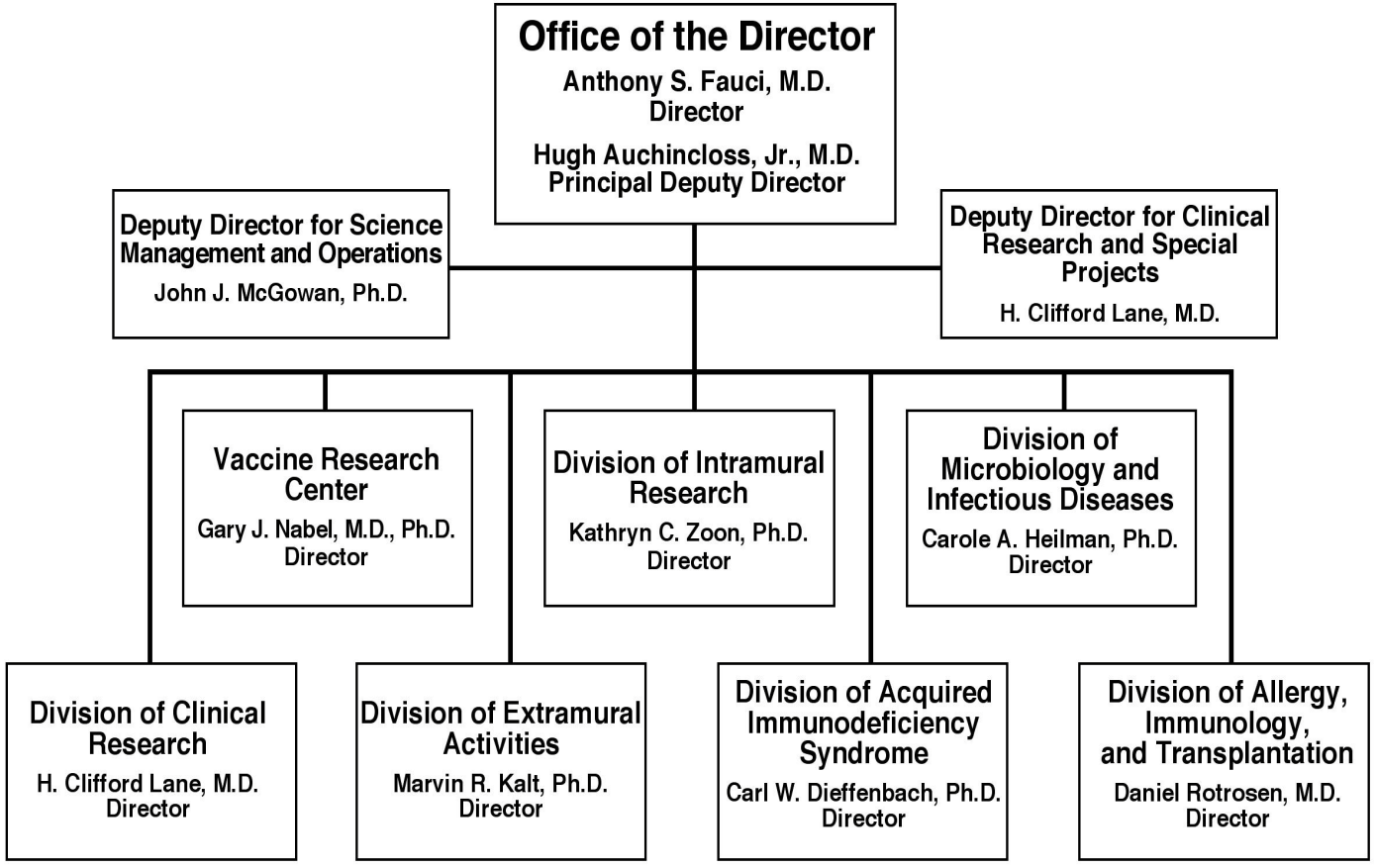
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases (NIAID)

FY 2010 Budget — Page No.

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



FY 2010 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, [$4,702,572,000] *$4,760,295,000* (Department of Health and Human Services Appropriation Act, 2009)

National Institutes of Health
National Institute of Allergy and Infectious Diseases

Amounts Available for Obligation 1/

Source of Funding	FY 2008 Actual	FY 2009 Estimate	FY 2010 PB
Appropriation	$4,641,746,000	$4,702,572,000	$4,760,295,000
Rescission	-81,091,000	0	0
Supplemental	22,689,000	0	0
Subtotal, adjusted appropriation	4,583,344,000	4,702,572,000	4,760,295,000
Real transfer under Director's one-percent transfer authority (GEI)	-2,174,000	0	0
Real transfer to the Global Fund to fight HIV/AIDS, Malaria and Tuberculosis	-294,759,000	0	0
Comparative transfer under Director's one-percent transfer authority (GEI)	2,174,000	0	0
Comparative transfer to the Global Fund to fight HIV/AIDS, Malaria and Tuberculosis	294,759,000	0	0
Subtotal, adjusted budget authority	4,583,344,000	4,702,572,000	4,760,295,000
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	4,583,344,000	4,702,572,000	4,760,295,000
Unobligated balance lapsing	-1,000	0	0
Total obligations	4,583,343,000	4,702,572,000	4,760,295,000

1/ Excludes the following amounts for reimbursable activities carried out by this account: FY 2008 - $13,036,000 FY 2009 Estimate - $14,300,000 FY 2010 Estimate - $15,675,000 Excludes $11,494,116 Actual in FY 2008; estimate $13,400,347 in FY 2009 and Estimate $16,281,153 in FY 2010 for royalties.

