	33,702	769	33,918	0	216
Total, Training	872	38,354	872	38,354	872	38,600	0	246
Research & development contracts	294	139,830	294	142,727	294	145,727	0	3,000
(SBIR/STTR)			(0)	(0)	(0)	(0)	(0)	(0)
			FTEs		FTEs		FTEs	
Intramural research	380	159,375	383	162,590	386	165,029	3	2,439
Research management and support	180	56,016	180	56,832	181	57,684	1	852
Construction				0		0		0
Buildings and Facilities				0		0		0
Total, NICHD	560	1,254,144	563	1,254,708	567	1,255,920	4	1,212

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

NATIONAL INSTITUTES OF HEALTH
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Budget Authority by Program
(Dollars in thousands)

	FY 2005 Actual		FY 2006 Actual		FY 2007 Actual		FY 2007 Comparable		FY 2008 Enacted		FY 2009 Estimate		Change	
Extramural Research	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Detail:														
Center for Developmental Biology and Perinatal Medicine		--		$321,315		$303,541		$303,983		$302,969		$302,360		($609)
Center for Research for Mothers and Children		$651,342		314,400		338,085		338,578		337,448		336,770		(678)
Center for Population Research		326,417		324,563		319,096		319,561		318,494		317,855		(639)
National Center for Medical Rehabilitation Research		80,147		90,019		76,520		76,631		76,375		76,222		(153)
Subtotal, Extramural		1,057,906		1,050,297		1,037,242		1,038,753		1,035,286		1,033,207		(2,079)
Intramural research	354	159,036	370	159,051	380	159,495	380	159,375	383	162,590	386	165,029	3	2,439
Res. management & support	194	53,379	177	54,552	180	56,028	180	56,016	180	56,832	181	57,684	1	852
TOTAL	548	1,270,321	547	1,263,900	560	1,252,765	560	1,254,144	563	1,254,708	567	1,255,920		1,212

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

Major Changes in the Fiscal Year 2009 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 FY 2009 budget request for NICHD, which is $1.212 million increase over the FY 2008 Estimate, for a total of $1,255,920.

Research Project Grants (RPGs) (-$5.3.0 million, total $671.9 million). The NIH Budget policy for RPGs in FY 2009 is to provide no inflationary increase in noncompeting awards and no increase in average cost for competing RPGs. NICHD will support a total of 1743 Research Project Grant (RPG) awards in FY 2009. Non-competing RPGs will decrease by 63 awards and decrease by $24.6 million. Competing RPGs will increase by 60 awards and increase by $19.3 million.

Research and Development Contracts (+$3.0 million, total $145.7 million): NICHD will support the Pediatric and Perinatal research program, by funding an additional $3 million in FY 2009. This pediatric/perinatal clinical trial evaluates therapeutic agents in HIV-infected children and pregnant women and is a high priority for the Institute.

Major Change: No funding requested for the NCS program support (-$110.9 million; total $0.0 million): Consistent with the FY 2007 and FY 2008 President's Budget, the NIH OD budget does not continue the National Children's Study (NCS) in FY 2009. The FY 2008 appropriated support of $110.9 million within the Office of the Director sustains the support for existing activities of the vanguard centers, study sites and the data coordination center and provides funding for the laboratory and biospecimens repository. The NICHD provides program support of $1.7 million in FY 2008 from existing NICHD resources. To phase out this study, existing contracts for pilot studies and other activities will be allowed to expire when the FY 2008 funds provided for planning are exhausted and no additional contracts will be awarded.

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

FY 2008 enacted				$1,254,708,000
FY 2009 estimated budget authority				1,255,920,000
Net change				1,212,000
	2008 Current Enacted Base		Change from Base	
CHANGES	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural research:				
a. Annualization of January 2008 pay increase		$68,498,000		$769,000
b. January FY 2009 pay increase		68,498,000		1,490,000
c. One less day of pay		68,498,000		(270,000)
d. Payment for centrally furnished services		30,684,000		460,000
e. Increased cost of laboratory supplies, materials, and other expenses		63,408,000		1,173,000
Subtotal				3,622,000
2. Research management and support:				
a. Annualization of January 2008 pay increase		$25,568,000		$287,000
b. January FY 2009 pay increase		25,568,000		556,000
c. One less day of pay		25,568,000		(101,000)
d. Payment for centrally furnished services		8,242,000		124,000
e. Increased cost of laboratory supplies, materials, and other expenses		23,022,000		413,000
Subtotal				1,279,000
Subtotal, Built-in				4,901,000

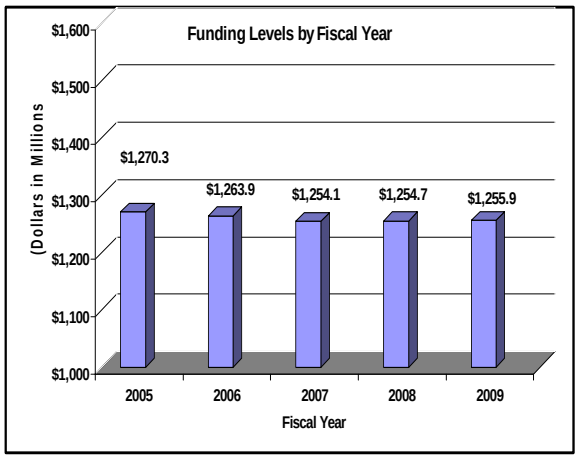
NATIONAL INSTITUTES OF HEALTH
Eunice Kennedy Shriver National Institute of Child Health and Human Development

