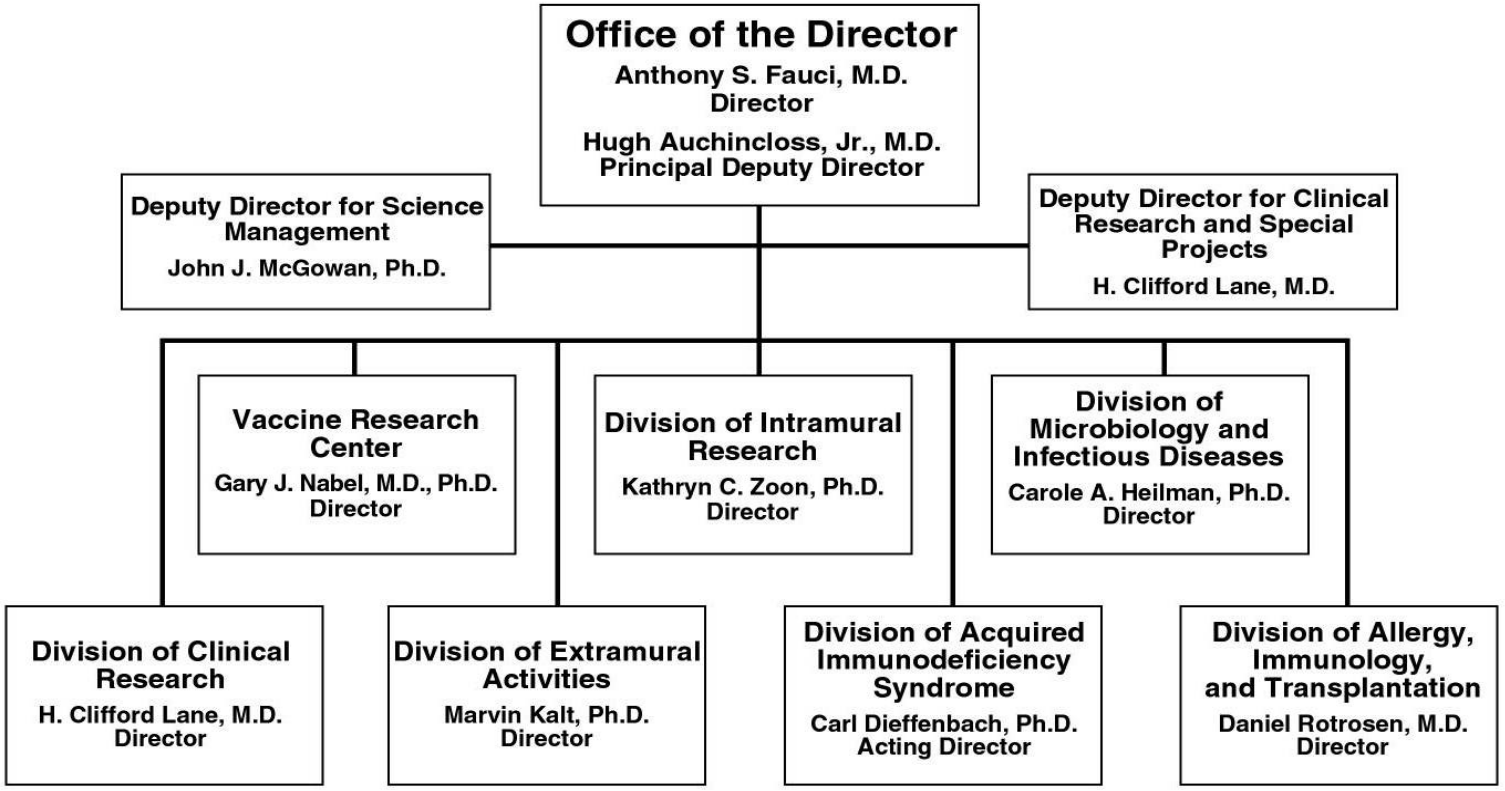
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases

National Institutes of Health
National Institute of Allergy and Infectious Diseases
Organizational Structure



FY 2009 Proposed Appropriation Language

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases
(Including Transfer of Funds)

For carrying out section 301 and title IV of the Public Health Service Act with respect to Allergy and infectious diseases, ~~[$4,641,746,000]~~ **$4,568,778,000***: Provided*, That $300,000,000 may be made available to International Assistance Programs "Global Fund to Fight HIV/AIDS, Malaria, and Tuberculosis", to remain available until expended: ~~Provided further, That such sums obligated in fiscal years 2003 through 2007 for extramural facilities construction projects are to remain available until expended for disbursement, with prior notification of such projects to the House of Representatives and Senate Committees on Appropriations~~.

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases

Language Analysis

Language Provision	Explanation
~~**Provided further, That such sums obligated in fiscal years 2003 through 2007 for extramural facilities construction projects are to remain available until expended for disbursement, with prior notification of such projects to the House of Representatives and Senate Committees on Appropriations**~~	NIAID received the authority in the FY 2008 Omnibus Appropriation to transfer the unspent funds for the construction of extramural facilities to a no-year account and does not need this language to continue in the FY 2009 Appropriation.

National Institutes of Health
National Institute of Allergy and Infectious Diseases

Amounts Available for Obligation 1/

Source of Funding	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Appropriation	$4,414,801,000	$4,641,746,000	$4,568,778,000
Pay cost add-on	2,407,000	0	0
Rescission	0	-81,091,000	0
Subtotal, adjusted appropriation	4,417,208,000	4,560,655,000	4,568,778,000
Real transfer under Director's one-percent transfer authority (GEI)	-4,674,000	0	0
Real transfer to the Global Fund to fight HIV/AIDS, Malaria and Tuberculosis	-99,000,000	0	0
Real transfer to the Office of Public Health Emergency Preparedness	-49,500,000	0	0
Comparative transfer to NIBIB	-211,000	0	0
Comparative transfer to OD	-96,000	0	0
Comparative transfer to NCRR	-947,000	0	0
Comparative transfers to the Office of the Assistant Secretary for Admin. and Mgmt. and to the Office of the Assistant Secretary for Public Affairs	-9,000	0	0
Comparative transfer to (specify)			
Comparative transfer under Director's one-percent transfer authority (GEI)	4,674,000	0	0
Comparative transfer to the Global Fund to fight HIV/AIDS, Malaria and Tuberculosis	99,000,000	0	0
Subtotal, adjusted budget authority	4,366,445,000	4,560,655,000	4,568,778,000
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	4,366,445,000	4,560,655,000	4,568,778,000
Unobligated balance lapsing	0	0	0
Total obligations	4,366,445,000	4,560,655,000	4,568,778,000

1/ Excludes the following amounts for reimbursable activities carried out by this account:
FY 2007 - $7,456,164 FY 2008 - $8,920,000 FY 2009 - $10,198,000
Excludes $11,512,759 in FY 2008 and $15,714,045 in FY 2009 for royalties.

