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# The National Institutes of Health (NIH): Background and Congressional Issues

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SUMMARY

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# The National Institutes of Health (NIH): Background and Congressional Issues

The National Institutes of Health (NIH), under the Department of Health and Human Services (HHS), is the primary federal agency charged with performing and supporting biomedical and behavioral research. In FY2018, NIH used its over $34 billion budget to support more than 300,000 scientists and research personnel working at over 2,500 institutions across the United States and abroad, as well as to conduct biomedical and behavioral research and research training at its own facilities. The agency consists of the Office of the Director, in charge of overall policy and program coordination, and 27 institutes and centers, each of which focuses on particular diseases or research areas in human health. A broad range of research is funded through a highly competitive system of peer-reviewed grants and contracts.

The Public Health Service Act (PHSA) provides the statutory basis for NIH programs, and funding levels are mostly provided through the annual appropriations process. In December 2016, Congress introduced major reforms and programs at the NIH through the 21st Century Cures Act (P.L. 114-255). Prior to 2016, the last time Congress addressed NIH with comprehensive legislation was in December 2006, when it passed the NIH Reform Act (P.L. 109-482). Congress also gives direction to NIH through appropriations report language, but usually not through budget line items or earmarks. Historically, Congress has accepted, for the most part, the scientific and public health priorities established by the agency through its planning and grant-making activities that involve members of the scientific community and the general public.

NIH has seen periods of both low and high funding growth. From FY1998 to FY2003, Congress doubled the NIH budget from $13.7 billion to $27.1 billion. The agency then saw low funding growth or cuts from FY2004 to FY2015. Starting in FY2016, Congress provided NIH with funding increases of over 5% each year, raising the program level from $30.3 billion in FY2015 to $39.3 billion in FY2019. Under President Trump's budget request for FY2020, NIH would be provided a program level of $34.3 billion—a 12.6% reduction from the FY2019 program level.

NIH officials and scientific observers have cited funding variability and uncertainty as a challenge for the agency. Along with funding uncertainty, other challenges facing the agency and the research enterprise include:

- allocating funding across disease types, areas of human health, and types of research;
- addressing congressional priorities and concerns, while ensuring the scientific merit and quality of NIH-funded research;
- helping new and early-stage scientists obtain their first independent research grants;
- balancing the public and private sectors' relative roles in biomedical research.

NIH is the largest single public funder of biomedical research in the world, yet other countries—particularly China—have increased their funding levels for such research. Some Members of Congress have voiced concern about the position of U.S. biomedical research compared with other countries. A January 2015 study found that the total U.S. (public and private) share of global biomedical research funding declined from 57% in 2004 to 44% in 2011, while countries in Asia increased investment into biomedical research from $28 billion (2004) to $52.4 billion (2011), with especially large increases in China (analysis included Japan, China, India, Singapore and South Korea). Globally, the United States continues to be the top supporter of both public and industry medical research.

# Contents

Introduction ..... 1
Background on NIH ..... 2
History ..... 2
Organizational Structure ..... 3
NIH Reform Act of 2006 ..... 4
Authority ..... 6
Authorization of Appropriations ..... 6
NIH Research Activities ..... 6
Types of Research at the NIH ..... 7
Extramural Research ..... 8
Peer Review Process for Extramural Funding ..... 9
Awards ..... 12
Issues and Reforms in the Peer Review and Grant Award Process ..... 12
Grants Compliance and Oversight ..... 13
Intramural Research ..... 13
Research Training ..... 14
Information Dissemination ..... 15
Budget ..... 15
Sources of Funding ..... 17
Budget Formulation ..... 18
Private Funding from the Foundation for the NIH ..... 18
Setting NIH Research Priorities ..... 19
Congressional Involvement in NIH Research Priorities ..... 20
Alzheimer's Disease Research ..... 20
Research Restrictions ..... 22
Cures Acceleration Network ..... 23
21st Century Cures Act ..... 24
NIH Process in Setting Research Priorities ..... 25
Balancing New and Existing Funding Commitments ..... 27
NIH Initiatives to Recruit and Retain a Research Workforce ..... 31
Workforce Diversity at NIH ..... 34
U.S. vs. Global Research ..... 35
Balancing Federal and Industry Support of Research ..... 37
Public-Private Partnerships ..... 39
Publicly Funded Research and Pharmaceutical Drug Development ..... 41
Concluding Observations ..... 44

## Figures

Figure 1. FY2018 NIH Obligations, by Funding Mechanism ..... 7
Figure 2. "Continuum" of Biomedical Research at NIH ..... 8
Figure 3. NIH Peer Review Process for Extramural Funding ..... 11
Figure 4. National Institutes of Health (NIH) Funding, FY1994-FY2020 ..... 16

Figure 5. Research Project Grants (RPG) Awarded by NIH and Success Rates ..... 29

## Tables

Table 1. Authorization of Appropriations for NIH Innovation Projects Under the Cures Act ..... 25
Table 2. Components of NIH, with History and Scope ..... 45

## Contacts

Author Information..... 50

# Introduction

The National Institutes of Health (NIH) is the primary agency of the federal government charged with performing and supporting biomedical and behavioral research. It has major roles in training biomedical researchers and disseminating health information. The NIH mission is "to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability."[1] As of FY2018, NIH was the largest single public funder of biomedical research in the world.[2]Congress maintains a high level of interest in NIH for a variety of reasons. NIH funds extramural researchers in every state, and widespread constituencies contact Congress about funding for particular diseases and levels of research support in general. NIH is the largest and most visible contributor to the federal biomedical research effort; it represents about half of federal spending for non-Department of Defense research and development (R&D) and about one-fifth of total federal R&D funding.[3] It has the largest budget of the eight health-related agencies that make up the Public Health Service (PHS) within the Department of Health and Human Services (HHS).[4] In FY2018, discretionary appropriations to NIH constituted about 40% of all HHS discretionary budget authority.[5]

NIH-funded research has contributed to major scientific advances. To date, 156 NIH-funded researchers have received Nobel Prizes for their work.[6] NIH-funded research has led to major medical innovations such as treatments for heart disease, cancer, and HIV/AIDs. Such advances have been credited with helping increase life expectancy and prevent millions of deaths.[7] However, in light of the high cost of new medical innovations, some question whether NIH priorities are too focused on research that leads to new treatments rather than on disease prevention or improving the value of medical care.[8] The allocation of NIH research dollars is a major source of debate.

NIH has seen periods of both low and high funding growth. From FY1998 to FY2003, Congress doubled the NIH budget over a five-year period, from $13.7 billion to $27.1 billion.[9] The agency then saw low funding growth or cuts from FY2004 to FY2015. From FY2016 through FY2019, Congress provided NIH with funding increases of over 5% each year, increasing funding from

[1] National Institutes of Health (NIH), About the National Institutes of Health, at http://www.nih.gov/about/mission.htm.

[2] NIH, "Impact of NIH Research- Our Society," May, 2018, https://www.nih.gov/about-nih/what-we-do/impact-nih-research/our-society.

[3] CRS Report R45150, *Federal Research and Development (R&D) Funding: FY2019*, based on numbers from FY2017.

[4] The Public Health Service also includes the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Agency for Healthcare Research and Quality (AHRQ), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Indian Health Service (IHS), and the Agency for Toxic Substances and Disease Registry (ATSDR). For further information, see CRS Report R44916, *Public Health Service Agencies: Overview and Funding (FY2016-FY2018)*.

[5] CRS analysis using data from HHS, *Budget in Brief, FY2020*, pp. 9-10, https://www.hhs.gov/sites/default/files/fy-2020-budget-in-brief.pdf.

[6] NIH, "Nobel Laureates," https://www.nih.gov/about-nih/what-we-do/nih-almanac/nobel-laureates.

[7] NIH, "Report of the Director: National Institutes of Health: Fiscal Years 2014 and 2015," pp. 9-10, https://report.nih.gov/biennialreport/NIH_Directors_Biennial_Report.pdf.

[8] Commentaries include Robert Cook-Deegan, "Has NIH Lost Its Halo?," *Issues in Science and Technology*, vol. 31, no. 2 (Winter 2015); Ezekiel Emanuel, "The Future of Biomedical Research," *Journal of the American Medical Association (JAMA)*, vol. 309, no. 15 (April 17, 2013), pp. 1589-1590; and Michael M. Crow, "Time to Rethink the NIH," *Nature*, vol. 471 (March 31, 2011), pp. 569-571.

[9] CRS Report R43341, *NIH Funding: FY1994-FY2019*.

$30.3 billion in FY2015 to $39.3 billion in FY2019.[10] Under President Trump's budget request for FY2020, NIH would be provided a program level of $34.3 billion—a 12.6% reduction from the FY2019 program level.[11]

Some members of the scientific community have cited funding variability and uncertainty as a hindrance for advancing biomedical research. They have called for steady and predictable funding growth to support the multiyear nature of research.[12] Others have questioned whether universities and other research institutions are too reliant on NIH funding and if institutions should diversify their funding sources or use institutional funds to pay for research.[13]

Aside from funding, other potential issues of for many in Congress and the research community may include

- allocating funding across disease types, areas of human health, and types of research;
- addressing congressional priorities and concerns, while ensuring the scientific merit and quality of NIH-funded research;
- helping new and early-stage investigators obtain their first independent research grants;
- maintaining the United States' role as a leader in biomedical research;
- balancing the public and private sectors' relative roles in biomedical research.

This report provides background and analysis on NIH organization, mission, budget, and history; outlines the agency's major responsibilities; and discusses some of the issues facing Congress as it works to guide and monitor the nation's investment in medical research.

# Background on NIH

## History

NIH traces its roots to 1887, when a one-room Laboratory of Hygiene was established at the Marine Hospital in Staten Island, NY. Relocated to Washington, DC, in 1891, and renamed the Hygienic Laboratory, it operated for its first half century as an intramural research lab for the Public Health Service.[14] Congress designated the research laboratory the National Institute of Health in 1930 (P.L. 71-251). It moved to donated land in the Maryland suburbs in 1938. By 1948, several new institutes and divisions had been created, and the agency became the National Institutes of Health (P.L. 80-655). Congress has continued to create new institutes and centers, most recently in 2011 with the establishment of the National Center for Advancing Translational Sciences (NCATS, P.L. 112-74; see **Table 2**). NIH now occupies a 322-acre main campus in

[10] CRS Report R43341, *NIH Funding: FY1994-FY2019*.

[11] HHS, *Budget in Brief- FY2020, h*ttps://www.hhs.gov/sites/default/files/fy-2020-budget-in-brief.pdf, p. 52.

[12] Jeremy Berg, "Benefits of Steady Growth," *Science*. vol. 353, no. 6302 (August 26, 2016), p. 849; and Christopher L. Pickett, Benjamin W. Corb, C. Robert Matthews, et al., "Toward a Sustainable Biomedical Research Enterprise: Finding Consensus and Implementing Recommendations," *Proceedings of the National Academy of Sciences*, vol. 112, no. 35 (2015), pp. 10832-10836.

[13] Henry R. Bourne, "Expansion Fever and Soft Money Plague the Biomedical Research Enterprise," *Proceedings of the National Academy of Sciences*, vol. 115, no. 35 (2018), pp. 8647-8651.

[14] NIH, "History," "Chronology of Events," at https://www.nih.gov/about-nih/who-we-are/history.

Bethesda, MD, and several off-campus sites, including locations in Maryland, North Carolina, Montana, Arizona.[15]

## Organizational Structure

Today, NIH is a large and complex organization. NIH consists of the Office of the Director and 27 components—20 research institutes, three research centers, the National Library of Medicine (NLM), and three other support centers: the Clinical Center, the Center for Information Technology, and the Center for Scientific Review (for details, see **Table 2**).

The Office of the Director (OD) sets overall policy for NIH and coordinates the programs and activities of all NIH components, particularly transinstitute research initiatives and issues. The individual institutes and centers (ICs) may focus on particular diseases (i.e., The National Cancer Institute), areas of human health and development (i.e., The National Institute on Aging), scientific fields (i.e., National Institute of Environmental Health Sciences), or biomedical professions and technology (i.e., National Institute of Biomedical Imaging and Bioengineering). Each IC plans and manages its own research programs in coordination with OD. Congress provides separate appropriations to 24 (all 20 institutes, NLM, and the three research centers) of the 27 ICs, to OD, and to a buildings and facilities account (see "Budget").[16] The institutes, NLM, and the three research centers have the authority to award research grants; the three operational support centers do not award research grants.[17]Under President Trump's FY2020 budget request, the activities of the Agency for Healthcare Research and Quality (AHRQ) would be consolidated into NIH as the National Institute for Research on Safety and Quality (NIRSQ), forming a 28th IC.[18] The creation of a new NIH institute would require an amendment to the Public Health Service Act (PHSA) Section 401(d), which specifies that "[i]n the National Institutes of Health, the number of national research institutes and national centers may not exceed a total of 27" (see discussion in "NIH Reform Act of 2006").[19] President

**Selected NIH Resources**
**https://www.nih.gov/**

Background: https://www.nih.gov/about-nih

Budget: https://officeofbudget.od.nih.gov/index.htm

Research, condition & disease funding estimates: https://report.nih.gov/categorical_spending.aspx

Health Information: https://www.nih.gov/health-information

Office of the Director, Institutes & Centers: https://www.nih.gov/institutes-nih

Grants & grants policy: https://grants.nih.gov/grants/oer.htm

Grants searchable by topic: https://projectreporter.nih.gov/reporter.cfm

Grants searchable by principal investigator, organization, etc.: https://report.nih.gov/index.aspx

Peer review: https://grants.nih.gov/grants/peer-review.htm

Chronologies (historical & legislative): https://www.nih.gov/about-nih/what-we-do/nih-almanac/timelines

Congressional Liaison: 301-496-3471, https://www.nih.gov/institutes-nih/nih-office-director/olpa

[15] NIH Intramural Research Program, "Research Campus Locations," at https://irp.nih.gov/about-us/research-campus-locations.

[16] The three support centers are financed by the NIH Management Fund, through collections from other NIH ICs for services provided by the support centers. See NIH, "FY2020 Congressional Budget Justificiation, Overview Vol. I," p. 94, https://officeofbudget.od.nih.gov/pdfs/FY20/br/Overview-Volume-FY-2020-CJ.pdf.

[17] Authorities of the ICs are detailed in Title IV of the Public Health Service Act (PHSA). See "Authority."

[18] HHS, *Budget in Brief- FY2020, h*ttps://www.hhs.gov/sites/default/files/fy-2020-budget-in-brief.pdf, p. 52.

[19] 42 U.S.C. §281.

Trump's FY2019 and FY2018 budget requests also proposed consolidating AHRQ and other HHS institutes into NIH; however, Congress did not adopt these proposals.[20]

NIH's large and decentralized organizational structure has been an issue of concern.[21] There are costs and complexities of administering an agency made of 27 ICs, each with its own mission, budget, staff, review office, and other organizational apparatus. The resulting fragmentation may create research duplication or gaps, and might adversely affect NIH's ability to respond appropriately to new scientific and public health challenges. A number of laws have addressed administration and priorities at NIH, including the NIH Reform Act of 2006 and the 21st Century Cures Act.

## NIH Reform Act of 2006

In 2003, Congress requested that the National Academy of Sciences (NAS, now called the National Academies of Sciences, Engineering, and Medicine) study the structure and organization of NIH. The NAS report was released in 2003: *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*.[22] The 2003 NAS report found that "the most common mechanism of origin of the institutes has been the congressional mandate responding to the health advocacy community."[23] The first institute was the National Cancer Institute (NCI) established in 1937. "From the middle 1940s to 1974, health advocates were successful in persuading Congress to establish additional institutes, often against the wishes of administrations, which generally opposed creation of new categorical institutes."[24] Health advocacy "groups have continued the long established pattern of pushing for creation of named entities at NIH to create focal points for developing more research funding for particular diseases. That has often resulted in the establishment by Congress of a named program at the office level. Through continued pressure, offices may then be elevated to centers and, in some cases, to institute status."[25] The 2003 NAS report noted challenges with NIH's large and decentralized organizational structure, but said that any proposals for changing the number of ICs or OD program offices should be subject to a public evaluation process.[26]

Many of the recommendations in the 2003 NAS report were incorporated into the NIH Reform Act of 2006 (P.L. 109-482). The law enhanced the authority of the NIH Director's Office to

[20] See CRS Report R45150, *Federal Research and Development (R&D) Funding: FY2019*, and CRS Report R44888, *Federal Research and Development Funding: FY2018*.

[21] Various articles from the scientific community have critically examined NIH's organizational structure, including Harold Varmus, "Proliferation of National Institutes of Health," *Science*, vol. 291 (March 9, 2001), pp. 1903-1905; Richard A. Rettig, "Reorganizing The National Institutes Of Health,' vol. 23, no. 1 (January/February 2004), pp. 257-262; and Michael M. Crow, "Time to Rethink the NIH," *Nature*, vol. 471 (March 31, 2011), pp. 569-571.

[22] National Research Council and Institute of Medicine, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges* (Washington: National Academies Press, 2003), http://www.nap.edu/catalog/10779.html. Congress requested this study from NAS in 2000. U.S. Congress, Senate Committee on Appropriations, *Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriation Bill, 2001*, Report to Accompany S. 2553, 106th Cong., 2nd sess., May 21, 2000, S.Rept. 106-293, p. 179.

[23] National Research Council and Institute of Medicine, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*, p. 36.

[24] Ibid., p. 46.

[25] Ibid.

[26] Ibid., p. 7. The NAS report recommended more rigorous and frequent review of the performance of top NIH and IC leaders, including the possibility of term limits; reassessment by Congress of the National Cancer Institute's special status regarding appointments and budget authority; and reform of the advisory council system so that it is more independent and protected from political influences.

perform strategic planning, provided for trans-NIH initiatives by enacting the Common Fund into law and required strategic planning for the Fund. It established the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the Office of the Director and moved a number of individual program offices (coordinating research on AIDS, women's health, behavioral and social sciences, and disease prevention) in OD to DPCPSI. The law established the Council of Councils to advise the NIH Director on the policies and activities of DPCPSI and to participate in developing proposals for trans-NIH research.[27] The law requires a biennial report from the Director to Congress assessing the state of biomedical research and reporting in detail on the research activities of NIH, including strategic planning and initiatives, and summaries of research in a number of broad areas.[28]

The Reform Act required the creation of a comprehensive electronic reporting system to catalogue research activities in specific disease, health areas, or by other congressionally-mandated categories from all of the ICs in a standardized format. Information from the tracking system assists the Director and DPCPSI in planning trans-NIH research initiatives that cannot be handled within individual ICs. The reporting system, called Research Portfolio Online Reporting Tools (RePORT), "provides access to reports, data, and analyses of NIH research activities, including information on NIH expenditures and the results of NIH-supported research."[29]

The Reform Act did not contain any provisions on specific diseases or fields of research, nor did it eliminate or consolidate any existing ICs. However, it did provide certain authorities to HHS and NIH officials for making organizational changes to NIH. It also created the Scientific Management Review Board (SMRB) to provide advice on the use of those organizational authorities.[30] SMRB is charged with formally and publicly reviewing NIH organizational structure at least once every seven years. SMRB may recommend restructuring but the number of ICs is capped at the current 27. The law set out time frames for the Director to take action on such recommendations, and provided for review by Congress.

As required by the Reform Act, SMRB has conducted public reviews of NIH's organizational structure and processes. In its first report on organizational change and effectiveness at the agency in 2010, SMRB "recognized that a far reaching overhaul of the NIH structure is neither advisable nor feasible."[31] Instead, SMRB proposed a framework for considering and evaluating potential organizational changes at NIH.[32] Since the first report, SMRB has issued evaluations of specific research areas or ICs at NIH, with recommendations for organizational change. SMRB also issued a report in 2014 on assessing the value of biomedical research, and a report in 2015 on streamlining the NIH grant process.[33]21st Century Cures Act—Administrative Reforms

[27] The Council of Councils is composed of representatives from the IC advisory councils, OD offices, and the Council of Public Representatives. See https://dpcpsi.nih.gov/council.

[28] See https://report.nih.gov/biennialreport/. All other duplicative reporting requirements were eliminated. The law added new reporting requirements on clinical trials, human tissue storing and tracking, whistleblower complaints, and special consultant hires (all had been the subject of investigations by the House Energy and Commerce Committee, the committee of jurisdiction for NIH).

