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

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SUMMARY

R41705

January 13, 2025

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The National Institutes of Health (NIH), under the Department of Health and Human Services (HHS), is the leading federal agency for biomedical and health research. In FY2024, NIH used its over $47 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 research and 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, research areas, or agency support services. Over 80% of NIH-supported 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 provided mostly through the annual appropriations process. In December 2016, Congress introduced major reforms and programs at 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 through the NIH Reform Act (P.L. 109-482). Congress also gives some direction to NIH through appropriations report language and some program-specific authorizations. In recent decades, 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 budget fluctuations throughout its history. From FY1998 to FY2003, Congress doubled the NIH budget from $13.7 billion to $27.1 billion, which rapidly increased NIH's purchasing power and subsequently the nation's funded research workforce and projects. The agency then saw low funding growth or cuts from FY2004 to FY2015, which resulted in increased competition for NIH funding as the agency's purchasing power decreased. Starting in FY2016, Congress provided NIH with funding increases each year, raising the program level from about $30 billion in FY2015 to $47.7 billion in FY2023. In FY2024, NIH's funding level slightly decreased from the prior year.

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 broader research enterprise include

- whether to change NIH's large and decentralized structure, and if so, how;
- determining NIH's research priorities across disease types, areas of human health, and types of research;
- how to balance new and existing funding commitments amid budget fluctuations;
- how to ensure a robust research workforce pipeline, particularly to enable early-career researchers to enter the field;
- how to address geopolitical and security dimensions of NIH research, particularly interference from foreign governments and other potential biosecurity issues;
- how to balance the public and private sectors' relative roles in biomedical research;
- whether and how to formulate policies around pharmaceutical drugs developed, in part, through NIH-funded research, and, in particular, how to address issues associated with access and affordability of such drugs.

This CRS report provides background and analysis on NIH's 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 and health research through NIH.

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Introduction

The National Institutes of Health (NIH) is the leading federal agency for biomedical and health research. The agency 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] NIH supports two categories of research: *extramural research*, performed by nonfederal scientists using NIH grants or other awards, and *intramural research*, performed by federal NIH scientists in NIH-operated research facilities.

Congress maintains a high level of interest in NIH for a variety of reasons. NIH funds research 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 medical and health research effort; it represents about one-fifth of total federal research and development (R&D) funding and represents close to half of all federal R&D spending outside of the Department of Defense.[2] NIH has the largest budget of the nine health-related agencies that make up the Public Health Service (PHS) within the Department of Health and Human Services (HHS).[3]

NIH-funded research has contributed to major scientific advances. To date, 174 NIH-funded researchers have received Nobel Prizes for their work.[4] 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.[5]

In recent years, NIH has drawn Congress's attention for many additional reasons. First, during the Coronavirus Disease 2019 (COVID-19) pandemic, NIH played a major role in supporting research related to the novel virus; in particular, NIH helped develop new tests, vaccines, and therapeutics. In addition, NIH leaders became a public face of the federal government during the pandemic, communicating health and scientific information. At the same time, NIH faced increased scrutiny, in particular, during investigations into the origins of the virus. These investigations drew public attention to NIH's funding of coronavirus research in China and to the agency's challenges in monitoring laboratories in China that received subawards from other NIH grantees. These discussions also drew attention to NIH's support of so-called "gain-of-function" research, or research that can make viruses more transmissible or pathogenic. These conversations have led to policy discussions around broader geopolitical and security issues associated with NIH research.

NIH has also seen a major leadership shift recently: NIH's longtime Director Dr. Francis Collins stepped down in 2021, after serving under three presidential administrations, and was replaced by Director Dr. Monica Bertagnolli in 2023. Additionally, a new complementary independent agency

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[1] National Institutes of Health (NIH), "About the National Institutes of Health," at https://www.nih.gov/about-nih/what-we-do/mission-goals.

[2] CRS analysis of federal research and development budget data provided by the Office of Management and Budget.

[3] 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), the Agency for Toxic Substances and Disease Registry (ATSDR), and the Administration for Strategic Preparedness and Response (ASPR). For further information, see CRS Report R48060, *Department of Health and Human Services: FY2025 Budget Request*.

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

[5] NIH, "Report of the Director: National Institutes of Health: Fiscal Years 2014 and 2015," pp. 9-10, https://dpcpsi.nih.gov/sites/default/files/NIH_Directors_Biennial_Report-2014-2015.pdf.

housed within NIH was established in 2022, the Advanced Research Projects Agency for Health (ARPA-H), which is focused on boosting health and medical innovation. In recent years, many within and outside of Congress have discussed whether NIH warrants further reform in light of the challenges the agency faces as discussed further in this report.

NIH is the largest single funder of health and medical research in the world, though the agency's funding has fluctuated over time. From FY1998 to FY2003, Congress doubled the NIH budget over a five-year period, from $13.7 billion to $27.1 billion. The agency then saw low funding growth or cuts from FY2004 to FY2015. From FY2016 through FY2023, Congress provided NIH with funding increases each year, until FY2024 when NIH saw a slight decrease in its overall budget.[6]

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

- whether to change NIH's large and decentralized structure, and if so, how;
- determining NIH's research priorities across disease types, areas of human health, and types of research;
- how to balance new and existing funding commitments amid budget fluctuations;
- how to ensure a robust research workforce pipeline, particularly how to support early-career researchers to enter the field;
- how to address geopolitical and security dimensions of NIH research, particularly interference from foreign governments and other potential security biosecurity issues;
- how to balance the public and private sectors' relative roles in biomedical research;
- whether and how to formulate policies around pharmaceutical drugs developed, in part, through NIH-funded research, and, in particular, how to address issues associated with access to and affordability of such drugs.