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases

(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	3,073	$1,700,099	3,043	$1,711,226	3,227	$1,784,054	184	$72,828
Administrative supplements	(71)	41,138	(97)	45,408	(55)	41,138	(-42)	-4,270
Competing:								
Renewal	238	105,059	252	109,203	225	97,672	(27)	-11,531
New	880	396,749	1,064	396,796	960	358,287	(104)	-38,509
Supplements	9	2,065	7	1,635	7	1,572	0	-63
Subtotal, competing	1,127	503,873	1,323	507,634	1,192	457,531	(131)	-50,103
Subtotal, RPGs	4,200	2,245,110	4,366	2,264,268	4,419	2,282,723	53	18,455
SBIR/STTR	222	100,351	232	105,621	232	105,621	0	0
Subtotal, RPGs	4,422	2,345,461	4,598	2,369,889	4,651	2,388,344	53	18,455
Research Centers:								
Specialized/comprehensive	33	130,768	32	127,109	32	117,109	0	-10,000
Clinical research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative medicine	2	841	2	821	2	821	0	0
Research Centers in Minority Institutions	0	899	0	872	0	872	0	0
Subtotal, Centers	35	132,508	34	128,802	34	118,802	0	-10,000
Other Research:								
Research careers	314	38,126	306	37,965	306	37,965	0	0
Cancer education	0	0	0	0	0	0	0	0
Cooperative clinical research	0	0	0	0	0	0	0	0
Biomedical research support	0	0	0	0	0	0	0	0
Minority biomedical research support	0	1,030	0	998	0	998	0	0
Other	88	9,974	87	9,734	87	9,734	0	0
Subtotal, Other Research	402	49,130	393	48,697	393	48,697	0	0
Total Research Grants	4,859	2,527,099	5,025	2,547,388	5,078	2,555,843	53	8,455
Research Training:	FTTPs		FTTPs		FTTPs			
Individual awards	159	7,340	159	7,334	159	7,392	0	58
Institutional awards	1,043	48,300	1,029	47,649	1,029	47,982	0	333
Total, Training	1,202	55,640	1,188	54,983	1,188	55,374	0	391
Research & development contracts	252	1,010,002	254	1,213,962	254	1,202,335	0	-11,627
(SBIR/STTR)	(2)	(230)	(2)	(224)	(2)	(224)	(0)	(0)
	FTEs		FTEs		FTEs		FTEs	
Intramural research	789	542,176	805	523,566	817	531,159	12	7,593
Research management and support	818	217,428	832	220,756	832	224,067	0	3,311
Construction		14,100		0		0		0
Buildings and Facilities		0		0		0		0
Total, NIAID	1,607	4,366,445	1,637	4,560,655	1,649	4,568,778	12	8,123

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

NATIONAL INSTITUTES OF HEALTH
National Institute of Allergy and Infectious Diseases
BA 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:														
HIV/AIDS		1,234,503		1,260,811		1,261,889		1,263,252		1,270,509		1,269,557		-952
Biodefense and Emerging Infectious Diseases		1,342,780		1,313,626		1,258,220		1,259,970		1,262,230		1,254,701		-7,529
Infectious and Immunologic Diseases		1,098,777		1,084,341		1,083,005		1,083,619		1,283,594		1,289,294		5,700
Subtotal, Extramural		3,676,060		3,658,778		3,603,114		3,606,841		3,816,333		3,813,552		-2,781
Intramural research	780	527,708	793	540,118	789	542,403	789	542,176	805	523,566	817	531,159	12	7,593
Res. management & support	769	199,073	796	212,872	818	217,517	818	217,428	832	220,756	832	224,067	0	3,311
TOTAL	1,549	4,402,841	1,589	4,411,768	1,607	4,363,034	1,607	4,366,445	1,637	4,560,655	1,649	4,568,778	12	8,123

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research
Includes the Global Fund to Fight HIV/AIDS, Tuberculosis, and Malaria

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 NIAID, which is $8.123 million greater than the FY 2008 Estimate, for a total of $4,568,778,000.

Research Project Grants (+$18.5 million, total $2.4 billion): NIAID will support a total of 4,651 Research Project Grant (RPG) awards in FY 2009. Noncompeting RPGs will increase by 184 awards and $72.8 million. Competing RPGs will decrease by 131 awards and $50.1 million. The NIH funding policy for FY 2009 RPGs includes no inflationary increases for noncompeting awards and no increase in the average cost of competing awards. NIAID will continue to support new investigators and maintain an adequate number of competing RPGs.

Research Centers (-$10.0 million; total $118.8 million): NIAID will decrease support in research centers to help maintain a steady level of unsolicited RPGs including support for first-time investigators.

Research and Development Contracts (-$11.6 million; total $1.2 billion): NIAID will decrease support in research contracts to help maintain a steady level of unsolicited RPGs including support for first-time investigators and to partially offset the expected increased operating costs of the new biodefense biocontainment laboratories.

Global Fund to Fight HIV/AIDS, Malaria, and Tuberculosis (+$5.2 million; total $300.0 million): NIAID will increase its contribution to the International Assistance Program ‘‘Global Fund to Fight HIV/AIDS, Malaria, and Tuberculosis’’ in FY 2009.

Biodefense and Emerging Infectious Diseases (-$7.5M; total $1.3 billion): NIAID will realign funds within its biodefense and emerging infectious diseases research portfolio from R&D contracts to the intramural research program to partially offset the expected increase operating costs of the new biocontainment laboratories coming online at Fort Detrick, MD and the Rocky Mountain Laboratories in Hamilton, MT.

Infectious and Immunologic Diseases (+$5.7M; total $1.3 billion): NIAID will increase its contribution by $5.2 million to the International Assistance Program ‘‘Global Fund to Fight HIV/AIDS, Malaria, and Tuberculosis’’ in FY 2009.