[29] The home page for RePORT is at https://report.nih.gov/index.aspx. It includes links to a number of compiled tables, charts, and data sets, as well as sites for performing tailored searches on funded awards and other topics of interest. See https://projectreporter.nih.gov/reporter.cfm for grant searches and https://report.nih.gov/categorical_spending.aspx for "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)."

[30] See https://smrb.od.nih.gov/.

[31] Scientific Management Review Board, *Report on Deliberating Organizational Change and Effectiveness*, November 2010, p. 4, https://smrb.od.nih.gov/documents/announcements/DOCE_112010.pdf.

[32] Ibid.

[33] A list of SMRB's reports is available at https://smrb.od.nih.gov/reports.html.

The 21st Century Cures Act (P.L. 114-255), enacted in 2016, introduced a number of administrative reforms at NIH. The act newly requires the NIH Director to develop and make publicly available an NIH-wide Strategic Plan every six years (the first to be developed within two years of enactment). The Strategic Plan is expected to provide direction to the biomedical investments made by NIH, facilitate IC collaboration, leverage scientific opportunity, and advance biomedicine (for more information about the 2016-20 NIH-Wide Strategic Plan, see "NIH Process in Setting Research Priorities.") The act also changed the biennial report of the NIH Director to Congress to a triennial requirement.

Other reforms include efforts to reduce administrative burden at NIH, such as by exempting NIH researchers from requirements of the Paperwork Reduction Act. The Act also introduced accountability measures such as five-year terms and other requirements for IC Directors, and efforts to prevent and eliminate duplicative research across the agency. The 21st Century Cures Act also introduced a number of new programs and research efforts at NIH, as detailed in the "21st Century Cures Act" section of this report.

## Authority

NIH derives its statutory authority from the Public Health Service Act (PHSA) of 1944, as amended (42 U.S.C. §§201-300mm-61). Section 301 of the PHSA (42 U.S.C. §241) grants the Secretary of HHS broad permanent authority to conduct and sponsor research. In addition, Title IV, "National Research Institutes" (42 U.S.C. §§281-290b), authorizes in greater detail various activities, functions, and responsibilities of the NIH Director and the ICs. All of the ICs are covered by specific provisions in the PHSA, but they vary considerably in the amount of detail included in the statutory language.

### Authorization of Appropriations

In 2016, the 21st Century Cures Act (P.L. 114-255) amended the PHSA (Section 402A), authorizing appropriations for NIH in FY2018 ($34,851,000,000), FY2019 ($35,585,871,000), and FY2020 ($36,472,442,775) to carry out activities authorized in Title IV of the PHSA.

The previous major NIH reauthorization was the NIH Reform Act of 2006 (P.L. 109-482). The NIH Reform Act authorized total funding levels for NIH appropriations for FY2007 through FY2009. Overall authority for NIH, or explicit authorization of individual ICs, has lapsed at times. However, NIH continued to receive annual appropriations, with authority provided by PHSA Section 301 and the annual appropriations acts. The current authorization of appropriations for NIH is set to expire at the end of FY2020.

# NIH Research Activities

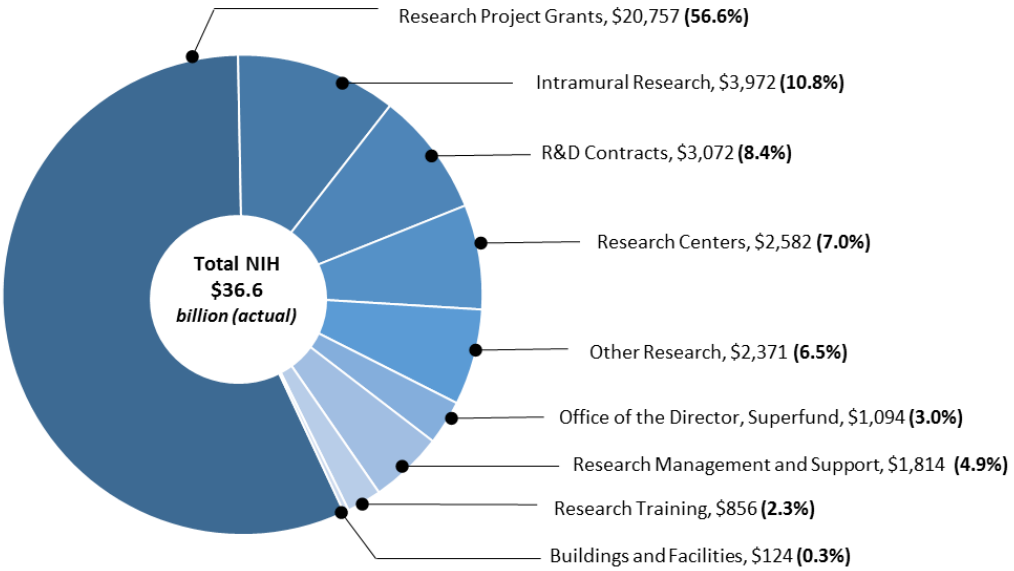
NIH research spans all fields of biomedical and behavioral research, from basic investigation of biological mechanisms to testing new therapeutics in clinical research. The ICs sponsor two categories of research: *extramural research*, performed by nonfederal scientists using NIH grant or contract money, and *intramural research*, performed by federal NIH scientists in the NIH-operated laboratories and Clinical Center. In both the extramural and intramural programs, the research projects are largely investigator-initiated. NIH also supports a range of extramural and intramural *research training programs* to prepare young investigators for research careers, and it engages in a number of *information dissemination* activities to reach various audiences.

Funding for research makes up most of NIH spending. **Figure 1** shows the breakdown of NIH obligations by mechanism. Displaying budget data by mechanism reveals the balance between

extramural (e.g., research grants, research centers, and R&D contracts) and intramural funding, as well as the relative emphasis on support of individual investigator-led research (e.g., research grants and intramural research) versus funding of contracted projects (e.g., R&D contracts).

**Figure 1. FY2018 NIH Obligations, by Funding Mechanism**

Dollars in Millions




**Source:** Developed by CRS using budget data from NIH, "FY2020 Justification of Estimates for Appropriations Committees, Vol I: Overview- History of Obligations by Total Mechanism," p. 87.

## Types of Research at the NIH

According to NIH, the agency conducts and supports the "full continuum" of biomedical and behavioral research to understand the causes and mechanisms of disease, and then translates that knowledge into clinical practice and health interventions. NIH defines the continuum of research as follows (see **Figure 1**):[34]

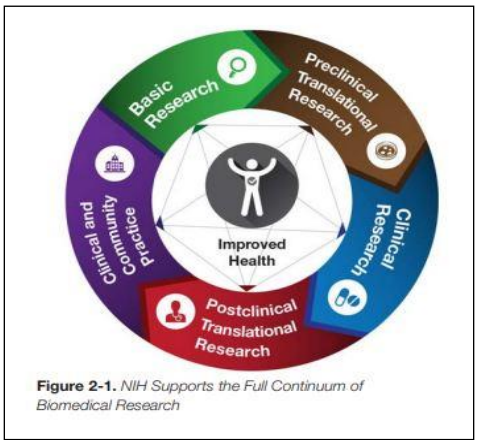
- **Basic research** involves studying the fundamental mechanisms of biology and behavior.
- **Preclinical translational research** involves developing and testing new diagnostics, therapeutics, and preventive measures. This research is conducted using laboratory animals, cell cultures, samples of human or animal tissues, computer modeling, or other approaches.
- **Clinical research** is conducted with human subjects. Clinical research can include (1) clinical trials of diagnostics, therapeutics, and preventive measures, as well as any basic or other research conducted with patients; (2) epidemiological and behavioral studies; and (3) outcomes research and health services research.
- **Postclinical translational research** investigates the best methods to enhance access to and the implementation of newly discovered biomedical interventions.

[34] All definitions based on NIH, *Report of the Director of National Institutes of Health: Fiscal Years 2014 & 2015*, pp. 55-57, at https://report.nih.gov/biennialreport/NIH_Biennial_Report_2014-15_non508.pdf.

- **Clinical and community practice** involves translating new biomedical research discoveries into widespread clinical and community practice. It includes NIH's effort to ensure that scientific findings are communicated rapidly and clearly to the public.

NIH reports that about half of its funding is for basic research.[35] NIH emphasizes that the research continuum is not linear. Progress in research may involve moving back and forth between different stages. For instance, a failed clinical trial on a therapeutic for a given disease may lead to new questions that then require more basic research to make progress in treating that disease.[36]

**Figure 2. "Continuum" of Biomedical Research at NIH**




**Source:** NIH, "Report of the Director of the National Institutes of Health: Fiscal Years 2012 & 2013," at https://report.nih.gov/biennialreport1213/NIH_OD_Biennial_report_2012-2013_508complete.pdf, p. 25.

## Extramural Research

NIH extramural research funding makes up more than 80% of the overall NIH budget and supports 300,000 scientists and research personnel affiliated with over 2,500 universities, academic health centers, hospitals, and independent research institutions in every state and around the world.[37] Extramural awards include research grants, research and development contracts, training awards, and a few smaller categories. Within the large "research grants" category, the bulk of the funding goes for research project grants (RPGs) awarded to individual investigators and small teams, mostly at universities and medical centers. Other types of grants are provided to groups of researchers who work in collaborative programs or in multidisciplinary centers that focus on particular diseases or areas of research, often called "centers of excellence."[38] Data on

[35] NIH, "FY 2002 - FY 2017 Distribution of Budget Authority: Percentage for Basic and Applied Research," https://officeofbudget.od.nih.gov/pdfs/FY19/Basic%20and%20Applied%20FY%202002%20-%20FY%202017%20(V).pdf.

[36] NIH, *Report of the Director of National Institutes of Health: Fiscal Years 2014 & 2015*, p. 55 at https://report.nih.gov/biennialreport/NIH_Biennial_Report_2014-15_non508.pdf.

[37] NIH, "What We Do- Budget," https://www.nih.gov/about-nih/what-we-do/budget.

[38] See "Budget Mechanism Table" in *NIH, Justification of Estimates for Appropriations Committees: Overview, Vol.1, FY2019*, https://officeofbudget.od.nih.gov/pdfs/FY19/br/Overview.pdf, p. 87, and NIH, "Types of Grant Programs," at https://grants.nih.gov/grants/funding/funding_program.htm.

awards and recipients by state, by congressional district, by type of institution, and by subject of the research, are available on the NIH website.[39]

## Peer Review Process for Extramural Funding

Scientists who wish to compete for NIH extramural research funding, whether for totally new proposals or for renewal of previous grant awards, submit detailed plans in their grant applications describing the research they plan to undertake. All NIH grant, fellowship, and cooperative agreement applications undergo review through a two-tiered system of peer review, a competitive and committee-based process to evaluate the applications.[40] The peer review system is pursuant to Section 492 of PHSA (42 U.S.C. §289a), and federal regulations (42 C.F.R. §52).[41] The first stage of peer review assesses the application on scientific and technical merit. In the second stage, the NIH IC makes a funding decision—weighing the project's scientific merit against the IC's research priorities (see **Figure 3**).[42]

Grant applications may be either investigator-initiated or in response to a specific Funding Opportunity Announcement for targeted research.[43] Most applications are investigator-initiated, meaning that a scientist or group of scientists generates an original research project idea and then submits a grant application through an NIH-wide submission process. Some applications are submitted in response to solicitations by ICs for research areas the ICs wish to target and/or for which they have set aside funding, called program announcements (PAs) or requests for applications (RFAs), broadly referred to as Funding Opportunity Announcements (FOAs).[44]

In the first stage of peer review, the applications are received by the NIH Center for Scientific Review (CSR). CSR then assigns each application that meets basic requirements to both a potential awarding IC and an associated Scientific Review Group (SRG) of the IC.[45] The potential awarding IC is the one whose mission best aligns with the objectives of the research project.[46] Applications responding to FOAs are usually reviewed by SRGs within the IC with funding authority, as specified in the FOA.[47]

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[39] See the NIH Awards by Location & Organization, at https://report.nih.gov/award/index.cfm.

[40] NIH, *Report of the Director of the National Instiutes of Health: Fiscal Years 2014 & 2015*, p. 25, https://report.nih.gov/biennialreport/NIH_Biennial_Report_2014-15_non508.pdf.

[41] NIH, "Peer Review," at https://grants.nih.gov/grants/peer-review.htm.

[42] NIH, *NIH Peer Review: Grants and Cooperative Agreements*, https://grants.nih.gov/grants/peerreview22713webv2.pdf.

[43] NIH Office of Extramural Research, "Description of the NIH Guide for Grants and Contracts," https://grants.nih.gov/grants/guide/description.htm.

[44] An umbrella term is "Funding Opportunity Announcement" (FOA), which is defined as follows in the "Glossary of NIH Terms" (https://grants.nih.gov/grants/glossary.htm#F): "A publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. Funding opportunity announcements may be known as program announcements, requests for applications, notices of funding availability, solicitations, or other names depending on the Agency and type of program. Funding opportunity announcements can be found at Grants.gov/FIND and in the NIH Guide for Grants and Contracts."

[45] NIH, *NIH Peer Review: Grants and Cooperative Agreements*,https://grants.nih.gov/grants/peerreview22713webv2.pdf.

[46] NIH, *Report of the Director of the National Instiutes of Health: Fiscal Years 2014 & 2015*, p. 26, https://report.nih.gov/biennialreport/NIH_Biennial_Report_2014-15_non508.pdf.

[47] Ibid., p. 26.

An SRG is a peer-review committee composed of 12 to 22 scientists who are experts in the relevant fields of research.[48] No more than one-fourth of the members of any SRG may be federal employees.[49] Peer reviewers are expected to disclose conflicts of interest and may not participate in evaluations of grant applications where they have conflicts of interest.[50] In FY2018, over 26,000 individuals participated in over 2,600 NIH peer review meetings.[51]

The SRG is responsible for evaluating a grant proposal on the basis of scientific merit and potential impact of the research. After discussing the application, each member gives the application a final score, and an overall impact score is determined from the average of members' final scores. The application is also given a percentile ranking, based on how the overall impact score compares to other applications reviewed by the SRG in the past year. [52]

In the second stage, the funding decisions are refined by the National Advisory Councils or Boards of the potential awarding ICs. Advisory Councils and Boards are composed of scientific and lay representatives. These groups examine applications recommended for funding, place their impact scores and percentile rankings in the context of the IC's research priorities, and then make recommendations for final funding decisions. Many ICs establish a "payline," or percentile cutoff for applications that get funded, though ICs may prioritize applications outside of the payline based on other considerations. [53] The IC director then makes final funding decisions.[54] Section 2033 of the 21st Century Cures Act (P.L. 115-255) added a new requirement that the IC Director weigh the Advisory Board or Council's advice against the IC's mission and research priorities, the NIH-Wide Strategic Plan, and programs or projects funded by other ICs on similar topics before awarding a research grant.[55]

[48] Jeffrey Mervis, "Peering into peer review," *Science*, vol. 343 (February 7, 2014), pp. 596-598.

[49] NIH, *Report of the Director of the National Instiutes of Health: Fiscal Years 2014 & 2015*, p. 26, https://report.nih.gov/biennialreport/NIH_Biennial_Report_2014-15_non508.pdf.

[50] NIH Office of Extramural Research, "Managing Conflict of Interest in NIH Peer Review of Grants and Contracts," https://grants.nih.gov/grants/peer/peer_coi.htm.

[51] NIH, "NIH Data Book- Peer Review," 2019, https://report.nih.gov/nihdatabook/category/12.

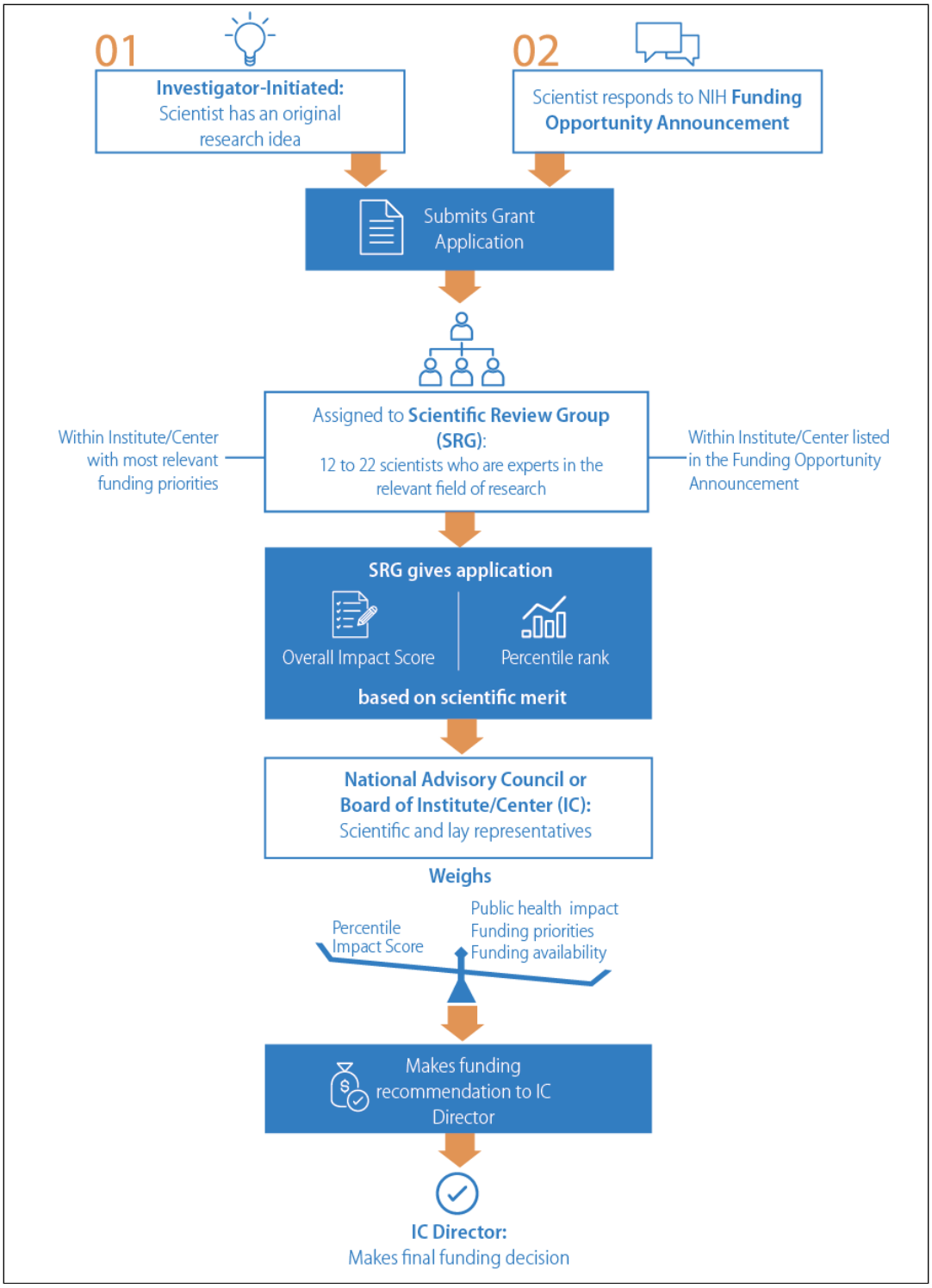
[52] NIH, "Peer Review-Scoring," at https://grants.nih.gov/grants/peer-review.htm#scoring2; and Sally Rockey, "Paylines, Percentiles and Success Rates," 2011, https://nexus.od.nih.gov/all/2011/02/15/paylines-percentiles-success-rates/.

[53] NIH, *Report of the Director of the National Instiutes of Health: Fiscal Years 2014 & 2015*, p. 26, https://report.nih.gov/biennialreport/NIH_Biennial_Report_2014-15_non508.pdf.

[54] NIH, "Peer Review," at https://grants.nih.gov/grants/peer-review.htm.

[55] For more information, see CRS Report R44720, *The 21st Century Cures Act (Division A of P.L. 114-255)*.

**Figure 3. NIH Peer Review Process for Extramural Funding**




**Source:** Developed by CRS using information from NIH, *Report of the Director of the National Institutes of Health: Fiscal Years 2014 & 2015*, p. 26-27, https://report.nih.gov/biennialreport/NIH_Biennial_Report_2014-15_non508.pdf; NIH, *NIH Peer Review: Grants and Cooperative Agreements*, https://grants.nih.gov/grants/peerreview22713webv2.pdf; and NIH, "Peer Review," at https://grants.nih.gov/grants/peer-review.htm.

