DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Center for Advancing Translational Sciences (NCATS)

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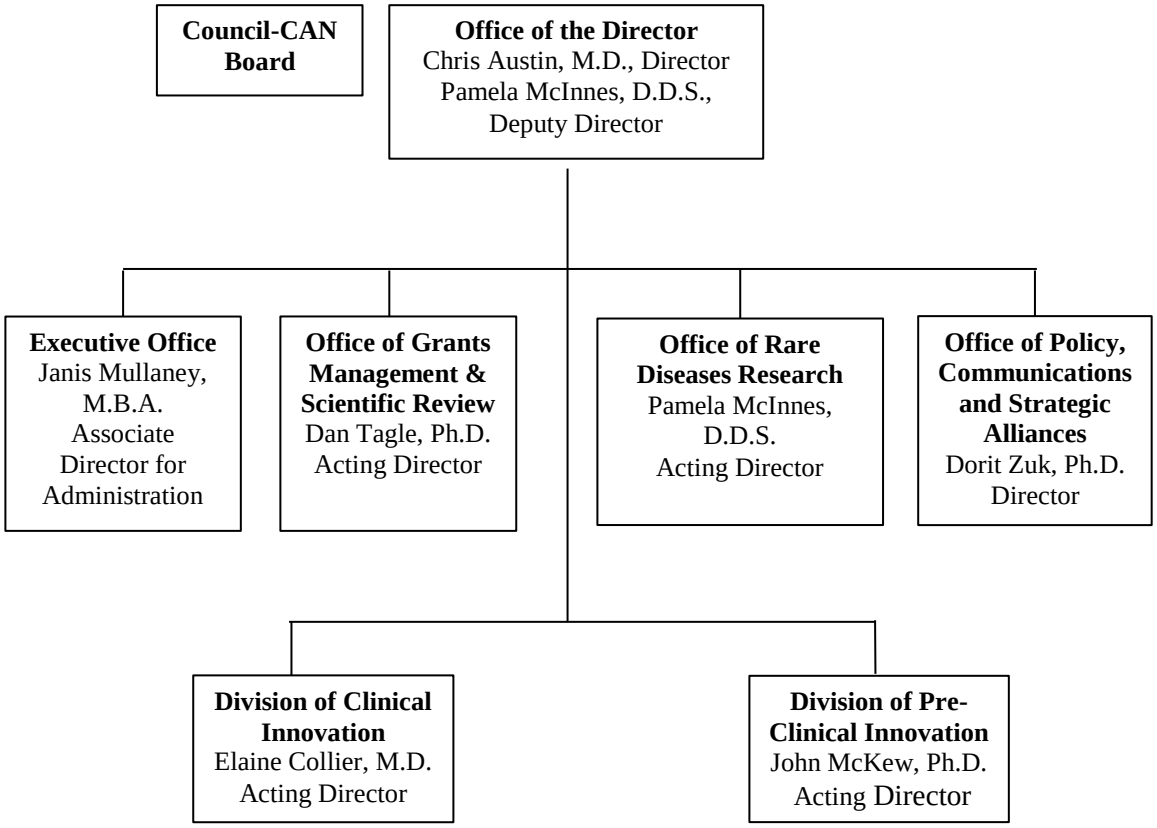

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Center for Advancing Translational Sciences (NCATS)

For carrying out section 301 and title IV of the PHS Act with respect to translational sciences, [$633,267,000]*$657,471,000*: *Provided,* That up to [$9,835,000]*$29,810,000* shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network[:*Provided further*, That at least $474,746,000 is provided to the Clinical and Translational Sciences Awards program].

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National Center for Advancing Translational Sciences

Amounts Available for Obligation[1]

(Dollars in Thousands)

Source of Funding	FY 2013 Actual	FY 2014 Enacted	FY 2015 President's Budget
Appropriation	$575,366	$633,267	$657,471
Type 1 Diabetes	0	0	0
Rescission	-1,151	0	0
Sequestration	-28,879	0	0
Subtotal, adjusted appropriation	$545,336	$633,267	$657,471
FY 2013 Secretary's Transfer	-3,181	0	0
OAR HIV/AIDS Transfers	0	0	0
Comparative transfers to NLM for NCBI and Public Access	-644	-871	0
National Children's Study Transfers	462	0	0
Subtotal, adjusted budget authority	$541,973	$632,396	$657,471
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	$541,973	$632,396	$657,471
Unobligated balance lapsing	-20	0	0
Total obligations	$541,953	$632,396	$657,471

[1] Excludes the following amounts for reimbursable activities carried out by this account:
FY 2013 - $46,344 FY 2014 - $20,565 FY 2015 - $20,565

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National Center for Advancing Translational Sciences

Budget Mechanism - Total[1]

(Dollars in Thousands)

MECHANISM	FY 2013 Actual		FY 2014 Enacted[2]		FY 2015 President's Budget		FY 2015 +/- FY 2014	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	0	$7,942	0	$7,946	1	$10,947	1	$3,001
Administrative Supplements	*(1)*	37	*(0)*	37	*(1)*	37	*(1)*	0
Competing:								
Renewal	0	0	1	3,000	12	20,000	11	17,000
New	0	0	0	0	0	0	0	0
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	0	$0	1	$3,000	12	$20,000	11	$17,000
Subtotal, RPGs	0	$7,979	1	$10,983	13	$30,984	12	$20,001
SBIR/STTR	26	13,715	31	16,107	31	16,974	0	867
Research Project Grants	26	$21,695	32	$27,090	44	$47,958	12	$20,868
Research Centers:								
Specialized/Comprehensive	6	$16,153	5	$13,209	5	$13,209	0	$0
Clinical Research	58	368,200	58	404,947	58	399,861	0	-5,086
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	0	190	0	190	0	190	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	64	$384,543	63	$418,346	63	$413,260	0	-$5,086
Other Research:								
Research Careers	61	$46,048	65	$49,142	65	$49,142	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	0	0	0	0	0	0	0	0
Other	11	3,142	30	17,563	30	17,563	0	0
Other Research	72	$49,190	95	$66,705	95	$66,705	0	$0
Total Research Grants	162	$455,428	190	$512,141	202	$527,923	12	$15,782
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	0	$0	0	$0	0	$0	0	$0
Institutional Awards	298	13,186	298	13,337	298	13,487	0	150
Total Research Training	298	$13,186	298	$13,337	298	$13,487	0	$150
Research & Develop. Contracts	187	$20,889	35	$20,808	35	$22,729	0	$1,921
(SBIR/STTR) (non-add)	*(8)*	*(1,361)*	*(9)*	*(1,509)*	*(9)*	*(1,590)*	*(0)*	*(81)*
Intramural Research	36	22,572	36	53,127	36	61,627	0	8,500
Res. Management & Support	91	29,898	91	31,393	91	31,705	0	312
Res. Management & Support (SBIR Admin) (non-add)	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NCATS	127	$541,973	127	$632,396	127	$657,471	0	$25,075

[1] All items in italics and brackets are non-add entries. FY 2013 and FY 2014 levels are shown on a comparable basis to FY 2015.

