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National Institutes of Health

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Highlights

- The National Institutes of Health (NIH) budget would rise 1.5 percent to $31.3 billion.
- NIH's fiscal year (FY) 2014 budget highlights four themes: basic research, translational research, recruitment and retention of scientific talent, and U.S. competitiveness. Notable new projects include the BRAIN Initiative, Big Data to Knowledge (BD2K) and the Biomedical Research Workforce Diversity Initiative.

Overview of the FY 2014 NIH Budget

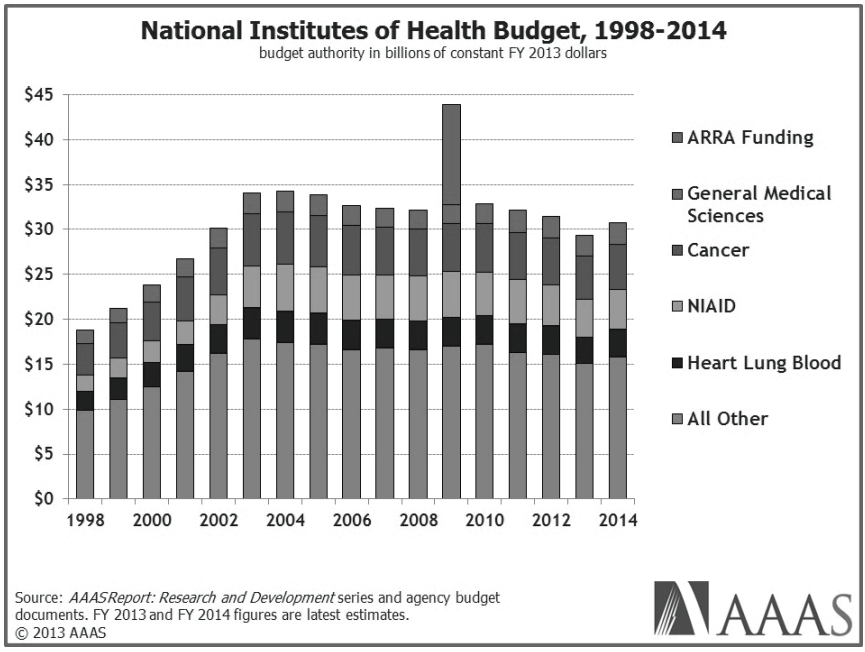
NIH, part of the Department of Health and Human Services (HHS), is the second largest supporter of R&D in the federal government, after the Department of Defense. In its mission to promote biomedical research and other fundamental inquiries that may lead to medical advances, it is by far the largest 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 (see Chapter 3 for more on sequestration). This meant a drop of more than 700 new (competing) research grants.

The FY 2014 NIH budget (see Figure 1) request is $31.3 billion, a boost of $471 million, or 1.5 percent, over FY 2012 (at the time of the drafting of the President's budget, FY 2013 numbers were not available for comparison). NIH classifies 97.3 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 $30.5 billion next year.

Figure 1. National Institutes of Health Budget



In FY 2014, inflation in the economy as a whole is projected to be at 1.9 percent, and 4 percent since FY 2012. 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 2014 to be 2.7 percent.

NIH Institutes in the FY 2014 Budget

The NIH budget is actually appropriated in 26 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.

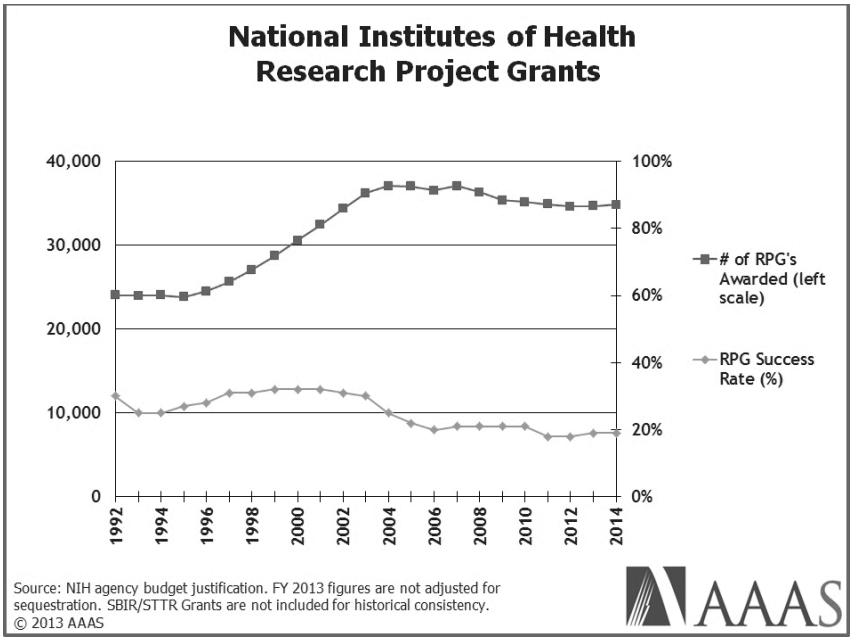
In the FY 2014 budget, most ICs would see small budget boosts. The National Center for Advancing Translational Sciences (NCATS), now in its second year, again stands apart from the other institutes with a boost of 15.9 percent. Trans-NIH initiatives in the Common Fund would receive $573 million, an increase of 5.1 percent over FY 2012. This fund, designed for multidisciplinary collaborative research, would represent about 1.8 percent of the total NIH budget.