## Awards

NIH awards numerous types of research grants, administered by each IC. The most common and well-known type of grant is the R01 Research Project Grant, which is awarded for three to five years to conduct a research project. Other grants may be shorter-term exploratory grants that limit funding to two years or less.[56] Because of the multiyear grants, in any given year, about three-fourths of the grantees are in "noncompeting," or "continuation," status. "Noncompeting" grantees have already applied and been awarded NIH funding for multiple years. Each year, a noncompeting grantee has to submit a project report to the IC that supplied the funding, but the grantee does not have to compete for the second, third, and fourth year of funding—the IC considers the award a budgetary commitment (although it is still subject to appropriations). Prior to the expiration of the award, the grantee may choose to compete for a renewal of the project. According to one IC, reviewing a new application can take up to eight weeks from submission to the final funding decision.[57]

In FY2018, in addition to making over 11,000 new and competing renewal awards, NIH made almost 26,000 noncompeting awards and over 2,000 small business awards, for a total of over 39,000 research project grants (RPG).[58] The average annual cost of an RPG award was about $519,000 in FY2018, including both direct and indirect costs.[59] The direct costs, averaging 72.3% of the total award in FY2018, cover project-specific expenses, while the indirect costs, averaging 27.7%, pay for facility and administration costs (i.e., overhead) of the institution where the research is conducted.[60]

## Issues and Reforms in the Peer Review and Grant Award Process

Some critics of the NIH peer review and grant award process contend that it is cumbersome, biased, and ineffective at identifying promising research project proposals.[61] Others have defended the peer review system as a rigorous and competitive process that has been honed over many years.[62]

To evaluate the process, the NIH requested an SMRB report on the peer review and award process. In its 2015 report, SMRB recommendations included fast-tracking high-scoring and high-priority applications, increasing the pool of peer reviewers, reviewing administrative processes to improve efficiency, and piloting innovative methods of peer review.[63] In addition, the NIH Strategic Plan 2016-20 includes ways to improve the peer review process by testing and

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[56] NIH, "Types of Grant Programs," at https://grants.nih.gov/grants/funding/funding_program.htm.

[57] National Institute of Allergy and Infectious Diseases (NIAID), "Timelines for Assignment, Review, & Funding," https://www.niaid.nih.gov/grants-contracts/timelines-assignment-review-funding.

[58] NIH, *FY2020 Justification of Estimates for Appropriations Committees, Vol. I, Overview-Supplementary Tables,* "Budget Mechanism Table," p. 80.

[59] NIH, *FY2020 Justification, Vol. I, Overview- Supplementary Tables,* table on "Research Project Grants: Total Number of Awards and Dollars," p. 89.

[60] NIH, *FY2020 Justification, Vol. I, Overview-Supplementary Tables,* table on "Statistical Data—Direct and Indirect Costs Awarded," p. 88.

[61] Critiques include Jeffrey Mervis, "Peering into peer review," Science, vol. 343 (February 7, 2014), pp. 596-598, and Derek Lowe, "Peer Review's Problems," *Science Translational Medicine*, November 5, 2010.

[62] Letter from Coalition to Promote Research to U.S. Senate, December 2, 2014, https://www.aamc.org/download/416270/data/coalitiontopromoteresearchletterinsupportofnihpeerreview.pdf.

[63] SMRB, *Report on Streamlining the NIH Grant, Review, Award, and Management Process,* 2015, https://smrb.od.nih.gov/documents/reports/GRAMP_10292015.pdf.

validating new approaches "including asynchronous, electronic reviews and two- or three-stage 'editorial board' models," along with measures to compare the performance of each SRG. [64]

### Grants Compliance and Oversight

Congress has enacted many requirements for NIH-funded research, including requirements related to human subjects protections, use of animals, and others.[65] Based on federal laws and regulations, NIH maintains an updated "Grants Policy Statement" on all terms and conditions of NIH grant awards.[66] Grantees are also informed of specific award requirements in their "Notice of Award." Grant awards are made to institutions, not to specific researchers. Therefore, both NIH and recipient institutions share responsibility in grant compliance and oversight of researchers. For instance, Institutional Review Boards and Institutional Animal Care and Use Committees at grantee institutions are responsible for ensuring the ethical use of human subjects and animals in research.[67] The NIH Division of Grants Compliance and Oversight (DGCO) provides training and resources to grantees and institutions to ensure compliance. The division also conducts site visits and reviews as needed.[68]

## Intramural Research

The NIH intramural research program (IRP), at about $4.0 billion in FY2018, accounts for approximately 11% of the total NIH budget.[69] It includes about 1,100 principal investigators and 6,000 trainees ranging from high school students to postdoctoral and clinical fellows in NIH-operated laboratories.[70] Other IRP personnel include administrative support staff, guest researchers, and contractors. Intramural research takes place at the 322-acre main campus in Bethesda, MD, and several off-campus sites, including locations in Maryland, North Carolina, Montana, Arizona.[71]

Almost all of the ICs have an intramural research program, but the size, structure, and activities of the programs vary greatly.[72] As with extramural funding, most intramural research proposals are investigator-initiated. However, NIH sets the direction for its intramural research program by hiring scientists of targeted expertise, through allocating resources to certain laboratories and

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[64] National Institutes of Health, *NIH-Wide Strategic Plan: Fiscal Years 2016-2020,* https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2016-2020-508.pdf.

[65] See PHSA §491 and PHSA§495.

[66] NIH Office of Extramural Research, "NIH Grants Policy Statement," https://grants.nih.gov/policy/nihgps/index.htm.

[67] See 45 C.F.R. §46 for Institutional Review Board requirements, and NIH, "The Institutional Animal Care and Use Committee," https://olaw.nih.gov/resources/tutorial/iacuc.htm.

[68] NIH Office of Extramural Research, "Grants Compliance & Oversight," https://grants.nih.gov/policy/compliance.htm.

[69] CRS analysis of NIH, *FY2019 Justification of Estimates for Appropriations Committees, Vol. I, Overview-Supplementary Tables*, "Budget Mechanism Table," p. 87, at https://officeofbudget.od.nih.gov/pdfs/FY19/br/Supplementary%20Tables.pdf; and HHS, "Budget in Brief, FY2018," p. 37, https://www.hhs.gov/sites/default/files/Consolidated%20BIB_ONLINE_remediated.pdf.

[70] NIH, *Report of the Director National Institutes of Health: Fiscal Years 2014 & 201*5, p. 29 at https://report.nih.gov/biennialreport/NIH_Biennial_Report_2014-15_non508.pdf.

[71] NIH Intramural Research Program, "Research Campus Locations," at https://irp.nih.gov/about-us/research-campus-locations.

[72] See links to individual IC programs at https://irp.nih.gov/about-us/our-programs/text. ICs that do not have an intramural research component are the National Institute of General Medical Sciences (NIGMS), the Fogarty International Center (FIC), and the Center for Scientific Review (CSR).

programs, and through external reviews. Each intramural scientist is evaluated by an external Board of Scientific Counselors from their IC every four years to review their work and research portfolio. Each IC's intramural research program is reviewed by an external panel every 10 years, concerning the entire research portfolio and impact of the research.[73]

Some intramural scientists work in the Clinical Center, which houses both basic research laboratories and clinics for scientists involved with patient care in clinical research studies. The Clinical Center is the nation's largest hospital devoted to clinical research. Along with scientists, the Clinical Center employs over 1,000 nurses and allied health professionals to support its work.[74] Most ICs with intramural research programs fund research at the center. This arrangement facilitates interdisciplinary collaboration and the direct clinical application of new knowledge derived from basic research.

## Research Training

As stated by the agency, "NIH's ability to ensure that it remains a leader in scientific discovery and innovation is dependent upon a pool of creative, diverse, and highly talented researchers."[75] Research training activities are designed to support every stage of a biomedical research career (see "Stages of a Research Career" below) in both the extramural and intramural research programs. Programs range from summer internships for high school students to mentoring programs for independent investigators. Predoctoral and postdoctoral training opportunities are available through a variety of training grants, fellowships, and loan repayment programs.[76] The largest extramural program is called the Ruth L. Kirschstein National Research Service Awards (NRSA) program, authorized by PHSA Section 487, which supports pre- and postdoctoral research training awards to both institutions and individuals. In 2015, NIH supported more than 15,600 graduate and postdoctoral students at universities, teaching hospitals, and research centers.[77]

**Stages of a Scientific Research Career**

- **Undergraduate and Postbacclaurate**. Current students or recent recipients of bachelor's degrees who are studying and/or working in scientific research.
- **Predoctoral/Graduate Training.** Graduate students working toward a research or clinical doctorate degree. Usually involves working on highly structured research projects under the supervision of an experienced mentor.
- **Postdoctoral/Clinical Residency**. New doctorate recipients who gain further training to help transition to an independent researcher.
- **Early-Stage Investigator.** Scientists who have recently obtained independent positions as investigators, faculty members, clinician scientists, or industry scientists.
- **Established Investigator.** Scientists who have demonstrated expertise in their research field through a record of independent and original scientific contributions. Often serve as mentors to trainees at undergraduate, predoctoral, and postdoctoral levels.

**Source:** NIH, "Research Training and Career Development," at https://researchtraining.nih.gov/.

[73] NIH, *Report of the Director National Institutes of Health: Fiscal Years 2014 & 201*5, pp. 29-30, at https://report.nih.gov/biennialreport/NIH_Biennial_Report_2014-15_non508.pdf.

[74] Ibid., p. 30.

[75] NIH, "The Biomedical Research Workforce," https://researchtraining.nih.gov/dbrw/biomedical-research-workforce.

[76] NIH, "Research Training and Career Development," https://researchtraining.nih.gov/.

[77] NIH, Report of the Director National Institutes of Health: Fiscal Years 2014 & 2015, p. 33, at https://report.nih.gov/biennialreport/NIH_Biennial_Report_2014-15_non508.pdf.

## Information Dissemination

NIH has important roles in translating the knowledge gained from biomedical research into medical practice and useful health information for the general public. The individual ICs carry out many relevant activities, such as sponsoring seminars, meetings, and consensus development conferences to inform health professionals of new findings; answering thousands of telephone, mail, and online inquiries; publishing physician and patient education materials on the internet and in print; supporting information clearinghouses and running public information campaigns on various diseases; making specialized databases available; and fostering partnerships for educating clinicians and other healthcare professionals on the latest science.[78]

# Budget

At $39 billion for FY2019, NIH's budget is much larger than those of other PHS agencies such as the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA). About 40% of all discretionary HHS funding is provided to NIH.[79] Moreover, NIH represents about half of federal spending for non-Department of Defense research and development (R&D) and about one-fifth of total federal R&D funding.[80]

NIH has seen periods of high and low budget increases. Prior to 2004, Congress had doubled the NIH program level over a five-year period from its FY1998 base of $13.7 billion to the FY2003 level of $27.1 billion. Subsequently, NIH experienced a decade of stagnant growth in the agency's budget. Congress provided budget increases generally around 1%-3.2% from FY2004 to FY2015, often lower than the rate of inflation for biomedical research, which resulted in reduced purchasing power for the agency. In some years, (FY2006, FY2011, and FY2013) funding for the agency decreased in nominal dollars.[81] Starting in FY2016 through FY2019, Congress provided NIH with funding increases of over 5% each year, increasing the program level from $30.3 billion in FY2015 to $39.3 billion in FY2019. In inflation-adjusted FY2019 dollars, the NIH program level remains 9% below the 2003 level. Under President Trump's FY2020 budget request, NIH would be provided a program level of $34.3 billion—a 12.6% reduction from the FY2019 program level. In inflation-adjusted FY2020 dollars, this proposed FY2020 program level would be 22.6% below the peak 2003 level. See **Figure 4** for a visualization of NIH budget trends from FY1994 to FY2020.[82]

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[78] NIH, Report of the Director National Institutes of Health: Fiscal Years 2014 & 2015, pp. 48-53, at https://report.nih.gov/biennialreport/NIH_Biennial_Report_2014-15_non508.pdf. Free searching of MEDLINE citations and other NLM databases, together with resources for health questions, is available at https://medlineplus.gov/ and at https://www.nih.gov/health-information.

[79] CRS analysis using data from U.S. Department of Health and Human Services, *Fiscal Year 2019 Budget in Brief*, pp. 10-11, https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf.

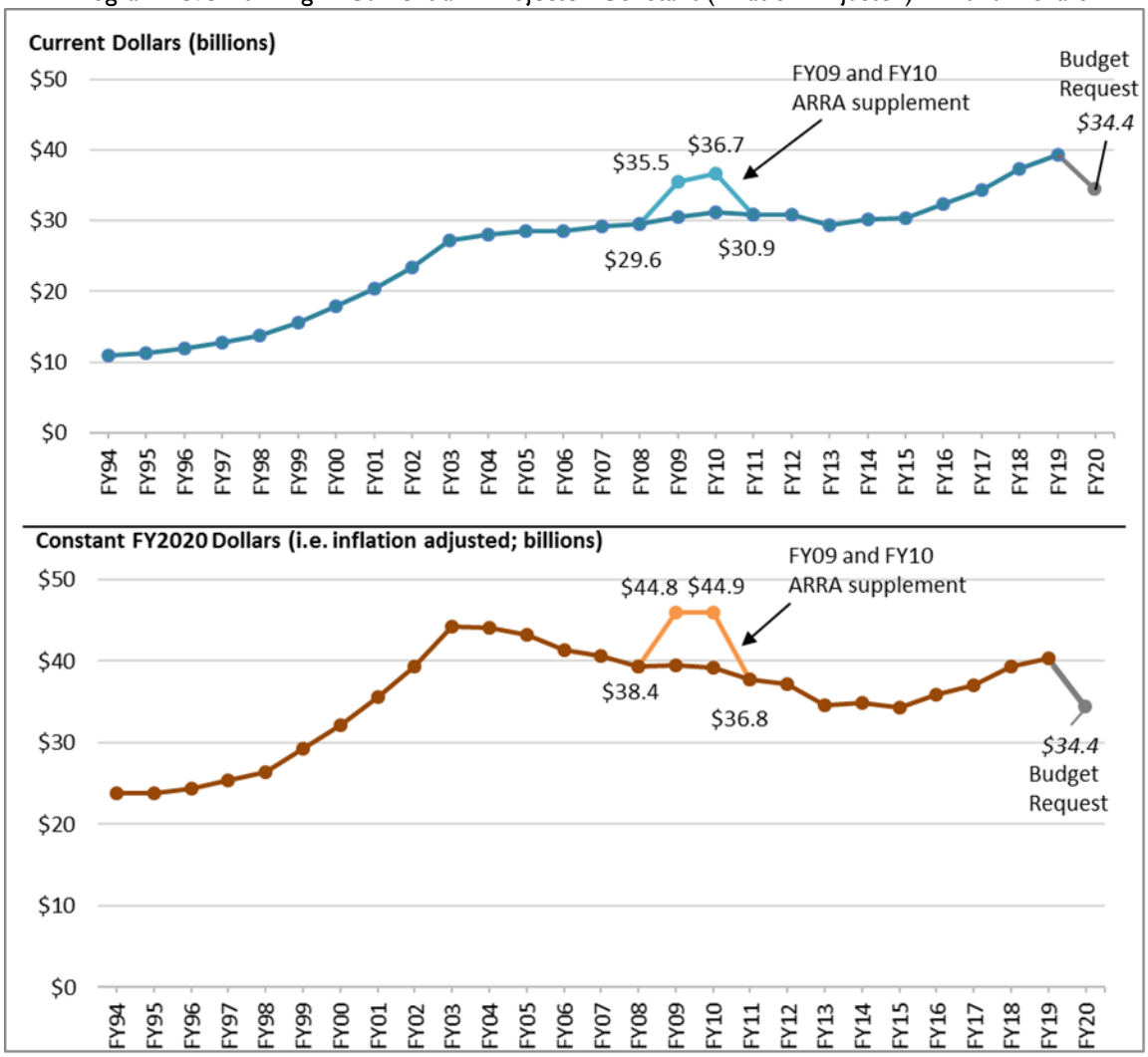
[80] CRS Report R45150, *Federal Research and Development (R&D) Funding: FY2019*.

[81] For instance, in the FY2006 total was 0.1% lower than the previous year, the first time that the NIH appropriation had decreased since FY1970; the FY2011 total, provided in the Full-Year Continuing Appropriations Act, 2011 (P.L. 112-10), was 1.0% below the previous fiscal year; and the FY2013 total, provided in the Consolidated and Further Continuing Appropriations Act, 2013 (P.L. 113-6), was reduced by the March 2013 sequestration and a transfer of funding under the authority of the HHS Secretary ($1.553 billion and $173 million, respectively), resulting in a budget that was 5.0% lower than the prior year.

[82] CRS Report R43341, *National Institutes of Health (NIH) Funding: FY1994-FY2020*.

**Figure 4. National Institutes of Health (NIH) Funding, FY1994-FY2020**

Program Level Funding in Current and Projected Constant (Inflation-Adjusted) FY2020 Dollars




**Source:** NIH Budget Office, Appropriations History by Institute/Center (1938 to Present), at http://officeofbudget.od.nih.gov/approp_hist.html. The FY2019 and F2020 program levels are based on budget data from NIH, "Justification of Estimates for Appropriations Committees FY2020- Overview, Vol. 1," p. 78, except for FY2019 appropriations to NIEHS through the Consolidated Appropriations Act, 2019 (P.L. 116-6). Inflation adjustment reflects the Biomedical Research and Development Price Index (BRDPI), updated January 2019, https://officeofbudget.od.nih.gov/gbiPriceIndexes.html.

**Notes:** By convention, program level totals include amounts "transferred in" pursuant to PHS tap, but do not include amounts "transferred out" under this same authority. Program level includes all budget authority, including appropriations for the Global Fund to Fight AIDS, TB, and Malaria (FY2002-FY2011) that were subject to transfer-out. As of FY2012, NIH no longer receives appropriations for the National Institute of Allergy and Infectious Diseases (NIAID) identifying resources for the Global Fund; this responsibility was transferred to another federal agency. ARRA supplementary funding is from the American Recovery and Reinvestment Act of 2009, P.L. 111-5. In general, amounts provided to NIH for emergency requirements are excluded from these totals (e.g., FY2015 amount does not include $238,000,000 for the NIAID for research on Ebola that was provided in P.L. 113-235, Title VI of Division G).

## Sources of Funding

NIH receives funding from mostly discretionary budget authorities and one mandatory budget authority. The total NIH budget is called the "program level." Discretionary funding for NIH comes primarily from the annual Labor-HHS-Education (LHHS) appropriations bill, which funds the agency through 27 separate accounts, including the 24 ICs with research grant-awarding authority. An additional small amount for environmental research and training related to the Superfund program comes from the Interior, Environment, and Related Agencies (Interior-Environment) appropriations bill for the National Institute of Environmental Health Sciences (NIEHS).[83] Those two sources constitute NIH's discretionary budget authority.

The NIH "program level" takes into account other funds that are added to or transferred from the agency.[84] In FY2019, NIH received mandatory funds ($150 million in FY2019) for Special Diabetes Programs for Type 1 Diabetes under PHSA Section 330B (42 U.S.C §254c-2). The type 1 diabetes program was most recently reauthorized by the Bipartisan Budget Act of 2018 (P.L. 115-123), which provided $150 million for each of FY2018 and FY2019 for the Special Diabetes Program for type I diabetes to the NIH.

NIH also receives funds from a "program evaluation" transfer authorized by PHSA Section 241 (42 U.S.C. §238j). NIH and other PHS agencies (funded through LHHS appropriations) are subject to this budget "tap," which has been used to fund not only program evaluation activities, but also programs such as NLM, the National Center for Health Statistics in CDC, and the entire discretionary budget of the Agency for Healthcare Research and Quality.[85] These and other uses of the evaluation tap by the appropriators have the effect of redistributing appropriated funds among PHS agencies.

Although the PHSA provision limits the tap to no more than 1% of eligible appropriations, in recent years annual LHHS appropriations bills have specified a higher amount (2.5% for FY2019 in P.L. 115-245), and have typically directed specific amounts of funding from the tap for transfer to a number of HHS programs. The assessment has the effect of redistributing appropriated funds for specific purposes among PHS and other HHS agencies. NIH, with the largest budget among the PHS agencies, has historically been the largest "donor" of program evaluation funds. Until recently, it had been a relatively minor recipient.[86] In FY2019, NIH received $1.15 billion in funds subject to the evaluation tap through P.L. 115-245. Under President Trump's FY2020 budget request, NIH would receive $741 million in funding subject to the evaluation tap.[87]

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[83] The Superfund research program, or the Hazardous Substance Basic Research and Training Program, funds research grants to find solutions for exposures to hazardous substances (from NIEHS, "Superfund Research Program," https://www.niehs.nih.gov/research/supported/centers/srp/index.cfm).