National Institutes of Health
National Institute of Allergy and Infectious Diseases

(Dollars in Thousands)
Budget Mechanism – Total

MECHANISM	FY 2008 Actual		FY 2009 Estimate		FY 2010 PB		Change	
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	3,031	$1,811,409	2,913	$1,786,249	2,980	$1,801,965	67	$15,716
Administrative supplements	(81)	33,066	(74)	24,000	(74)	24,000	(0)	0
Competing:								
Renewal	284	137,816	241	112,769	247	104,714	6	-8,055
New	806	300,924	1,026	413,668	1,052	445,035	26	31,367
Supplements	0	0	7	1,815	8	3,258	1	1,443
Subtotal, competing	1,090	438,740	1,274	528,252	1,307	553,007	33	24,755
Subtotal, RPGs	4,121	2,283,215	4,187	2,338,501	4,287	2,378,972	100	40,471
SBIR/STTR	256	101,310	274	107,310	282	110,310	8	3,000
Subtotal, RPGs	4,377	2,384,525	4,461	2,445,811	4,569	2,489,282	108	43,471
Research Centers:								
Specialized/comprehensive	34	126,211	34	120,119	34	121,560	0	1,441
Clinical research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative medicine	2	1,703	2	1,749	2	1,770	0	21
Research Centers in Minority Institutions	0	422	0	433	0	439	0	6
Subtotal, Centers	36	128,336	36	122,301	36	123,769	0	1,468
Other Research:								
Research careers	299	37,388	319	39,897	319	40,376	0	479
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	1,170	1	1,202	1	1,216	0	14
Other	84	9,826	83	10,091	83	10,212	0	121
Subtotal, Other Research	383	48,384	403	51,190	403	51,804	0	614
Total Research Grants	4,796	2,561,245	4,900	2,619,302	5,008	2,664,855	108	45,553
Research Training:	FTTPs		FTTPs		FTTPs			
Individual awards	161	7,395	172	7,969	174	8,049	2	80
Institutional awards	1,008	47,523	1,029	48,998	1,039	49,488	10	490
Total, Training	1,169	54,918	1,201	56,967	1,213	57,537	12	570
Research & development contracts	233	1,213,193	231	1,254,907	230	1,254,355	-1	-552
(SBIR/STTR)	(2)	(232)	(2)	(232)	(2)	(232)	0	0
	FTEs		FTEs		FTEs		FTEs	
Intramural research	785	528,921	799	541,085	821	549,200	22	8,115
Research management and support	845	225,067	871	230,311	882	234,348	11	4,037
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NIAID	1,630	4,583,344	1,670	4,702,572	1,703	4,760,295	33	57,723

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 2006 Actual		FY 2007 Actual		FY 2008 Actual		FY 2008 Comparable		FY 2009 Estimate		FY 2010 PB		Change	
Extramural Research	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Detail:														
HIV/AIDS		$1,260,811		$1,261,889		$1,270,693		$1,270,693		$1,308,804		$1,330,734		21,930
Biodefense and Emerging Infectious Diseases		1,313,626		1,258,220		1,267,563		1,267,563		1,298,205		1,307,957		9,752
Infectious and Immunological Diseases		1,084,341		1,083,005		994,167		1,291,100		1,324,167		1,338,056		13,889
Subtotal, Extramural		3,658,778		3,603,114		3,532,423		3,829,356		3,931,176		3,976,747		45,571
Intramural research	793	540,118	789	542,403	785	528,920	785	528,921	799	541,085	821	549,200	22	8,115
Res. management & support	796	212,872	18	217,517	845	225,067	845	225,067	871	230,311	882	234,348	11	4,037
TOTAL	1,589	4,411,768	1,607	4,363,034	1,630	4,286,410	1,630	4,583,344	1,670	4,702,572	1,703	4,760,295	33	57,723

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

Major Changes in the Fiscal Year 2010 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 2010 budget request for NIAID, which is $57.723 million greater than the FY 2009 Estimate, for a total of $4,760,295,000.

Research Project Grants (+$43.471 million, total $2.489 billion): NIAID will support a total of 4,569 Research Project Grant (RPG) awards in FY 2010. Noncompeting RPGs will increase by 67 awards and $15.716 million. Competing RPGs will increase by 33 awards and $24.755 million. The NIH funding policy for FY 2010 RPGs includes 2% inflationary increases for noncompeting awards and a 2% increase in the average cost of competing awards. NIAID will continue to support new investigators and maintain an adequate number of competing RPGs.

Biodefense and Emerging Infectious Diseases (+$9.752 million; total $1.308 billion): NIAID will increase funds for its biodefense and emerging infectious diseases research portfolio to support the expected increase operating costs of the new biocontainment laboratories that have recently come online at Fort Detrick, MD and the Rocky Mountain Laboratories in Hamilton, MT.

Infectious and Immunologic Diseases (+$13.889 million; total $1.338 billion): NIAID will increase funds for its Infectious and Immunologic Diseases research portfolio to support critical clinical research on malaria, vaccine development and for selected pathogens which are responsible for significant morbidity and mortality, result in major health care costs and can be difficult to treat due to resistance against multiple antibiotics. Additionally, $2.758 million is included to support the development of innovative diagnostics, treatments, and cures for cancer. This funding is central to the Administration's sustained, multi-year plan to double cancer research support. The proposal includes no change in the $300.000 million contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria from FY 2009.

HIV/AIDS Research (+$21.930 million; total $1.331 billion): NIAID will increase the HIV/AIDS funding to support a broad range of research, from basic discovery through clinical trials on vaccine and topical microbicide candidates as well as other prevention strategies.

Intramural Research (+$8.115 million; total $0.549 billion): The FY 2010 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 research on infectious diseases such as AIDS, malaria, and influenza, including the causative agent, vectors and the human host.

National Institutes of Health
National Institute of Allergy and Infectious Diseases

Summary of Changes

FY 2009 estimate	$4,702,572,000
FY 2010 estimated budget authority	4,760,295,000
Net change	57,723,000

CHANGES	2009 Current Estimate Base FTEs	2009 Current Estimate Base Budget Authority	Change from Base FTEs	Change from Base Budget Authority
A. Built-in:				
1. Intramural research:				
b. January FY 2010 pay increase		136,155,000		2,042,000
c. Payment for centrally furnished services		72,742,000		1,455,000
d. Increased cost of laboratory supplies, materials, and other expenses		332,188,000		5,347,000
Subtotal				10,471,000
2. Research management and support:				
a. Annualization of January 2009 pay increase		$114,004,000		$1,362,000
b. January FY 2010 pay increase		114,004,000		1,710,000
c. Payment for centrally furnished services		37,605,000		752,000
d. Increased cost of laboratory supplies, materials, and other expenses		78,702,000		1,291,000
Subtotal				5,115,000
Subtotal, Built-in				15,586,000

