DEPARTMENT OF HEALTH AND HUMAN SERVICES

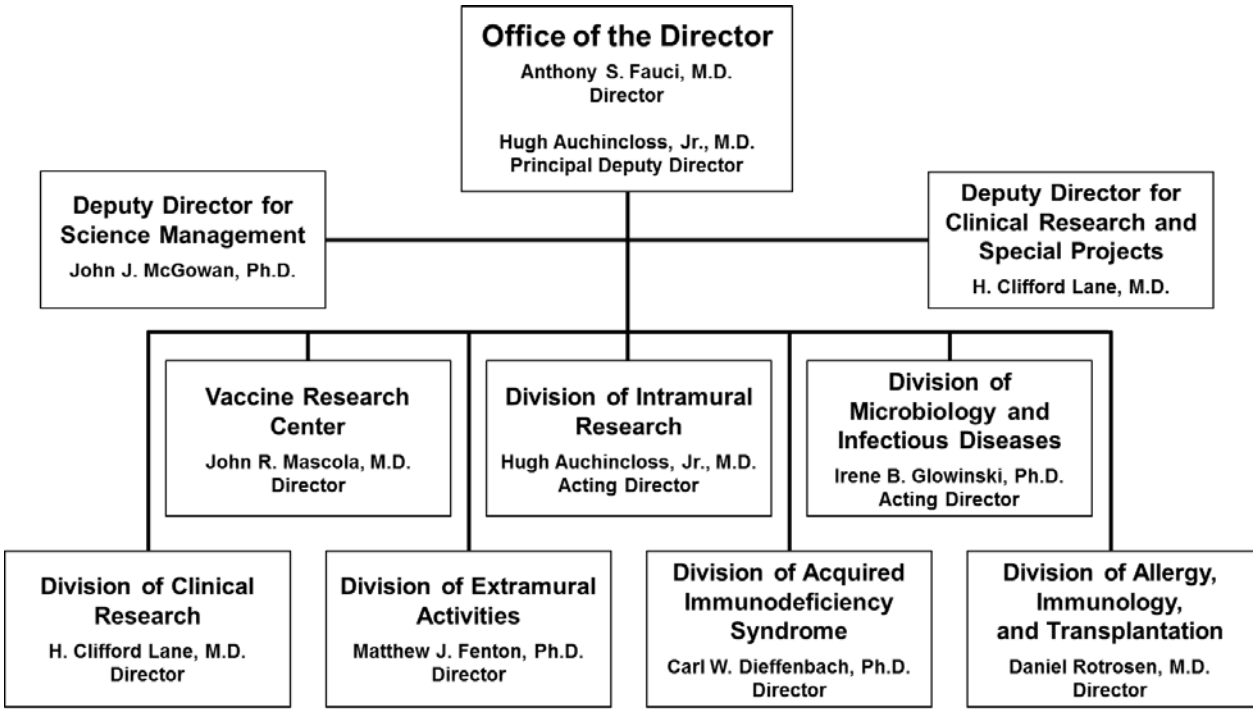
NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases (NIAID)



NOTE: The FY 2016 Enacted funding amounts cited throughout this chapter reflect the effects of OAR HIV/AIDS Transfers.

# National Institutes of Health
# National Institutes 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, [$4,629,928,000]*$4,700,548,000*.

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

## Amounts Available for Obligation[1]

(Dollars in Thousands)

| Source of Funding | FY 2015 Actual | FY 2016 Enacted | FY 2017 President's Budget |
|---|---|---|---|
| Appropriation | $4,358,841 | $4,629,928 | $4,715,697 |
| Mandatory Appropriation: (non-add) | | | |
| *Type 1 Diabetes* | *(0)* | *(0)* | *(0)* |
| *Other Mandatory financing* | *(0)* | *(0)* | *(15,149)* |
| Rescission | 0 | 0 | 0 |
| Sequestration | 0 | 0 | 0 |
| FY 2015 First Secretary's Transfer | 0 | 0 | 0 |
| FY 2015 Second Secretary's Transfer | 0 | 0 | 0 |
| Subtotal, adjusted appropriation | $4,358,841 | $4,629,928 | $4,715,697 |
| OAR HIV/AIDS Transfers | 58,717 | 85,769 | 0 |
| National Children's Study Transfers | 0 | 0 | 0 |
| Subtotal, adjusted budget authority | $4,417,558 | $4,715,697 | $4,715,697 |
| Unobligated balance, start of year | 0 | 0 | 0 |
| Unobligated balance, end of year | 0 | 0 | 0 |
| Subtotal, adjusted budget authority | $4,417,558 | $4,715,697 | $4,715,697 |
| Unobligated balance lapsing | -29 | 0 | 0 |
| Total obligations | $4,417,529 | $4,715,697 | $4,715,697 |

[1] Excludes the following amounts for reimbursable activities carried out by this account:
FY 2015 - $11,737 FY 2016 - $12,207 FY 2017 - $12,207

**NATIONAL INSTITUTES OF HEALTH**
**FY 2017 Congressional Justification**
**NIAID**

**Budget Mechanism - Total[1]**

(Dollars in Thousands)

| MECHANISM | FY 2015 Actual | | FY 2016 Enacted | | FY 2017 President's Budget[3] | | FY 2017 +/- FY 2016 | |
|---|---|---|---|---|---|---|---|---|
| | No. | Amount | No. | Amount | No. | Amount | No. | Amount |
| Research Projects: | | | | | | | | |
| Noncompeting | 2,525 | $1,882,670 | 2,630 | $1,961,119 | 3,058 | $2,167,313 | 428 | $206,194 |
| Administrative Supplements | *(57)* | 15,129 | *(57)* | 14,995 | *(57)* | 14,995 | | |
| Competing: | | | | | | | | |
| Renewal | 171 | 84,022 | 227 | 157,886 | 174 | 116,626 | -53 | -41,260 |
| New | 1,100 | 493,215 | 1,352 | 586,416 | 1,030 | 449,016 | -322 | -137,400 |
| Supplements | 1 | 134 | 1 | 179 | 1 | 151 | | -28 |
| Subtotal, Competing | 1,272 | $577,371 | 1,580 | $744,481 | 1,205 | $565,793 | -375 | -$178,688 |
| Subtotal, RPGs | 3,797 | $2,475,170 | 4,210 | $2,720,594 | 4,263 | $2,748,100 | 53 | $27,506 |
| SBIR/STTR | 230 | 120,915 | 252 | 133,752 | 274 | 141,502 | 22 | 7,750 |
| Research Project Grants | 4,027 | $2,596,085 | 4,462 | $2,854,346 | 4,537 | $2,889,602 | 75 | $35,256 |
| Research Centers: | | | | | | | | |
| Specialized/Comprehensive | 31 | $35,679 | 34 | $37,102 | 34 | $37,102 | | |
| Clinical Research | | | | | | | | |
| Biotechnology | | | | | | | | |
| Comparative Medicine | | 774 | | 599 | | 599 | | |
| Research Centers in Minority Institutions | | | 3 | 426 | 3 | 426 | | |
| Research Centers | 31 | $36,453 | 37 | $38,127 | 37 | $38,127 | | |
| Other Research: | | | | | | | | |
| Research Careers | 256 | $38,594 | 264 | $40,306 | 264 | $40,306 | | |
| Cancer Education | | | | | | | | |
| Cooperative Clinical Research | | | | | | | | |
| Biomedical Research Support | | | | | | | | |
| Minority Biomedical Research Support | 3 | 629 | 3 | 654 | 3 | 654 | | |
| Other | 103 | 21,091 | 122 | 24,104 | 122 | 24,104 | | |
| Other Research | 362 | $60,313 | 389 | $65,064 | 389 | $65,064 | | |
| Total Research Grants | 4,420 | $2,692,851 | 4,888 | $2,957,537 | 4,963 | $2,992,793 | 75 | $35,256 |
| Ruth L Kirchstein Training Awards: | FTTPs | | FTTPs | | FTTPs | | FTTPs | |
| Individual Awards | 206 | $9,041 | 214 | $9,558 | 210 | $9,558 | -4 | |
| Institutional Awards | 852 | 45,768 | 882 | 48,323 | 883 | 49,323 | 1 | 1,000 |
| Total Research Training | 1,058 | $54,809 | 1,096 | $57,881 | 1,093 | $58,881 | -3 | $1,000 |
| Research & Develop. Contracts | 187 | $854,744 | 190 | $846,049 | 189 | $800,407 | -1 | -$45,642 |
| *(SBIR/STTR) (non-add)[2]* | *(12)* | *(5,740)* | *(18)* | *(11,706)* | *(18)* | *(11,706)* | | |
| Intramural Research | 873 | $527,037 | 882 | $554,618 | 882 | $554,618 | | |
| Res. Management & Support | 1,079 | 288,117 | 1,090 | 299,611 | 1,090 | 308,998 | | 9,386 |
| *Res. Management & Support (SBIR Admin) (non-add)[2]* | | | | *(650)* | | *(650)* | | |
| *Office of the Director - Appropriation[2]* | | | | | | | | |
| Office of the Director - Other | | | | | | | | |
| *ORIP/SEPA (non-add)[2]* | | | | | | | | |
| *Common Fund (non-add)[2]* | | | | | | | | |
| Buildings and Facilities | | | | | | | | |
| *Appropriation* | | | | | | | | |
| Type 1 Diabetes | | | | | | | | |
| Program Evaluation Financing | | | | | | | | |
| Cancer Initiative Mandatory Financing | | | | | | | | |
| Other Mandatory Financing | | | | | | -15,149 | | -15,149 |
| **Subtotal, Labor/HHS Budget Authority** | | **$4,417,558** | | **$4,715,697** | | **$4,700,548** | | **-$15,149** |
| Interior Appropriation for Superfund Res. | | | | | | | | |
| **Total, NIH Discretionary B.A.** | | **$4,417,558** | | **$4,715,697** | | **$4,700,548** | | **-$15,149** |
| Type 1 Diabetes | | | | | | | | |
| **Proposed Law Funding** | | | | | | | | |
| Cancer Initiative Mandatory Financing | | | | | | | | |
| Other Mandatory Financing | | | | | | 15,149 | | 15,149 |
| **Total, NIH Budget Authority** | | **$4,417,558** | | **$4,715,697** | | **$4,715,697** | | |
| Program Evaluation Financing | | | | | | | | |
| **Total, Program Level** | | **$4,417,558** | | **$4,715,697** | | **$4,715,697** | | |

