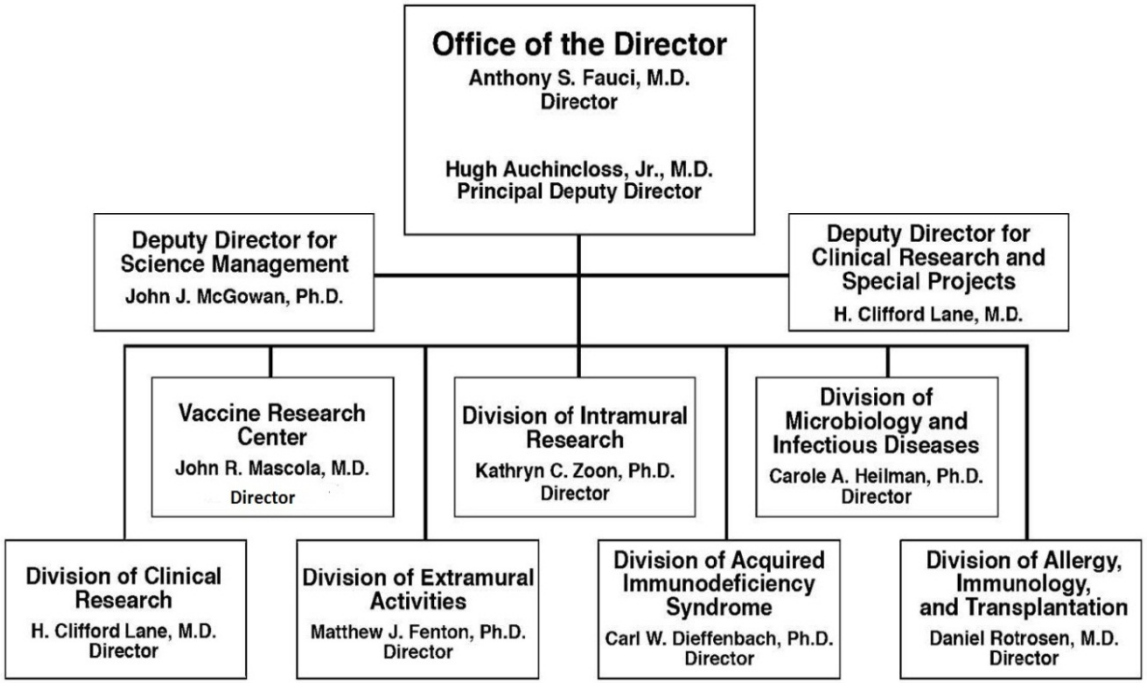
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases (NIAID)

FY 2016 Budget — Page No.

# National Institutes 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, [$4,358,841,000]*$4,614,779,000*.
[For an additional amount for National Institute of Allergy and Infectious Diseases to prevent, prepare for, and respond to Ebola domestically and internationally, including expenses related to carrying out section 301 and title IV of the PHS Act, $238,000,000, to remain available until September 30, 2016: Provided, That such amount is designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A)(i) of the Balanced Budget and Emergency Deficit Control Act of 1985.]

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

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

| Source of Funding | FY 2014 Actual | FY 2015 Enacted | FY 2016 President's Budget |
|---|---|---|---|
| Appropriation | $4,358,841 | $4,358,841 | $4,614,779 |
| Type 1 Diabetes | 0 | 0 | 0 |
| Rescission | 0 | 0 | 0 |
| Sequestration | 0 | 0 | 0 |
| FY 2014 First Secretary's Transfer | -10,942 | 0 | 0 |
| FY 2014 Second Secretary's Transfer | -855 | 0 | 0 |
| Subtotal, adjusted appropriation | $4,347,044 | $4,358,841 | $4,614,779 |
| OAR HIV/AIDS Transfers | 39,826 | 58,717 | 0 |
| National Children's Study Transfers | 14,326 | 0 | 0 |
| Subtotal, adjusted budget authority | $4,401,196 | $4,417,558 | $4,614,779 |
| Unobligated balance, start of year | 0 | 0 | 0 |
| Unobligated balance, end of year | 0 | 0 | 0 |
| Subtotal, adjusted budget authority | $4,401,196 | $4,417,558 | $4,614,779 |
| Unobligated balance lapsing | -11 | 0 | 0 |
| Total obligations | $4,401,185 | $4,417,558 | $4,614,779 |

[1] Excludes the following amounts for reimbursable activities carried out by this account:
FY 2014 - $20,011 FY 2015 - $20,090 FY 2016 - $20,994

[2] Excludes $238 million in Ebola Emergency funding.

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

### Budget Mechanism - Total[1]
(Dollars in Thousands)

| MECHANISM | FY 2014 Actual | | FY 2015 Enacted | | FY 2016 President's Budget | | FY 2016 +/- FY 2015 | |
|---|---|---|---|---|---|---|---|---|
| | No. | Amount | No. | Amount | No. | Amount | No. | Amount |
| Research Projects: | | | | | | | | |
| Noncompeting | 2,453 | $1,421,819 | 2,536 | $1,902,675 | 2,448 | $1,936,918 | -88 | $34,243 |
| Administrative Supplements | *(97)* | 19,927 | *(76)* | 6,154 | *(76)* | 6,154 | *(0)* | 0 |
| Competing: | | | | | | | | |
| Renewal | 248 | 403,285 | 286 | 133,533 | 350 | 159,210 | 64 | 25,677 |
| New | 1,009 | 576,137 | 979 | 450,433 | 1,104 | 531,719 | 125 | 81,286 |
| Supplements | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Subtotal, Competing | 1,257 | $979,422 | 1,265 | $583,967 | 1,454 | $690,930 | 189 | $106,963 |
| Subtotal, RPGs | 3,710 | $2,421,168 | 3,801 | $2,492,796 | 3,902 | $2,634,001 | 101 | $141,205 |
| SBIR/STTR | 235 | 122,253 | 225 | 117,253 | 241 | 125,356 | 16 | 8,103 |
| Research Project Grants | 3,945 | $2,543,420 | 4,026 | $2,610,049 | 4,143 | $2,759,357 | 117 | $149,308 |
| Research Centers: | | | | | | | | |
| Specialized/Comprehensive | 29 | $37,396 | 30 | $39,488 | 38 | $44,646 | 8 | $5,159 |
| Clinical Research | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Biotechnology | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Comparative Medicine | 0 | 1,413 | 0 | 1,413 | 0 | 1,413 | 0 | 0 |
| Research Centers in Minority Institutions | 0 | 426 | 0 | 426 | 0 | 426 | 0 | 0 |
| Research Centers | 29 | $39,235 | 30 | $41,327 | 38 | $46,485 | 8 | $5,159 |
| Other Research: | | | | | | | | |
| Research Careers | 259 | $37,071 | 259 | $37,071 | 259 | $37,071 | 0 | $0 |
| Cancer Education | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cooperative Clinical Research | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Biomedical Research Support | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Minority Biomedical Research Support | 4 | 960 | 4 | 960 | 4 | 960 | 0 | 0 |
| Other | 91 | 15,282 | 98 | 18,282 | 98 | 18,282 | 0 | 0 |
| Other Research | 354 | $53,313 | 361 | $56,313 | 361 | $56,313 | 0 | $0 |
| Total Research Grants | 4,328 | $2,635,968 | 4,417 | $2,707,689 | 4,542 | $2,862,156 | 125 | $154,467 |
| Ruth L Kirchstein Training Awards: | FTTPs | | FTTPs | | FTTPs | | FTTPs | |
| Individual Awards | 187 | $8,522 | 187 | $8,649 | 187 | $8,779 | 0 | $130 |
| Institutional Awards | 953 | 45,507 | 953 | 45,962 | 953 | 46,422 | 0 | 460 |
| Total Research Training | 1,140 | $54,029 | 1,140 | $54,612 | 1,140 | $55,201 | 0 | $589 |
| Research & Develop. Contracts | 192 | $914,878 | 188 | $851,028 | 194 | $881,676 | 6 | $30,647 |
| *(SBIR/STTR) (non-add)* | *(4)* | *(1,476)* | *(13)* | *(7,626)* | *(13)* | *(7,626)* | *(0)* | *(0)* |
| Intramural Research | 885 | 521,726 | 890 | 526,888 | 890 | 535,631 | 0 | 8,744 |
| Res. Management & Support | 1,087 | 274,595 | 1,093 | 277,341 | 1,093 | 280,115 | 0 | 2,773 |
| *Res. Management & Support (SBIR Admin) (non-add)* | *(0)* | *(380)* | *(0)* | *(400)* | *(0)* | *(0)* | *(0)* | *(-400)* |
| Construction | | 0 | | 0 | | 0 | | 0 |
| Buildings and Facilities | | 0 | | 0 | | 0 | | 0 |
| Total, NIAID | 1,972 | $4,401,196 | 1,983 | $4,417,558 | 1,983 | $4,614,779 | 0 | $197,221 |

[1] All items in italics and brackets are non-add entries.