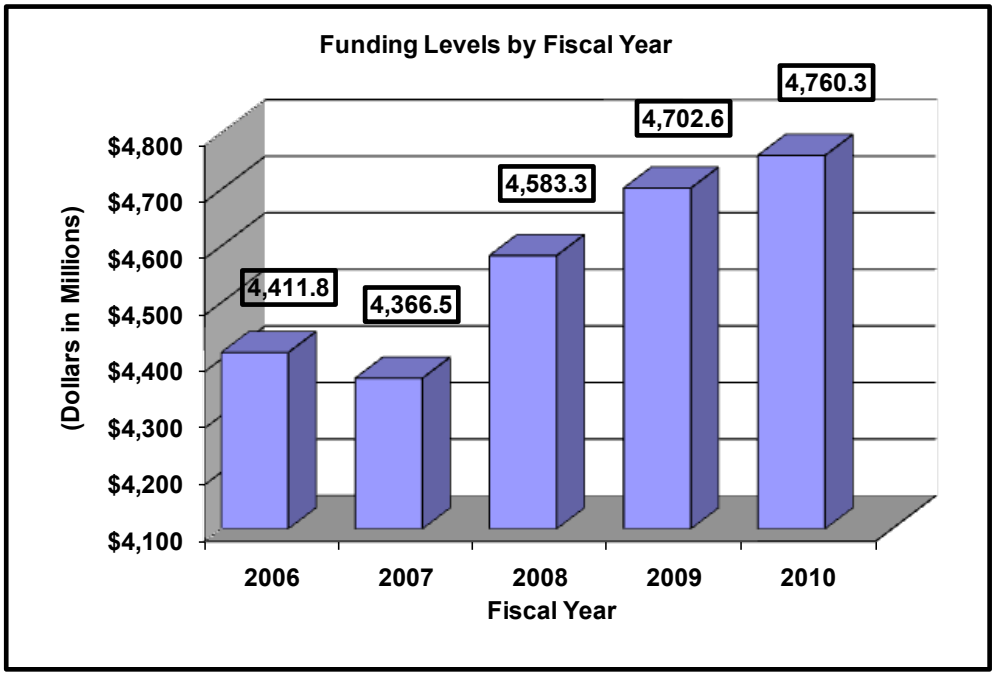
National Institutes of Health
National Institute of Allergy and Infectious Diseases

Summary of Changes--continued

CHANGES	2009 Current Estimate Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	2,913	$1,810,249,000	67	$15,716,000
b. Competing	1,274	528,252,000	33	24,755,000
c. SBIR/STTR	274	107,310,000	8	3,000,000
Total	4,461	2,445,811,000	108	43,471,000
2. Research centers	36	122,301,000	0	1,468,000
3. Other research	403	51,190,000	0	614,000
4. Research training	1,201	56,967,000	12	570,000
5. Research and development contracts	231	1,254,907,000	(1)	(552,000)
Subtotal, extramural				45,571,000
	FTEs		FTEs	
6. Intramural research	799	541,085,000	22	(2,356,000)
7. Research management and support	871	230,311,000	11	(1,078,000)
Subtotal, program		4,702,572,000		42,137,000
Total changes	1,670		33	57,723,000

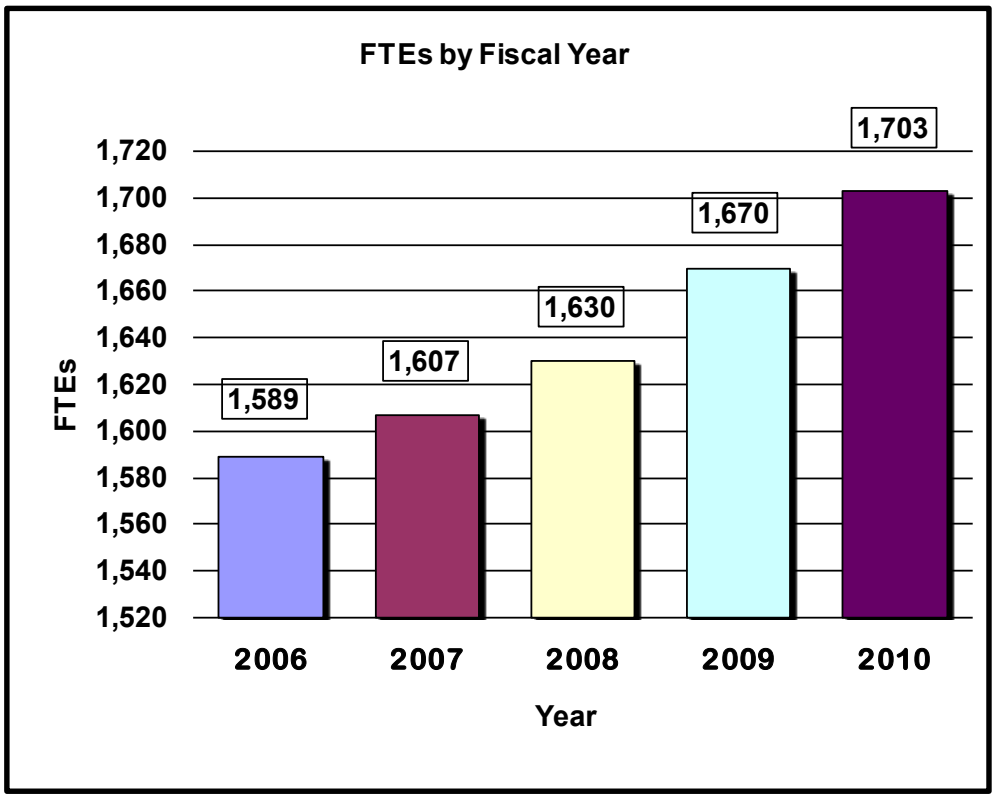
Fiscal Year 2010 Budget Graphs

History of Budget Authority and FTEs:



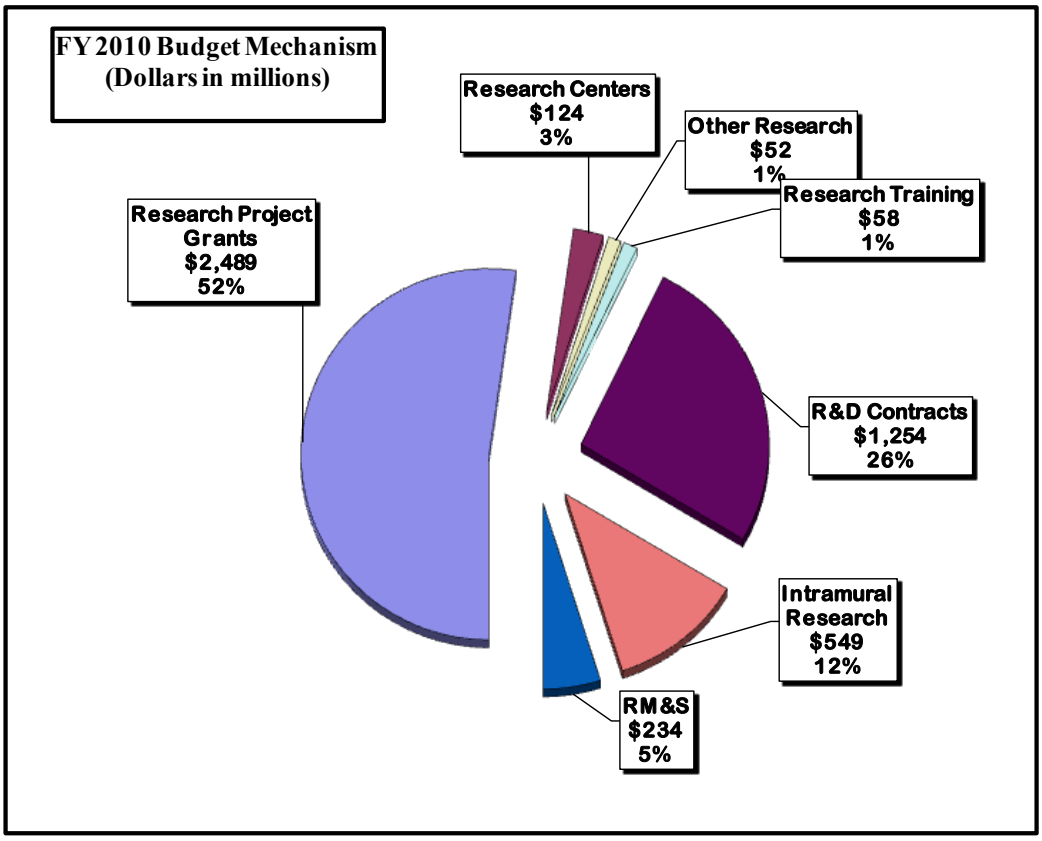
Fiscal Year	Funding
2006	4,411.8
2007	4,366.5
2008	4,583.3
2009	4,702.6
2010	4,760.3

History of Budget Authority and FTEs (continued):



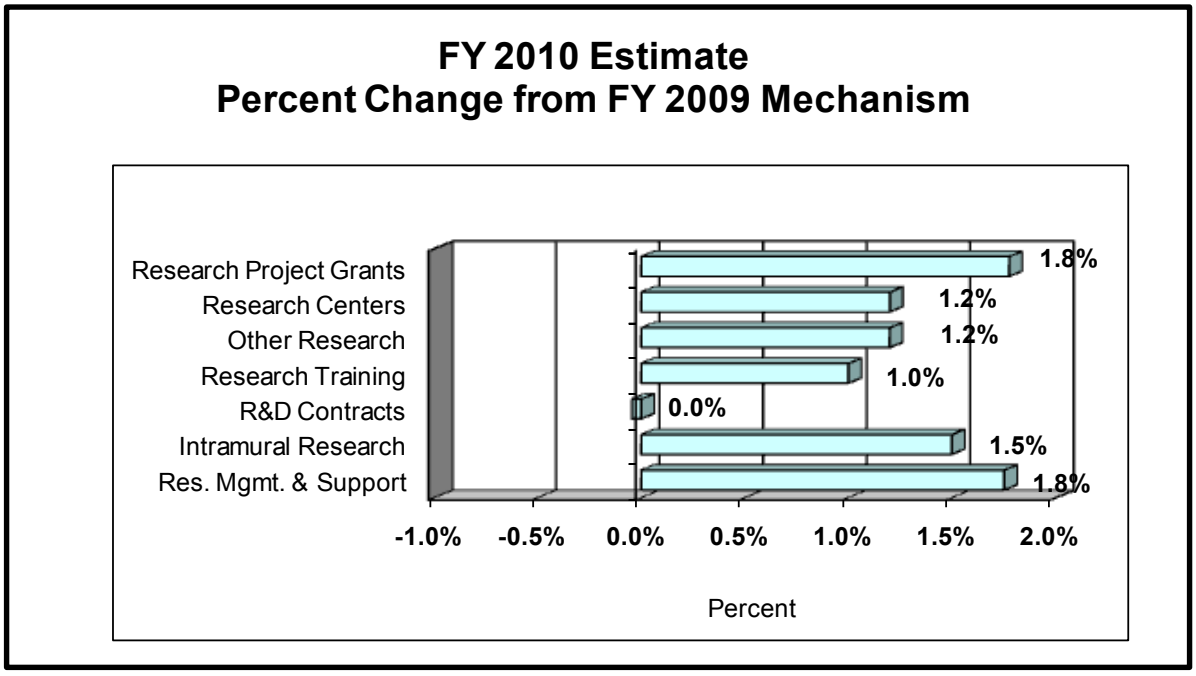
Fiscal Year	FTEs
2006	1,589
2007	1,607
2008	1,630
2009	1,670
2010	1,703

Distribution by Mechanism



Mechanism	Amount
Research Project Grants	2,489
Research Centers	124
Other Research	52
Research Training	58
R&D Contracts	1,254
Intramural Research	549
RM&S	234

Change by Selected Mechanisms:



Mechanism	Percent
Research Project Grants	1.8
Research Centers	1.2
Other Research	1.2
Research Training	1.0
R&D Contracts	0.0
Intramural Research	1.5
Res. Mgmt. & Support	1.8

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 2008 Appropriation		FY 2009 Omnibus		FY 2009 Recovery Act		FY 2010 President's Budget		FY 2010 +/- 2009 Omnibus	
FTE	BA	FTE	BA	FTE	BA	FTE	BA	FTE	BA
1,630	$4,583,344	1,670	$4,702,572,000	0	$1,113,288,000	1,703	$4,760,295,000	+33	$57,723,000

This document provides justification for the Fiscal Year (FY) 2010 activities of the National Institute of Allergy and Infectious Diseases, including HIV/AIDS activities. Details of the FY 2010 HIV/AIDS activities are in the "Office of AIDS Research (OAR)" Section of the Overview. Details on the Common Fund are located in the Overview, Volume One. Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

In FY 2009, a total of $1,113,288,000 American Recovery and Reinvestment Act (ARRA) funds were transferred from the Office of the Director. These funds will be used to to support scientific research opportunities that help support the goals of the ARRA. The ARRA allows NIH to execute these funds via any NIH funding mechanism. Funds are available until September 30, 2010. These funds are not included in the FY 2009 Omnibus amounts reflected in this document

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 global 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, asthma, allergies, and problems associated with transplantation. In today's globalized society, the biomedical research that NIAID supports to combat diseases of worldwide concern has taken on added importance, contributing to our country's pre-paredness against the threat of bioterrorism as well as naturally occurring disease outbreaks. In addition, NIAID research is advancing efforts to address other domestic health problems, including HIV/AIDS, influenza, and immune-related disorders, that are causes of significant disease and disability in the United States and throughout the world.