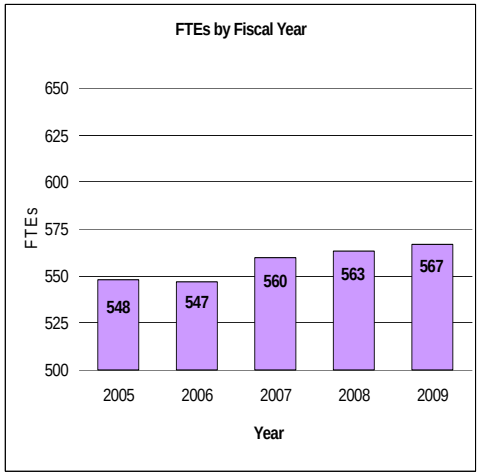
Summary of Changes--continued

CHANGES	2008 Current Enacted Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	1,254	$521,833,000	-63	-24,624,000
b. Competing	392	126,326,000	60	19,299,000
c. SBIR/STTR	100	29,061,000	0	0
Total	1,746	677,220,000	-3	-5,325,000
2. Research centers	50	63,739,000	0	0
3. Other research	533	113,246,000	0	0
4. Research training	872	38,354,000	0	246,000
5. Research and development contracts	294	142,727,000	0	3,000,000
Subtotal, extramural				-2,079,000
	FTEs		FTEs	
6. Intramural research	383	162,590,000	3	-1,183,000
7. Research management and support	180	56,832,000	1	-427,000
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program		1,254,708,000		-3,689,000
Total changes	563		4	1,212,000

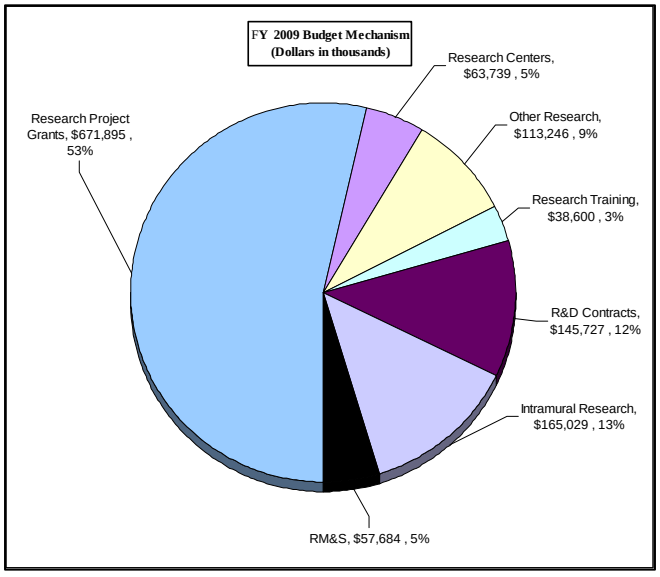
FY 2008 Budget Graphs

History of Budget Authority and FTEs:

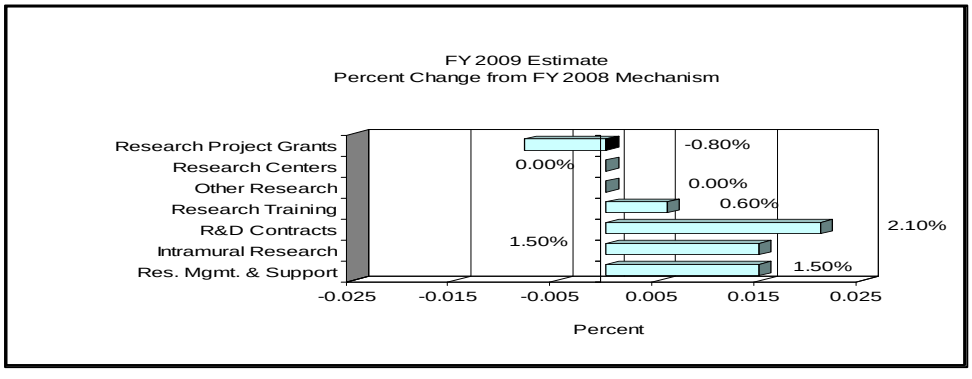




Distribution by Mechanism:



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 2007 Actual		FY 2008 Enacted		FY 2009 Estimate		Increase or Decrease	
FTEs	BA	FTEs	BA	FTEs	BA	FTEs	BA
560	$1,254,144,000	563	$1,254,708,000	567	$1,255,920,000	+4	$1,212,000

This document provides justification for the Fiscal Year (FY) 2009 activities of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), including HIV/AIDS activities. Details of the FY 2008 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.

Director's Overview

Institute Mission

This year, the National Institute of Child Health and Human Development is renamed the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), in recognition of her vision and dedication, not only in helping to establish the Institute, but also in leading efforts to advance the understanding of intellectual and developmental disabilities. The mission of the NICHD 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 to ensure the health, productivity, independence and well-being of all people through optimal rehabilitation

The course of discovery starts with knowing how cells, tissues and organ systems form and communicate and how they influence the processes associated with fetal development, pregnancy and birth, and childhood growth and maturation. This, in turn, influences our understanding of how these early processes affect health and performance into adulthood. The Institute's mission embodies the concepts of prevention, preemption, participation and personalization. Understanding the spectrum of normal developmental processes will allow researchers to predict why and how things can go wrong; clinicians to be pre-emptive by interceding early to prevent or mitigate adverse consequences of diseases or conditions; and patients to better understand and participate more fully in developing personalized treatment plans.