[84] For a number of years, part of NIH annual appropriations was transferred to the Global Fund to Fight HIV/AIDS, Tuberculosis, and Malaria. In FY2002-FY2007, about $100 million of the annual appropriation to NIAID was transferred to the Global Fund (the FY2004 amount was $149 million). For FY2008, the amount was increased to $300 million in the request, and the final amount of the transfer from the NIH/NIAID appropriation was $295 million. For FY2009 and FY2010, $300 million of NIH/NIAID appropriations was transferred to the Global Fund. In FY2011, $297 million was transferred. The "NIH program level" cited in agency and OMB budget documents, however, did not reflect the Global Fund transfer. Congress decided to terminate the Global Fund transfer from NIH in the FY2012 Consolidated Appropriations Act and instead provided all funding for the Global Fund through the Department of State/Foreign Operations appropriations.

[85] For more information, see the "PHS Evaluation Set-Aside" section of CRS Report R44916, *Public Health Service Agencies: Overview and Funding (FY2016-FY2018)*.

[86] Ibid.

[87] HHS, *Budget in Brief- FY2020*, *h*ttps://www.hhs.gov/sites/default/files/fy-2020-budget-in-brief.pdf, p. 52.

## Budget Formulation

The NIH budget request that Congress receives from the President each February for the next fiscal year reflects both recent history and professional judgments about the future, because it needs to support both ongoing research commitments and new initiatives. The request is formulated through a lengthy process that starts more than a year before in the ICs. The budget then evolves over a number of months as it moves from the ICs to NIH, then to HHS, and finally to the Office of Management and Budget (OMB). At each stage, IC and NIH needs are weighed in the context of the larger budget. Eventually, Congress is called upon to make similar judgments.

As a continuing process, IC leaders, with input from the scientific community, define the most important and promising areas in their respective fields. They consider whether their existing research portfolio needs rebalancing, and they decide on possible new initiatives for the coming budget year. An annual budget retreat in May brings together the IC leaders with top NIH management to discuss policies and priorities under various budget scenarios. They might consider, for example, what the different emphases in their programs would be if the appropriation turned out to be a certain percentage decrease, a flat budget, or an increase. The presentations and discussions allow NIH management to develop the budget request it will submit to HHS, taking into account the estimated funding amount needed to support the "commitment base" of continuing awards, the funding desired for unsolicited new research proposals, the new initiatives that the Director wants to incorporate, and guidance from the department about the request (e.g., there might be an instruction to pay no inflation increases on grants).

At the HHS level, NIH's request is considered in the context of the overall department budget, resulting in a notice back to NIH on the department's allowance. There are usually appeals and adjustments made before the final HHS budget goes to OMB. The process of submission, passback, and appeals is repeated as OMB considers the entire federal budget and tells HHS what amounts and policy approaches are approved for incorporation into the President's final budget that will be sent to Congress. Once the budget is made public, all agency comments about the request are expected to support the President's proposed levels.

## Private Funding from the Foundation for the NIH

The Foundation for the National Institutes of Health (FNIH) is a 501(c)(3) charitable organization that raises private funding and manages public-private partnerships to support NIH's mission. FNIH was established in 1990 by P.L. 101-613 and began operations in 1996. FNIH supports research projects and programs, education and training, conferences and events, and other support activities for NIH, such as drug donations to the clinical center.[88] Pursuant to PHSA Section 499 (42 U.S.C. §290b), there are terms and restrictions on activities, requirements for the board of directors, reporting requirements, and other requirements for FNIH.

In its history, FNIH has raised over $1 billion in support of NIH's mission. By the end of 2017, FNIH had raised over $555 million in multiyear funding commitments for over 100 programs: $541 million for research projects, $8.7 million for education and seminars, $3.2 million for capital projects, and $2.8 million for events.[89]

[88] FNIH, "About Us," https://fnih.org/about and FNIH, "Patient Support Programs," https://fnih.org/what-we-do/current-patient-support-programs/all.

[89] FNIH, *2017 Annual Report to the National Institutes of Health*, May 25, 2018,

# Setting NIH Research Priorities

NIH funds research on hundreds of diseases, conditions, and areas of human health.[90] NIH funding is highly competitive—20.9% of all grant applications were funded in FY2018.[91] NIH and Congress face trade-offs in allocating funding in a fair manner that balances the scientific merit of proposals with meeting the diverse health needs of the population. Funding decisions are especially difficult because science is a process of discovery—even experts cannot always predict which proposals will lead to breakthroughs. Historic tensions have included whether to designate funding for specific diseases and areas of research or to allow untargeted funding for the most meritorious proposals identified through the peer review process; balancing funding for basic scientific research with applied research; whether funding should go to certain ethically contentious research areas, such as embryonic stem cell research; how to fund research on the most pervasive diseases and conditions while also funding research on rare diseases; and how to allocate funding among established and successful scientists while enabling new scientists to enter the field.

Historically, Congress allowed NIH ICs, for the most part, to fund research based on their own internal prioritization process, which involves scientific experts, patient advocates, and others. In recent years, Congress has provided more direction to NIH funding in both appropriations report language and legislation. The following sections summarize (1) congressional involvement in NIH research priorities, including recent major efforts, legislation, and research restrictions, and (2) NIH internal processes for setting research priorities through strategic planning and advisory groups.

NIH is not the only federal agency that supports biomedical and health-related research. The Department of Defense (DOD) and the Department of Veterans Affairs (VA) and others also support medical research programs. In FY2019, the NIH program level was $39.3 billion, the VA appropriation for medical research was $779 million, and the DOD's Defense Health Program's Research, Development, Test, and Evaluation (RDT&E) account received $2.18 billion, including $1.47 billion for the Congressionally Directed Medical Research program (CDMRP).[92] A 2016 National Academies of Sciences, Engineering, and Medicine (NASEM) report examined duplication and coordination of research funded by NIH, DOD, and VA. The report found that some formal mechanisms helped reduce duplication, such as interagency coordinating committees, common grant portals, and assessing other funding sources in grant application review. However, the agencies each lack comprehensive information about the other agencies' activities, which "limits their ability to identify potential areas of duplication."[93] In addition, other agencies support health-related research, such as the Centers for Disease Control and Prevention (CDC) and the Agency for Healthcare Quality and Research (AHRQ). Although the below discussion focuses on research priorities at NIH, Congress may consider how to prioritize and coordinate funding for medical and health-related research across the federal government.

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https://fnih.org/sites/default/files/final/pdf/Statutory%20Report%202017.pdf#overlay-context=.

[90] The NIH "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)" table includes over 280 categories of diseases, conditions, or research areas for which NIH categorizes its funding. The table is not comprehensive of all types of research funded by NIH.

[91] NIH, "Justification of Estimates for Appropriations Committees FY2020, Overview Vol. I," p. 90.

[92] See VA, "Department of Veterans Affairs – Budget in Brief FY2020," p. 3, https://www.va.gov/budget/docs/summary/fy2020VAbudgetInBrief.pdf, and CRS In Focus IF10349, *Congressionally Directed Medical Research Programs Funding for FY2019*.

[93] NASEM, "Coordination of Research Priorities," in *Evaluation of the Congressionally Directed Medical Research Programs Review Process* (Washington, DC: National Academies Press, 2016), pp. 99-114.

## Congressional Involvement in NIH Research Priorities

Congress's primary role in NIH research priorities is through annual appropriations to the IC accounts. From time to time, Congress addresses NIH research priorities through legislation authorizing specific programs, such as the 21st Century Cures Act (P.L. 114-255) and through restrictions and other requirements for research.

Appropriators have traditionally avoided specifying dollar amounts for particular disease areas, fields of research, or mechanisms of funding in both report and bill text, aside from the level of the IC accounts. Generally, specific amounts are appropriated to each IC, and then funding is awarded through competitive grants, contracts, or to intramural researchers.

In recent years, report language accompanying appropriations acts and laws such as the 21st Century Cures Act (P.L. 114-255) have included more specified funding amounts for research areas and programs. For example, the report accompanying the FY2019 LHHS conference appropriations bill (H.Rept. 115-952, pp. 529-530) directed specific funding increases for the following at NIH: Alzheimer's disease research, antibiotic resistant bacteria research, universal flu vaccine development, opioids-related research, and the Institutional Development Awards (IDeA) program.[94] The 21st Century Cures Act, passed in 2016, authorized specific appropriations for four innovation projects (as described in the "21st Century Cures Act" section of this report). Other laws that have directed funding to specific research areas include the Gabriella Miller Kids First Research Act (P.L. 113-94), which authorizes $12.6 million for each of FY2014-FY2023 for pediatric research, and mandatory appropriations of $150 million for research on type 1 diabetes, authorized by PHS Act §330B and extended most recently by the Bipartisan Budget Act of 2018 (P.L. 115-123) for FY2018 and FY2019.

### Alzheimer's Disease Research

Changes in congressional practice have occurred most notably with research funding for Alzheimer's disease. From FY2001 through FY2014, Congress provided broad directives to NIH in report language, encouraging the agency to prioritize Alzheimer's disease and to increase resources toward its research through the National Institute on Aging (NIA).[95] The explanatory statement accompanying the FY2014 omnibus included the following language:

> In keeping with longstanding practice, the House and Senate Appropriations Committees do not recommend a specific amount of NIH funding for this purpose or for any other individual disease. Doing so would establish a dangerous precedent that could politicize the NIH peer review system. Nevertheless, in recognition that Alzheimer's disease poses a serious threat to the Nation's long-term health and economic stability, the agreement expects that a significant portion of the recommended increase for NIA should be directed to research on Alzheimer's. The exact amount should be determined by the scientific opportunity of additional research on this disease and the quality of grant applications that are submitted for Alzheimer's relative to those submitted for other diseases.[96]

[94] The Institutional Development Award (IDeA) program builds research capacity in states that have historically had low levels of NIH funding. Currently, 23 states and Puerto Rico are eligible for IDeA funding. From the National Institute of General Medical Sciences (NIGMS), "Institutional Development Award," https://www.nigms.nih.gov/Research/DRCB/IDeA/Pages/default.aspx.

[95] Based on CRS search of "Alzheimer's" in enacted appropriations laws, accompanying committee reports, and House and Senate committee appropriations bills from FY2001 to FY2014.

[96] *Congressional Record*, January 15, 2014, vol. 160, no. 9—Book II, H1037.

The explanatory statement for the FY2015 omnibus included similar language but noted that the agreement provided a $25 million increase for Alzheimer's disease research at NIA; still, it did not direct NIH to reserve a specific total dollar amount.[97] Then, in a significant departure from past precedent, the explanatory statements to the appropriations measures for each of FY2016 through FY2018 directed NIH to reserve a specific amount for Alzheimer's disease research.[98] The conference report accompanying the FY2019 LHHS Appropriations Act continues this trend.[99]

The change in congressional practice was driven by the National Plan to Address Alzheimer's Disease, first announced in 2012.[100] Established by the National Alzheimer's Project Act (NAPA; P.L. 111-375), the National Plan includes "Prevent and Effectively Treat Alzheimer's Disease and Related Dementias by 2025" as the first of five key goals.[101] To help meet this goal, NIH began to publish an annual bypass budget in FY2015 to estimate funding needs for Alzheimer's disease research, starting for FY2017. A bypass budget, also known as a professional judgement budget, is a budget proposal submitted directly by NIH to Congress to estimate research funding needs based on scientific opportunity, rather than as determined by the regular budget and appropriations process (detailed in "Budget Formulation"). The bypass budget was mandated by the Consolidated and Further Continuing Appropriations Act, of 2015 (P.L. 113-235), which specified that the NIH Director submit an annual independent Alzheimer's research budget request directly to Congress, pursuant to the National Alzheimer's Plan.[102] To determine its bypass budget proposal, NIH has convened research summits starting in 2012, and has worked across its ICs to determine recommendations and funding needs for Alzheimer's disease research. To meet its research goals, NIH has used targeted FOAs to solicit research proposals related to Alzheimer's disease from scientists.[103]

Alzheimer's disease research represents an area of major congressional involvement in directing large amounts of research funding toward a specific disease. A *Science* magazine article from August 2018, asserts that the large increase in funding for Alzheimer's disease research has affected the NIH and the scientific community in an unprecedented way:

> Such a dramatic increase in research funding for a disease has no precedent at NIH aside from the War on Cancer, an effort launched in 1971, and an explosion of AIDS funding in the late 1980s. With the largesse come logistical challenges. Overworked NIH staff are scrambling to review and process thousands of grant proposals, including those for this

[97] *Congressional Record*, December 11, 2014, vol. 160, no. 151—Book II, H9832.

[98] Explanatory statements with specified funding amounts for Alzheimer's research include *Congressional Record*, December 11, 2014, vol. 160, no. 151—Book II, H9832; *Congressional Record*, December 17, 2015, vol. 161, no. 184—Book III, H10285; *Congressional Record*, May 3, 2017, vol. 163, no. 76—Book III, H3952, and *Congressional Record*, March 22, 2018, vol. 164, no.50—Book III, H2701.

[99] H.Rept. 115-952, p. 529.

[100] HHS, "Obama Administration Presents National Plan to Fight Alzheimer's Disease," press release, May 15, 2012, https://aspe.hhs.gov/obama-administration-presents-national-plan-fight-alzheimers-disease.

[101] HHS, *National Plan to Address Alzheimer's Disease*, 2012, p. 6, https://aspe.hhs.gov/system/files/pdf/102526/NatlPlan2012%20with%20Note.pdf.

[102] National Institutes of Health, *Reaching for a cure: Alzheimer's Disease and Related Dementias Research at NIH, Bypass Budget Proposal for Fiscal Year 2017*, July 27, 2015, https://www.nia.nih.gov/sites/default/files/2017-07/reaching-for-a-cure-alzheimers-disease-and-related-dementias-research-at-nih.pdf.

[103] National Institutes of Health, *Open Science, Big Data, and You: Working Together to Treat and Prevent Alzheimer's Disease and Related Dementias. NIH Bypass Budget Proposal for Fiscal Year 2020.*, July 30, 2018, https://www.nia.nih.gov/sites/default/files/2018-07/fy2020-bypass-budget-report-final.pdf.

> year's [FY2018] $414 million bolus—a sum that equals the entire budget of some smaller NIH institutes—which Congress approved in March.
>
> NIA, which oversees the new funds, doesn't just want to plump up existing Alzheimer's labs, says Director Richard Hodes. The institute is also luring investigators...from other fields to bring in fresh ideas. Many are answering the call. "Nearly everyone I know is putting the words 'Alzheimer's disease' in their grants in an effort to tap into the money," says Matt Kaeberlein of the University of Washington in Seattle, who studies aging.[104]

Even with the windfall of funding, many in the scientific community are skeptical of meeting the goal to prevent and treat Alzheimer's disease by 2025. Many potential cures for Alzheimer's diseases have failed in recent clinical trials.[105] According to a 2016 study, a few drugs have been approved that help relieve some of the symptoms of Alzheimer's disease, but they have a "modest" clinical effect. The authors determined that only a few drug candidates in the clinical trial pipeline could potentially meet the 2025 deadline.[106] While the funding has helped accelerate the scientific understanding of Alzheimer's disease, some members of the scientific community worry that the attention on Alzheimer's disease research may detract from research on other diseases like cancer. Others argue that accelerating Alzheimer's disease research and drug development is ultimately beneficial, regardless of whether the 2025 goal is met.[107]

## Research Restrictions

From time to time, Congress has placed restrictions on NIH research. Current restrictions for FY2019 relate to research advocating or promoting gun control, payment for abortions, human embryo research, promoting legalization of controlled substances, and others.[108] In the past, members of the research community have been unsettled by congressional attempts to cancel funding for specific existing peer-reviewed grants.[109] The targeted studies have tended to be in fields of behavioral research, including some in mental health and human sexuality research. Sponsors and supporters of such amendments to the LHHS appropriations bills say that NIH should not be devoting scarce resources to research studies whose value they question. Researchers, however, including NIH leadership, have expressed alarm at what they view as an assault on the peer review system, saying that such studies were funded because of their technical merit and the important research questions they addressed.[110] Perhaps the most prominent example is the restriction on federal funding of research on human embryonic stem cells. Although President Barack Obama signed an executive order in March 2009 that reversed the nearly eight-year-old George W. Bush Administration restriction on federal funding for human embryonic stem cell research, funding for some aspects of such research is still limited by a provision in the annual LHHS appropriations bill—the so-called Dickey-Wicker amendment.[111]

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[104] Jocelyn Kaiser, "The Alzheimer's Gamble," *Science*, August 31, 2018, http://science.sciencemag.org/content/361/6405/838.

[105] Ibid.

[106] Jeffrey Cummings, Paul S. Aisen, Bruno DuBois, et al., "Drug Development in Alzheimer's Disease: The Path to 2025," *Alzheimer's Research and Therapy*, vol. 8, no. 39 (2016).

[107] Jocelyn Kaiser, "The Alzheimer's Gamble," *Science*, August 31, 2018, http://science.sciencemag.org/content/361/6405/838.

[108] NIH, "Notice of Legislative Mandates in Effect for FY 2019," from https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-030.html.

[109] Jocelyn Kaiser, "House 'Peer Review' Kills Two NIH Grants," *Science*, vol. 309 (July 1, 2005), pp. 29-31.

[110] Ibid.

[111] For further information, see CRS Report RL33540, *Stem Cell Research: Science, Federal Research Funding, and*

## Cures Acceleration Network

The Cures Acceleration Network (CAN) allows NIH to award large grants of up to $15 million per year (that require a 1:3 matching ratio), and other flexible awards, to "advance the development of high-need cures and reduce significant barriers between research discovery and clinical trials."[112] CAN grant recipients can be public or private entities, including institutions of higher education, pharmaceutical companies, and disease advocacy organizations.[113]

Authorizing language for the Cures Acceleration Network was provided in the Patient Protection and Affordable Care Act (ACA; P.L. 111-148), enacted in March 2010. Subsequent legislation (P.L. 112-74) assigned CAN to NIH's National Center for Advancing Translational Science (NCATS).[114] ACA authorized $500 million for CAN in FY2010 and such sums as necessary for subsequent fiscal years; however, CAN is to be funded via a specific appropriation and cannot be funded using the general NIH appropriation or other funds appropriated under the PHSA. Congress has designated up to the following amounts for CAN in its appropriations to NCATS: $10 million in FY2012; $40 million in FY2013; $9.8 million in FY2014; $9.8 million in FY2015; $25.8 million in each of FY2016, FY2017, and FY2018, respectively; and $80 million in FY2019.[115] The actual program level for CAN may be lower than the maximum amount authorized by Congress for each fiscal year, though actual funding levels are available only for some, but not all, fiscal years.[116]

CAN authorizing language states that the NIH Director determines which medical products (drugs, devices, biological products, or combination products) are "high need cures," based on (1) their ability to diagnose, prevent, or treat harm from a disease or condition, and (2) the lack of market incentives for their adequate or timely development. NIH then makes awards to public or private research entities, including medical centers, biotechnology or pharmaceutical companies, and patient advocacy groups in order to accelerate the development of such high-need cures.[117] CAN is directed to conduct and support revolutionary advances in basic research and to facilitate FDA review for CAN-funded cures, as specified. A CAN Review Board advises the Director on the activities of CAN and on significant barriers to the translation of basic science into clinical applications. The CAN Review Board submits reports to HHS regarding any barrier identified. The Director is required to respond to such recommendations in writing. Advocacy groups, such as the Parkinson's Action Network and the Council for American Medical Innovation, have voiced strong support for the creation of CAN. Others, however, have concerns about providing federal funds to industry without measures to ensure that taxpayers receive a return on the investment, such as through reasonable prices on resulting products.[118]

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*Regulatory Oversight*.

[112] NCATS, "Cures Acceleration Network," https://ncats.nih.gov/funding/review/can.

[113] PHSA §480(e)(2).

[114] The Patient Protection and Affordable Care Act (ACA, P.L. 111-148) amended the PHS Act by adding Section 402C, which was subsequently renumbered as PHS Act Section 480 and amended by the Consolidated Appropriations Act, 2012 (P.L. 112-74, Division F, Title II, Section 221(c)(1)) on December 23, 2011.

[115] Based on CRS review of language in enacted appropriations legislation for each fiscal year cited.

[116] Ibid.