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, 2.7 million were newly infected, and 2.0 million died of AIDS.[1] In the United States, more than 1 million people are living with HIV infection, and approximately 56,300 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. While much has been accomplished, much remains to be done. Controlling and ultimately eliminating AIDS will require safe, effective vaccines and other preventive measures. The development of such vaccines remains one of NIAID's highest priorities and greatest challenges. This effort will require significant advances in research to broaden our understanding of the virus and the disease, and progress in basic research to develop new vaccine strategies.

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. NIAID's research agenda in biodefense and emerging infectious diseases guides basic research on numerous pathogens and their interactions with human hosts, and applies the results of that research to the development of new vaccines, therapeutics, and diagnostics that would be needed in emerging public health crises.

NIAID has conducted numerous successful clinical tests of candidate interventions to predict and preempt public health threats such as smallpox, anthrax, botulinum toxin, pandemic 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 people domestically and abroad 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. Yet, we are making progress. A small, international clinical trial for a candidate malaria vaccine – designed to block the malaria parasite from entering human blood cells – showed that the vaccine was safe and produced strong immune responses in 40 Malian adults who received it. In FY 2008, NIAID strengthened and expanded its nationwide network of Vaccine Treatment and Evaluation Units that conduct clinical trials of promising candidate vaccines and therapies for infectious diseases.

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 2008, NIAID-funded researchers began to test new approaches to transplanting clusters of insulin-producing islets in adults with difficult-to-control type 1 diabetes. NIAID also renewed its emphasis on food allergy by co-sponsoring a workshop to examine the ethical, regulatory, and design issues related to conducting food allergy trials in children. This effort led to the establishment of a process for developing the first guidelines on managing and treating food allergies.

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] 2008 Report on the Global AIDS Epidemic. Accessed 9/26/08 at http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008 Global_report.asp

[2] Hall, HI, Song, R., Rhodes, P. et al. Estimation of HIV incidence in the United States. *JAMA.* 300:520-9, 2008.

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

Overall Budget Policy: Within the President's Budget request, NIAID is providing a 2.0 percent inflationary increase for non-competing and competing grants. NIAID support for research grants will help to sustain the scientific momentum of investigator-initiated research while pursuing new research opportunities, including awards to new investigators, and early stage investigators. Additionally, NIAID will continue to support basic and applied research to prevent, diagnose, and treat infectious and immune-mediated illnesses, including illness from emerging infectious diseases, agents with bioterrorism potential, human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), tuberculosis, malaria, autoimmune disorders, asthma, and allergies. Funding for NIAID's Intramural Research and Research Management and Support programs receive modest increases to help offset the cost of pay and other increases.

NIAID FY 2010 Congressional Justification Narrative
Program Descriptions and Accomplishments

HIV/AIDS

The goal of NIAID HIV/AIDS research is to develop effective tools to prevent HIV infection and improve treatment strategies for AIDS and its co-infections. To that end, NIAID maintains a comprehensive research portfolio, which includes basic research to understand the pathogenesis and natural history of HIV disease through the clinical evaluation of treatment and/or prevention strategies in humans.

Development of safe and effective HIV vaccines remains one of NIAID's highest priorities and greatest challenges. Designing an HIV vaccine will require significant advances in fundamental research to expand our understanding of the virus and the disease. It also will require basic research to develop new vaccine strategies. NIAID is also pursuing non-vaccine prevention strategies, such as pre-exposure prophylaxis with antiretroviral drugs, topical microbicides to prevent infection, and adult male circumcision. In 2008, analysis of long-term follow-up data from a NIAID-funded clinical trial showed that medical circumcision of adult men significantly reduces the risk of acquiring HIV through heterosexual intercourse for at least 3.5 years.

Budget Policy. The FY 2010 extramural budget estimate for HIV/AIDS research is $1.331 billion, an increase of $21.930 million and 1.7 percent above the FY 2009 budget estimate of $1.309 billion. The FY 2010 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 2010 AIDS research plan is a renewed focus on vaccine discovery research and continued support for the development of new, high-priority prevention strategies, including topical microbicides. FY 2010 funding will continue to support a broad range of research, from basic discovery through clinical trials on vaccine and topical microbicide candidates as well as other prevention strategies. Key research activities include activities to advance vaccine discovery, to identify novel approaches to interrupt HIV transmission and to

better understand complex interactions of HIV with the immune system by using a systems biology approach.

PORTRAIT of a Program: HIV Prevention Research

FY 2009 Level	$728 million
FY 2010 Level	$743 million
Change	$+15 million

The AIDS epidemic continues to grow worldwide, despite the identification of proven methods to prevent sexual, blood-borne, and mother-to-child transmission of HIV. The limitations of current HIV prevention efforts are underscored by the fact that two to three persons become infected for each person starting treatment worldwide.

Safe and efficacious vaccines to prevent HIV infection, disease, and/or transmission are essential for global control of the HIV/AIDS pandemic. In response to the new results from both clinical and basic research, NIAID redesigned its strategy for HIV/AIDS vaccine research. Through a new HIV vaccine discovery research program, NIAID is stimulating fundamental research that will contribute directly to the design of a vaccine. In addition, NIAID initiated a new program in FY 2008 to study B cells, immune cells that can produce antibodies with the capacity to neutralize HIV. NIAID also supported 16 clinical trials that are currently evaluating the safety and, in some cases, the efficacy of HIV vaccine candidates. Finally, NIAID has released a funding announcement to stimulate research on innovative vaccine approaches to provide long-term, safe protection from HIV infection.