[1] All Subtotal and Total numbers may not add due to rounding.
[2] All numbers in italics and brackets are non-add.
[3] Includes mandatory financing.

## Major Changes in the Fiscal Year 2017 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 2017 President's Budget for NIAID, is unchanged from the FY 2016 level, for a total of $4,715.697 million.

Research Project Grants (+$35.256 million; total $2,889.602 million):
NIAID will support a total of 4,537 Research Project Grant (RPG) awards in FY 2017. Funding will provide ongoing support for the Biodefense and Emerging Infectious Diseases, Infectious and Immunologic Diseases and HIV/AIDS research agendas including Antimicrobial Resistance, Influenza Vaccine, the President's Cure initiative and NIH-Wide programs.

Research and Development Contracts (-$45.642 million; total $800.407 million):
The reduced funding will help support NIAID's RPG science portfolio and the Technology Transfer and Intellectual Property Office.

Research Management and Support (+$9.386 million; total $308.998 million):
The NIAID RMS budget increase will provide program management and administrative support for the Technology Transfer and Intellectual Property Office.

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

**Summary of Changes**

(Dollars in Thousands)

| | |
|---|---|
| **FY 2016 Enacted** | $4,715,697 |
| **FY 2017 President's Budget** | $4,715,697 |
| **Net change** | $0 |

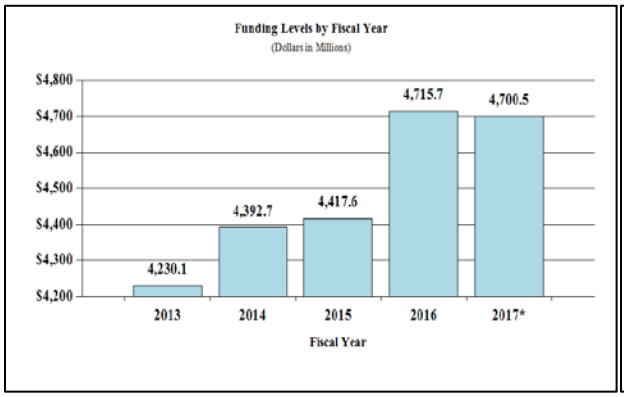
| CHANGES | FY 2017 President's Budget[1] FTEs | FY 2017 President's Budget[1] Budget Authority | Change from FY 2016 FTEs | Change from FY 2016 Budget Authority |
|---|---|---|---|---|
| A. Built-in: | | | | |
| 1. Intramural Research: | | | | |
| a. Annualization of January 2016 pay increase & benefits | | $153,355 | | $379 |
| b. January FY 2017 pay increase & benefits | | 153,355 | | 1,138 |
| c. Two less days of pay | | 153,355 | | -1,094 |
| d. Differences attributable to change in FTE | | 153,355 | | 0 |
| e. Payment for centrally furnished services | | 76,211 | | 2,184 |
| f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs | | 325,053 | | 809 |
| Subtotal | | | | $3,416 |
| 2. Research Management and Support: | | | | |
| a. Annualization of January 2016 pay increase & benefits | | $172,757 | | $416 |
| b. January FY 2017 pay increase & benefits | | 172,757 | | 1,247 |
| c. Two less days of pay | | 172,757 | | -1,278 |
| d. Differences attributable to change in FTE | | 172,757 | | 0 |
| e. Payment for centrally furnished services | | 22,442 | | 76 |
| f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs | | 113,799 | | 13 |
| Subtotal | | | | $474 |
| Subtotal, Built-in | | | | $3,890 |

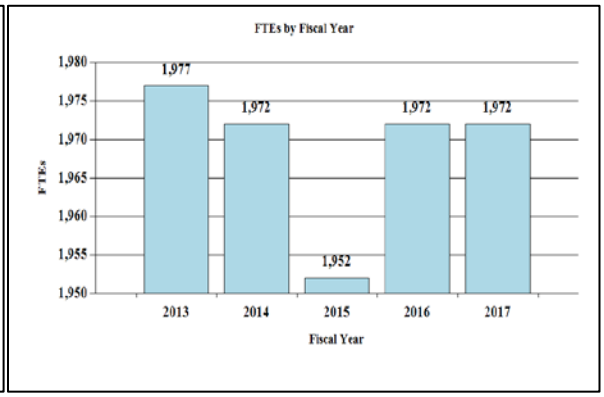
| CHANGES | FY 2017 President's Budget[1] No. | FY 2017 President's Budget[1] Amount | Change from FY 2016 No. | Change from FY 2016 Amount |
|---|---|---|---|---|
| B. Program: | | | | |
| 1. Research Project Grants: | | | | |
| a. Noncompeting | 3,058 | $2,182,307 | 428 | $206,194 |
| b. Competing | 1,205 | 565,793 | -375 | -178,688 |
| c. SBIR/STTR | 274 | 141,502 | 22 | 7,750 |
| Subtotal, RPGs | 4,537 | $2,889,602 | 75 | $35,256 |
| 2. Research Centers | 37 | $38,127 | 0 | $0 |
| 3. Other Research | 389 | 65,064 | 0 | 0 |
| 4. Research Training | 1,093 | 58,881 | -3 | 1,000 |
| 5. Research and development contracts | 189 | 800,407 | -1 | -45,642 |
| Subtotal, Extramural | | $3,852,081 | | -$9,386 |
| | FTEs | | FTEs | |
| 6. Intramural Research | 882 | $554,618 | 0 | -$3,416 |
| 7. Research Management and Support | 1,090 | 308,998 | 0 | 8,912 |
| 8. Construction | | 0 | | 0 |
| 9. Buildings and Facilities | | 0 | | 0 |
| Subtotal, Program | 1,972 | $4,715,697 | 0 | -$3,890 |
| Total changes | | | | $0 |

[1] Includes mandatory financing.