NATIONAL INSTITUTES OF HEALTH
National Institute of Allergy and Infectious Diseases
Summary of Changes

FY 2008 enacted				$4,560,655,000
FY 2009 estimated budget authority				4,568,778,000
Net change				8,123,000
	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		$523,566,000		$1,465,000
b. January FY 2009 pay increase		523,566,000		2,870,000
c. One less day of pay		523,566,000		(500,000)
d. Payment for centrally furnished services		0		1,649,000
e. Increased cost of laboratory supplies, materials, and other expenses		0		5,653,000
Subtotal				11,137,000
2. Research management and support:				
a. Annualization of January 2008 pay increase		$220,756,000		$1,158,000
b. January FY 2009 pay increase		220,756,000		2,270,000
c. One less day of pay		220,756,000		(395,000)
d. Payment for centrally furnished services		0		684,000
e. Increased cost of laboratory supplies, materials, and other expenses		0		1,498,000
Subtotal				5,215,000
Subtotal, Built-in				16,352,000

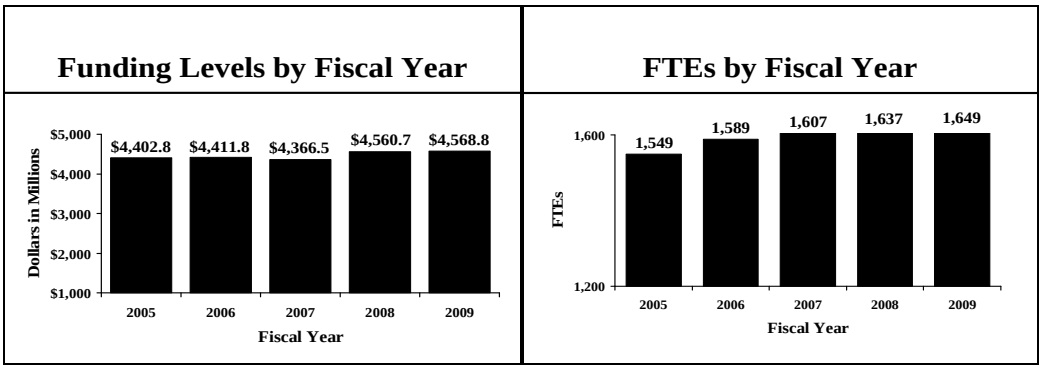
NATIONAL INSTITUTES OF HEALTH
National Institute of Allergy and Infectious Diseases

Summary of Changes--continued

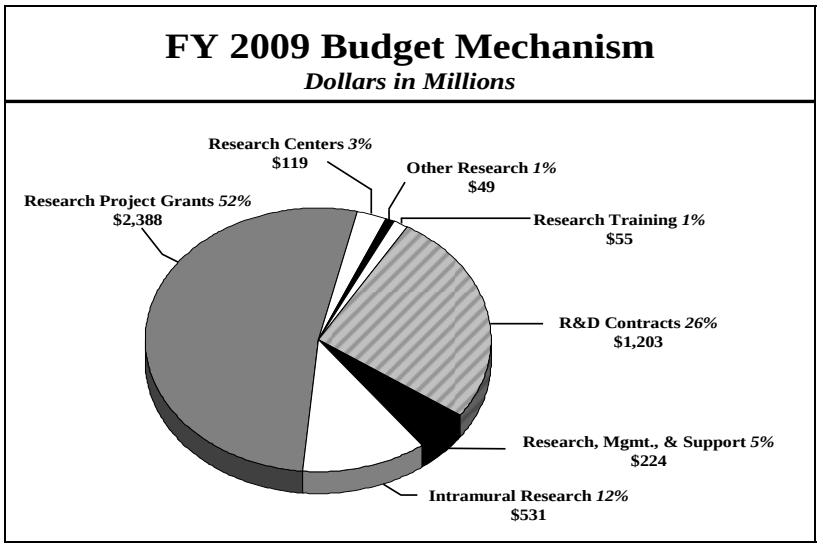
CHANGES	2008 Current Enacted Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	3,043	$1,756,634,000	184	$68,558,000
b. Competing	1,323	507,634,000	(131)	(50,103,000)
c. SBIR/STTR	232	105,621,000	0	0
Total	4,598	2,369,889,000	53	18,455,000
2. Research centers	34	128,802,000	0	(10,000,000)
3. Other research	393	48,697,000	0	0
4. Research training	1,188	54,983,000	0	391,000
5. Research and development contracts	254	1,213,962,000	0	(11,627,000)
Subtotal, extramural				(2,781,000)
	FTEs		FTEs	
6. Intramural research	805	523,566,000	12	(3,544,000)
7. Research management and support	832	220,756,000	0	(1,904,000)
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program		4,560,655,000		(8,229,000)
Total changes	1,637		12	8,123,000

Fiscal Year 2009 Budget Graphs

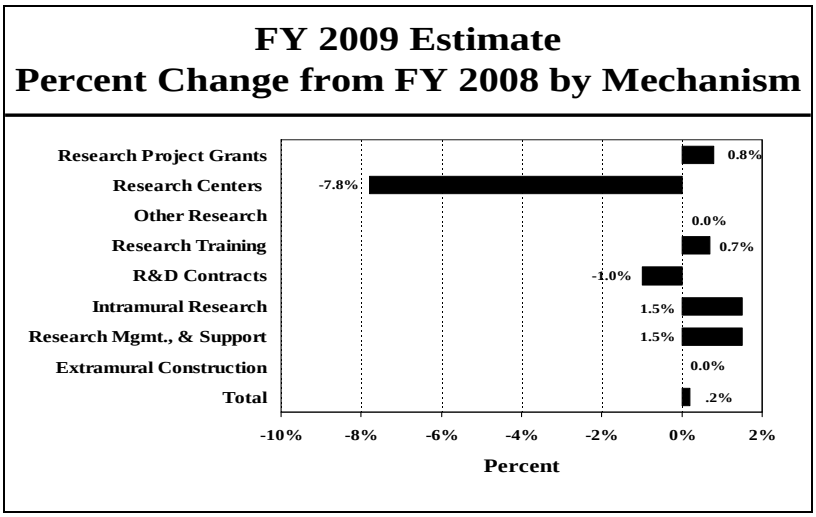
History of Budget Authority and FTEs:



Distribution by Mechanism:



Change by Selected Mechanisms:



Justification

National Institute of Allergy and Infectious Diseases

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	
FTE	BA	FTE	BA	FTE	BA	FTE	BA
1,607	$4,366,455,000	1,637	4,560,655,000	1,649	4,568,778,000	+12	+8,123,000

The following narrative provides justification for the Fiscal Year 2009 research activities of NIAID. It is organized into three major categories: HIV/AIDS, Biodefense and Emerging Infectious Diseases, and Infectious and Immunologic Diseases. A more detailed description of NIH-wide Fiscal Year 2009 HIV/AIDS activities can be found in the Office of AIDS Research (OAR) section of the Overview Volume One. Details on the Roadmap/Common Fund are located in the Overview, Volume One.