Discovery and development of other effective biomedical prevention strategies are critical to curbing the continued spread of the HIV/AIDS pandemic, particularly in resource-poor settings. NIAID supports a broad research portfolio covering basic research through all phases of human clinical trials to evaluate prevention strategies, including, topical microbicides, pre-exposure prophylaxis using antiretroviral agents, medical male circumcision, preventing sexual transmission of HIV, and treatment of sexually transmitted infections, as well as other biomedical and behavioral risk reductions. Recent data indicate that the protective effect of circumcision against HIV acquisition among sexually active men is sustained, and possibly strengthened, up to 3.5 years. In FY 2008, NIAID-supported researchers demonstrated that earlier and longer treatment of infants born to HIV-infected mothers in developing countries decreased HIV transmission via breastfeeding, and reduced infant mortality.

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.

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. The current strategy reflects the focus of the 2007 update of the NIAID 2002 *Strategic Plan for Biodefense Research,* and increases emphasis on (a) developing countermeasures that are effective against a variety of pathogens, (b) developing technologies that can improve entire classes of products, and (c) 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 a larger HHS strategy.

Despite remarkable advances in medical research and treatments for infectious diseases, new challenges are constantly arising. New infectious diseases (e.g. SARS) are emerging and bacterial strains no longer responsive to our current treatments (e.g. multi- and extensively drug-resistant tuberculosis) are re-emerging. In addition, respiratory, sexually-transmitted, and enteric pathogens can cause serious epidemic and endemic global health problems. NIAID continues to support basic and clinical research to understand the pathogenesis, microbiology, and epidemiology of infectious diseases with the goal of developing better diagnostics, vaccines, and therapeutics.

Budget Policy. The FY 2010 extramural budget estimate for biodefense and emerging infectious diseases research is $1.308 billion, an increase of $9.752 million and 0.8 percent above the FY 2009 budget estimate of $1.298 billion. The FY 2010 budget increase reflects a commitment 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. NIAID will continue to focus on basic research, such as systematic evaluations of microbe-host interactions, and its application to product development such as 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 including MDR/XDR TB; and the development of platform technologies to support the development of a broad range of therapeutic agents. The FY 2010 NIH total request for biodefense and emerging infectious diseases research is $1.793 million with NIAID comprising $1.656 million of the NIH total.

PORTRAIT of a Program: Antimicrobial Resistance Research

FY 2009 Level	$171 million
FY 2010 Level	$173 million
Change	$ +2 million

Increasing use of antimicrobials in humans, animals, and agriculture has resulted in many microbes developing resistance to these powerful drugs. Overuse or misuse of antibiotics can make resistance develop even faster. Many infectious diseases are increasingly difficult to treat because of antimicrobial-resistant organisms, including HIV infection, staphylococcal infection, tuberculosis, influenza, gonorrhea, *Candida* infection, and malaria. Between 5 – 10% of all hospital patients develop an infection, leading to an increase of about $5 billion in annual U.S. healthcare costs, and about 90,000 deaths each year, up from 13,300 patient deaths in 1992.

NIAID supports a range of programs geared towards addressing the problem of antimicrobial resistance, including basic research to understand how microbes develop resistance and how our innate immune system interacts with these pathogens; translational research aimed at turning targets discovered through basic research into new diagnostics, therapeutics or vaccines; and clinical research on how best to use strategies for new and existing antimicrobial treatments. In FY 2008, NIAID intramural researchers studying *Staphylococcus aureus* (*S. aureus)* revealed potential targets to protect against methicillin-resistant *S. aureus* infections (MRSA). NIAID also funded an initiative to determine the optimal treatment protocol for community-acquired MRSA infections using off-patent antibiotics rather than the commonly prescribed final-option drugs such as vancomycin and the antibacterial drug, linezolid (LZD). Such studies represent a research niche that pharmaceutical companies have no incentive to fund. Optimized use strategies will help realize the full potential of these off-patent drugs and will also preserve the use of final-option antibiotics against the more widely-resistant hospital-acquired infections. NIAID also collaborated with South Korea to design a clinical trial to learn how patients infected with extensively drug resistant tuberculosis respond to LZD.

Antimicrobial resistance is a complex issue requiring the organized efforts of many partners, including federal agencies, academic researchers, industry, and healthcare providers. As a participant in the *Interagency Task Force on Antimicrobial Resistance,* NIAID helped to create the *Public Health Action Plan to Combat Antimicrobial Resistance,* which outlines specific steps needed to combat resistance in healthcare and agricultural settings.

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 conditions, in which the immune system itself contributes to the disease process, include primary immune deficiencies; 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 2008, NIAID completed the *NIAID Research Agenda for Malaria*, convened an expert panel to oversee the development of clinical guidelines for managing food allergies, and advanced the goals established in the *NIAID Research Agenda on Multidrug-Resistant and Extensively Drug-Resistant Tuberculosis* and in the *Report of the NIH Expert Panel on Food Allergy Research.* These detailed agendas, plans, and reports will guide the extensive NIAID research programs in these areas. In 2008, 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.

Program Announcements and research initiatives continuing in 2009 support a broad spectrum of research, including research on the diseases identified above as well as research to better understand and counter the effects of autoimmune diseases, asthma, and allergies, For example, in 2008, NIAID awarded grants to support high impact, innovative exploratory/developmental grants to determine the immune mechanisms and risk factors associated with food allergy and related co-morbid conditions

Budget Policy. The FY 2010 extramural budget estimate for infectious and immunologic diseases research is $1.338 billion, an increase of $13.889 million and 1.1 percent above the FY 2009 budget estimate of $1.324 billion. The proposal includes no change in the $300 million contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria from FY 2009. The FY 2010 IID research plan supports critical long-range research priorities of NIAID with funds carefully aligned to support key research activities which include the International Centers of Excellence for Malaria Research designed to support critical clinical research on malaria; and Partnerships for the Development of Vaccines for Selected Pathogens which will focus on developing vaccines for several pathogens including *Staph aureus* and *C. difficile*, which are responsible for significant morbidity and mortally in the U.S., result in major health care costs and can be difficult to treat due to resistance against multiple antibiotics. Funding will also continue to support research priorities on allergy/asthma and organ transplantation through initiatives such as the Consortium of Food Allergy Research and the Immunobiology of Xenotransplantation.

PROGRAM PORTAIT of a Program: Asthma and Allergic Diseases Research

FY 2009 Level	$159 million
FY 2010 Level	$161 million
Change	$ +2 million

Asthma and allergic diseases are the sixth leading cause of chronic illness in the country, affecting a patient's quality of life, well being, productivity, and can be life-threatening. Though the underlying causes of these conditions are not clear, recent scientific advances in understanding the genetic basis and immunologic mechanisms of asthma and allergic diseases provide new opportunities for prevention and treatment. NIAID's asthma and allergy research portfolio addresses the roles of the environment, innate immune system, defenses against infection, and airway inflammation in asthma and allergic diseases.