Recent Progress

The NICHD's research impacts people's daily lives, starting at the beginning: NICHD research has led to effective contraceptive and assisted reproductive technologies to support men and women as they manage their fertility. Each day, results from NICHD-supported research continue to ensure healthy pregnancies, deliveries and newborns. Because of improved understanding of the role of genetic and nutritional factors in fetal development, fewer babies are born with certain birth defects and life-long disabling conditions. Research on preterm birth led to the discovery that giving a form of progesterone to women with a history of preterm birth can reduce their risk of delivering a subsequent baby prematurely. Studies also showed that giving antenatal steroids to women in preterm labor can hasten lung maturation in their infants -- a finding that has dramatically reduced the incidence of neonatal respiratory distress syndrome, a potentially fatal condition. Because of these and other NICHD-supported research findings, premature infants are now more likely to survive with improved outcomes.

Advances in newborn screening have allowed physicians to identify some abnormalities, such as congenital hypothyroidism (CH), at birth and begin treatments immediately to prevent or mitigate adverse outcomes. Without treatment, an infant with CH will suffer irreparable brain damage, develop intellectual disabilities, and require a lifetime of special care. Data on normal developmental patterns has helped pediatricians, schools, and parents identify developmental delays early, getting children the help they need when it can be most effective. School children benefit from NICHD research that provides evidence on how children learn reading and math, informing curriculum development and helping children who would otherwise have difficulty learning. This type of research is especially critical for children for whom English is a second language and children with developmental disabilities. Furthermore, rehabilitation research has led to improved therapies for stroke victims, while evaluation of other common therapies, previously untested for their effectiveness, has improved the use of health care resources.

Future Directions

The NICHD regularly reviews and evaluates its programs and research priorities to ensure that it identifies and adapts to changing public health concerns, addresses newly emerging priorities, and takes advantage of emerging scientific opportunities and research tools. Strategic planning and program evaluation are routinely informed by outside scientific experts, advocates, professional organizations and community representatives. These efforts help lay the foundation for future research directions.

Similarly, the emergence of new scientific findings and health trends challenge conventional wisdom and point to new research needs. For instance in women's health, research has revealed the complexity of the biological processes underlying fertility, pregnancy, development, and aging. Given this and the dramatic increase in the number of older U.S. women, the NICHD will target research to help answer scientific questions about the best way to help women transition into menopause. The Institute will also focus on how to alleviate the dramatic increase in the personal health and financial burden associated with pelvic floor disorders (PFD) by attracting new

researchers to the field and by increasing the number of clinical studies designed to develop effective therapies. The increase in the number of pregnant women who are obese before conception has made it clear that we need to know more about the endocrine functions of adipose tissue and how excessive body fat can affect fertility and birth outcomes, another NICHD research priority in FY 2009.

As infertility treatments have become more available, some data suggest that infants conceived using such methods may be at greater risk for adverse outcomes, such as prematurity, low birth weight, childhood cancers and developmental disabilities, compared to children conceived naturally. There also appears to be a corresponding increase in maternal complications. Research is needed to identify the mechanisms that can lead to these adverse outcomes, and determine how to prevent them. Recognizing the dearth of information regarding the safety and effectiveness of drug therapies being used in pregnant women, the NICHD plans to focus research in obstetric pharmacology to ensure that drugs used to treat pregnant women are safe and appropriate. Building on its success with newborn screening, the NICHD will support research to develop the next generation of technologies needed to screen for an even greater number of conditions.

Despite over 50 clinical trials to date, no single drug has proven to significantly improve outcomes in traumatic brain injury (TBI) patients. Given the complexity of the damage to the brain and nervous system observed in TBI, the NICHD is encouraging researchers are now beginning to explore whether using a multi-drug “cocktail” might achieve better results. Also in the area of rehabilitation, the Institute sees the opportunity to develop prosthetic devices that can be directly attached to bone, eliminating the instability, discomfort and complications of current prosthetic sockets. Advances in nanotechnology and bioengineering may allow pylons to traverse the skin and soft tissues, into bone, without the risk of infection that has limited previous attempts at direct skeletal attachment of prosthetic devices.

Finally, to maintain progress in these and other key priority areas, the Institute will continue to recruit, train, and retain the most promising scientists through a number of innovative training and career development efforts.

Justification of FY 2009 Budget

Program Descriptions and Accomplishments

Overall Budget Policy

The NICHD’s research priorities are to support investigator-initiated research projects, new investigator research, career development and crucial infrastructure programs that enable both new and experienced investigators to conduct pre-clinical and clinical trials at established sites with experience in recruiting and conducting trials in specific, high-priority populations, including children, pregnant women, and individuals with disabling conditions. The Institute carefully balances the portfolio mix and utilizes the appropriate support mechanism to meet the requirements of the scientific program. The NICHD also supports systematic planning and evaluation activities to assess the Institute’s unique research, career development and training programs. The NICHD conducts program

reviews, with consultation and input from members of the NICHD Advisory Council and other outside experts, and uses the results to make decisions concerning future program directions and related funding. Intramural Research and Research Management and Support receive modest increases to help offset the cost of pay and other increases. The NICHD will continue to support new investigators and to maintain an adequate number of competing RPGs.

Center for Developmental Biology and Perinatal Medicine

The Center for Developmental Biology and Perinatal Medicine (CDBPM) supports a broad range of research to advance fundamental and clinical knowledge about maternal health and problems of child development. The CDBPM supports research on congenital and genetic disorders, as well as intellectual and other developmental disabilities such as Down syndrome, Fragile X, and autism. The Center also studies factors that affect maternal and fetal health during pregnancy, such as the causes and consequences of fetal growth restriction, preterm labor and birth, and stillbirth; and conditions affecting early life, such as respiratory distress syndrome and Sudden Infant Death Syndrome. The goals are to maximize early human development to prevent later disease and disability, and to improve diagnoses, therapy, and clinical care for disabling conditions that appear early in life.