[2] The amounts in the FY 2014 column take into account funding reallocations, and therefore may not add to the total budget authority reflected herein.

Major Changes in the Fiscal Year 2015 President's Budget Request

Major changes by budget mechanism and/or budget activity 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 2015 budget request for NCATS, which is $25.075 million more than FY 2014 Enacted level, for a total of $657.471 million.

Cures Acceleration Network (CAN): (+$19.975 million; total $29.810 million):
CAN will fund initiatives designed to address scientific and technical challenges that impede translational research, including support for the Tissue Chips for Drug Screening Program, and other new initiatives that will accelerate the development of treatments and cures and utilize the unique funding authorities under CAN.

Research Project Grants (RPGs): (+$20.867 million; total $47.958 million):
In FY 2015, NCATS will award an additional 11 competing RPGs over FY 2014. These CAN Program related investigator-initiated ideas will play a significant role in the mission of NCATS. Additionally, NCATS will support 31 SBIR/STTR awards at a total cost of $16.974 million, which is an increase of $0.867 million over FY 2014.

Clinical and Translational Science Activities (-$3.027 million; total $471.719 million):
The CTSAs are a national consortium designed to transform research and training environments to enhance clinical and translational research. The CTSA program is comprised of research centers, research career awards, and research training through linked grant awards. The reduction for FY 2015 primarily reflects redirected AIDS research funds to expand NIH support for research directed toward a cure for HIV.

Intramural Research (+$8.500 million; total $61.627 million):
The FY 2015 budget includes an increase in funding for Intramural Research in NCATS. This is intented to expand and enhance NCATS collaboration with the NIH Clinical Center, and to assume a portion of its financial support.

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Summary of Changes[1]
(Dollars in Thousands)

FY 2014 Enacted				$632,396
FY 2015 President's Budget				$657,471
Net change				$25,075
CHANGES	**FY 2015 President's Budget**		**Change from FY 2014**	
	FTEs	**Budget Authority**	**FTEs**	**Budget Authority**
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2014 pay increase & benefits		$6,778		$12
b. January FY 2015 pay increase & benefits		6,778		34
c. Zero more days of pay (n/a for 2015)		6,778		0
d. Differences attributable to change in FTE		6,778		0
e. Payment for centrally furnished services		9,266		8,513
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		45,584		65
Subtotal				$8,624
2. Research Management and Support:				
a. Annualization of January 2014 pay increase & benefits		$12,451		$31
b. January FY 2015 pay increase & benefits		12,451		88
c. Zero more days of pay (n/a for 2015)		12,451		0
d. Differences attributable to change in FTE		12,451		0
e. Payment for centrally furnished services		683		11
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		18,571		112
Subtotal				$242
Subtotal, Built-in				$8,866

Summary of Changes[1]

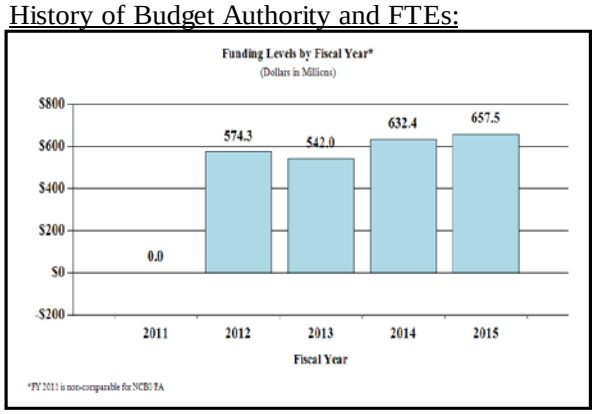
(Dollars in Thousands)

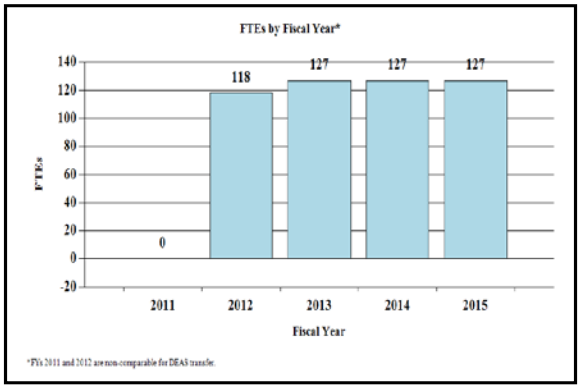
CHANGES	FY 2015 President's Budget		Change from FY 2014	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	1	$10,984	1	$3,001
b. Competing	12	20,000	11	17,000
c. SBIR/STTR	31	16,974	0	867
Subtotal, RPGs	44	$47,958	12	$20,868
2. Research Centers	63	$413,260	0	-$5,086
3. Other Research	95	66,705	0	0
4. Research Training	298	13,487	0	150
5. Research and development contracts	35	22,729	0	1,921
Subtotal, Extramural		$564,139		$17,853
	FTEs		FTEs	
6. Intramural Research	36	$61,627	0	-$124
7. Research Management and Support	91	31,705	0	70
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	127	$657,471	0	$17,799
Total changes				$25,075

[1] The amounts in the Change from FY 2014 column take into account funding reallocations, and therefore may not add to the net change reflected herein.

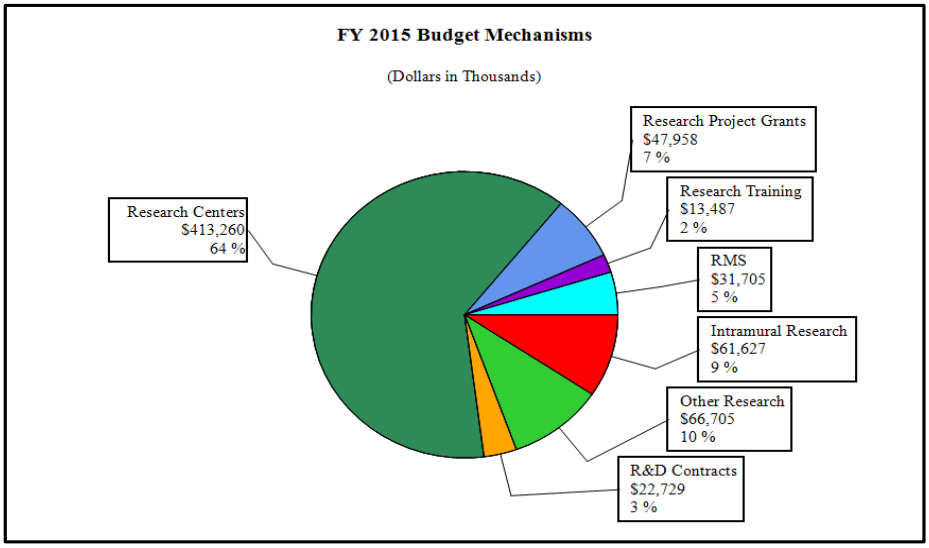
Fiscal Year 2015 Budget Graphs

History of Budget Authority and FTEs:

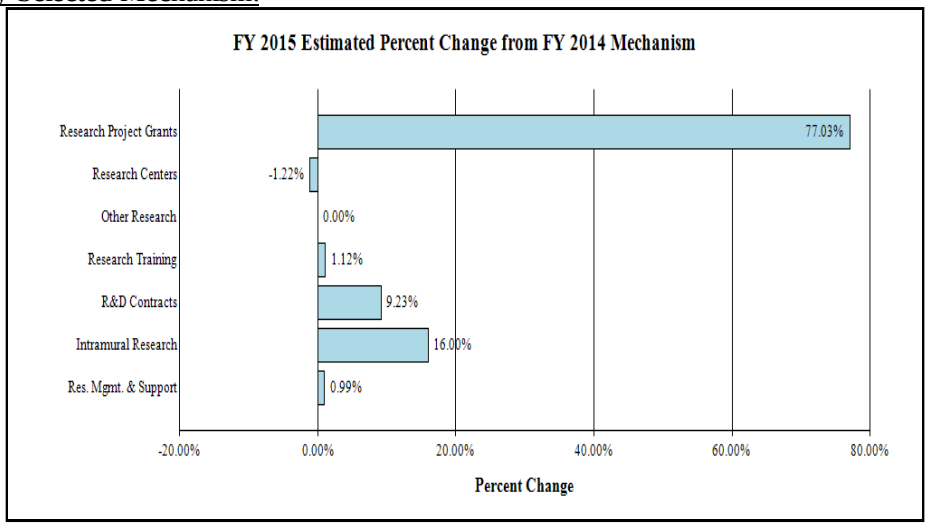




Distribution by Mechanism:



Change by Selected Mechanism:



NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

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

	FY 2013 Actual		FY 2014 Enacted [2]		FY 2015 President's Budget		FY 2015 +/- FY 2014	
Research	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**
Detail								
Clinical and Translational Science Activities		$431,986		$474,746		$471,719		-$3,027
Rare Disease Research and Therapeutics		36,446		37,101		45,601		8,500
Reengineering Translational Sciences		15,076		61,516		62,464		948
Cures Acceleration Network		9,405		9,835		29,810		19,975
Translational Research Resources		19,162		17,432		16,172		-1,260
Subtotal, Research		**$512,075**		**$599,413**		**$625,766**		**$26,353**
Intramural Research (non-add)	***36***	***$22,572***	***36***	***$53,127***	***36***	***$61,627***	***0***	***$8,500***
Research Management & Support	**91**	**$29,898**	**91**	**$31,393**	**91**	**$31,705**	**0**	**$312**
TOTAL	**127**	**$541,973**	**127**	**$632,396**	**127**	**$657,471**	**0**	**$25,075**

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

[2] The amounts in the FY 2014 column take into account funding reallocations, and therefore may not add to the total budget authority reflected herein.

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2014 Amount Authorized	FY 2014 Enacted	2015 Amount Authorized	FY 2015 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$632,396,000	Indefinite	$657,471,000
National Center for Advancing Translational Sciences	Section 479 *et seq.*	42§287 *et seq.*	Indefinite		Indefinite	
Total, Budget Authority				$632,396,000		$657,471,000

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2005				
Rescission				$0
2006				
Rescission				$0
2007				
Rescission				$0
2008				
Rescission				$0
2009				
Rescission				$0
2010				
Rescission				$0
2011				
Rescission				$0
2012	$721,601,000		$582,326,000	$576,456,000
Rescission				($1,089,502)
2013	$639,033,000		$631,346,000	$575,366,498
Rescission				($1,150,733)
Sequestration				($28,879,442)
2014	$665,688,000		$661,264,000	$633,267,000
Rescission				$0
2015	$657,471,000			

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National Center for Advancing Translational Sciences

Justification of Budget Request
National Center for Advancing Translational Sciences

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended and Section 480 of the PHS Act, relating to the Cures Acceleration Network.

Budget Authority (BA):

	FY 2013 Actual	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
BA	$541,973,456	$632,396,000	$657,471,000	+25,075,000
FTE	127	127	127	

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

Director's Overview

In recent years, basic scientists have made significant advances in our understanding of the human body's biology and chemistry. The human genome has been sequenced, stem cells better understood, and RNA interference discovered. All of these advances have been celebrated for holding enormous promise for improving human health. But the road from promise to health impact, what is called "translation" in medical research terms, is long, complex and full of obstacles. Indeed, much has been written about the scientific and operational problems, but much less has been written about potential solutions to these problems. NCATS was created to develop these kinds of system-wide solutions and is committed to ***developing*** technologies and paradigms that improve the efficiency and effectiveness of one or more steps in the translational process, ***demonstrating*** that these innovations work in specific use cases, and ***disseminating*** the translational advances widely to catalyze improvements in all translational efforts in the public, private, and nonprofit communities with the ultimate and critically important goal of improving health.

One NCATS program that exemplifies these goals is the Discovering New Therapeutic Uses for Existing Molecules program. In 2013, NIH funded nine projects that match academic research groups with pharmaceutical companies to explore new disease indications for investigational compounds in eight disease areas, including Alzheimer's disease, Duchenne muscular dystrophy and schizophrenia. This project addresses several challenges in the translation process: the urgent need for medicines to treat the several thousand known diseases that do not have effective therapies; the large number of partially developed molecules that failed partway along the path to making a new medicine; the complicated process of negotiating agreements between parties who want to work together, particularly pharmaceutical companies and academic investigators, and; the largely ad hoc process by which academic and pharmaceutical researchers develop collaborative projects, which prevents consideration of all possible ideas.