This report provides background and analysis on NIH's history, organization, authorities, and budget; 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 through NIH.

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 a research lab for the Public Health Service.[7] Congress designated the research laboratory the National Institute of Health in 1930 (P.L. 71-251). NIH moved to donated land in the Maryland suburbs in 1938. By 1948, several new institutes and divisions had been created, and the agency was renamed as the National Institutes of Health (P.L. 80-655). Congress and the executive branch created new institutes and

[6] CRS Report R43341, *National Institutes of Health (NIH) Funding: FY1996-FY2025*.

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

centers (ICs) over the following decades, resulting in the 27 ICs that exist today (see **Table 3**). The most recent institute was established in 2011, the National Center for Advancing Translational Sciences (NCATS, P.L. 112-74; see **Table 3**). NIH now occupies a 322-acre main campus in Bethesda, MD, and several off-campus sites, including locations in Maryland, North Carolina, Montana, and Arizona.[8]

In addition, the Advanced Research Projects Agency for Health (ARPA-H) was established recently in 2022 as an independent agency housed within NIH to advance "high-potential, high-impact" biomedical and health research. ARPA-H was first established by an appropriation in FY2022 (P.L. 117-103) and then codified in FY2023 (P.L. 117-328). ARPA-H is modelled after other "ARPA" agencies within the federal government, in particular, the Defense Advanced Research Projects Agency (DARPA).

The ARPA-H Director directly reports to the HHS Secretary; ARPA-H is not considered an NIH IC.[9] In March 2023, the HHS Secretary exempted ARPA-H from all of NIH policies, except where the ARPA-H Director identifies a need to follow NIH policy.[10] Therefore, most of the policies discussed in this report do not apply to ARPA-H. For more information on ARPA-H, see CRS Report R47568, *Advanced Research Projects Agency for Health (ARPA-H): Overview and Selected Issues*.

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

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

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

Research, condition and disease funding estimates: https://report.nih.gov/funding/categorical-spending#/

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

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

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

Funded projects database: https://reporter.nih.gov/.

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

Chronologies (historical and 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.

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 (see **Figure 1**). As detailed in **Table 3**, NIH's ICs were established over time through separate laws or administrative actions, starting with the National Cancer Institute, established in 1937.

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 ICs focus on particular diseases (e.g., the National Cancer Institute), body systems (e.g., National Heart, Lung, and Blood Institute), life stages (e.g., the National Institute on Aging), and scientific fields (e.g., the 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 of the 27 ICs. This includes all 20 institutes,

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

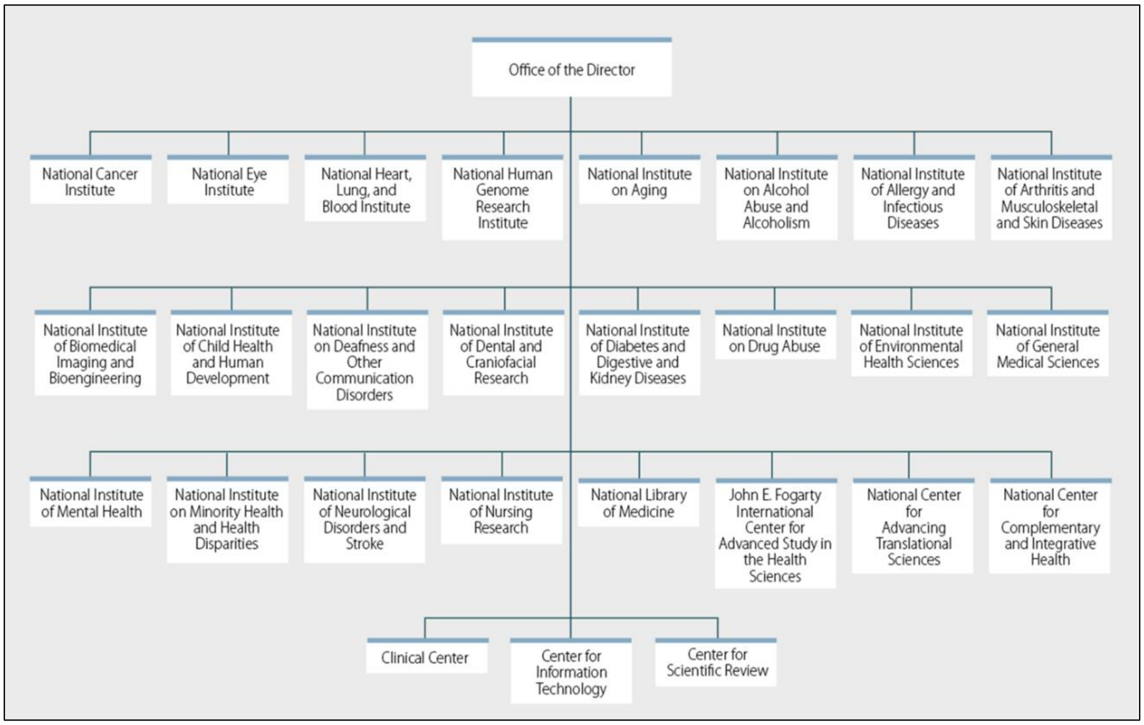
[9] CRS Report R47568, *Advanced Research Projects Agency for Health (ARPA-H): Overview and Selected Issues*.

