

DEPARTMENT OF HEALTH AND HUMAN SERVICES

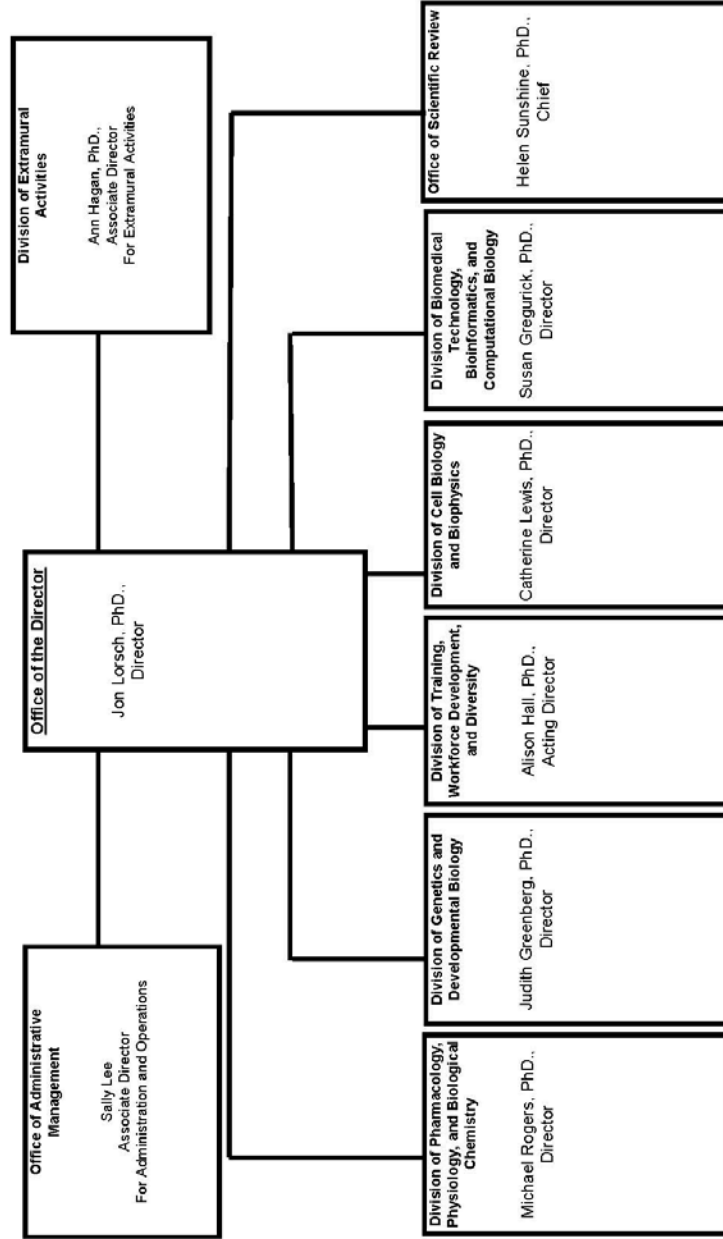
NATIONAL INSTITUTES OF HEALTH

National Institute of General Medical Sciences (NIGMS)

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NATIONAL INSTITUTES OF HEALTH  
National Institute of General Medical Sciences

Organization Structure



## **NATIONAL INSTITUTES OF HEALTH**

### National Institute of General Medical Sciences

For carrying out section 301 and title IV of the PHS Act with respect to general medical sciences, [~~\$2,371,476,000~~]~~\$2,433,780,000~~, of which [~~\$715,000,000~~]~~\$847,489,000~~ shall be from funds available under section 241 of the PHS Act [~~:Provided, That not less than \$273,325,000 is provided for the Institutional Development Award program~~].

**NATIONAL INSTITUTES OF HEALTH**  
**National Institute of General Medical Sciences**

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

Source of Funding	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget
Appropriation	\$2,364,147	\$2,371,476	\$2,433,780
Type 1 Diabetes	0	0	0
Rescission	0	0	0
Sequestration	0	0	0
FY 2014 First Secretary's Transfer	-5,935	0	0
FY 2014 Second Secretary's Transfer	-464	0	0
Subtotal, adjusted appropriation	\$2,357,748	\$2,371,476	\$2,433,780
OAR HIV/AIDS Transfers	1,000	825	0
National Children's Study Transfers	7,770	0	0
Subtotal, adjusted budget authority	\$2,366,518	\$2,372,301	\$2,433,780
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$2,366,518	\$2,372,301	\$2,433,780
Unobligated balance lapsing	-89	0	0
Total obligations	\$2,366,429	\$2,372,301	\$2,433,780

<sup>1</sup> Excludes the following amounts for reimbursable activities carried out by this account:  
FY 2014 - \$5,000,000    FY 2015 - \$720,000,000    FY 2016 - \$852,489,000

**NATIONAL INSTITUTES OF HEALTH**  
**National Institute of General Medical Sciences**  
**Budget Mechanism - Total<sup>1</sup>**