Director's Overview

The mission of the National Institute of Allergy and Infectious Diseases (NIAID) is to conduct and support research to understand, prevent, and treat infectious and immune-related diseases. Infectious diseases include well-known killers such as human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), tuberculosis (TB), and malaria; emerging or re-emerging threats such as influenza, extensively drug-resistant tuberculosis (XDR TB), and methicillin-resistant S*taphylococcus aureus* (MRSA); and "deliberately emerging" threats from potential agents of bioterrorism. Immune-related disorders include autoimmune diseases such as lupus and type 1 diabetes, as well as asthma, allergies, and problems associated with transplantation.

To accomplish its mission, the NIAID research program must be able to respond quickly to new infectious disease threats as they arise. To address this challenge, and to take advantage of the unprecedented scientific opportunities that will transform infectious and immune-related disease treatments in the years to come, NIAID is updating its FY 2000 strategic plan, *NIAID: Planning for the 21st Century*.

HIV/AIDS

Since AIDS was first described in 1981, it has become one of the deadliest pandemics in history. Recent estimates from the World Health Organization indicate that more than 25 million men, women, and children worldwide have already died. In 2007, an estimated 33 million people were living with HIV infection, 2.5 million were newly infected, and 2.1 million died of AIDS.[1] In the United States, more than 1 million people are living with HIV infection, and approximately 40,000 new infections occur each year.[2]

Advances in HIV/AIDS research have facilitated the rapid development of potent anti-HIV drugs that have saved an estimated 3 million years of life in the United States alone[3], and helped prevent mother-to-child transmission worldwide. To control and ultimately eliminate AIDS requires safe, effective vaccines and other preventive measures. Candidate vaccines, topical microbicides to prevent sexual transmission of HIV, and new drugs are being developed and tested through NIAID-supported HIV/AIDS clinical trials networks. NIAID collaborates with researchers in countries most severely affected by the AIDS pandemic, with multilateral institutions, and with international organizations. NIAID's research complements the President's Emergency Plan for AIDS Relief (PEPFAR), which provides HIV/AIDS treatment, care, and prevention to millions of people worldwide.

Biodefense and Emerging Infectious Diseases

Biodefense, broadly defined as the ability to respond effectively to deliberate and naturally occurring infectious disease threats, is a key component of national security. In the aftermath of the terrorist attacks of 2001, NIAID developed a *Strategic Plan for Biodefense Research* as well as research agendas for pathogens that could threaten public health. In 2007, NIAID updated the plan to guide basic research on biodefense pathogens and their interactions with human hosts, and apply the results of that research to the development of new vaccines, therapeutics, and diagnostics that would be needed in emerging public health crises.

To date, NIAID has conducted numerous successful clinical tests of candidate interventions to predict and preempt public health threats such as smallpox, anthrax, botulinum toxin, H5N1 avian influenza, and others. Beyond developing specific biodefense products, as well as new and improved medical countermeasures against chemical and nuclear/radiological threats, basic scientific advances could point toward novel biodefense technologies with broad-spectrum potential. These include DNA-based vaccines and interventions based on stimulating non-specific, "innate" immune defenses that combat a wide array of viruses and bacteria.

Infectious and Immunologic Diseases

NIAID efforts to develop vaccines, drugs, and diagnostic tools to benefit the public depend on a foundation of basic research into the fundamental biological properties of pathogens and immune system responses. Despite advances in medicine and public health interventions, infectious diseases still account for approximately 26 percent of all deaths worldwide, including approximately two-thirds of all deaths among children younger than 5 years of age. Two diseases alone, malaria and TB, kill millions every year, and the emergence of XDR TB poses an increased threat.

To enhance the ability to create new, more effective countermeasures, NIAID collaborates with private industry and non-governmental partners to leverage resources and speed product development. For example, in FY 2007 NIAID awarded $51 million to an international consortium of researchers to develop a comprehensive model of the immune response. Based on a "systems biology" approach, the research will draw on

the most up-to-date biochemical and genomic data to create a detailed and inclusive view of how the immune system as a whole responds to multiple pathogens.

Many immune-related disorders, including asthma, allergies, autoimmune diseases, and transplant rejection, arise when the immune system targets cells or tissues inappropriately. The development of new interventions for these diseases depends on understanding more completely how the immune system functions normally and in disease processes. In FY 2007, NIAID continued to emphasize research on immune-mediated diseases, and renewed its support for the Immune Tolerance Network (ITN), a consortium of investigators in the United States, Canada, Western Europe, and Australia. The ITN, which will receive $220 million over seven years, clinically evaluates therapies that allow the immune system to tolerate tissues, organs, or cells that are being inappropriately attacked.

Conclusion

The research conducted by NIAID intramural and extramural investigators benefits the American public and individuals worldwide. NIAID is building on its long record of accomplishment, and will continue to develop new and improved interventions for preventing, diagnosing, and treating the wide range of infectious and immune-mediated diseases that afflict humanity.

[1]UNAIDS/WHO 2007 AIDS epidemic update. Accessed 11/30/07 at http://www.unaids.org/en/HIV_data/2007EpiUpdate/default.asp

[2]CDC Fact Sheet: A Glance at the HIV/AIDS Epidemic. Accessed 11/30/07 at http://www.cdc.gov/hiv/resources/factsheets/At-A-Glance.htm

[3]RP Walensky et al. The survival benefits of AIDS treatment in the US. *J Infect Dis*.194:1, 2006.

[4] http://www.dcp2.org/main/Home.html

NIAID FY 2009 Congressional Justification Narrative
Program Descriptions and Accomplishments

HIV/AIDS

The goal of NIAID HIV/AIDS research is to create effective means to treat and prevent HIV infection. To that end, NIAID maintains a comprehensive portfolio of basic research to understand the pathogenesis and natural history of HIV disease. NIAID also conducts research that promotes progress in HIV/AIDS diagnosis, treatment, and prevention, including development of therapies for HIV infection and its complications, HIV vaccines, and non-vaccine prevention strategies.