Accomplishments for 2007 include: continuing leadership in newborn screening by encouraging research to develop therapies for screenable heritable conditions, and by assisting other countries in establishing newborn screening programs; collaborating to provide funding opportunities for research into the causes of, and therapies for primary immunodeficiency diseases; funding new grants studying spinal muscular atrophy (SMA); partnering in establishing the Autism Centers of Excellence (ACE) to capitalize on gains made through previous autism research efforts; and leading the development of an international stillbirth classification system necessary for uniformity in reporting research results. The Center also led a trans-NIH working group to develop a plan to guide NIH research investments in Down syndrome for the next decade.

Budget Policy

A total of $302.4 million will support the FY 2009 NICHD program in Developmental Biology and Perinatal Medicine, a .2% decrease from the FY 2008 level. The program will continue its strong support for multidisciplinary research in genetic disorders, with an emphasis on understanding how gene dosage and modifier genes affect the severity of birth defects. The program will also maintain a strong focus on maternal and fetal health and continue support of basic, translational, and clinical research on intellectual and developmental disabilities. Research priorities for FY 2009 include a partial renewal (at current funding levels) of the Intellectual and Developmental Disabilities Research Centers, which form a strong infrastructure for multidisciplinary collaborations among leading scientists in neuroscience, developmental biology, genetics, and other fields. In addition, the program will provide an estimated $2.0 million to develop new technologies that can be used to expand the number of conditions that can be detected through newborn screening. The resulting tools will make it possible to expand the number and types of genetic conditions that doctors and nurses can identify at birth,

allowing for early prevention and treatment. Another priority for the program is to enhance developmental biology research training at the undergraduate level. Increasing students' exposure to this field, especially at undergraduate and minority institutions, will provide a larger future pool of researchers to study the causes and treatments of birth defects. The program will also continue to support two research centers on muscular dystrophy and to collaborate with the NIH Office of Rare Diseases in support of the Rare Disease Cooperative Research Centers.
As several current initiatives reach the end of their funding cycle, the Institute will review their funding levels and make the necessary adjustments to take advantage of these emerging scientific opportunities and address growing public health needs.

Portrait of a Program: Down Syndrome

FY 2008 Level: $8.6 million
FY 2009 Level: $9.7 million
Change: 1.1 million

Down syndrome is the most common cause of mild to moderate intellectual disability and occurs in 1 out of 800 births in the United States. Most frequently, Down syndrome results from an extra copy of chromosome 21 in the body's cells, usually from the mother, and the chances of giving birth to a baby with Down syndrome increase as women age. For over 40 years, the NIH has supported research relating to the causes and consequences of Down syndrome, and significant progress has been made toward understanding the condition. Ongoing studies include wide-ranging research to better understand the prevalence of dementia in adults with Down syndrome, why children with Down syndrome are significantly more prone to childhood leukemias, and what genes may contribute to heart malformations in individuals with Down syndrome. New developments, however, such as a greatly increased lifespan for some individuals with Down syndrome, and a widening disparity between the longevity of whites with Down syndrome and other racial and ethnic minorities, warrant a reinvigorated and coordinated NIH research effort.

In October 2007, the NIH Research Plan for Down Syndrome was published, which outlines current research activities across the NIH and lays out immediate and longer term plans for expanded and new efforts over the next ten years. The plan was drafted by the trans-NIH Down Syndrome Working Group, headed by the NICHD, following a year of preparation and gathering input from the scientific community outside of the NIH and key organizations that represent researchers in the area and individuals with Down syndrome and their families. For example, a pressing concern facing families is managing the many health and care issues of older individuals with Down syndrome as they themselves are aging. The research plan will provide the NIH, and its member Institutes and Centers, with guidelines for prioritizing and coordinating future research related to Down syndrome, whether basic, translational, or clinical. Based on the plan, in FY 2009, the NIH will solicit applications to conduct research on research priorities, including a focus on maximizing and maintaining cognitive function in individuals with Down syndrome, particularly during life transitions in adolescence and adulthood. The NICHD is dedicating $1.1 million to a Request for Applications related to Down syndrome. The object of this solicitation is to create a more substantive base of evidence to better meet the medical, psychosocial and psychiatric needs of a growing population of adults with Down syndrome.

Center for Research for Mothers and Children

The Center for Research for Mothers and Children (CRMC) supports a vast array of maternal and child health research, including: factors affecting growth and development; gestational diabetes; antecedents of adult diseases; obesity and overweight; growth

retardation; congenital and infectious diseases, including HIV/AIDS in children, adolescents and women. The CRMC 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 the effects and effectiveness of pharmaceuticals on maternal and child health.

Accomplishments for 2007 include: supporting a new collaboration to explore environmental and family influences on childhood obesity, and grants to develop and evaluate school-based obesity prevention interventions; establishing a cooperative research network to reduce the incidence of low blood sugar and improve management of type 1 diabetes in children and young adults; and expanding research into learning disabilities by funding new studies to identify factors that influence mathematical learning and develop effective interventions. The CRMC also conducted an independent review of the maternal, adolescent, and child AIDS program to guide future research directions; funded new grants to evaluate the impact of new nutritional guidelines on treatment of people affected by HIV/AIDS; and continued support for a large Adolescent Medicine Trials Network, which serves a unique, high-risk population. Under the Best Pharmaceuticals for Children Act, the Center also launched a large clinical trial to evaluate and compare the safety and efficacy of two drugs currently being used to treat prolonged or repeated seizures in children that can lead to brain damage.