(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
<b>Research Projects:</b>								
Noncompeting	2,731	\$1,021,946	2,717	\$994,562	2,783	\$1,050,600	66	\$56,038
Administrative Supplements	(224)	14,641	(300)	19,641	(300)	14,641	(0)	-5,000
<b>Competing:</b>								
Renewal	408	162,628	465	194,439	474	198,125	9	3,686
New	544	192,116	619	229,695	628	233,209	9	3,514
Supplements	5	521	6	625	6	636	0	11
Subtotal, Competing	957	\$355,266	1,090	\$424,759	1,108	\$431,970	18	\$7,211
Subtotal, RPGs	3,688	\$1,391,852	3,807	\$1,438,962	3,891	\$1,497,211	84	\$58,249
SBIR/STTR	181	64,602	183	65,352	198	70,587	15	5,235
Research Project Grants	3,869	\$1,456,454	3,990	\$1,504,314	4,089	\$1,567,798	99	\$63,484
<b>Research Centers:</b>								
Specialized/Comprehensive	173	\$390,206	163	\$342,872	165	\$348,377	2	\$5,505
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	34	59,231	34	59,231	34	59,231	0	0
Comparative Medicine	0	528	1	3,304	1	3,304	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	207	\$449,964	198	\$405,407	200	\$410,912	2	\$5,505
<b>Other Research:</b>								
Research Careers	87	\$23,359	91	\$24,359	91	\$24,359	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	274	97,727	274	97,727	274	97,727	0	0
Other	149	39,183	150	39,483	150	39,483	0	0
Other Research	510	\$160,269	515	\$161,569	515	\$161,569	0	\$0
Total Research Grants	4,586	\$2,066,688	4,703	\$2,071,290	4,804	\$2,140,279	101	\$68,989
<b>Ruth L. Kirchstein Training Awards:</b>								
Individual Awards	347	\$19,317	366	\$20,169	385	\$21,370	19	\$1,201
Institutional Awards	3,661	176,188	3,661	169,229	3,661	166,465	0	-2,764
Total Research Training	4,008	\$195,505	4,027	\$189,398	4,046	\$187,835	19	-\$1,563
Research & Develop. Contracts <i>(SBIR/STTR) (non-add)</i>	24 <i>(0)</i>	\$34,418 <i>(1,327)</i>	24 <i>(0)</i>	\$41,007 <i>(3,132)</i>	20 <i>(0)</i>	\$34,354 <i>(3,132)</i>	-4 <i>(0)</i>	-\$6,653 <i>(0)</i>
Intramural Research	9	4,234	5	4,276	0	4,319	-5	43
Res. Management & Support <i>Res. Management &amp; Support (SBIR Admin) (non-add)</i>	176 <i>(0)</i>	65,673 <i>(11)</i>	181 <i>(0)</i>	66,330 <i>(11)</i>	186 <i>(0)</i>	66,993 <i>(0)</i>	5 <i>(0)</i>	663 <i>(-11)</i>
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Program Evaluation Financing		0		-715,000		-847,489		-132,489
<b>Total, NIGMS, Discretionary BA</b>	185	\$2,366,518	186	\$1,657,301	186	\$1,586,291	0	-\$71,010
Program Evaluation Financing				715,000		847,489		132,489
<b>Total, NIGMS, Program Level</b>	185	\$2,366,518	186	\$2,372,301	186	\$2,433,780	0	\$61,479

<sup>1</sup> All items in italics and brackets are non-add entries.

## Major Changes in the Fiscal Year 2016 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 NIGMS, which is \$61.479 million more than the FY 2015 level, for a total of \$2,433.8 million.

### Research Project Grants (+\$63.484 million; total \$1,567.798 million):

In FY 2016, NIGMS will increase support of investigator-initiated research across the entire portfolio in competing and non-competing RPGs.

### Research Center Grants (+\$5.505 million; total \$410.912 million):

In FY 2016, NIGMS will continue to maintain its center grant portfolio that comprises centers in systems biology, biomedical technology, structural biology, trauma and burn, as well as the Institutional Development Award (IDeA) program components.

**Precision Medicine.** NIH proposes to launch a national research 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 who voluntarily choose to join this effort will be able to share their genomic data, biological specimens, and behavioral data, and, if they choose, link it to their electronic health records (EHRs), taking advantage of the latest in social media and mobile applications, and with appropriate privacy protections in place. Bona fide researchers from across the country will have access to data voluntarily provided, thereby crowdsourcing rich data to the brightest minds in biomedical research. The cohort will be built largely by linking existing cohorts together taking advantage of infrastructure, data security and expertise already in place. NIH will help to connect these existing cohorts, but the current sponsors of the cohorts will maintain their ownership and management. 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. The estimated NIGMS contribution to this initiative is \$8.309 million.

### Research Training (-\$1.563 million; total \$187.835 million):

In FY 2016 several of the Ancillary Training Activity T36 grants end as commitments. Those applicants will have the opportunity to compete in the Innovative Programs to Enhance Research Training

### Research and Development Contracts (-\$6.653 million; total \$34.354 million):

By FY 2016 NIGMS will have fully transitioned the Cell Repository contract to a grant in Comparative Medicine Centers. Additionally, one time supplements to Synchrotron line support in FY 2015 will not be required in FY 2016.

**NATIONAL INSTITUTES OF HEALTH  
National Institute of General Medical Sciences**

**Summary of Changes**

(Dollars in Thousands)

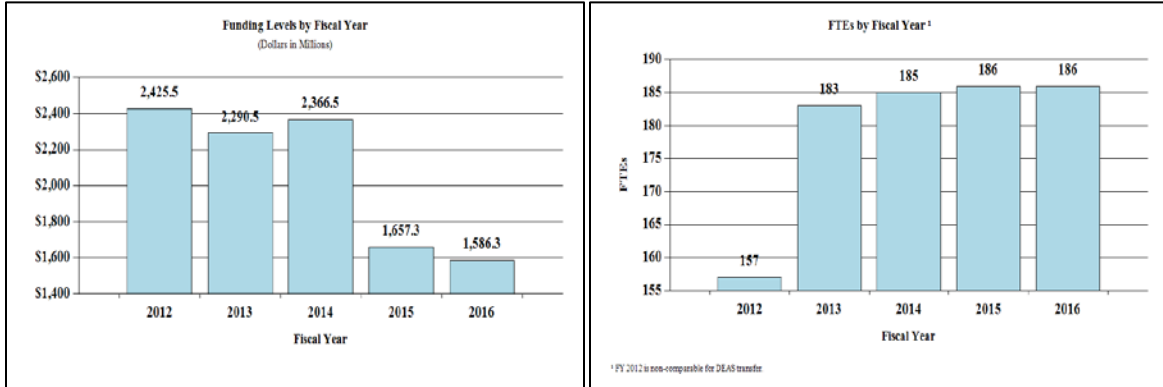
<b>FY 2015 Enacted</b>				\$2,372,301
<b>FY 2016 President's Budget</b>				\$2,433,780
<b>Net change</b>				\$61,479
CHANGES	FY 2016 President's Budget		Change from FY 2015	
	FTEs	Budget Authority	FTEs	Budget Authority
<b>A. Built-in:</b>				
<b>1. Intramural Research:</b>				
a. Annualization of January 2015 pay increase & benefits		\$1,319		\$4
b. January FY 2016 pay increase & benefits		1,319		11
c. One more day of pay (n/a for 2015)		1,319		6
d. Differences attributable to change in FTE		1,319		-119
e. Payment for centrally furnished services		163		4
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		2,837		138
Subtotal				\$43
<b>2. Research Management and Support:</b>				
a. Annualization of January 2015 pay increase & benefits		\$28,566		\$66
b. January FY 2016 pay increase & benefits		28,566		206
c. One more day of pay (n/a for 2015)		28,566		110
d. Differences attributable to change in FTE		28,566		768
e. Payment for centrally furnished services		8,680		346
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		29,747		-840
Subtotal				\$654
Subtotal, Built-in				\$697