NIAID continues to support the discovery and development of new therapeutic and prevention strategies. Development of safe and effective HIV vaccines remains one of NIAID's highest priorities. Dozens of vaccine candidates are in pre-clinical development, and NIAID is involved in human clinical testing of 16 candidates. NIAID also is pursuing non-vaccine prevention strategies, such as adult male circumcision, pre-exposure prophylaxis with antiretroviral drugs, and topical microbicides to prevent infection. Research-based prevention strategies that rely on behavior modification have already contributed to the maintenance of low infection rates in a number of settings and to declining HIV rates in some populations. NIAID's recent restructuring of its HIV/AIDS Clinical Trials Networks is accelerating development and evaluation of HIV treatment and prevention strategies.

Budget Policy. The NIAID FY 2009 budget proposal for HIV/AIDS research is $1.270 billion, a decrease of 0.1 percent from the FY 2008 estimate of $1.271 billion. The FY 2009 AIDS research plan was carefully crafted to support long-range strategic priorities for AIDS research. The plan balances support of high-priority research initiatives in AIDS research with support for the best investigator-initiated research. A critical focus of the FY 2009 AIDS research plan is the continued support for development of new, high-priority prevention strategies, including the development and testing of new vaccines and topical microbicides. NIAID will support an estimated $740 million, a $7 million increase, in HIV/AIDS prevention research in FY 2009. These funds will support a broad range of research, from basic discovery through an estimated 17 clinical trials on vaccine candidates plus numerous other clinical trials on topical microbicide candidates and other prevention strategies. Key activities include: realigning AIDS clinical trial funds to more effectively support the clinical testing and evaluation of AIDS vaccine and microbicide candidates, particularly in developing countries where the pandemic is most prevalent; recompeting the Multicenter AIDS Cohort Study (MACS), a collaborative, multi-site, natural history study of the long-term impact of HIV infection on homosexual and bisexual men, with a special focus on minority men; and initiating research to develop new diagnostic tools for infants.

PORTRAIT of a Program: HIV Prevention Research

FY 2008	$733 million
FY 2009	$740 million
Change	$ 7 million

Despite major advances in our understanding of the pathogenesis and treatment of HIV infection, the virus continues to spread rapidly. Although some strategies for preventing infection, such as treatment with antiretroviral drugs during childbirth, are already in use, others, such as microbicides and vaccines, are in the development pipeline.

The development of a safe and effective HIV vaccine is the most important goal of NIAID's HIV/AIDS research effort. A vaccine that is easy to administer, inexpensive, and induces long-lasting protective immune responses to all known HIV strains would be the optimal preventive intervention. NIAID is currently supporting 16 clinical trials of HIV vaccine candidates, some of which have advanced to larger trials to evaluate their safety and immune responses in humans. But the scientific hurdles that must be overcome to create even a partially protective vaccine are enormous, as are the logistic difficulties of conducting large-scale efficacy testing. Despite the recent disappointing results from the STEP study (HVTN 502), a Phase IIb clinical trial of an adenovirus-based HIV vaccine, NIAID remains fully committed to the development of an effective vaccine.

In the absence of an HIV vaccine, NIAID is working to better understand and improve existing prevention methods for reducing HIV transmission. These include research to strengthen HIV/AIDS education and behavior modification programs that can increase condom usage and otherwise reduce risk of sexual transmission. Medically supervised circumcision of adult males, carried out in appropriate settings, was recently shown to reduce the risk of HIV infection by more than 50 percent. NIAID works closely with programs such as the President's Emergency Plan for AIDS Relief and the Global Fund to Fight AIDS, Tuberculosis and Malaria as prevention strategies are implemented. NIAID also supports research to create evidence-based approaches to HIV prevention, such as topical microbicides—anti-HIV gels or creams that could reduce sexual transmission—and preventive regimens of antiretroviral medications that could be used prior to HIV exposure.

BIODEFENSE AND EMERGING INFECTIOUS DISEASES

Biodefense is a critical component of the Nation's comprehensive homeland security strategy. The ability to counter both naturally occurring emerging infections and deliberate bioterror attacks depends in large measure on biomedical research on disease-causing microorganisms and the immune responses to them.

In 2007, NIAID released an updated version of its 2002 *Strategic Plan for Biodefense Research*, which builds upon the successes and investments of the earlier plan and is consistent with the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for Chemical, Biological, Radiological and Nuclear Threats, the HHS PHEMCE Implementation Plan, and Homeland Security Presidential Directive (HSPD)-18. The focus of NIAID biodefense research continues to be basic research and its application to product development. The program is designed to improve the knowledge base and research capacity needed to respond rapidly to emerging and re-emerging threats. However, the updated strategy increases emphasis on developing countermeasures that are effective against a variety of pathogens, developing technologies that can improve entire classes of products, and establishing platforms that speed development of new products. To carry out the strategy, NIAID collaborates extensively with other Federal agencies, academia and industry in the context of the larger HHS strategy.

Budget Policy. The NIAID FY 2009 extramural budget proposal for biodefense and emerging infectious diseases research is $1.3 billion, a decrease of 0.6 percent from the FY 2008 budget estimate of $1.262 billion. The FY 2009 budget decrease reflects an internal realignment of funds within the broader biodefense and emerging infectious diseases research portfolio, from R&D contracts to the intramural research program, to partially offset the increase operating costs of the new intramural biocontainment laboratories expected to come online in FY 2008 and FY 2009. The focus of the FY 2009 portion of the strategic plan and budget is to continue to strengthen the high-priority activities that are critical to the long-term success of the plan, and to address research questions and concerns with the highest priorities. These include vaccines for pandemic influenza and viral hemorrhagic fevers; candidate therapeutics for high priority viral pathogens such as smallpox and viral hemorrhagic fevers; new drugs and diagnostics to counter drug-resistant pathogens; development of platform technologies to support the development of a broad range of therapeutic agents; and systematic evaluations of microbe-host interactions.

(Note: Total NIAID Biodefense and Emerging Infectious Diseases activities, including those from Intramural Research and Research Management and Support, will be $1.7 billion in FY 2009, an increase of $1.7 million over FY 2008.)