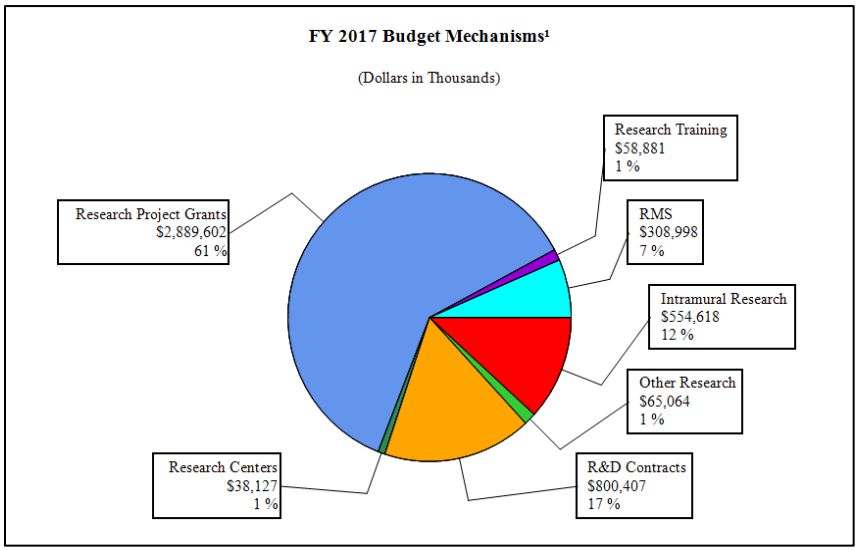
# Fiscal Year 2017 Budget Graphs

History of Budget Authority and FTEs:

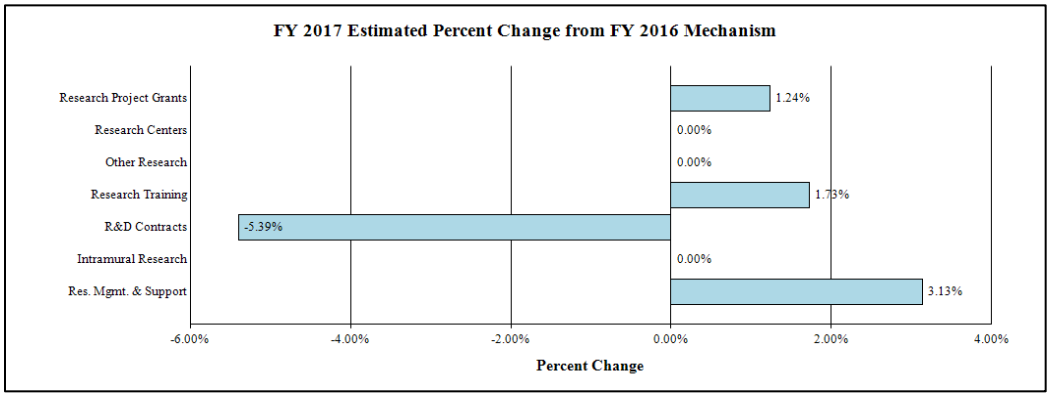



Distribution by Mechanism:




Change by Selected Mechanisms:



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

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

| | FY 2015 Actual | | FY 2016 Enacted | | FY 2017 President's Budget[2] | | FY 2017 +/- FY2016 | |
|---|---|---|---|---|---|---|---|---|
| **Extramural Research** | **FTE** | **Amount** | **FTE** | **Amount** | **FTE** | **Amount** | **FTE** | **Amount** |
| Detail | | | | | | | | |
| HIV/AIDS[3] | | $1,334,616 | | $1,400,047 | | $1,400,047 | | $0 |
| Biodefense & Emerging Infectious Diseases[4] | | 1,263,032 | | 1,375,042 | | 1,370,349 | | -4,693 |
| Infectious & Immunological Diseases | | 1,004,756 | | 1,086,378 | | 1,081,685 | | -4,693 |
| **Subtotal, Extramural** | | **$3,602,404** | | **$3,861,467** | | **$3,852,081** | | **-$9,386** |
| **Intramural Research** | **873** | **$527,037** | **882** | **$554,618** | **882** | **$554,618** | **0** | **$0** |
| **Research Management & Support** | **1,079** | **$288,117** | **1,090** | **$299,611** | **1,090** | **$308,998** | **0** | **$9,386** |
| **TOTAL** | **1,952** | **$4,417,558** | **1,972** | **$4,715,697** | **1,972** | **$4,715,697** | **0** | **$0** |

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.
[2] Includes mandatory financing.
[3] NIH total for HIV/AIDS: $1,586.804M Actual in FY 2015; Estimate $1,663.823M in FY 2016; Estimate $1,663.823M in FY 2017'.
[4] NIH total for Biodefense: $1,610.560M Actual in FY 2015; Estimate $1,739.471M in FY 2016; Estimate $1,739.471M in FY 2017.

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

## Authorizing Legislation

| | PHS Act/ Other Citation | U.S. Code Citation | 2016 Amount Authorized | FY 2016 Enacted | 2017 Amount Authorized | FY 2017 President's Budget[1] |
|---|---|---|---|---|---|---|
| Research and Investigation | Section 301 | 42§241 | Indefinite | $4,715,697,000 | Indefinite | $4,700,548,000 |
| National Institute of Allergy and Infectious Diseases | Section 401(a) | 42§281 | Indefinite | | Indefinite | |
| Total, Budget Authority | | | | $4,715,697,000 | | $4,700,548,000 |

[1]Excludes mandatory financing.

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

### Appropriations History

| Fiscal Year | Budget Estimate to Congress | House Allowance | Senate Allowance | Appropriation |
|---|---|---|---|---|
| 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 |
| 2016 | $4,614,779,000 | $4,512,918,000 | $4,710,342,000 | $4,629,928,000 |
| Rescission | | | | $0 |
| 2017[1] | $4,715,697,000 | | | |

[1] 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 2015 Actual | FY 2016 Enacted | FY 2017 President's Budget | FY 2017 + / - FY 2016 |
|---|---|---|---|---|
| BA | $4,358,841,000 | $4,715,697,000 | $4,715,697,000 | 0 |
| FTE | 1,952 | 1,972 | 1,972 | 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. The robust and comprehensive NIAID basic research portfolio – the core of Institute research activities and a central focus for the NIH Director – expands 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. This research underpins efforts to develop and test diagnostics, vaccines, and therapeutics to prevent and treat the many infectious and immune-mediated diseases that afflict people throughout the world.

Since its discovery more than 30 years ago, HIV/AIDS has claimed more than 34 million lives worldwide, and vanquishing this disease remains a key Institute priority.[1] NIAID research continues to lead us closer to an "AIDS-free generation," in which new HIV infections, as well as illness and death due to AIDS, are rare. A decade of well-designed studies of antiretroviral therapy (ART) regimens culminated in July 2015, when results of the major international Strategic Timing of Antiretroviral Treatment (START) study showed that when individuals with HIV initiated ART as soon as they were diagnosed, their overall risk of developing AIDS or other serious illnesses was reduced considerably compared to those who delayed therapy. In light of these data, the World Health Organization (WHO) recommended that all HIV-infected persons be treated immediately to improve their health and prevent transmission of the virus to others. NIAID also remains committed to developing a safe and effective HIV/AIDS vaccine – the holy grail of HIV research. Finally, we aspire ultimately to cure individuals with HIV – that is, either to eradicate the virus completely or, more likely, to suppress the virus to the point

[1] WHO Fact sheet No. 360, updated July 2015. http://www.who.int/mediacentre/factsheets/fs360/en/

where a person with HIV can suspend ART without the virus rebounding. With this goal in mind, NIAID is supporting research to learn more about persistent hiding places or "reservoirs" of HIV and how antiretroviral therapies affect these sites.

