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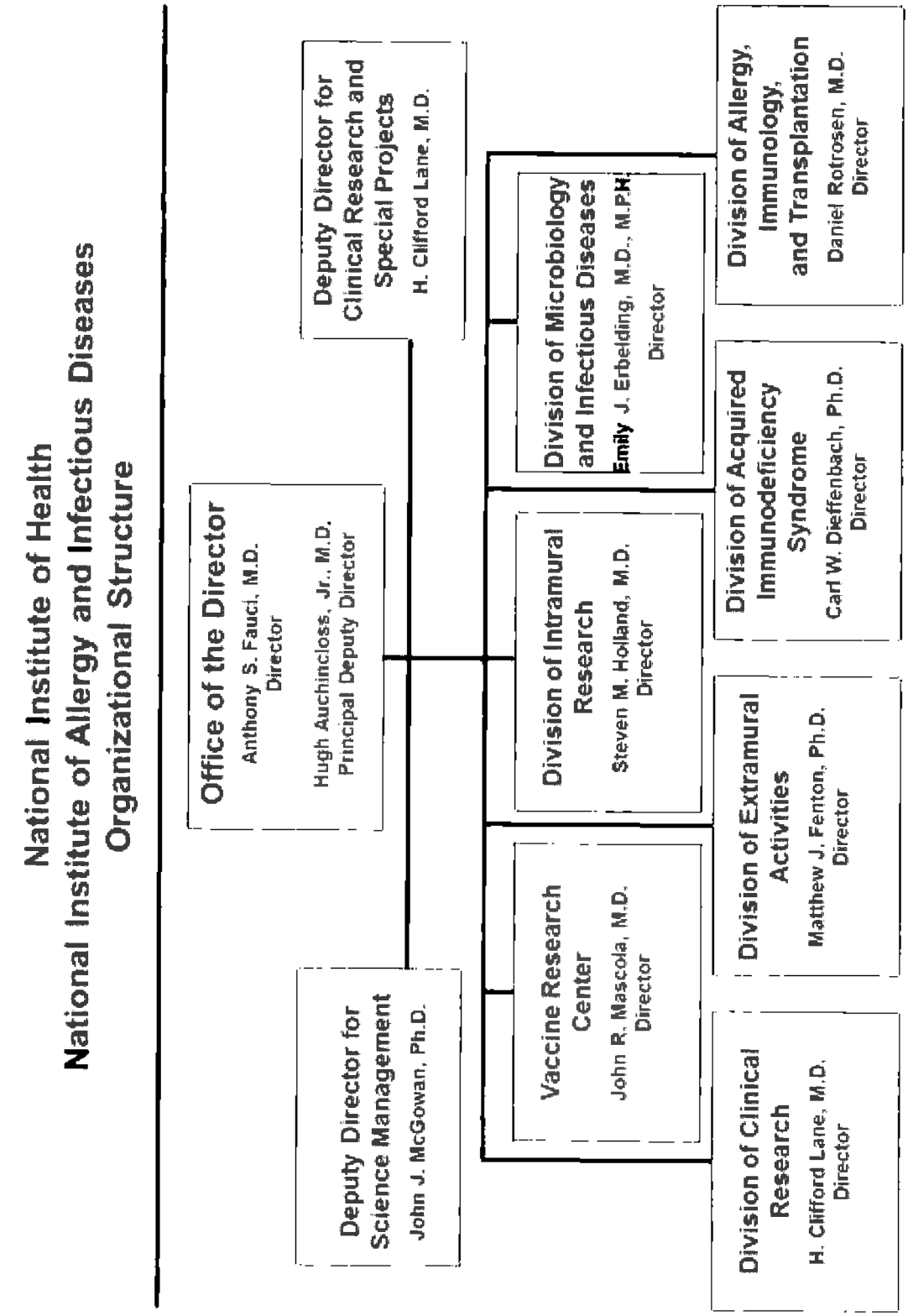
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases (NIAID)

FY 2020 Budget


National Institute of Health
National Institute of Allergy and Infectious Diseases
Organizational Structure
Office of the Director
Anthony S. Fauci, M.D.
Director
Hugh Auchincloss, Jr., M.D.
Principal Deputy Director
Deputy Director for Clinical Research and Special Projects
H. Clifford Lane, M.D.
Deputy Director for Science Management
John J. McGowan, Ph.D.
Division of Microbiology and Infectious Diseases
Emily J. Erbelding, M.D., M.P.H.
Director
Division of Allergy, Immunology, and Transplantation
Daniel Rotrosen, M.D.
Director
Division of Intramural Research
Steven M. Holland, M.D.
Director
Division of Acquired Immunodeficiency Syndrome
Carl W. Dieffenbach, Ph.D.
Director
Vaccine Research Center
John R. Mascola, M.D.
Director
Division of Extramural Activities
Matthew J. Fenton, Ph.D.
Director
Division of Clinical Research
H. Clifford Lane, M.D.
Director

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases

For carrying out section 301 and title IV of the PHS Act with respect to allergy and infectious diseases, [$5,523,324,000]*$4,754,379,000*.

NATIONAL INSTITUTES OF HEALTH
National Institute of Allergy and Infectious Diseases

Amounts Available for Obligation[1]
(Dollars in Thousands)

Source of Funding	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Appropriation	$5,260,210	$5,523,324	$4,754,379
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	*(0)*	*(0)*	*(0)*
Other Mandatory financing	*(0)*	*(0)*	*(0)*
Rescission	0	0	0
Sequestration	0	0	0
Secretary's Transfer	-12,358	0	0
Subtotal, adjusted appropriation	$5,247,852	$5,523,324	$4,754,379
OAR HIV/AIDS Transfers	14,455	0	0
HEAL Initiative Transfer	6,000	0	0
Subtotal, adjusted budget authority	$5,268,307	$5,523,324	$4,754,379
Unobligated balance, start of year[2]	0	5,909	0
Unobligated balance, end of year [2]	-5,909	0	0
Subtotal, adjusted budget authority	$5,262,398	$5,529,233	$4,754,379
Unobligated balance lapsing	-1	0	0
Total obligations	$5,262,397	$5,529,233	$4,754,379

[1] Excludes the following amounts (in thousand) for reimbursable activities carried out by this account:
FY 2018 - $26,467 FY 2019 - $31,759 FY 2020 - $30,452

[2]Reflects funding from HEAL transfer not obligated in FY 2018, and carried over into FY 2019.

NATIONAL INSTITUTES OF HEALTH
National Institute of Allergy and Infectious Diseases

Budget Mechanism - Total[1]

(Dollars in Thousands)

MECHANISM	FY 2018 Final[2]		FY 2019 Enacted		FY 2020 President's Budget		FY 2020 +/- FY 2019 Enacted	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	3,009	$2,379,949	3,372	$2,347,514	3,508	$2,127,483	136	-$220,031
Administrative Supplements	*(72)*	27,004	*(65)*	7,055	*(58)*	6,313	*(-2)*	-742
Competing:								
Renewal	156	91,482	182	176,326	132	85,194	-50	-91,132
New	1,264	517,526	1,340	632,986	1,026	474,068	-314	-158,918
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	1,420	$609,008	1,522	$809,312	1,158	$559,262	-364	-$250,050
Subtotal, RPGs	4,429	$3,015,961	4,894	$3,163,881	4,666	$2,693,058	-228	-$470,823
SBIR/STTR	265	140,879	289	153,650	259	132,293	-30	-21,358
Research Project Grants	4,690	$3,156,840	5,183	$3,317,531	4,925	$2,825,351	-258	-$492,181
Research Centers:								
Specialized/Comprehensive	24	$37,615	24	$37,615	20	$32,389	-4	-$5,226
Clinical Research	0	943	0	948	0	816	0	-132
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	0	500	0	500	0	428	0	-72
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	24	$39,058	24	$39,063	20	$33,633	-4	-$5,429
Other Research:								
Research Careers	264	$45,128	274	$46,930	235	$40,407	-39	-$6,523
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	406	0	422	0	363	0	-59
Other	110	27,704	115	28,225	99	24,302	-16	-3,923
Other Research	374	$73,237	389	$75,577	334	$65,072	-55	-$10,505
Total Research Grants	5,088	$3,269,135	5,596	$3,432,171	5,279	$2,924,056	-317	-$508,115
Ruth L. Kirschstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	212	$9,423	215	$9,741	185	$8,387	-30	-$1,354
Institutional Awards	938	50,153	957	51,909	824	44,693	-133	-7,217
Total Research Training	1,150	$59,575	1,172	$61,650	1,009	$53,080	-163	-$8,571
Research & Develop. Contracts	219	$928,436	234	$969,449	217	$853,115	-17	-$116,334
(SBIR/STTR) (non-add)	*(19)*	*(18,213)*	*(22)*	*(24,213)*	*(19)*	*(20,480)*	*(-3)*	*(-3,733)*
Intramural Research	880	681,363	880	715,416	880	613,953	0	-101,462
Res. Management & Support	1,055	329,797	1,083	344,638	1,083	310,174	0	-34,464
Res. Management & Support (SBIR Admin) (non-add)	*(0)*	*(0)*	*(0)*	*(525)*	*(0)*	*(510)*	*(0)*	*(-15)*
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NIAID	1,935	$5,268,307	1,963	$5,523,324	1,963	$4,754,379	0	-$768,945