PORTRAIT of a Program: Drug-resistant Tuberculosis (MDR/XDR-TB)

FY 2008	$39 million
FY 2009	$44 million
Change	+$5 million

Tuberculosis (TB) is among the world's most deadly infectious diseases, killing more than 1.5 million people each year. Worse, forms of tuberculosis resistant to available antibiotics are increasingly prevalent. The World Health Organization estimated that in 2004, 4.3 percent of all TB cases worldwide were MDR TB, that is, resistant to at least two first-line TB drugs. [J. Infect. Dis. 2006: 194:479-485] Even more dangerous extensively-drug resistant forms of the disease (XDR TB) have appeared. Although still quite rare, some forms of XDR TB can resist almost every antibiotic currently licensed [http://www.cdc.gov/eid/content/13/5/780.htm]. While no one knows the true extent of drug-resistant TB, MDR/XDR TB has the potential to spark a global health emergency.

NIAID has a long history of supporting an extensive program of basic and applied research on TB in general, and on drug-resistant TB in particular. The program includes all aspects of basic TB science, including the factors that give rise to drug resistance, host-pathogen interactions, and the factors that control activation of latent TB infection. NIAID-supported translational and clinical research is focused on the identification and development of new diagnostics, drugs, and vaccines. Two special populations at special risk of TB are people with HIV infection and children. Therefore, NIAID conducts research specifically to understand the interaction of HIV and TB in HIV-infected people, and to improve TB prevention and treatment for children. To date, NIAID's investment in fundamental, translational, and clinical science has led to the development of several new TB drug, diagnostic, and vaccine candidates.

Many challenges remain. In June 2007, NIAID released the *NIAID Research Agenda on Multidrug-Resistant and Extensively Drug-Resistant Tuberculosis* that details those challenges, and describes how NIAID, in cooperation with other government agencies, non-governmental organizations, and corporations, will address them. The agenda calls broadly for expansion of basic biomedical TB research to meet the special problems of drug-resistant tuberculosis. It identifies six high priority research areas, such as developing diagnostic tests that can rapidly identify patients with resistant strains and determining how immune status and other host factors affect the evolution of resistant strains. It also proposes specific activities in each high-priority area that will advance scientific understanding, improve clinical care for those infected with MDR/XDR-TB, and prevent TB infection in persons at risk. NIAID is in the process of evaluating its research portfolio to determine opportunities to broadly support this research agenda. In 2008, NIAID expects to announce its first two research initiatives supporting this agenda, with the first awards expected in FY 2009.

INFECTIOUS AND IMMUNOLOGIC DISEASES (IID)

NIAID conducts and supports research on a large number of infectious and immunologic diseases. Infectious diseases include malaria and TB—major international killers that together account for nearly three million deaths each year—parasitic diseases, respiratory infections, and vector-borne pathogens. Immunologic diseases, in which the immune system itself contributes to the disease process, include severe combined immune deficiency; asthma and allergic diseases such as hay fever, food allergies, and contact dermatitis; autoimmune diseases such as Type 1 diabetes and systemic lupus erythematosus; acute and chronic inflammatory disorders such as Crohn's Disease; and rejection of transplanted organs, tissues, and cells.

In 2007, NIAID completed or updated several scientific research agendas and reports, including the *NIAID Research Agenda on Multidrug-Resistant and Extensively Drug-Resistant Tuberculosis,* the *Report of the NIH Expert Panel on Food Allergy Research* and the soon-to-be-completed *NIAID Research Agenda on Malaria.* These detailed agendas, plans and reports will guide the extensive NIAID research programs in these areas. Program Announcements and research initiatives continuing in 2008 support a broad spectrum of research, including research on the diseases identified above plus research to better understand and counter the effects of asthma, allergies and autoimmune diseases. NIAID also increased the number of long-term partnerships with developing countries for research on TB, malaria, and other infectious diseases. These partnerships both enhance the fight against infectious diseases in the countries that bear the greatest burden and help the United States respond quickly to newly emerging disease threats.

Budget Policy. The NIAID FY 2009 extramural budget proposal for infectious and immunologic diseases research is $1.3 billion. The proposal includes a $300 million contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria, a $5 million increase over the FY 2008 contribution. The FY 2009 IID research plan supports critical long-range research priorities of NIAID, with funds carefully aligned to support key research activities, such as the continued support for the Autoimmunity Centers of Excellence, Clinical Trails in Organ Transplantation, and the NIAID Inner City Asthma Consortium, which studies approaches to reducing asthma severity in the inner cities of the U.S., particularly for minority children. Key infectious diseases research activities will focus on sustaining the clinical trial infrastructure needed to test and evaluate new vaccine and drug candidates, including a special focus on drug-resistant microbes, as well as developing new research tools to better collect clinical data from the field and to translate laboratory concepts to the bedside.

PORTRAIT of a Program: Transplantation Research

FY 2008	$175 million
FY 2009	$175 million
Change	$ 0

In the five decades since the first successful solid organ transplant, replacement of organs, tissues, and cells has become a routine but life-saving treatment for people with many serious medical conditions. However, the immune system is primed to reject transplanted material, and the powerful drugs needed to prevent rejection cause serious side effects. Demand for organs exceeds donations, and many potential recipients die while still on a waiting list.

NIAID plays an essential and unifying role in research to improve transplantation outcomes. At the most fundamental level, NIAID's broad portfolio of basic research in transplantation immunology seeks to expand our understanding of how the immune system recognizes transplanted organs, tissues, and cells, and to characterize the cellular and molecular processes that lead to graft injury. Basic research provides the foundation for reaching key NIAID transplantation research goals, such as the discovery of new interventions that will "teach" the immune system to tolerate transplanted organs and cells without increasing the patient's risk of infection, malignancy, and the other adverse effects of current immunosuppression regimens.

Many of the transplant procedures and therapies in current use were developed empirically, and their safety and efficacy were evaluated through clinical observations and small-scale studies. NIAID support for large clinical research networks that link many academic institutions, clinical centers, and pharmaceutical companies has changed that paradigm. These NIAID networks allow transplant clinicians and researchers to exchange information much more efficiently, and to jointly conduct systematic and rigorous trials involving large numbers of transplant recipients. All of the studies incorporate detailed laboratory investigations of the physiologic mechanisms underlying the clinical observations.