In FY2008, NIAID funded 15 *Asthma and Allergic Diseases Research Centers* to conduct basic and clinical research on the mechanisms, diagnosis, prevention, and treatment of asthma and allergic diseases. Other NIAID-supported asthma research programs focus on genetic susceptibility, development of effective immune-based therapies, and mechanisms that contribute to flare ups of asthma symptoms. Programs like the Inner City Asthma Consortium evaluate the safety and efficacy of promising immune-based therapies and contributing factors for asthma in inner city children. In FY2008, NIAID-supported researchers evaluated whether measuring exhaled nitric oxide (NO) as part of the overall management of the disease in children led to improved asthma outcomes. Although the researchers found no difference in outcomes between those who did and did not use NO measurement, the study reinforced the importance of following asthma management guidelines.

Food allergy, a growing health concern that occurs in 6-8% of children under the age of 4 and 3.7% of adults in the United States, is the most frequent single cause of emergency room visits for anaphylaxis. In FY2008, NIAID re-issued funding announcements to continue support of two food allergy initiatives. The *Consortium on Food Allergy Research*, initially launched in 2005, assesses the immunologic events associated with the development of new food allergies and tolerance to foods in high-risk children. The *Exploratory Investigations in Food Allergy* encourages new investigators to perform innovative, exploratory/developmental food allergy research. With the U.S. Food and Drug Administration, NIAID cosponsored the *Food Allergy Clinical Design Workshop* to examine issues related to conducting food allergy trials in children. NIAID is also leading a process to develop guidelines for diagnosis and management of food allergies.

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. 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. Examples of intramural research include the development and testing of vaccines for a wide range of diseases including HIV, malaria, pandemic influenza,and Ebola.

Budget Policy. The FY 2010 budget estimate for Intramural Research is $549.200 million, an increase of $8.115 million and 1.5 percent above the FY 2009 budget estimate of $541.085 million. The FY 2010 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 research on 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 2010 budget increase is to enhance clinical research and support operating costs of Intramural labs including the three new biocontainment laboratories that have recently come online.

RESEARCH MANAGEMENT SUPPORT

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 activities include strategic planning, coordination, and evaluation of the Institute's programs, as well as regulatory compliance, international coordination, and liaison with other Federal agencies, Congress, and the public. The Institute will oversee approximately 5,000 research grants and approximately 230 research and support contracts in 2010.

Budget Policy. The FY 2010 budget estimate is $234.348 million, an increase of $4.037 million and 1.8 percent above the FY 2009 budget estimate of $230.311 million. The total number of NIAID FTEs is slated to increase from 1,670 in FY 2009 to 1,703 in FY 2010. The 1,703 FTE requested for FY 2010 includes 882 FTE for RMS with the remainder in the Division of Intramural Research.

National Institutes of Health
National Institute of Allergy and Infectious Diseases
Budget Authority by Object

	FY 2009 Estimate	FY 2010 PB	Increase or Decrease	Percent Change
Total compensable workyears:				
Full-time employment	1,670	1,703	33	2.0
Full-time equivalent of overtime and holiday hours	6	6	0	0.0
Average ES salary	$163,724	$166,998	$3,274	2.0
Average GM/GS grade	12.0	12.0	0.0	0.0
Average GM/GS salary	$95,479	$97,388	$1,909	2.0
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$90,018	$91,818	$1,800	2.0
Average salary of ungraded positions	131,608	134,240	2,632	2.0

OBJECT CLASSES	FY 2009 Estimate	FY 2010 Estimate	Increase or Decrease	Percent Change
Personnel Compensation:				
11.1 Full-time permanent	$114,215,000	$119,403,000	$5,188,000	4.5
11.3 Other than full-time permanent	51,748,000	54,366,000	2,618,000	5.1
11.5 Other personnel compensation	6,141,000	6,431,000	290,000	4.7
11.7 Military personnel	4,638,000	4,863,000	225,000	4.9
11.8 Special personnel services payments	22,507,000	23,732,000	1,225,000	5.4
Total, Personnel Compensation	199,249,000	208,795,000	9,546,000	4.8
12.0 Personnel benefits	47,637,000	49,902,000	2,265,000	4.8
12.2 Military personnel benefits	3,273,000	3,427,000	154,000	4.7
13.0 Benefits for former personnel	0	0	0	0.0
Subtotal, Pay Costs	**250,159,000**	**262,124,000**	**11,965,000**	**4.8**
21.0 Travel and transportation of persons	10,067,000	9,954,000	(113,000)	-1.1
22.0 Transportation of things	893,000	888,000	(5,000)	-0.6
23.1 Rental payments to GSA	741,000	756,000	15,000	2.0
23.2 Rental payments to others	904,000	922,000	18,000	2.0
23.3 Communications, utilities and miscellaneous charges	1,765,000	1,800,000	35,000	2.0
24.0 Printing and reproduction	375,000	368,000	(7,000)	-1.9
25.1 Consulting services	11,710,000	11,668,000	(42,000)	-0.4
25.2 Other services	115,976,000	115,589,000	(387,000)	-0.3
25.3 Purchase of goods and services from government accounts	752,708,000	754,274,000	1,566,000	0.2
25.4 Operation and maintenance of facilities	7,620,000	7,772,000	152,000	2.0
25.5 Research and development contracts	795,368,000	794,204,000	(1,164,000)	-0.1
25.6 Medical care	2,279,000	2,271,000	(8,000)	-0.4
25.7 Operation and maintenance of equipment	9,164,000	9,081,000	(83,000)	-0.9
25.8 Subsistence and support of persons	0	0	0	0.0
25.0 Subtotal, Other Contractual Services	**1,694,825,000**	**1,694,859,000**	**34,000**	**0.0**
26.0 Supplies and materials	45,542,000	45,359,000	(183,000)	-0.4
31.0 Equipment	21,030,000	20,871,000	(159,000)	-0.8
32.0 Land and structures	2,000	2,000	0	0.0
33.0 Investments and loans	0	0	0	0.0
41.0 Grants, subsidies and contributions	2,676,269,000	2,722,392,000	46,123,000	1.7
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	**4,452,413,000**	**4,498,171,000**	**45,758,000**	**1.0**
Total Budget Authority by Object	**4,702,572,000**	**4,760,295,000**	**57,723,000**	**1.2**

