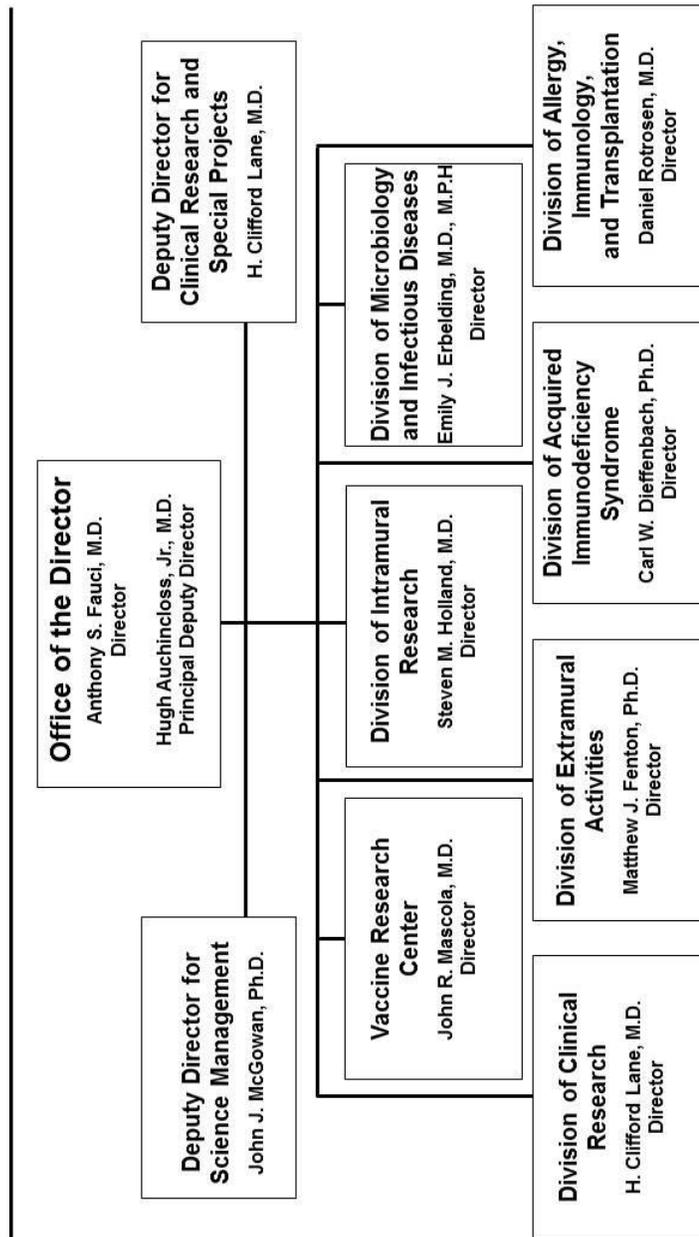


DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NATIONAL INSTITUTES OF HEALTH  
National Institute of Allergy and Infectious Diseases (NIAID)

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NOTE: The FY 2017 Annualized CR funding amounts cited throughout this chapter reflect the effects of no OAR HIV/AIDS Transfers.

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



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, \$3,782,670,000.*

**NATIONAL INSTITUTES OF HEALTH**  
**National Institute of Allergy and Infectious Diseases**

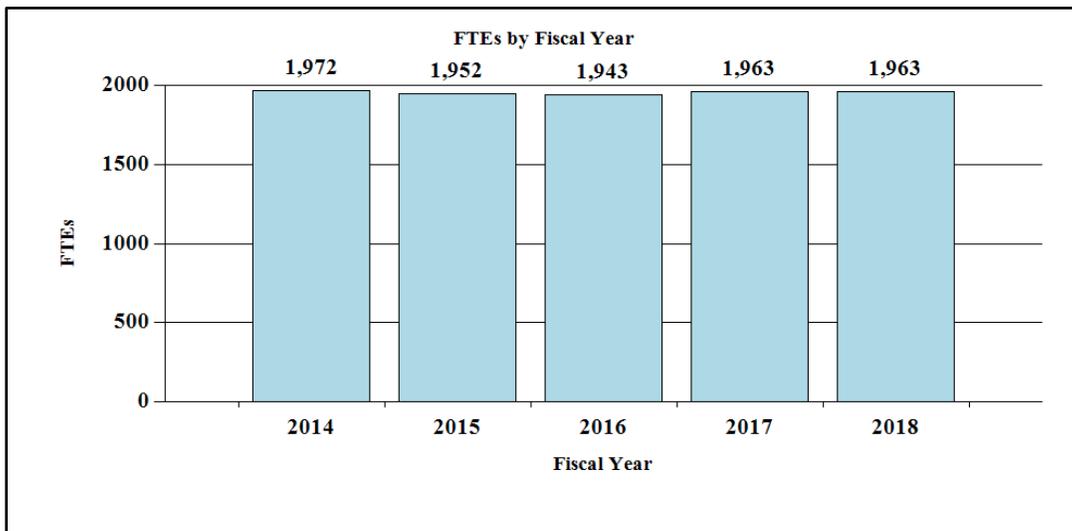
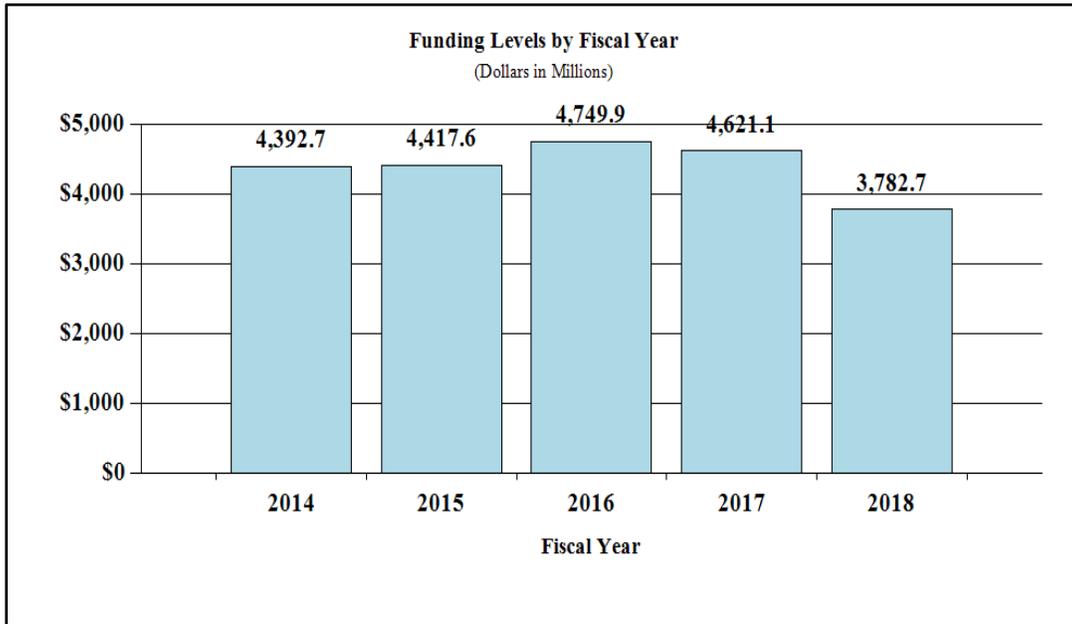
**Amounts Available for Obligation<sup>1</sup>**  
(Dollars in Thousands)