[10] Pursuant to statutory authority provided in Public Health Service Act Section 499A(a)(3). See Advanced Research Projects Agency for Health, Department of Health and Human Services, "Exemption of the Advanced Research Projects Agency for Health (ARPA-H) From Policies and Requirements of the National Institutes of Health (NIH)," 88 *Federal Register* 19157, March 30, 2023.

NLM, the three research centers, to OD, and to a buildings and facilities account (see the "Budget" section). The three research centers include the John E. Fogarty International Center for Advancing Study in the Health Sciences, the National Center for Advancing Translational Sciences, and the National Center for Complementary and Integrative Health. The three support centers are funded through transfers from other NIH components: the Clinical Center, the Center for Information Technology, and the Center for Scientific Review.[11] The institutes, NLM, the three research centers, and OD have the authority to award research grants; the three operational support centers do not award research grants.[12]

Figure 1. NIH Organization

Office of the Director and 27 Institutes and Centers



Source: Adapted based on information from NIH, "Organization," https://www.nih.gov/about-nih/who-we-are/organization and Public Health Service Act Title IV.

Notes: Does not include the Advanced Research Projects Agency for Health (ARPA-H), an independent agency housed within NIH. The ARPA-H Director reports to the HHS Secretary.

Recent Major Legislative History

Since the 1980s, Congress has passed comprehensive NIH laws about once a decade. This is in addition to many laws that have addressed specific NIH programs (discussed further in the "Authorizations" section). Major laws have included the following:

The Health Research Extension Act of 1985 (P.L. 99-158) created the current structure of Public Health Service Act (PHSA) Title IV, NIH's main authorizing title (see the "Authority"

[11] 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 Justification, Overview Vol. I," p. 94, https://officeofbudget.od.nih.gov/pdfs/FY20/br/Overview-Volume-FY-2020-CJ.pdf.

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

section), providing explicit statutory authority for all of NIH and its institutes, including the authority and duties of the NIH Director and the institute directors.[13] Specifically, the law authorized 14 research institutes and centers, the National Library of Medicine, and the Division of Research Resources. Some of these institutes and components were newly authorized in this law. The law also included authority for the HHS Secretary to establish new or abolish existing NIH institutes with advance notice to Congress. The law also included new statutory requirements for the ethical treatment of both humans and animals in research.

The NIH Revitalization Act of 1993 (P.L. 103-43) extended NIH authorizations of appropriations for three years and included many amendments throughout PHSA Title IV. A major provision was the establishment of requirements to include women and minorities in clinical research as appropriate for the scientific question under study (see the "Inclusion Policies" section). The law also codified several offices at NIH, such as the Office of Women's Health, the Office of Research on Minority Health, and the Office of Behavioral and Social Sciences Research. The law included several provisions focused on research integrity, and it codified an Office of Research Integrity, along with new protections for whistleblowers and new requirements to protect against financial conflicts of interest among researchers. In addition, the law included many provisions focused on specific diseases, particularly many HIV/AIDS provisions to enhance NIH-wide coordination on related research.

The NIH Reform Act of 2006 (P.L. 109-482) included major revisions to NIH's authorizations. Specifically, it sought to limit the creation of new NIH institutes and centers, as well as to enhance the NIH Director's ability to coordinate across the agency. The law followed a congressionally requested report published in 2003 by the Institute of Medicine and National Research Council (IOM/NRC) that had examined NIH's structure and need for organization reform.[14] The report noted some challenges with NIH's large and decentralized organizational structure, made up of 27 Institutes and Centers (ICs), but stated that any proposals for changing the number of ICs or OD program offices should be subject to a public evaluation process.[15] Many of the recommendations in the 2003 IOM/NRC report were incorporated into the NIH Reform Act of 2006 (P.L. 109-482). Among many other reforms, the act created the Scientific Management Review Board (SMRB) to provide advice on NIH's organization and management. SMRB is charged with formally and publicly reviewing NIH organizational structure at least once every seven years. The law also required a biennial report to Congress on NIH activities and strategic planning, as well as the creation of a comprehensive database on NIH research.[16] The Reform Act also consolidated many authorizations of appropriations for specific NIH programs to a single authorization of appropriations for the entire agency, extended from FY2007 to FY2009.

[13] Prior to enactment, most of NIH's Institutes and Centers were explicitly authorized in law, whereas others were not. See U.S. Congress, House Energy and Commerce Committee, *Health Research Extension Act of 1985*, 99th Cong., 1st sess., June 4, 1985, 99-158, pp. 19-20.

[14] Institute of Medicine and National Research Council, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*, 2003, https://nap.nationalacademies.org/catalog/10779/enhancing-the-vitality-of-the-national-institutes-of-health-organizational. The IOM is now known as the National Academy of Medicine.

[15] Ibid., p. 7. The IOM/NRC 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.

[16] Now known as the Research Portfolio Online Reporting Tools (RePORT) system. See https://report.nih.gov/. 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).

The 21st Century Cures Act (P.L. 114-255), enacted in 2016, reauthorized appropriations for NIH until FY2020 and introduced several administrative reforms at NIH. The act required the NIH Director to develop and make publicly available an NIH-wide Strategic Plan every six years (see the "Strategic Planning" section). The act also introduced accountability measures, such as five-year terms for IC Directors. Other reforms included efforts to reduce administrative burden at NIH, such as by exempting NIH research from requirements of the Paperwork Reduction Act, and efforts to prevent and eliminate duplicative research across the agency. The act also authorized several programs and research efforts at NIH, in particular, by creating a new NIH Innovation Account for funding four major research initiatives (detailed further in the "21st Century Cures Act Innovation Projects" section).