[117] ACA specified three different CAN awards. The *Cures Acceleration Partnership Awards* provide up to $15 million for the first year with a matching requirement; eligible entities must provide nonfederal matching funds of $1 for every $3 funded by CAN. *The Cures Acceleration Grant Awards* are similar but have no matching requirement. The *Cures Acceleration Flexible Research Awards* would be available if the Director determined that the goals of CAN could not be met otherwise, and would consist of awards not to exceed 20% of the total funds appropriated for CAN.

[118] Alyah Khan, "Proposal to Expedite Product Development Makes Senate Health Bill," *Inside Health Policy—Inside*

In the summer of 2018, the Cures Acceleration Network was actively supporting three programs: (1) tissue chip for drug screening, (2) biomedical data translator, and (3) 3-D tissue bioprinting. The programs are aimed at using emerging technology, such as modelling human organs on microchips or using novel computational methods with patient biomedical data, for innovating either drug development or disease diagnosis.[119]

## 21st Century Cures Act

The 21st Century Cures Act (P.L. 114-255; hereinafter referred to as the "Cures Act") was signed into law on December 13, 2016. This law authorizes $4.8 billion for NIH over a 10-year period (FY2017-FY2026), with varying amounts allocated each fiscal year (see **Table 1**).[120] The following is a summary of provisions in Title I of the Cures Act that authorized funding for new programs at NIH, and provisions in Title II that established or amended other programs.

Title I of the Cures Act, Section 1001 establishes the "NIH Innovation Account" to which specified amounts are authorized to be transferred for each of FY2017 through FY2026 (see **Table 1**) for the purpose of carrying out the following four NIH Innovation Projects:

- The Precision Medicine Initiative (PMI) *All of Us* Research Program ($1.5 billion for FY2017 through FY2026), which is collecting clinical, environmental, lifestyle, and genetic data from more than 1 million participants over many years.
- The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative ($1.5 billion for FY2017 through FY2026), which uses new technology to understand how individual cells and the neural circuits they form interact in time and space—scientific understanding that may help treat, cure, or prevent brain-related disorders.
- The *Beau Biden Cancer Moonshot* ($1.8 billion for FY2017 through FY2023), which aims to accelerate progress in cancer research by enhancing data access and facilitating collaborations.
- The Regenerative Medicine project ($30 million for FY2017 through FY2020), which supports clinical research using adult stem cells, in coordination with FDA.

To date, amounts authorized for the Innovation Projects have been fully appropriated. The first round of funding was provided by Section 194 of the Further Continuing and Security Assistance Appropriations Act, 2017 (CR, P.L. 114-254). The CR appropriated $352 million in the NIH Innovation account for necessary expenses to carry out the four NIH Innovation Projects as described in Section 1001(b)(4) of the Cures Act. The second round of funding ($496 million) was provided by the FY2018 omnibus (P.L. 115-141). The third round of funding ($711 million) is provided by the FY2019 Consolidated Defense, LHHS, and Continuing Resolution Appropriations Act (P.L. 115-245). Under President Trump's FY2020 budget request, NIH would be provided the full $492 million authorized by the Cures Act for FY2020.[121]

*Health Reform*, January 6, 2010.

[119] NCATS, *Cures Acceleration Network*, 2018, https://ncats.nih.gov/files/CAN-fact-sheet.pdf.

[120] This section is adapted from CRS Report R44720, *The 21st Century Cures Act (Division A of P.L. 114-255)*.

[121] HHS, Budget in Brief- FY2020, https://www.hhs.gov/sites/default/files/fy-2020-budget-in-brief.pdf, p. 53.

**Table 1. Authorization of Appropriations for NIH Innovation Projects Under the Cures Act**

Millions of dollars

| Fiscal Year | PMI | BRAIN | Cancer Moonshot | Regenerative Medicine | Total Innovation Account |
|---|---|---|---|---|---|
| 2017 | 40 | 10 | 300 | 2 | 352 |
| 2018 | 100 | 86 | 300 | 10 | 496 |
| 2019 | 186 | 115 | 400 | 10 | 711 |
| 2020 | 149 | 140 | 195 | 8 | 492 |
| 2021 | 109 | 100 | 195 | | 404 |
| 2022 | 150 | 152 | 194 | | 496 |
| 2023 | 419 | 450 | 216 | | 1,085 |
| 2024 | 235 | 172 | | | 407 |
| 2025 | 36 | 91 | | | 127 |
| 2026 | 31 | 195 | | | 226 |
| **TOTAL** | **1,455** | **1,511** | **1,800** | **30** | **4,766** |

**Source:** P.L. 114-255, Sec. 1001(b)(4).

Title II of the Cures Act addresses the NIH in numerous ways, including administrative reforms and new programs. Among new programs in Title II, the Next Generation Initiative (NGI) was established to coordinate NIH programs related to retaining and recruiting new researchers. As a part of NGI, NIH is required to use findings from a National Academies report to make reforms to existing programs (see "NIH Initiatives to Recruit and Retain a Research Workforce"). Title II also includes reforms to ensure inclusion in biomedical research, as related to race/ethnicity, gender, sexual orientation, and age. Finally, Title II extends NCATS's authority to support clinical trial activities, consolidates existing NIH intramural loan repayment programs, specifies administrative requirements for PMI and ClinicalTrials.gov, and establishes a working group to make recommendations to enhance the rigor and reproducibility of NIH-funded scientific research, among other provisions.

## NIH Process in Setting Research Priorities

Each NIH IC has separate research priorities, which are specified in statutory authority in varying levels of detail.[122] IC research priorities are broadly captured by their mission statements.[123] ICs establish research priorities through strategic planning, annual planning, and periodically reviewing and assessing their research portfolios. Each IC has an advisory council that makes recommendations for IC research priorities and funding decisions. The IC advisory councils are made up of both scientific and public representatives, who may have expertise, interest, and other affiliations relevant to the IC's mission.[124] According to the agency, decision-makers at NIH seek

[122] Title IV of PHSA includes statutory authorities for all NIH ICs. See "Authority" section.

[123] NIH, Report of the Director National Institutes of Health: Fiscal Years 2014 & 2015, pp. 389-390, at https://report.nih.gov/biennialreport/NIH_Biennial_Report_2014-15_non508.pdf.

[124] NASEM, "Coordination of Research Priorities- National Institutes of Health," in *Evaluation of the Congressionally*

advice from many groups when setting research priorities, including scientific researchers and professional science societies; patient organizations and voluntary health associations; IC Advisory Councils; Congress and the Administration; the Advisory Committee to the NIH Director; the SMRB; and NIH staff.[125]

For many years, each IC has undergone a periodic strategic planning process to determine its funding priorities among the research areas in its broadly defined mission.[126] The IC strategic planning processes are conducted pursuant to PHSA Section 402(b)(5), which specifies that the NIH Director "shall ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health."[127] The Cures Act (P.L. 114-255) amended PHSA Section 402 to require an NIH-Wide Strategic Plan, in part to facilitate IC collaboration and coordination.[128]

In the first NIH-Wide Strategic Plan 2016-2020, the NIH specifies its agency-wide process for setting research priorities. As stated in the Strategic Plan, "The process of setting NIH's research priorities must balance the opportunities presented by the best science, public health needs, and the unique ability of NIH to address challenges in human health that would otherwise go unmet."[129] In its Strategic Plan, the NIH reaffirmed its commitment to a transparent and evidence-based process for funding decisions that prioritized the four principles listed below. NIH does not specify percentages or funding amounts for any of the four principles:

- Enhance the nimbleness needed to meet public health needs and capitalize upon scientific opportunity, using new portfolio analysis tools.
- Incorporate burden of disease as an important, but not sole, factor.
- Take advantage of opportunities presented by rare diseases to advance research.
- Consider the value of permanently eradicating a disease.[130]

The NIH-Wide Strategic Plan is designed to complement the strategic plans of the individual ICs. The agency seeks to better identify areas of research overlap and gaps across its portfolios, including by comparing the portfolio of each IC with another to assess if resources are optimally allocated. In addition, the Strategic Plan also stated that NIH would take leadership in "developing and validating the methodologies that are needed to evaluate scientific investments."[131]

According to NIH, the Strategic Plan was developed with "input from hundreds of stakeholders and scientific advisers, and in collaboration with leadership and staff of NIH's Institutes, Centers, and Offices."[132] The NIH Reform Act of 2006 (P.L. 109-482) enhanced the authority of the NIH Director's Office to perform strategic planning, especially facilitating and funding

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*Directed Medical Research Programs Review Process* (Washington, DC: National Academies Press, 2016), pp. 102-103.

[125] NIH, "NIH Research Planning," https://www.nih.gov/about-nih/nih-research-planning.

[126] Each individual IC strategic plan specifies its planning process; from NIH, "NIH Strategic Plans and Visions," at https://report.nih.gov/strategicplans/index.aspx.

[127] 42 U.S.C. §282(b)(5).

[128] 42 U.S.C. §282(m).

[129] National Institutes of Health, *NIH-Wide Strategic Plan: Fiscal Years 2016-2020*, https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2016-2020-508.pdf. p. 28

[130] Ibid., pp. 29-31.

[131] Ibid., p. 42

[132] NIH, "NIH-Wide Strategic Plan," 2015, https://www.nih.gov/about-nih/nih-wide-strategic-plan.

transdisciplinary, cross-institute research initiatives. The Reform Act also created a special office, the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI). It "identifies important areas of emerging scientific opportunity or rising public health challenges to assist in the acceleration of research investments in these areas."[133] The Office of Strategic Coordination within DPCPSI manages the NIH Common Fund, which supports large complex research efforts that involve the collaboration of two or more research institutes or centers. The Office of Strategic Coordination works with staff and leadership across NIH to identify and promote NIH-wide scientific opportunities that receive Common Fund support.[134]

# Balancing New and Existing Funding Commitments

Because of variation in annual appropriations, NIH cannot support the same number of research projects from year to year. In years of large funding increases, the agency may proportionally increase research awards. When funding is cut the agency may limit the number of research grants awarded. Given that most grants are multiyear grants that have "non-competing" status during the duration of the project, much of NIH funding is committed even before appropriations are finalized (though these grant renewals remain "subject to appropriations"). Reductions in NIH purchasing power may lead to reductions in "competing" grants awarded, or grants for new research projects—potentially creating a more competitive environment for new NIH awards.

**Figure 5** shows NIH research project grant (RPG) numbers and success rates for new grant applications annually from FY2003 to FY2018. NIH supported about the same total number of RPGs each year from FY2003 to FY2008, but it supported fewer RPGs after FY2008 and has only started to increase the annual number of RPGs awarded in FY2016. Concurrently, the average cost of an RPG has increased from $337.8 thousand in 2003 to $518.0 thousand in 2018. To maintain existing funding commitments, NIH mostly maintained the number of noncompeting grants from year to year, while cutting back on awarding competing project grants from FY2009 to FY2015—grants that fund new research projects.

Success rates for grant applications, or the percentage of applications that received funding, has also varied from year to year—likely due to a combination of decreased purchasing power as well as an increasing pool of applicants. As shown in **Figure 5**, the success rate for new grant applications was 30% in FY2003, fell to a low of 17% in FY2013, and rose to 21% in FY2018.[135] The decrease in purchasing power—22% lower in FY2013 than in FY2003— may have curtailed NIH's ability to support new projects, and therefore reduced the proportion of grant applicants who received funding.[136] In addition, though the number of competing grants awarded by NIH in FY2016 returned to above FY2007 levels, the success rate for applicants was lower in FY2016-FY2018 than prior to FY2007. The decline in success rates therefore also reflects a growing pool of investigators who are competing for NIH funding. In FY2003, NIH received 34,710 applications for RPGs, which rose to 49,581 applications in FY2013 and then to 54,834 in FY2018. The number of applications rose by 58% between FY2003 and FY2018.[137]

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[133] NIH, "NIH Research Planning," http://www.nih.gov/about/researchplanning.htm.

[134] NIH, "Office of Strategic Coordination- The Common Fund," http://dpcpsi.nih.gov/osc/.

[135] NIH, *Justification of Estimates for Appropriations Committees, FY2012, Vol. I, Overview*, table on "Research Project Grants: Success Rates, FY2003-FY2012," p. OA-47, at http://officeofbudget.od.nih.gov/pdfs/FY12/Tab%202%20Overall%20Appropriations.pdf.

[136] NIH, *FY2019 Congress Justification, Vol. I, Overview*, table on "Research Project Grants: Success Rates," p. 97, https://officeofbudget.od.nih.gov/pdfs/FY19/br/Overview.pdf.

[137] NIH, "NIH Data Book- Success Rates: R01-Equivalent and Research Project Grants," 2019, https://report.nih.gov/nihdatabook/category/10.

The average success rate at NIH reflects varying success rates for applications to different ICs. Success rates for the various ICs in FY2018 range from 10.3% for the National Institute of Nursing Research (NINR) and 10.7% for the National Institute on Minority Health and Health Disparities (NIMHD), at the low end, to 34.8% for the National Center for Advancing Translational Sciences (NCATS) and 33.3% for the National Institute on Drug Abuse (NIDA), at the high end.

*Science* editor-in-chief, Jeremy Berg argues that variation in funding from year to year may affect scientific progress:

> Such fluctuations have important consequences. Outstanding applications that would have been funded one year go unsupported the next year, so that potentially ground-breaking research may be missed for arbitrary reasons of timing. Low success rates result in scientists spending more time writing and reviewing proposals instead of conducting research. Investigators, particularly those at vulnerable career stages, can become demoralized by the apparently capricious nature of funding decisions.[138]

Members of the scientific community have called for steady, predictable annual growth in NIH funding; a long-term strategy for federal research investment; and greater increases in federal funding for biomedical research.[139]

Some argue that research institutions and universities have become too reliant on NIH funding. In 2017, federal dollars made up about 60% of all funding to higher education institutions for "biological and biomedical sciences research," and 53% of all funding for "health sciences" research.[140] One commentary, published in 2018, explored how universities rely on NIH funding for researchers' salaries and laboratory facilities. During the doubling period of NIH funding from 2000 to 2004, universities rapidly increased square footage of laboratory space and hired more scientists—possibly assuming future increases in NIH funds to support their growth. The growth in laboratories heightened the need and competition for NIH grants. According to the author, universities have switched to mostly financing researchers' salaries with grant funds in the past few decades. In the 1970s, universities paid about 75% of researchers' salaries; in 2014, many researchers received, on average, 65% of their salary from grants (based on available evidence; many universities do not share salary data).[141]

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[138] Jeremy Berg, "Benefits of Steady Growth," *Science*, vol. 353, no. 6302 (August 26, 2016), p. 849.

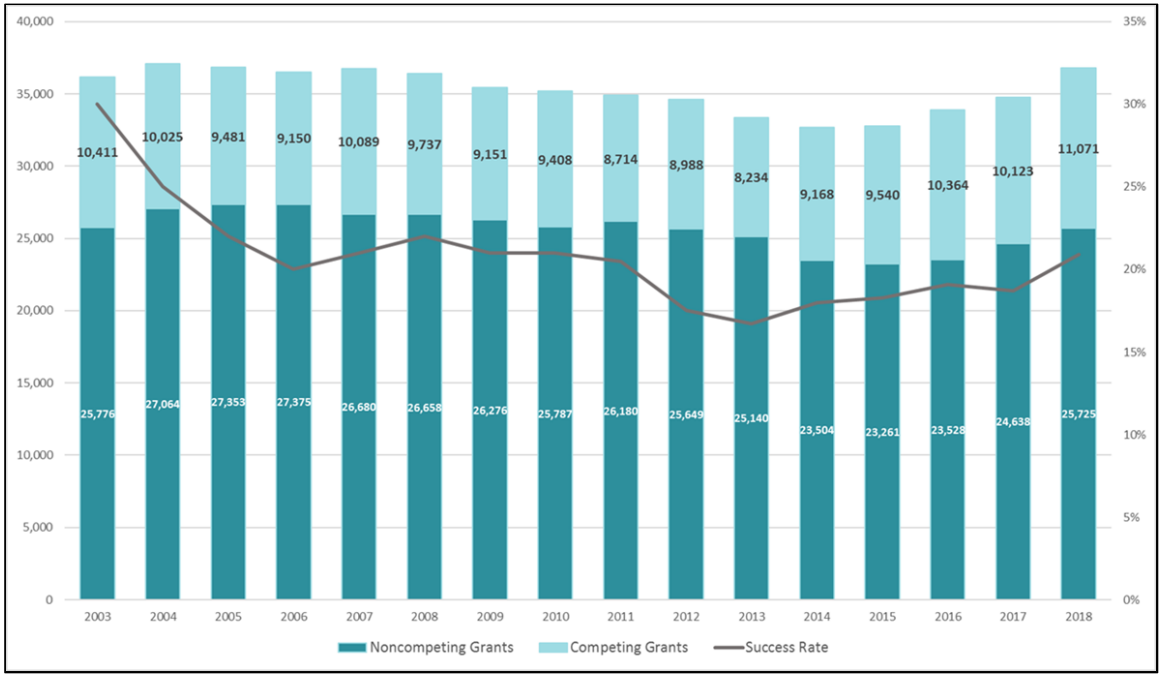
[139] Ibid.; Victor J. Dzau and Harvey V. Fineberg, "Restore the US Lead in Biomedical Research," *Journal of the American Medical Association*, vol. 313, no. 2 (January 13, 2015), pp. 143-144; and Christopher L. Pickett, Benjamin W. Corb, Robert Matthews, et al., "Toward a Sustainable Biomedical Research Enterprise: Finding Consensus and Implementing Recommendations," *Proceedings of the National Academy of Sciences*, vol. 112, no. 35 (2015), pp. 10832-10836.

[140] CRS analysis using data from National Science Foundation (NSF), "Table 12-Higher Education R&D expenditures by selected area by source of funds and R&D field: FY2017," *Higher Education Research and Development Survey, Fiscal Year 2017,* https://ncsesdata.nsf.gov/herd/2017/.

[141] Based on analysis of salaries for researchers who primarily conduct research. Some researchers who earn a significant portion of their salary from clinical activities earn a much smaller portion of their salaries from NIH funding. (From Henry R. Bourne, "Expansion Fever and Soft Money Plague the Biomedical Research Enterprise"" *Proceedings of the National Academy of Sciences*, vol. 115, no. 35 [2018], pp. 8647-8651).

**Figure 5. Research Project Grants (RPG) Awarded by NIH and Success Rates**

FY2003-FY2018




**Source:** Developed by CRS using data from NIH, "Actual Total Obligations by Budget Mechanism: FY2000-FY2018," https://officeofbudget.od.nih.gov/spending_hist.html; NIH, "FY 2020 Budget Request- Supplementary Tables," pp. 80-90, and NIH, "FY2011 Budget Request- Tabular Data," https://officeofbudget.od.nih.gov/pdfs/FY11/Tabular%20Data.pdf.

As a result of reliance on competitive grant funding, researchers are spending increasing amounts of their time writing grant applications rather than conducting science. The author argues that universities should commit more of their "hard money," or institutional funds, for research salaries and facilities to ensure the sustainability of biomedical research.[142]

NIH Director Francis Collins alluded to this issue in a January 2010 interview, stating that universities are "becoming too reliant on NIH money, allowing faculty members to obtain all their income from federal research grants."[143] Dr. Collins indicated that when faculty members run multiple research projects at the same time, "that turns that investigator into a grant-writing machine perhaps more than a doing-of-science machine."[144] However, he said, any new restrictions on NIH grants "would have to be phased in over a fairly long period of time because many universities and faculty members would find that quite disruptive."[145]President Trump's FY2018, FY2019, and FY2020 budget proposals have included initiatives designed to "stretch available grant dollars." The FY2018 budget proposal would cap the indirect costs that could be covered by NIH grants (facilities and administrative—or F&A—costs) at 10% of the total grant award to reduce the overall cost of an RPG. Over the previous 10 years, approximately 28% of grants were used to cover F&A costs. Both the House and Senate Appropriations Committees rejected the proposal to cap F&A costs. The report accompanying H.R. 3358 (H.Rept. 115-244) stated that the Trump Administration's proposed cap on indirect (F&A) costs was "misguided and would have a devastating impact on biomedical research across the country."[146] The FY2019 budget request proposed capping the percentage of an investigator's salary that can be paid with grant funds at 90%. It also proposed capping investigator salaries at $152,000, a 19% reduction from the current $187,000 limit. In the report accompanying H.R. 6470, the House Appropriations Committee stated that it did not include the general provision in the budget request to limit the percentage of a researcher's salary that may be paid for using NIH grant funds, as the impact of such a change is unclear. The report stated, "The Committee requests an analysis of the projected impact of such a policy change on the number and average cost of NIH grants, as well as on academic institutions, in the fiscal year 2020 Congressional Justification"[147]

The FY2020 budget request, again, included the proposal to cap the percentage of an investigator's salary that can be paid with grant funds at 90%.[148] In the requested analysis published in the FY2020 Congressional Justification, NIH stated that "no previous research examines the impact of reducing the salary cap on the number of grants and the average cost per grant."[149] NIH noted that a salary cap reduction in FY2011 did not reduce the average cost of NIH grants and that the number of NIH grants awarded decreased, though other factors may have affected grant numbers and average costs. NIH also noted that an unintended consequence of the policy could be that institutions will have to make up for the rest of researchers' salaries, which

[142] Henry R. Bourne, "Expansion Fever and Soft Money Plague the Biomedical Research Enterprise," *Proceedings of the National Academy of Sciences*, vol. 115, no. 35 (2018), pp. 8647-8651.