[1] All items in italics and brackets are non-add entries.
[2] Includes $5.9 million of funding for HEAL not obligated in FY 2018, and carried over into FY 2019.

Major Changes in the Fiscal Year 2020 President's Budget Request

Major changes by budget mechanism and/or budget 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 2020 President's Budget. The FY 2020 President's Budget for NIAID is $4,754.4 million, a decrease of $768.9 million from the FY 2019 Enacted level. Overall reductions of 13.9 percent are distributed across all programmatic areas including basic, translational and clinical research. NIAID is committed to aligning support within the funding levels provided in the FY 2020 President's Budget for these key priorities along with the rest of our research portfolio, which reflects the Administration's fiscal policy goals for the Federal Government. Within that framework, NIAID will pursue its highest research priorities through strategic investments and careful stewardship of appropriated funds.

Research Project Grants (RPGs) (-$492.2 million; total $2,825.4 million):
NIAID will make similar dollar adjustments to competing and noncompeting RPGs resulting in reduction of noncompeting RPGs by 9.4 percent which is a $220.0 million decrease from the FY 2019 Enacted level. Competing RPGs are expected to decrease by 30.9 percent which is a $250.1 million decrease compared to the FY 2019 Enacted level. The number of competing grant awards will also decrease consistent with the funding reduction. Overall, RPG funding is expected to decrease by 14.8 percent.

Other Mechanisms including Centers, Other Research, and Training (-$24.5 million; total $151.8 million):
NIAID will reduce funding by 13.9 percent for Centers, Other Research, and Training, resulting in decreases of $5.4 million, $10.5 million and $8.6 million respectively from their FY 2019 Enacted levels.

Research and Development (R&D) Contracts (-$116.3 million; total $853.1 million):
NIAID will reduce funding for R&D Contracts by 12.0 percent across all program areas.

Intramural Research (IR) (-$101.5 million; total $614.0 million):
NIAID will reduce funding for IR by 14.2 percent. IR will continue to support critical long-range priorities with funds carefully aligned to key research activities including infectious diseases, such as AIDS, malaria, and influenza, albeit at a reduced funding level.

Research Management and Support (RMS) (-$34.5 million; total $310.2 million):
NIAID will reduce funding for RMS by 10.0 percent which will reduce NIAID's overall level of program management and administrative support, consistent with the decrease in grant awards.

NATIONAL INSTITUTES OF HEALTH
National Institute of Allergy and Infectious Diseases

Summary of Changes

(Dollars in Thousands)

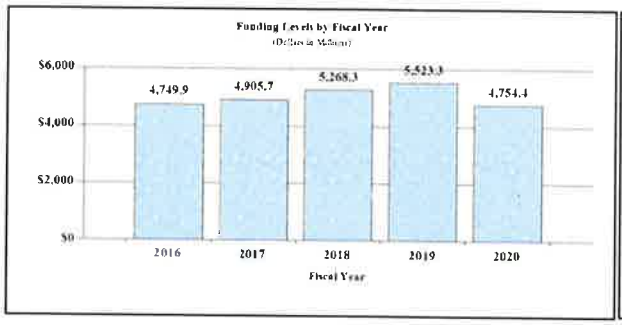
FY 2019 Enacted	**$5,523,324**
FY 2020 President's Budget	**$4,754,379**
Net change	-$768,945

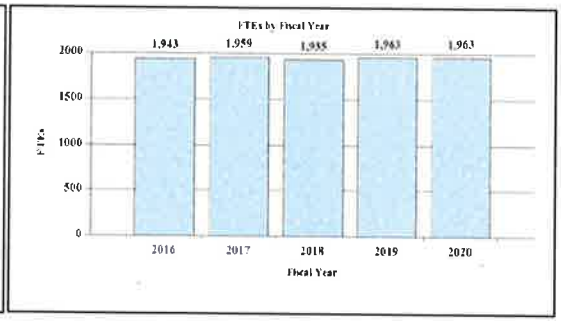
CHANGES	FY 2020 President's Budget FTEs	FY 2020 President's Budget Budget Authority	Change from FY 2019 Enacted FTEs	Change from FY 2019 Enacted Budget Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2019 pay increase & benefits		$169,384		$420
b. January FY 2020 pay increase & benefits		169,384		1,261
c. Paid days adjustment		169,384		521
d. Differences attributable to change in FTE		169,384		0
e. Payment for centrally furnished services		88,928		0
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		355,641		524
Subtotal				$2,726
2. Research Management and Support:				
a. Annualization of January 2019 pay increase & benefits		$181,288		$450
b. January FY 2020 pay increase & benefits		181,288		1,349
c. Paid days adjustment		181,288		689
d. Differences attributable to change in FTE		181,288		0
e. Payment for centrally furnished services		26,908		0
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		101,978		6
Subtotal				$2,494
Subtotal, Built-in				$5,220

CHANGES	FY 2020 President's Budget No.	FY 2020 President's Budget Amount	Change from FY 2019 Enacted No.	Change from FY 2019 Enacted Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	3,508	$2,133,796	136	-$220,773
b. Competing	1,158	559,262	-364	-250,050
c. SBIR/STTR	259	132,293	-30	-21,358
Subtotal, RPGs	4,925	$2,825,351	-258	-$492,181
2. Research Centers	20	$33,633	-4	-$5,429
3. Other Research	334	65,072	-55	-10,505
4. Research Training	1,009	53,080	-163	-8,571
5. Research and development contracts	217	853,115	-17	-116,334
Subtotal, Extramural		$3,830,251		-$633,019
	FTEs		FTEs	
6. Intramural Research	880	$613,953	0	-$104,188
7. Research Management and Support	1,083	310,174	0	-36,958
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	1,963	$4,754,379	0	-$774,165
Total changes				-$768,945

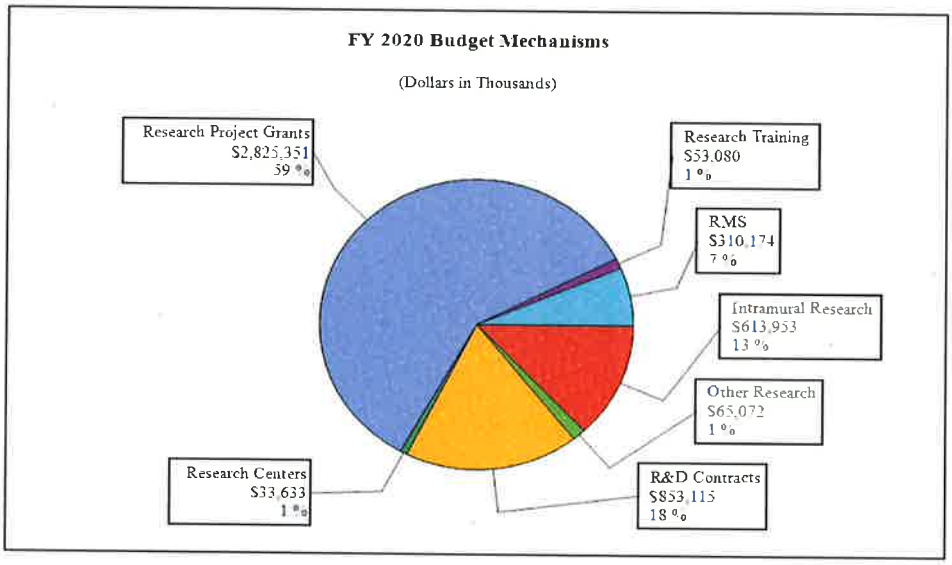
Fiscal Year 2020 Budget Graphs

History of Budget Authority and FTEs:

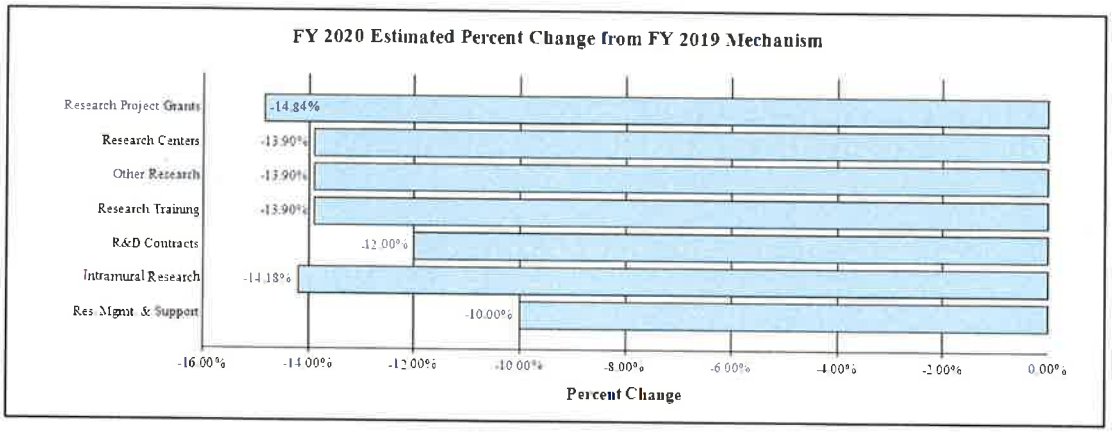




Distribution by Mechanism:



Change by Selected Mechanisms:



NATIONAL INSTITUTES OF HEALTH
National Institute of Allergy and Infectious Diseases

Budget Authority by Activity[1]
(Dollars in Thousands)

	FY 2018 Final		FY 2019 Enacted		FY 2020 President's Budget		FY 2020 +/- FY2019	
Extramural Research	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**
Detail								
HIV/AIDS[2]		$1,355,116		$1,345,942		$1,176,263		-$169,679
Biodefense & Emerging Infectious Diseases[3]		1,662,433		1,820,763		1,550,879		-269,884
Infectious & Immunological Diseases		1,239,597		1,296,564		1,103,109		-193,455
Subtotal, Extramural		**$4,257,145**		**$4,463,270**		**$3,830,251**		**-$633,019**
Intramural Research	**880**	**$681,363**	**880**	**$715,416**	**880**	**$613,953**	**0**	**-$101,462**
Research Management & Support	**1,055**	**$329,797**	**1,083**	**$344,638**	**1,083**	**$310,174**	**0**	**-$34,464**
TOTAL	**1,935**	**$5,268,307**	**1,963**	**$5,523,324**	**1,963**	**$4,754,379**	**0**	**-$768,945**

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.
[2] Reflects NIAID extramural totals for HIV/AIDS NIAID-wide totals for HIV/AIDS, including intramural research, are (in thousands): FY 2018 actual of $1,684,054, FY 2019 Enacted of $1,713,305, and FY 2020 estimate of $1,474,813.
[3] Reflects NIAID extramural totals for Biodefense NIAID-wide totals for Biodefense, including intramural research, are (in thousands): FY 2018 actual of $2,046,438; FY 2019 Enacted of $2,211,733, and FY 2020 estimate of $1,903,821.

NATIONAL INSTITUTES OF HEALTH
National Institute of Allergy and Infectious Diseases

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2019 Amount Authorized	FY 2019 Enacted	2020 Amount Authorized	FY 2020 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$5,523,324,000	Indefinite	$4,754,379,000
National Institute of Allergy and Infectious Diseases	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$5,523,324,000		$4,754,379,000

NATIONAL INSTITUTES OF HEALTH
National Institute of Allergy and Infectious Diseases

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2011	$4,977,070,000		$4,969,301,000	$4,818,275,000
Rescission				$42,307,326
2012	$4,915,970,000	$4,915,970,000	$4,725,288,000	$4,499,215,000
Rescission				$8,503,516
2013	$4,495,307,000		$4,508,932,000	$4,490,711,484
Rescission				$8,981,423
Sequestration				($225,402,837)
2014	$4,578,813,000		$4,548,383,000	$4,358,841,000
Rescission				$0
2015	$4,423,357,000			$4,358,841,000
Rescission				$0
2016	$4,614,779,000	$4,512,918,000	$4,710,342,000	$4,629,928,000
Rescission				$0
2017[1]	$4,715,697,000	$4,738,883,000	$4,961,305,000	$4,906,638,000
Rescission				$0
2018	$3,782,670,000	$5,005,813,000	$5,127,866,000	$5,260,210,000
Rescission				$0
2019	$4,761,948,000	$5,368,029,000	$5,506,190,000	$5,523,324,000
Rescission				$0
2020	$4,754,379,000			

[1] Budget Estimate to Congress includes mandatory financing.

Justification of Budget Request

National Institute of Allergy and Infectious Diseases

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended.

Budget Authority (BA):

	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 + / - FY 2019
BA	$5,268,307,000	$5,523,324,000	$4,754,379,000	-$768,945,000
FTE	1,935	1,963	1,963	0

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

Director's Overview

The National Institute of Allergy and Infectious Diseases (NIAID) has a unique dual mandate to conduct and support basic and applied research on established infectious, immunologic, and allergic diseases, and also to quickly launch a research response to newly emerging and reemerging infectious threats. As outlined in the *NIAID Strategic Plan*[1], the priorities of the Institute align with its main scientific areas of emphasis—infectious diseases (non-AIDS), including emerging and reemerging diseases and biodefense; HIV/AIDS; and allergy, immunology, and immune-mediated diseases—to advance research that improves the quality of human life in the United States and around the world. With NIAID support, scientists are designing and developing new diagnostics, treatments, and preventive strategies, including vaccines, which can be deployed to protect and treat people worldwide. Consistent with the strategic priorities outlined below, NIAID strives to improve public health, as illustrated by the many key advances made possible by NIAID research, training, and infrastructure investments.

Exploring the Next Frontier

NIAID is aggressively pursuing several opportunities to transform the way we diagnose, prevent, and treat infectious and immunologic diseases. For example, NIAID influenza research aims to address the ongoing threat of seasonal influenza and the potential for pandemic influenza to arise. In parallel with improving seasonal influenza vaccine approaches, a key priority is to develop a "universal" influenza vaccine that will provide robust, long-lasting protection against multiple strains of influenza, including emerging forms that could cause a global pandemic. In

[1] www.niaid.nih.gov/sites/default/files/NIAIDStrategicPlan2017.pdf

2018, NIAID released a strategic plan[2] that outlines multiple approaches for developing a safe and effective universal influenza vaccine. Several clinical trials testing different universal influenza vaccine strategies are already underway.

NIAID also continues to lead the fight against HIV/AIDS. Since AIDS was first described in the early 1980s, a sustained NIAID research effort has helped transform the lives of people living with HIV. Today, antiretroviral therapy (ART) can provide a near-normal life expectancy; however, NIAID continues to pursue innovative strategies that could improve current HIV prevention and treatment strategies. One such emerging approach is the passive transfer of broadly neutralizing antibodies (bNAbs) that can stop a wide variety of HIV strains from infecting human cells. Initial results are promising: in early phase clinical studies, bNAb treatment suppressed HIV for more than 15 weeks after interrupting ART.