NCATS places a high value on partnerships and team science, since translation requires highly skilled researchers from a wide variety of disciplines to work together to span the translational divide, sometimes known as the "valley of death." This kind of teamwork recently enabled the creation of a brain-computer-interface technology that allows paralyzed patients to move a robotic arm using only their thoughts. This remarkable work, published in *The Lancet* and featured on CBS' 60 Minutes, was possible because of the contributions of many members of a diverse research team, made up of four federal agencies (NIH, the Department of Defense, the Department of Veterans Affairs, and the Food and Drug Administration), a private foundation, a private company and two academic research centers, including the University of Pittsburgh, funded in part by NCATS' Clinical and Translational Science Awards (CTSA) program.

Speeding up the translation process is a top priority for NCATS, and the CTSA program is key to these efforts. This program focuses on developing solutions to the many problems that impede efficiency in human subjects research. CTSA institutions develop new technologies, methods, resources and operational paradigms that catalyze clinical research progress, and lead training and career development for a new breed of team-oriented scientists and clinicians focused on translation. NCATS is continuing to evolve the CTSA program to meet the needs of clinical and translational investigators and the communities they serve. In June 2013, the Institute of Medicine (IOM) issued a report following a review of the CTSA program. Its recommendations included having NCATS take a far more active role in the program's governance and direction, formalizing the evaluation processes of the program, advancing innovation in education and training programs, and ensuring community engagement in all phases of research. These recommendations are already being implemented by NCATS, with the help of a NCATS Advisory Council Working Group, chartered to help shape the future of the CTSAs.

By design, NCATS' focus is complementary to that of the other NIH ICs and the biopharmaceutical industry. NCATS serves as a catalyst to make the work of other members of the research ecosystem more efficient, as an adaptor to connect fundamental research with health impact, and as a convener to bring about systematic solutions to translational problems that affect research on all diseases. NCATS is an *integrative* Center, focused not on what is different about a disease but what is common among them, and common to the translational process.

Because of its orientation, NCATS is deeply committed to developing treatments for rare diseases. The Human Genome Project catalyzed the discovery of the molecular basis of thousands of rare diseases, providing an unprecedented opportunity to deliver therapeutics. But given the enormous number of individual rare diseases, the current "one disease at a time" paradigm for therapeutic development will not work. NCATS is therefore taking a "systems" approach to rare diseases, developing approaches to characterizing, diagnosing, and treating rare diseases that are based on modern understanding of genomics, disease mechanisms, and drug action. The Therapeutics for Rare and Neglected Diseases (TRND) program advances potential treatments for rare and neglected diseases to first-in-human trials, an approach known as "de-risking." This strategy makes new drugs more commercially attractive to biopharmaceutical companies despite the small patient population. For example, in 2013, a clinical trial was started to evaluate a drug candidate called cyclodextrin as a possible treatment for Niemann-Pick

disease type C1 (NPC), a rare and fatal genetic brain disease affecting children. A TRND-led team of over 20 investigators from four NIH ICs, three universities, a pharmaceutical company, and multiple patient groups, developed cyclodextrin as a treatment, as well as an NPC biomarker that is guiding its clinical development. An Investigational New Drug application for cyclodextrin was approved by the FDA, and a Phase I clinical trial is currently ongoing. With the foundation of last year's accomplishments, the pace of NCATS' ambitious and transformative agenda will accelerate further in FY2015. Guided by the IOM report, the CTSA program will continue to evolve to realize its potential to dramatically improve our national capacity for clinical research. The preclinical programs at NCATS will be expanded to enable the entire research community by conducting target validation, pharmacological probe development, toxicity testing, preclinical drug development, and repurposing. Finally, NCATS will continue to innovate in the areas of strategic alliances, science policy, and operations, to devise and promulgate new and more efficient ways for the research community to collaborate, communicate, and operate across the spectrum of translational research.

Program Descriptions and Accomplishments

(1) Clinical and Translational Science Activities

The NCATS program in clinical and translational science is focused on enhancing the quality and efficiency of the full spectrum of translational research, from basic discovery, to first in human studies, to clinical testing, through application in health care, to public health impact. To address this broad mission, NCATS has been implementing modest changes in its Clinical and Translational Science Award (CTSA) program in response to community input. Further modifications of the program are planned in FY 2015 based on recommendations from the Institute of Medicine (IOM) Report on The CTSA Program at NIH.

In response to language contained in the FY 2012 Conference Committee Report (Report 112-331) accompanying the Consolidated Appropriations Act, 2012, NCATS commissioned the Institute of Medicine (IOM) to review the CTSA program and to recommend whether changes were needed. The IOM report, released on June 25, 2013, included seven recommendations: 1. Strengthen NCATS leadership of the CTSA program. 2. Reconfigure and streamline the CTSA Consortium. 3. Build on the strengths of individual CTSAs across the spectrum of clinical and translational research. 4. Formalize and standardize evaluation processes for individual CTSAs and the CTSA program. 5. Advance innovation in education and training programs. 6. Ensure community engagement in all phases of research, and 7. Strengthen clinical and translational research relevant to child health.

NCATS embraced the recommendations by immediately implementing increased oversight of the program by staff as well as changes to streamline the CTSA Consortium. NCATS also established a Working Group of the NCATS Advisory Council, which is advising the NCATS Director on implementation of additional recommendations of the report, including designation of clear, measurable goals and objectives for the program. In particular, NCATS is focused on

metrics for improving innovation in removing the critical bottlenecks across the full spectrum of clinical and translational research. NCATS is committed to enhancing the ability of investigators to work efficiently and collaboratively throughout the translation pipeline.

NCATS is also focused on ensuring the appropriate training and career development path for the various members of the research teams needed to make significant progress at each stage of translation. Participation of patients, their families, as well as their care providers is critical as translational research becomes integrated in ensuring a healthy lifespan from birth to active maturity.

Program Portrait: The CTSA Program Evolves
FY 2014 Level: $ 474.7 million
FY 2015 Level: $ 471.7 million
Change: - $ 3.0 million

NCATS funded 15 new CTSA sites in 2013, bringing the total to 61. These new programs are the first CTSA grants funded in response to an NCATS solicitation. One important change with these awards was the movement of the allowable budget to one based on the level of funded NIH research at the participating institutions rather than the funding level of legacy programs. This model is similar to that of other large successful NIH programs. Importantly, in the application, these grantees were able to focus on their strengths rather than a number of required areas, while at the same time retaining an emphasis on embracing the entire spectrum of translational research. As an example, Dartmouth College and its partners bring the strengths of the Dartmouth Center for Translational Population Research in the analysis of Medicare data to provide information about national, regional, and local health care markets, hospitals, and doctors to address the impact of changes in care on health.

Budget Policy:
The FY 2015 President's Budget request is $471.719 million, a decrease of $3.027 million or 0.6 percent below the FY 2014 Enacted level. This reduction primarily reflects redirected AIDS research funds to expand NIH support for research directed toward a cure for HIV.