[2] Excludes $238 million in Ebola Emergency funding.

## Major Changes in the Fiscal Year 2016 President's Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail and these highlights will not sum to the total change for the FY 2016 President's Budget for NIAID, which is $197.221 million more than the FY 2015 level, for a total of $4,614.779 million.

Biodefense and Emerging Infectious Diseases (extramural) (+$94.508 million; total $1,355.837 million):
NIAID will continue to focus on advancing drugs, vaccines and diagnostics for emerging pathogens and pathogens that can be used as agents of bioterrorism. This includes maximizing our efforts by pursuing development of medical countermeasures with wide impact such as broad-spectrum antibiotics and antiviral drugs effective against multiple bacteria or viruses. NIAID is working to extend understanding of how microbes develop resistance and develop and evaluate vaccines and therapeutics against drug-resistant microbes. Also, development of a universal flu vaccine that induces a potent immune response to common elements of the influenza virus and effective against both seasonal and pandemic strains is an important part of this portfolio.

Infectious and Immunologic Diseases (extramural) (+$33.156 million; total $1,041.790 million):
NIAID will continue to support its Infectious and Immunologic Diseases research portfolio to support critical research on malaria, tuberculosis, food allergies and asthma, autoimmune diseases, rejection of transplanted tissues and organs, applying new discoveries to the development of vaccines, drugs, diagnostic tools and prevention strategies that will improve the health of millions around the world.

HIV/AIDS Research (extramural) (+$58.040 million; total $1,401.406 million):
NIAID will continue funding to support a broad range of HIV/AIDS research, from basic discovery through clinical trials on effective vaccine and non-vaccine prevention strategies. In FY 2016, NIAID's research plan was carefully crafted to support the goals of the President's National HIV/AIDS Strategy including the HIV Cure Initiative. Additionally, NIAID will focus on research of co-infections that complicate treatment and prevention of HIV/AIDS.

Research Project Grants (+$149.308 million; total $2,759.357 million):
NIAID will support a total of 4,143 Research Project Grant (RPG) awards in FY 2016. The increased funding will help support the Biodefense and Emerging Infectious Diseases, Infectious and Immunologic Diseases and HIV/AIDS research agendas including Antimicrobial Resistance, and Flu Vaccine, and NIH-wide programs including Precision Medicine.

Research and Development Contracts (+$30.647 million; total $881.647 million):
The increased funding will help support the Biodefense and Emerging Infectious Diseases, Infectious and Immunologic Diseases and HIV/AIDS research agendas including Antimicrobial Resistance and Flu Vaccine, and NIH-wide programs.

Intramural Research (+$8.744 million; total $535.631 million):
The NIAID intramural research program will continue to respond to diverse disease challenges. The increase funding will support the President's HIV Cure Initiative, increased focus on influenza vaccine research and the proposed pay increase in FY 2016.

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

### Summary of Changes
(Dollars in Thousands)

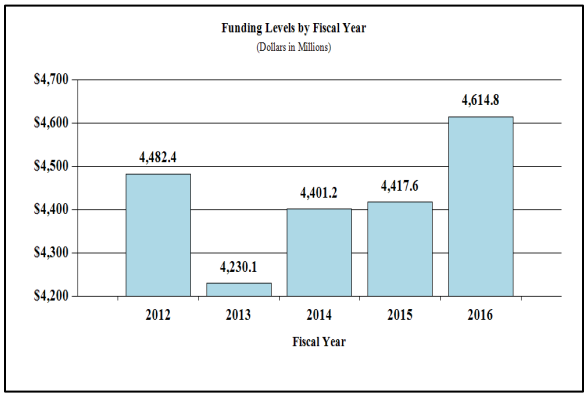
| | |
|---|---|
| **FY 2015 Enacted** | $4,417,558 |
| **FY 2016 President's Budget** | $4,614,779 |
| **Net change** | $197,221 |

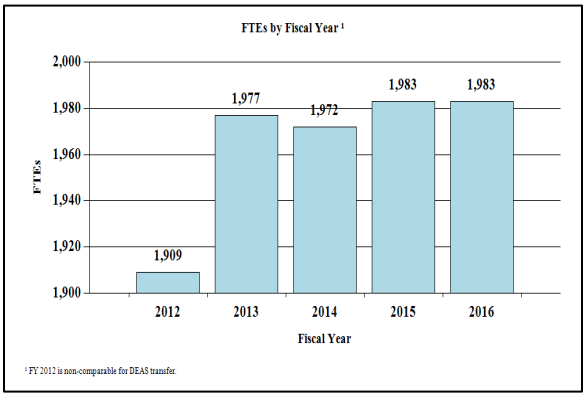
| CHANGES | FY 2016 President's Budget | | Change from FY 2015 | |
|---|---|---|---|---|
| | FTEs | Budget Authority | FTEs | Budget Authority |
| A. Built-in: | | | | |
| 1. Intramural Research: | | | | |
| a. Annualization of January 2015 pay increase & benefits | | $150,332 | | $371 |
| b. January FY 2016 pay increase & benefits | | 150,332 | | 1,113 |
| c. One more day of pay (n/a for 2015) | | 150,332 | | 532 |
| d. Differences attributable to change in FTE | | 150,332 | | 0 |
| e. Payment for centrally furnished services | | 75,995 | | 1,854 |
| f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs | | 309,304 | | 612 |
| Subtotal | | | | $4,481 |
| 2. Research Management and Support: | | | | |
| a. Annualization of January 2015 pay increase & benefits | | $158,382 | | $391 |
| b. January FY 2016 pay increase & benefits | | 158,382 | | 1,173 |
| c. One more day of pay (n/a for 2015) | | 158,382 | | 599 |
| d. Differences attributable to change in FTE | | 158,382 | | 0 |
| e. Payment for centrally furnished services | | 28,520 | | 598 |
| f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs | | 93,213 | | 13 |
| Subtotal | | | | $2,773 |
| Subtotal, Built-in | | | | $7,255 |

| CHANGES | FY 2016 President's Budget | | Change from FY 2015 | |
|---|---|---|---|---|
| | No. | Amount | No. | Amount |
| B. Program: | | | | |
| 1. Research Project Grants: | | | | |
| a. Noncompeting | 2,448 | $1,943,072 | -88 | $34,243 |
| b. Competing | 1,454 | 690,930 | 189 | 106,963 |
| c. SBIR/STTR | 241 | 125,356 | 16 | 8,103 |
| Subtotal, RPGs | 4,143 | $2,759,357 | 117 | $149,308 |
| 2. Research Centers | 38 | $46,485 | 8 | $5,159 |
| 3. Other Research | 361 | 56,313 | 0 | 0 |
| 4. Research Training | 1,140 | 55,201 | 0 | 589 |
| 5. Research and development contracts | 194 | 881,676 | 6 | 30,647 |
| Subtotal, Extramural | | $3,799,033 | | $185,704 |
| 6. Intramural Research | 890 | $535,631 | 0 | $4,262 |
| 7. Research Management and Support | 1,093 | 280,115 | 0 | 0 |
| 8. Construction | | 0 | | 0 |
| 9. Buildings and Facilities | | 0 | | 0 |
| Subtotal, Program | 1,983 | $4,614,779 | 0 | $189,966 |
| Total changes | | | | $197,221 |