CHANGES	FY 2016 President's Budget		Change from FY 2015	
	No.	Amount	No.	Amount
<b>B. Program:</b>				
<b>1. Research Project Grants:</b>				
a. Noncompeting	2,783	\$1,065,241	66	\$51,038
b. Competing	1,108	431,970	18	7,211
c. SBIR/STTR	198	70,587	15	5,235
Subtotal, RPGs	4,089	\$1,567,798	99	\$63,484
2. Research Centers	200	\$410,912	2	\$5,505
3. Other Research	515	161,569	0	0
4. Research Training	4,046	187,835	19	-1,563
5. Research and development contracts	20	34,354	-4	-6,653
Subtotal, Extramural		\$2,362,468		\$60,773
6. Intramural Research	<u>FTEs</u> 0	\$4,319	<u>FTEs</u> -5	\$0
7. Research Management and Support	186	66,993	5	9
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	186	\$2,433,780	0	\$60,782
Total changes				\$61,479

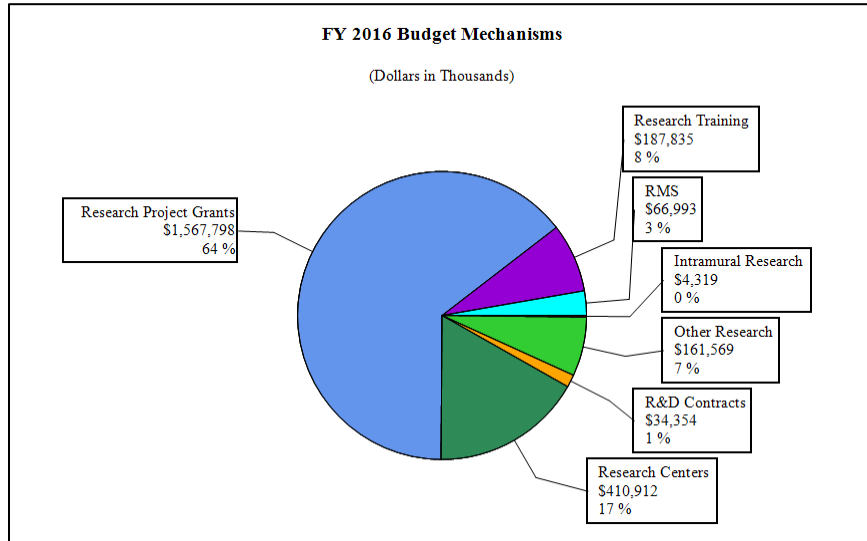


## Fiscal Year 2016 Budget Graphs

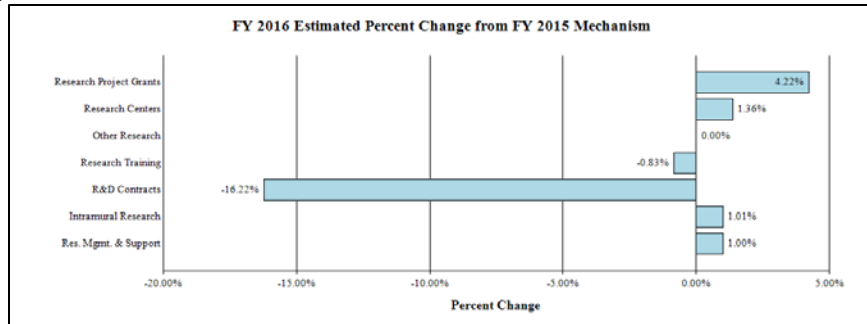
### History of Budget Authority and FTEs:



### Distribution by Mechanism:



### Change by Selected Mechanism:



**NATIONAL INSTITUTES OF HEALTH**  
**National Institute of General Medical Sciences**

**Budget Authority by Activity<sup>1</sup>**  
(Dollars in Thousands)

	FY 2014 Actual		FY 2015 Enacted <sup>2</sup>		FY 2016 President's Budget		FY 2015 +/- FY 2014	
	FTE	Amount	FTE	Amount	FTE	Amount	FTE	Amount
<b>Extramural Research</b>								
<u>Detail</u>								
Cell Biology and Biophysics		\$552,852		\$554,075		\$568,705		\$14,630
Biomedical Technology, Bioinformatics and Computational		226,798		227,300		233,301		6,002
Genetics and Developmental Biology		492,234		493,324		506,349		13,026
Pharmacology, Physiology and Biological Chemistry		405,148		406,045		416,766		10,721
Training, Workforce Development and Diversity		619,579		620,951		637,346		16,395
<i>Institutional Development Award (IDeA)</i>		<i>(273,325)</i>		<i>(273,325)</i>		<i>(273,325)</i>		<i>(0)</i>
<b>Subtotal, Extramural</b>		<b>\$2,296,611</b>		<b>\$2,301,695</b>		<b>\$2,362,468</b>		<b>\$60,773</b>
<b>Intramural Research</b>	<b>9</b>	<b>\$4,234</b>	<b>5</b>	<b>\$4,276</b>	<b>5</b>	<b>\$4,319</b>	<b>0</b>	<b>\$43</b>
<b>Research Management &amp; Support</b>	<b>176</b>	<b>\$65,673</b>	<b>181</b>	<b>\$66,330</b>	<b>181</b>	<b>\$66,993</b>	<b>0</b>	<b>\$663</b>
<b>TOTAL</b>	<b>185</b>	<b>\$2,366,518</b>	<b>186</b>	<b>\$2,372,301</b>	<b>186</b>	<b>\$2,433,780</b>	<b>0</b>	<b>\$61,479</b>

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

<sup>2</sup> Item in italics is a "non-add".