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 bump in the number of RPGs in FY 2014 to 36,610, up from 36,259. Within that number, Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) grants total 1,775. NIH expects to offer 10,269 new (competing) RPGs in FY 2014, a significant increase of 1,283 (see Figure 2).

For FY 2014, NIH is estimating a success rate of 19 percent. From funding an average of 1 out of 3 grant applications early in the past decade, NIH's success rate has hovered around 1 in 5 applications in recent years. The success rate for new grant applications has shrunk in large part because recent surges in the number of applications have far outpaced the number of grants awarded. Total funding for RPGs would be $16.9 billion (with $735 million going to SBIR/STTR).

Figure 2. National Institutes of Health Research Project Grants

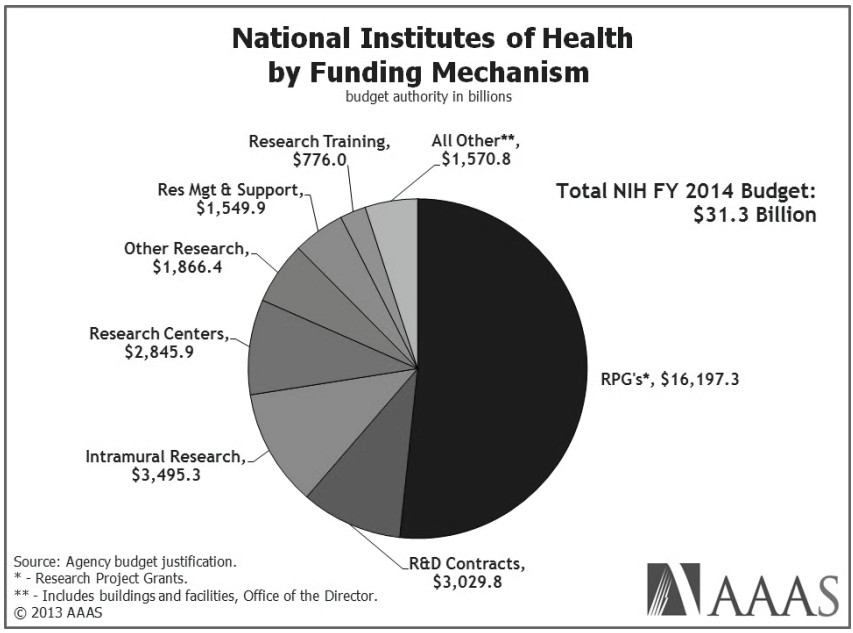


NIH distributes about 10 percent of its budget through R&D contracts. Funding for these contracts would increase by 4.1 percent to $3.0 billion in FY 2014 (see Figure 3). NIH funding of research centers would decrease by 6.4 percent to $2.8 billion for support of 1,380 centers.

The institutes also operate an enormous federal research enterprise, mostly in Bethesda, MD. Intramural research would total $3.5 billion in FY 2014, rising by 1.9 percent; 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 $776 million in FY 2014, up 1.8 percent from FY 2012. NIH would have 16,197 full-time training positions, down by 108.

Figure 3. National Institutes of Health FY 2014 Budget by Funding Mechanism



NIH Priority Areas

NIH's FY 2014 budget highlights four themes: basic research, translational research, recruitment and retention of scientific talent, and U.S. competitiveness. These themes have loomed large for the agency since Director Francis Collins took the helm of NIH in August 2009.

Basic research: Highlights in the basic research category include research on the human brain, single cell biology, and epigenomics. NIH is one of three agencies (along with the Defense Advanced Research Projects Agency and the National Science Foundation) supporting the Administration's new Brain Research through Application of Innovative Neurotechnologies (BRAIN) Initiative, which aims to "develop a deeper understanding of brain function through the creation of new tools capable of examining the activity of the millions of nerve cells, networks, and pathways in the brain in real time." Big Data is another key topic; this refers to the vast amount of data that biomedical researchers are able to generate with advanced technological and computational capabilities—datasets generated from sources like genome sequencing machines, high-

resolution medical imagers, electronic health records, and smartphone applications that monitor patient health. To address the challenges inherent to using and sharing complex datasets, NIH plans to launch the Big Data to Knowledge (BD2K) program in FY 2014, investing at least $40 million through the Common Fund.