(2) Rare Diseases Research and Therapeutics

- *The Therapeutics for Rare and Neglected Diseases (TRND) Program*

  The goal of the TRND program is to encourage and speed the development of new treatments for disease of rare prevalence, as well as diseases of higher prevalence that otherwise have been traditionally neglected by the biopharmaceutical industry. TRND stimulates research collaborations among NIH and academic scientists, nonprofit organizations, and pharmaceutical and biotechnology companies by forming public-private partnerships, which leverage the unique strengths and capabilities of each party. In addition to advancing development of specific therapeutic candidates, TRND seeks to develop new technologies and collaborative models to improve the efficiency of therapeutic development generally.

The TRND program, initiated in May 2009, now has a portfolio of 15 active projects targeting drug development for some of the most devastating diseases afflicting either small populations in the U.S. or large populations in the developing world. Four projects, targeting Sickle Cell Disease, Hereditary Inclusion Body Myopathy, Chronic Lymphocytic Leukemia, and Niemann-Pick Type C1 Disease have already yielded successful Investigational New Drug (IND) applications to the Food and Drug Administration (FDA), and are currently in first-in-human clinical trials. Two additional projects are on schedule for IND submission in FY 2014.

In addition to meeting project-specific goals, TRND continues to develop novel collaborations and technologies to improve the efficiency of the translational process. For example, TRND is a founding member of The Learning Collaborative (TLC), a novel partnership between the University of Kansas Institute for Advancing Medical Innovation, the Leukemia and Lymphoma Society, and TRND. TLC serves as a model for establishing multi-party public-private partnerships to speed the development of new drugs, in this case for blood cancers. In addition, three TRND projects aim to advance novel platform technologies that can be used to develop therapeutics to treat a variety of other human disorders. One such platform, focused on developing a cellular therapy for a rare eye disease, will enable TRND to work with the FDA in refining the regulatory pathway for cell-based treatments in general.

- *Office of Rare Diseases Research (ORDR)*

In the United States, a disease is considered to be rare if it affects fewer than 200,000 Americans. There are up to 6,500 rare diseases, affecting approximately 25 million Americans and their families. Rare diseases are severe and can be progressive chronic illnesses that include disability and often premature death. A large percentage of rare diseases are genetic and can affect infants and children. More than 95 percent of rare diseases have no or inadequate treatment. Though progress has been made, few drug companies develop treatments for rare diseases since it is difficult to recover the costs of developing treatments for small, geographically dispersed populations. The Office of Rare Diseases Research (ORDR) supports a number of programs and activities to address the needs for more treatments and for information about rare diseases for patients and their families.

  - *The Rare Diseases Clinical Research Network (RDCRN)*

The RDCRN is an innovative international clinical studies network led by ORDR in collaboration with other NIH Institutes. From 2009 – 2014, the network consisted of 17 separate consortia, a Data Management and Coordination Center, and 95 collaborating patient advocacy groups. The RDCRN consortia studied 200 rare diseases in natural history and clinical studies at 225 clinical sites located in the US and in 14 countries. In 2013 there were 86 active protocols.

In the fall of 2013, ORDR re-issued a request for applications (RFA) for new consortia applications. The purpose of these consortia is to support clinical research in rare diseases through: 1) collaborative clinical research in rare diseases, including longitudinal studies of individuals with rare diseases; clinical studies; or clinical trials; 2) training of clinical investigators in rare diseases research; 3) pilot or demonstration clinical research projects; 4) inclusion of patient advocacy groups as research partners; and 5) development of websites to provide access to information related to rare diseases for basic and clinical researchers, academic and practicing physicians, healthcare professionals, patients, and the public. ORDR also re-issued an RFA for a Data Management and Coordinating Center (DMCC) for the RDCRN in 2013. The DMCC provides a secure, customizable, scalable coordinated clinical data management system for the collection, storage, and analysis of diverse data types from clinical researchers working on many different types of rare diseases. It houses all data for the RDCRN via in-house scalable and customizable electronic data capture systems and has collected over 22 million data points.

- *The Genetic and Rare Diseases Information Center (GARD)*

GARD was established in 2002 by ORDR and the National Human Genome Research Institute to provide patients, healthcare providers, researchers, and the public accurate information about 6,500 rare and genetic diseases, in English and Spanish. Each month, there are an average of 180,000 unique visitors to the GARD webpages and 475 inquiries to GARD information specialists. Seventy-seven percent of the inquiries are from the United States and 13 percent are from other countries. GARD also develops patient-friendly guides to address frequently asked questions, such as How to Find a Disease Specialist and Tips for Those with an Undiagnosed Condition.

- *Global Rare Diseases Patient Registry (GRDR) Data Repository*

The goal of the Global Rare Diseases Patient Registry Data Repository (GRDR) is to enable data analysis within and across many rare diseases and to facilitate clinical trials and other biomedical studies. During the early pilot period of the GRDR development, 12 patient group registries were established. Once the repository patient data were made anonymous, they were mapped and aggregated into GRDR. ORDR has developed a set of common data elements to help patient advocacy groups establish patient registries and a template for informed consent for participating patients. ORDR will expand the GRDR functions and capabilities by developing appropriate software and systems, to be maintained by ORDR. Anonymized patient information from the GRDR will be available for analysis and accessible to research investigators to mine the data within a disease and across different and possibly related diseases in 2014.

Budget Policy:

The FY 2015 President's Budget request is $45.601 million, an increase of $8.500 million, or 22.9 percent above the FY 2014 Enacted level. This is intented to expand and enhance NCATS collaboration with the NIH Clinical Center, and to assume a portion of the Clinical Center's financial support. Included in this request is $31.727 million for the TRND program and

$13.874 million for the ORDR, an increase of $8.500 million and $0.000 million, respectively, over the FY 2014 Enacted level.

(3) Re-engineering Translational Sciences

- *Bridging Interventional Development Gaps*

  The Bridging Interventional Development Gaps (BrIDGs) program assists researchers in advancing promising therapeutic agents through late-stage preclinical development and into clinical testing. The high cost of translating therapeutic discoveries into clinically-available agents can deter the development of promising therapeutics for a variety of diseases and disorders. Researchers may partner with private sector entities to advance projects with significant commercial potential, but high risk ideas or therapies for uncommon disorders frequently do not attract investment. When private sector resources are limited, BrIDGs services can help researchers span the gap between the preclinical and clinical therapy development and continue to evaluate agents that may improve the standard of care for patients.

  Investigators do not receive grant funds through this program. Instead, researchers receive access to NIH contractors who are experts in conducting preclinical studies. These studies include synthesis, formulation, pharmacokinetic, and toxicology services in support of Investigational New Drug (IND) applications to the FDA.