**NATIONAL INSTITUTES OF HEALTH  
National Institute of General Medical Sciences**

**Authorizing Legislation**

	<b>PHS Act/ Other Citation</b>	<b>U.S. Code Citation</b>	<b>2015 Amount Authorized</b>	<b>FY 2015 Enacted</b>	<b>2016 Amount Authorized</b>	<b>FY 2016 President's Budget</b>
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Institute of General Medical Sciences	Section 401(a)	42§281	Indefinite	\$1,657,301,000	Indefinite	\$1,586,291,000
<b>Total, Budget Authority</b>				<b>\$1,657,301,000</b>		<b>\$1,586,291,000</b>

**NATIONAL INSTITUTES OF HEALTH  
National Institute of General Medical Sciences**

**Appropriations History**

<b>Fiscal Year</b>	<b>Budget Estimate to Congress</b>	<b>House Allowance</b>	<b>Senate Allowance</b>	<b>Appropriation</b>
2006	\$1,955,170,000	\$1,955,170,000	\$2,002,622,000	\$1,955,170,000
Rescission				(\$1,952,000)
2007	\$1,923,481,000	\$1,923,481,000	\$1,934,888,000	\$1,935,618,000
Rescission				\$0
2008	\$1,941,462,000	\$1,966,019,000	\$1,978,601,000	\$1,970,228,000
Rescission				(\$34,420,000)
Supplemental				\$10,296,000
2009	\$1,937,690,000	\$2,004,295,000	\$1,991,609,000	\$1,997,801,000
Rescission				\$0
2010	\$2,023,677,000	\$2,069,156,000	\$2,031,886,000	\$2,051,798,000
Rescission				\$0
2011	\$2,125,090,000		\$2,121,783,000	\$2,051,798,000
Rescission				(\$18,016,009)
2012	\$2,102,300,000	\$2,102,300,000	\$2,347,309,000	\$2,434,637,000
Rescission				(\$4,601,464)
2013	\$2,378,835,000		\$2,387,112,000	\$2,430,035,536
Rescission				(\$4,860,071)
Sequestration				(\$121,971,075)
2014	\$2,401,011,000		\$2,435,570,000	\$2,364,147,000
Rescission				\$0
2015	\$2,368,877,000			\$2,371,476,000
Rescission				\$0
2016	\$2,433,780,000			

## Justification of Budget Request

### *National Institute of General Medical Sciences*

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 PB	FY 2015 +/- FY 2014
BA	\$2,366,517,928	\$2,372,301,000	\$2,433,780,000	+\$61,479,000
FTE	185	186	186	0

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

### Director's Overview

Medical advances are built on a foundation of basic research on how living systems work at the molecular, cellular, and organismal level. As NIH's basic research institute, the National Institute of General Medical Sciences (NIGMS) takes very seriously its commitment to optimizing its investments of taxpayer funds in order to provide scientific advances that lead to new treatments and cures. NIGMS fulfills this promise by funding a broadly distributed portfolio of investigator-initiated research to maximize chances of important discoveries and lifesaving advances.

#### **Unraveling Life's Mysteries through Basic Research**

Again this year, a Nobel Prize went to an NIGMS grantee, physicist-turned chemist Dr. William Moerner of Stanford University. The 2014 chemistry prize recognizes Moerner's pioneering work in microscopy that enables scientists to visualize the insides of cells much more closely than before. This capability reveals the overall health of cells in real time. Other discoveries of note this year include follow-on work in the breakthrough clustered regularly interspaced short palindromic repeats (CRISPR) technology that lets scientists easily change the sequences of genes inside cells with extreme precision. In the new findings, two young researchers – each using money from their very first NIH R01 grant, and one also using a Center of Biomedical Research Excellence (COBRE) grant from NIGMS' Institutional Development Award (IDeA) program in Montana – have determined the three-dimensional structures of CRISPR's cellular DNA-repair machines. These new insights will accelerate efforts to engineer even more accurate and efficient CRISPR technologies for gene therapy and other biotechnology applications.

Nature has been dubbed the master chemist due to the astonishing number of chemical reactions that occur constantly, and seemingly effortlessly, in our bodies and in our environments. As one example, the cholesterol-lowering drug simvastatin had already been in widespread use in people at risk for heart disease when, a few years ago, scientists found that a naturally occurring enzyme harvested from soil could produce a simvastatin-like molecule. Although using a biological process to make molecules is an environmentally friendly alternative to traditional chemical manufacturing, the enzyme proved far too slow at making simvastatin to be commercially

practical. A team of NIGMS-supported biologists, chemists, and engineers, working alongside the California-based company Codexis, re-engineered the drug-making enzyme, using a supercomputer. Together, they were able to tweak the enzyme work 1,000 times faster, making it possible in the future to manufacture simvastatin in a more cost-effective and yet environmentally sensitive manner.