Authority

NIH derives most of its statutory authority for its programs from the Public Health Service Act (PHSA) of 1944, as amended (42 U.S.C. §§201-300mm-61):

PHSA Section 301 (42 U.S.C. §241) grants the HHS Secretary broad and permanent authority to conduct and sponsor research.

PHSA Title IV, "National Research Institutes," (42 U.S.C. Chapter 6A, Subchapter III) is the main authorizing title for NIH. It defines the agency's overall structure, the responsibilities of the NIH Director and the IC Directors, overall policy requirements, and the research areas of each IC. Key governing provisions include the following:

- **PHSA Section 401** (42 U.S.C. §281) establishes NIH as an agency within the Public Health Service that consists of 27 ICs and the Office of the Director, and caps the number of ICs at 27. This section also provides authority for NIH reorganization to the HHS Secretary, as advised by the Scientific Management Review Board (see the "Recent Major Legislative History" section).
- **PHSA Section 402** (42 U.S.C. §282) establishes the position of the NIH Director and outlines its responsibilities.
- **PHSA Section 405** (42 U.S.C. §284) establishes the positions of IC Directors and specifies their responsibilities, including to oversee funded research and to make final decisions for new research grant awards.
- **PHSA Section 406** (42 U.S.C. §284a) establishes advisory councils and boards for each of the ICs to oversee their programs.
- **PHSA Title IV, Part C-Part E** (42 U.S.C. Chapter 6A, Subchapter III, Part C-Part E) outlines the specific statutory authorizations for each of the research ICs. All of the research ICs are covered by specific provisions in these sections, but the provisions vary considerably in the amount of detail included in the statutory language.

Some NIH programs are authorized elsewhere in the PHSA or in other laws. For example, PHSA Title XXIII authorizes the NIH Office of AIDS Research (PHSA Section 2351)[17] and other HIV/AIDS research programs and authorities.[18] As another example, the 21st Century Cures Act (P.L. 114-255) authorizes NIH Innovation projects (see the "21st Century Cures Act Innovation Projects" section).

[17] 42 U.S.C. §300cc-40.

[18] 42 U.S.C. §§300cc-1 et seq.

Recent Authorization of Appropriations

In 2016, the 21st Century Cures Act (P.L. 114-255) amended the PHSA (§ 402A), authorizing overall 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 current authorization of appropriations for NIH expired at the end of FY2020.

The overall authority for NIH, or explicit authorizations of individual ICs, has lapsed at times, including currently. However, NIH has continued to receive annual appropriations even when its authorization of appropriations has lapsed. In general, when Congress appropriates funds for a program whose funding authorization has expired, that appropriation provides sufficient legal basis to continue the program during that period of availability absent indication of congressional intent to terminate the program.[19]

NIH Research Activities

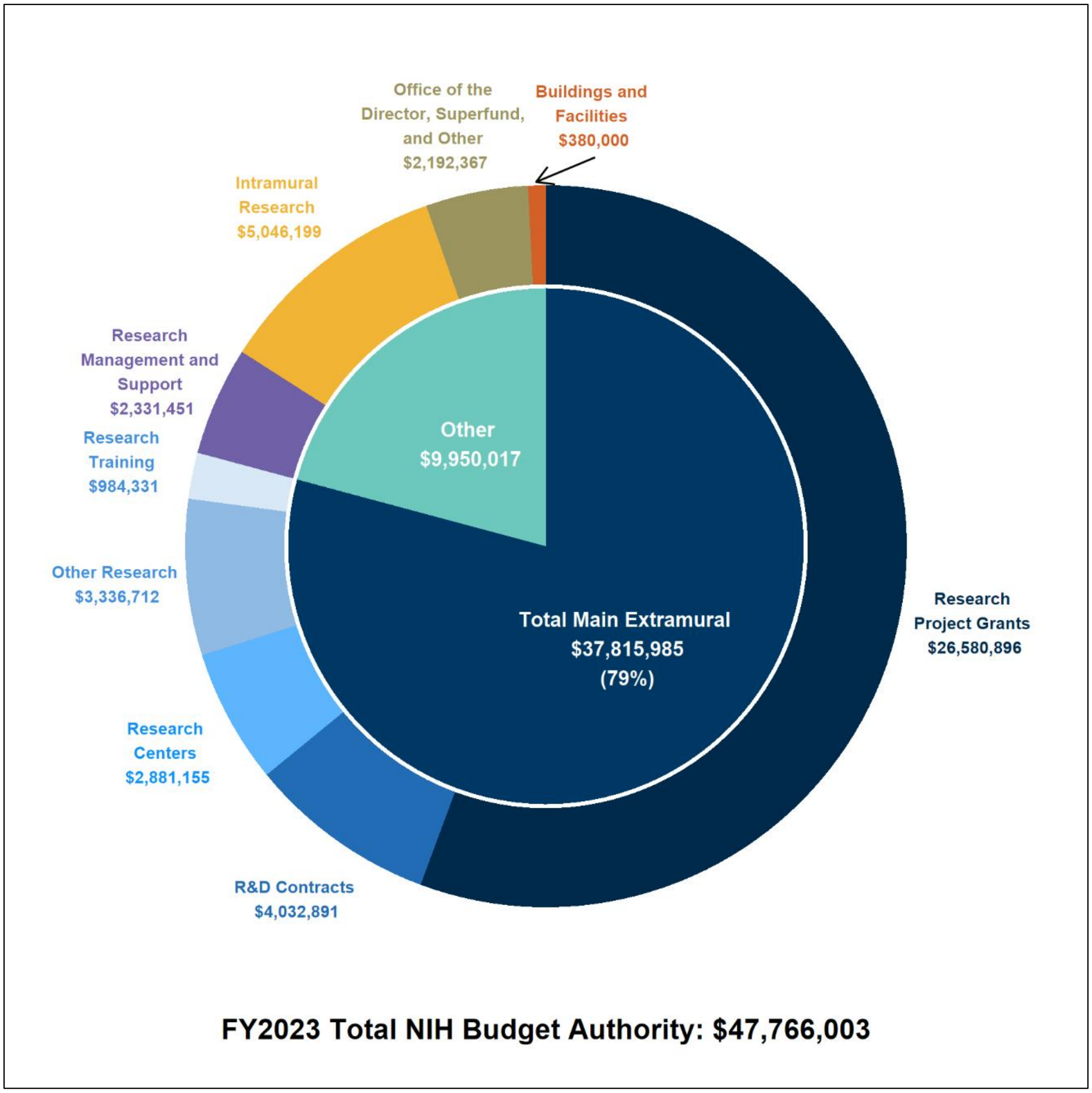
NIH research spans all fields of medical, health, and behavioral research, from basic investigation of biological mechanisms to testing new therapeutics in clinical research. The ICs sponsor two categories of research: *extramural research*, performed by nonfederal scientists using NIH grants or other awards, and *intramural research*, performed by federal scientists in the NIH-operated research facilities and the Clinical Center. NIH also supports a range of extramural and intramural *research training programs*, especially to prepare early-career 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 2** shows the breakdown of NIH obligations by funding 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).

