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National Institutes of Health

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HIGHLIGHTS

– The National Institutes of Health (NIH) budget would rise 0.7 percent to $30.4 billion.

– NIH's fiscal year (FY) 2015 budget highlights four themes: basic research; precision medicine; big data; and talent and innovation.

– The Opportunity, Growth, and Security Initiative (OGSI), if embraced by Congress, would add $970 million to the NIH budget.

OVERVIEW OF THE FY 2015 NIH BUDGET

NIH, part of the Department of Health and Human Services (HHS), is the second largest supporter of R&D in the federal government, after the Department of Defense. In its mission to promote biomedical research and other fundamental inquiries that may lead to medical advances, it is by far the largest federal supporter of basic research, applied research, and R&D at colleges and universities.

Originating from a one-room lab in 1887, NIH has grown to 27 institutes and centers and is a major player in the biomedical research arena. Its success stories are numerous; more than 100 researchers supported by NIH have won Nobel Prizes. However, the previous decade has brought challenges to the agency. Though NIH saw its budget double between 1998 and 2003, its budget from 2004 onward has declined in real dollars. Success rates—indicating the percentage of reviewed grant applications that receive funding—have also declined, and the average age for a researcher to get his or her first Research Project Grant (called the R01) has hovered around 42. There are genuine fears that numbers like these will deter the next generation of potential researchers.

Largely due to the significant across-the-board cuts known as sequestration, NIH lost about 5 percent of its funding in FY 2013, putting its budget at $29.2 billion, $1.7 billion below FY 2012 levels. This meant a drop of about 640 new (competing) research grants. NIH was further hurt by the government shutdown in October; for 16 days it had to turn away patients from clinical trials and watch grant applications pile up without review.

The Ryan-Murray budget agreement of December 2013 resulted in some much-needed relief to NIH, leading to a FY 2014 budget of $30.2 billion, though NIH still finds itself in a weaker position than it was a decade ago in terms of purchasing power. See Chapters 1 and 3 for more information on the budget agreement.

The FY 2015 NIH budget request (see Figure 1) is $30.4 billion, a boost of $211 million, or 0.7 percent, over FY 2014. NIH classifies 97 percent of its budget as R&D, including R&D facilities; the remainder is for overhead costs and research training. NIH R&D would total $29.5 billion next year.

The Office of Management and Budget projects the rate of inflation in the economy as a whole to be 1.7 percent in FY 2015. In addition, NIH calculates a Biomedical Research and Development Price Index (BRDPI), an index that estimates the inflation rate for goods and services purchased by the NIH budget. NIH predicts the BRDPI rate for FY 2015 to be 2.2 percent.

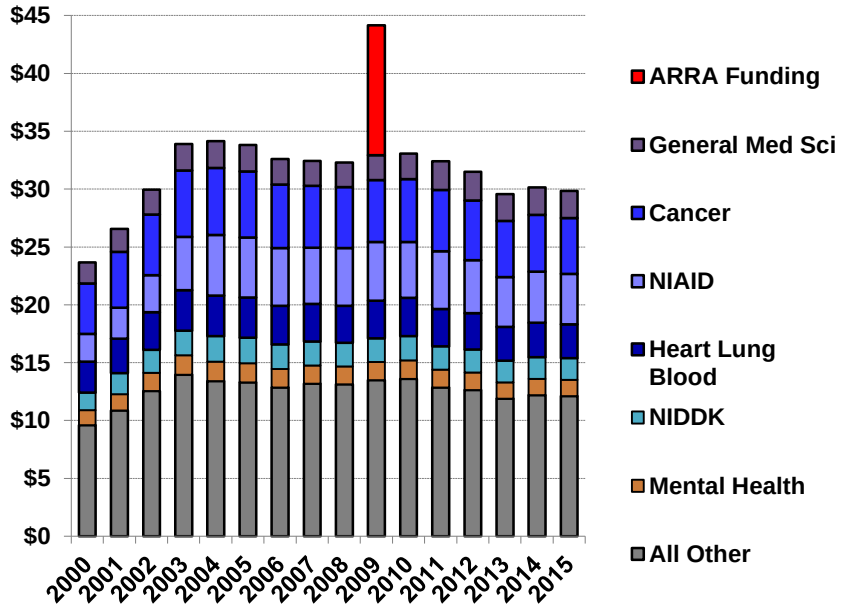
The FY 2015 request also includes the Opportunity, Growth, and Security Initiative (OGSI), an additional $56 billion that would require Congressional action. Though its prospects are slim at press time, the OGSI would allocate an additional $5.3 billion to R&D, including $970 million to NIH.