Source of Funding	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Appropriation	\$4,629,928	\$4,629,928	\$3,782,670
Mandatory Appropriation: (non-add)	-	-	-
<i>Type 1 Diabetes</i>	(0)	(0)	(0)
<i>Other Mandatory financing</i>	(0)	(0)	(0)
Rescission	0	-8,801	0
Sequestration	0	0	0
Zika Intra-NIH Transfer	34,200	0	0
Subtotal, adjusted appropriation	\$4,664,128	\$4,621,127	\$3,782,670
OAR HIV/AIDS Transfers	85,769	0	0
Subtotal, adjusted budget authority	\$4,749,897	\$4,621,127	\$3,782,670
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$4,749,897	\$4,621,127	\$3,782,670
Unobligated balance lapsing	-13	0	0
Total obligations	\$4,749,884	\$4,621,127	\$3,782,670

<sup>1</sup> Excludes the following amounts for reimbursable activities carried out by this account:  
FY 2016 - \$14,709    FY 2017 - \$14,709    FY 2018 - \$14,709

## Fiscal Year 2018 Budget Graphs

### History of Budget Authority and FTEs:



**NATIONAL INSTITUTE OF HEALTH  
National Institute of Allergy and Infectious Diseases**

**Authorizing Legislation**

	PHS Act/ Other Citation	U.S. Code Citation	2017 Amount Authorized	FY 2017 Annualized CR	2018 Amount Authorized	FY 2018 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	\$4,621,127,000	Indefinite	\$3,782,670,000
National Institute of Allergy and Infectious Diseases	Section 401(a)	42§281	Indefinite		Indefinite	
<b>Total Budget Authority</b>				<b>\$4,621,127,000</b>		<b>\$3,782,670,000</b>

**NATIONAL INSTITUTES OF HEALTH**  
**National Institute of Allergy and Infectious Diseases**

**Appropriations History**

<b>Fiscal Year</b>	<b>Budget Estimate to Congress</b>	<b>House Allowance</b>	<b>Senate Allowance</b>	<b>Appropriation</b>
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
Rescission				\$0
2010	\$4,760,295,000	\$4,859,502,000	\$4,777,457,000	\$4,818,275,000
Rescission				\$0
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 <sup>1</sup>	\$4,715,697,000	\$4,738,883,000	\$4,961,305,000	\$4,629,928,000
Rescission				\$8,801,000
2018	\$3,782,670,000			

<sup>1</sup> 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 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
BA	\$4,749,897,000	\$4,621,127,000	\$3,782,670,000	-\$838,457,000
FTE	1,943	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) conducts and supports basic and applied research to understand, diagnose, prevent, treat, and, ultimately, cure infectious and immune-mediated disease. The NIAID basic research portfolio informs all Institute research activities and extends our knowledge of the biology of pathogenic organisms and the host response to microbes, and of the mechanisms of normal immune function and dysfunction that result in allergy, asthma, autoimmune diseases, and transplant rejection. NIAID advances its public health mission through high-impact research to develop and test diagnostics, vaccines, and therapeutics to prevent and treat infectious and immune-mediated diseases.