With increasing movement of people and goods, many infectious diseases are global concerns. Ongoing NIAID research on a variety of emerging infections, such as pandemic influenza, chikungunya, Zika, and dengue, provides the foundation for developing effective medical countermeasures and strategies and enables swift research responses to disease outbreaks. This capacity came into dramatic focus in 2014, with the unprecedented Ebola outbreak in West Africa. NIAID scientists working with international partners, including health ministries in Liberia, Guinea, and Sierra Leone, traveled repeatedly to Africa to advance critical research toward possible treatments, develop and test vaccines, and strengthen field diagnostics capability to help stem the spread of the deadly Ebola virus disease (EVD). At home, NIAID infectious disease experts cared for several patients exposed to or infected with the Ebola virus at the NIH Clinical Center's state-of-the-art Special Clinical Studies Unit. To help stem the outbreak, NIAID launched the Liberia-U.S. clinical research partnership known as the "Partnership for Research on Ebola Vaccines in Liberia" (PREVAIL). In PREVAIL I, scientists working with pharmaceutical companies showed that two experimental vaccines, both developed with NIAID support, are safe and capable of inducing a significant immune response against the virus. The PREVAIL I partnership has expanded to Sierra Leone and Guinea, where NIAID is working with host countries to further evaluate the most promising Ebola vaccine candidates. PREVAIL II is evaluating the safety and efficacy of a candidate Ebola therapy called ZMapp and optimized standard of care compared to optimized standard of care alone. ZMapp consists of three different antibodies that target Ebola and together are protective in nonhuman primates. PREVAIL III is an observational study focusing on people who have survived EVD and their contacts. Study investigators hope to gain insights on the long-term health consequences of EVD, learn whether survivors are protected from future Ebola infection, determine how long the virus may persist within certain protected sites within the body such as the genitourinary system, and observe whether sexual transmission of EVD to others can occur.

NIAID continues to study Middle East respiratory syndrome coronavirus (MERS-CoV), which emerged in 2012 in the Middle East. Since then, cases of MERS have been reported in 26 countries, and more than 35 percent of those patients have died. While MERS is not highly transmissible, it remains a significant global public health threat, and NIAID is actively advancing research to develop vaccines and drugs that limit its spread, as well as screening existing, FDA-approved drugs for activity against MERS-CoV. Recent animal studies of two experimental MERS vaccines, designed using structural and genomic sequence information about a viral protein called the spike glycoprotein, have yielded promising results.

In 2015, the growing problem posed by antibiotic-resistant pathogens received emphasis at the highest U.S. Government levels when the White House released its National Action Plan for Combating Antibiotic-Resistant Bacteria.[2] NIAID plays a key role in advancing the goals of the White House initiative through research to understand how microbes develop resistance and studies to identify novel ways to combat them; translation of laboratory findings into potential treatments, vaccines, and new diagnostic tests; clinical validation of diagnostic tests; and clinical

[2] National Action Plan for Combating Antibiotic-Resistant Bacteria

trials to evaluate vaccines and new and existing therapies against drug-resistant microbes. In an exciting discovery this year, NIAID-supported researchers used an innovative screening method to discover a novel antibiotic called teixobactin from soil. Teixobactin appears to be a potent killer of a broad range of bacteria, including Staphylococcus aureus, Streptococcus pneumonia, and Mycobacterium tuberculosis, and NIAID is supporting work to develop this molecule into a novel therapeutic. The research that unearthed teixobactin also may lead to the identification of additional antibiotics that can avoid development of resistance.

NIAID is committed to improving treatment and prevention of immune-mediated disorders including asthma, allergic diseases, autoimmunity, and rejection of transplanted organs, tissues, and cells. Immune-mediated disorders result in significant chronic disease and disability, and can impose large social and financial burdens on patients and their families. By conducting basic and clinical research, we are working to delineate further the mechanisms of immune function and to develop and test novel approaches to suppress aberrant immune responses or enhance beneficial immune responses. For example, peanut allergy is an increasing global health problem affecting between one and three percent of children in many westernized countries. This year, the NIAID Immune Tolerance Network (ITN) released clinical trial results that transformed our understanding of peanut allergy prevention. ITN researchers showed that introducing peanut-containing foods into the diets of high-risk infants at an early age was safe and reduced their risk of developing peanut allergy by 81 percent by five years of age. Based on this research, NIAID is leading the development of an addendum to the 2010 Food Allergy Guidelines, to be published in FY 2016, which will address prevention of peanut allergy through early peanut introduction.

Overall Budget Policy:
The FY 2017 President's Budget request is $4,715.697 million, unchanged from the FY 2016 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 2016 level.

In FY 2017, 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, HIV/AIDS, tuberculosis, malaria, autoimmune disorders, drug-resistant microbes, asthma, and allergies.

The NIAID's Research Management and Support program reflects a budget increase for the program management and administrative support for the Technology Transfer and Intellectual Property Office. Funds are included in RPGs, Research Centers, Other Research and Research and Development Contract to support the NIAID research agenda and NIH-wide programs.

## Program Descriptions and Accomplishments

**HIV/AIDS**: NIAID remains committed to ending the HIV pandemic by advancing research to improve HIV prevention and optimize treatments for HIV infection, co-infections, and diseases or conditions associated with HIV/AIDS. To this end, the HIV/AIDS research portfolio is designed to increase knowledge about the biology of HIV/AIDS and support development of effective strategies for combating the disease.

While antiretroviral drugs have significantly helped to control HIV infections and dramatically improve the prognosis for people living with HIV/AIDS (see Program Portrait: The Unequivocal Benefits of Treating HIV Early), new therapeutic approaches are needed that target the virus but do not require daily adherence. Researchers are working to develop anti-HIV antibodies or antibody-like molecules that can neutralize diverse strains of the virus. The first human study of such a broadly neutralizing anti-HIV antibody, funded in part by NIAID, showed a significant reduction in HIV levels in HIV-infected individuals after a single intravenous dose of the antibody. Another group of NIAID-funded scientists developed an antibody-like molecule, known as eCD4-Ig, which provided effective long-term control of a wide-range of HIV strains in the lab and safely protected monkeys from infection with an HIV-like virus. With further research, this molecule may be able to subdue infection in humans.

NIAID also focuses on optimizing ART for HIV prevention. These efforts encompass two main approaches: averting transmission by treating HIV-infected individuals with ART, and preventing HIV infection by using ART as daily pre-exposure prophylaxis (PrEP) in high-risk, HIV-uninfected individuals. Recent NIAID-funded studies evaluating PrEP adherence in high-risk populations in New York, South Africa and Bangkok, showed that most people in these high-risk groups adhered to the daily pill regimen. To facilitate greater adherence, NIAID is supporting the development of sustained-release agents that would need to be administered only once every two to three months, including injectable forms of PrEP for both men and women and a vaginal ring that could be co-formulated with a contraceptive.

In the long term, developing a safe and effective HIV vaccine is a critical component of the NIAID strategy to prevent new HIV infections. A large HIV vaccine trial in Thailand (RV144) funded by the U.S. Army, NIAID, and industry and non-profit partners was the first to show modest protection against HIV. To build on these results, NIAID recently launched a new study in South Africa to evaluate a vaccine regimen designed to provide stronger and longer protection than the one tested in the RV144 trial. NIAID also is planning to launch several vaccine trials over the next three to five years through the Pox-Protein Public-Private Partnership (P5), including a large efficacy study in South Africa and a series of Phase I studies that will evaluate a new pox vaccine vector and unique adjuvants. NIAID also is pursuing a vaccine strategy that elicits anti-HIV antibodies with the capacity to neutralize a wide range of HIV strains. Stimulating the production of these broadly neutralizing antibodies may be an effective way to prevent HIV infection through vaccination. NIAID-supported studies are investigating how specifically designed proteins can stimulate the body's production of immune cells called B cells that produce these antibodies. Recently, the NIAID Vaccine Research Center (VRC) advanced this goal by engineering an HIV surface molecule with a stable configuration that allows for more effective binding of neutralizing antibodies. Multiple animal studies are underway to test

experimental vaccines that induce broadly neutralizing antibodies against HIV; promising results have been seen in both rabbits and non-human primates.