[143] Paul Basken, "NIH Will Give Less and Demand More in 2010, New Leader Says," *The Chronicle of Higher Education*, January 17, 2010.

[144] Ibid.

[145] Ibid.

[146] See CRS Report R44888, *Federal Research and Development Funding: FY2018*, National Institutes of Health section.

[147] See CRS Report R45150, *Federal Research and Development (R&D) Funding: FY2019*, National Institutes of Health section

[148] NIH, "Congressional Budget Justification FY2020- Overview, Vol I," p. 13.

[149] NIH, "Congressional Budget Justification FY2020- Significant Items," p. 33.

"may limit the number of applicants with sufficient resources to participate in Federally-funded research."[150]

# NIH Initiatives to Recruit and Retain a Research Workforce

NIH is concerned about retaining and attracting new scientists for biomedical research careers.[151] In the past two decades, early-stage scientists have received a declining percentage of NIH grants and have spent more time in low-paid postdoctoral training positions.[152] The number of traditional faculty positions in biomedical research has declined, while the number of postdoctoral positions has increased, creating a highly competitive and pessimistic outlook for obtaining traditional academic research positions.[153] A 2018 National Academies of Sciences, Engineering and Medicine (NASEM) report stated that, "these obstacles to success have created a research career path that is increasingly unattractive in terms of pay, duration, culture, risk-taking, and future job prospects."[154]

A relatively large portion of NIH funding goes to older and more established researchers. Between 1998 and 2014, the proportion of NIH-funded investigators over the age of 65 increased from 5% to 12%, while those younger than 50 declined from 54% to 39%.[155] The average age at which an investigator first obtained an independent grant increased by more than five years between 1990 and 2016. During that time, the average age at which a new investigator first obtained a R01 grant (independent research project grant) increased from 36 years for PhDs and 38 years for MDs, to 42 years for PhDs and 45 years for MDs, respectively.[156] Another analysis from the NIH Office of Extramural Research also found that the percentage of the NIH workforce made up of new investigators and early-stage investigators had declined between 2009 and 2016.[157]

In addition, the success rate for new investigators fell from 40% in 1962 to 27% in 2013.[158] A 2018 GAO analysis found that "extramural investigators who had received at least one large NIH

[150] Ibid., p. 33.

[151] See, for example, the testimony of NIH Director Francis S. Collins, "Driving Innovation through Federal Investments," appearing before the Senate Appropriations Committee, hearing, April 29, 2014, http://www.nih.gov/about/director/congressionalhearings/04292014drivinginnovation.htm.

[152] Ron Daniels and Victor Dzau, "Supporting the Next Generation of Biomedical Researchers," *Journal of the American Medical Association*, vol. 320, no.1 (July 3, 2018) p. 29-30.

[153] Sara Frueh, "The Postdoctoral Experience," *The National Academies in Focus*, vol. 15 (Spring 2015) p. 8. Trends at NIH are similar to trends for many academic fields; see Laura McKenna, "The Ever-Tightening Job Market for PhDs," *The Atlantic*, April 21, 2016, https://www.theatlantic.com/education/archive/2016/04/bad-job-market-phds/479205/.

[154] Ronald Daniels, Lisa Beninson, and Committee on the Next Generation Initiative, *Breaking Through: The Next Generation of Biomedical and Behavioral Sciences Researchers*, National Academies of Science, Engineering, and Medicine, Washington, DC, 2018, p. 2, https://www.nap.edu/read/25008/chapter/1#ii.

[155] Ron Daniels and Victor Dzau, "Supporting the Next Generation of Biomedical Researchers," *Journal of the American Medical Association*, vol. 320, no.1 (July 3, 2018) p.29-30.

[156] NIH, Office of Extramural Research, *Early Stage and Early Established Investigator Policies*, Grants & Funding, https://grants.nih.gov/policy/early-investigators/index.htm#data, updated August 29, 2017.

[157] Silda Nikaj, Deepshikha Roychowdhury, P. Kay Lund, et al., "Examining Trends in Diversity of the U.S. National Institutes of Health Participating and Funded Workforce," *The FASEB Journal*, vol. 32 (2018).

[158] Ibid.

research grant during fiscal years 2013 through 2017 were more likely to receive such grants in subsequent application cycles than investigators who had not yet received such grants."[159]

According to a 2017 study, a minority of highly funded researchers have received an increasing percentage of NIH grants in recent years.[160] In 2015, the top 10% of NIH grant winners by total award received 37% of NIH funding, an increase from the 32% received in 1985, but down from a peak of 40% of total funding in 2010.[161] In contrast, the bottom 40% of principal investigators received 12% of total funding in 2015, down from 16% in 1985. Of note, 2010 and 2015 were years of low funding growth, and therefore NIH might have been expected to make fewer new grant commitments to new investigators in these years, in order to sustain funding for ongoing research. In addition, the authors of the study described a lack of mobility for investigators. They concluded that researchers who start at the top tend to remain there, while researchers receiving a lower portion of funding remain poorly funded. Scientists in the top 20% of funding have more publications and citations, which may help explain grant success.[162]

As previously mentioned, the 21st Century Cures Act (P.L. 114-255) established the Next Generation of Researchers Initiative (NGRI) within the office of the NIH Director. This initiative is intended to provide opportunities for earlier independence while enhancing workforce diversity. Superseding previous policy on early-stage investigators, it requires the NIH Director to develop new policies and programs that promote opportunities for new researchers to receive funding, enhance training, and encourage workforce diversity.

NIH has faced challenges in attempting to implement NGRI. In May 2017, NIH proposed to cap funding for highly funded investigators through a measure termed the Grant Support Index (GSI) to free up funding to early-stage investigators and others who receive less funding.[163] Some members of the scientific community strongly opposed the GSI, arguing that it represented a move away from a merit-based system of allocating funding, would discourage collaboration and training, and was based on flawed analysis.[164] Others argued that the highly funded researchers and institutions who would be affected by the policy could afford to diversify their funding sources.[165] Ultimately, NIH cancelled the proposal after facing criticism at a Council of Councils meeting.[166]

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[159] U.S. Government Accountability Office, *NIH Research: Action Needed to Ensure Workforce Diversity Strategic Goals Are Achieved*, 18-545, August 2018, pp. 17-19, https://www.gao.gov/assets/700/693872.pdf.

[160] Yarden Katz and Ulrich Matter, *On the Biomedical Elite: Inequality and Stasis in Scientific Knowledge Production*, Berkman Klein Center for Internet & Society at Harvard University, July 11, 2017, pp. 1-22.

[161] Maggie Kuo, "Relatively few NIH grantees get lion's share of agency's funding," *Science*, July 18, 2017, http://www.sciencemag.org/news/2017/07/relatively-few-nih-grantees-get-lion-s-share-agency-s-funding.

[162] Ibid.

[163] NIH Extramural News, "Implementing Limits on Grant Support to Strengthen the Biomedical Research Workforce," May, 2, 2017, https://nexus.od.nih.gov/all/2017/05/02/nih-grant-support-index/.

[164] Derek Lowe, "Changes in NIH Grant Policy?," *Science Translational Medicine*, May 11, 2017, http://blogs.sciencemag.org/pipeline/archives/2017/05/11/changes-in-nih-grant-policy; and Shane Crotty, "The new NIH 'Rule of 21' Threatens to Give Up on American Preeminence in Biomedical Research Based on a Flawed Concept and Flawed Analysis," *Medium*, June 8, 2017, https://medium.com/@shane_52681/the-new-nih-rule-of-21-threatens-to-give-up-on-american-preeminence-in-biomedical-research-based-c40060bd3022.

[165] "Which Institutions May be Hardest Hit by the Proposed NIH Funding Cap?," *Future of Research*, June 1, 2017, http://www.futureofresearch.org/2017/06/01/which-institutions-may-be-hardest-hit-by-the-proposed-nih-funding-cap/.

[166] Jocelyn Kaiser, "Updated: NIH Abandons Controversial Plan to Cap Grants to Big Labs, Creates New Fund for Younger Scientists," *Science*, June 8, 2017, http://www.sciencemag.org/news/2017/06/updated-nih-abandons-controversial-plan-cap-grants-big-labs-creates-new-fund-younger.

As an alternative to GSI, in August 2017 NIH announced the official policy for the NGRI, which called on ICs to prioritize awards that fund early stage investigators (ESI) and early established investigators (EEIs). The policy defined ESIs as those who had completed training within 10 years and were gaining their first independent research award, and EEIs as those who had completed training within 10 years and who were at risk of losing NIH support or were supported only one active award.[167] Through NGRI, NIH would free up "substantial funds" from its base budget to support ESIs and EEIs. NIH announced the program would start with $210 million in FY2017 and increase to $1.1 billion in five years, pending funding availability.[168] NGRI was established to complement existing grant award opportunities that support ESIs and EEIs, such as the New Innovator Award and the Early Independence Award.[169] Under NGRI, ICs would develop evidence-based strategies to increase and retain ESIs/EEIs, and NIH would track their outcomes.[170]

NIH again faced criticism that the program would prioritize ESIs and EEIs at the expense of established investigators, and that the rules for who qualified to be an ESI or EEI were too strict. NIH revised the policy to eliminate the EEI category, instead prioritizing investigators at risk of losing funding regardless of age, and to be "flexible" in designating who qualified for ESI status.[171] NIH has established a working group to advise NIH on NGRI policy development.[172] Despite apparent challenges, NIH Director Francis Collins stated at an August 2018 congressional hearing that the agency expects to fund more early-stage investigators than ever—1,100 researchers— with their first grant in 2018 as a result of NGRI.[173]The FY2020 budget request included further details about NIH plans for NGRI. NIH stated that it regularly collects data and evaluates outcomes on NIH-funded trainees and their transition to an independent career.[174] In addition, the FY2020 budget request would provide $100 million in dedicated funding for NGRI, and the request stated:

> in response to an advisory committee recommendation and a recent report from the National Academy of Sciences, NIH is creating a new pathway for applications from early-stage investigators that does not require preliminary data and continues to provide a separate review of applications. NIH is also lengthening the window for early-stage eligibility to 11 years with additional flexibility due to significant life events.[175]

As referred to in the above quote, in 2018, NASEM published a report that identified policy reforms to better support the next generation of biomedical researchers. NIH was directed to fund

[167] NIH, *Policy Supporting the Next Generation Researchers Initiative*, Notice Number: NOT-OD-17-101, August 31, 2017, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-101.html.

[168] NIH, "Launching the Next Generation Researchers Initiative to Strengthen the Biomedical Research Enterprise," June 8, 2017, https://www.nih.gov/about-nih/who-we-are/nih-director/statements/launching-next-generation-researchers-initiative-strengthen-biomedical-research-enterprise.

[169] NIH, Office of Extramural Research, *Early Stage and Early Established Investigator Policies*, Grants & Funding, https://grants.nih.gov/policy/early-investigators/index.htm#data, updated August 29, 2017.

[170] NIH, "Next General Researchers Initiative," https://grants.nih.gov/ngri.htm.

[171] Jocelyn Kaiser, "NIH Tweaks Plan to Award More Grants to Younger Researchers," *Science*, December 15, 2017, http://www.sciencemag.org/news/2017/12/nih-tweaks-plan-award-more-grants-younger-researchers.

[172] NIH, "Next Generation Researchers Initiative," August 31, 2017, https://grants.nih.gov/ngri.htm.

[173] U.S. Congress, Senate Committee on Health, Education, Labor, and Pensions, *Prioritizing Cures: Science and Stewardship at the National Institutes of Health*, 115th Cong., August 28, 2018. Transcription from Congressional Quarterly, "Senate Health, Education, Labor and Pensions Committee Holds Hearing on Science and Stewardship at NIH," https://plus.cq.com/doc/congressionaltranscripts-5378816?0.

[174] NIH, "Congressional Budget Justification-Overview, Significant Items, FY2020," p. 175.

[175] HHS, "Budget in Brief, FY2020," p. 56, https://www.hhs.gov/sites/default/files/fy-2020-budget-in-brief.pdf.

the report through the FY2016 LHHS Appropriations Act (P.L. 114-113, Division H), and is required by the Cures Act to consider its recommendations and submit a report on actions taken to Congress in 2020. In the 2018 report, the NASEM committee found that while reductions in NIH purchasing power have constrained grant funding available to early-stage investigators, universities and research institutions have been slower to make reforms and less responsive to the needs of early-stage investigators than NIH. For instance, many universities and research institutions may provide inadequate career counseling or job opportunities for new researchers. The NASEM committee therefore recommended policies that hold universities and research institutions accountable alongside the NIH in supporting ESIs, and preparing them for diverse and nonacademic careers. The committee also made recommendations for Congress to create a council on ongoing challenges in biomedical research, and for NIH to strengthen its programs for ESIs, among many others[176]

## Workforce Diversity at NIH

Apart from age and experience, other inequalities also persist in grant funding, such as by gender and race/ethnicity. NIH has found that women and racial and ethnic minorities make up a larger portion of new and early-stage investigators than experienced investigators, and generally make up a larger portion of the applicant pool than the awardee pool for grants.[177] There is also less representation of women and minorities among faculty positions in the biomedical sciences.[178]

On average, women scientists are awarded smaller grant sizes than those awarded to men.[179] One study found that from 1991 to 2010, while women made up half of all PhDs awarded in the biomedical sciences, one-third of first-time NIH research grants were awarded to women investigators.[180] However, after winning their first grant, women were as likely as male scientists to win another grant.[181] The researchers attributed these findings to women dropping out of an academic research career at a higher rate than men in early stages of their career.[182] NIH has found that women tend to get their first grant award at a later age than men; however, the age differences between genders appears to have narrowed in recent years.[183]

From 2002 to 2016, there was a 7.5% to 10.5% gap in funding rates between scientists from underrepresented minority groups compared to those from majority groups.[184] A 2018 GAO analysis of NIH data from 2013 to 2017 found that 17% of investigators from underrepresented racial groups—African Americans, American Indians/Alaska Natives, and Native

[176] National Academies of Sciences, Engineering, and Medicine, *Breaking Through: The Next Generation of Biomedical and Behavioral Sciences Researchers*, National Academies of Science, Engineering, and Medicine, Washington, DC, 2018, p. 5-11.

[177] Silda Nikaj, Deepshikha Roychowdhury, P. Kay Lund, et al., "Examining Trends in Diversity of the U.S. National Institutes of Health Participating and Funded Workforce," *The FASEB Journal*, vol. 32 (2018).

[178] Ron Daniels and Victor Dzau, "Supporting the Next Generation of Biomedical Researchers," *Journal of the American Medical Association*, vol. 320, no.1 (July 3, 2018) p.29-30.

[179] Ron Daniels and Victor Dzau, "Supporting the Next Generation of Biomedical Researchers," *Journal of the American Medical Association*, vol. 320, no.1(July 3, 2018)p.29-30

[180] Holly Else, "Leaky Pipeline for Women Scientists Dries Up After They Win First Big Grant," *Nature News*, July 18, 2018.

[181] Ibid.

[182] Ibid.

[183] Silda Nikaj, Deepshikha Roychowdhury, P. Kay Lund, et al., "Examining Trends in Diversity of the U.S. National Institutes of Health Participating and Funded Workforce," *The FASEB Journal*, vol. 32 (2018).

[184] Ibid.

Hawaiian/Pacific Islanders combined—who applied for large grants received them, compared to 24% of Hispanic or Latino applicants, 24% of Asian applicants, and 27% of white applicants.[185] In addition, the percentage of underrepresented minorities in the NIH grant applicant pool increased from 2002 to 2016.[186]

GAO noted that NIH has taken steps to support a diverse workforce, such as by hiring a Chief Officer of Scientific Workforce Diversity, who then created a workforce diversity strategic plan.[187]GAO found that although NIH has developed initiatives for diversity, these programs have not been evaluated and that the programs do not have adequate performance measures to track their success. NIH diversity initiatives have included bias training for the intramural hiring committees, training and fellowship opportunities targeted at underrepresented groups, and ongoing career development, such as mentoring and conferences, for scientists from underrepresented groups.[188]

# U.S. vs. Global Research

While the United States remains the lead funder of research and development, other countries—particularly China— have increased public funding for research in recent years. A 2015 study compared investment in biomedical research in the United States and in other developed countries. It found that U.S. government research funding declined from 57% (2004) to 49% (2011) of the global total, as did that of U.S. companies (50% to 41%), with the total U.S. (public plus private) share of global research funding declining from 57% to 44%. Asian countries (China, Japan, South Korea, India and, Singapore) increased investment from $28 billion (2004) to $52.4 billion (2011).[189] China, in particular, almost quadrupled funding on medical research, from $2 billion in 2007 to $8.4 billion in 2012.[190] Globally, the United States continues to be the top supporter of research and development.[191] NIH is the top non-industry (governmental or philanthropic) single funder of health research in the world.[192]

The growth in international biomedical research can lead to certain benefits shared globally—such as a larger pool of scientists across the world contributing to new knowledge and medical innovations. However, more research and development in other countries also means more competition for U.S. industries. In 2011, the United States led the world in publication of biomedical research articles—accounting for 33% of articles published. However, in 2011, China

[185] U.S. Government Accountability Office, *NIH Research: Action Needed to Ensure Workforce Diversity Strategic Goals Are Achieved*, 18-545, August 2018, pp. 17-19, https://www.gao.gov/assets/700/693872.pdf.

[186] Silda Nikaj, Deepshikha Roychowdhury, P. Kay Lund, et al., "Examining Trends in Diversity of the U.S. National Institutes of Health Participating and Funded Workforce," *The FASEB Journal*, vol. 32 (2018).

[187] U.S. Government Accountability Office, *NIH Research: Action Needed to Ensure Workforce Diversity Strategic Goals Are Achieved*, 18-545, August 2018, pp. 33-35, https://www.gao.gov/assets/700/693872.pdf.

[188] Ibid., pp. 35-36.

[189] Hamilton Moses, David H. M. Matheson, Sarah Cairns-Smith, et al., "The Anatomy of Medical Research: U.S. and International Comparisons," *Journal of the American Medical Association*, vol. 313, no. 2 (January 13, 2015), pp. 174-189.

[190] Justin Chakma, Gordon H. Sun, Jeffrey D. Steinberg, et al., "Asia's Ascent — Global Trends in Biomedical R&D," *The New England Journal of Medicine*, vol. 370, no. 1 (January 2, 2014), pp. 3-6.

[191] CRS Report R44283, *Global Research and Development Expenditures: Fact Sheet*.

[192] Roderik F. Viergever and Thom C.C. Hendrisks, "The 10 Largest Public and Philanthropic Funders of Health Research in the World: What They Fund and How They Distribute Their Funds," Health Research Policy and Systems, vol. 14, no. 12 (2016); and NIH, "Impact of NIH Research- Our Society," 2018, https://www.nih.gov/about-nih/what-we-do/impact-nih-research/our-society.

was the leader in life science patent applications—filing 30% of such patents globally. The United States followed with 24% of life science patents.[193] Academic scientists often seek partnerships with colleagues or recruit students from other countries to advance their work.[194] Yet, as new discoveries are translated to commercial products, such partnerships could complicate the economic development goals of public investment in research.

Some Members of Congress have expressed concern over the investments being made by other countries in biomedical research. In Section 809, "Policy Statement on Medical Discovery, Development, Delivery and Innovation," H.Con.Res. 27 found that the "United States leadership role is being threatened, however, as other countries contribute more to basic research from both public and private sources" and that the "Organisation for Economic Development and Cooperation [sic] predicts that China, for example, will outspend the United States in total research and development by the end of the decade."