In the 35 years since AIDS was identified, the disease has claimed more than 35 million lives worldwide<sup>1</sup> and remains one of the most devastating pandemics in human history. Now, the momentous goal of ending the HIV/AIDS pandemic, a key NIH priority, is within reach. In recent years, rigorous NIAID-supported studies showed indisputably that individuals with HIV should initiate antiretroviral therapy (ART) regimens as soon as possible after diagnosis to diminish dramatically their overall risk of developing AIDS or other serious HIV-associated illnesses and prevent transmission to their sexual partners. NIAID continues to advance research to prevent HIV infection, with intensified focus on long-acting prevention strategies. A large, multinational trial in sub-Saharan Africa found that using an anti-HIV drug-infused vaginal ring reduced the risk of HIV infection by at least 56 percent in women who used the ring most consistently. The ring reduced HIV infection by 27 percent in the study population overall. To reduce the incidence of HIV infection, young women at highest risk urgently need discreet, long-acting HIV prevention tools that they control and want to use. NIAID is extending the trial to gather additional data on the safety of the vaginal ring and to study what factors would encourage women to use the device consistently. NIAID also remains committed to developing an effective HIV vaccine that would prevent HIV infection. NIAID is part of a public-private

<sup>1</sup> WHO Fact sheet No. 360, updated July 2016. <http://www.who.int/mediacentre/factsheets/fs360/en/>

collaboration that aims to build on the landmark NIAID-funded RV144 vaccine trial, which showed for the first time that an investigational vaccine could confer a modest degree of protection against HIV infection in humans. A recent clinical trial in South Africa evaluated an investigational HIV vaccine regimen designed to improve upon the RV144 regimen. Early data from this trial show that the improved vaccine is safe and induces an immune response against the virus. NIAID has initiated a Phase IIb/III clinical trial to further evaluate the vaccine's efficacy.

The emergence and re-emergence of infectious diseases continues to threaten the health of people worldwide. NIAID has designed its flexible research infrastructure to fulfill its unique dual mandate: conducting basic and applied infectious diseases research on established diseases while building the capacity to respond rapidly to emerging and re-emerging infectious diseases. When Ebola virus disease spread quickly through three West African nations in 2014, NIAID immediately took a leadership role in the global research response. NIAID was a founding member of the Partnership for Research on Ebola Virus in Liberia (PREVAIL), a research partnership between NIH, CDC, and the Ministry of Health in Liberia that later included Sierra Leone and Guinea. NIAID-supported research led to development of therapeutic candidates including ZMapp, a monoclonal antibody cocktail that was studied in the PREVAIL II clinical trial, and BCX4430, a broad-spectrum antiviral drug. These drug candidates hold promise for development into licensed products that could be stockpiled for use in future Ebola outbreaks. In addition to two vaccines being tested in the PREVAIL I study, NIAID also facilitated the development of a prime-boost Ebola vaccine regimen through a collaboration with industry and supported its preclinical testing.

In 2015, the emergence of Zika virus disease in Brazil focused international attention on a new pandemic threat, which moved quickly through South and Central America and the Caribbean and then into Florida. Zika is a flavivirus that can cause devastating developmental symptoms in infants and neurological disorders in adults. In keeping with the NIH Director's theme "Treatments and Cures," NIAID responded to this public health threat by quickly expanding its flavivirus research portfolio to elucidate the biology and pathogenesis of Zika virus and accelerate the development of diagnostics, vaccines, and therapeutics. In addition to supporting the development of several early-stage Zika vaccine candidates, NIAID launched a Phase I clinical trial in August 2016 of an investigational DNA-based Zika vaccine developed by scientists at the NIAID Vaccine Research Center (VRC). If the results are favorable, NIAID plans to initiate a Phase II trial in Zika-endemic regions in early 2017. The Walter Reed Army Institute of Research, in collaboration with NIAID, developed and produced an inactivated Zika vaccine candidate. A trial of this inactivated vaccine candidate was launched in November 2016 and four additional clinical trials of the candidate are planned. NIAID also has partnered with other NIH Institutes and the Fundação Oswaldo Cruz in Brazil to support the Zika in Infants and Pregnancy study to determine the risks of Zika infection during pregnancy and to follow the infants for one year.

NIAID continues to advance understanding of the mechanisms of immune function and to develop and test novel approaches to treat and prevent immune-mediated disorders including asthma, allergic diseases, autoimmune diseases, and rejection of transplanted organs, tissues, and cells. Through the NIAID Immune Tolerance Network, researchers are transforming approaches to preventing development of food allergies (see Program Portrait: Immunotherapy for

Preventing and Treating Food Allergy). NIAID-supported basic and clinical research is advancing progress toward treatments for immune-mediated diseases, including the use of cellular therapy, in which cells are injected into a patient to treat disease. For example, a NIAID-supported clinical trial used stem cell transplantation to reset the immune system of people with multiple sclerosis (MS). Five years after transplantation, approximately 70 percent of participants remained in remission without receiving MS drugs after the transplant. These findings will inform further studies in people with MS who respond poorly to available medical therapies. NIAID-funded researchers also recently reported results of a clinical trial of a cellular therapy to treat people with severe type 1 diabetes. These patients were unable to sense low blood sugar and had frequent severe hypoglycemic events (SHEs), which can cause substantial morbidity and death. Two years after transplantation of purified pancreatic islets—clusters of insulin-producing cells—71 percent of study participants were free from SHEs, had near-normal control of glucose levels, and had restored hypoglycemic awareness. The FDA and NIH are determining the next steps toward licensure of this cellular product.

#### Overall Budget Policy:

The FY 2018 President’s Budget request is \$3,782.670 million, a decrease of \$838.457 million compared with the FY 2017 Annualized CR level. These reductions are distributed across all programmatic areas and basic, epidemiology, or clinical research.

### **Program Descriptions and Accomplishments**

**HIV/AIDS:** HIV/AIDS is one of the most devastating pandemics in human history. NIAID is committed to improving treatment and prevention strategies and, ultimately, developing a preventive vaccine and a cure for HIV/AIDS. To this end, NIAID conducts and supports basic, preclinical, and clinical research to better understand the epidemiology of the disease, the molecular basis of infection, and the human immune response, and to develop improved treatment and prevention strategies. Other NIAID-supported efforts focus on improving adherence to treatment and prevention. Through this multipronged research approach, NIAID aims to end the HIV/AIDS pandemic and help usher in the first AIDS-free generation.