Tuberculosis (TB) remains the leading cause of death among infectious diseases and is one of the top ten causes of death worldwide. In 2018, to help end this devastating disease and support the World Health Organization (WHO) goal of ending the TB epidemic by 2035, NIAID developed the *NIAID Strategic Plan for Tuberculosis Research*[3]. The plan outlines a multipronged effort to address fundamental TB research questions and to stimulate the clinical translation of promising diagnostic, therapeutic, and vaccine candidates. NIAID presented key elements of the plan at the United Nations General Assembly High-Level Meeting on Ending TB in September 2018.

NIAID is also committed to addressing the growing problem of antibiotic-resistant bacteria. The Antibacterial Resistance Leadership Group (ARLG), established by NIAID in 2013, oversees clinical research to reduce the threat of antibacterial resistance. NIAID is a partner in the international public-private Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) initiative, which is bolstering innovation in antibacterial product development.

Building on Basic Science

Although challenges in understanding, preventing, and effectively treating HIV/AIDS remain, investments in HIV/AIDS research have already provided extraordinary benefits. HIV/AIDS research has led to substantial advances in other scientific areas, from innovations in basic immunology and structural biology to treatments for immunologic diseases and cancer[4]. The knowledge gained about the effects of HIV infection on the human immune system has provided critical insights into the role of immune activation and inflammation in diseases such as TB and cardiovascular disease. Similarly, advances in structure-based HIV vaccine design have greatly influenced the design of vaccines for other viruses.

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[2] Erbelding E.J., Post D.J., Stemmy E.J., Roberts P.C., Augustine A.D., Ferguson S., Paules C.I., Graham B.S., and Fauci A.S. Universal Influenza Vaccine: The Strategic Plan for the National Institute of Allergy and Infectious Diseases. *The Journal of Infectious Diseases*. 2018 July 2; 218(3):347–354. doi.org/10.1093/infdis/jiy103

[3] www.niaid.nih.gov/sites/default/files/TBStrategicPlan2018.pdf

[4] Schwetz T.A. and Fauci A.S. The Extended Impact of Human Immunodeficiency Virus/AIDS Research, *The Journal of Infectious Diseases*, jiy441, doi.org/10.1093/infdis/jiy441

NIAID leads fundamental research efforts to enhance responses to emerging public health threats. Preparedness in the face of infectious disease threats that require a rapid response, such as the 2018 outbreaks of Ebola virus disease in the Democratic Republic of the Congo (DRC) and Lassa fever in Nigeria, can save countless lives and may even stop a disease outbreak from developing into a pandemic. NIAID is exploring the use of monoclonal antibodies (mAbs)—antibodies that precisely bind to a single target—to treat select infectious diseases and to serve as a first-line intervention to prevent or slow the progress of outbreaks, especially while vaccines are being developed. During the 2018 Ebola outbreaks, the DRC approved the compassionate use of several experimental therapies, including ZMapp, a cocktail of three mAbs targeting Zaire Ebola virus, and mAb114, a mAb that NIAID researchers originally isolated from a human survivor of the 1995 Ebola outbreak in the DRC.

Transformational Tools and Technologies

NIAID-supported technologies and strategies, such as versatile vaccine platform approaches, are enabling the development of new medical countermeasures at an unprecedented pace. For example, NIAID scientists developed a DNA-based vaccine candidate that moved from concept to a clinical trial in less than four months during the 2015–2016 Zika virus outbreak in the Americas. The gene-based construct of this Zika vaccine—the same platform originally used for a candidate West Nile virus vaccine—provides a versatile model that could be applied to make vaccines for other emerging and re-emerging infectious disease threats.

NIAID also continues to advance life-saving treatments to combat the debilitating effects of immune-mediated disorders, such as the often-fatal disease diffuse cutaneous systemic sclerosis, which causes a hardening of tissues including skin, blood vessels, and internal organs. A recent NIAID-supported clinical trial showed that a therapeutic regimen involving transplantation of a person's own blood-forming stem cells increased patient survival rates and improved long-term outcomes. NIAID-supported researchers have also provided groundbreaking evidence that oral immunotherapy (OIT)—repeated exposures to small, increasing amounts of an allergen—may be effective in treating allergy to single foods, such as peanut or egg.

Overall Budget Policy:
The FY 2020 President's Budget request is $4,754.4 million, a decrease of $768.9 million or 13.9 percent compared with the FY 2019 Enacted level. Within the President's Budget request, noncompeting RPG grant awards will be reduced by 9.4 percent and competing RPG grant awards will also be reduced at a comparable level resulting in an overall average cost decrease of 9.2 percent from the FY 2019 Enacted level. R&D contracts awards will be reduced by12.0 percent from the FY 2019 Enacted level.

In FY 2020, NIAID will support opportunities for new researchers to receive funding equivalent to those of established investigators submitting new R01 applications. 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, HIV/AIDS, influenza, tuberculosis, malaria, autoimmune disorders, drug-resistant microbes, asthma, and allergies but at reduced levels when compared to the FY 2019 Enacted level.

The NIAID's Intramural Research and Research Management and Support programs reflect a modest increase for pay and benefits for military and reductions in the non-pay categories consistent with the overall reduction in budgetary resources and NIH budget policy.

Program Description and Accomplishments

HIV/AIDS

In recent years, approximately 40,000 people have been infected with HIV annually in the United States, and in 2015, approximately 6,500 people died from HIV disease[5]. Moreover, in 2017, an estimated 1.8 million people globally were newly infected with HIV and 940,000 died of HIV/AIDS[6]. NIAID-supported investigators continue to research all areas of HIV infection, including potential cures, HIV vaccines and other prevention strategies, and new treatments for HIV and HIV-associated opportunistic infections. Thanks to these efforts, today, an array of prevention and treatment methods is available to patients.

In regard to a potential cure, effective ART can prevent HIV replication, but the virus remains latent (dormant) in a small number of cells, called the HIV reservoir. This latency enables a resurgence of the virus when treatment is interrupted. NIAID is supporting several unique research approaches to destroy the reservoirs, or to enable a functional cure, where a person with HIV could maintain an undetectable viral load without regular treatment.

While NIAID and the HIV research community work to develop an effective vaccine (see *Program Portrait*), preventing new HIV infections through other means is also key to ending the HIV/AIDS pandemic. NIAID research has demonstrated that many of the effects of this devastating disease can be largely halted through sustained ART, which reduces HIV, or the viral load, to undetectable levels. People who maintain an undetectable viral load will not transmit virus to their uninfected sexual partners ("U=U"; Undetectable = Untransmittable). Additionally, pre-exposure prophylaxis (PrEP) is a highly effective strategy whereby HIV-uninfected people take medications to prevent the acquisition of HIV. However, the challenge of taking HIV medicines daily limits the efficacy of this approach, so NIAID is investigating longer-acting, easier-to-use HIV therapies and injectable medication for HIV prevention. Two ongoing, large-scale clinical trials are comparing daily oral PrEP to injections of the investigational anti-HIV drug cabotegravir once every eight weeks.

Recently, several long-term studies provided evidence that implementing HIV prevention measures can substantially reduce new HIV infections at the population level. In the Rakai district of Uganda, NIAID-supported researchers found that combining voluntary medical male circumcision with ART decreased HIV incidence by 42 percent. In parallel, the NIAID-supported Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (PopART) study, which is focused on patients with symptoms of TB or sexually transmitted infections in Zambia, is examining a broad array of HIV prevention measures, including voluntary male circumcision, prevention of mother-to-child transmission, and linkage to care. Early findings are

[5] HIV in the United States: At a Glance, updated Aug. 6, 2018. Centers for Disease Control. www.cdc.gov/hiv/statistics/overview/ataglance.html

[6] Global AIDS Update 2018. Miles to Go: Closing Gaps, Breaking Barriers, Righting Injustices. UNAIDS. www.unaids.org/en/20180718_GR2018

encouraging: after one year, nearly 90 percent of women and 80 percent of men with HIV know their HIV status, and about 75 percent of these individuals are on ART. In another NIAID-supported study, researchers demonstrated improved health outcomes following annual health fairs that integrated HIV testing and treatment with screenings for multiple conditions. The outcomes of this study, called SEARCH, include fewer cases of TB, better control of hypertension and diabetes, and approximately 30 percent fewer new HIV infections. Notably, the SEARCH study findings exceed international HIV testing and treatment goals set by UNAIDS (Joint United Nations Programme on HIV/AIDS), which call for 90 percent of people living with HIV to be diagnosed, 90 percent of those diagnosed to be on ART, and 90 percent of those on treatment to be virally suppressed by 2020.