The growth in global biomedical research funding has contributed to a surge in research produced outside of the United States, as well as increasing collaboration between U.S. and international institutions. A study of articles published from 2004 to 2013 in PubMed (a database of biomedical research literature based at the U.S. National Library of Medicine) found that published research funded by non-U.S. government sources had increased significantly during that period.[195] Publications authored by European and Asian authors had increased at a higher rate than those by American authors.[196] Collaboration between U.S. and international institutions has also grown in the past few decades. A study of cardiovascular research publications found that cross-border collaboration increased from 1992 to 2012, with the United States having the highest number of cross-border collaborations.[197] NIH actively encourages international collaboration through some of its grant opportunities.[198]

A congressional hearing in August 2018 raised the issue of undue foreign influence in U.S. biomedical research. NIH Director Francis Collins announced an investigation of research institutions for undue foreign influence in three key areas:

> First, failure by some researchers at NIH-funded institutions to disclose substantial contributions of resources from other organizations, including foreign governments, which threatens to distort decisions about the appropriate use of NIH funds. Second, diversion of intellectual property and grant applications [that] are produced by NIH-supported biomedical research to other entities, including other countries. And third, failure by some peer reviewers to keep information on grant applications confidential, including in some instances disclosure to foreign entities or other attempts to influence funding decisions.[199]

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[193] Hamilton Moses, David H. M. Matheson, Sarah Cairns-Smith, et al., "The Anatomy of Medical Research: U.S. and International Comparisons," Journal of the American Medical Association, vol. 313, no. 2 (January 13, 2015), pp. 180-181.

[194] George Radda, "Biomedical Research and International Collaboration," *Science*, vol. 295, no. 5554 (January 18, 2002), pp. 445-446.

[195] Konstantinos Z. Vardakas, Grigorios Tsopanakis , Alexandra Poulopoulou, et al., "An analysis of factors contributing to PubMed's growth," *Journal of Infometrics*, vol. 9, no. 3 (July 15, 2015), pp. 592-617.

[196] Ibid.

[197] Diane Gal, Wolfgang Glanzel, and Karin R. Sipido, "Mapping cross-border collaboration and communication in cardiovascular research from 1992-2012," *European Heart Journal*, vol. 38, no. 16 (October 25, 2016), pp. 1249-1258.

[198] See the following grant opportunities: International Research Collaboration on Alcohol and Alcoholism, at https://grants.nih.gov/grants/guide/pa-files/PAR-11-282.html, and the U.S.-South African Program for Collaborative Biomedical Research, at https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-14-009.html.

[199] U.S. Congress, Senate Committee on Health, Education, Labor, and Pensions, *Prioritizing Cures: Science and*

Dr. Collins also announced a working group of university leaders to develop methods and policies that mitigate undue foreign influence. Despite the presence of bad actors, Collins stressed the important role that foreign scientists have played in U.S.-funded research and reasserted the NIH's commitment to "preserve the vibrancy of the diverse workforce."[200]

In a December 2018 report, the working group identified a Chinese research training program that facilitates the transfer of U.S. intellectual property to the Chinese government.[201] Some participants from the program have received NIH funding, though they represent a small portion of foreign researchers in the United States. The report makes recommendations to educate institutions about disclosing and monitoring international ties, and to enhance cybersecurity to prevent information breaches.[202] Other federal agencies, such as the Department of State, Department of Justice (DOJ), and Federal Bureau of Investigation (FBI), are also actively monitoring, investigating, and issuing guidance and/or new policies related to foreign theft of intellectual property from U.S. academic and research institutions.[203]

## Balancing Federal and Industry Support of Research

NIH basic research is valued as a source of new and improved treatment and prevention measures, but it may also be used as a basis for policy decisions, economic development, and potentially new commercial products. The primary rationale for a federal government role in funding basic research is that private firms do not perform enough such research relative to the needs of society. The federal government may also invest in research to advance national and economic security for the nation.[204]

There are competing views about what roles the federal government and private industry should play in biomedical research and development (R&D). In traditional economics terms, science—especially basic science— is viewed as a public good: scientific knowledge may have widespread benefits that are difficult for an individual firm to "capture," and society may not produce enough of it through industry alone.[205] In the traditional economic view, the public sector should fund basic research, while private firms will concentrate on applied research and product development. However, the line between basic and applied research is blurred. There is some concern that,

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*Stewardship at the National Institutes of Health*, 115th Cong., August 28, 2018.

[200] Ibid.

[201] Lawrence A. Tabak and M. Roy Wilson, "Foreign Influences on Research Integrity," 117th Meeting of the Advisory Committee to the Director, NIH, December 2018, https://acd.od.nih.gov/documents/presentations/12132018ForeignInfluences.pdf.

[202] Lev Facher, "NIH Report Scrutinizes Role of China in Theft of U.S. Scientific Research," *STAT*, December 13, 2018, https://www.statnews.com/2018/12/13/nih-report-scrutinizes-role-of-china-in-theft-of-u-s-scientific-research/.

[203] The State Department has issued guidance on international ties in higher education: U.S. Dept. of State, *U.S. Government Resources Guide: Higher Education Community*, https://educationusa.state.gov/sites/default/files/info_guide_higher_education_final.pdf. It has also changed visa policy for Chinese graduate students in certain fields: Jeffrey Mervis, "More Restrictive U.S. policy on Chinese Graduate Student Visas Raises Alarm," *Science*, June 11, 2018. DOJ has published a related fact sheet: DOJ, *Attorney General Jeff Sessions' China Initiative Fact Sheet*, November 1, 2018, https://www.justice.gov/opa/speech/file/1107256/download. And the FBI has issued the following: FBI, *Preventing Loss of Academic Research*, June 2015, https://info.publicintelligence.net/FBI-SPIN-ProtectingAcademicResearch.pdf.

[204] OMB, "FY2019 Budget- Analytical Perspectives," https://www.whitehouse.gov/omb/analytical-perspectives/.

[205] Richard R. Nelson, "The Simple Economics of Basic Scientific Research," *Journal of Political Economy*, vol. 67, no. 3 (June 1959), pp. 297-306; and Dana Dalrymple, *Scientific Knowledge as a Global Public Good: Contributions to Innovation and the Economy*, National Research Council (US) Steering Committee on the Role of Scientific and Technical Data and Information in the Public Domain, https://www.ncbi.nlm.nih.gov/books/NBK221876/.

given the size of federal research funding, some of the federal funding could possibly "crowd out private-sector investment in R&D"—meaning that absent public investment, industry would fund more research.[206] On the other hand, one 2019 economic analysis found no evidence that NIH funding crowded out private sector R&D funding.[207] Economist Mariana Mazzucato argues that the U.S. government has played a more directive role in strategically accelerating innovation in technologies and industries through research and development, including in pharmaceuticals and biotechnologies. Mazzucato argues that federal efforts have been a driving force behind "high risk" innovation.[208] Others view the public and private sector's respective roles in pharmaceutical research and development as a necessary collaboration, given the scientific complexity of current medical innovations. Academic and industry partnerships are increasingly common, with public sector institutions contributing to the early discovery phases of new medical advancements, and the private sector conducting more late-stage product development and clinical trials.[209] The correct balance of federal and industry contributions to biomedical innovation is difficult to determine, and a source of debate.

In recent years, both NIH and industry have shifted their allocation of R&D investments. A 2015 study showed that industry shifted from funding less basic and translational research to spending more on clinical trials. From 2004 to 2011, the pharmaceutical industry increased spending by 36% for phase 3 clinical trials (late-stage clinical trials required to prove drug safety and efficacy), while it decreased spending by 4% for preclinical research activities (prehuman research; includes basic and applied) in the same period. According to the authors, "[t]his shift toward clinical research and development reflects increasing costs, complexity, and length of clinical trials but may also reflect a de-emphasis of early discovery efforts by the U.S. pharmaceutical industry."[210] In recent years, NIH has also shifted to spending a slightly larger percentage on applied research compared to basic research—in FY2017, NIH allocated 48.8% of its research budget authority for applied research (as opposed to basic research), compared to 41.2% in FY2002.[211] Thus, NIH may be shifting to spending more on research than was previously funded by the industry.

One analysis found that in 2015, industry accounted for 67.4% of all U.S. expenditures on medical and health research, followed by the federal government (27%) and universities (5%).[212] Some argue that federal support of basic research not only stimulates industry spending on applied research and development (R&D) through scientific discoveries that expand industry

[206] Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, Washington, DC, October 2006, p. 3; and Paul A. David, Bronwyn H. Hall, and Andrew A. Toole, "Is Public R&D a Complement or Substitute for Private R&D? A Review of the Econometric Evidence," *Research Policy*, vol. 29, no. 4-5 (April 2000), pp. 497-529.

[207] Pierre Azoulay, Joshua S. Graff Zivin, Danielle Li, et al., "Public R&D Investments and Private-Sector Patenting: Evidence from NIH Funding Rules," *Review of Economic Studies*, vol. 86 (2019), pp. 117-152.

[208] Mariana Mazzucato, *The Entrepreneurial State: Debunking Public vs. Private Sector Myths* (New York, NY: Anthem Press), 2015.

[209] Ranjana Chakravarthy, Kristina Cotter, Joseph DiMasi, et al., "Public- and Private-Sector Contritbutions to the Research and Development of the Most Transformational Drugs in the Past 25 Years: From Theory to Therapy," *Therapeutic Innovation and Regulatory Science*, vol. 50, no. 6 (May 20, 2016), pp. 759-768.

[210] Hamilton Moses, David H. M. Matheson, Sarah Cairns-Smith, et al., "The Anatomy of Medical Research: U.S. and International Comparisons," *Journal of the American Medical Association*, vol. 313, no. 2 (January 13, 2015), p. 177.

[211] NIH, "FY 2002 - FY 2017 Distribution of Budget Authority Percentage for Basic and Applied Research," https://officeofbudget.od.nih.gov/pdfs/FY19/Basic%20and%20Applied%20FY%202002%20-%20FY%202017%20(V).pdf.

[212] Research America, *U.S. Investments in Medical and Health Research and Development*, 2017, https://www.researchamerica.org/sites/default/files/RA-2017_InvestmentReport.pdf.

R&D opportunities, but also stimulates industry R&D by training many of the researchers that are hired by industry.[213] The training provided by NIH programs "enhances the productivity and profitability of the companies' R&D investments."[214] In contrast, NIH funding may indirectly affect the number of researchers available for the private sector, which can indirectly affect the salaries of these researchers. Many refer to the combination of federal and industry support for biomedical research as a "biomedical ecosystem," or the "biomedical research enterprise."

## Public-Private Partnerships

One approach that the NIH has taken to stretch funding dollars and boost innovative research is to engage in public-private partnerships. Such partnerships include the Accelerating Medicines Partnership between the NIH, the FDA, 12 biopharmaceutical companies, and 13 nonprofit organizations to transform the way diagnostics and therapeutics are developed "by jointly identifying and validating promising biological targets for therapeutics."[215] Another partnership, the Biomarkers Consortium, aims to identify promising biomarkers for disease and treatment and includes the NIH, FDA, Centers for Medicare and Medicaid Services (CMS), the Pharmaceutical Research and Manufacturers of America (PhRMA), the Biotechnology Industry Organization (BIO), and over 30 other companies and nonprofit organizations.[216] Public-private partnerships are facilitated by the Foundation for the National Institutes of Health (FNIH).[217]

Two recent controversies have invoked scrutiny of NIH's public-private partnerships. In March 2018, the *New York Times* published an investigative report about scientists and NIH officials who solicited funding from members of the alcohol industry to support a large clinical trial about the health benefits of moderate alcohol consumption. The industry's donations to the study would have been channeled through the FNIH.[218] After the article was published, NIH conducted an investigation and subsequently shut down the study in June 2018.[219] In addition, in April 2018, NIH cancelled a planned opioids research partnership with dozens of pharmaceutical companies aimed at finding new therapies for addiction and pain as a part of the Helping to End Addiction Long-term (HEAL) Initiative.[220] The cancellation occurred after NIH faced criticism and a working group subsequently recommended to avoid "reputational and ethical risks" created by receiving funds from certain drug makers, who were involved in litigation for their role in the

[213] Hamilton Moses, David H. M. Matheson, Sarah Cairns-Smith, et al., "The Anatomy of Medical Research: U.S. and International Comparisons," *Journal of the American Medical Association*, vol. 313, no. 2 (January 13, 2015), p. 174.

[214] Ibid.

[215] National Institutes of Health, *Acclerating Medicines Partnership (AMP): Overview*, https://www.nih.gov/research-training/accelerating-medicines-partnership-amp.

[216] Foundation for the National Institutes of Health, *Biomarkers Consortium*, https://fnih.org/what-we-do/biomarkers-consortium.

[217] Foundation for the National Institutes of Health, *About Us*, https://fnih.org/about.

[218] Roni C. Rabin, "Federal Agency Courted Alcohol Industry to Fund Study on Benefits of Moderate Drinking," *The New York Times*, March 17, 2018.

[219] Roni Caryn Rabin, "Major Study of Drinking Will Be Shut Down," *The New York Times*, June 15, 2018.

[220] Lev Facher, "NIH abruptly changes course on industry opioids partnership after ethics flags raised," *STAT*, April 19, 2018. The HEAL Initiative is "an aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis," through funding various types of opioids related research; from NIH, "About the HEAL Initiative," https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative.

opioid crisis.[221] NIH has continued to fund the initiative with federal dollars only, and without cash contributions from industry members.[222]

As a result of the controversies, members of the biomedical research community have called for the NIH to change its practices around public-private partnerships. In the *Journal of the American Medical Association*, two observers argued that NIH should issue standard guiding principles for public-private partnerships and should have full transparency about funding sources on all relevant webpages and materials. They also argued that NIH should limit undue influence and bias of the industry in research design and protocols.[223]Another observer argued that NIH should broadly limit industry involvement in research because of the subtle ways industry may influence research—by funding certain types of studies or researchers that may favor their industry.[224]In a December 2018 *New York Times* editorial, one medical researcher argued that while industry bias in scientific research is important to address, many forms of bias exist in science and therefore advocated for "open science," where researchers' methods, data, funding, and affiliations are maximally transparent.[225]At an August 2018 Senate hearing, NIH Director Francis Collins defended NIH's use of public-private partnerships: "It brings around the same table scientists from both public and private sectors who design together what the research ought to be, building on the strengths of both groups and it advances the cause of science more rapidly than might otherwise have been."[226] He noted, however, that NIH should be careful when the funder has a "vested interest in a particular outcome of the study."[227]

The FNIH is small in the context of NIH's large portfolio. In FY2017, the total revenues for FNIH were $64 million, including in-kind contributions.[228] Federal funding of over $30 billion per year therefore dwarfs private contributions to the FNIH. However, private sector funding and influence has increased in the larger biomedical research context. A study found that from 1988 to 2008, the proportion of industry-funded studies in three prominent American medical journals had doubled, from 17% to 40% of all studies.[229] Moving forward, NIH may continue to define its relationship with the private sector in advancing biomedical research.

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[221] Working Group Report to the Advisory Committee to the Director, NIH, *Ethical Considerations for Industry Partnership on Research to Help End the Opioid Crisis*, March 2018, https://acd.od.nih.gov/documents/presentations/032018_opioids-draft-report.pdf.

[222] Private companies may still submit in-kind contributions to the HEAL initiative; from Lev Facher, "NIH abruptly changes course on industry opioids partnership after ethics flags raised," *STAT*, April 19, 2018.

[223] Bernard Lo and Deborah Grady, "Protecting NIH's Integrity and Trustworthiness in Public-Private Partnerships," *JAMA*, vol. 320, no. 5 (2018), pp. 439-440.

[224] Linda Bauld, "Funders must be wary of industry alliances," *Nature*, vol. 560, no. 283 (August 14, 2018).

[225] Aaron E. Carroll, "Congratulations on the Promotion. But Did Science Get a Demotion?," *New York Times*, December 31, 2018, https://www.nytimes.com/2018/12/31/upshot/congratulations-on-the-promotion-but-did-science-get-a-demotion.html.

[226] U.S. Congress, Senate Committee on Health, Education, Labor, and Pensions, *Prioritizing Cures: Science and Stewardship at the National Institutes of Health*, 115th Cong., August 28, 2018.

[227] Ibid.

[228] Foundation for the National Institutes of Health, Inc. , *Financial Statements and Supplementary Information, Years Ended December 31, 2017 and 2016*, https://fnih.org/sites/default/files/final/pdf/2017%20Audited%20Financial%20Statements.pdf.

[229] Alexander Ivanov, Beata A. Kaczkowska, Saadat A. Khan, et al., "Review and Analysis of Publication Trends over Three Decades in Three High Impact Medicine Journals," *PLoS One*, vol. 12, no. 1 (2017).

## Publicly Funded Research and Pharmaceutical Drug Development

NIH is involved, both directly and indirectly, in pharmaceutical drug development. NIH funding *directly* contributes to pharmaceutical development when NIH-funded scientists develop a chemical compound or other invention that is patented and then licensed to the pharmaceutical industry. NIH also funds a limited amount of clinical research on new or existing pharmaceuticals to assess drug safety and effectiveness for FDA approval. Since over 50% of NIH funding supports basic research, NIH funded research is, to a greater extent, *indirectly* involved—by generating scientific knowledge and innovations that aid in pharmaceutical development.[230] For example, important basic advances in research, such as recombinant DNA, can lead to the development of whole new classes of drugs.[231] NIH also supports the education and training of biomedical scientists, some of whom then work for the pharmaceutical industry. It is therefore difficult to quantify and assign credit for the role of NIH funding in the development of a given drug.

Drugs with a patent held by NIH or NIH-funded researchers represent a small portion of all FDA-approved drugs. An invention may be patented if it is "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" that is novel, useful, and nonobvious, and the inventor is the first person to file a patent application.[232] NIH-funded researchers may discover drug candidates that are then patented by or licensed to the pharmaceutical industry. According to a 2011 study by Sampat and Lichtenberg, 9% of the new drugs (i.e., new molecular entities) approved by the FDA from 1988 to 2005 were based on a patent held by either a government agency or a nongovernmental institution that had received government support.[233] NIH makes up a large portion of all government funding for medical research in the United States; therefore many of the drugs in the Sampat and Lichtenberg study were likely developed with NIH funding (although the authors did not specify whether NIH funded the research). However, in 2012, Rai and Sampat noted that federal funding can go unreported on patent applications, despite requirements to report such information.[234] Therefore more drugs may have been developed with federal funding than is accounted for through patent information.

A study by Ashley J. Stevens et al. published in 2011 explored the contribution of publicly funded research to the discovery of new drugs.[235] The Stevens study found that of the 1,541 drugs approved by FDA from 1990 through 2007, 143, or 9.3%, resulted from work conducted in public sector research institutions, including all universities, research hospitals, nonprofit research institutes, and federal laboratories in the United States. Of the 1,541 total drug applications, FDA

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[230] NIH, "FY 2002 - FY 2017 Distribution of Budget Authority Percentage for Basic and Applied Research," https://officeofbudget.od.nih.gov/pdfs/FY19/Basic%20and%20Applied%20FY%202002%20-%20FY%202017%20(V).pdf.

[231] Recombinant DNA is the joining of DNA molecules from different species in a host organism to produce a new genetic combination. Publicly funded research played an instrumental role in the development of recombinant DNA beginning in the 1970s. See Rajendra K. Bera, "The Story of the Cohen-Boyer Patents," *Current Science*, vol. 96, no. 6 (March 2009), pp. 760-763.

[232] CRS In Focus IF10986, *Intellectual Property Law: A Brief Introduction*.

[233] Bhaven N. Sampat and Frank R. Lichtenberg, "What are the Respective Roles of the Public and Private Sector in Pharmaceutical Innovation?," Health Affairs, vol. 30, no. 2 (February 2011), pp. 332-339.

[234] Arti K. Rai and Bhaven N. Sampat, "Accountability in patenting of federally funded research," *Nature, Biotechnology*, vol. 30, no. 10 (October 2012), pp. 953-956.