[19] CRS Report R46497, *Authorizations and the Appropriations Process*.

Figure 2. FY2023 NIH Obligations, by Funding Mechanism

Dollars in Millions



Source: Developed by CRS using budget data from NIH, "FY2025 Justification of Estimates for Appropriations Committees, Vol I: Overview–History of Obligations by Total Mechanism," p. 87. Amounts shown do not account for the Public Health Service Evaluation Set-Aside funding or ARPA-H.

Notes: "Total main extramural" category includes the main NIH mechanisms of research support, including research project grants, contracts, research center grants, training grants, and other mechanisms of support. Some extramural programs are integrated into the "Other" category, particularly for the "Office of the Director, Superfund, and Other" category. Figure is based on NIH's categorization system used in source linked above.

Types of Research at NIH

According to NIH, the agency conducts and supports the "full continuum" of biomedical, health, 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 3**):[20]

- **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.
- **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.

Figure 3. "Continuum" of Biomedical Research at NIH

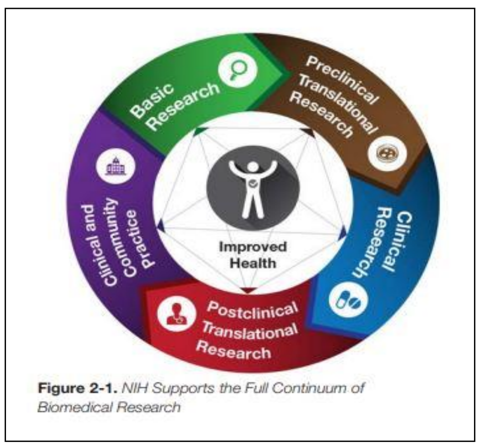


Figure 2-1. *NIH Supports the Full Continuum of Biomedical Research*

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. The same figure appears in NIH's most recent triennial report. See page 55 of NIH, *Report of the Director National Institutes of Health: Fiscal Years 2019-2021*, https://dpcpsi.nih.gov/sites/default/files/2023-09/FY19-21%20Triennial_Report_FINAL_508C.pdf.

In addition, NIH has identified population-based, epidemiological research as one of the key drivers behind the research continuum. This type of research provides statistical evidence of the association between disease and human biology, behavior, and environmental circumstances. In addition, NIH's investment in research tools and resources helps drive the continuum.[21]

[20] All definitions based on NIH, *Report of the Director of National Institutes of Health: Fiscal Years 2019- 2021*, pp. 55-57, at https://dpcpsi.nih.gov/sites/default/files/2023-09/FY19-21%20Triennial_Report_FINAL_508C.pdf.

[21] Ibid.

NIH reports that about half of its funding is for basic research.[22] NIH emphasizes that the research continuum is not always 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, rather than advancing directly into postclinical translational research or other stages.[23]

Extramural Research

NIH extramural research funding makes up nearly 83% of the overall NIH budget and supports 300,000 scientists and research personnel affiliated with over 2,500 universities, medical schools, and other research institutions in every state and around the world.[24] Extramural awards include multiple types of research and training grants (see the **text box** below), cooperative agreements, and contracts, Within the large "research grants" category, the bulk of the funding goes to research project grants (RPGs) awarded to individual investigators and small teams, most of whom are based 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." Data on awards and recipients by state, congressional district, type of institution, and subject of the research are available on the NIH website.[25]

Types of Extramural NIH Grants

NIH awards many types of grants and uses activity codes to differentiate its programs. Not all NIH ICs fund all types of grant programs. Common types of grants and their activity codes include the following:

Research Grants: NIH's research grants fall into its R-series. NIH's most commonly used grant program, the standard independent Research Project Grants (RPG, R01) are used to support a discrete, specified research project carried out by an independent Principal Investigator. This grant mechanism is used by all ICs, and grants are generally awarded for three to five years. NIH can also award RPGs for smaller, more exploratory grants (e.g., R03, R15, R21) and award grants to small businesses under the federal governmentwide Small Business Technology Transfer (STTR)/Small Business Innovative Research (SBIR) program (e.g., R41 R43, and R44). (For more information on STTR/SBIR, see CRS Report R43695, *Small Business Research Programs: SBIR and STTR*.)