Many individuals infected with HIV die not from AIDS but from HIV co-infections and associated conditions. Reducing the incidence and health toll of co-infections and associated conditions is a top NIAID HIV research priority, and a number of studies and clinical trials are in progress. As an example, the planned trial PHOENIX/A5300, a collaboration between NIAID and NICHD, will compare two treatments to prevent tuberculosis (TB) infection in household contacts of people with multidrug-resistant TB, especially those at high risk of developing disease due to age, HIV status, or prior TB infection.

As noted above, research to find a cure for HIV infection remains among the top priorities for NIAID. Current studies are aimed at identifying latent viral reservoirs – areas in the body where the virus lies hidden and dormant – and developing approaches to control or eliminate them. NIAID-funded scientists recently discovered a strategy to "awaken" dormant immune cells that are the primary viral reservoirs and boost the immune response against these HIV-infected cells. Another promising approach to eliminating HIV reservoirs is early initiation of ART. To test this strategy, a NIAID clinical trial (IMPAACT P1115) is examining whether starting ART soon after birth for infants who were infected with HIV in the womb leads to remission of the virus. The hope is to enable the children eventually to stop treatment for an extended period.

Budget Policy:
The FY 2017 President's Budget estimate for the extramural component of the HIV/AIDS research is $1,400.047 million, unchanged from the FY 2016 Enacted level. The FY 2017 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 2017 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 2017 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 will include initiatives that support research to reduce the incidence of HIV/AIDS, including the development of safe and effective HIV/AIDS vaccines; development of the next generation of HIV therapies with improved safety and ease of use; research towards a cure for HIV/AIDS; and HIV-associated comorbidities and co-infections.

**Program Portrait: The Unequivocal Benefits of Treating HIV Early**

| | |
|---|---|
| FY 2016 Level | $64.8 million |
| FY 2017 Level | $64.8 million |
| Change | $0.0 million |

The greatest achievement in HIV research has been the discovery, development, and delivery of ART to millions of HIV-infected people around the world. ART has typically been started when an HIV-positive person's level of CD4+ T-cells – a key measure of immune system health and a main target of the virus – decreases to 350 cells per cubic millimeter ($mm^3$) of blood. But a series of studies has now yielded incontrovertible evidence that starting ART earlier – at a higher CD4 count – not only yields better health outcomes for HIV-infected individuals but also reduces the risk of transmitting to their partners.

By 2009, evidence from observational cohorts such as NIAID-funded International Epidemiologic Databases to Evaluate AIDS reported that HIV therapy improved clinical outcomes and mortality when initiated early in the course of asymptomatic HIV infection. In 2011, a NIAID-sponsored clinical trial, HPTN 052, conclusively showed that early ART – starting when CD4+ T-cell counts were still above 350 cells per $mm^3$ – reduced HIV transmission from heterosexuals to their partners by 96 percent, showing that treatment can function as prevention. A third study, the START trial systematically examined the benefits of early ART. START study findings released in 2015 demonstrated that immediate treatment with ART not only prevents serious AIDS-related diseases but also prevents the onset of cancer, cardiovascular disease, and other non-AIDS-related diseases and deaths. These results were so significant – a 57 percent decrease in disease and death – that all participants were informed of the findings and those participants not on ART were offered immediate treatment.

The next major HIV treatment research challenge is to determine whether early initiation of ART may eliminate HIV reservoirs and achieve sustained remission once treatment is stopped. An ongoing study through the International Maternal Pediatric Adolescent AIDS Clinical Trial Network (IMPAACT) is exploring the effects of early intensive ART on achieving HIV remission in newborns. These and other NIAID-supported studies will inform the development of guidelines on the optimal time to begin ART to yield the best possible individual and public health outcomes.

**Biodefense and Emerging Infectious Diseases:** NIAID is committed to fulfilling its unique, dual mandate of conducting basic and applied infectious diseases research on endemic diseases while maintaining the ability to respond rapidly to infectious diseases that emerge naturally or through bioterror activities. NIAID coordinates all NIH-supported activities to develop measures to prevent or treat disease and injury caused by biological, chemical, radiological, and nuclear threats. The Institute bases its ability to mount rapid research responses on basic biomedical studies, development of treatment strategies and technologies applicable to an array of diseases, and flexible research infrastructure that enlists the greatest strengths of university, Federal, and industry partners.

When the novel and deadly MERS-CoV was first recognized in humans in 2012, NIAID joined with international partners to mount a rapid research response. This concerted effort drew on experience NIAID had in tackling similar viruses (such as the coronavirus that causes SARS) and quickly extended knowledge of the pathogenesis, natural history, and transmission of MERS. NIAID researchers identified dromedary camels as the likely primary reservoir for MERS-CoV, and a NIAID-led team recently showed that a two-step regimen of experimental vaccines against MERS induced neutralizing antibodies in camels, mice, and rhesus macaques. The vaccine design may provide a model for a similar human MERS vaccine regimen. MERS has not expanded widely, but its threat continues, as evidenced by a large outbreak in South Korea in 2015. NIAID-supported researchers continue to characterize MERS-CoV disease, identify possible routes of transmission, and develop vaccines and new treatments as well as screen existing, FDA-approved drugs for activity against the virus.

A top NIAID research priority is to develop a "universal" influenza vaccine that eliminates the need to reformulate seasonal vaccines annually in response to circulating influenza strains and that could be used in response to the emergence of a novel influenza virus with pandemic potential. With increasing basic understanding of the structure and immunological characteristics of the influenza surface protein hemagglutinin (HA), NIAID researchers and grantees are moving closer to developing universal flu vaccine strategies. Unlike the highly variable "head" portion of the mushroom-shaped HA molecule, the "stem" portion of the molecule remains relatively constant among different influenza strains and is an attractive cross-protective immunologic target. With agency partners, NIAID is initiating a Phase I trial to investigate the human immune response to HA stem-based universal flu vaccine candidates. In other promising research, scientists at the NIAID VRC developed an HA stem-ferritin nanoparticle vaccine that appears promising in preclinical studies. In addition, NIAID researchers are advancing other promising vaccination strategies, such as a combination of virus-like particles that incorporate multiple HAs.

TB is one of the world's oldest and deadliest diseases, and the threat grows as multidrug-resistant (MDR) and extensively drug-resistant strains emerge. NIAID is advancing early and translational research to develop new treatments and therapeutic regimens and new vaccines and preventive strategies. In addition, new diagnostics are being developed to identify patients who harbor TB bacteria and to discern whether a strain is drug resistant, knowledge that can shorten the time to treatment with an effective drug. (Also see Program Portrait: Combating the Growing Threat of Antimicrobial Resistance.) In FY 2015, NIAID expanded the Tuberculosis Research Units program, which focuses on TB latency and persistence and their relation to active

TB disease, to ultimately identify new strategies for immunization, treatment, and diagnosis of TB. NIAID researchers also collaborate, through the Bill & Melinda Gates Foundation-supported TB Drug Accelerator, with pharmaceutical companies and research institutions to generate innovative new drug candidates. In addition, the NIAID-supported TB Clinical Diagnostic Research Consortium is evaluating several investigational diagnostic approaches and their effect on TB management in countries where the disease is endemic. NIAID support has contributed to more than two-thirds of approximately 20 investigational TB drugs and drug combinations and to about half of the vaccine candidates currently in clinical testing. The Institute plans to contribute to an ongoing clinical trial to test the efficacy, safety, and tolerability of a three-drug combination in people with MDR TB and in those with drug-sensitive TB with the goal of shortening the standard treatment course.