### **Translating Discovery into Health**

According to the Centers for Disease Control and Prevention, sepsis affects more than 800,000 Americans annually and is the ninth leading cause of disease-related deaths. The Agency for Healthcare Research and Quality lists sepsis as the most expensive condition treated in U.S. hospitals, costing more than \$20 billion in 2011.<sup>1</sup> One of the reasons sepsis is so difficult to treat is that it affects several organs at once, causing a septic patient to deteriorate very quickly and complicating effective treatment. NIGMS sponsored a clinical trial to compare three currently used approaches to sepsis care. The results of this large-scale randomized trial done in 31 academic hospital emergency departments nationwide indicate that survival was the same regardless of whether people received pre-defined, protocol-based procedures, including inserting a venous catheter, or the usual high-level standard of care. The trial's conclusions should aid clinical decision-making, improve care for sepsis patients, and save costs. The researchers estimate that eliminating the mandated use of central-venous catheterization that offers no health advantage could save up to a third of the annual U.S. hospital cost for managing sepsis.

### **Harnessing Data and Technology to Improve Health**

In a cyclic fashion, technology drives science, and science creates technologies to tackle scientific problems as they arise. The Institute is committed to enabling the development of innovative new technologies and making them available to researchers across the Nation. NIGMS aims to make the most efficient use of taxpayer funds by creating synergies, employing economies of scale, and maintaining a diversified portfolio to maximize the chances for technological breakthroughs.

The specter of unanticipated and life-threatening situations like the recent Ebola virus outbreak is a reminder that readiness for emerging threats is essential. For several years, NIGMS has funded the Models of Infectious Disease Agent Study (MIDAS), a collaboration of research and informatics groups that develop computational models of the interactions between infectious agents and their hosts. NIGMS-funded MIDAS projects study and track the dynamics of the spread of disease-causing microorganisms such as polio, dengue fever, tuberculosis, influenza – and most recently, Ebola – in the United States and around the world.

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<sup>1</sup> Torio CM, Andrews RM. National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2011: Statistical Brief #160. Healthcare Cost and Utilization Project Statistical Briefs. Rockville (MD): Agency for Health Care Policy and Research (US); 2006-2013 PMID: 24199255

## **Preparing a Diverse and Talented Biomedical Research Workforce**

NIGMS continues its focus on supporting investigator-initiated research – in particular, ensuring that researchers are trained to produce the best quality science possible. In keeping with NIH's focus on enhancing research rigor and reproducibility, NIGMS is funding grants to develop training modules and plans to support efforts to improve tools, methods, and quality control for studies using cells as research models. NIGMS has also developed a pilot program (see program portrait) to optimize the conduct of investigator-initiated, fundamental biomedical research. The Maximizing Investigators' Research Award (MIRA) program will provide support for all NIGMS-relevant research in an investigator's laboratory, reducing administrative burden for both scientists and NIH staff. NIGMS has long supported a variety of efforts to enhance and/or complement research training to develop and sustain a highly skilled and diverse workforce to meet the Nation's biomedical research needs. Consistent with NIGMS' emphasis on data-driven decision-making and the use of program evaluation to optimize returns on investments, the Institute has begun a process of examining the outcomes of its training and workforce development programs and will use the results to iteratively improve its portfolio and procedures.

## **Program Descriptions and Accomplishments**

**Cell Biology and Biophysics (CBB):** The CBB program fosters the study of cells and their components. Physics- and chemistry-based technological advances, driven by new types of microscopy, structural biology tools, and other novel imaging techniques, have deepened understanding of life at the level of molecules and atoms. Critical basic research supported by the program promotes the development of precise, targeted therapies, as well as diagnostics for a range of diseases. In FY 2014, CBB started a new initiative to support Regional Consortia for High-Resolution Cryoelectron Microscopy. This program will provide access to state-of-the-art cryoelectron microscopy technology to a broad range of investigators. CBB also continues to support research that makes use of advanced techniques in cell biology, biophysics, cellular imaging, and structural biology to provide fundamental insights into biological processes. CBB will continue to support PSI:Biology, a program that applies the paradigm of high-throughput structure determination via highly organized networks of investigators, through FY 2015.

### Budget Policy:

The FY 2016 President's Budget request for the CBB program is \$568.705 million, an increase of \$14.630 million or 2.64 percent above the FY 2015 Enacted level. The majority of CBB funds will be used to support investigator-initiated research projects in cell biology, biophysics, cellular imaging, and structural biology. In FY 2016, CBB will support current grantees to extend the scope of their studies of living systems to probe interactions among the large and diverse complexes that govern cell function. CBB will also use FY 2016 funds to support its AIDS-related structural biology projects.

**Genetics and Developmental Biology (GDB):** The GDB program promotes a comprehensive research program on the fundamental mechanisms of genetic, cellular, developmental, and evolutionary processes. This basic research provides a strong foundation for more disease-targeted projects that are supported by other NIH Institutes and Centers. To complement GDB's large investment in research that is performed in model organisms, GDB will also employ FY

2015 and FY 2016 funds to bolster human research studies both in individuals and in diverse populations. This research will be directed toward revealing the underpinnings of genetic components of human biology and human disease. GDB also continues to support research that reveals fundamental insights about the basic biology of stem cells and that unravels the genetics and ecology underlying the interactions and dynamics of microbial communities (“microbiota”) normally associated with the human body and in model systems.

Budget Policy:

The FY 2016 President's Budget request for the GDB program is \$506.349 million, an increase of \$13.026 million, or 2.64 percent above the FY 2015 Enacted level. As with FY 2014, most GDB expenditures will support individual investigators seeking fundamental knowledge about life processes. In FY 2016, GDB will continue its support for collaborative research for molecular and genomic studies in animal models, as well as research into specific genetic variants within complex disorders. FY 2016 funds will also support research to explore interactions between hosts and microorganisms that make up the microbiota in humans and in model organisms. These relationships have a major impact on human health but remain poorly understood.