HIV infection also may increase the risk of certain health complications. A person living with HIV is up to twice as likely as a person without HIV to have heart attacks and other forms of cardiovascular disease, even after controlling for traditional risk factors such as high blood cholesterol, high blood pressure, and smoking. NIAID has partnered with the National Heart, Lung, and Blood Institute (NHLBI) to support a multicenter international clinical trial to test whether statin administration can reduce the risk of cardiovascular disease–related events in people living with HIV.

Looking ahead, NIAID will continue to develop innovative prevention, cure, and treatment strategies needed to turn the corner on the HIV/AIDS pandemic. Since 2005, NIAID has supported a consortium of HIV researchers applying state-of-the-art technologies and immunologic tools to focus on iterative, rational vaccine discovery and design. In 2019, NIAID will establish the next iteration of this collaborative program, known as the Consortia for HIV/AIDS Vaccine Development (CHAVD). Gathering extensive input from the research community, NIAID also developed a plan to restructure the clinical research networks, culminating with awards planned for early FY 2021. The estimated level of funding for the clinical research networks in FY 2020 is $296.8 million, which will help to support this effort. They will continue to focus on developing science-based strategies, including vaccine, prevention, cure, and therapeutic approaches, particularly for people disproportionately affected by HIV, such as adolescents, women, and other underserved populations.

Budget Policy:
The FY 2020 President's Budget request for the extramural component of the HIV/AIDS research is $1,176.3 million, a decrease of $169.7 million or 12.6 percent compared with the FY 2019 Enacted level. NIAID will continue to support research from basic discovery through clinical trials on vaccine candidates as well as other prevention strategies. We are working to better understand HIV and how it causes disease, find new tools to prevent HIV infection including a preventive vaccine, develop new and more effective treatments for people living with HIV, and hopefully, find a cure. NIAID is committed to supporting these key priorities along with the rest of our research portfolio within available resources.

Program Portrait: Evaluating New HIV Vaccine Strategies

FY 2019 Level	$96.1 million
FY 2020 Level	$82.7 million
Change	-$13.4 million

Developing a safe and effective HIV vaccine remains a key priority in the global effort to realize a durable end to the HIV/AIDS pandemic. NIAID has supported several foundational studies that suggested promising approaches to HIV vaccine design, including a 2009 study in Thailand called RV144, which was the first—and to date the only—large clinical trial to demonstrate efficacy for an investigational HIV vaccine. Today, NIAID and its global partners continue to build on findings from this and other HIV vaccine trials that test novel vaccines targeting a variety of HIV subtypes, including the following studies:

- **HVTN 702:** A large-scale HIV vaccine efficacy study in South Africa, HVTN 702 is testing a newer version of the vaccine regimen tested in the 2009 RV144 trial in Thailand (discussed above). The investigators aim to enroll 5,400 men and women, making it the largest and most advanced HIV vaccine clinical trial to take place in South Africa, where more than 1,000 people become infected with HIV every day.
- **Imbokodo/HVTN 705:** Of 1.8 million new HIV infections worldwide in 2016, 43 percent occurred in eastern and southern Africa, with women and girls disproportionately affected. Imbokodo/HVTN 705, which enrolls HIV-uninfected women in sub-Saharan Africa, is a large-scale study to assess a different type of experimental HIV vaccine regimen. This vaccine regimen is based on "mosaic" immunogens—vaccine components designed to induce immune responses against a wide variety of global HIV strains. Researchers selected this specific regimen for further evaluation based on data from two early stage studies that evaluated the safety and immunogenicity of several different mosaic vaccine regimens. The study is co-sponsored through a public-private partnership between NIAID, the Bill & Melinda Gates Foundation, and Johnson & Johnson.

Biodefense and Emerging Infectious Diseases

As described above, NIAID has a dual mandate to conduct basic and applied research and to respond rapidly to emerging public health threats, including infectious disease outbreaks and the increasing prevalence of resistance to antimicrobial drugs worldwide. The severity of the 2017–2018 influenza season served as a reminder of the urgent need for more effective, durable, and broadly protective influenza vaccines. NIAID is conducting and supporting research to improve seasonal vaccines, including the use of adjuvants that may enhance and broaden protection against diverse influenza strains, as well as to achieve the highly transformational goal of developing a universal influenza vaccine. In support of this goal, NIAID-funded researchers recently demonstrated that a unique, multi-domain antibody derived from llamas showed promise in protecting against multiple influenza strains. In 2019, NIAID will establish the Collaborative Influenza Vaccine Innovation Centers (CIVICs)—a multidisciplinary program to support research and development of promising new influenza vaccine candidates. NIAID also is planning a cohort study in infants to examine how initial and repeated exposures to influenza viruses shape our immunity to future influenza exposures and vaccines. These studies will inform the design of universal influenza vaccine strategies. NIAID also maintains a scientific focus on novel influenza viruses with pandemic potential, such as the H7N9 "bird flu," and is currently supporting two clinical trials of experimental H7N9 vaccine strategies. A third H7N9 trial will launch soon.

NIAID leverages its versatile domestic and international infrastructure to respond rapidly to today's infectious disease emergencies and prepare for the next infectious threat, whether natural or manmade. Through a coordinated biodefense research effort with partners in industry, academia, and the federal Public Health Emergency Medical Countermeasures Enterprise

(PHEMCE), including the HHS Biomedical Advanced Research and Development Authority (BARDA), NIAID ensures that promising countermeasures for biological, chemical, and radiological public health threats can proceed to advanced development. Through this collaboration, NIAID supported the development of TPOXX, which recently was approved by the Food and Drug Administration for the treatment of smallpox, the first drug with that indication.

Vaccines are critical tools to counteract infectious disease threats, including vector-borne diseases such as Zika, dengue, and chikungunya infection. In a major advance, the NIAID team that developed a live-attenuated Zika vaccine also developed a related vaccine to dengue virus, which is in late-stage clinical testing. Moreover, plans are underway to develop a single vaccine that would protect against both Zika and dengue viruses. Chikungunya virus emerged in the Americas in 2013, and by 2016 had spread to 48 countries and infected more than 1 million people, causing intense joint and muscle pain, fever, and rash. No specific treatment or approved vaccine exists. However, one promising chikungunya vaccine candidate, developed by NIAID scientists, uses virus-like particles (VLPs) to induce protective immune responses. Building on a completed NIAID-sponsored clinical trial testing the VLP vaccine's safety and ability to elicit an immune response, the VLP vaccine from NIAID was licensed and a clinical trial is ongoing to evaluate multiple dosing regimens.

Resistance to antibiotics and other antimicrobial drugs is a growing global public health threat. As pathogens are exposed to antibiotics, they can develop antibiotic resistance that results in infections that are difficult or even impossible to treat. To address this threat, NIAID supports the development of novel products, including vaccines, immunoprophylactics (which harness the host's immune system to prevent infection), non-traditional microbiome approaches, and monoclonal antibodies (see *Program Portrait*) that could prevent or treat infections with drug-resistant bacteria. One non-traditional microbiome approach is fecal microbiota transplantation (FMT), which uses a stool preparation from a healthy human donor to treat intractable infections that occur when the normal community of microbes, or microbiota, in a person's gut is disrupted. NIAID recently launched a clinical trial to assess the safety and efficacy of FMT for people with recurrent *Clostridium difficile*–associated disease, a major healthcare-associated infection that can occur after antibiotic treatment. Further, a recent study led by NIAID scientists, done in collaboration with colleagues in Thailand, showed that a "good" bacterium commonly found in probiotic digestive supplements helps eliminate *Staphylococcus aureus* (*S. aureus*), a type of bacteria that can cause serious antibiotic-resistant infections.