As noted above, NIAID coordinates all NIH-supported activities for developing medical countermeasures against radiological and nuclear threats. In 2015, the drug filgrastim became the first FDA-approved treatment for acute radiation injury, largely on the basis of NIAID-supplied data. In FY 2016, NIAID will support new research projects through the Centers for Medical Countermeasures against Radiation Consortium, established in 2005 to develop drugs and devices that can assess, diagnose, mitigate, and treat the short- and long-term consequences of radiation exposure. NIAID also is planning FY 2017 initiatives focused on mechanisms of radiation injury, devices to detect acute radiation injury, and medical countermeasures against acute radiation syndrome.

Budget Policy:
The FY 2017 President's Budget estimate for the extramural component of biodefense and emerging infectious diseases research supported by NIAID is $1,370.349 million, a decrease of $4.693 million or 0.3 percent below the FY 2016 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, multi-drug-resistant tuberculosis, and other high priority pathogens. A top NIAID priority is to support research leading to better therapeutics and vaccines for influenza including the development of cross-protective universal vaccine that protects against pandemic and seasonal influenza strains over several years. NIAID will continue to promote basic and clinical research aimed at the development of antimicrobials and vaccines for emerging and re-emerging infectious diseases including antibiotic resistant bacteria. NIAID supports the development of medical countermeasures and new platform technologies against biodefense and emerging infectious disease pathogens and will continue to coordinate with BARDA in the advanced development of therapeutics and vaccines.

**Program Portrait: Combating the Growing Threat of Antibiotic Resistance**

FY 2016 Level $343.0 million
FY 2017 Level $343.0 million
Change $0.0 million

Antimicrobial drugs save countless lives, but bacteria and other microbes can evolve in ways that enable them to resist a drug's intended effect. Misuse or overuse of antibiotics has made antibiotic resistance (AR) evolve even faster. The increasing number of drug-resistant infections is a serious and growing global health problem and a key NIAID priority. In the United States alone, an estimated 2 million people develop drug-resistant bacterial infections each year, leading to more than 23,000 deaths.[3]

To counter AR, the NIAID research portfolio encompasses basic through clinical research to test new ways to treat and prevent resistant infections; develop rapid, point-of-care diagnostics to identify highly resistant bacterial infections; and create a new generation of vaccines aimed at drug-resistant microbes. NIAID's pioneering approach to this emerging global health problem is described in its 2014 AR strategic plan, NIAID's Antibacterial Resistance Program: Current Status and Future Directions, and in a White House initiative set forth in the 2015 National Action Plan for Combating Antibiotic-Resistant Bacteria.[4,5] Key NIAID priorities include optimizing the use of existing drugs; combination therapies; and alternative, non-antibiotic treatment strategies, such as modulating the immune system and microbiome. In 2015, NIAID awarded more than $11 million in first-year funding for research to develop diagnostics to rapidly detect antibiotic-resistant bacteria. In addition, NIAID released four targeted AR initiatives in 2015 in an effort to stimulate research in this area. The FY 2016 Budget provided an increase of $100 million for research on combatting antimicrobial resistance (AMR). Recent results from the intense research focus by NIAID include findings that skin infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA) can be treated inexpensively and effectively with either clindamycin or TMP-SMX, two off-patent drugs; preclinical development of a novel beta-lactamase inhibitor to treat high-priority bacterial pathogens, including drug-resistant strains such as *Klebsiella pneumoniae*; and development of NDV-3, the first vaccine candidate to show protection against both bacterial and fungal infections, including *Staphylococcus aureus* and *Candida*. This vaccine could especially benefit patients at high risk for infection and individuals with recurrent infections. The estimated total NIH-wide support for combating AMR will be $413 million in FY 2017.

To ensure a multifaceted and nimble response to this problem, NIAID also works closely with partners including the Task Force on Combating Antibiotic-Resistant Bacteria, the NIH-FDA Joint Leadership Council, and the Trans-Atlantic Task Force on Antimicrobial Resistance. Through these and other efforts, NIAID is committed to reducing the morbidity, mortality, and costs of the growing problem of AR.

[3] CDC: Antibiotic Resistance Threats in the United States, 2013 http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf
[4] NIAID's Antibacterial Resistance Program: Current Status and Future Directions
[5] National Action Plan for Combating Antibiotic-Resistant Bacteria

**Infectious and Immunologic Diseases:** NIAID supports fundamental research to expand our understanding of the regulation of the human immune system and improve treatment strategies for immune-mediated disorders such as asthma, allergy, autoimmune diseases, and transplant rejection. The Institute studies more than 300 infectious agents, including bacteria, viruses, parasites, fungi, and prions.

Diseases such as malaria continue to be significant public health threats, particularly in the developing world. For this reason, global research is a major NIAID focus. A central feature of the NIAID malaria research effort is the International Centers of Excellence for Malaria Research (ICEMR) program, a global network of independent centers in malaria-endemic regions. In FY 2017–2018, NIAID plans to fund ICEMR centers to expand understanding of malaria transmission and develop interventions to accelerate disease control, prevention, and elimination. NIAID supports research, development, and evaluation of a variety of malaria vaccine candidates. The PfSPZ vaccine was found to be safe, well-tolerated, and protective against controlled human malaria infection in two early-phase clinical trials conducted by NIAID scientists. The PfSPZ vaccine is composed of attenuated sporozoites of the species *Plasmodium falciparum*, the most deadly of the malaria-causing parasites. Follow-on clinical studies now aim to determine the duration and degree of protection and to optimize intravenous vaccine delivery.

Efforts by NIAID to facilitate research and discovery on infectious and immunologic diseases increasingly employ innovative tools and data-sharing technologies – an example of NIAID activities that align with the NIH Director's Theme "Applying Big Data and Technology to Improve Health." One such resource is ImmPort, a scientific database that serves as a repository for NIAID-supported research results as well as other relevant immunological information from a variety of public databases. In FY 2017, NIAID will solicit proposals to develop new tools and methods that facilitate access to, and use of, ImmPort data. Another NIAID-supported resource is TrialShare, a data-sharing tool of the ITN, which is a clinical research consortium dedicated to advancing immune tolerance therapies for immune-mediated disease. TrialShare provides researchers with public access to the data and analysis code underlying ITN-published manuscripts in order to promote transparency, reproducibility, and scientific collaboration. Thousands of biological samples from well-characterized ITN study participants are also available. TrialShare is an example of how NIAID is advancing the NIH Director's aim to realize the promise of precision medicine.

In two clinical studies conducted via the ITN, scientists reported promising results toward new treatment approaches for multiple sclerosis (MS) and type 1 diabetes. In one study, doctors collected blood-forming stem cells from participants with MS and then gave them high-dose chemotherapy to destroy their immune systems. The doctors then returned the stem cells to the participants to rebuild and reset their immune systems. This approach halted progression of the most common form of MS in nearly 80 percent of patients. In another study, individuals with type 1 diabetes receiving the immune-suppressing drug alefacept, which helps preserve the function of insulin-producing cells, maintained a healthier blood sugar range and required less insulin than those who did not receive the drug. Larger clinical trials will be needed to further evaluate these promising treatments for MS and type 1 diabetes.

Determining mechanisms that underlie the human immune response in people of all ages is a continuing NIAID basic research focus. (See Program Portrait: Understanding the Infant Immune System.) In FY 2015, NIAID renewed funding for the Human Immunology Project Consortium (HIPC), which supports research to profile the immune response to immunization or infection. The HIPC's publicly accessible online database of research findings, called ImmuneSpace, provides a unique and powerful resource for human immune profiling data and analytic platforms, and is another example of how NIAID is advancing efforts in support of the NIH Director's theme "Applying Big Data and Technology to Improve Health."

NIAID plays a leading role in the trans-NIH Human Microbiome Project, which is creating computational tools and datasets to facilitate large-scale analyses of the microbiome, the trillions of microbes that co-exist in and on the human body. These publicly accessible datasets catalyze efforts by U.S. and International scientists to understand and improve human health, and to address risks such as antibiotic-resistant microbes. NIAID-funded projects are exploring the interactions between pathogens and the microbiome; investigating the role of the microbiome in health and infectious and immune-mediated diseases; identifying potential predictive markers for health and disease status that could inform future efforts in precision medicine – a theme of the NIH Director – and advancing our understanding of immune responses in the gut and skin.