The HIV pre-exposure prophylaxis (PrEP) strategy, in which uninfected, at-risk individuals take antiretroviral therapy (ART) drugs to reduce their risk of contracting HIV, is becoming the standard of care for prevention in this country and around the world. A series of clinical trials convincingly demonstrated that regularly taking Truvada, a single daily pill containing two anti-HIV drugs, can reduce an individual’s risk of contracting HIV by more than 90 percent. NIAID is also testing a second oral drug, maraviroc, for use in PrEP. Scientists showed this drug to be safe and well tolerated in a Phase II clinical trial.

NIAID’s leadership in developing and evaluating PrEP is a compelling example of the commitment to the NIH Director’s theme “Health Promotion and Disease Prevention.” NIAID has conducted several clinical studies to determine whether at-risk, often-marginalized populations will adhere to the strict daily PrEP regimen. Several studies in the United States and abroad showed a moderate to high level of adherence for men who have sex with men, transgender women, and single black women in South Africa. These studies confirm that, if given access to PrEP, people in at-risk populations are willing to take it on a daily basis.

Approaches to prevent sexual transmission of HIV also include use of long-acting products that could release anti-HIV drugs over the course of a month or even a year. NIAID products in clinical testing include several drug-infused vaginal rings and injectable drugs. Other studies explore the use of HIV treatment to prevent transmission. For example, a landmark NIAID study showed a 93 percent reduction of HIV transmission within heterosexual couples when the HIV-infected partner was taking ART. Effective treatment with ART reduced the virus to low levels, preventing sexual transmission to the uninfected heterosexual partner.

NIAID is evaluating the effectiveness of combining prevention strategies such as HIV testing, counseling, and voluntary medical male circumcision. In the Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (PopART) study, NIAID is including all of these strategies as a prevention package for communities in Zambia and South Africa, and offering immediate ART for individuals infected with HIV. Results from the PopART study will determine whether providing a package of prevention strategies can reduce HIV transmission at a population level. Due to increased desire for private, personal health monitoring, a new NIAID-funded initiative will pursue the development of innovative diagnostic tools that can detect HIV at the earliest stages of infection and allow individuals to test themselves at home.

Taking anti-HIV drugs enables HIV-infected mothers to protect their newborns from infection. Findings from the large Promoting Maternal-Infant Survival Everywhere trial, conducted in sub-Saharan Africa and India, showed that treating an HIV-infected mother with a three-drug antiretroviral regimen protects her infant during pregnancy and birth, and also eliminates HIV transmission by breast milk. Safe breastfeeding is crucial to many HIV-infected mothers in low and middle income countries, who may not have access to clean water and formula.

NIAID continues research toward an HIV cure that either clears the virus from the body or enables an infected person's immune system to suppress virus levels and replication to extremely low levels without the need for daily ART. One strategy being explored involves using broadly neutralizing antibodies (bNAbs) to target and inhibit multiple HIV strains. Two recent early-phase clinical studies that tested this approach showed modest effects with one bNAb. Researchers plan to investigate combinations of more potent anti-HIV antibodies as long-term therapy to control HIV and induce sustained viral remission. NIAID also is funding research that aims to silence the virus genetically and thus eliminate production of new virus particles. In separate research, bNAbs show promise in preventing HIV. (See Program Portrait: Exploiting Neutralizing Antibodies for HIV Prevention.)

An important challenge to achieving a cure is targeting latent HIV reservoirs that persist in certain body tissues and elude the effects of ART. Through the Martin Delaney Collaboratory, NIAID is partnering with academia, industry, and HIV-affected communities to characterize these viral reservoirs and develop strategies to eliminate them. Promising laboratory results have shown that combinations of latency-reversing agents can efficiently activate latent HIV, thus allowing the latently infected cells to be destroyed by the immune system or by other anti-HIV therapy. The hope is to develop strategies that deplete the HIV reservoirs in humans to the point where the immune system can control the infection without ART.

In addition, NIAID is supporting research to identify safe and effective strategies to prevent and treat infections that commonly occur with HIV, such as hepatitis C virus (HCV) infection and tuberculosis (TB). NIAID supports a broad range of basic, translational, and clinical research to combat TB in the United States and abroad, including the growing threat of multidrug-resistant

(MDR) and extensively drug-resistant (XDR) TB. NIAID also continues to develop new and innovative prevention and treatment strategies to combat HCV in HIV/HCV co-infected individuals.

**Program Portrait: Exploiting Neutralizing Antibodies for HIV Prevention**

FY 2017 Level	\$ 146.9 million
<u>FY 2018 Level</u>	<u>\$ 132.5 million</u>
Change	-\$ 14.4 million

In an effort to develop an effective vaccine against HIV infection and help end the HIV/AIDS pandemic, NIAID is pioneering strategies to stop the virus before it can enter human cells. This promising vaccine approach, currently being tested in laboratory models, seeks to stimulate production of so-called broadly neutralizing antibodies (bNAbs) to stop infection by a wide range of HIV strains.