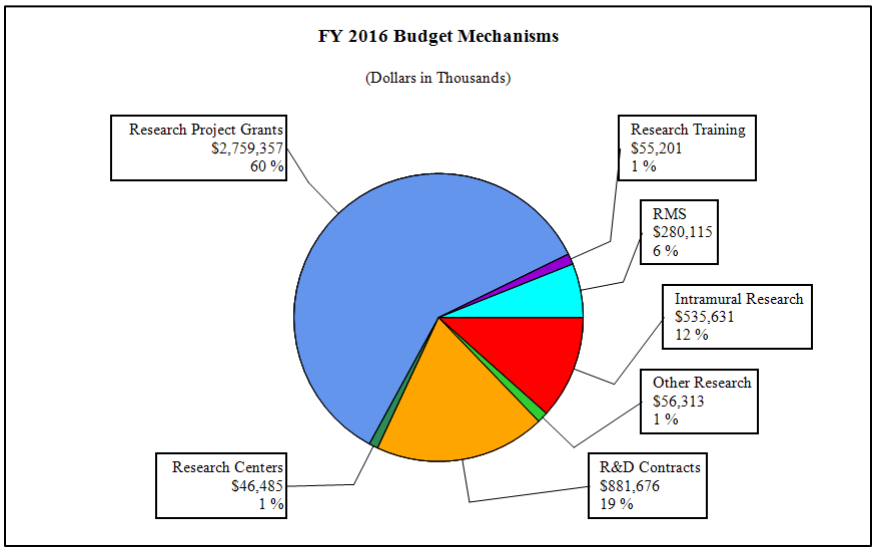
# Fiscal Year 2016 Budget Graphs

## History of Budget Authority and FTEs:

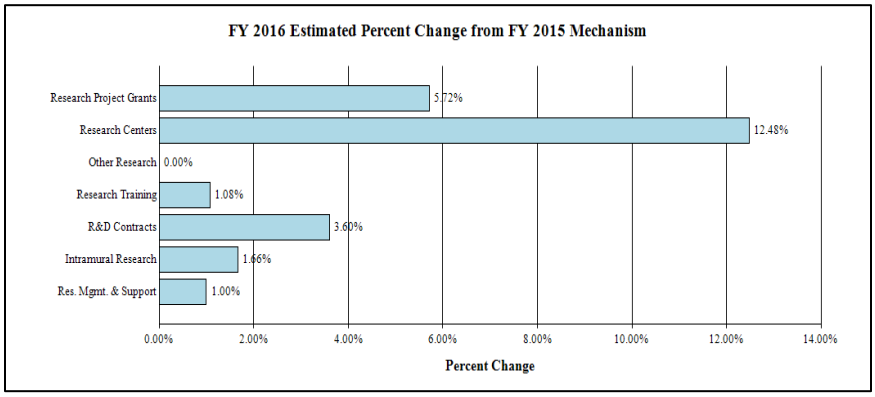



## Distribution by Mechanism:




## Change by Selected Mechanisms:



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

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

| | FY 2014 Actual[2] | | FY 2015 Enacted | | FY 2016 President's Budget | | FY 2016 +/- FY 2015 | |
|---|---|---|---|---|---|---|---|---|
| **Extramural Research** | **FTE** | **Amount** | **FTE** | **Amount** | **FTE** | **Amount** | **FTE** | **Amount** |
| Detail | | | | | | | | |
| HIV/AIDS [3] | | $1,322,795 | | $1,343,366 | | $1,401,406 | | $58,040 |
| Biodefense & Emerging Infectious Diseases [4] | | 1,268,522 | | 1,261,330 | | 1,355,837 | | 94,508 |
| Infectious & Immunological Diseases | | 1,013,546 | | 1,008,634 | | 1,041,790 | | 33,156 |
| **Subtotal, Extramural** | | **$3,604,863** | | **$3,613,329** | | **$3,799,033** | | **$185,704** |
| **Intramural Research** | **885** | **$521,726** | **890** | **$526,888** | **890** | **$535,631** | **0** | **$8,744** |
| **Research Management & Support** | **1,087** | **$274,595** | **1,093** | **$277,341** | **1,093** | **$280,115** | **0** | **$2,773** |
| **TOTAL** | **1,972** | **$4,401,185** | **1,983** | **$4,417,558** | **1,983** | **$4,614,779** | **0** | **$197,221** |

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

[2] Total $1,563.878M Actual in FY 2014; Estimate $1,586.804M in FY 2015; Estimate $1,648.753M in FY 2016 for HIV/AIDS.

[3] Total $1,614.294M Actual in FY 2014; Estimate $1,610.560M in FY 2015; Estimate $1,710.560M in FY 2016 for Biodefense.

[4] Excludes $238 million in Ebola Emergency funding.

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

### Authorizing Legislation

| | PHS Act/ Other Citation | U.S. Code Citation | 2015 Amount Authorized | FY 2015 Enacted[1] | 2016 Amount Authorized | FY 2016 President's Budget |
|---|---|---|---|---|---|---|
| Research and Investigation | Section 301 | 42§241 | Indefinite | $4,417,558,000 | Indefinite | $4,614,779,000 |
| National Institute of Allergy and Infectious Diseases | Section 401(a) | 42§281 | Indefinite | | Indefinite | |
| Total, Budget Authority | | | | $4,417,558,000 | | $4,614,779,000 |

[1] Excludes $238 million in Ebola Emergency funding.

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

## Appropriations History

| Fiscal Year | Budget Estimate to Congress | House Allowance | Senate Allowance | Appropriation |
|---|---|---|---|---|
| 2006 | $4,459,395,000 | $4,459,395,000 | $4,547,136,000 | $4,459,395,000 |
| Rescission | | | | ($44,594,000) |
| 2007 | $4,395,496,000 | $4,270,496,000 | $4,395,496,000 | $4,414,801,000 |
| Rescission | | | | $0 |
| Supplemental | | | | $2,407,000 |
| 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 |
| Emergency | | | | $238,000,000 |
| 2016 | $4,614,779,000 | | | |

## 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 2014 Actual | FY 2015 Enacted | FY 2016 President's Budget | FY 2016 + / - FY 2015 |
|---|---|---|---|---|
| BA | $4,358,841,000 | $4,417,558,000 | $4,614,779,000 | +$197,221,000 |
| FTE | 1,972 | 1,983 | 1,983 | 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 diseases. NIAID's research portfolio includes global killers, such as HIV/AIDS, tuberculosis (TB), and malaria; emerging and resurging threats such as Ebola virus disease, influenza, and drug-resistant TB, and diseases caused by bioterror threats. NIAID also advances research to better understand normal function of the immune system, and its role in immune-mediated disorders such as asthma, allergy, autoimmune diseases, and transplant rejection. NIAID supports a comprehensive basic research portfolio, and builds on this research to develop vaccines, therapeutics, and diagnostics to prevent and treat the myriad infectious and immune-mediated diseases that afflict people around the world.

NIAID remains committed to achieving an AIDS-free generation by supporting and conducting research to prevent, treat, and ultimately cure HIV/AIDS. Since its discovery more than 30 years ago, HIV/AIDS has claimed more than 39 million lives. During this time, NIAID's scientific leadership and investment in HIV research has been central to the development of potent prevention and treatment interventions, including more than 30 Food and Drug Administration (FDA)-approved antiretroviral drugs and drug combinations. These potent medications have averted an estimated 7.6 million deaths globally since 1995, and have nearly eliminated mother-to-child transmission of HIV in many parts of the developed world. Recent NIAID-supported studies have demonstrated that antiretroviral drugs also can prevent HIV acquisition – when used as pre-exposure prophylaxis (PrEP) – and transmission. The NIAID-supported "treatment as prevention" (TasP) study (HPTN 052) showed that, in the discordant couples studied, early HIV treatment in the HIV-infected dramatically reduced the likelihood of HIV transmission to the uninfected partner. NIAID studies are now exploring the effectiveness of TasP in diverse settings and populations.

To end the HIV pandemic, both a cure for HIV and a vaccine that provides lasting and durable protection are essential. HIV's ability to rapidly establish hidden reservoirs in the body makes finding an HIV cure extremely challenging. Even with effective treatment, low levels of HIV can persist for years in HIV-infected patients as hidden reservoirs of infected cells that can cause viral rebound if treatment stops. NIAID investigators are pursuing a variety of strategies to eradicate hidden virus reservoirs, and are striving to develop strategies that will achieve and maintain sustained viral remission in the absence of antiretroviral treatment. Several NIAID initiatives are supporting research to better understand HIV reservoirs and pursue novel strategies targeting these reservoirs, including The Martin Delaney Collaboratories: Towards an HIV Cure (FY 2012); Targeting Persistent HIV Reservoirs (FY 2013); and Delivering Therapeutics to Residual Active HIV Reservoirs (FY 2014). The President's HIV/AIDS Cure Initiative is providing vital support for these and other HIV cure research efforts. NIAID also continues to support research to develop an HIV vaccine. As a key part of this effort, NIAID-supported researchers are striving to understand and build on the modest efficacy observed in the Department of Defense-NIAID RV144 HIV vaccine trial.