NIH INSTITUTES IN THE FY 2015 BUDGET

The NIH budget is actually appropriated in 27 separate budget accounts, roughly corresponding to NIH's institutes and centers (ICs). There are 20 institutes with separate budgets, along with four centers, an Office of the Director (OD) and a Buildings and Facilities account. There are three other centers that are not separately budgeted. An additional appropriated account, the NIEHS superfund account, is part of the Interior bill.

In the FY 2015 budget, most ICs would see small budget boosts. The newest center, the National Center for Advancing Translational Sciences (NCATS), would receive the largest boost of 4 percent. Trans-NIH initiatives in the Common Fund would receive $583 million, an increase of 9.4 percent over FY 2014. This fund, designed for multidisciplinary collaborative research, would represent about 1.9 percent of the total NIH budget.

Figure 1. National Institutes of Health Budget (constant 2014 dollars)



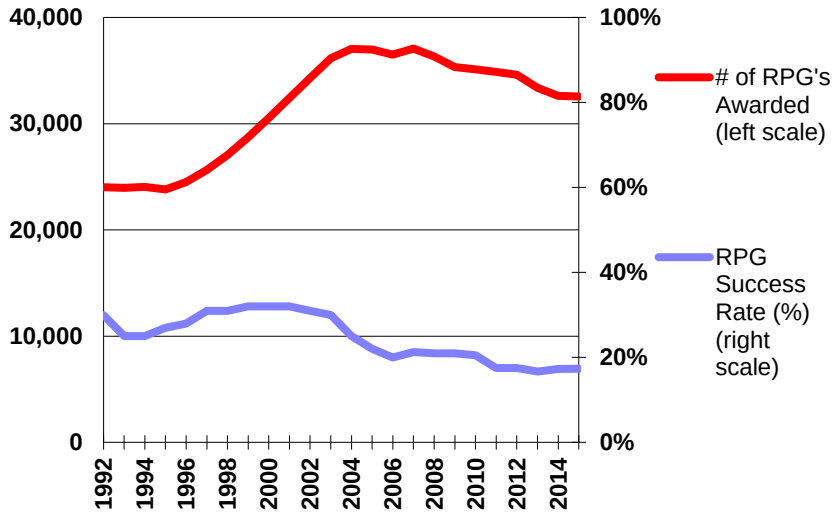
Source: AAAS data and agency budget documents. Does not include additional $970 million in Opportunity, Growth, and Security Initiative funding. © 2014 AAAS

NIH FUNDING MECHANISMS

The majority of NIH's budget is distributed to external performers through Research Project Grants (RPGs), which are investigator initiated, peer reviewed, and competitively awarded throughout the NIH budget. NIH projects a slight drop in the number of RPGs in FY 2015 to 34,197, down from 34,213. Within that number, Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) grants total 1,635. NIH expects to offer 9,326 new (competing) RPGs in FY 2015, an increase of 329 (see Figure 2).

For FY 2015, NIH is estimating a success rate of 17.4 percent, a slight increase from the FY 2014 rate of 17.3 percent. From funding an average of 1 out of 3 grant applications early in the past decade, NIH's success rate has hovered below 1 in 5 applications in recent years. The success rate for new grant applications has shrunk in part because surges in the number of applications have outpaced the number of grants awarded. Total funding for RPGs would be $16.2 billion (with $717 million going to SBIR/STTR).