Tried-and-true vaccine approaches for other viral diseases mimic natural infection to stimulate an immune response and spur production of neutralizing antibodies that clear the virus from the body and provide lifelong immunity. But such traditional approaches fail to conquer HIV, as the virus hides vulnerable regions on its surface to prevent a robust protective immune response and can mutate rapidly, evading neutralization. To overcome these challenges, HIV vaccine researchers employ methods rarely seen in other branches of vaccine research, such as rigorous analyses of antibody-producing B cells and their evolution, and sophisticated structural biology studies that determine the precise molecular shapes of viral proteins and their interactions with bNAbs. In one example, a team led by NIAID Vaccine Research Center (VRC) scientists recently reported a research trifecta: They discovered a new vulnerable site on HIV for a vaccine to target, a bNAb that binds to that target site, and the mechanism by which the antibody stops the virus from infecting a cell. These results indicate that this site may be an important focus for vaccine design against HIV, and VRC scientists are now working to create a vaccine designed to elicit antibodies similar to the newly discovered bNAb.

NIAID also supports a major research initiative, the Center for HIV/AIDS Vaccine Immunology and Immunogen Discovery program, consisting of two multidisciplinary research consortia that aim to understand how bNAbs and other immune responses work to protect against HIV infection, and to generate model vaccine components that can induce these protective immune responses. The Institute also recently established a public-private partnership with GlaxoSmithKline to develop one or more bNAbs into a product to prevent or treat HIV infection.

Infusions of bNAbs have been effective in preventing infection in animal models of HIV infection. NIAID is now leading two multinational clinical trials to test the safety and effectiveness in humans of an investigational anti-HIV bNAb called VRC01 for preventing HIV infection. Study findings will provide crucial data toward the goal of developing an effective HIV vaccine. Achieving such a feat would be the culmination of decades of extensive research and would represent one of the most complex scientific approaches toward any vaccine in history.

The decrease in funding in FY 2018 for this program will bring commitments in line with available resources.

**Biodefense and Emerging Infectious Diseases:** NIAID plays a pivotal role in global efforts to anticipate, prevent, and treat emerging infectious diseases that threaten the health of humans worldwide. NIAID conducts and supports research to understand basic mechanisms of disease, the vectors that transmit them, and the human immune system's responses to infection, and works to develop or improve diagnostics, therapeutics, and vaccines for both established and emerging diseases. Through a broad scientific portfolio that features basic research, and a versatile domestic and international clinical research infrastructure, NIAID mounts rapid research responses to infectious disease emergencies, whether pandemic influenza (2009 H1N1), Middle East respiratory syndrome coronavirus (2012), Ebola virus (2014), Zika virus (2015), or the next threat.

An arsenal of effective antimicrobial drugs is an essential resource for treating people who contract infectious diseases. However, bacteria can adapt to the effects of antibiotics and the choices for treating many bacterial infections are becoming increasingly limited, expensive, and, in some cases, nonexistent. Stemming the increase in resistance is key to the NIH Director's theme "Health Promotion and Disease Prevention," and comprises a vital component of the NIAID research agenda. To achieve key goals of the 2015 *National Action Plan for Combatting Antibiotic-Resistant Bacteria*,<sup>2</sup> NIAID is advancing research on many aspects of antimicrobial resistance, including basic research on how microbes develop resistance; development of potential diagnostics, vaccines, and treatments; and clinical trials to evaluate promising therapeutics and prevention strategies. In FY 2016, NIAID awarded approximately \$5 million in funding for 24 research projects seeking to develop nontraditional treatments for bacterial infections. Ongoing NIAID-funded clinical trials also aim to optimize the use of licensed drugs for the treatment of drug-resistant infections and evaluate novel broad-spectrum antibiotics. NIAID is a member of the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator, or CARB-X, one of the world's largest public-private partnerships accelerating the development of new antimicrobial products. With the HHS Office of the Assistant Secretary for Preparedness and Response, NIAID launched a \$20 million challenge competition for new, innovative, and novel laboratory diagnostic tests. The diagnostic tests being sought are those that identify and characterize antibiotic resistant bacteria and those that distinguish between viral and bacterial infections to reduce unnecessary uses of antibiotics, a major cause of drug resistance.

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<sup>2</sup> [https://www.whitehouse.gov/sites/default/files/docs/national\\_action\\_plan\\_for\\_combating\\_antibiotic-resistant\\_bacteria.pdf](https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf)

The connection between inappropriate antibiotic use and the development of drug resistance is well documented. The NIAID Antibacterial Resistance Leadership Group (ARLG) is working to better inform the use of antibiotics by developing a blood test to determine whether a bacterium or a virus is the cause of a patient's respiratory symptoms. In 2016, the ARLG also:

- Expanded the number of sites performing clinical studies on drug-resistant bacteria
- Conducted a Phase I trial of oral administration of fosfomycin, a broad-spectrum antibiotic, for treating complicated urinary tract infections
- Studied the natural history of carbapenem-resistant Enterobacteriaceae infections within the United States and South America
- Initiated studies of a shortened course of therapy for community-acquired pneumonia in children via the NIAID Vaccine Treatment Evaluation Units (VTEUs)

Multidrug-resistant tuberculosis cannot be cured with traditional drug regimens. In response to this emerging threat, the White House released the *National Action Plan for Combating Multidrug-Resistant Tuberculosis*<sup>3</sup> in FY 2016. NIAID plays a key role in achieving Goal 3 of the plan—Accelerate Basic and Applied Research and Development—through support of a long-standing and broad TB research and product development portfolio. NIAID-funded researchers have identified biosignatures that can identify persons at high risk for developing active TB. This finding suggests that these signatures may form the basis for a diagnostic test that could facilitate targeting of therapies to highly susceptible individuals. NIAID continues work to expand the GenXpert diagnostic platform to detect drug resistance markers indicative of XDR-TB and to make the test more suitable for pediatric patients. NIAID also supports multiple candidate TB vaccines in different stages of development. In addition, NIAID has a significant role in the identification, preclinical testing, and clinical evaluation of novel therapeutic approaches and drug regimens that are badly needed to provide treatment options for patients with MDR/XDR TB.