In keeping with its mission, NIAID responds rapidly to newly emerging or resurging infectious disease threats, while maintaining and growing basic and clinical research on numerous pathogens and endemic infectious diseases. NIAID's flexible infrastructure and longstanding research portfolio on hemorrhagic fever viruses has enabled a swift response to the recent Ebola public health emergency. NIAID is now supporting development of novel diagnostics and therapeutics, including partnering with other federal agencies to advance testing of ZMapp, a therapeutic found to be effective in animal models. NIAID is also playing a critical role in advancing several Ebola vaccine candidates. A safe and effective vaccine could help to prevent or contain future Ebola outbreaks, and protect frontline healthcare workers. Similarly, NIAID has responded rapidly to the novel, highly lethal Middle East respiratory syndrome coronavirus (MERS-CoV) that emerged in 2012 and the H7N9 influenza virus – a strain with pandemic potential – that emerged in China in 2013. Building on NIAID's established coronavirus research portfolio, NIAID scientists recently developed a marmoset animal model that mimics severe MERS-CoV infection, providing a valuable – and much needed – resource for testing potential treatments.

Vaccines are a proven tools for preventing infectious diseases, and NIAID is a world leader in vaccine design and development. NIAID is developing a universal flu vaccine – designed to induce a potent immune response to common elements of the virus – intended to protect against seasonal and pandemic influenza strains. NIAID researchers and grantees recently completed an early-stage clinical trial showing that the PfSPZ vaccine, a novel vaccine composed of weakened malaria sporozoites, was safe and protected against malaria. Pertussis, or whooping cough, is particularly dangerous for newborns who are too young to receive the tetanus, diphtheria and acellular pertussis (Tdap) vaccine. A recent NIAID clinical trial demonstrated that vaccinating pregnant women with Tdap is safe and likely to protect their newborn infants against pertussis. NIAID also has developed a groundbreaking vaccine for respiratory syncytial virus (RSV), a serious respiratory infection primarily of young children. Researchers designed this vaccine, which is now being tested in clinical trials, by building on previous findings about the structure of a critical RSV protein. *Science* magazine highlighted this discovery as a top 10 scientific breakthrough of 2013.

The increase in drug-resistant infections (and a corresponding reduction in the effectiveness of therapies) is an urgent global public health problem and a key NIAID priority. NIAID is advancing research on many aspects of antimicrobial resistance, including basic research on how microbes develop resistance, studies translating lab findings into potential treatments, and clinical trials to evaluate vaccines and therapeutics against drug-resistant microbes. NIAID's Antibacterial Resistance (AR) Leadership Group, a major research effort modeled after the HIV/AIDS Clinical Trials Networks' Leadership Groups, is a key part of NIAID's AR research effort.

NIAID also is committed to research on basic and clinical immunology that will improve treatment and prevention of immune-mediated disorders, including asthma, allergic diseases, and rejection of transplanted tissues and organs. Immune-mediated disorders cause significant chronic disease and disability and can inflict enormous social and financial burdens on patients and their families. Through basic research to understand the immunological causes of these diseases, NIAID is working to define what constitutes human immune competence; evaluate the immune response to infection, vaccination, and immune-mediated and inflammatory diseases; and prevent the rejection of transplanted organs, tissues, and cells. A recently published NIAID-funded study in mice found that bacteria colonizing the gut may be essential to mount a strong immune response to seasonal flu vaccine. The results suggest that antibiotic treatment, which reduces the number and diversity of gut bacteria, may reduce the immune response to the vaccine. In another small clinical study, NIAID-funded investigators identified an immune signature from blood samples taken from patients undergoing hip replacement surgery that correlated with recovery times. The results hold promise for the development of diagnostic tests to improve care and predict recovery from surgical procedures.

Overall Budget Policy:
The FY 2016 President's Budget request is $4,614.779 million, an increase of $197.221 million or 4.5 percent, above the FY 2015 Enacted level. Within the President's Budget request, noncompeting grants will be funded at committed levels. The average cost of competing RPGs will be comparable to the FY 2015 level.

In FY 2016, NIAID will support new investigators on R01 equivalent awards at success rates equivalent to those of established investigators submitting new R01 equivalent 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, Ebola, HIV/AIDS, tuberculosis, malaria, autoimmune disorders, drug-resistant microbes, asthma, and allergies.

The NIAID's Intramural Research program will reflect a budget increase to support the President's HIV Cure Initiative, increased focus on influenza vaccine research and the proposed pay increase in FY 2016. The NIAID's Research Management and Support program will reflect a budget increase to support the proposed pay increase in FY 2016. Funds are included in RPGs, Research Centers and Research and Development Contract to support the NIAID research agenda and NIH-wide programs.

Within the President's Budget request, NIH proposes to launch a national research cohort, Precision Medicine Cohort, of one million or more Americans – to propel our understanding of

health and disease and set the foundation for a new way of doing research through engaged participants and open, responsible data sharing. Participants will share their genomic data, biological specimens, and behavioral data, all linked to their electronic health records (EHRs), taking advantage of the latest in social media and mobile applications. Bona fide researchers from across the country will have access to data from the cohort, thereby crowdsourcing rich data to the brightest minds in biomedical research. The cohort will be built largely by linking existing cohorts together, thus minimizing the initial enrollment work and taking advantage of infrastructure and expertise already in place. Research on this scale promises to lead to new prevention strategies, novel therapeutics and medical devices, and improvements in how we prescribe drugs – on an *individual and personalized* basis.

## Program Descriptions and Accomplishments

**HIV/AIDS:** NIAID is dedicated to supporting basic, clinical, and translational research to prevent, treat, and ultimately cure HIV/AIDS, its related co-morbidities, and common co-infections such as malaria and TB. This research addresses biological, social, and epidemiological aspects of HIV as well as efforts to develop prevention and treatment measures targeted to diverse populations, settings, and cultures. In addition, NIAID is working to develop strategies to cure HIV, or achieve sustained remission in the absence of HIV therapy. (See Program Portrait: In Search of a Cure for HIV/AIDS.)

Multiple biomedical approaches are needed to achieve an AIDS-free generation. The best long-term hope for achieving this goal is a safe, effective, and affordable HIV vaccine that could be used alone or in combination with other prevention and treatment methods. NIAID is currently supporting more than 20 HIV vaccine clinical trials. With the aim of improving the 31 percent preventive efficacy observed in the RV144 vaccine trial ("Thai trial"), NIAID is planning a series of vaccine trials through the "P5" initiative, a public-private research collaboration that will test modified RV144 vaccine candidates and regimens. NIAID also supports basic research programs that provide the foundation for tomorrow's vaccine discoveries. Scientists at NIAID's Vaccine Research Center continue their success in identifying and characterizing naturally occurring, powerful antibodies that can neutralize over 90 percent of known HIV-1 strains and can do so with greater overall strength than previously known antibodies to the virus. Scientists are now testing these antibodies in Phase I clinical trials to determine if, when administered, they can confer passive protection against HIV infection in humans. NIAID has also launched three new programs to increase basic knowledge of the mechanisms, pathways, and components involved in generating a protective immune response to HIV, as well as an initiative to better understand how the carbohydrate structure of the HIV envelope may inform improved vaccine design.

As the search for an effective HIV vaccine continues, NIAID is also conducting and supporting research to develop other prevention approaches such as TasP, PrEP, and topical microbicides. Two NIAID-supported clinical trials are evaluating the TasP strategy: the TLC+ study is evaluating TasP at the community level, while the PopART study is testing TasP in a larger adult population in countries with high HIV prevalence. NIAID also will further investigate PrEP as a prevention method in a Phase II clinical trial using additional drug regimens. Because treatment adherence is critical to the effectiveness of these prevention methods, NIAID is stepping up

efforts to make interventions more acceptable to target populations. In FY 2014, NIAID solicited applications to develop new ways to quantify adherence to HIV prevention interventions. NIAID, with the National Institute of Mental Health, sponsored two behavioral and social research programs to better understand and improve the conditions that promote or impede adherence to antiretroviral therapy (ART). NIAID also launched the Sustained Release of Antivirals for Treatment or Prevention of HIV program in FY 2015 to develop sustained-release HIV treatment approaches, because the need to take ART daily reduces adherence that is critical to keeping virus levels low.