Each network is devoted to a specific aspect of transplantation research. For example, in the Cooperative Clinical Trials in Pediatric Transplantation (CCTPT) consortium, clinicians conduct studies of new immunosuppression regimens in children undergoing kidney transplantation while laboratory-based immunologists study how these pharmacologic interventions affect the immune system. This network is being expanded in FY 2008 to include children receiving other types of organ transplants. Other NIAID-funded clinical networks study the immunologic mechanisms of graft injury and the influence of genetics on the outcome of transplantation procedures in adults; explore new ways to reduce or eliminate the need for immunosuppressive drugs; seek to improve immunosuppressive and anti-retroviral drug regimens in HIV-infected liver or kidney recipients; and evaluate the effects of donation on living organ donors. NIAID-supported pre-clinical programs support the evaluation of new transplantation approaches in non-human primates, and explore the potential of animal tissues, organs, and cells for use in human patients. Taken together, these programs represent a unique national resource that is transforming the practice of transplantation.

INTRAMURAL RESEARCH

In addition to funding extramural research and development through grants and contracts to non-government institutions, NIAID maintains intramural laboratories in which NIAID employees conduct laboratory and clinical research related to infectious diseases, immunology and allergies. The purpose of the intramural program is to make scientific discoveries that promote the development of new vaccines, therapeutics and diagnostics to treat infectious and immune-related diseases and improve human health. To that end, intramural scientists work to expand knowledge of normal immune system components and functions; define mechanisms responsible for abnormal immune function (immunodeficiency, allergy and autoimmunity); understand the biology of infectious agents (viruses, bacteria, fungi, parasites) and the host response to infection; and develop strategies to prevent and treat immunologic, allergic and infectious diseases. Examples of past and present intramural research include the development and testing of vaccines for a wide range of diseases including Ebola, HIV, malaria and pandemic influenza. Most intramural laboratories are located on the NIH campus in Bethesda and in nearby Rockville, Maryland; NIAID also operates intramural facilities in Frederick, Maryland, and Hamilton, Montana. Because clinical research is integral to the rapid translation of new findings into methods to prevent, diagnose, or treat disease, the NIAID intramural program has a strong clinical research component, both on the NIH campus and in collaboration with national and international partners.

Budget Policy. The NIAID FY 2009 budget proposal for Intramural Research is $531 million, an increase of 1.5% from the FY 2008 estimated budget of $524 million. The FY 2009 Intramural Research plan supports critical long-range research priorities of NIAID, with funds carefully aligned to support key research activities. These include the continued support for all aspects of infectious diseases such as AIDS, malaria, and influenza, including the causative agent, vectors and the human host. In addition, we are developing countermeasures against bioterrorism through basic research and our strong clinical research component allowing key lab discoveries to be rapidly translated into methods to prevent, diagnose, or treat disease. The FY 2009 budget increase is to partially offset the operating costs of the new biocontainment laboratories expected to come online in FY 2008 and FY 2009.

RESEARCH MANAGEMENT SUPPORT (RMS)

NIAID 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 Institute will oversee approximately 5,000 research grants in FY 2009, as well as over 250 research and support contracts.

Budget Policy. The FY 2009 estimate for RMS is $224 million, an increase of 1.5 percent from the FY 2008 estimate of $220 million; the total number of NIAID FTEs is slated to increase from 1,637 in FY 2008 to 1,649 in FY 2009; of the FY 2008 FTEs,

819 will be in RMS and the remainder in the Division of Intramural Research. Efforts to increase efficiency in RMS functions will continue in FY 2009.

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Budget Authority by Object

	FY 2008 Enacted	FY 2009 Estimate	Increase or Decrease	Percent Change
Total compensable workyears:				
Full-time employment	1,637	1,649	12	0.7
Full-time equivalent of overtime and holiday hours	6	6	0	0.0
Average ES salary	156,151	162,174	6,023	3.9
Average GM/GS grade	12	12	0	0.0
Average GM/GS salary	89,404	91,997	2,593	2.9
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	86,133	88,631	2,498	2.9
Average salary of ungraded positions	124,625	128,239	3,614	2.9

OBJECT CLASSES	FY 2008 Enacted	FY 2009 Estimate	Increase or Decrease	Percent Change
Personnel Compensation:				
11.1 Full-time permanent	$122,001,000	$126,496,000	$4,495,000	3.7
11.3 Other than full-time permanent	33,267,000	34,470,000	1,203,000	3.6
11.5 Other personnel compensation	5,601,000	5,806,000	205,000	3.7
11.7 Military personnel	4,517,000	4,680,000	163,000	3.6
11.8 Special personnel services payments	21,608,000	22,347,000	739,000	3.4
Total, Personnel Compensation	186,994,000	193,799,000	6,805,000	3.6
12.0 Personnel benefits	44,618,000	46,247,000	1,629,000	3.7
12.2 Military personnel benefits	2,985,000	3,093,000	108,000	3.6
13.0 Benefits for former personnel	0	0	0	0.0
Subtotal, Pay Costs	**234,597,000**	**243,139,000**	**8,542,000**	**3.6**
21.0 Travel and transportation of persons	8,747,000	8,394,000	(353,000)	-4.0
22.0 Transportation of things	676,000	652,000	(24,000)	-3.6
23.1 Rental payments to GSA	47,000	48,000	1,000	2.1
23.2 Rental payments to others	22,000	22,000	0	0.0
23.3 Communications, utilities and miscellaneous charges	2,888,000	2,942,000	54,000	1.9
24.0 Printing and reproduction	513,000	490,000	(23,000)	-4.5
25.1 Consulting services	8,983,000	8,622,000	(361,000)	-4.0
25.2 Other services	133,731,000	129,779,000	(3,952,000)	-3.0
25.3 Purchase of goods and services from government accounts	437,824,000	441,481,000	3,657,000	0.8
25.4 Operation and maintenance of facilities	12,708,000	13,034,000	326,000	2.6
25.5 Research and development contracts	1,041,364,000	1,027,736,000	(13,628,000)	-1.3
25.6 Medical care	4,349,000	4,216,000	(133,000)	-3.1
25.7 Operation and maintenance of equipment	9,660,000	9,290,000	(370,000)	-3.8
25.8 Subsistence and support of persons	0	0	0	0.0
25.0 Subtotal, Other Contractual Services	**1,648,619,000**	**1,634,158,000**	**(14,461,000)**	**-0.9**
26.0 Supplies and materials	43,414,000	42,041,000	(1,373,000)	-3.2
31.0 Equipment	18,761,000	18,081,000	(680,000)	-3.6
32.0 Land and structures	0	0	0	0.0
33.0 Investments and loans	0	0	0	0.0
41.0 Grants, subsidies and contributions	2,602,371,000	2,618,811,000	16,440,000	0.6
42.0 Insurance claims and indemnities	0	0	0	0.0
43.0 Interest and dividends	0	0	0	0.0
44.0 Refunds	0	0	0	0.0
Subtotal, Non-Pay Costs	**4,326,058,000**	**4,325,639,000**	(419,000)	**0.0**
Total Budget Authority by Object	**4,560,655,000**	**4,568,778,000**	8,123,000	**0.2**