Many promising ideas for vaccines, therapeutics, and devices fail to make the difficult transition from the early, preclinical stages of research to commercial development. NIAID works to fill knowledge gaps critical to scientific research, helping to translate early research into products that protect public health, even as infectious diseases continue to emerge and re-emerge. NIAID provides infectious disease investigators with a comprehensive set of services and resources needed to move discoveries from laboratory testing to more advanced preclinical development. These services include access to data/reagent repositories and state-of-the-art molecular technologies, animal models, and screening tests. These resources are used to validate the effectiveness of candidate products against a full range of bacteria, viruses, parasites, and fungi, as well as against pathogen-produced toxins. NIAID preclinical services were indispensable during the Ebola and Zika virus outbreaks by facilitating the early assessment and preclinical development of numerous candidate products.

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<sup>3</sup>[https://www.whitehouse.gov/sites/default/files/microsites/ostp/national\\_action\\_plan\\_for\\_tuberculosis\\_20151204\\_final.pdf](https://www.whitehouse.gov/sites/default/files/microsites/ostp/national_action_plan_for_tuberculosis_20151204_final.pdf)

**Program Portrait: Rapid Responses as Vector-Borne Diseases Emerge**

FY 2017 Level	\$ 490.0 million
FY 2018 Level	\$ 380.1 million
Change	-\$ 109.9 million

More than 17 percent of all infectious diseases and more than 1 million deaths annually worldwide can be attributed to diseases caused by bacteria, viruses, or parasites transmitted by vectors such as mosquitoes, sand flies, ticks, or freshwater snails. Recent outbreaks of mosquito-transmitted viruses such as dengue, Zika, and chikungunya in the Americas attest to the importance of maintaining a foundation of research and development efforts to respond effectively to these and other emerging infectious diseases.

A strong base of research on flaviviruses, including dengue and yellow fever, is crucial to NIAID's rapid response to the Zika virus, which spread across the Americas in 2015 and 2016. NIAID quickly launched an emergency response to this emerging infectious disease threat. The Institute expanded its basic research portfolio to better understand the disease-causing pathogen and other flaviviruses, and accelerated efforts to develop improved diagnostics and candidate therapies and vaccines. To develop vaccine candidates against Zika virus, NIAID is building on a foundation of research that led to vaccine approaches effective against other mosquito-borne viruses:

- The NIAID Vaccine Research Center is pursuing a DNA-based vaccine similar to a NIAID-developed West Nile virus vaccine candidate that was shown to be safe and effective in early-phase clinical testing. This DNA-based Zika vaccine candidate entered an early-stage clinical trial at NIAID in August 2016.
- An inactivated Zika vaccine, developed and produced by Walter Reed Army Institute of Research in collaboration with NIAID, uses the same approach that led to the currently licensed vaccine against Japanese encephalitis virus. To evaluate the inactivated Zika vaccine, a Phase I clinical trial was launched in November 2016, and four additional Phase I clinical trials are planned.
- Through its VTEU network, NIAID is supporting an early-stage clinical trial to evaluate the safety and efficacy of an investigational vaccine against yellow fever virus, a recently resurgent mosquito-borne virus that is related to the dengue virus.

NIAID also supports research on the vectors themselves, vector-host and pathogen-vector interactions, ecology, genomics, and insecticide resistance. NIAID supports research to identify potential targets that could inform development of novel vector control methods such as larvicides, insecticides, and repellents. For instance, NIAID is evaluating the effectiveness of larvicide-treated male mosquitoes in reducing mosquito populations. Similarly, NIAID supports research and development of a biopesticide approach whereby male mosquitoes are infected with *Wolbachia*, a bacterium that naturally infects many species of mosquitoes. Findings may advance efforts to suppress mosquito populations by preventing the production of viable offspring.

The decrease in funding in FY2018 for this program will bring commitments in line with available resources.

**Infectious and Immunologic Diseases:** NIAID conducts and supports research to develop diagnostics, vaccines, and treatments for infectious diseases caused by hundreds of pathogens. The Institute also supports research to expand understanding of the human immune system, including how to suppress harmful immune responses or enhance beneficial responses, thereby decreasing disease and disability. Through immunology research, NIAID seeks to improve treatment and prevention strategies for immune-mediated disorders such as asthma, allergy, autoimmune diseases, and transplant rejection. NIAID facilitates knowledge sharing among researchers and facilitates data analysis and reproducibility of research by funding resources such as TrialShare, ImmPort, and the Immune Epitope Database. A free online crowdsourcing platform called OMics Compendia Commons created recently by NIAID scientists and their colleagues enables researchers without computational expertise to analyze existing genetic information to gain insights into possible mechanisms of immune disorders.

Malaria continues to pose an urgent threat to global health, especially in children. NIAID is committed to advancing understanding of malaria and to developing comprehensive protection against this global killer. NIAID researchers recently found that the rapidly spreading parasites resistant to artemisinin, the primary treatment for malaria in Southeast Asia, are able to infect the main malaria-bearing mosquito species in Africa. This finding demonstrates potential for the further global spread of drug-resistant malaria and highlights the pressing need for new antimalarial drugs. Nine candidate drugs developed with NIAID support are in clinical testing, and one shows potential as a single-dose cure and as a weekly prevention strategy. A malaria vaccine is a top NIAID research priority and could prevent many of the estimated 438,000 malaria deaths each year. Clinical testing of 11 NIAID-supported malaria vaccine candidates are underway. An investigational malaria vaccine, PfSPZ, is the first to show durable protection—more than one year—in people with no prior infection. NIAID-funded researchers also have learned why the first licensed malaria vaccine, RTS,S, prevented malaria infection in some children but not others: The malaria protein targeted by the vaccine shows genetic variability, and the vaccine best protects children who have malaria with the same protein variant as that in the vaccine.