NIAID also is addressing HIV co-infections with targeted research initiatives and clinical trials. The Multidisciplinary Studies of HIV and Viral Hepatitis Co-infection initiative seeks to fill gaps in our knowledge of the interactions and effects of viral hepatitis as an HIV co-infection. The REMEMBER trial will determine the safety and efficacy of initiating TB treatment and HIV treatment at the same time, even when TB infection has not been found.

Budget Policy:
The FY 2016 President's Budget estimate for the extramural component of the HIV/AIDS research is $1,401.406 million, an increase of $58.040 million or 4.3 percent above the FY 2015 Enacted level. The FY 2016 AIDS research plan was carefully crafted to support the goals of the President's National HIV/AIDS Strategy including the President's $100 million HIV Cure Initiative announced in December 2013. The plan balances support of high-priority research initiatives in AIDS research with support for the best investigator-initiated research. The critical areas of focus in the FY 2016 AIDS research plan is research on therapeutics and vaccine discovery, an expanded focus on HIV Cure activities, research of co-infections that complicate treatment and prevention of HIV/AIDS, and an expanded focus on understanding and improving adherence to antiretroviral therapy. FY 2016 funding will continue to support a broad range of research, from basic discovery through clinical trials on vaccine and topical microbicide candidates as well as other prevention strategies. Continuations of key research activities include advancing vaccine discovery, identifying novel approaches to interrupt HIV transmission and, increasing understanding of the complex interactions of HIV with the immune system by using a systems biology approach, expanding HIV Cure Initiatives that focus on discovery of the mechanisms of latency and persistence of HIV in the human body, and establishing and expanding manufacturing capacity and processes for biological based prevention strategies. New key research activities include gaining a better understanding of how to make adherence to prevention methods more acceptable to target populations through behavioral and social research programs, and clinical studies designed to fill gaps in our knowledge of the effects and appropriate treatments of TB and Viral Hepatitis Co-infections in HIV infected individuals.

**Program Portrait: In Search of a Cure for HIV/AIDS**

| | |
|---|---|
| FY 2015 Level | $ 102.5 million |
| FY 2016 Level | $ 124.1 million |
| Change | +$21.6 million |

Antiretroviral therapy (ART) can effectively reduce viral load and control disease progression in HIV-infected individuals. Even with treatment, however, low levels of virus persist in latent reservoirs, leading to viral rebound if ART is discontinued. Developing a cure that eradicates HIV reservoirs or provides sustained remission in the absence of ART is the best hope for the nearly 35 million people worldwide living with HIV. The search for a cure has become increasingly important for NIH, as indicated by the December 2013 announcement to reallocate $100 million of HIV/AIDS funding to HIV cure research. NIAID began its commitment to such research in 2010 with a series of programs focused on understanding basic HIV reservoir biology and identifying new strategies to eliminate or control HIV reservoirs. Several new NIAID programs will expand the search for a cure. *Beyond HAART: Innovative Approaches to Cure HIV* will support development of nontraditional treatments to provide HIV remission without a lifetime of ART. *Targeting Latently Infected Cells Without Reactivation* seeks novel ways to eradicate viral reservoirs directly without the need to "awaken" HIV from its latent state. Two other initiatives will search for improved methods to detect and quantify latently infected cells.

In 2013, NIAID-supported researchers reported a breakthrough in the search for a cure. In Mississippi, a one-day-old baby born to a mother who was diagnosed with HIV at the time of delivery was placed on ART due to the high risk of HIV exposure. Testing soon confirmed HIV infection. The infant continued treatment until she was 18 months old, when there was a lapse in her clinical treatment. When the child was tested when she was brought to the clinic 5 months later, the child had no detectable HIV. The child continued to do well in the absence of ART and was free of detectable HIV for more than 2 years, until blood tests once again detected HIV infection. Despite the fact that HIV rebounded in the child, the ability to sustain remission for 27 months signifies a crucial first step toward achieving long-term remission in infants and opens promising directions for HIV cure research. NIAID initiated a clinical study in 2014 to explore whether giving ART very early to newborns infected with HIV *in utero* leads to viral remission and could allow them to eventually stop treatment. An expert panel will join in evaluating the appropriateness of treatment interruption. Through this effort, scientists will continue investigating the factors that enabled the "Mississippi baby" to remain in remission for more than two years and what might be done to extend the period of sustained HIV remission.

**Biodefense and Emerging Infectious Diseases:** NIAID is committed to fulfilling its dual mandate of conducting basic and applied research while maintaining the ability to respond rapidly to emerging public health threats, whether natural or bioterror-related. NIAID coordinates all NIH-supported activities for developing medical countermeasures against biological, chemical, radiological, and nuclear threats. The Institute emergency preparedness strategy spans a continuum from basic biomedical studies to development of broad-spectrum treatment strategies, multi-platform technologies, and flexible research infrastructure that affords collaboration with university, Federal agencies, and industry partners.

Despite worldwide research and public health efforts to treat, contain, and eradicate microbial pathogens, disease threats continue to emerge and re-emerge. Cases of chikungunya, a mosquito-borne viral disease found in Africa and Asia, appeared in the Western Hemisphere in 2013; since then, more than 1,200 cases have been reported throughout the United States. Through research initiated in 2010 by the NIAID Vaccine Research Center, a vaccine candidate recently was tested in early-stage clinical trials and was found to be safe and effective in a small group of test subjects. In response to the emergence of MERS-CoV, NIAID researchers mobilized to develop therapeutics and vaccines, characterized MERS Co-V disease and transmission, and provided strong evidence for dromedary camels as the primary MERS-CoV reservoir and the likely source

of transmission to humans. Another emerging disease of great concern is Valley Fever (coccidioidomycosis), a serious and potentially life-threatening disease found in the southwestern United States. NIAID scientists are studying the epidemiology and natural history of the disease as well as developing novel treatment protocols for affected patients.

In addition, in response to the deadly Ebola epidemic that has already affected many countries, NIAID is building on its past research to develop promising therapies and a preventive vaccine for Ebola virus disease. The $238 million of emergency funding provided by Congress in FY 2015 will greatly accelerate these efforts. NIAID has established a laboratory field site in Monrovia; staffed by intramural scientists highly experienced in biosafety level-4 environments, the lab is processing an average of 70 samples a day. Identifying the presence or absence of virus in samples in Monrovia provides real-time data that is critical in tracking both the epidemic and the effectiveness of intervention efforts. NIAID scientists are carefully monitoring this work to ensure that the diagnostic tests being used continue to effectively detect virus as the outbreak continues to evolve. NIAID also is working with industry partners to develop accurate and accessible diagnostics for Ebola virus. (See Program Portrait: The Challenge of Outpacing Emerging Infectious Diseases.)

Microbes excel in their natural capacity to adapt and become resistant to antimicrobial treatment. NIAID is addressing the growing problem of antimicrobial resistance (AR) through basic research to understand how microbes acquire and transmit resistance genes and clinical efforts including studies to optimize the use of currently licensed drugs, combination therapies, and alternative, non-antibiotic treatment strategies. The NIAID Antibacterial Resistance Leadership Group (ARLG) is using the NIAID clinical trials network to evaluate diagnostic devices in clinical settings and optimize treatment regimens to reduce the emergence of resistance. In addition, the ARLG will test new antibiotics in individuals infected with highly resistant strains. Notable NIAID advances in research include development of products that are part of a new class of antibiotics against Gram-positive bacteria such as methicillin-resistant Staphylococcus aureus and the clinical evaluation of a novel drug to treat Clostridium difficile infections, which CDC recently identified as an urgent antibiotic-resistant public health threat. In FY 2015, NIAID established two initiatives that support AR research: Partnerships for Diagnostics to Address Antimicrobial Resistance of Select Bacterial Pathogens and Development of Novel Therapeutics for Select Pathogens.