[235] Ashley J. Stevens et al., "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines," *The New England Journal of Medicine*, vol. 364, no. 6 (February 10, 2011), pp. 535-541.

granted priority review to 348 applications, and 66 of these (19%) resulted from publicly funded research. The authors stated that "viewed from another perspective, 46.2% of the new-drug applications from PSRIs [public-sector research institutions] received priority reviews, as compared with 20.0% of applications that were based purely on private-sector research, an increase by a factor of 2.3."[236] An FDA designation of priority review is for "the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications."[237] According to the authors, their data "suggest that PSRIs tend to discover drugs that are expected to have a disproportionately important clinical effect."[238]

Some studies have focused on the public sector's role in developing the most innovative drugs. A 2015 study focused solely on the public sector's role in "transformative" drug development from 1984 to 2009. The researchers defined a transformative drug as both innovative and having a groundbreaking effect on patient care. They identified transformative drugs by surveying physicians from the top 30 U.S. academic medical centers. The researchers then focused on 21 transformative drugs and five drug classes and followed their development history through FDA documentation and interviews with scientists and drug developers. They found that most of these transformative drugs originated in academic and/or publicly funded institutions that conceptualized therapeutic approaches through basic research, and were then further developed by industry partners for clinical testing.[239]Another study analyzing case histories of the same set of transformative drugs, published in 2016, concluded that only 4 out of 26 transformative drugs identified were developed by one sector alone—either public or private. [240] Although the public sector conducted most of the basic science activities to develop the drugs, the private sector accounted for most of the drug development activities in bringing the drugs to market. The authors estimated that total NIH funding would need to increase by 2.5 times to maintain the current level of drug development without industry support.[241] However, the authors did not appear to account for potential revenues to NIH if the agency produced the drugs.

Rather than directly leading to a new drug, NIH-funded researchers are more often *indirectly* involved in drug development by producing scientific research and innovations that contribute to the knowledge base and available methods for the pharmaceutical industry. For instance, the methodology used by the Stevens et al. 2011 study "excluded the role of PSRIs in the development of platform technologies that have contributed to the development of whole new classes of drugs." These platform technologies enabled the development of many of the products approved by FDA during the period evaluated in the study. The platform technologies were excluded "because the PSRI scientists who developed the platforms generally did not use them to

[236] Ibid., p. 539.

[237] FDA, "Priority Review" at http://www.fda.gov/ForPatients/Approvals/Fast/ucm405405.htm. A priority review designation means FDA's goal is to take action on an application within 6 months (compared to 10 months under standard review).

[238] Ashley J. Stevens et al., "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines," *The New England Journal of Medicine*, vol. 364, no. 6 (February 10, 2011), p. 541.

[239] Aaron S. Kesselheim, Yongtian T. Tian, and Jerry Avorn, "The Roles Of Academia, Rare Diseases, And Repurposing In the Development of The Most Transformative Drugs," *Health Affairs*, vol. 34, no. 2 (2015), pp. 286-293.

[240] Ranjana Chakravarthy, Kristina Cotter, Joseph DiMasi, et al., "Public- and Private-Sector Contributions to the Research and Development of the Most Transformational Drugs in the Past 25 Years: From Theory to Therapy," *Therapeutic Innovation and Regulatory Science*, vol. 50, no. 6 (2016), pp. 759-768.

[241] Ibid.

develop specific drug candidates."[242] For example, the following platform technologies were developed with public funds and were excluded from the study:

- recombinant DNA technology (Cohen-Boyer patents);
- bacterial production methods for recombinant DNA (Riggs-Itakura patents);
- production and chimerization methods for antibodies (Cabilly patents);
- methods to produce glycosylated recombinant proteins in mammalian cells (Axel patents); and
- methods of gene silencing with the use of small interfering RNAs (Mello-Fire patents).

These platform technologies have enabled the development of entirely new classes of drugs, such as the production of synthetic insulin and growth hormones using recombinant DNA technology, and antibody drugs using Cabilly patents.[243] Without these underlying scientific innovations, the result may have been a vastly different economic outlook for the pharmaceutical industry.

A few studies have aimed to ascertain the total impact of NIH funding on drug development. A 2018 study by Cleary et al. on the broad impact of NIH funding on drug development found that public funding contributed to every new molecular entity (NME)[244] approved by the FDA from 2010 to 2016.[245] The study, which looked at peer-reviewed literature and public data on NIH grant funding, determined that funding from NIH was "directly or indirectly associated with every one of 210 NMEs approved from 2010-2016." Almost a third (29%) of the publications identified were directly associated with NIH-funded projects. The analysis in this study captured basic research, in addition to applied research on NMEs. The study found that up to 20% of the NIH budget allocation from 2000 to 2016, or about $100 billion, "was associated with published research that directly or indirectly contributed to NMEs approved from 2010-2016."[246] The authors concluded that their results suggest that "the NIH contribution to research associated with new drug approvals is greater than previously appreciated."[247] A 2019 study by Azoulay et al. used a new economic method to measure the impact of NIH research funding on private industry, particularly on patenting by private-sector firms. The study determined that NIH investments in a particular research area increase subsequent private sector patenting in that area—a $10 million increase in NIH funding for a research area results in 2.7 additional patents. Alternatively phrased, one private sector patent results from every two to three NIH grants. Though the authors

[242] Ashley J. Stevens et al., "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines," *The New England Journal of Medicine*, vol. 364, no. 6 (February 10, 2011), p. 537.

[243] Rajendra K. Bera, "The Story of the Cohen-Boyer Patents," *Current Science*, vol. 96, no. 6 (March 2009), pp. 760-763, and Ashley J. Stevens et al., "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines," *The New England Journal of Medicine*, vol. 364, no. 6 (February 10, 2011), p. 537.

[244] According to FDA, "[c]ertain drugs are classified as new molecular entities ("NMEs") for purposes of FDA review. Many of these products contain active moieties that have not been approved by FDA previously, either as a single ingredient drug or as part of a combination product; these products frequently provide important new therapies for patients." FDA, Novel Drug Approvals for 2018, at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm592464.htm

[245] Ekaterina Galkina Cleary et al., "Contribution of NIH Funding to New Drug Approvals 2010-2016," *PNAS*, vol. 115, no. 10 (March 6, 2018), pp. 2329-2334.

[246] Ibid., p. 2333

[247] Ibid., p. 2333

faced difficulty measuring the economic value of such patents, they stated that, "one rough calculation suggests that $1 dollar in NIH funding generates around $2.34 in drug sales."[248]

NIH-funded research has contributed to the development of new pharmaceutical drugs, largely by supporting and conducting the science that underpins the industry. In light of high list prices for certain branded drugs, some question whether the American public is getting an adequate return on taxpayer investment in biomedical research.[249] Others argue that pharmaceutical drug development is an increasingly expensive endeavor, and therefore requires significant research and development contributions from both the public and private sector.[250] NIH contributions to drug development is one component of a larger debate about the role of federal funding and policies (including health care finance, regulatory, and tax policy) in the development, price, and profitability of pharmaceutical drugs.[251]

# Concluding Observations

With over $39 billion in funding for FY2019, NIH is a significant contributor to the U.S. and global biomedical research enterprise. Congress may consider how to allocate funding, introduce reforms, and provide oversight to NIH in a way that maximizes benefits to taxpayers through science-driven improvements to health, quality of life, and medical care. NIH has well-established internal processes for allocating research funding through scientific peer review and advisory committees. Congress may consider how to oversee these internal mechanisms; address gaps, duplication, and needs in the research portfolio; and provide funding in a manner that maintains the sustainability and productivity of research. Finally, Congress may consider how to help NIH support new and early-stage scientists, maintain its role as a global leader in biomedical research, and balance the public and private sector's role in research and innovation.

[248] Pierre Azoulay, Joshua S. Graff Zivin, and Danielle Li, et al., "Public R&D Investments and Private-Sector Patenting: Evidence from NIH Funding Rules," *Review of Economic Studies*, vol. 86 (2019), pp. 117-152.

[249] Alfred B. Engelberg, "How Government Policy Promotes High Drug Prices," *Health Affairs*, October 29, 2015, https://www.healthaffairs.org/do/10.1377/hblog20151029.051488/full/.

[250] Ranjana Chakravarthy, Kristina Cotter, Joseph DiMasi, et al., "Public- and Private-Sector Contritbutions to the Research and Development of the Most Transformational Drugs in the Past 25 Years: From Theory to Therapy," *Therapeutic Innovation and Regulatory Science*, vol. 50, no. 6 (May 20, 2016), pp. 759-768; and Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, "The Cost of Drug Development," *The New England Journal of Medicine*, vol. 372, no. 20 (May 14, 2015), p. 1972.

[251] For other analyses on prescription drug policy and pricing, see CRS Report R44832, *Frequently Asked Questions About Prescription Drug Pricing and Policy*; CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*; and CRS Report R44333, *Health-Related Tax Expenditures: Overview and Analysis*.

## Table 2. Components of NIH, with History and Scope

| Institute/Center<br>Statutory Authority in Public Health Service Act and *U.S. Code* | When and How Established;<br>Chronology of Name Changes | Major Research Focus |
|---|---|---|
| National Cancer Institute (NCI)<br>PHSA §410-417D,<br>42 U.S.C. §285-285a-10 | 1937—National Cancer Institute Act (P.L. 75-244).<br>1944—under the PHS Act of 1944 (P.L. 78-410), NCI became a division of the National Institute of Health. | All aspects of cancer—cause, diagnosis, prevention, treatment, rehabilitation, and continuing care of patients. |
| National Heart, Lung, and Blood Institute (NHLBI)<br>PHSA §415-425,<br>42 U.S.C. §285b-285b-8 | 1948—National Heart Act (P.L. 80-655): National Heart Institute.<br>1969—National Heart and Lung Institute.<br>1976—NHLBI. | Diseases of the heart, blood vessels, lungs, and blood; sleep disorders; and blood resources management. |
| National Institute of Dental and Craniofacial Research (NIDCR)<br>PHSA §453,<br>42 U.S.C. §285h | 1948—National Dental Research Act (P.L. 80-755): National Institute of Dental Research.<br>1998—NIDCR. | Oral, dental, and craniofacial diseases and disorders. |
| National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)<br>PHSA §426-434A,<br>42 U.S.C. §285c-285c-9 | 1950—Omnibus Medical Research Act (P.L. 81-692): National Institute of Arthritis and Metabolic Diseases.<br>1972—National Institute of Arthritis, Metabolism, and Digestive Diseases.<br>1981—National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.<br>1985—NIDDK. | Diabetes, endocrinology, metabolic diseases; digestive diseases, nutrition; kidney, urologic, hematologic diseases. |
| National Institute of Neurological Disorders and Stroke (NINDS)<br>PHSA §457-460,<br>42 U.S.C. §285j-285j-3 | 1950—Omnibus Medical Research Act (P.L. 81-692): National Institute of Neurological Diseases and Blindness.<br>1968—National Institute of Neurological Diseases and Stroke.<br>1975—National Institute of Neurological and Communicative Disorders and Stroke.<br>1988—NINDS. | Convulsive, neuromuscular, demyelinating, and dementing disorders; fundamental neurosciences; stroke, trauma. |
| National Institute of Allergy and Infectious Diseases (NIAID)<br>PHSA §446-447B,<br>42 U.S.C. §285f-285f-3 | 1955—established under authority of Omnibus Medical Research Act (P.L. 81-692). | Allergic, immunologic, and infectious diseases. |

| Institute/Center<br>Statutory Authority in Public Health Service Act and *U.S. Code* | When and How Established;<br>Chronology of Name Changes | Major Research Focus |
|---|---|---|
| National Institute of General Medical Sciences (NIGMS)<br>PHSA §461,<br>42 U.S.C. §285k | 1962—PHS Act Amendment (P.L. 87-838) authorized the Surgeon General to establish an institute for general (basic) biomedical sciences.<br>1963—NIGMS created in the Department of Health, Education, and Welfare (HEW). | Research and research training in basic biomedical sciences (cellular and molecular biology, genetics, pharmacology, physiology). Special focus on minority researchers and institutional capacity building. |
| *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)<br>PHSA §448-452G,<br>42 U.S.C. §285g-285g-10 | 1962—PHS Act Amendment (P.L. 87-838) authorized the Surgeon General to establish an institute for research on child health and human development.<br>1963—NICHD created in HEW. | Reproductive biology; population issues; embryonic development; maternal, child, and family health; medical rehabilitation. |
| National Eye Institute (NEI)<br>PHSA §455-456,<br>42 U.S.C. §285i-285i-1 | 1968—National Eye Institute Establishment Act (P.L. 90-489) (functions were formerly in the institute covering neurological diseases and blindness). | Eye diseases, visual disorders, visual function, preservation of sight, health problems of the visually impaired. |
| National Institute of Environmental Health Sciences (NIEHS)<br>PHSA §463-463A,<br>42 U.S.C. §285*l*-285*l*-1 | 1969—The NIH Division of Environmental Health Sciences (established by the Surgeon General in 1965) was elevated to institute status by the Secretary of HEW. | Interrelationships of environmental factors, individual genetic susceptibility, and age as they affect health.<br>NIEHS is located in Research Triangle Park, NC. |
| National Institute on Aging (NIA)<br>PHSA §443-445J,<br>42 U.S.C. §285e-285e-11 | 1974—Research on Aging Act of 1974 (P.L. 93-296). | Biomedical, social, and behavioral research on the aging process; diseases, problems, and needs of the aged. |
| National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)<br>PHSA §435-442A,<br>42 U.S.C. §285d-285d-8 | 1986—Established under authority of the Health Research Extension Act of 1985 (P.L. 99-158). For earlier history, see NIDDK. | Arthritis; bone, joint, connective tissue and muscle disorders; skin diseases. |
| National Institute on Deafness and Other Communication Disorders (NIDCD)<br>PHSA §464-464F,<br>42 U.S.C. §285m-285m-6 | 1988—National Deafness and Other Communication Disorders Act of 1988 (P.L. 100-553) (functions were formerly in the institute covering neurological and communicative disorders and stroke). | Disorders of hearing, balance, smell, taste, voice, speech, and language. |

| Institute/Center<br>Statutory Authority in Public Health Service Act and *U.S. Code* | When and How Established;<br>Chronology of Name Changes | Major Research Focus |
|---|---|---|
| National Institute of Nursing Research (NINR)<br>PHSA §464V-464Y,<br>42 U.S.C. §285q-285q-3 | 1986—National Center for Nursing Research established under authority of the Health Research Extension Act of 1985 (P.L. 99-158).<br>1993—NINR. | Acute and chronic illness, health promotion/disease prevention, nursing systems, clinical therapeutics. |
| National Institute on Alcohol Abuse and Alcoholism (NIAAA)<br>PHSA §464H-464J,<br>42 U.S.C. §285n-285n-2 | 1970—Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act (P.L. 91-616) established NIAAA within NIMH in PHS.<br>1974—moved to Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) (P.L. 93-282).<br>1992—moved to NIH (P.L. 102-321). | Causes of alcoholism, how alcohol damages the body, prevention and treatment strategies. |
| National Institute on Drug Abuse (NIDA)<br>PHSA §464L-464P,<br>42 U.S.C. §285o-285o-4 | 1974—established under authority of Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255).<br>1974—moved to ADAMHA (P.L. 93-282).<br>1992—moved to NIH (P.L. 102-321). | Social, biological, behavioral, and neuro-scientific bases of drug abuse and addiction; causes, prevention, and treatment strategies. |
| National Institute of Mental Health (NIMH)<br>PHSA §464R-464U,<br>42 U.S.C. §285p-285p-3 | 1949—established under authority of National Mental Health Act of 1946 (P.L. 79-487).<br>1967—transferred out of NIH to PHS (P.L. 90-31).<br>1974—moved to ADAMHA (P.L. 93-282).<br>1992—moved back to NIH (P.L. 102-321). | Brain research, mental illness, and mental health. |
| National Human Genome Research Institute (NHGRI)<br>PHSA §464z-1,<br>42 U.S.C. §285s | 1989—National Center for Human Genome Research (NCHGR) established.<br>1993—NCHGR authorized (P.L. 103-43).<br>1997—designated an institute by the HHS Secretary.<br>2007—name officially changed in the PHS Act from NCHGR to NHGRI (P.L. 109-482). | Chromosome mapping, DNA sequencing, database development, ethical/legal/social implications of genetics research. |
| National Institute of Biomedical Imaging and Bioengineering (NIBIB)<br>PHSA §464z,<br>42 U.S.C. §285r | 2000—NIBIB Establishment Act (P.L. 106-580). | Research, training and coordination in biomedical imaging, bioengineering and related technologies and modalities, including biomaterials and informatics. |

| Institute/Center<br>Statutory Authority in Public Health Service Act and *U.S. Code* | When and How Established;<br>Chronology of Name Changes | Major Research Focus |
|---|---|---|
| National Institute on Minority Health and Health Disparities (NIMHD)<br>PHSA §464z-3-464z-6,<br>42 U.S.C. §285t-285t-3 | 1990—Office of Research on Minority Health (ORMH) created by NIH in OD.<br>1993—ORMH authorized (P.L. 103-43).<br>2000—National Center on Minority Health and Health Disparities (NCMHD) created (P.L. 106-525).<br>2010—NCMHD redesignated as NIMHD (P.L. 111-148). | Research, training, and coordination on minority health conditions and populations with health disparities. |
| National Center for Complementary and Integrative Health (NCCIH)<br>PHSA §485D,<br>42 U.S.C. §287c-21 | 1992—Office of Alternative Medicine (OAM) created in OD.<br>1993—OAM authorized (P.L. 103-43).<br>1999—National Center for Complementary and Alternative Medicine (NCCAM) created (P.L. 105-277).<br>2014—name changed from NCCAM to National Center for Complementary and Integrative Health (P.L. 113-235). | Identifies, evaluates, and researches unconventional health care practices. |
| John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC)<br>PHSA §482,<br>42 U.S.C. §287b | 1968—established by HEW.<br>1985—established in law (P.L. 99-158). | Focal point for NIH's international collaboration activities and scientific exchanges; provides leadership in global health. |
| National Center for Advancing Translational Sciences (NCATS)[a]<br>PHSA §479-480,<br>42 U.S.C. §287-287a | 2011—NCATS established (P.L. 112-74). | Research to improve the processes for translating laboratory-based scientific discoveries into new drugs, diagnostics, and medical devices for patients. |
| National Library of Medicine (NLM)<br>PHSA §465-478A,<br>42 U.S.C. §286-286d | 1836—established as the Library of the Office of the Surgeon General of the Army, later Army Medical Library (1922), Armed Forces Medical Library (1952), and NLM under PHS (1956, NLM Act, P.L. 84-941).<br>1968—moved to NIH. | Collects, organizes, and makes available biomedical information; sponsors programs to improve U.S. medical library services. |
| Office of the Director (OD)<br>PHSA §402,<br>42 U.S.C. §282 | 1930—Ransdell Act (P.L. 71-251) created the National Institute of Health. | Overall NIH leadership, planning, and coordination; liaison with HHS. Includes program offices overseeing research on AIDS, women's health, behavioral and social sciences, disease prevention, and research infrastructure support. |
| Buildings and Facilities (B&F)<br>PHSA §402(b),<br>42 U.S.C. §282(b) | First separate appropriation FY1970. | Provides for the design, construction, improvement, and repair of NIH clinical and laboratory buildings. |

| Institute/Center Statutory Authority in Public Health Service Act and *U.S. Code* | When and How Established; Chronology of Name Changes | Major Research Focus |
|---|---|---|
| NIH Clinical Center (CC) | 1944—authorized by the PHS Act (P.L. 78-410).<br>1953—first patient admitted. | NIH's hospital and outpatient facility for clinical research. |
| Center for Scientific Review (CSR) | 1946—Division of Research Grants created.<br>1997—reorganized and renamed CSR. | Receives, assigns, and reviews research and training grant applications. |
| Center for Information Technology (CIT) | 1964—Division of Computer Research and Technology (DCRT) established.<br>1998—CIT formed (DCRT combined with other offices). | Provides, coordinates, and manages information technology for NIH; research to advance computational science. |

**Source:** *NIH Almanac,* http://www.nih.gov/about/almanac/index.html.

a. The former National Center for Research Resources (NCRR) was dissolved on December 23, 2011, by the law that created the National Center for Advancing Translational Sciences (P.L. 112-74, Division F, §221). NCRR programs were transferred to NCATS, various other NIH institutes, and OD. NCRR authority was formerly found in PHSA §479-481D (42 U.S.C. §287-287a-4). History: 1970—Division of Research Resources (DRR) moved to NIH from PHS. 1990—NCRR created by merging DRR and Division of Research Services (statutory authority in NIH Revitalization Act of 1993, P.L. 103-43). Major programs focused on extramural and intramural research resources and technologies: clinical research resources and training, biomedical technology including computing, instrument systems, animal resources and facilities, nonmammalian research models, research infrastructure and capacity building.

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