**Pharmacology, Physiology, and Biological Chemistry (PPBC):** The PPBC program supports fundamental research in chemistry, biochemistry, pharmacology, and physiology that contributes to understanding human biology in health and disease and generates knowledge for new ways to diagnose and treat disease. In addition, PPBC funds research that explores clinical issues involving whole-body responses, including traumatic injury, burns, wound healing, sepsis, anesthesia, and clinical pharmacology. In FY 2014, PPBC began an initiative to uncover novel, and currently unapproachable, natural products for drug discovery and made awards for a collaborative effort with National Heart, Lung, and Blood Institute to dissect the mechanisms of sepsis through multi-disciplinary approaches. In FY 2015, PPBC plans to make awards for and assemble a next-generation version of the NIH Pharmacogenomics Research Network with the goal of enhancing research in Precision Medicine.

Budget Policy:

The FY 2016 President's Budget request for the PPBC program is \$416.766 million, an increase of \$10.721 million or 2.64 percent over the FY 2015 Enacted level. In FY 2016, this program will continue to emphasize the support of investigator-initiated research grants related to basic physiology, pharmacology, and chemistry that inform knowledge of how small molecules influence human health. In FY 2016, the NIH Pharmacogenomics Research Network will continue promoting the goal of Precision Medicine using requested funds to support research on novel methods to identify and produce new potentially useful chemical entities using synthetic chemistry and synthetic biology.



### **Program Portrait: Chemistry Brings Life to Medicine**

FY 2015 Level: \$1.0 million

FY 2016 Level: \$1.1 million

Change: +\$0.1 million

Drug design and manufacturing is a multi-billion dollar enterprise with substantial impact on American health and the economy. This enterprise has been helped significantly by NIH-supported chemistry. Two examples are: 1) transition-state chemistry and 2) the ability to optimize natural substances using novel chemistry. All life's chemistry requires enzymatic reactions, which transform one substance into another. The most important step in any enzyme reaction is its "transition state," which is ultra-fast – a femtosecond, or one millionth of one billionth, of a second. New tools can capture this brief encounter between the key molecular actors in an enzyme reaction, which forms a fleeting three-dimensional shape. Chemists can fit the transition-state shape precisely with a stable, copycat molecule that blocks the reaction. Already, the technique has been used to make a glaucoma drug, and new transition-state-based drugs are being tested for their use in immune disorders, infections, gout, and ulcers. A second example of how chemistry brings life to medicine is the use of biology to engineer molecules that are more useful and safe than their natural counterparts. Like any drug, those made from natural substances can have unwanted side effects. Such is the case for the medicine amphotericin B, the last line of defense in treating fungal infections like valley fever. Amphotericin B is so notorious for its severe and potentially lethal side effects that physicians call it "ampho-terrible." NIGMS-supported research shows significant promise for developing safer versions of this important medicine. For years, scientists thought amphotericin B punched holes in fungal cells, letting their insides leak out. In the new work, however, the researchers used clever chemistry- and physics-based techniques to show that amphotericin B does something else: it extracts a molecule called ergosterol from the microorganisms' cell walls. Ergosterol is the the fungal equivalent of cholesterol, which is a vital element of human cell membranes. The drug's toxicity thus likely arises because amphotericin B can't tell the difference between ergosterol and cholesterol, and it rips out cholesterol from human cells, which kills them. With the goal of making the treatment more tolerable, the team used advanced chemistry methods to make a version of amphotericin B that can discriminate between ergosterol and human cholesterol. In addition to being a chemical tour de force, the new work creates a drug that kills disease-causing fungi but spares human cells.

### **Division of Biomedical Technology, Bioinformatics and Computational Biology (BBCB):**

The BBCB program supports quantitative and computationally-intensive research to understand complex biological systems. It also supports research and development of technologies, tools, and methods to solve problems in biomedicine. A major effort in BBCB is the Biomedical Technology Research Resources initiative that creates critical pioneering technologies and methods and applies them to a broad range of basic, translational, and clinical research areas. These resources are used by thousands of NIH-supported scientists each year. In FY 2015, BBCB will cultivate new opportunities to support technology development and access to research resources. It will also promote integrated systems approaches for studying biological processes and supports the development of computational, mathematical, and statistical methods for advancing biomedical research. Examples include genetic approaches to uncover how the environment affects human biology and computational methods that model relationships between therapeutic drugs and humans. BBCB will also support research addressing new computational challenges in accessing, managing, analyzing, integrating, and using the many types of biological and behavioral Big Data generated by biomedical scientists.

### Budget Policy:

The FY 2016 President's Budget request for the BBCB program is \$233.301 million, an increase of \$6.002 million or 2.64 percent over the FY 2015 Enacted level. As with all NIGMS programs, highest priority will go to investigator-initiated research that explores complex

biological systems. Major initiatives employing FY 2016 funds include the Biomedical Technology Research Centers (BTRCs). In FY 2016, BBCB plans to fund investigator-initiated approaches to enable maximal usability of biomedical data and information.

**Division of Training, Workforce Development, and Diversity (TWD):** The TWD program is responsible for training an outstanding and diverse biomedical workforce for the future. TWD supports training of Ph.D. and M.D.-Ph.D. students, as well as postdoctoral fellows, in basic, translational, and clinical research. The program also designs student development programs focused on enhancing diversity in undergraduate STEM programs leading to research careers. TWD supports the Institutional Development Award (IDeA) program that expands research infrastructure development at institutions in States that have received limited NIH research support. Two current IDeA initiatives are under way. One extends clinical and translational research infrastructure through national networks and the other will foster, in IDeA States, the development of products to advance public health through small-business research funding. In FY 2015 and FY 2016, TWD will continue its support for specialized programs in the biomedical and behavioral sciences that recruit and train students from diverse backgrounds.

Budget Policy:

The FY 2016 President's Budget request for the TWD program is \$637.346 million, an increase of \$16.395 million, or 2.64 percent above the FY 2015 Enacted level. The budget includes funds and 2 percent stipend increases for the Ruth L. Kirschstein NRSA training program, which supported over 4,000 trainees in FY 2014. High priority will go to activities that promote diversity in the biomedical and behavioral research workforce.