Influenza continues to be a high-priority NIAID research focus. Despite availability of a seasonal vaccine, influenza causes more than 200,000 hospitalizations and thousands of deaths each year in the United States. Major areas of effort include basic research on influenza biology, and establishment and maintenance of a robust product development pipeline for influenza vaccines, treatments, and diagnostics. NIAID is conducting two concurrent Phase II clinical trials of an investigational vaccine against H7N9 influenza, a strain with pandemic potential. Because seasonal vaccines provide little or no protection against pandemic influenzas, a universal vaccine that would prompt the immune system to produce “broadly neutralizing” antibodies is an urgent research focus. A universal flu vaccine would protect against pandemic and seasonal influenza strains and could confer long-term protection, thereby eliminating the need for annual flu shots.

Successes from the investment in NIAID's biodefense program include several countermeasure candidates that have been transferred to the HHS Biomedical Advanced Research and Development Authority for further development. NIAID also provided information that informed FDA's decision to approve the first antibiotic for pneumonic plague, which causes severe and deadly lung infections. Recently launched NIAID initiatives seek to advance biodefense research through development of a diagnostic tool that could detect multiple bio-threat pathogens in a single test; move drug candidates to clinical testing more rapidly; and advance the development of candidate vaccines against pathogens that pose bioterror threats.

Budget Policy:

The FY 2016 President's Budget estimate for the extramural component of biodefense and emerging infectious diseases research supported by NIAID is $1,355.837 million, an increase of $94.508 million or 7.5 percent above the FY 2015 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, viral hemorrhagic fevers and other high priority viral pathogens. A top NIAID priority is development of cross-protective universal vaccines that protects against pandemic and seasonal influenza strains over several years. NIAID will support advanced clinical development of the lead vaccine candidate to accelerate development of more effective influenza vaccines. NIAID is building upon its past research to develop accurate and accessible diagnostics, promising therapies and a preventative vaccine for Ebola virus. In FY 2016, NIAID will support pre-clinical testing and discovery of new Ebola vaccines, therapeutics and diagnostic candidates and accelerate the evaluation of their toxicity, immunogenicity and efficacy. In FY 2016, NIAID will continue research on diagnostic platforms and devices to detect antimicrobial resistance of select bacterial pathogens, and continue to advance the development and production of non-traditional/innovative therapeutics for antibacterial resistant strains. NIAID supports the development of medical countermeasures against biodefense-related pathogens and will continue to coordinate with BARDA in the advanced development of therapeutics and vaccines against biodefense pathogens. Jointly funded at $20 million with BARDA, NIH is working to design a public competition for the accelerated development of an affordable, accurate, and rapid diagnostic test to be used by healthcare providers to identify highly resistant bacterial infections at the point of patient care.

**Program Portrait: The Challenge of Outpacing Emerging Infectious Diseases**

| | |
|---|---|
| FY 2015 Level | $1,717.4 million |
| FY 2016 Level | $1,815.4 million |
| Change | + $98.0 million |

In a few short years, the world has witnessed the emergence of numerous diseases, including MERS-CoV, chikungunya, and Ebola. Microbes can evolve quickly, sometimes with adaptations that enable them to emerge as epidemics or pandemics. They adapt to our attempts to thwart them, and we adapt our approaches, racing to "outsmart" nature's ingenuity.

The 2014 Ebola crisis is a case in point. NIAID's long-standing basic and translational research on Ebola and other hemorrhagic fever viruses has yielded some of today's most promising therapeutic candidates, including ZMapp, the monoclonal antibody cocktail used to treat U.S. aid workers; BCX4430, a broad-spectrum antiviral; and the NIAID/GSK chimpanzee adenovirus-vectored vaccine (cAd3). These drug candidates hold promise for development into licensed products that could be stockpiled for use in future public health emergencies. NIAID funded scientists have also made great strides toward elucidating other emerging infectious disease pathogens of public health importance. Chikungunya, a mosquito-borne infection, continues to spread, now posing a threat to temperate and tropical climates. Researchers are examining the pathogenesis and modes of replication of this virus, as well as ways to prevent, diagnose, and treat the disease. NIAID has supported development of a genetically engineered, live-attenuated chikungunya vaccine that protected non-human primates with a single dose and may also interrupt viral transmission in mosquitoes.

NIAID also supports research to prevent, treat, and diagnose long-standing, still emerging, diseases. Some newly emerged TB strains are resistant to first-line treatments. NIAID's ongoing support of a comprehensive TB research portfolio has led to discoveries that are improving treatment options. In one project, scientists found than an existing class of antimicrobials (known as spectinamides) can be modified to work against TB, combatting even drug-resistant strains without harming mammalian cells. Basic research also has revealed a complex network of protein-gene interactions within the TB bacterium that may offer new targets for vaccines and drugs. Collaborative efforts have placed us on the brink of eradicating polio, a concept that was unimaginable just a half-century ago. NIAID, in accord with its dual mandate, built and maintains a nimble scientific enterprise that enables it to respond to emerging and unanticipated threats while also supporting innovative research essential to combatting persistent infectious diseases.

**Infectious and Immunologic Diseases:** NIAID supports biomedical research on the human immune system, its role in immune-mediated diseases, and its response to nearly 300 infectious agents including bacteria, viruses, parasites, fungi, and prions. NIAID also supports research on the biological properties of these pathogens, as well as the aberrant immune system responses underlying immune-related disorders such as asthma, allergic diseases, autoimmune diseases, and transplant rejection. Research on these diseases and disorders provides a more complete understanding of how the immune system functions in health and disease, and lays the foundation for research on vaccines, therapeutics, and diagnostic devices that can be deployed to protect and improve the health of people throughout the world.

In the past year, NIAID reported significant progress in addressing major global killers including TB, malaria, and hepatitis C virus (HCV).

- Tuberculosis, an ancient disease, remains a major cause of disability and death. Two teams of NIAID scientists recently developed TB treatment strategies that may be particularly beneficial for treating drug-resistant TB. One strategy, a novel, host-directed TB therapy, manipulates the body's immune response to TB bacteria. Another therapy

resulted from the modification of a common antibiotic, rendering it effective against TB bacteria.

- NIAID researchers and grantees recently completed a Phase I clinical trial showing that a novel malaria vaccine composed of weakened sporozoites (the infectious form of the parasite) was safe and protected against malaria.
- HCV is a significant cause of chronic liver disease and cancer and a common HIV coinfection. NIH investigators demonstrated that the new drug sofosbuvir and the antiviral ribavirin were highly effective at combating HCV, and were well tolerated even in patients who respond poorly to traditional HCV treatment. Sofosbuvir and similar therapies, now approved by FDA, could revolutionize HCV treatment.

NIAID research is also a key contributor to the development of new diagnostics. A promising advance in the fight against malaria is the recent development of low-cost diagnostic tests that can rapidly detect resistance of malaria to artemisinin, a first-line antimalarial drug. Early detection of resistance allows clinicians to administer effective medications. Creutzfeldt-Jakob disease (CJD), an incurable and ultimately fatal neurodegenerative disorder, is usually diagnosed by detecting prions in brain tissue post mortem. A nasal brush test developed by NIAID scientists and Italian colleagues allows differentiation of CJD from other brain diseases, facilitating the development and evaluation of treatments for CJD.

NIAID is committed to advancing the understanding of immune-mediated diseases and applying basic research findings to clinical investigations to develop more effective treatment and prevention strategies. Food allergy and eosininophilic esophagitis (EoE) are important public health problems that are mechanistically related and increasing in prevalence. EoE is a potentially debilitating inflammation of the esophagus that affects children and adults. A NIAID-sponsored clinical trial in EoE has shown that high doses of an oral corticosteroid safely induced remission, and also identified genes that may help predict which patients will do well on this treatment. Another NIAID-sponsored study offers hope that a rapid molecular diagnostic test could be used to identify people with eosinophilic disorders.

NIAID also funds several networks committed to research on autoimmune diseases. The Hematopoietic Stem Cell Transplant Consortium (HSCTC) is conducting studies on multiple sclerosis and scleroderma. In partnership with NIAID's Immune Tolerance Network, the HSCTC demonstrated that hematopoietic stem cell transplantation is effective in inducing sustained remission of active multiple sclerosis. NIAID-funded researchers are also shedding light on primary immune deficiency diseases. One study showed that early hematopoietic stem cell transplantation is a highly effective treatment for infants with severe combined immunodeficiency (SCID), a group of rare, life-threatening, inherited immune disorders. Another study demonstrated that screening all newborns for SCID reliably identifies infants with these disorders, leading to prompt treatment and increased survival. The third study found that gene therapy can safely restore the immune systems of children with X-linked SCID, a rare, life-threatening inherited condition that primarily affects boys. A team of NIAID and NHGRI scientists identified a new, genetic human immunodeficiency called PASLI disease, which may be treatable with a drug already approved to prevent transplant rejection.