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

National Institutes of Health
National Institute of Allergy and Infectious Diseases
Salaries and Expenses

OBJECT CLASSES	FY 2009 Estimate	FY 2010 PB	Increase or Decrease	Percent Change
Personnel Compensation:				
Full-time permanent (11.1)	$114,215,000	$119,403,000	$5,188,000	4.5
Other than full-time permanent (11.3)	51,748,000	54,366,000	2,618,000	5.1
Other personnel compensation (11.5)	6,141,000	6,431,000	290,000	4.7
Military personnel (11.7)	4,638,000	4,863,000	225,000	4.9
Special personnel services payments (11.8)	22,507,000	23,732,000	1,225,000	5.4
Total Personnel Compensation (11.9)	**199,249,000**	**208,795,000**	**9,546,000**	**4.8**
Civilian personnel benefits (12.1)	47,637,000	49,902,000	2,265,000	4.8
Military personnel benefits (12.2)	3,273,000	3,427,000	154,000	4.7
Benefits to former personnel (13.0)	0	0	0	0.0
Subtotal, Pay Costs	**250,159,000**	**262,124,000**	**11,965,000**	**4.8**
Travel (21.0)	10,067,000	9,954,000	(113,000)	-1.1
Transportation of things (22.0)	893,000	888,000	(5,000)	-0.6
Rental payments to others (23.2)	904,000	922,000	18,000	2.0
Communications, utilities and miscellaneous charges (23.3)	1,765,000	1,800,000	35,000	2.0
Printing and reproduction (24.0)	375,000	368,000	(7,000)	-1.9
Other Contractual Services:				
Advisory and assistance services (25.1)	11,710,000	11,668,000	(42,000)	-0.4
Other services (25.2)	115,976,000	115,589,000	(387,000)	-0.3
Purchases from government accounts (25.3)	688,654,000	690,248,000	1,594,000	0.2
Operation and maintenance of facilities (25.4)	7,620,000	7,772,000	152,000	2.0
Operation and maintenance of equipment (25.7)	9,164,000	9,081,000	(83,000)	-0.9
Subsistence and support of persons (25.8)	0	0	0	0.0
Subtotal Other Contractual Services	**833,124,000**	**834,358,000**	**1,234,000**	**0.1**
Supplies and materials (26.0)	29,816,000	29,693,000	(123,000)	-0.4
Subtotal, Non-Pay Costs	876,944,000	877,983,000	1,039,000	0.1
Total, Administrative Costs	**1,127,103,000**	**1,140,107,000**	**13,004,000**	**1.2**

National Institutes of Health
National Institute of Allergy and Infectious Diseases
Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2009 Amount Authorized	FY 2009 Estimate	2010 Amount Authorized	FY 2010 PB
Research and Investigation	Section 301	42§241	Indefinite	$4,702,572,000	Indefinite	$4,760,295,000
National Institute of Allergy and Infectious Diseases	Section 402(a)	42§281	Indefinite	$4,702,572,000	Indefinite	$4,760,295,000
Total, Budget Authority				4,702,572,000		4,760,295,000

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/
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)
Supplemental				22,689,000
2009	4,568,778,000	4,716,283,000	4,688,828,000	4,702,572,000
2010	4,760,295,000			

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

National Institutes of Health
National Institute of Allergy and Infectious Diseases
Details of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2008 Actual	FY 2009 Estimate	FY 2010 PB
Office of the Director	300	307	307
Division of Allergy, Immunology, and Transplantation	78	80	82
Division of Microbiology and Infectious Diseases	149	153	157
Division of Extramural Activities	183	187	187
Division of Acquired Immunodeficiency	135	144	149
Division of Intramural Research	623	637	659
Vaccine Research Center	88	88	88
Division of Clinical Research	74	74	74
Total	1,630	1,670	1,703

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
2006	12.0
2007	12.0
2008	12.0
2009	12.0
2010	12.0

National Institutes of Health
National Institute of Allergy and Infectious Diseases
Detail of Positions

GRADE	FY 2008 Actual	FY 2009 Estimate	FY 2010 PB
Total, ES Positions	2	2	2
Total, ES Salary	321,028	327,449	333,998
GM/GS-15	115	116	117
GM/GS-14	312	316	317
GM/GS-13	242	245	246
GS-12	206	209	210
GS-11	149	151	152
GS-10	2	2	2
GS-9	81	82	82
GS-8	27	27	27
GS-7	50	51	51
GS-6	15	15	15
GS-5	1	1	1
GS-4	2	2	2
GS-3	2	2	2
GS-2	0	0	0
GS-1	3	3	3
Subtotal	1,207	1,222	1,227
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	1	1	1
Director Grade	23	23	23
Senior Grade	15	15	15
Full Grade	1	1	1
Senior Assistant Grade	3	3	3
Assistant Grade	0	0	0
Co-Step	4	4	4
Subtotal	47	47	47
Ungraded	459	473	480
Total permanent positions	1,279	1,300	1,308
Total positions, end of year	1,715	1,744	1,756
Total full-time equivalent (FTE) employment, end of year	1,630	1,670	1,703
Average ES salary	160,514	163,724	166,998
Average GM/GS grade	12.0	12.0	12.0
Average GM/GS salary	91,123	95,479	97,388

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

National Institutes of Health
National Institute of Allergy and Infectious Diseases
New Positions Requested

	FY 2010		
Positions	**Grade**	**Number**	**Annual Salary**
BIOLOGIST	GS-11	2	$ 60,989
BIOLOGIST	GS-12	2	73,100
BIOLOGIST	AD	4	98,518
MEDICAL OFFICER	GS-14	2	116,419
MEDICAL OFFICER	GS-15	2	136,941
MEDICAL OFFICER	AD	3	140,969
MICROBIOLOGIST	GS-12	3	73,100
MICROBIOLOGIST	AD	2	101,416
NURSE CONSULTANT	GS-12	2	77,194
PROGRAM ANALYST	GS-9	2	50,408
PUBLIC HEALTH ANALYST	GS-12	3	73,100
STAFF CLINICIAN	GS-13	1	86,927
GRANTS MANAGEMENT SPEC	GS-12	2	73,100
ADMINISTRATIVE OFFICER	GS-12	2	73,100
ADMINISTRATIVE ASSISTANT	GS-9	1	50,408
Total Requested		33	