In FY 2020, NIAID will recompete its antibacterial resistance clinical research program (Antibacterial Research Leadership Group), which was designed to develop, implement, and manage activities that address key clinical research questions in antibiotic resistance. As a partner in the public-private CARB-X program, NIAID has provided technical support and preclinical services to more than half of CARB-X awardees to further advance the development of diagnostics, treatments, and vaccines. In addition, NIAID collaborates with BARDA to support the Antimicrobial Resistance Diagnostic Challenge, which aims to develop innovative, rapid diagnostics to identify drug-resistant pathogens and determine optimal treatment strategies at the point-of-need.

Budget Policy:
The FY 2020 President's Budget request for the extramural component of biodefense and emerging infectious diseases research supported by NIAID is $1,550.9 million, a decrease of $269.9 million or 14.8 percent compared with the FY 2019 Enacted level. 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, multi-drug-resistant tuberculosis, and other high priority pathogens. A top NIAID priority is to support research leading to better therapeutics and vaccines for influenza including the development of a broadly cross-protective or universal vaccine that protects against pandemic and seasonal influenza strains over several years. NIAID will continue to promote basic and clinical research aimed at the development of antimicrobials and vaccines for emerging and re-emerging infectious diseases including antibiotic resistant bacteria, Ebola and Zika. NIAID supports the development of medical countermeasures and new platform technologies against biodefense and emerging infectious disease pathogens and will continue to coordinate with BARDA in the advanced development of therapeutics and vaccines. NIAID is committed to supporting these key priorities along with the rest of our research portfolio within available resources.

Program Portrait: Using Monoclonal Antibodies to Treat and Prevent Infectious Diseases

FY 2019 Level	$234.2 million
FY 2020 Level	$201.6 million
Change	-$32.6 million

Recent advances in mAb technologies have provided scientists with valuable tools to prevent and treat infectious diseases. mAbs are a specific type of antibody that bind to a single target, eliciting a more precise immune response compared to traditional intervention strategies. Improvements in the selection and manufacture of mAbs have reduced the time needed for their development, and their applicability in either prevention or treatment approaches make mAbs a powerful intervention against infectious diseases, particularly essential in the case of an outbreak. Current high-priority research on mAbs includes:

- **Ebola therapeutics:** mAb114 is being tested for safety in healthy volunteers in an early-stage clinical trial being conducted at the NIH. mAb114 and several other investigational therapeutics are also being administered under compassionate use protocols to infected individuals as part of the World Health Organization (WHO)-DRC coordinated response to the current 2018 Ebola outbreak in the DRC. Additionally, NIAID researchers recently discovered a set of bNAbs that protected against multiple strains of the Ebola virus in animal studies, including the three species of Ebola known to cause death.
- **Prophylactic applications against global diseases:** NIAID is supporting work on several bNAbs that could prevent infection by a range of influenza virus subtypes. Recently, NIAID researchers showed that one such antibody, MEDI8852, can protect ferrets from airborne transmission of the influenza strain H1N1. If confirmed through clinical studies, MEDI8852 could be used as a prophylactic measure for at-risk populations to reduce the incidence of seasonal, and potentially even pandemic, influenza.
- **Treatment of antimicrobial-resistant bacteria:** People with weakened immune systems in healthcare settings, especially those on breathing machines or with catheters, face an increased risk of becoming seriously ill from infections. An ongoing international Phase 2 clinical trial supported by NIAID is evaluating whether a novel mAb, MEDI3902, can prevent pneumonia caused by *Pseudomonas aeruginosa* in patients on mechanical ventilation. Additionally, NIAID researchers have shown that a newly discovered mAb can enhance the ability of the immune system to kill carbapenem-resistant *Klebsiella pneumoniae* bacteria.

Infectious and Immunologic Diseases

Infectious and immunologic diseases, many of which have far-reaching, global consequences, continue to pose a significant threat to human health. NIAID leads and supports basic and clinical research to better understand, treat, and prevent infectious diseases and immune-mediated disorders, such as asthma, allergy, autoimmune diseases, and transplant rejection *(see Program Portrait)*.

As described in the Director's Overview, NIAID's priorities for addressing the major public health threat of TB are framed in the *NIAID Strategic Plan for Tuberculosis Research*[7]. One priority is to develop and test improved vaccine candidates. The current TB vaccine protects young children against a severe form of the disease; however, it is not effective against the most common form of pulmonary TB in adults. NIAID-supported researchers developed a promising vaccine candidate that protected animals from TB. In a recent large clinical trial, another TB vaccine candidate that NIAID helped to develop provided 54 percent protection against active pulmonary TB disease, without evident safety concerns. NIAID also played a key role in developing bedaquiline, a new TB drug that is taken orally and could replace painful and potentially toxic injectable TB medications. Early clinical trial results are promising, and, as of August 2018, WHO guidance recommends a fully oral treatment regimen that includes bedaquiline for multidrug-resistant TB. Additionally, for people living with HIV, TB coinfection increases disease severity and is the leading cause of death for people with HIV. A recent NIAID-supported study showed that a one-month antibiotic regimen to prevent active TB disease in HIV-infected individuals was as safe and effective as the standard nine-month therapy. This ultra-short treatment course could become an important tool to control TB in persons living with HIV and improve global TB control efforts.

Malaria continues to be an urgent global public health threat, particularly for children. Although several approved treatments for this mosquito-borne disease exist, increasing drug resistance among malaria-causing parasites is diminishing effective drug options. In a novel strategy, NIAID-supported researchers developed a technique to determine which genes are essential for the parasite's growth. These genes may be useful targets for new antimalarial compounds. In addition, NIAID-supported investigators are designing improved anti-malaria drugs. NIAID is supporting an early-phase trial of a new treatment, DM1157, a derivative of the antimalarial chloroquine. Researchers hope that DM1157 may provide an effective alternative treatment for chloroquine-resistant malaria strains. NIAID also is supporting the development of several malaria vaccine candidates and other prevention strategies.

NIAID is addressing the rising threat of tick-borne diseases, including Lyme disease, and is coordinating with HHS and other federal partners through participation on the HHS Tick-Borne Disease Working Group[8] established by the 21st Century Cures Act. NIAID studies are increasing the understanding of tick-borne disease pathogenesis to facilitate the development of better ways to diagnose, prevent, and treat these diseases. Developing rapid, accurate, point-of-care diagnostics is a priority, because early treatment generally leads to better outcomes. Clinical studies are characterizing how Lyme disease develops and responds to treatment and

[7] www.niaid.nih.gov/sites/default/files/TBStrategicPlan2018.pdf
[8] www.hhs.gov/ash/advisory-committees/tickbornedisease/index.html

include patients who report persistent symptoms after treatment has ended. Investigators are exploring novel vaccine formulations and targets, including approaches focused on proteins in tick saliva that are critical for transmitting the Lyme bacteria to humans. More broadly, NIAID is encouraging further research into the immune response to bites from arthropods, including ticks, mosquitoes, fleas, and flies.

NIAID is investigating how the fungal pathogen *Coccidioides*, the causative agent of Valley fever (or coccidioidomycosis), causes disease and why some cases are particularly severe. In an ongoing clinical study, NIAID-supported researchers are measuring the prevalence of Valley fever pneumonia (or primary pulmonary coccidioidomycosis) among patients with community-acquired pneumonia in areas where the Valley fever-causing fungi are endemic, such as Arizona and California. The study also is assessing the response of participants to antifungal treatment and factors that lead to better outcomes. NIAID anticipates that this clinical study, as well as other ongoing studies, will raise awareness of the disease, encourage early diagnostic testing, and inform optimal management of Valley fever pneumonia.