Portrait of a Program: Infertility Treatment, Child Growth and Development

FY 2008 Level: $6.2 million
FY 2009 Level: $6.3 million
Change: $0.1 million

To enhance its research to understand and develop treatments for infertility, the NICHD is investigating if and how current infertility treatments might affect future generations. Are children conceived through infertility treatments at increased risk for any illnesses or disorders, either at birth or as they grow older? The simple answer is that researchers aren't sure. Some studies suggest that infants conceived through infertility treatments are more likely to be born too small or too early, contributing to the nation's growing prematurity rate. Such early delivery and other factors related to infertility treatment are also thought to potentially increase the risk of children being diagnosed with developmental disabilities.

For scientists, finding the answers to these questions poses a difficult and complex problem. Researchers must be able to discern, for instance, if such increased risks are due to the infertility treatments, or to the fact that women who require them to get pregnant are often older than other women who don't require such treatments to get pregnant. (Older mothers are at greater risk for giving birth prematurely and for having an infant who is small for gestational age.) Determining the longer-term effect of infertility treatment on the resulting children is also difficult without biomarkers that can measure functioning very early in life.

Now, NICHD researchers are poised to find answers. Scientists will track the health of 1500 children conceived through infertility treatments and compare their development to that of 4500 children conceived naturally. The researchers will follow the children until their third birthday, and then reassess the need to do further studies as the children age. At the same time, the researchers will develop new biomarkers of very early immune functioning and link these to genetic and functional outcomes. Because some animal studies suggest that subtle changes to the egg shortly before and after fertilization might influence later development, scientists are especially interested in finding out whether treatments in which the egg is fertilized outside the body increase the risk of illnesses or disorders more than those where the egg is fertilized inside the uterus.

NICHD-sponsored research in reproduction has fostered major breakthroughs in treating infertility, allowing couples to overcome significant health problems and technological hurdles to start the families they want. As many as 3 percent of U.S. children are conceived through infertility treatments each year, and these numbers are likely to grow in the future. Research targeting various infertility treatments through the early windows of development will tell us if the increasing numbers of children conceived through these treatments face any future health problems, and if so, how to prevent them.

Budget Policy

The budget for the Research for Mothers and Children program is estimated to be $336.8 million in FY 2009, a .2% decrease from the FY 2008 level. This funding supports ongoing programs such as the Pediatric, Adolescent, and Maternal AIDS program; the Pediatric Pharmacology Research Units; and the Global Network for Women's and Children's Health Research. In the endocrinology and nutrition research area, the NICHD plans to build on previously-funded research showing that oligosaccharides, a non-nutritive component of breast milk, have important antimicrobial properties. An important goal of this $2.5 million research initiative is to develop personalized therapy based on specifically tailored oligosaccharides to treat certain kinds of bacterial or viral infection. The program will also continue its collaborations with

the National Institute of Diabetes and Digestive and Kidney Diseases to study diabetes in children. As several current initiatives reach the end of their funding cycle, the Institute will review their funding levels and make the necessary adjustments to take advantage of emerging scientific opportunities and address growing public health needs.

Center for Population Research

The Center for Population Research (CPR) supports a diverse range of population studies to understand reproductive health and biology with the goal of alleviating human infertility and reproductive disorders. The Center supports development of a variety of contraceptive methods that are safe and effective, inexpensive and readily available, preferably reversible, and meet the diverse needs of women and men throughout their reproductive lives, including the need to prevent the spread of sexually transmitted diseases. The Center's research also includes behavioral and social science research to understand the consequences of changes in population size, composition and distribution; factors that affect family formation, functioning, stability, and influence on child well-being; and the antecedents and consequences of migration and immigration.

Accomplishments for 2007 include: completing an independent review of the Center's demographic and behavioral research program and reproductive sciences program to guide future research directions; establishing research priorities for fertility preservation; and renewing funding for a multi-center program to help translate basic research findings into clinical investigations that address important problems in reproductive medicine, including infertility. The Center also expanded the portfolio of Fragile X research to study the association between premature ovarian failure and Fragile X pre-mutation carriers and created new funding opportunities to study chronic pelvic pain, including vulvodynia.

Budget Policy

The budget for the population research program is estimated at $317.9 million for FY 2009, a .2% decrease from the FY 2008 level. This funding supports a wide range of ongoing population research programs in reproductive health and biology, including basic and translational research on uterine fibroids, pregnancy prevention, and demographic factors underlying population changes. For example, the program will seek to stimulate new research regarding the endocrine functions of adipose (fatty) tissue, specifically its role in regulating reproduction, and its possible role in the etiology of diseases and disorders that impact fertility. Also, the program plans to devote $1.5 million to projects using multi-disciplinary teams of researchers to examine potential adverse outcomes on the health and development of children, from birth through three years of age, who were exposed to infertility treatment. Other research priorities for FY 2009 include funding for specialized centers in reproduction and infertility research. These highly productive centers provide an arena for multidisciplinary interactions among basic, clinical and translational scientists, accelerating the transfer of knowledge between the laboratory and clinic on a wide variety of topics including those targeting women's health, reproductive, and public health concerns. This will complement additional research to develop new approaches to male contraception. In FY 2009, the

program will provide $2.4 million in AIDS funding to develop and test new AIDS prevention programs for preadolescents, based on previous research that identified key factors that predispose youth to risky behavior and $3.4 million to strengthen behavioral and social sciences research on HIV risk and prevention among youth. The NICHD is reevaluating the HIV research investment in natural history and epidemiology to support these new initiatives. Recognizing the great public health need and with encouragement from Congress, the NICHD has made research related to female pelvic floor disorders a high priority. Despite previous efforts, critical limitations still exist in understanding the basic biological abnormalities that lead to these conditions, which is necessary for developing effective treatments. Therefore, in FY 2009, the program will support collaborations between basic scientists and clinical researchers to attract more basic scientists to the field of pelvic floor disorders. This initiative should help further treatments that could affect the health of millions of women. As several current initiatives reach the end of their funding cycle, the Institute will review their funding levels and make the necessary adjustments to take advantage of emerging scientific opportunities and address growing public health needs.