  This program has been successful in demonstrating the power of data to de-risk therapeutics development. BrIDGs has completed 20 projects since its inception. Thirteen of these have successfully filed INDs or clinical trials agreements and subsequently initiated clinical testing. During or after involvement with the BrIDGs program, six therapeutics have been licensed or acquired by companies from the principle investigator, providing additional funding to support further development of these treatments.

Program Portrait: Bridging Interventional Development Gaps (BrIDGs) Program: Potential Treatment for Parkinson's Disease Project
FY 2014 Level: $ 5.3 million
FY 2015 Level: $ 5.3 million
Change: $0

Parkinson's disease is a disorder that affects nerve cells, or neurons, in a part of the brain that controls muscle movement. As symptoms worsen, people with the disease may have trouble walking, talking or doing simple tasks. They also may suffer from depression or have problems sleeping, chewing or swallowing. About 50,000 Americans are diagnosed per year with the disease, for which there is no cure. Researchers have discovered a protein that supports the growth and health of the neurons that produce dopamine, which is lacking or malfunctioning in the brains of patients with Parkinson's disease. This protein, glia-derived growth factor (GDNF), is considered to be a promising candidate for treating Parkinson's.

BrIDGs supported the pre-clinical development of a GDNF-based gene therapy by providing the pre-clinical toxicology and chemistry, manufacturing and control studies that researchers at the University of California, San Francisco (UCSF) needed in order to file an Investigational New Drug application with the FDA. The application was successful, and the first patient was dosed in May 2013. UCSF leveraged the data generated by BrIDGs and the ongoing clinical trial to enter into a collaboration agreement with uniQure, a leading gene therapy company. UniQure has accepted responsibility for the continued development of GDNF, if early clinical trials are successful.

- *The NIH Molecular Libraries Probe Production Centers Network (MLPCN)*

  The MLPCN is a network of national laboratories, whose aim is to generate novel small

  molecule probes by performing high throughput screening, secondary screens, and medicinal chemistry. The assays for these probes are sourced from the scientific community. The NIH Chemical Genomics Center (NCGC) is one of the centers in the MLPCN. Through this program, extramural and intramural biomedical researchers gain access to the collaborative assay development, large-scale small molecule screening, informatics, and medicinal chemistry necessary to identify chemical probes which are used both to validate new drug targets and to initiate new drug development programs. All of the NCGC's projects are highly collaborative and interactive. The NCGC's portfolio currently consists of over 230 collaborations with external scientists throughout the U.S. in the areas of biology and disease, with projects spanning from rare and neglected diseases to basic research in study of novel proteins. NCATS scientists also develop new technologies for high-throughput assay development and screening, big data informatics and modeling, and analytical and medicinal chemistry, to increase the efficiency of the probe development process.

  In FY 2013, as part of the MLPCN, the NCGC developed a chemical informatics (cheminformatics) platform called the BioAssay Research Database (BARD). When completed in FY 2014, BARD will allow researchers around the world to access and ask research questions using the chemical and biological data produced over the ten years of the NIH Molecular Libraries Program. This will be the world's largest collection of information on the pharmaceutical and biological activities of chemical compounds, and will be

invaluable for the research community, public and private, in their translational programs. Given the importance of this resource for advancing translational science, NCATS plans to continue the development of BARD as an open-source platform, and maintain and continuously improve it with new data deposited from the research community.
The Molecular Libraries Small Molecule Repository (MLSMR) is a chemical library containing 377,000 small molecule compounds. The MLSMR, the product of ten years of NIH effort, was created as part of the MLPCN program and is a gold-standard collection of diverse and analytically verified compounds. The collection has been tested in over 540 diverse assays as part of the Molecular Libraries program, all the data from which are in BARD, making these by far the best studied chemicals in the world and therefore an unmatched resource for translational discovery. NCATS intends to continue its support for this large compound library, in order to acquire, purify, manage and disseminate the compounds to researchers throughout the country to empower their translational science.

- *Toxicology in the 21st Century*

  The Toxicology in the 21st Century (Tox21) program, a cross-agency collaboration involving the NIH (NIEHS and NCATS), EPA, and FDA, is aimed at developing better ways to assess the potential toxicity of drugs and environmental chemicals. To accomplish this goal, Tox21 is testing 10,000 different chemicals for their ability to disrupt biological processes that may lead to adverse health effects. A major part of Tox21 is the robotic screening and informatics platform at NCATS that uses fast, completely automated robotic screening to test thousands of chemicals each day for toxic effects on cells. Computational analysis of the effects of the thousands of chemicals in hundreds of different cell types and biological pathways is allowing Tox21 to create predictive algorithms that will be used to refine, and ultimately replace, animal testing. This promises to revolutionize both hazard assessment of environmental chemicals and the development of new drugs, since unpredicted drug toxicity is one of the primary reasons programs to develop new drugs fail.

  The data derived through the Tox21 research efforts are being delivered to the entire scientific community through deposition into PubChem, a free-access scientific database, which in turn is expected to spur multiple collaborative efforts aimed at building better models for toxicity risk assessment.

- *Discovering New Therapeutic Uses for Existing Molecules: Rescuing and Repurposing Drugs*

  Developing a brand-new drug takes an enormous amount of time, money, and effort, mainly because of bottlenecks in the drug discovery process. To help combat these challenges, NCATS launched the Discovering New Therapeutic Uses for Existing Molecules program. It is a collaborative pilot program designed to develop partnerships between pharmaceutical companies and the biomedical research community to advance therapeutic development. This innovative program matches researchers with proprietary molecules from industry to test for their therapeutic potential for treating diseases with unmet or under-met medical

need. NCATS has collaborated with eight companies: Abbott, AstraZeneca, Bristol-Myers Squibb Company, Eli Lilly and Company, GlaxoSmithKline, Janssen Research & Development, L.L.C., Pfizer, and Sanofi. Collectively, these companies made 58 proprietary agents available for the pilot program. In June 2013, with funds from NCATS and the Common Fund, nine awards were made to develop therapeutics for 8 different diseases. Within months of receiving the awards, several projects began testing the investigational drugs in patients.
Projects that meet their milestone will be supported through FY 2015.

- *The Small Business Innovation Research and Small Business Technology Transfer Programs*

  The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are resources for small businesses to further expand upon the NCATS' mission of catalyzing "the generation of innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions." Since the main goal of the SBIR/STTR programs is to develop and commercialize novel technologies and products, NCATS' has developed various specialized contract topics that address the development of innovative tools, technologies, and intervention platforms that would support the creation of novel therapeutics and/or diagnostics. NCATS also participates in various RFAs and PAs across the NIH of specialized topics that are of interest and consistent with the mission of NCATS.