Career and Training Grants: Several NIH grant programs support training and career development, including its Research Career Development Awards (K-series), Institutional Training Grants (T-series), and Individual Fellowships program (F-series). (For more information, see the "Research Training" section.)

Program Project/Center Grants: The P-series consists of grants for large, multiproject efforts, including grants for research centers (e.g., P30, P50) that support shared resources and facilities or projects by a number of different investigators within the same research category (e.g., National Cancer Institute Cancer Centers).

Resource Grants: NIH also awards research resource grants that fund research-related support or access to resources, rather than a specific research project, which includes support for research resources or infrastructure (e.g., R24) or for research education projects (e.g., R25).

Sources: NIH, "Types of Grant Programs," https://grants.nih.gov/grants/funding/funding_program.htm, and NIH Research Training and Career Development, "Programs," https://researchtraining.nih.gov/programs.

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[22] NIH, "FY 2003–FY 2023 Distribution of Budget Authority: Percentage for Basic and Applied Research," https://officeofbudget.od.nih.gov/pdfs/FY25/spending_hist/Basic%20and%20Applied%20FY%202003%20-%20FY%202023%20(V).pdf.

[23] NIH, *Report of the Director of National Institutes of Health: Fiscal Years 2019- 2021*, pp. 57, at https://dpcpsi.nih.gov/sites/default/files/2023-09/FY19-21%20Triennial_Report_FINAL_508C.pdf.

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

[25] See the NIH Awards by Location & Organization, at https://report.nih.gov/award/index.cfm. See also the "Selected NIH Resources" **text box** above for other resources on awards.

Scientific Peer Review Process for Extramural Funding

Scientists who seek to compete for NIH extramural research funding, whether for new proposals or for the renewal of previous awards, submit detailed plans in their funding applications describing the research they plan to undertake. In 2023, NIH received 70,746 applications for competing (new) research and training grants, and awarded a total of 16,670 grants.[26] All NIH grant, cooperative agreement, and R&D contract concept applications (referred to as "grants" throughout this report for simplicity and as consistent with NIH sources) undergo review through a two-tiered system of peer review, which includes a competitive and committee-based process to evaluate the applications.[27] The peer review system is pursuant to statute, especially Section 492 of PHSA (42 U.S.C. §289a),[28] and federal regulations (42 C.F.R. Part 52h). 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 and funding availability (see **Figure 4**).[29] According to one IC, it typically takes between 8 to 20 months after the due date for an investigator to receive an award (known as the "Notice of Award").[30]

Grant solicitations and receipt: Researchers can submit applications in response to NIH Notices of Funding Opportunity (NOFO); applications are either investigator-initiated or in response to a specific notice for targeted research.[31] 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.[32] Some applications are submitted in response to solicitations by ICs for research areas the ICs seek to target or for which they have set aside funding.[33]

NIH's Center for Scientific Review (CSR) receives most applications. CSR assigns each application that meets basic eligibility requirements to a Scientific Review Group for the first stage of review and then to a potential awarding IC for the second stage.[34] The potential awarding

[26] NIH Data Book, "Research and Training Grants" https://report.nih.gov/nihdatabook/category/24.

[27] 42 C.F.R. §52h.1.

[28] Other statutes also govern aspects of NIH peer review requirements, such as PHSA Sections 402(b)(16) and PHSA Sections 402(b)(25), 405(b)(1)(B), 405(b)(2), and 406(a)(3)(A).

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

[30] NIH National Institute of Allergy and Infectious Diseases, "Timeline for Funding Decisions," September 30, 2024, https://www.niaid.nih.gov/grants-contracts/timelines-funding-decisions.

[31] NIH, "Understanding Funding Opportunities," https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/understand-funding-opportunities.htm.

[32] Called "Parent Announcements"; see NIH, "Parent Announcements (For Unsolicited or Investigator-Initiated Applications)," https://grants.nih.gov/grants/guide/parent_announcements.php.

[33] These include Program Announcements and Requests for Applications. Program Announcements are issued by one or more ICs to highlight areas of scientific interest, and Requests for Applications are funding opportunities issued by one or more ICs to highlight well-defined areas of scientific interest to accomplish specific program objectives. See NIH, "Understanding Funding Opportunities," https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/understand-funding-opportunities.htm.

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

IC is the one whose mission best aligns with the objectives of the research proposal.[35] In some cases, ICs directly receive and provide initial review of applications.[36]

First stage: In the first stage of peer review, the applications are assigned for review by a Scientific Review Group (SRG), which is a peer-review committee composed of roughly 12 to 22 scientists who are experts in the relevant fields of research.[37][38] NIH convenes many SRGs to review applications. As of 2023, there were over 250 chartered or recurring study sections (or SRGs) in addition to temporary SRGs. About 19,000 distinct peer reviewers participated in approximately 1,200 peer review meetings each year.[39]

Per statute, no more than one-fourth of the members of any SRG may be federal employees.[40] Peer reviewers are expected to disclose conflicts of interest and may not participate in evaluations of grant applications where they have conflicts of interest.[41]