Translational research: The National Center for Advancing Translational Sciences (NCATS) was established in December 2011 to serve as a focal point for innovation in the development of medical products. The idea arose out of concern that despite recent advances in biomedical research, the number of FDA-approved drugs has fallen over the past decade, while biotech companies have cut back in several areas of R&D. The center brings together several cross-cutting programs within NIH, including the Clinical and Translational Science Awards (CTSAs), which fund a consortium of biomedical research institutions focused on improving the way clinical and translational research is conducted nationwide; the Cures Acceleration Network (CAN), aimed at bridging the gap between basic research discoveries and human clinical trials; the Office of Rare Diseases Research, which coordinates rare diseases research; and the Therapeutics for Rare and Neglected Diseases (TRND) program, which seeks to speed the development of therapies for rare and neglected diseases. NCATS is partnering with other agencies to evaluate chemical toxicity and to develop 3-D tissue chips for drug testing. In May 2012, NCATS announced the creation of the Discovering New Therapeutic Uses for Existing Molecules Program, a collaboration between the biomedical research community and pharmaceutical company partners to explore new uses for discontinued proprietary drug candidates. Other fields of translational medicine highlighted in the FY 2014 budget are regenerative medicine—which includes work with induced pluripotent stem (iPS) cells, adult skin or blood cells that have been reprogrammed to be able to become nearly any type of cell in the body—and exploring nanotechnologies as a means to deliver therapeutics for the central nervous system. In addition, NIH is part of an effort to establish a National Clinical Research Network to bring together tens of millions of patients to participate in clinical research studies. The initiative will be a collaboration among patients, researchers, health care delivery organizations, electronic health record providers, payers, and government agencies. Beyond seeking to advance research on diagnosis, treatment, and prevention, the network will focus on innovating the conduct of clinical research itself through novel study methods and trial designs.

Recruitment and retention of scientific talent: NIH has moved forward on its desire to recruit and retain a diverse pool of biomedical researchers through a new Biomedical Research Workforce Diversity Initiative. The centerpiece of this initiative is the Building Infrastructure Leading to Diversity (BUILD) Program, designed to provide mentoring resources, scholarships and infrastructure support to institutions. Also part of the initiative will be a National Research Mentoring Network and a new Chief Officer for Scientific Workforce Diversity at NIH, as well as a stronger focus on bias and diversity awareness research and tracking NIH trainees. Concurrent with efforts to bolster diversity, NIH is taking a number of other actions aimed at strengthening the biomedical workforce. These include: establishing a grant program to encourage innovative training approaches; increasing postdoctoral stipends; increasing support for awards that encourage independent research; developing a simple and comprehensive tracking system for trainees; revising training grant review processes to account for a range of career choices; and creating a unit within NIH that focuses on continued assessment of the biomedical research workforce. NIH will also be continuing several award programs designed to encourage innovation, including the Early Independence Award, the New Innovator Award, the Pioneer Award, and the Transformative Research Award.

U.S. competitiveness: It is important to note that biomedical research has led to significant reductions in death rates for some of the nation's most serious conditions, including cancer, heart disease, and stroke. In addition, research has led to more therapeutically effective and cost effective approaches to diagnosing and treating disease. NIH work continues to be an "economic engine" for the United States, supporting hundreds of thousands of jobs nationwide. This public funding triggers complementary private investment and produces measurable benefits to the American economy.

Other developments: An area that has historically been small in funding but large in policy interest is human embryonic stem cell research. Since President Obama issued an executive order expanding federal funding of human embryonic stem cell research, more than 200 stem cell lines have been approved for the NIH Human Embryonic Stem Cell Registry. In January 2013, the U.S. Supreme Court declined to hear a case challenging the Administration policy—a case that, in the summer of 2010, saw a U.S. district judge issue a preliminary injunction that forced NIH to shut down human embryonic stem cell experiments for more than two weeks before U.S. appeals court judges overturned the injunction. The district judge

later dismissed the lawsuit, and the Supreme Court decision signaled the end of the years-long legal saga. Another notable event for the agency was Collins's decision in November of 2012 to back away from a plan to merge the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism, instead opting to better coordinate agency research on substance use, abuse, and addiction.

R&D in Other HHS Agencies

Total R&D in HHS would be $32 billion in FY 2014. NIH dominates the HHS R&D portfolio, but other agencies within HHS would fund a still-substantial $1.6 billion of R&D in FY 2014.

Outlook for the NIH Budget

Sequestration has cast a cloud over NIH and other research agencies. The President's support of NIH in a dire budget climate is notable, but concerns continue to abound about the need to rein in government spending. 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.