Budget Policy:
The FY 2016 President's Budget estimate for the extramural component of infectious and immunologic diseases (IID) research is $1,041.790 million, an increase of $33.156 million or 3.3 percent above the FY 2015 Enacted level. The FY 2016 IID research plan supports critical long-range research priorities of NIAID with funds carefully aligned to support key research activities which include supporting basic and clinical research aimed at the development of countermeasures for diseases of global health significance, including malaria; and promoting basic and clinical research aimed at the development of antimicrobials and vaccines for emerging and re-emerging infectious diseases, including antibiotic resistant bacteria. In FY 2016 funding will reflect NIAID's commitment and long-term interest in fundamental immunology and support research on organ transplantation, autoimmune diseases, asthma and other allergic diseases through initiatives such as the Asthma and Allergic Disease Cooperative Research Centers (AADCRC) and the Collaborative Network for Clinical Research on Immune Tolerance.

**Program Portrait: New Insights into the Early Development and Prevention of Allergy and Asthma**

| | |
|---|---|
| FY 2015 Level | $143.7 million |
| FY 2016 Level | $143.7 million |
| Change | $0.0 million |

Allergies result when normally harmless substances, known as allergens, induce an immune response. Inhaled allergens derived from dust mites, pets, cockroaches, molds and pollen can lead to asthma, a chronic respiratory disease that affects more than seven million children in the United States. NIAID is dedicated to expanding understanding of the causes and to developing new therapies and prevention strategies for asthma. Since 1991, a series of NIAID initiatives have focused on asthma in urban, low-income children, who have the highest levels of asthma morbidity and mortality. The current initiative, the Inner-city Asthma Consortium (ICAC), recently completed a study demonstrating that virus-induced asthma exacerbations in the fall can be almost eliminated with the seasonal use of the monoclonal antibody omalizumab, which suppresses the allergic component of asthma. In one longitudinal study, ICAC researchers are following children from birth. They recently found that higher exposure to microbe's in house dust, together with higher exposure to common allergens, is associated with protection against early life wheezing and the development of allergies. These and other studies funded by NIAID are creating new opportunities for the prevention of allergic diseases and asthma.

NIAID also supports research on the prevention and treatment of food allergies. The Consortium of Food Allergy Research, established in 2005, and the Immune Tolerance Network, established in 1999, are conducting studies in children with food allergies to produce desensitization and tolerance by giving food allergens orally, sublingually, or in the form of a skin patch. In addition, a large study comparing the early introduction of peanut in the diet versus peanut avoidance to prevent the development of peanut allergy is ongoing and in analysis. Using a mouse model of food allergy, NIAID-funded investigators found that certain bacteria present in the mouse gut protect against experimental induction of food allergy, indicating that harmful immune responses leading to food allergy involve interactions with microbes and these interactions can be explored as prevention strategies.

**Intramural Research:** For more than six decades, the NIAID intramural research program (IRP) has been at the forefront of research to expand knowledge of normal immune system function; define mechanisms that underlie immunologic disease (immunodeficiency, allergy, and autoimmunity); understand the biology of infectious agents (viruses, bacteria, fungi, parasites, and prions) and elucidate the host response to infection. State-of-the-art laboratories and clinical facilities combined with a workforce characterized by diverse scientific expertise enable the IRP to translate basic discoveries into new vaccines, therapies, and diagnostics for infectious and

immune-related diseases. The NIAID IRP is advancing high-priority research that includes the development of a new class of antimalarial compounds and the development of a "universal" flu vaccine as well as vaccine candidates for HIV/AIDS and malaria.

The NIAID IRP has three components:

- The Division of Intramural Research (DIR), in which more than 120 principal investigators in Maryland and Montana lead basic, translational, and clinical research efforts on a wide range of topics in immunology and infectious and immune-mediated diseases.
- The Vaccine Research Center (VRC), which applies fundamental advances in immunology, virology, and vaccine science to discover new and improved vaccines for human diseases.
- The Division of Clinical Research (DCR), which facilitates efficient and effective NIAID clinical research programs in the United States and internationally.

An IRP strength is its ability to respond to diverse disease challenges, ranging from swift deployment of resources to emerging infectious threats, to innovating treatments for rare immunological syndromes, and to developing public-private partnerships in the battle against long-standing infectious diseases that exact a high public health toll in the United States and globally. One example is the development and preclinical testing of a dual-purpose, candidate vaccine to protect against rabies and Ebola viruses. The vaccines were created by scientists at NIAID and Thomas Jefferson University, and are being further developed through a partnership with the German pharmaceutical company, IDT Biologika. The vaccines have now been licensed to Exxell BIO of Shoreview, Minnesota, which aims to advance the products through clinical testing and potential commercialization.

Budget Policy:
The FY 2016 President's Budget estimate for Intramural Research is $535.631 million, an increase of $8.744 million or 1.7 percent above the FY 2015 Enacted level. The increased funding will support the President's HIV Cure Initiative, increased focus on influenza vaccine research, and the proposed pay increase in FY 2016. The FY 2016 Intramural Research plan supports critical long-range research priorities of NIAID, with funds carefully aligned to support key research activities. These include the continued support for all aspects of research on infectious diseases such as AIDS, malaria, and influenza, including the causative agent, vectors and the human host. In addition, we are developing countermeasures against bioterrorism through basic research and our strong clinical research component allowing key lab discoveries to be rapidly translated into methods to prevent, diagnose, or treat disease.

**Research Management and Support (RMS):** NIAID RMS activities provide administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of research grants, training awards, and research and development contracts. RMS activities include strategic planning, coordination, and evaluation of the Institute's programs, as well as regulatory compliance, international coordination, and liaison with other Federal agencies, Congress, and the public.

Budget Policy:
The FY 2016 President's Budget estimate is $280.115 million, an increase of $2.773 million or 1.0 percent above the FY 2015 Enacted level. The budget increase will help to support the proposed pay increase.

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

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

| | FY 2015 Enacted | FY 2016 President's Budget | FY 2016 +/- FY 2015 |
|---|---|---|---|
| Total compensable workyears: | | | |
| Full-time employment | 1,983 | 1,983 | 0 |
| Full-time equivalent of overtime and holiday hours | 0 | 0 | 0 |
| Average ES salary | $180 | $182 | $1 |
| Average GM/GS grade | 12.2 | 12.2 | 0.0 |
| Average GM/GS salary | $101 | $102 | $1 |
| Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207) | $92 | $93 | $1 |
| Average salary of ungraded positions | $132 | $133 | $1 |

| | OBJECT CLASSES | FY 2015 Enacted | FY 2016 President's Budget | FY 2016 +/- FY 2015 |
|---|---|---|---|---|
| | Personnel Compensation | | | |
| 11.1 | Full-Time Permanent | $142,252 | $144,219 | $1,967 |
| 11.3 | Other Than Full-Time Permanent | 65,278 | 66,181 | 903 |
| 11.5 | Other Personnel Compensation | 5,009 | 5,078 | 69 |
| 11.7 | Military Personnel | 4,517 | 4,579 | 62 |
| 11.8 | Special Personnel Services Payments | 19,633 | 19,904 | 272 |
| **11.9** | **Subtotal Personnel Compensation** | **$236,688** | **$239,962** | **$3,274** |
| 12.1 | Civilian Personnel Benefits | $64,834 | $65,483 | $648 |
| 12.2 | Military Personnel Benefits | 3,225 | 3,270 | 45 |
| 13.0 | Benefits to Former Personnel | 0 | 0 | 0 |
| | **Subtotal Pay Costs** | **$304,747** | **$308,714** | **$3,967** |
| 21.0 | Travel & Transportation of Persons | $7,855 | $7,981 | $126 |
| 22.0 | Transportation of Things | 983 | 998 | 15 |
| 23.1 | Rental Payments to GSA | 3 | 3 | 0 |
| 23.2 | Rental Payments to Others | 1 | 1 | 0 |
| 23.3 | Communications, Utilities & Misc. Charges | 3,106 | 3,155 | 50 |
| 24.0 | Printing & Reproduction | 12 | 12 | 0 |
| 25.1 | Consulting Services | $15,899 | $16,153 | $254 |
| 25.2 | Other Services | 144,732 | 146,282 | 1,549 |
| 25.3 | Purchase of goods and services from government accounts | 552,748 | 596,644 | 43,896 |
| 25.4 | Operation & Maintenance of Facilities | $6,628 | $6,628 | $0 |
| 25.5 | R&D Contracts | 619,637 | 629,551 | 9,914 |
| 25.6 | Medical Care | 3,237 | 3,318 | 81 |
| 25.7 | Operation & Maintenance of Equipment | 17,014 | 17,265 | 251 |
| 25.8 | Subsistence & Support of Persons | 0 | 0 | 0 |
| **25.0** | **Subtotal Other Contractual Services** | **$1,359,894** | **$1,415,840** | **$55,946** |
| 26.0 | Supplies & Materials | $40,620 | $41,249 | $630 |
| 31.0 | Equipment | 20,698 | 20,983 | 286 |
| 32.0 | Land and Structures | 0 | 0 | 0 |
| 33.0 | Investments & Loans | 0 | 0 | 0 |
| 41.0 | Grants, Subsidies & Contributions | 2,679,638 | 2,815,840 | 136,202 |
| 42.0 | Insurance Claims & Indemnities | 2 | 2 | 0 |
| 43.0 | Interest & Dividends | 0 | 0 | 0 |
| 44.0 | Refunds | 0 | 0 | 0 |
| | **Subtotal Non-Pay Costs** | **$4,112,811** | **$4,306,065** | **$193,254** |
| | **Total Budget Authority by Object Class** | **$4,417,558** | **$4,614,779** | **$197,221** |