Portrait of a Program: Work, Family, Health and Well-Being Initiative

FY 2008 Level: $1.7 million
FY 2009 Level: $4.0 million
Change: $2.3 million

Long hours, a heavy work load, and job stress can contribute to health problems such as anxiety, depression and heart disease. As parents struggle to balance work and home life, children and families may suffer. Children may receive less parental supervision, and get less help with homework. Children of workers who don't receive paid sick leave may miss out on doctor's appointments. Not only might they forego important checkups, but children sick with a cold or flu who attend school because their parents can't get time off may get their classmates sick as well. Over time, these individual consequences may have cumulative and ongoing effects on children and families, and a pervasive and significant impact on overall child health and well-being.

Recognizing the financial, personal, and health costs of workplace stress, many major corporations have implemented programs to assist their employees in balancing work and family responsibilities. Flexible scheduling or other supportive policies are clearly popular, and may have more important benefits for children's and families' health. For example, such policies may allow workers to better supervise children after school, potentially reducing risky behaviors; may encourage breastfeeding; and may reduce stress and associated health complications for both parents and children. However, little scientific evidence exists to determine what types of employer practices and programs have the most significant benefits for the health of children and families.

The NIH, working with the Centers for Disease Control and Prevention, has developed a unique partnership with major corporations and leading universities to test the effects of work-life balance programs in real-world settings. Researchers in the network have partnered with corporate employers to develop an intervention to alleviate the many problems employees encounter when career and family demands conflict. Along with providing for flexible scheduling, the intervention provides training for supervisors to help them deal more effectively with their employees' work family scheduling conflicts. The researchers will evaluate the program for its impact on health and other outcomes using a clinical trial methodology. Similar units within a corporation will be placed into two groups—one group will receive the intervention and the other will continue to work under the company's current policies. Researchers will measure program outcomes by comparing data from employees and their families. Outcome measures include biomarkers such as cortisol and blood pressure, as well as reports from parents and children. The results of this study—as well as the network's other research on existing workplace programs—will be disseminated widely to help develop and implement work-life balance programs that can contribute to the health and well-being of children and families throughout the nation.

National Center for Medical Rehabilitation Research

The National Center for Medical Rehabilitation Research (NCMRR) aims to enhance the health, productivity, independence, and quality-of-life of people with disabilities by supporting a broad range of research including: the underlying biology of injury and disability and the body's normal mechanisms of recovery and adaptation; spinal cord and traumatic brain injuries and stroke; childhood disabilities and long-term outcomes for survivors of trauma, congenital anomalies, harmful deprivation of oxygen in newborns, infections and septic shock -- a form of severe infection that may lead to very low blood pressure, organ failure, and death. The NCMRR supports the development of equipment, devices and treatments to improve mobility and enhance an individual's capacity to function in his/her environment.

Accomplishments for 2007 include: launching a national network to support training and career development of allied health professionals, including physical and occupational therapists interested in research careers in rehabilitative medicine; funding new Bioengineering Research Partnership grants to help integrate the technical and biomedical principles needed to develop innovative assistive technologies and devices; creating a new research agenda to promote the development of creative rehabilitation approaches to enhance the recovery, adaptation and continued long-term functional progress of persons with disabilities; and initiating a new clinical trial to determine if treating head injured patients with citicoline -- a neuro-protective drug that has shown promise in treating stroke victims -- will minimize the cascade of neurological damage that follows a brain injury and improve recovery.

Emerging priorities for the medical rehabilitation research program include developing medical nanoparticles that are engineered to target delivery of drugs or other therapeutic agents directly to muscle and skeletal tissues, and community-based research partnerships to develop ways to test and measure the effects of clinical interventions in day-to-day life, away from rigorously-controlled laboratory conditions.

Budget Policy

A total of $76.2 million, a decrease of .2% over FY 2008, will support the NICHD Medical Rehabilitation Research program. This funding will maintain ongoing research efforts in traumatic brain injury (TBI), spinal cord injury, pediatric critical care, and rehabilitation injury. It will also include targeting research to test the promise of multi-drug approaches to treating TBI. Because severe TBI is a massive, crude insult to the nervous system, it is probably unrealistic to hope for a single “magic bullet” drug that can rescue damaged neurons. However, some commonly-available agents have shown promise in animal models. Data from these studies will supply the basis to launch clinical trials in humans using these optimal combinations. Taking advantage of recent advances in nanotechnology and bioengineering, the program will enhance research in the area of osteo-integration, a method of attaching prosthetic devices directly to bone. Such a device would enable patients to eliminate or avoid the pain and discomfort associated with the sockets currently used to indirectly attach artificial limbs to the body. This is a growing concern for all patients using prosthetic devices, including disabled veterans and the growing number of individuals at risk for amputations due to diabetes. As several current initiatives reach the end of their funding cycle, the Institute will review their funding levels and make the necessary adjustments to take advantage of emerging scientific opportunities and address growing public health needs.