Budget Policy:

The FY 2017 President's Budget estimate for the extramural component of Infectious and Immunologic Diseases (IID) research is $1,081.685 million, a decrease of $4.693 million or 0.4 percent below the FY 2016 Enacted level. The FY 2017 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 tuberculosis; 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. Initiatives will include support of novel vaccine technologies and renewal of the International Centers of Excellence in Malaria Research. In FY 2017, funding will also continue to reflect NIAID's commitment and long-term interest in fundamental immunology and support research on organ transplantation, autoimmune diseases, asthma and other allergic diseases through initiatives such as Emerging Science and Technologies in Transplantation Research and Systems Approach to Immunity and Inflammation.

**Program Portrait: Understanding the Infant Immune System**

| | |
|---|---|
| FY 2016 Level | $60.3 million |
| FY 2017 Level | $60.3 million |
| Change | $0.0 million |

NIAID supports a broad portfolio of research to enhance our understanding of the infant immune system and to develop strategies to protect this vulnerable population from infection and immune-mediated diseases such as food allergy, asthma, and primary immune deficiency. The infant immune system is not fully developed at birth, and infants and young children require multiple boosts of certain vaccines to develop protective immunity. In addition, there are still many pediatric infectious diseases for which there are no effective vaccines. As a result of these factors, infectious diseases remain the leading cause of childhood mortality. To better understand host defense mechanisms and development of immunity, which will lead to new and improved vaccines, NIAID supports the Infant Immune System initiative. Since 2013, the primary investigators and their collaborators have convened annually at an Infant Immunity Program meeting to share promising research and facilitate its translation into vaccine development to improve the health of infants worldwide.

In 2015, the NIAID-supported ITN reported the ground-breaking results of the "Learning Early About Peanut (LEAP)" clinical trial. The LEAP study showed that introducing peanut-containing foods into the diets of infants at high risk of developing peanut allergy was safe and led to an 81 percent reduction in the subsequent development of peanut allergy. The study identified a novel, low-cost, high-impact means of eliminating peanut allergy and will change clinical practice. Since 2005, NIAID has funded the Urban Environment and Childhood Asthma Study, a longitudinal study of asthma risk factors in nearly 600 inner-city children. Results suggest that exposure to specific combinations of allergens and bacteria within the first year of life may protect children from wheezing and allergic disease later in life.

Infants born with genetic defects of the immune system face immediate challenges. NIAID-funded researchers recently developed a reliable newborn screening test for severe combined immunodeficiency (SCID), a life-threatening inherited condition resulting from defects in the function of infection-fighting immune cells. In 2014, investigators from the Primary Immune Deficiency Treatment Consortium, which is co-funded by NIAID, found that healthy infants with SCID who received a transplant of blood-forming stem cells from healthy donors by 3½ months of age had better health outcomes than those who were older or had an infection at the time of transplantation. These promising results are changing the standard of care for children with primary immune deficiency disorders and provide an evidence-based rationale for the wider implementation of newborn screening programs.

**Intramural Research Program (IRP):** IRP remains at the forefront of efforts 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. By providing state-of-the-art laboratories and clinical facilities to investigators from diverse scientific backgrounds, IRP enables the translation of basic discoveries into new vaccines, therapies, and diagnostics for infectious and allergic diseases.

IRP consists of three components:

- The Division of Intramural Research (DIR), in which more than 120 principal investigators in Maryland and at the Rocky Mountain Laboratories in Montana lead basic, translational, and clinical research efforts on a wide range of topics in infectious diseases, allergy, and immunology.

- 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.

Recent IRP achievements include the identification of primary immune diseases, development of a dengue vaccine, and advancement toward a "universal" flu vaccine and vaccine candidates for Ebola, MERS, respiratory syncytial virus, HIV/AIDS, and malaria. A new IRP study will expose healthy adult volunteers to respiratory syncytial virus (RSV), which causes cold-like symptoms in adults but serious lower respiratory tract infections in young children worldwide. Improved understanding of how adults develop and then mount an immune response to RSV infection will help researchers develop and test antivirals and vaccines to combat RSV and potentially other viral infections. In another study, NIAID scientists joined with researchers at the University of California, Berkeley, to create CellScope Loa. This mobile phone-based video microscope uses a custom iPhone app to rapidly screen for infection with the parasitic filarial worm *Loa loa*. People infected with *Loa* can suffer serious and potentially fatal side effects when treated with certain drugs used in mass eradication campaigns against two other common parasitic diseases in Central Africa. Having a highly portable, user-friendly diagnostic tool will enable field workers to identify individuals with high blood levels of *Loa,* so that they do not receive the drugs used in mass eradication campaigns.

Budget Policy:

The FY 2017 President's Budget estimate for Intramural Research is $554.618 million, unchanged from the FY 2016 Enacted level. The FY 2017 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):** 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.

Budget Policy:
The FY 2017 President's Budget estimate is $308.998 million, an increase of $9.386 million or 3.1 percent above the FY 2016 Enacted level. The budget increase will provide program management and administrative support for the Technology Transfer and Intellectual Property Office.

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

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

| | FY 2016 Enacted | FY 2017 President's Budget[2] | FY 2017 +/- FY 2016 |
|---|---|---|---|
| Total compensable workyears: | | | |
| Full-time employment | 1,972 | 1,972 | 0 |
| Full-time equivalent of overtime and holiday hours | 0 | 0 | 0 |
| Average ES salary | $185 | $187 | $2 |
| Average GM/GS grade | 12.2 | 12.2 | 0.0 |
| Average GM/GS salary | $103 | $104 | $1 |
| Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207) | $0 | $0 | $0 |
| Average salary of ungraded positions | $0 | $0 | $0 |

| | OBJECT CLASSES | FY 2016 Enacted | FY 2017 President's Budget[2] | FY 2017 +/- FY 2016 |
|---|---|---|---|---|
| | Personnel Compensation | | | |
| 11.1 | Full-Time Permanent | $147,728 | $151,967 | $4,239 |
| 11.3 | Other Than Full-Time Permanent | 67,376 | 68,297 | 921 |
| 11.5 | Other Personnel Compensation | 5,243 | 5,359 | 116 |
| 11.7 | Military Personnel | 4,764 | 4,870 | 105 |
| 11.8 | Special Personnel Services Payments | 19,118 | 19,269 | 151 |
| **11.9** | **Subtotal Personnel Compensation** | **$244,229** | **$249,762** | **$5,532** |
| 12.1 | Civilian Personnel Benefits | $70,353 | $72,847 | $2,494 |
| 12.2 | Military Personnel Benefits | 3,417 | 3,503 | 86 |
| 13.0 | Benefits to Former Personnel | 0 | 0 | 0 |
| | **Subtotal Pay Costs** | **$317,999** | **$326,112** | **$8,113** |
| 21.0 | Travel & Transportation of Persons | $8,505 | $8,529 | $24 |
| 22.0 | Transportation of Things | 1,043 | 1,062 | 19 |
| 23.1 | Rental Payments to GSA | 6 | 6 | 0 |
| 23.2 | Rental Payments to Others | 13 | 13 | 0 |
| 23.3 | Communications, Utilities & Misc. Charges | 4,091 | 4,165 | 74 |
| 24.0 | Printing & Reproduction | 6 | 6 | 0 |
| 25.1 | Consulting Services | $17,985 | $18,308 | $324 |
| 25.2 | Other Services | 158,884 | 159,020 | 136 |
| 25.3 | Purchase of goods and services from government accounts | 562,165 | 572,434 | 10,269 |
| 25.4 | Operation & Maintenance of Facilities | $9,608 | $9,781 | $173 |
| 25.5 | R&D Contracts | 592,448 | 547,413 | -45,035 |
| 25.6 | Medical Care | 3,447 | 3,540 | 93 |
| 25.7 | Operation & Maintenance of Equipment | 18,302 | 18,591 | 289 |
| 25.8 | Subsistence & Support of Persons | 0 | 0 | 0 |
| **25.0** | **Subtotal Other Contractual Services** | **$1,362,839** | **$1,329,088** | **-$33,751** |
| 26.0 | Supplies & Materials | $46,856 | $47,683 | $827 |
| 31.0 | Equipment | 18,123 | 18,402 | 280 |
| 32.0 | Land and Structures | 0 | 0 | 0 |
| 33.0 | Investments & Loans | 0 | 0 | 0 |
| 41.0 | Grants, Subsidies & Contributions | 2,956,211 | 2,980,625 | 24,415 |
| 42.0 | Insurance Claims & Indemnities | 0 | 0 | 0 |
| 43.0 | Interest & Dividends | 6 | 6 | 0 |
| 44.0 | Refunds | 0 | 0 | 0 |
| | **Subtotal Non-Pay Costs** | **$4,397,698** | **$4,389,585** | **-$8,113** |
| | **Total Budget Authority by Object Class** | **$4,715,697** | **$4,715,697** | **$0** |