[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 2015 Enacted | FY 2016 President's Budget | FY 2016 +/- FY 2015 |
|---|---|---|---|
| **Personnel Compensation** | | | |
| Full-Time Permanent (11.1) | $142,252 | $144,219 | $1,967 |
| Other Than Full-Time Permanent (11.3) | 65,278 | 66,181 | 903 |
| Other Personnel Compensation (11.5) | 5,009 | 5,078 | 69 |
| Military Personnel (11.7) | 4,517 | 4,579 | 62 |
| Special Personnel Services Payments (11.8) | 19,633 | 19,904 | 272 |
| **Subtotal Personnel Compensation (11.9)** | **$236,688** | **$239,962** | **$3,274** |
| Civilian Personnel Benefits (12.1) | $64,834 | $65,483 | $648 |
| Military Personnel Benefits (12.2) | 3,225 | 3,270 | 45 |
| Benefits to Former Personnel (13.0) | 0 | 0 | 0 |
| **Subtotal Pay Costs** | **$304,747** | **$308,714** | **$3,967** |
| Travel & Transportation of Persons (21.0) | $7,855 | $7,981 | $126 |
| Transportation of Things (22.0) | 983 | 998 | 15 |
| Rental Payments to Others (23.2) | 1 | 1 | 0 |
| Communications, Utilities & Misc. Charges (23.3) | 3,106 | 3,155 | 50 |
| Printing & Reproduction (24.0) | 12 | 12 | 0 |
| **Other Contractual Services:** | | | |
| Consultant Services (25.1) | 14,591 | 14,824 | 233 |
| Other Services (25.2) | 144,732 | 146,282 | 1,549 |
| Purchases from government accounts (25.3) | 239,444 | 253,038 | 13,594 |
| Operation & Maintenance of Facilities (25.4) | 6,628 | 6,628 | 0 |
| Operation & Maintenance of Equipment (25.7) | 17,014 | 17,265 | 251 |
| Subsistence & Support of Persons (25.8) | 0 | 0 | 0 |
| **Subtotal Other Contractual Services** | **$422,410** | **$438,038** | **$15,628** |
| Supplies & Materials (26.0) | $40,620 | $41,249 | $630 |
| **Subtotal Non-Pay Costs** | **$474,986** | **$491,435** | **$16,448** |
| **Total Administrative Costs** | **$779,734** | **$800,149** | **$20,415** |

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

## Detail of Full-Time Equivalent Employment (FTE)

| OFFICE/DIVISION | FY 2014 Actual | | | FY 2015 Est. | | | FY 2016 Est. | | |
|---|---|---|---|---|---|---|---|---|---|
| | Civilian | Military | Total | Civilian | Military | Total | Civilian | Military | Total |
| Division of Acquired Immunodeficiency | | | | | | | | | |
| Direct: | 149 | 9 | 158 | 149 | 9 | 158 | 149 | 9 | 158 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 149 | 9 | 158 | 149 | 9 | 158 | 149 | 9 | 158 |
| Division of Allergy, Immunology, and Transplantation | | | | | | | | | |
| Direct: | 86 | 1 | 87 | 86 | 1 | 87 | 86 | 1 | 87 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 86 | 1 | 87 | 86 | 1 | 87 | 86 | 1 | 87 |
| Division of Clinical Research | | | | | | | | | |
| Direct: | 87 | 11 | 98 | 88 | 11 | 99 | 88 | 11 | 99 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 87 | 11 | 98 | 88 | 11 | 99 | 88 | 11 | 99 |
| Division of Extramural Activities | | | | | | | | | |
| Direct: | 231 | - | 231 | 233 | - | 233 | 233 | - | 233 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 231 | - | 231 | 233 | - | 233 | 233 | - | 233 |
| Division of Intramural Research | | | | | | | | | |
| Direct: | 691 | 16 | 707 | 693 | 16 | 709 | 693 | 16 | 709 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 691 | 16 | 707 | 693 | 16 | 709 | 693 | 16 | 709 |
| 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: | 419 | 3 | 422 | 421 | 3 | 424 | 421 | 3 | 424 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 419 | 3 | 422 | 421 | 3 | 424 | 421 | 3 | 424 |
| Vaccine Research Center | | | | | | | | | |
| Direct: | 91 | - | 91 | 93 | - | 93 | 93 | - | 93 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 91 | - | 91 | 93 | - | 93 | 93 | - | 93 |
| Total | 1,925 | 47 | 1,972 | 1,936 | 47 | 1,983 | 1,936 | 47 | 1,983 |
| 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 |
|---|---|
| 2012 | 12.3 |
| 2013 | 12.3 |
| 2014 | 12.2 |
| 2015 | 12.2 |
| 2016 | 12.2 |

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

### Detail of Positions[1]

| GRADE | FY 2014 Actual | FY 2015 Enacted | FY 2016 President's Budget |
|---|---|---|---|
| Total, ES Positions | 2 | 2 | 2 |
| Total, ES Salary | 357,794 | 360,477 | 363,181 |
| GM/GS-15 | 152 | 152 | 152 |
| GM/GS-14 | 411 | 412 | 412 |
| GM/GS-13 | 294 | 296 | 296 |
| GS-12 | 234 | 235 | 235 |
| GS-11 | 138 | 140 | 140 |
| GS-10 | 1 | 1 | 1 |
| GS-9 | 92 | 95 | 95 |
| GS-8 | 25 | 26 | 26 |
| GS-7 | 72 | 73 | 73 |
| GS-6 | 16 | 16 | 16 |
| GS-5 | 11 | 11 | 11 |
| GS-4 | 6 | 6 | 6 |
| GS-3 | 7 | 7 | 7 |
| GS-2 | 4 | 4 | 4 |
| GS-1 | 3 | 3 | 3 |
| Subtotal | 1,466 | 1,477 | 1,477 |
| Grades established by Act of July 1, 1944 (42 U.S.C. 207) | 0 | 0 | 0 |
| Assistant Surgeon General | 0 | 0 | 0 |
| Director Grade | 25 | 25 | 25 |
| Senior Grade | 5 | 5 | 5 |
| Full Grade | 7 | 7 | 7 |
| Senior Assistant Grade | 5 | 5 | 5 |
| Assistant Grade | 0 | 0 | 0 |
| Co-Step | 5 | 5 | 5 |
| Subtotal | 47 | 47 | 47 |
| Ungraded | 475 | 475 | 475 |
| Total permanent positions | 1,504 | 1,515 | 1,515 |
| Total positions, end of year | 1,990 | 2,001 | 2,001 |
| Total full-time equivalent (FTE) employment, end of year | 1,972 | 1,983 | 1,983 |
| Average ES salary | 178,897 | 180,238 | 181,590 |
| Average GM/GS grade | 12.2 | 12.2 | 12.2 |
| Average GM/GS salary | 100,391 | 101,144 | 101,903 |

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