**Intramural:** NIGMS has a small but unique intramural research training program, the NIGMS Postdoctoral Research Associate Program (PRAT). PRAT postdoctoral research fellows (currently 17) are supported for up to three years. They pursue independent research in intramural NIH or FDA laboratories under the guidance of tenured/tenure-track investigators, and they receive specialized training and career mentoring from NIGMS staff. Fellows in this highly regarded program have received numerous honors and awards for their innovative research in areas ranging from cell and molecular biology to pharmacology to genetics.

Budget Policy:

The FY 2016 President's Budget request for the Intramural Research program is \$4.319 million, which is \$43 thousand or 1.0 percent above the FY 2015 Enacted level. FY 2016 funds will provide training for outstanding postdoctoral fellows conducting research in emerging areas of science, while working in the intramural laboratories of other NIH Institutes or in the FDA. In FY 2016, the PRAT program will prioritize funding for fellows conducting research in quantitative/systems pharmacology and computational biology.

**Research Management and Support (RMS):** The RMS program provides administrative, budgetary, logistical, and scientific support toward the review, award, and monitoring of research grants, training awards, and research and development contracts. The program also encompasses strategic planning, coordination, and evaluation of NIGMS programs; regulatory compliance; and international coordination and liaison with other Federal agencies, Congress, and the public. RMS funds improvements in information technology tools to facilitate the peer-review process,

to conduct portfolio analyses, and to assist with grants administration. In FY 2016, NIGMS will use RMS funds to enable integrated data, video, and voice communications. This action will produce significant savings in telecommunications expenses, as well as enhance staff's capabilities for communicating with its stakeholders and the public. The Institute will also update its information-technology user environment to include more efficient desktops, laptops, and printers. All of these investments will better serve the business needs of NIGMS and its customers.

Budget Policy:

The FY 2016 President's Budget request for RMS is \$66.993 million, an increase of \$663 thousand or 1.0 percent above the FY 2015 Enacted level. RMS funds support the operational requirements of the Institute, including its necessary investments in information technology. In FY 2016, requested funds will also be used to continue the management of the Office of Emergency Care Research. The office will serve as the primary NIH coordinating component for emergency care research, coordinate relevant emergency medicine efforts across NIH, and communicate with the extramural community and other federal agencies.

**Program Portrait: Maximizing Investigators' Research Award**

FY 2015 Level: \$0 million  
FY 2016 Level: \$60 million  
Change: +\$60 million

As part of its focus on optimizing the return on investment of taxpayer dollars, NIGMS is developing strategies to address inefficiencies in the biomedical research enterprise. With the decrease in funding success rates over the past decade, scientists at universities across the nation have had to devote an increasing proportion of their time to writing research proposals to support their work, leaving dwindling amounts of time and energy to actually perform the important research they propose to do. To combat this problem, NIGMS is currently piloting a new approach that offers a chance to improve the efficiency and effectiveness of basic biomedical research funding.

The Maximizing Investigators' Research Award (MIRA) will provide support for all of the NIGMS-relevant research in an investigator's laboratory for five years, providing an average level of funding larger and longer than that provided by traditional, individual project-focused R01 grants. Because this idea represents a significant departure from current NIH approaches, NIGMS issued a request for information to solicit stakeholder input on this concept and received an overwhelmingly positive response. By reducing the number of grants per laboratory (and de-emphasizing lab size as a proxy for lab quality), extending grant "shelf-life," and broadening grant scope, MIRA aims to increase the stability of individual-investigator funding. Doing so should enhance the ability of these highly skilled women and men to take on ambitious scientific problems and to develop creative approaches to solving them. The program should also increase flexibility for innovators to follow important new research directions as scientific work proceeds and opportunities arise — often in unexpected yet fruitful directions. Other potential benefits of the MIRA approach include evening out the distribution of funds among talented scientific researchers at a range of institutions across the nation, increasing the chances for breakthrough discoveries. Of course, it will be important for us to monitor MIRA's impact on scientific productivity and biomedical workforce diversity. Because NIGMS needs to generate a moderate number of applications to test the MIRA review process, it will perform pilots of the MIRA approach with various targeted groups of grantees, one of which will be early-stage investigators new to the process of NIH funding. NIGMS expects that MIRA will improve overall scientific productivity and achievement of outcomes by enabling scientists to spend more time doing science.

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**Budget Authority by Object Class<sup>1</sup>**  
(Dollars in Thousands)

	<b>FY 2015 Enacted</b>	<b>FY 2016 President's Budget</b>	<b>FY 2016 +/- FY 2015</b>
Total compensable workyears:			
Full-time employment	186	186	0
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary	\$0	\$0	\$0
Average GM/GS grade	12.5	12.5	0.0
Average GM/GS salary	\$111	\$112	\$1
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$0	\$0	\$0
Average salary of ungraded positions	\$135	\$137	\$1
<b>OBJECT CLASSES</b>	<b>FY 2015 Enacted</b>	<b>FY 2016 President's Budget</b>	<b>FY 2016 +/- FY 2015</b>
Personnel Compensation			
11.1 Full-Time Permanent	\$17,067	\$17,786	\$718
11.3 Other Than Full-Time Permanent	4,579	4,687	108
11.5 Other Personnel Compensation	482	502	20
11.7 Military Personnel	0	0	0
11.8 Special Personnel Services Payments	369	343	-26
<b>11.9 Subtotal Personnel Compensation</b>	<b>\$22,497</b>	<b>\$23,317</b>	<b>\$821</b>
12.1 Civilian Personnel Benefits	\$6,335	\$6,567	\$232
12.2 Military Personnel Benefits	0	0	0
13.0 Benefits to Former Personnel	0	0	0
<b>Subtotal Pay Costs</b>	<b>\$28,832</b>	<b>\$29,885</b>	<b>\$1,053</b>
21.0 Travel & Transportation of Persons	\$413	\$420	\$7
22.0 Transportation of Things	1	1	0
23.1 Rental Payments to GSA	0	0	0
23.2 Rental Payments to Others	0	0	0
23.3 Communications, Utilities & Misc. Charges	265	269	4
24.0 Printing & Reproduction	0	0	0
25.1 Consulting Services	\$290	\$294	\$5
25.2 Other Services	8,838	8,979	141
25.3 Purchase of goods and services from government accounts	92,306	98,837	6,531
25.4 Operation & Maintenance of Facilities	\$57	\$57	\$0
25.5 R&D Contracts	4,847	4,780	-67
25.6 Medical Care	0	0	0
25.7 Operation & Maintenance of Equipment	1,709	1,736	27
25.8 Subsistence & Support of Persons	0	0	0
<b>25.0 Subtotal Other Contractual Services</b>	<b>\$108,047</b>	<b>\$114,684</b>	<b>\$6,637</b>
26.0 Supplies & Materials	\$167	\$170	\$3
31.0 Equipment	334	339	5
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	2,234,243	2,288,013	53,770
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	0	0	0
44.0 Refunds	0	0	0
<b>Subtotal Non-Pay Costs</b>	<b>\$2,343,469</b>	<b>\$2,403,895</b>	<b>\$60,426</b>
<b>Total Budget Authority by Object Class</b>	<b>\$2,372,301</b>	<b>\$2,433,780</b>	<b>\$61,479</b>