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

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

### Salaries and Expenses
(Dollars in Thousands)

| OBJECT CLASSES | FY 2016 Enacted | FY 2017 President's Budget | FY 2017 +/- FY 2016 |
|---|---|---|---|
| **Personnel Compensation** | | | |
| Full-Time Permanent (11.1) | $147,728 | $151,967 | $4,239 |
| Other Than Full-Time Permanent (11.3) | 67,376 | 68,297 | 921 |
| Other Personnel Compensation (11.5) | 5,243 | 5,359 | 116 |
| Military Personnel (11.7) | 4,764 | 4,870 | 105 |
| Special Personnel Services Payments (11.8) | 19,118 | 19,269 | 151 |
| **Subtotal Personnel Compensation (11.9)** | **$244,229** | **$249,762** | **$5,532** |
| Civilian Personnel Benefits (12.1) | $70,353 | $72,847 | $2,494 |
| Military Personnel Benefits (12.2) | 3,417 | 3,503 | 86 |
| Benefits to Former Personnel (13.0) | 0 | 0 | 0 |
| **Subtotal Pay Costs** | **$317,999** | **$326,112** | **$8,113** |
| Travel & Transportation of Persons (21.0) | $8,505 | $8,529 | $24 |
| Transportation of Things (22.0) | 1,043 | 1,062 | 19 |
| Rental Payments to Others (23.2) | 13 | 13 | 0 |
| Communications, Utilities & Misc. Charges (23.3) | 4,091 | 4,165 | 74 |
| Printing & Reproduction (24.0) | 6 | 6 | 0 |
| **Other Contractual Services:** | | | |
| Consultant Services (25.1) | 17,470 | 17,784 | 314 |
| Other Services (25.2) | 158,884 | 159,020 | 136 |
| Purchases from government accounts (25.3) | 297,024 | 302,520 | 5,497 |
| Operation & Maintenance of Facilities (25.4) | 7,685 | 7,823 | 138 |
| Operation & Maintenance of Equipment (25.7) | 18,302 | 18,591 | 289 |
| Subsistence & Support of Persons (25.8) | 0 | 0 | 0 |
| **Subtotal Other Contractual Services** | **$499,365** | **$505,740** | **$6,375** |
| Supplies & Materials (26.0) | $46,856 | $47,683 | $827 |
| **Subtotal Non-Pay Costs** | **$559,879** | **$567,198** | **$7,318** |
| **Total Administrative Costs** | **$877,878** | **$893,309** | **$15,431** |

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

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

| OFFICE/DIVISION | FY 2015 Actual | | | FY 2016 Est. | | | FY 2017 Est. | | |
|---|---|---|---|---|---|---|---|---|---|
| | Civilian | Military | Total | Civilian | Military | Total | Civilian | Military | Total |
| Division of Acquired Immunodeficiency | | | | | | | | | |
| Direct: | 150 | 9 | 159 | 152 | 9 | 161 | 152 | 9 | 161 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 150 | 9 | 159 | 152 | 9 | 161 | 152 | 9 | 161 |
| Division of Allergy, Immunology, and Transplantation | | | | | | | | | |
| Direct: | 87 | 1 | 88 | 88 | 1 | 89 | 88 | 1 | 89 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 87 | 1 | 88 | 88 | 1 | 89 | 88 | 1 | 89 |
| Division of Clinical Research | | | | | | | | | |
| Direct: | 86 | 12 | 98 | 87 | 12 | 99 | 87 | 12 | 99 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 86 | 12 | 98 | 87 | 12 | 99 | 87 | 12 | 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: | 676 | 16 | 692 | 683 | 16 | 699 | 683 | 16 | 699 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 676 | 16 | 692 | 683 | 16 | 699 | 683 | 16 | 699 |
| Division of Microbiology and Infectious Diseases | | | | | | | | | |
| Direct: | 167 | 7 | 174 | 169 | 7 | 176 | 169 | 7 | 176 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 167 | 7 | 174 | 169 | 7 | 176 | 169 | 7 | 176 |
| Office of the Director | | | | | | | | | |
| Direct: | 411 | 2 | 413 | 415 | 2 | 417 | 415 | 2 | 417 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 411 | 2 | 413 | 415 | 2 | 417 | 415 | 2 | 417 |
| Vaccine Research Center | | | | | | | | | |
| Direct: | 97 | - | 97 | 98 | - | 98 | 98 | - | 98 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 97 | - | 97 | 98 | - | 98 | 98 | - | 98 |
| Total | 1,905 | 47 | 1,952 | 1,925 | 47 | 1,972 | 1,925 | 47 | 1,972 |
| 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 |
|---|---|
| 2013 | 12.3 |
| 2014 | 12.3 |
| 2015 | 12.2 |
| 2016 | 12.2 |
| 2017 | 12.2 |

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

### Detail of Positions[1]

| GRADE | FY 2015 Actual | FY 2016 Enacted | FY 2017 President's Budget |
|---|---|---|---|
| Total, ES Positions | 2 | 2 | 2 |
| Total, ES Salary | 366,600 | 370,174 | 374,616 |
| GM/GS-15 | 160 | 160 | 160 |
| GM/GS-14 | 408 | 410 | 410 |
| GM/GS-13 | 316 | 326 | 326 |
| GS-12 | 224 | 228 | 228 |
| GS-11 | 130 | 130 | 130 |
| GS-10 | 1 | 1 | 1 |
| GS-9 | 88 | 92 | 92 |
| GS-8 | 25 | 25 | 25 |
| GS-7 | 66 | 66 | 66 |
| GS-6 | 12 | 12 | 12 |
| GS-5 | 12 | 12 | 12 |
| GS-4 | 8 | 8 | 8 |
| GS-3 | 13 | 13 | 13 |
| GS-2 | 2 | 2 | 2 |
| GS-1 | 6 | 6 | 6 |
| Subtotal | 1,471 | 1,491 | 1,491 |
| Grades established by Act of July 1, 1944 (42 U.S.C. 207) | 0 | 0 | 0 |
| Assistant Surgeon General | 0 | 0 | 0 |
| Director Grade | 23 | 23 | 23 |
| Senior Grade | 7 | 7 | 7 |
| Full Grade | 7 | 7 | 7 |
| Senior Assistant Grade | 5 | 5 | 5 |
| Assistant Grade | 4 | 4 | 4 |
| Subtotal | 46 | 46 | 46 |
| Ungraded | 459 | 486 | 486 |
| Total permanent positions | 1,495 | 1,486 | 1,486 |
| Total positions, end of year | 1,978 | 1,978 | 1,978 |
| Total full-time equivalent (FTE) employment, end of year | 1,952 | 1,972 | 1,972 |
| Average ES salary | 183,300 | 185,087 | 187,308 |
| Average GM/GS grade | 12.2 | 12.2 | 12.2 |
| Average GM/GS salary | 101,957 | 102,951 | 104,186 |

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