Intramural Research

NICHD intramural researchers conduct interdisciplinary and interactive research to answer basic biomedical research questions and solve difficult clinical problems in human development. This includes research in genetics, genomics (the study of how genes function) and epigenetics (DNA-associated, heritable switches that can affect gene function) and how these influence normal and abnormal development. The

intramural program also studies the basic biophysical mechanisms underlying cell and tissue function; early development, beginning with how cells signal within themselves or each other; and the prevention and treatment of conditions of childhood development and female reproduction, through innovative diagnostics, therapies and immunizations. Intramural researchers also develop innovative tools necessary for conducting increasingly sophisticated biomedical research at the cellular and subcellular levels.

In 2007, the intramural program completed its reorganization to enhance efficiency and collaborations between clinical and "bench" scientists and to stimulate closer interaction between scientists with diverse backgrounds. This included creating a new program focusing on women's health issues, such as ovarian function and processes that lead to successful fertilization and infertility treatment. To further trans-NIH collaborations and facilitate clinical research across the agency, the NICHD intramural clinical trials database has been made available to intramural researchers in other Institutes.

Budget Policy: The NICHD FY 2009 Intramural research program budget of $165.0 million, an increase of 1.5%, supports the Institute's in-house research program. The Intramural research program has 210 research projects, over half of which (107) include human subjects. Support for these projects includes the personnel costs of the research operation and the operational support for such items as equipment, supplies, and related bioinformatics. In FY 2009, the NICHD Intramural research program will continue a lead role in implementing the trans-NIH initiative in developmental epigenetics. It will also continue to strengthen its research on fibroids and initiate a new research program on the normal course of labor and on methods to prevent preterm birth.

Research Management and Support (RMS): NICHD RMS activities include technical and administrative functions required of the Institute's research investments. The NICHD supports 2326 research grants, 103 training awards and 294 Research and Development contracts. This includes over 2,230 extramural research projects involving human subjects; 376 of these projects involve clinical trials. The NICHD regularly reviews administrative functions to identify ways to streamline activities and save costs. The NICHD is evaluating the effectiveness of teleconferencing for use in scientific reviews. The Institute expects that teleconferencing reviews will produce significant savings in travel costs and overall time for reviewers and NICHD staff. The RMS budget also supports the Institute's international research activities and the outreach and public education activities in the prevention of SIDS, obesity, and osteoporosis. As part of these activities, the NICHD will support a new initiative, working with pharmacists, to disseminate information on reducing SIDS risk, recognizing the special communications and relationships that these professionals have with the public.

Budget Policy: The FY 2009 NICHD RMS activities provide administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of research grants, training awards and research and development contracts. RMS functions also encompass strategic planning, coordination, and evaluation of the Institute's programs, regulatory compliance, international coordination, and liaison with other Federal

agencies, Congress, and the public. The NICHD RMS budget request of $57.7 million is a 1.5% change from the FY 2008 level.

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Eunice Kennedy Shriver National Institute of Child Health and Human Development

Budget Authority by Object

	FY 2008 Enacted	FY 2009 Estimate	Increase or Decrease
Total compensable workyears:			
Full-time employment	563	567	4
Full-time equivalent of overtime and holiday hours	2	2	0
Average ES salary	$165,683	$171,147	$5,464
Average GM/GS grade	11.8	11.9	0.0
Average GM/GS salary	$89,085	$92,033	$2,948
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$76,764	$78,433	$1,669
Average salary of ungraded positions	133,065	137,453	4,388

OBJECT CLASSES	FY 2008 Estimate	FY 2009 Estimate	Increase or Decrease
Personnel Compensation:			
11.1 Full-time permanent	$37,148,000	$39,210,000	$2,062,000
11.3 Other than full-time permanent	18,349,000	19,022,000	673,000
11.5 Other personnel compensation	1,789,000	1,855,000	66,000
11.7 Military personnel	2,307,000	2,392,000	85,000
11.8 Special personnel services payments	16,063,000	16,653,000	590,000
Total, Personnel Compensation	**75,656,000**	**79,132,000**	**3,476,000**
12.0 Personnel benefits	16,385,000	17,284,000	899,000
12.2 Military personnel benefits	2,025,000	2,099,000	74,000
13.0 Benefits for former personnel	0	0	0
Subtotal, Pay Costs	**94,066,000**	**98,515,000**	**4,449,000**
21.0 Travel and transportation of persons	2,460,000	2,214,000	(246,000)
22.0 Transportation of things	405,000	405,000	0
23.1 Rental payments to GSA	0	0	0
23.2 Rental payments to others	65,000	65,000	0
23.3 Communications, utilities and miscellaneous charges	1,396,000	1,396,000	0
24.0 Printing and reproduction	775,000	736,000	(39,000)
25.1 Consulting services	1,455,000	1,455,000	0
25.2 Other services	11,324,000	11,324,000	0
25.3 Purchase of goods and services from government accounts	136,713,000	138,764,000	2,051,000
25.4 Operation and maintenance of facilities	470,000	470,000	0
25.5 Research and development contracts	96,797,000	97,352,000	555,000
25.6 Medical care	920,000	920,000	0
25.7 Operation and maintenance of equipment	2,293,000	2,293,000	0
25.8 Subsistence and support of persons	0	0	0
25.0 Subtotal, Other Contractual Services	**249,972,000**	**252,578,000**	**2,606,000**
26.0 Supplies and materials	9,578,000	9,099,000	(479,000)
31.0 Equipment	3,400,000	3,400,000	0
32.0 Land and structures	0	0	0
33.0 Investments and loans	0	0	0
41.0 Grants, subsidies and contributions	892,559,000	887,480,000	(5,079,000)
42.0 Insurance claims and indemnities	4,000	4,000	0
43.0 Interest and dividends	28,000	28,000	0
44.0 Refunds	0	0	0
Subtotal, Non-Pay Costs	**1,160,642,000**	**1,157,405,000**	**(3,237,000)**
Total Budget Authority by Object	**1,254,708,000**	**1,255,920,000**	**1,212,000**