Neglected tropical diseases (NTDs) take a tremendous toll on human health in the world's poorest communities and in conflict areas, affecting more than one billion people worldwide.<sup>4</sup> The NIAID-supported Tropical Medicine Research Centers create and sustain in-country research capacity in areas where neglected tropical diseases are endemic. One such NTD, leishmaniasis, is caused by parasites transmitted by sand flies and causes painful skin sores or even severe infection and death. NIAID researchers have developed a candidate vaccine for leishmaniasis based on a sand fly salivary protein; in a promising study, immunized animals were protected from disease after exposure to infected sand flies. NIAID also supports research investigating the biology of vectors such as mosquitoes and ticks to understand how they transmit disease, and to develop additional strategies to control infection (see Program Portrait: Rapid Responses as Vector-Borne Diseases Emerge). NIAID-supported researchers have sequenced the large and complex genome of the blacklegged tick (*Ixodes scapularis*), and will study the genome in hopes of identifying targets to prevent Lyme disease and other tick-borne illnesses.

NIAID-funded asthma and allergy research focuses on the role of the immune system in the development of these chronic diseases as well as ways to prevent and treat them. Researchers in the Inner-City Asthma Consortium recently identified major factors associated with asthma severity in children and identified five different patient clusters, or groups, distinguished by their asthma characteristics. Further study of the causes of asthma in these groups may allow researchers to tailor interventions to specific groups of children. A NIAID-supported clinical trial is assessing whether a school-based program reducing children's exposure to mouse allergens, mold, and air pollutants will decrease the burden of asthma among urban schoolchildren.

For many chronic immune-mediated diseases, transplanted organs, tissues, and cells may be the sole hope for cure or survival. To improve the likelihood that a transplant will succeed, NIAID supports research into the role of the immune system in transplant success or failure. NIAID-supported investigators are working to control or eliminate immune responses that impair graft

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<sup>4</sup> World Health Organization: [http://www.who.int/neglected\\_diseases/diseases/en/](http://www.who.int/neglected_diseases/diseases/en/)

survival while maintaining the immune system's ability to fight infection. For example, several clinical trials are examining approaches that would enable immune-suppressive drug therapy to be decreased or even discontinued after transplantation. NIAID also spearheaded implementation of the HIV Organ Policy Equity Act by developing guidelines to assess the safety and effectiveness of solid organ transplantation from HIV-infected donors to HIV-infected recipients. The first such transplants were performed in March 2016.

**Program Portrait: Immunotherapy for Preventing and Treating Food Allergy**

FY 2017 Level	\$ 13.3 million
<u>FY 2018 Level</u>	<u>\$ 10.3 million</u>
Change	-\$ 3.0 million

The prevalence of food allergies among U.S. children increased by 18 percent between 1997 and 2007, for unknown reasons. Allergic reactions can range from mild to fatal, and living with food allergies can be stressful and isolating for affected children and their families. Immunotherapy—repeated exposures to small, increasing amounts of an allergen—has long been used to treat pollen or stinging insect allergies and is now being studied to treat and prevent food allergies.

In 2015, the groundbreaking Learning Early About Peanut Allergy (LEAP) study showed that introducing peanut-containing foods into the diets of high-risk infants largely prevented the development of peanut allergy. Follow-up studies found that tolerance to peanut persisted even after children stopped eating peanut for one year, and importantly that early peanut consumption did not affect children's growth or compromise breastfeeding. In light of these findings, NIAID convened an expert panel to revise current clinical practice guidelines to recommend early peanut consumption to prevent peanut allergy. The new guidelines will be published in 2017. In a recent NIAID-supported study, researchers applied peanut proteins through a novel skin patch for the treatment of peanut allergy in people 4–25 years of age. After one year of treatment, almost 50 percent of those using the patch could consume at least 10 times more peanut protein than at the start of the study. Researchers have also tested the effectiveness of oral immunotherapy (OIT) to treat young children with peanut allergy. The study demonstrated that peanut OIT allowed nearly 80 percent of peanut-allergic preschoolers to add peanut-containing foods into their diets. A similar but preliminary study in adults identified early, distinct changes in immune T-cell populations of those who responded well to OIT. These changes may help researchers predict which people will respond well to treatment.

The demonstrated benefits of early exposure to peanut from the LEAP study have prompted NIAID to plan a clinical trial for prevention of milk or egg allergy. Healthy infants at risk for food allergy will be given small amounts of egg and milk proteins to evaluate whether early exposure blocks progression to egg or milk allergy. NIAID also is funding a \$6.1 million food allergy research initiative, the Consortium for Food Allergy Research, to conduct clinical trials and basic research on the best treatment and prevention strategies for food allergies.

The decrease in funding in FY2018 for this program will bring commitments in line with available resources.

**Intramural Research Program (IRP):** Complementing the NIAID extramural research program, IRP is at the forefront of efforts to expand knowledge of normal immune system function, define mechanisms that underlie immunologic diseases, understand the biology of infectious agents, and elucidate the host response to infection.