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

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**Salaries and Expenses**

(Dollars in Thousands)

OBJECT CLASSES	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
<b>Personnel Compensation</b>			
Full-Time Permanent (11.1)	\$17,067	\$17,786	\$718
Other Than Full-Time Permanent (11.3)	4,579	4,687	108
Other Personnel Compensation (11.5)	482	502	20
Military Personnel (11.7)	0	0	0
Special Personnel Services Payments (11.8)	369	343	-26
<b>Subtotal Personnel Compensation (11.9)</b>	<b>\$22,497</b>	<b>\$23,317</b>	<b>\$821</b>
Civilian Personnel Benefits (12.1)	\$6,335	\$6,567	\$232
Military Personnel Benefits (12.2)	0	0	0
Benefits to Former Personnel (13.0)	0	0	0
<b>Subtotal Pay Costs</b>	<b>\$28,832</b>	<b>\$29,885</b>	<b>\$1,053</b>
Travel & Transportation of Persons (21.0)	\$413	\$420	\$7
Transportation of Things (22.0)	1	1	0
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	265	269	4
Printing & Reproduction (24.0)	0	0	0
<b>Other Contractual Services:</b>			
Consultant Services (25.1)	290	294	5
Other Services (25.2)	8,838	8,979	141
Purchases from government accounts (25.3)	39,706	39,167	-539
Operation & Maintenance of Facilities (25.4)	57	57	0
Operation & Maintenance of Equipment (25.7)	1,709	1,736	27
Subsistence & Support of Persons (25.8)	0	0	0
<b>Subtotal Other Contractual Services</b>	<b>\$50,599</b>	<b>\$50,234</b>	<b>-\$366</b>
Supplies & Materials (26.0)	\$167	\$170	\$3
<b>Subtotal Non-Pay Costs</b>	<b>\$51,445</b>	<b>\$51,093</b>	<b>-\$352</b>
<b>Total Administrative Costs</b>	<b>\$80,277</b>	<b>\$80,978</b>	<b>\$701</b>

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**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 Biomedical Technology, Bioinformatics and Computational Biology									
Direct:	12	-	12	12	-	12	12	-	12
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	12	-	12	12	-	12	12	-	12
Division of Cell Biology and Biophysics									
Direct:	15	-	15	15	-	15	15	-	15
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	15	-	15	15	-	15	15	-	15
Division of Genetic and Developmental Biology									
Direct:	13	-	13	13	-	13	13	-	13
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	13	-	13	13	-	13	13	-	13
Division of Pharmacology, Physiology and Biological Chemistry									
Direct:	20	-	20	20	-	20	20	-	20
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	20	-	20	20	-	20	20	-	20
Division of Training, Workforce Development and Diversity									
Direct:	22	-	22	22	-	22	22	-	22
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	22	-	22	22	-	22	22	-	22
Office of Administrative Management									
Direct:	25	-	25	25	-	25	25	-	25
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	25	-	25	25	-	25	25	-	25
Office of Extramural Activities									
Direct:	47	-	47	47	-	47	47	-	47
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	47	-	47	47	-	47	47	-	47
Office of Scientific Review									
Direct:	17	-	17	17	-	17	17	-	17
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	17	-	17	17	-	17	17	-	17
Office of the Director									
Direct:	14	-	14	15	-	15	15	-	15
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	14	-	14	15	-	15	15	-	15
<b>Total</b>	<b>185</b>	<b>-</b>	<b>185</b>	<b>186</b>	<b>-</b>	<b>186</b>	<b>186</b>	<b>-</b>	<b>186</b>
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0
<b>FISCAL YEAR</b>	<b>Average GS Grade</b>								
2012	13.2								
2013	13.2								
2014	12.5								
2015	12.5								
2016	12.5								

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**Detail of Positions<sup>1</sup>**

GRADE	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget
Total, ES Positions	0	0	0
Total, ES Salary	0	0	0
GM/GS-15	21	20	20
GM/GS-14	55	55	55
GM/GS-13	40	41	41
GS-12	10	10	10
GS-11	7	7	7
GS-10	0	0	0
GS-9	2	2	2
GS-8	5	5	5
GS-7	18	18	18
GS-6	1	1	1
GS-5	0	0	0
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	159	159	159
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	0	0	0
Senior Grade	0	0	0
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	0	0	0
Ungraded	36	37	37
Total permanent positions	159	160	160
Total positions, end of year	195	196	196
Total full-time equivalent (FTE) employment, end of year	185	186	186
Average ES salary	0	0	0
Average GM/GS grade	12.5	12.5	12.5
Average GM/GS salary	109,678	110,775	111,883

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