Figure 2. National Institutes of Health Research Project Grants



Source: NIH agency budget justification. SBIR/STTR Grants are not included for historical consistency. © 2014 AAAS

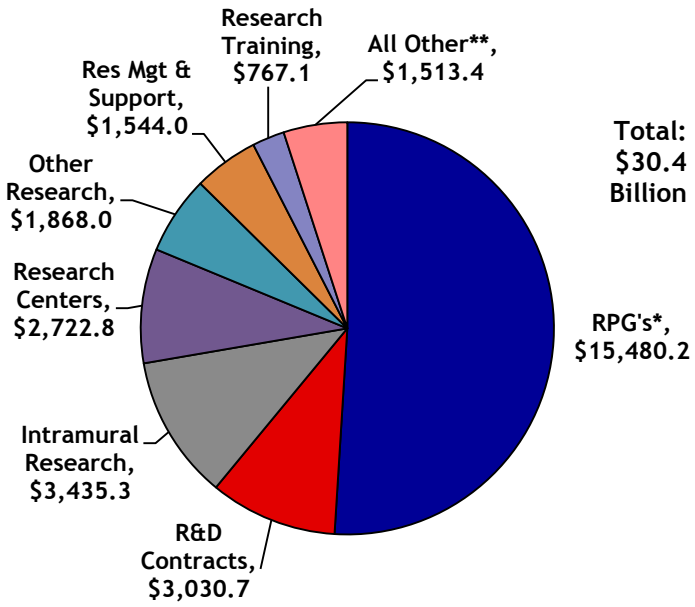
NIH distributes about 10 percent of its budget through R&D contracts. Funding for these contracts would increase by 1.4 percent to $3.0 billion in FY 2015 (see Figure 3). NIH funding of research centers would increase slightly to $2.7 billion for support of 1,370 centers.

The institutes also operate an enormous federal research enterprise, mostly in Bethesda, MD. Intramural research would total $3.4 billion in FY 2015, rising slightly; this constitutes 11 percent of NIH's budget.

NIH is heavily involved in training the next generation of biomedical researchers. Research training programs would receive $767 million in

FY 2015, up slightly from FY 2014. NIH would have 15,715 full-time training positions, up by 108.

Figure 3. NIH FY 2015 Budget by Funding Mechanism



* - Research Project Grants. ** - Includes buildings and facilities, Office of the Director.
Source: Agency budget justification. © 2014 AAAS

NIH PRIORITY AREAS

NIH's FY 2015 budget highlights four themes: basic research, precision medicine, big data, and talent and innovation.

Basic research: Basic research involves advancing knowledge of diseases and conditions, along with developing the foundation and tools to do so. NIH supports many collaborative projects, including the Knockout Mouse Phenotyping Program (KOMP2), which produces mice with specific traits; the Library of Integrated Network-based Cellular Signatures (LINCS), providing a blueprint of how basic cell parts interact; the Genotype Tissue Expression (GTEx) Program, illuminating how genes work in different tissues and people; the 1000 Genomes Project, developing cost effective, high-throughput genome sequencing methods; and the Encyclopedia of DNA Elements (ENCODE) to identify all functional elements of the human genome sequence.

A major priority within this category is the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative. The purpose of the multi-agency BRAIN Initiative is to accelerate the development and application of next-generation tools to construct dynamic pictures of the brain, revealing how millions of brain cells and neural circuits interact in real time. The FY 2015 budget includes $100 million for the BRAIN Initiative, a significant increase of $60 million, to ramp up activities in its second year.

Precision medicine: Precision medicine means, essentially, tailoring treatments and interventions to the individual patient. NIH is working to understand how humans differ in their susceptibility to disease, the trajectory of their diseases, and their response to treatments, and it partners with various public and private entities to achieve these goals. NCATS, for example, partners with academia, industry, and the Food and Drug Administration (FDA) to look for new uses of drugs already found to be safe in humans. The Accelerating Medicines Partnership (AMP) is a new venture in which NIH is working with 10 biopharmaceutical companies and several nonprofits in hopes of increasing the number of new diagnostics and therapies for patients and reducing the time and cost of their development. Pilot projects of the AMP focus on Alzheimer's disease, type 2 diabetes, and the autoimmune disorders rheumatoid arthritis and lupus. NIH is also partnering with the FDA and the Defense Advanced Research Projects Agency (DARPA) to develop 3-D human tissue chips that accurately model the structure and function of human organs. And NIH is working with the U.S. Army to study suicide and mental health among military personnel, to help the Army develop strategies to reduce rising suicide rates.