IRP consists of three components: 1) the Division of Intramural Research, in which more than 110 principal investigators in Maryland and at the Rocky Mountain Laboratories in Montana lead a wide range of basic, translational, and clinical research efforts in infectious diseases, allergy, and immunology; 2) the VRC, which applies fundamental advances in immunology, virology, and vaccine science to discover new and improved vaccines for human diseases; and 3)

the Division of Clinical Research (DCR), which facilitates efficient and effective NIAID clinical research programs in the United States and internationally. With access to state-of-the-art laboratories and clinical facilities, IRP investigators can rapidly translate basic discoveries into new diagnostics, therapies, and prevention strategies for infectious and allergic diseases. The IRP also leverages its longstanding and effective domestic and international partnerships to respond quickly to emerging infectious threats such as Zika virus and Ebola virus.

Another IRP strength is the ability to perform high-risk, high-impact studies, such as developing a vaccine to protect infants and young children from respiratory syncytial virus (RSV), the most common cause of lower respiratory tract infections in young children worldwide. This candidate RSV vaccine showed promise in an early-phase clinical trial. IRP scientists are leaders in identifying rare immunological syndromes and innovating treatments for these disorders. For example, a recent IRP-led study identified a genetic mutation responsible for vibratory urticaria, a rare form of inherited hives induced by vibration, such as from running, hand clapping, or towel-drying. Investigating such rare disorders can yield important insights into how the immune system functions, which could also help in understanding and treating common diseases.

IRP scientists also participate in research aimed at understanding the link between the microbiota—the community of microbes that live in and on us—and health and disease. As part of this effort, NIAID scientists showed, in experimental models, that disruption of the gut microbiota following acute infections can permanently compromise immunity. Another study found that the protective immune barrier provided by the skin is controlled by distinct skin microbes. NIAID scientists also explore the role of the microbiota as a reservoir for antimicrobial-resistant pathogens and in the pathogenicity of infectious diseases including HIV.

**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, coordination, and evaluation of Institute programs, as well as regulatory compliance, international coordination, and liaison with other Federal agencies, Congress, and the public.

**NATIONAL INSTITUTES OF HEALTH**  
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**Detail of Full-Time Equivalent Employment (FTE)**

OFFICE/DIVISION	FY 2016 Final			FY 2017 Annualized CR			FY 2018 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Acquired Immunodeficiency	-	-	-	-	-	-	-	-	-
Direct:	145	9	154	147	9	156	147	9	156
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	145	9	154	147	9	156	147	9	156
Division of Allergy, Immunology, and Transplantation	-	-	-	-	-	-	-	-	-
Direct:	89	-	89	90	-	90	90	-	90
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	89	-	89	90	-	90	90	-	90
Division of Clinical Research	-	-	-	-	-	-	-	-	-
Direct:	85	13	98	86	13	99	86	13	99
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	85	13	98	86	13	99	86	13	99
Division of Extramural Activities	-	-	-	-	-	-	-	-	-
Direct:	226	-	226	228	-	228	228	-	228
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	226	-	226	228	-	228	228	-	228
Division of Intramural Research	-	-	-	-	-	-	-	-	-
Direct:	666	14	680	673	14	687	673	14	687
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	666	14	680	673	14	687	673	14	687
Division of Microbiology and Infectious Diseases	-	-	-	-	-	-	-	-	-
Direct:	171	7	178	173	7	180	173	7	180
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	171	7	178	173	7	180	173	7	180
Office of the Director	-	-	-	-	-	-	-	-	-
Direct:	418	2	420	422	2	424	422	2	424
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	418	2	420	422	2	424	422	2	424
Vaccine Research Center	-	-	-	-	-	-	-	-	-
Direct:	98	-	98	99	-	99	99	-	99
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	98	-	98	99	-	99	99	-	99
<b>Total</b>	<b>1,898</b>	<b>45</b>	<b>1,943</b>	<b>1,918</b>	<b>45</b>	<b>1,963</b>	<b>1,918</b>	<b>45</b>	<b>1,963</b>
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
<b>FISCAL YEAR</b>	<b>Average GS Grade</b>								
2014	12.2								
2015	12.3								
2016	12.4								
2017	12.4								
2018	12.4								

**NATIONAL INSTITUTES OF HEALTH**  
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**Detail of Positions<sup>1</sup>**

GRADE	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Total, ES Positions	2	2	2
Total, ES Salary	370,200	377,234	384,590
GM/GS-15	168	169	169
GM/GS-14	427	430	430
GM/GS-13	321	324	324
GS-12	233	237	237
GS-11	120	122	122
GS-10	1	1	1
GS-9	82	85	85
GS-8	28	28	28
GS-7	59	61	61
GS-6	15	16	16
GS-5	8	9	9
GS-4	6	6	6
GS-3	13	13	13
GS-2	2	2	2
GS-1	1	1	1
Subtotal	1,484	1,504	1,504
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	1	1	1
Director Grade	19	19	19
Senior Grade	7	7	7
Full Grade	7	7	7
Senior Assistant Grade	4	4	4
Assistant Grade	3	3	3
Subtotal	41	41	41
Ungraded	459	459	459
Total permanent positions	1,507	1,507	1,507
Total positions, end of year	1,986	2,006	2,006
Total full-time equivalent (FTE) employment, end of year	1,943	1,963	1,963
Average ES salary	185,100	188,617	192,295
Average GM/GS grade	12.4	12.4	12.4
Average GM/GS salary	105,129	107,126	109,215

<sup>1</sup> Includes FTEs whose payroll obligations are supported by the NIH Common Fund.