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

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Salaries and Expenses

OBJECT CLASSES	FY 2008 Enacted	FY 2009 Estimate	Increase or Decrease
Personnel Compensation:			
Full-time permanent (11.1)	$122,001,000	$126,496,000	$4,495,000
Other than full-time permanent (11.3)	33,267,000	34,470,000	1,203,000
Other personnel compensation (11.5)	5,601,000	5,806,000	205,000
Military personnel (11.7)	4,517,000	4,680,000	163,000
Special personnel services payments (11.8)	21,608,000	22,347,000	739,000
Total Personnel Compensation (11.9)	**186,994,000**	**193,799,000**	**6,805,000**
Civilian personnel benefits (12.1)	44,618,000	46,247,000	1,629,000
Military personnel benefits (12.2)	2,985,000	3,093,000	108,000
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	**234,597,000**	**243,139,000**	**8,542,000**
Travel (21.0)	8,747,000	8,394,000	(353,000)
Transportation of things (22.0)	676,000	652,000	(24,000)
Rental payments to others (23.2)	22,000	22,000	0
Communications, utilities and miscellaneous charges (23.3)	2,888,000	2,942,000	54,000
Printing and reproduction (24.0)	513,000	490,000	(23,000)
Other Contractual Services:			
Advisory and assistance services (25.1)	7,741,000	7,380,000	(361,000)
Other services (25.2)	133,731,000	129,779,000	(3,952,000)
Purchases from government accounts (25.3)	254,536,000	257,749,000	3,213,000
Operation and maintenance of facilities (25.4)	10,873,000	11,199,000	326,000
Operation and maintenance of equipment (25.7)	9,660,000	9,290,000	(370,000)
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	**416,541,000**	**415,397,000**	**(1,144,000)**
Supplies and materials (26.0)	43,414,000	42,041,000	(1,373,000)
Subtotal, Non-Pay Costs	472,801,000	469,938,000	(2,863,000)
Total, Administrative Costs	**707,398,000**	**713,077,000**	**5,679,000**

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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	$4,560,655,000	Indefinite	$4,568,778,000
National Institute of Allergy and Infectious Diseases	Section 402(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				4,560,655,000		4,568,778,000

NATIONAL INSTITUTES OF HEALTH
National Institute of Allergy and Infectious Diseases

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation 1/
2000	789,156,000 2/	1,714,705,000	1,786,718,000	1,803,063,000
Rescission	0	0	0	(5,025,000)
2001	935,166,000 2/	2,062,126,000	2,066,526,000	2,069,388,000
Rescission				(1,084,000)
2002	2,355,325,000	2,337,204,000	2,375,836,000	2,535,778,000
Rescission				(1,239,000)
2003	3,983,693,000	2,674,213,000	3,727,473,000	3,730,973,000
Rescission				(24,251,000)
2004	4,335,255,000	4,335,255,000	4,335,255,000	4,335,155,000
Rescission				(30,593,000)
2005	4,440,007,000	4,440,007,000	4,456,300,000	4,440,007,000
Rescission				(37,166,000)
2006	4,459,395,000	4,459,395,000	4,547,136,000	4,427,895,000
Rescission				(44,594,000)
2007	4,395,496,000	4,270,496,000	4,395,496,000	4,414,801,050
2008	4,592,482,000	4,632,019,000	4,668,472,000	4,641,746,000
Rescission				(81,091,000)
2009	4,568,778,000			

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

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Details of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Office of the Director	271	272	272
Division of Allergy, Immunology, and Transplantation	78	81	81
Division of Microbiology and Infectious Diseases	147	151	151
Division of Extramural Activities	189	191	191
Division of Acquired Immunodeficiency	133	137	137
Division of Intramural Research	789	805	817
Total	1,607	1,637	1,649
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research			
FTEs supported by funds from Cooperative Research and Development Agreements	(20)	(20)	(20)

FISCAL YEAR	Average GM/GS Grade
2005	11.0
2006	12.0
2007	12.0
2008	12.0
2009	12.0

The estimated number of FTEs in the intramural program is expected to increase by 12 in FY 2009 to support the research activities within the new biocontainment facilities.

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Detail of Positions

GRADE	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Total, ES Positions	2	2	2
Total, ES Salary	298,881	304,858	310,915
GM/GS-15	102	103	104
GM/GS-14	275	277	278
GM/GS-13	237	239	238
GS-12	181	184	185
GS-11	174	175	176
GS-10	3	3	3
GS-9	89	96	97
GS-8	30	30	30
GS-7	58	58	58
GS-6	11	11	11
GS-5	4	4	4
GS-4	3	3	3
GS-3	2	2	2
GS-2	0	0	0
GS-1	0	0	0
Subtotal	1,169	1,185	1,189
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	2	2	2
Director Grade	19	19	19
Senior Grade	16	16	16
Full Grade	3	3	3
Senior Assistant Grade	2	2	2
Assistant Grade	1	1	1
Co-Step	3	3	3
Subtotal	46	46	46
Ungraded	448	462	469
Total permanent positions	1,377	1,400	1,409
Total positions, end of year	1,665	1,693	1,704
Total full-time equivalent (FTE) employment, end of year	1,607	1,637	1,649
Average ES salary	149,441	156,151	162,174
Average GM/GS grade	12	12	12
Average GM/GS salary	85,554	89,404	91,997

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
ADMINISTRATIVE ASSISTANT	GS-9	1	48,113
BIOLOGIST	GS-11	1	58,213
BIOLOGIST	AD	4	92,731
MEDICAL OFFICER	GS-14	1	126,766
MEDICAL OFFICER	GS-15	1	139,392
MEDICAL OFFICER	AD	1	143,396
MICROBIOLOGIST	GS-12	1	69,772
MICROBIOLOGIST	AD	2	97,605
Total Requested		12	