NIH researchers are also working to develop a universal influenza vaccine that would have the potential to protect against multiple flu strains over several years. Currently the flu vaccine must change every year to respond to variation in seasonal influenza strains. On average, more than 30,000 people in the United States die each year from seasonal flu.

The Common Fund request for FY 2015 includes $30 million for a new DARPA-like program to support high-risk, goal-driven activities to achieve rapid technology development.

Big data: Big data refers to large and complex data sets from sources such as genomic sequencing machines, novel imaging techniques,

electronic health records, and smart phone applications that monitor patient health. Scientists are continually navigating the challenges inherent in managing, analyzing, storing and preserving such data sets. NIH launched the Big Data to Knowledge (BD2K) Initiative two years ago with the goal of maximizing the value of the growing volume and complexity of biomedical data. BD2K has four main components: developing policies, resources, and standards to facilitate broad use and sharing of large, complex data sets; developing and disseminating new analytical methods and software; enhancing the training of scientists, engineers and bioinformaticians; and establishing Centers of Excellence to address important problems in the big data arena.

Talent and innovation: NIH understands the importance of a diverse, well-trained and creative biomedical workforce. In 2012 a working group of the Advisory Committee to the Director (ACD) examined the future of the U.S. biomedical research workforce, and NIH is taking steps to implement its recommendations. Through the Common Fund, NIH has initiated the Strengthening the Biomedical Research Workforce Program, which seeks to better prepare students and postdoctoral researchers for the breadth of biomedical research careers and to establish a network to share best practices. NIH is also seeking to better track NIH-supported graduate students and postdocs, establishing programs such as SciENcv, a platform allowing researchers to record research activity and biographical information.

Diversity also continues to be a critical topic, which another ACD working group addressed in 2012. The group recommended enhanced mentoring and career preparation; increased support for under-resourced institutions with track records of producing and supporting scientists from underrepresented groups; improved research on peer review; and better data collection and evaluation. This led to NIH's Biomedical Research Workforce Diversity Initiative. The Building Infrastructure Leading to Diversity (BUILD) Program is designed to provide under-resourced institutions with the opportunity to develop novel approaches to training and mentoring their students, many of whom come from backgrounds that are disadvantaged and/or underrepresented in biomedical research. Another project, the National Research Mentoring Network, will create a nationwide network of mentors and mentees and provide strategies, standards, and training opportunities for mentors. NIH also recently named its first Chief Officer for Scientific Workforce Diversity.

NIH will continue to support early-career investigators through its NIH Director's Early Independence Award, which provides support for exceptional early investigators to skip the postdoc and jump into independent research, and the NIH Pathway to Independence Award, designed to facilitate the transition from postdoc to a stable research position. NIH also has awards that incentivize creativity: the NIH Director's Pioneer Award, the New Innovator Award, and the Transformative Research Award.

Opportunity, Growth, and Security Initiative: The OGSI would allow NIH to invest an additional $280 million for research project grants; $100 million each for Alzheimer's research and the BRAIN Initiative; $90 million for big data; $50 million for the Accelerating Medicines Partnership; and $125 million for vaccine development. It would fund an additional 650 research grants.

R&D IN OTHER HHS AGENCIES

Total R&D in HHS would be $31.1 billion in FY 2015. NIH dominates the HHS R&D portfolio, but other agencies within HHS would fund a still-substantial $1.5 billion of R&D in FY 2015.

OUTLOOK FOR THE NIH BUDGET

Following a rough 2013, NIH is looking to rebound, but progress is slow in a difficult budget climate. NIH officials will be under ongoing pressure to illustrate the fruits of investment in biomedical research, particularly in certain fields, and the agency will need new champions to join its longtime supporters. The possibilities for further groundbreaking medical advances are tantalizingly real, if this country commits to reaching for them.