The SRG is responsible for evaluating a grant proposal on the basis of scientific merit and potential impact of the research.[42] (See the "Changes to Peer Review Criteria for Research Grants" **text box** below for new developments). SRGs also review applications for certain NIH policy requirements, such as plans for protecting animals and humans involved in research (see the **Appendix**).[43] After discussing the application, each member gives the application a final score for scientific and technical merit, and an overall impact score is determined from the average of members' final scores.[44] The application may also be given a percentile ranking based on how the overall impact score compares with other applications reviewed by the SRG in the preceding two review rounds.[45]

Second stage: In the second stage, the funding decisions are refined by the National Advisory Councils or Boards of the potential awarding ICs, which are advisory committees that oversee each IC's research priorities and portfolios.[46] Advisory Councils and Boards are composed of scientific and lay representatives.[47] No federal employees may serve as regular voting members.[48]

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[35] NIH, *Report of the Director of the National Institutes of Health: Fiscal Years 2019-2021*, p. 14, https://dpcpsi.nih.gov/sites/default/files/2023-09/FY19-21%20Triennial_Report_FINAL_508C.pdf.

[36] NIH, *2.4.1 Initial Review*, NIH Grants Policy Statement, April 2024, https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.4.1_initial_review.htm.

[37] NIH, *NIH Peer Review: Grants and Cooperative Agreements*, https://grants.nih.gov/grants/peerreview22713webv2.pdf; NIH, *NIH Peer Review: Grants and Cooperative Agreements*, https://grants.nih.gov/grants/peerreview22713webv2.pdf; and Jeffrey Mervis, "Peering into peer review," *Science*, vol. 343 (February 7, 2014), pp. 596-598.

[38] 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.

[39] NIH Center for Scientific Review, "CSR Data and Evaluations: CSR Overview," https://public.csr.nih.gov/AboutCSR/Evaluations#overview.

[40] PHSA Section 402(b)(29); 42 U.S.C. §282(b)(29).

[41] 42 C.F.R. §52h.5.

[42] Review criteria are outlined broadly in regulations at 42 C.F.R. §§52h.8 and 11 and then further specified in each notice of funding opportunity announcement for the specific award. See NIH, *NIH Peer Review: Grants and Cooperative Agreements*, https://grants.nih.gov/grants/peerreview22713webv2.pdf.

[43] 42 C.F.R. §§52h.8 and 11 and NIH, *NIH Peer Review: Grants and Cooperative Agreements*, https://grants.nih.gov/grants/peerreview22713webv2.pdf.

[44] NIH, "Peer Review-Scoring," https://grants.nih.gov/grants/peer-review.htm#scoring2.

[45] NIH, "Funding Decisions," https://grants.nih.gov/grants-process/award/funding-decisions.

[46] Authorized in PHSA Section 406, 42 U.S.C. §284a.

[47] PHSA Section 406(b)(3), 42 U.S.C. §284a(b)(3).

[48] CRS Communication with NIH Office of Federal Advisory Committee Policy, June 30, 2022.

These groups examine summary statements of 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.[49] 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.[50] The IC director then makes final funding decisions.[51] The 21st Century Cures Act of 2016 (P.L. 114-255) added a requirement that the IC Director weigh the Advisory Council or Board'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.[52]

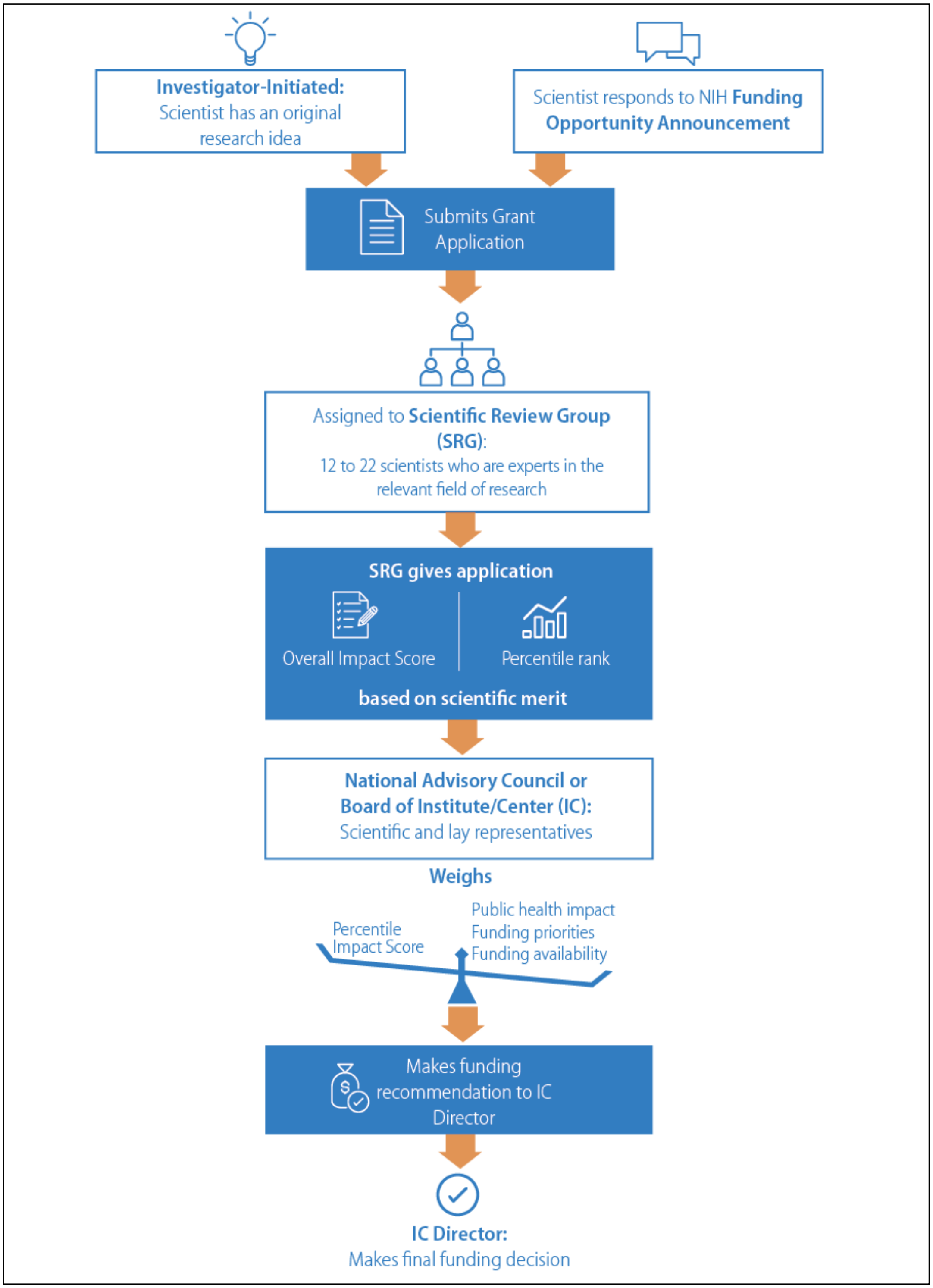
[49] NIH, *2.4.3 National Advisory Council or Board Review*, NIH Grants Policy Statement, April 2024, https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.4.1_initial_review.htm.