In addition to infectious health threats, diseases and conditions related to the immune system affect millions of Americans, resulting in considerable morbidity and mortality. Allergic responses to food, including red meat, are increasing in prevalence. NIAID-funded investigators determined that red meat allergies could be linked to a bite from the lone star tick, which can induce an allergic response against a sugar molecule called alpha-gal, found in most mammalian meat. A recent study led by NIAID scientists found that some cases of previously unexplained anaphylaxis (a life-threatening allergic reaction) were due to alpha-gal allergy, and that a diet free of red meat prevented anaphylaxis recurrence. In June 2018, NIAID held a scientific agenda–setting workshop on the prevention and treatment of alpha-gal allergy that identified research priorities in this field.

Another food-driven allergic disease, eosinophilic esophagitis, or EoE, is a chronic disease of the esophagus that causes difficult or painful swallowing, vomiting, and nutritional problems. EoE affects nearly 150,000 people in the United States, many of whom are children, and existing treatments are far from ideal. NIAID- and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)-funded scientists found that the absence of a specific protein, SPINK7, in cells lining the esophagus may result in inflammation and tissue damage in EoE. Studies have shown that an existing drug for a form of genetically induced emphysema could be helpful in treating EoE by reversing inflammation in the esophageal tissue.

Atopic dermatitis (AD), the most common inflammatory skin disease of childhood, is a chronic condition that leaves skin dry, red, and itchy; it also is linked to an increased risk of food allergy and respiratory allergies, including asthma. Many people with AD have large populations of harmful *Staphylococcus aureus* bacteria on their skin. NIAID-funded studies show that bacteria normally living on healthy skin can produce molecules that kill the harmful bacteria; in people with AD, the numbers of these beneficial, or commensal, bacteria are substantially reduced. A NIAID-funded, placebo-controlled clinical trial is examining whether applying a cream made from one type of commensal bacteria with potent anti-*S. aureus* activity blocks its growth on skin. In an ongoing early-phase clinical trial, NIAID scientists recently demonstrated that topical

treatment with another type of anti–*S. aureus* commensal bacteria was safe and may reduce AD severity.

For many people with end-stage organ disease, transplanted organs, tissues, or cells may be the sole hope for a cure or survival. In May 2018, the first large-scale clinical trial to study kidney transplantation between people with HIV—a population with a significant and growing need for transplanted organs—began at clinical centers across the United States. The study follows the 2013 passage of the HIV Organ Policy Equity (HOPE) Act, which allowed research on organ transplantation between HIV-infected donors and recipients. The study will determine the safety of this practice by evaluating kidney recipients for potential transplant-related and HIV-related complications following surgery. In other transplantation research, results of a NIAID- and NIDDK-funded clinical trial showed that transplantation of insulin-producing pancreatic islets improves the quality of life for people with hard-to-control type 1 diabetes mellitus.

Budget Policy:
The FY 2020 President's Budget request for the extramural component of Infectious and Immunologic Diseases (IID) research is $1,103.1 million, a decrease of $193.5 million or 14.9 percent compared with the FY 2019 Enacted level. The FY 2020 IID research plan continues to advance NIAID's long-range research priorities and is carefully aligned to support key research activities including basic and clinical research aimed at the development of countermeasures such as therapeutics, vaccines and diagnostics for emerging and re-emerging infectious diseases, including antibiotic resistant bacteria. Funding will also continue to reflect NIAID's commitment and long-term interest in fundamental immunology and support research on organ transplantation, autoimmune diseases, asthma and other allergic diseases. NIAID is committed to supporting these key priorities along with the rest of our research portfolio within available resources.

Program Portrait: Advancing Research Toward Optimal Diagnostics, Treatments, and Next-Generation Vaccines

FY 2019 Level	$537.1 million
FY 2020 Level	**$462.4 million**
Change	-$74.7 million

Next-generation countermeasures employ broad, flexible platform technologies that can be developed with enhanced speed and efficiency to address significant public health threats. NIAID continues to advance the next frontier of innovative public health solutions through the support of promising diagnostics, treatments, and vaccines, including:

- **Vaccines for Zika, influenza, and Ebola viruses:** NIAID researchers have applied advanced vaccine and adjuvant technologies to the development of promising vaccine candidates for recurring public health threats, such as influenza and emerging and re-emerging pathogens, including Zika and Ebola viruses. These pioneering vaccination strategies use advanced molecular biology technologies to stimulate a strong protective immune response. Using a vector-based platform, NIAID-funded researchers developed an Ebola vaccine candidate that has successfully been evaluated in Phase 1 and 2 clinical trials and deployed in Ebola virus outbreaks.
- **Immunotherapies for opioid use disorder (OUD):** Through the Helping to End Addiction Long-term (HEAL) Initiative, NIAID, the National Institute on Drug Abuse (NIDA), and the NIH Office of Research Infrastructure Programs have partnered to establish a coordinated, multidisciplinary consortium with the goal of developing opioid vaccines and testing them in clinical trials. The consortium will leverage NIAID's extensive vaccine development programs and resources, as well as NIDA investigators with expertise in opioid metabolism, biological transport, and mechanisms of action. To inform this effort, NIAID and NIDA hosted an October 2018 scientific agenda–setting meeting focused on immunotherapies for treatment of OUD.
- **First-line treatment for malaria:** NIAID-led researchers recently developed a human monoclonal antibody against *Plasmodium falciparum*, the malaria parasite that is most prevalent and causes the deadliest form of the disease. The protective antibody, called CIS43, binds a protein on the parasite's surface that is conserved across 99.8 percent of all known malaria strains. Researchers can leverage this knowledge to develop next-generation malaria vaccines.
- **Diagnostics to improve patient care:** NIAID is supporting the development of a promising diagnostic candidate to detect whether a lower respiratory infection is caused by a virus and therefore should not be treated with antibiotics. The diagnostic detects procalcitonin, a protein biomarker in the blood that at high levels is known to indicate a sepsis infection caused by bacteria. Researchers are investigating whether low levels of procalcitonin can be used to reliably indicate the presence of a lower respiratory infection caused by a virus that should not be treated with antibiotics.

Intramural Research Program (IRP)

Complementing the NIAID extramural research program, the IRP is at the forefront of efforts to translate basic discoveries into new tools and strategies that improve public health. The IRP consists of three components: 1) the Division of Intramural Research (DIR), which comprises more than 110 principal investigators in Maryland and at the Rocky Mountain Laboratories in Montana who lead a wide range of basic, translational, and clinical research efforts; 2) the Vaccine Research Center, which applies fundamental advances to discover and develop new and improved vaccines, such as the Zika and universal influenza vaccine candidates mentioned above; and 3) the Division of Clinical Research (DCR), which plays an integral role in facilitating the efficient and effective performance of NIAID research programs on both the domestic and the international level, and in managing special projects as directed by NIAID leadership. This is accomplished through a multifaceted approach to the provision and support of services vital to the research infrastructure.

The IRP performs high-risk, high-reward studies, such as developing a vaccine candidate to protect against respiratory syncytial virus (RSV), the most common cause of lower respiratory tract infections in young children worldwide. Several promising RSV vaccine candidates developed and refined by IRP scientists are progressing in clinical trials. IRP scientists also are leaders in identifying genetic links to allergic and immunologic disorders and devising new treatments for them. For example, NIAID scientists at the NIH Clinical Center discovered a rare familial form of Crohn's disease, a type of inflammatory bowel disease (IBD); uncovered its underlying genetic and molecular mechanisms; and identified a new target for treating IBD. An NIAID-led team is developing a rapid, practical test for the early diagnosis of prion diseases—a related group of rare, fatal brain diseases—and has modified the test to enable early diagnosis of Parkinson's disease and dementia with Lewy bodies. IRP scientists also unraveled the process by which *Francisella tularensis* bacteria cause tularemia, a life-threatening disease spread to humans by contact with an infected animal or through mosquito, tick, or deer fly bites.

The IRP also leverages longstanding domestic and international partnerships to respond quickly to global public health emergencies—for example, by accelerating testing and deployment of vaccines and mAbs against Zika and Ebola viruses. In April 2018, NIAID and WHO signed an agreement to expand collaboration to promote faster and more effective research responses, particularly during public health emergencies caused by emerging and re-emerging infectious diseases.