Budget Policy:
The FY 2015 President's Budget request is $62.464 million, an increase of $0.948 million, or 1.5 percent above the FY 2014 Enacted level. The increase reflects the increased proportion of research funding that is statutorily set aside for Small Business Innovation Research.

(4) Cures Acceleration Network: An Innovation in Scientific Discovery Support

The Cures Acceleration Network (CAN) was authorized by Congress to advance the development of highly needed cures and reduce significant barriers between research discovery and clinical trials. To achieve these objectives, CAN provides NCATS with new flexibilities in its funding authorities. Under CAN, NCATS may make large grant awards of up to $15 million per fiscal year, partnership awards that require 1:3 matching funds, and flexible research awards using the special funding mechanism called other transactions authority (OTA), which allows projects to be actively and aggressively managed by using mechanisms similar to those used by the Defense Advanced Research Projects Agency (DARPA) at the U.S. Department of Defense.

On June 4-5, 2012, the IOM Forum on Drug Discovery, Development, and Translation held a workshop to discuss approaches and strategies to accelerating translational science using the authorities provided through CAN, including flexible research authority and matching grant authority. The workshop also discussed promising models for public-private collaborations that could be strengthened or facilitated by activities under CAN and identified barriers and

potential solutions to facilitate coordination of activities under CAN with the FDA regulatory review process and timelines. The workshop summary was delivered to the CAN Review Board. The CAN Review Board, in conjunction with NCATS, is currently exploring possible projects and initiatives that will accelerate the development of treatments and cures and utilize the unique funding authorities under CAN.

- *Tissue Chips for Drug Screening*

The Tissue Chip Program, also known as the microphysiological systems (MPS) Program, was established to address the translational bottleneck issue found in the drug discovery pipeline. Partnerships with NIH/NCATS, DARPA and FDA aim to work with their respective awardees and performers to develop and integrate platform systems (or chips) that mimic human physiology in the ten major organ systems. These polymer-based chips will provide an environment that will enable complex human multicellular tissues to function and behave as if in the human body. The Tissue Chip Program will provide a solid foundation that enhances technologies for drug screening, provide a more relevant research option to study human physiology, replace animal models, and increase clinical success.

Monthly updates from each research group share site developments, providing resource accessibility, collaborations, and workshops. This collaboration has fostered a highly productive program. MPS investigators are making significant progress achieving their milestones, with consistent observations that cellular responses and functions differ greatly in dynamic, physiological-like systems compared with static, traditional cultures. MPS lung models are providing mechanistic insight to pulmonary diseases; neuronal, vascular, heart, skin and liver tissue derived from inducible pluripotent stem cells (iPSC) are viable and functional; complex cell systems are being incorporated into their respective organ chips; and 3D gastrointestinal, kidney and liver models are producing stunning results on organ function and disease.

The Tissue Chip Program addresses three major NIH/NCATS initiatives. For the translational bottleneck issue, organ chips will recapitulate human physiology and will enhance drug screen methodologies. And by providing a viable option for a research tool, these platform systems can also significantly reduce the frequency and number of animals used in research. Finally, in order for these organ chips to integrate with other platform systems to create a "human-on-a-chip," standardization, validation, comparison, and collaboration are key components to the program.

Program Portrait: **Microphysiological Systems or "Organs on Chips"**
FY 2014 Level: $ 9.8 million
FY 2015 Level: $ 20.0 million
Change: + $10.2 million

Organs on chips are bio-engineered microdevices that represent functional units of human organs, such as the lung, liver, and heart, which models both cell architecture and physiology. This unique and novel *in vitro* platform could help ensure that safe and effective therapeutics are identified sooner, and ineffective or toxic ones are rejected early in the drug development process. These microfabricated devices are also useful for modeling human diseases and may prove to be sufficient alternatives to the use of animal models. To accomplish this goal, NCATS has partnered with DARPA and FDA to launch the Microphysiological Systems program that will help improve the process for predicting whether drugs will be safe in humans.

In the 15 months that the program has been in existence, the following are some examples of progress towards representing human organs under this program:

Heart on a chip
- Demonstrated normal heart rhythm and contractility, and replicates physiological responses to known drugs, such as cancer chemotherapy drugs (doxyrubicin) that produces cardiotoxicity
- Modeling diseases, such as Barth syndrome showing cardiomyopathy and alterations in contractile strength

Lung on a chip
- Representations of alveoli on a chip and bronchiole on a chip that recapitulates human lung responses to known drug toxicities
- Modeling of human lung edema as a consequence of IL-2 chemotherapy, enabling the identification of a companion drug that mitigates this effect
- Modeling of asthma
- Modeling of pulmonary fibrosis

Liver on a chip
- 3-D modeling of liver tissue with multicellular architecture, including hepatocytes, parenchymal cells and Kupffer cells. Able to express urea and albumin, and other proteins similar to what is observed in human liver tissue

Kidney on a chip
- Creation of distal kidney tubules that is the major site of renal toxicity; can absorb drugs similar to human kidneys.

In addition to the above examples, progress has been made on brain, GI tract, blood vessels, skin, and female reproductive systems.

- *Proposed New Activities*

The CAN Review Board has established several parameters for selecting potential CAN projects. Projects need to be collaborative, have discrete and measurable outcomes, have a broad and significant impact, and be focused on a compelling disease. The timeline for completion of each project should be shorter than five years.
The CAN Review Board has discussed and identified several ideas for high priority projects. One of these is the use of the CAN matching authority to create foundation-academic-industry partnerships that support pilot studies to accelerate the development of cures. This could include projects aimed at developing biomarkers, disease models, patient-reported outcomes, processes, and diagnostic tests. Another idea is the use of the CAN Other Transactions Authority (OTA) to accelerate ongoing programs and projects, such as trying to

solve the "recruitment gap" in clinical trials, exploring drug development and regulatory innovation concepts, and using prize awards to solicit crowd sourcing ideas. Finally, the CAN Review Board discussed the idea of conducting regulatory science to develop standards for development, manufacturing, and clinical utilization of diagnostics, reagents, and devices.

Budget Policy:
The FY 2015 President's Budget request is $29.810 million, an increase of $19.975 million, or 203.1 percent above the FY 2014 Enacted level. Funding for this program will be used to support the Tissue Chip for Drug Screening program and other new initiatives, as proposed by the CAN Review Board and described above.

(5) Translational Research Resources (TRR)

The TRR program funds specialized programs and initiatives that provide support to NIH researchers. Additionally, TRR manages and administers the NCATS portion of the NIH Extramural Loan Repayment Program (LRP).