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

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

Salaries and Expenses

OBJECT CLASSES	FY 2008 Enacted	FY 2009 Estimate	Increase or Decrease
Personnel Compensation:			
Full-time permanent (11.1)	$37,148,000	$39,210,000	$2,062,000
Other than full-time permanent (11.3)	18,349,000	19,022,000	673,000
Other personnel compensation (11.5)	1,789,000	1,855,000	66,000
Military personnel (11.7)	2,307,000	2,392,000	85,000
Special personnel services payments (11.8)	16,063,000	16,653,000	590,000
Total Personnel Compensation (11.9)	**75,656,000**	**79,132,000**	**3,476,000**
Civilian personnel benefits (12.1)	16,385,000	17,284,000	899,000
Military personnel benefits (12.2)	2,025,000	2,099,000	74,000
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	**94,066,000**	**98,515,000**	**4,449,000**
Travel (21.0)	2,460,000	2,214,000	(246,000)
Transportation of things (22.0)	405,000	405,000	0
Rental payments to others (23.2)	65,000	65,000	0
Communications, utilities and miscellaneous charges (23.3)	1,396,000	1,396,000	0
Printing and reproduction (24.0)	775,000	736,000	(39,000)
Other Contractual Services:			
Advisory and assistance services (25.1)	1,455,000	1,455,000	0
Other services (25.2)	11,324,000	11,324,000	0
Purchases from government accounts (25.3)	71,676,000	72,751,000	1,075,000
Operation and maintenance of facilities (25.4)	470,000	470,000	0
Operation and maintenance of equipment (25.7	2,293,000	2,293,000	0
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	**87,218,000**	**88,293,000**	**1,075,000**
Supplies and materials (26.0)	9,578,000	9,099,000	(479,000)
Subtotal, Non-Pay Costs	101,897,000	102,208,000	311,000
Total, Administrative Costs	**195,963,000**	**200,723,000**	**4,760,000**

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Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2007 Amount Authorized	FY 2008 Enacted	2008 Amount Authorized	FY 2009 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite	$1,254,708,000	Indefinite	$1,255,920,000
Eunice Kennedy Shriver National Institute of Child Health and Human Development	Section 402(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				1,254,708,000		1,255,920,000

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

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation 1/
2000	694,114,000 2/	817,470,000	848,044,000	862,884,000
Rescission				(4,593,000)
2001	810,501,000 2/	984,300,000	986,069,000	976,455,000
Rescission				(486,000)
2002	1,096,650,000 2/	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
2008	1,264,946,000	1,273,863,000	1,282,231,000	1,254,708,000
Rescission				(22,309,000)
2009	1,255,920,000			

1/ Reflects enacted supplementals, rescissions, and reappropriations.
2/ Excludes funds for HIV/AIDS research activities consolidated in the NIH Office of AIDS Research.

NATIONAL INSTITUTES OF HEALTH

EKS National Institute of Child Health and Human Development

Details of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Office of the Director	94	94	94
Center for Developmental Biology and Perinatal Medicine	21	21	22
Center for Population Research	24	24	24
Center for Research for Mothers and Children	31	31	31
National Center for Medical Rehabilitation Research	10	10	10
Division of Intramural Research	380	383	386
Total	560	563	567
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research			
FTEs supported by funds from Cooperative Research and Development Agreements	(1)	(1)	(1)

FISCAL YEAR	Average GM/GS Grade
2005	11.8
2006	11.6
2007	11.7
2008	11.8
2009	11.9

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EKS National Institute of Child Health and Human Development

Detail of Positions

GRADE	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Total, ES Positions	4	4	4
Total, ES Salary	$635,155	656,543	678,652
GM/GS-15	46	47	47
GM/GS-14	70	70	71
GM/GS-13	46	47	48
GS-12	48	48	50
GS-11	40	40	40
GS-10	7	7	7
GS-9	28	28	28
GS-8	18	18	18
GS-7	18	18	18
GS-6	4	4	4
GS-5	4	4	4
GS-4	3	3	3
GS-3	0	0	0
GS-2	0		0
GS-1	1	1	1
Subtotal	333	335	339
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	15	16	16
Senior Grade	1	1	1
Full Grade	7	7	7
Senior Assistant Grade	4	4	4
Assistant Grade	1	1	1
Subtotal	28	29	29
Ungraded	234	234	234
Total permanent positions	421	424	428
Total positions, end of year	599	602	606
Total full-time equivalent (FTE) employment, end of year	560	563	567
Average ES salary	158,788	165,683	171,147
Average GM/GS grade	11.7	11.8	11.9
Average GM/GS salary	85,387	89,085	92,033

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

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New Positions Requested

	FY 2009		
	Grade	Number	Annual Salary
Intramural Research			
Staff Scientist/DIR	GS 12	1	$80,580
Research Management & Support			
Health Scientist Administrator	GS 12	1	80,580
Health Scientist Administrator	GS 13	1	95,820
Human Subjects Officer	GS 14	1	113,230
Total Requested		4	