Budget Policy:
The FY 2020 President's Budget request for Intramural Research is $614.0 million, a decrease of $101.5 million or 14.2 percent compared with the FY 2019 Enacted level. The FY 2020 Intramural Research plan supports critical long-range research priorities of NIAID with funding 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. NIAID is committed to supporting these key priorities along with the rest of our research portfolio within available resources.

Research Management and Support (RMS): 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, facilitation, and evaluation of Institute programs, as well as regulatory compliance, international coordination, and liaison activities with other Federal agencies, Congress, and the public.

Budget Policy:
The FY 2020 President's Budget request is $310.2 million, a decrease of $34.5 million or 10.0 percent compared with the FY 2019 Enacted level. This budget will reduce NIAID's overall level of program management and administrative support, consistent with the decrease in grant awards.

NATIONAL INSTITUTES OF HEALTH
National Institute of Allergy and Infectious Diseases

Budget Authority by Object Class[1]
(Dollars in Thousands)

		FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Total compensable workyears:				
	Full-time equivalent	1,963	1,963	0
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	$190	$190	$0
	Average GM/GS grade	12.6	12.6	0.0
	Average GM/GS salary	$113	$113	$0
	Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$107	$110	$3
	Average salary of ungraded positions	$153	$153	$0
	OBJECT CLASSES	**FY 2019 Enacted**	**FY 2020 President's Budget**	**FY 2020 +/- FY 2019**
	Personnel Compensation			
11.1	Full-Time Permanent	162,251	162,867	617
11.3	Other Than Full-Time Permanent	70,722	70,990	269
11.5	Other Personnel Compensation	7,610	7,639	29
11.7	Military Personnel	4,845	5,008	163
11.8	Special Personnel Services Payments	21,124	21,204	80
11.9	**Subtotal Personnel Compensation**	**$266,551**	**$267,708**	**$1,157**
12.1	Civilian Personnel Benefits	78,195	79,673	1,478
12.2	Military Personnel Benefits	3,185	3,292	107
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	**$347,931**	**$350,673**	**$2,742**
21.0	Travel & Transportation of Persons	10,294	8,365	-1,930
22.0	Transportation of Things	1,524	1,413	-111
23.1	Rental Payments to GSA	0	0	0
23.2	Rental Payments to Others	137	137	0
23.3	Communications, Utilities & Misc. Charges	2,528	2,349	-178
24.0	Printing & Reproduction	1	1	0
25.1	Consulting Services	37,274	23,474	-13,799
25.2	Other Services	216,976	142,310	-74,666
25.3	Purchase of goods and services from government accounts	689,929	627,732	-62,197
25.4	Operation & Maintenance of Facilities	21,451	20,057	-1,394
25.5	R&D Contracts	637,465	547,631	-89,834
25.6	Medical Care	6,763	6,296	-467
25.7	Operation & Maintenance of Equipment	22,482	21,010	-1,471
25.8	Subsistence & Support of Persons	0	0	0
25.0	**Subtotal Other Contractual Services**	**$1,632,339**	**$1,388,510**	**-$243,829**
26.0	Supplies & Materials	58,599	54,529	-4,070
31.0	Equipment	39,753	34,774	-4,979
32.0	Land and Structures	0	0	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	3,430,194	2,913,604	-516,590
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	25	25	0
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	**$5,175,393**	**$4,403,706**	**-$771,687**
	Total Budget Authority by Object Class	**$5,523,324**	**$4,754,379**	**-$768,945**

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

NATIONAL INSTITUTES OF HEALTH
National Institute of Allergy and Infectious Diseases

Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Personnel Compensation			
Full-Time Permanent (11.1)	$162,251	$162,867	$617
Other Than Full-Time Permanent (11.3)	70,722	70,990	269
Other Personnel Compensation (11.5)	7,610	7,639	29
Military Personnel (11.7)	4,845	5,008	163
Special Personnel Services Payments (11.8)	21,124	21,204	80
Subtotal Personnel Compensation (11.9)	**$266,551**	**$267,708**	**$1,157**
Civilian Personnel Benefits (12.1)	$78,195	$79,673	$1,478
Military Personnel Benefits (12.2)	3,185	3,292	107
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	**$347,931**	**$350,673**	**$2,742**
Travel & Transportation of Persons (21.0)	$10,294	$8,365	-$1,930
Transportation of Things (22.0)	1,524	1,413	-111
Rental Payments to Others (23.2)	137	137	0
Communications, Utilities & Misc. Charges (23.3)	2,528	2,349	-178
Printing & Reproduction (24.0)	1	1	0
Other Contractual Services:			
Consultant Services (25.1)	37,274	23,474	-13,799
Other Services (25.2)	216,976	142,310	-74,666
Purchases from government accounts (25.3)	557,090	494,893	-62,197
Operation & Maintenance of Facilities (25.4)	21,451	20,057	-1,394
Operation & Maintenance of Equipment (25.7)	22,482	21,010	-1,471
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	**$855,272**	**$701,744**	**-$153,528**
Supplies & Materials (26.0)	$58,599	$54,529	-$4,070
Subtotal Non-Pay Costs	**$928,355**	**$768,538**	**-$159,817**
Total Administrative Costs	**$1,276,285**	**$1,119,211**	**-$157,075**

NATIONAL INSTITUTES OF HEALTH
National Institute of Allergy and Infectious Diseases

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2018 Final			FY 2019 Enacted			FY 2020 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Acquired Immunodeficiency									
Direct:	141	10	151	145	10	155	145	10	155
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	141	10	151	145	10	155	145	10	155
Division of Allergy, Immunology, and Transplantation									
Direct:	96	-	96	99	-	99	99	-	99
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	96	-	96	99	-	99	99	-	99
Division of Clinical Research									
Direct:	86	13	99	86	13	99	86	13	99
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	86	13	99	86	13	99	86	13	99
Division of Extramural Activities									
Direct:	215	-	215	223	-	223	223	-	223
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	215	-	215	223	-	223	223	-	223
Division of Intramural Research									
Direct:	673	13	686	673	13	686	673	13	686
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	673	13	686	673	13	686	673	13	686
Division of Microbiology and Infectious Diseases									
Direct:	174	8	182	178	8	186	178	8	186
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	174	8	182	178	8	186	178	8	186
Office of the Director									
Direct:	397	1	398	406	1	407	406	1	407
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	397	1	398	406	1	407	406	1	407
Vaccine Research Center									
Direct:	107	1	108	107	1	108	107	1	108
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	107	1	108	107	1	108	107	1	108
Total	1,889	46	1,935	1,917	46	1,963	1,917	46	1,963
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0

FISCAL YEAR	Average GS Grade
2016	12.5
2017	12.5
2018	12.6
2019	12.6
2020	12.6

NATIONAL INSTITUTES OF HEALTH
National Institute of Allergy and Infectious Diseases

Detail of Positions[1]

GRADE	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Total, ES Positions	2	2	2
Total, ES Salary	379,200	379,200	379,200
GM/GS-15	178	183	183
GM/GS-14	427	430	430
GM/GS-13	348	351	351
GS-12	220	224	224
GS-11	110	113	113
GS-10	1	2	2
GS-9	60	65	65
GS-8	29	30	30
GS-7	50	53	53
GS-6	6	6	6
GS-5	3	3	3
GS-4	11	11	11
GS-3	4	4	4
GS-2	1	1	1
GS-1	4	4	4
Subtotal	1,452	1,480	1,480
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	1	1	1
Director Grade	20	20	20
Senior Grade	10	10	10
Full Grade	10	10	10
Senior Assistant Grade	4	4	4
Assistant Grade	1	1	1
Subtotal	46	46	46
Ungraded	444	444	444
Total permanent positions	1,481	1,481	1,481
Total positions, end of year	1,944	1,972	1,972
Total full-time equivalent (FTE) employment, end of year	1,935	1,963	1,963
Average ES salary	189,600	189,600	189,600
Average GM/GS grade	12.6	12.6	12.6
Average GM/GS salary	113,101	113,101	113,101

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