Budget Policy:
The FY 2015 President's Budget estimate is $16.172 million, a decrease of $1.260 million, or 7.2 percent below the FY 2014 Enacted level. The reduction is primarily due a reduction to other R&D contracts. This level will provide for NCATS share of trans-NIH programs and initiatives that support the entire spectrum of biomedical research.

(6) Research Management and Support

The NCATS 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.

Budget Policy:
In FY 2015, NCATS's request provides $31.705 million for RMS, an increase of $0.312 million or 1.0 percent above the FY 2014 Enacted level. These resources will be used to support the above activities, and to promote sound stewardship of our resources.

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

		FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Total compensable workyears:				
	Full-time employment	127	127	0
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	$172	$173	$0
	Average GM/GS grade	12.7	12.7	0.0
	Average GM/GS salary	$111	$111	$0
	Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$107	$107	$0
	Average salary of ungraded positions	$151	$151	$0
	OBJECT CLASSES	**FY 2014 Enacted**	**FY 2015 President's Budget**	**FY 2015 +/- FY 2014**
	Personnel Compensation			
11.1	Full-Time Permanent	$8,770	$8,858	$88
11.3	Other Than Full-Time Permanent	4,908	4,958	49
11.5	Other Personnel Compensation	201	203	2
11.7	Military Personnel	307	310	3
11.8	Special Personnel Services Payments	585	591	6
11.9	**Subtotal Personnel Compensation**	**$14,771**	**$14,918**	**$148**
12.1	Civilian Personnel Benefits	$3,951	$4,089	$138
12.2	Military Personnel Benefits	219	221	2
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	**$18,941**	**$19,229**	**$288**
21.0	Travel & Transportation of Persons	$327	$329	$2
22.0	Transportation of Things	108	110	2
23.1	Rental Payments to GSA	16	16	0
23.2	Rental Payments to Others	2	2	0
23.3	Communications, Utilities & Misc. Charges	347	353	6
24.0	Printing & Reproduction	6	6	0
25.1	Consulting Services	$582	$578	-$4
25.2	Other Services	39,837	39,383	-453
25.3	Purchase of goods and services from government accounts	$32,016	$41,255	$9,239
25.4	Operation & Maintenance of Facilities	$221	$224	$4
25.5	R&D Contracts	2,349	2,187	-162
25.6	Medical Care	754	782	28
25.7	Operation & Maintenance of Equipment	3,988	4,055	68
25.8	Subsistence & Support of Persons	0	0	0
25.0	**Subtotal Other Contractual Services**	**$79,746**	**$88,465**	**$8,719**
26.0	Supplies & Materials	$3,027	$3,078	$51
31.0	Equipment	4,399	4,474	75
32.0	Land and Structures	0	0	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	525,479	541,410	15,931
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	0	0	0
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	**$613,455**	**$638,242**	**$24,787**
	Total Budget Authority by Object Class	**$632,396**	**$657,471**	**$25,075**

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

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Salary and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Personnel Compensation			
Full-Time Permanent (11.1)	$8,770	$8,858	$88
Other Than Full-Time Permanent (11.3)	4,908	4,958	49
Other Personnel Compensation (11.5)	201	203	2
Military Personnel (11.7)	307	310	3
Special Personnel Services Payments (11.8)	585	591	6
Subtotal Personnel Compensation (11.9)	**$14,771**	**$14,918**	**$148**
Civilian Personnel Benefits (12.1)	$3,951	$4,089	$138
Military Personnel Benefits (12.2)	219	221	2
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	**$18,941**	**$19,229**	**$288**
Travel & Transportation of Persons (21.0)	$327	$329	$2
Transportation of Things (22.0)	108	110	2
Rental Payments to Others (23.2)	2	2	0
Communications, Utilities & Misc. Charges (23.3)	347	353	6
Printing & Reproduction (24.0)	6	6	0
Other Contractual Services:			
Consultant Services (25.1)	582	578	-4
Other Services (25.2)	39,837	39,383	-453
Purchases from government accounts (25.3)	13,070	21,789	8,719
Operation & Maintenance of Facilities (25.4)	221	224	4
Operation & Maintenance of Equipment (25.7)	3,988	4,055	68
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services (25.0)	**$59,287**	**$66,030**	**$6,743**
Supplies & Materials (26.0)	$3,027	$3,078	$51
Subtotal Non-Pay Costs	**$59,115**	**$65,852**	**$6,737**
Total Administrative Costs	**$78,056**	**$85,080**	**$7,025**

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Details of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2013 Actual			FY 2014 Est.			FY 2015 Est.		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Clinical Innovation									
Direct:	12	2	14	13	1	14	13	1	14
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	12	2	14	13	1	14	13	1	14
Division of Pre-Clinical Innovation									
Direct:	21	1	22	27	1	28	27	1	28
Reimbursable:	13		13	7		7	7		7
Total:	34	1	35	34	1	35	34	1	35
Executive Office									
Direct:	22		22	22		22	22		22
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	22		22	22		22	22		22
Office of Grants Management and Scientific Review									
Direct:	33		33	33		33	33		33
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	33		33	33		33	33		33
Office of Policy, Communications, and Strategic Alliances									
Direct:	11		11	11		11	11		11
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	11		11	11		11	11		11
Office of Rare Diseases Research									
Direct:	7		7	7		7	7		7
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	7		7	7		7	7		7
Office of the Director									
Direct:	5		5	5		5	5		5
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	5		5	5		5	5		5
Total	124	3	127	125	2	127	125	2	127
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
2011	0.0
2012	12.8
2013	12.7
2014	12.7
2015	12.7

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Details of Positions

GRADE	FY 2013 Actual	FY 2014 Enacted	FY 2015 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	170,916	172,198	172,625
GM/GS-15	17	17	17
GM/GS-14	27	27	27
GM/GS-13	28	28	28
GS-12	4	4	4
GS-11	3	3	3
GS-10	1	1	1
GS-9	5	5	5
GS-8	2	2	2
GS-7	4	4	4
GS-6	0	0	0
GS-5	0	0	0
GS-4	1	1	1
GS-3	1	1	1
GS-2	0	0	0
GS-1	0	0	0
Subtotal	93	93	93
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	2	1	1
Senior Grade	1	1	1
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	3	2	2
Ungraded	46	46	46
Total permanent positions	94	94	94
Total positions, end of year	142	142	142
Total full-time equivalent (FTE) employment, end of year	127	127	127
Average ES salary	170,916	172,198	172,625
Average GM/GS grade	12.7	12.7	12.7
Average GM/GS salary	110,004	110,829	111,104

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