[50] NIH, *Report of the Director of the National Institutes of Health: Fiscal Years 2019-2021*, pp. 15-16, https://dpcpsi.nih.gov/sites/default/files/2023-09/FY19-21%20Triennial_Report_FINAL_508C.pdf.

[51] PHSA §405(b)(3).

[52] See Section 2033 of the act.

Figure 4. NIH Scientific Peer Review Process for Extramural Funding



Sources: Developed by CRS based on 42 C.F.R. Part 52h, NIH, Public Health Service Act Section 405; NIH, *2.4. The Peer Review Process,* NIH Grants Policy Statement, April 2024, https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.4_the_peer_review_process.htm. *NIH Peer Review: Grants and Cooperative Agreements*, https://grants.nih.gov/grants/peerreview22713webv2.pdf; and NIH, "Grants and Funding: Peer Review," https://grants.nih.gov/grants/peer-review.htm.

Changes to Peer Review Criteria for Research Grants

In October 2023, NIH announced simplified peer review criteria for the scientific and technical review of research proposals, to be in effect for grant receipt deadlines as of January 25, 2025, and beyond. These new criteria were developed in response to concerns about the complexity of peer review and the burden on reviewers. NIH also sought to mitigate reputational bias in review. The agency has faced long-standing concerns that its review process favors experienced—and therefore often older—researchers at the expense of enabling new researchers to enter the field (see the "NIH and the Research Workforce Pipeline" section for further discussion). In addition, NIH working groups that helped develop the criteria stated that "persistent racial disparities in NIH funding raise the question of whether review criteria in any way perpetuate an unfair advantage or disadvantage."

The new criteria are designed to reduce NIH's five-factor rating framework to a three-factor framework. Prior to these changes, the five factors were: (1) Significance, (2) Innovation, (3) Approach, (4) Investigator, and (5) Environment, derived from factors listed in regulations governing the peer review process (42 C.F.R. §52h.8). The new criteria group these five into three factors: (1) Importance of the Research (Significance, Innovation); (2) Rigor and Feasibility (Approach); and (3) Expertise and Resources (Investigators, Environment). The first and second new factors are to receive scores from reviewers, while the third (Expertise and Resources) is to be considered, but not scored, in an effort to reduce reputational bias.

The new criteria are the result of a multiyear process to solicit feedback on the peer review criteria, develop proposed changes, and then solicit feedback on the proposal. According to an NIH summary of public comments, the majority of respondents favored the changes. Some disagreed with certain aspects of the changes. For example, some disagreed with making "Expertise and Resources," an unscored factor because they thought such criteria are critical to the work. Others argued that the changes did not go far enough to address bias in peer review. Many stressed the need for reviewer training to make the new criteria effective.

Sources: NIH, "Simplified Peer Review Framework," https://grants.nih.gov/policy/peer/simplifying-review/framework.htm; "Developing the Simplified Framework" in NIH, "Background—NIH Peer Review Process," https://grants.nih.gov/policy/peer/simplifying-review/background.htm; NIH Center for Scientific Review, "Announcing a Simplified Review Framework for NIH Research Project Grant Applications," October 19, 2023, https://www.csr.nih.gov/reviewmatters/2023/10/19/announcing-a-simplified-review-framework-for-nih-research-project-grant-applications/; Center for Scientific Review Advisory Council Simplifying Review Criteria Working Groups, "Recommendations for Simplifying R01 Review Criteria," April 27, 2021, https://public.csr.nih.gov/sites/default/files/2021-04/Recommendations_of_the_CSRAC_Working_Group_on_Simplifying_Review-non-CT_and_CT.pdf; and NIH, "Simplifying Review Framework: Feedback from the Request for Information," April 28, 2023, https://grants.nih.gov/sites/default/files/NIH%20SRF%20RFI%20Content%20Analyses%20April%202023%20508c.pdf.

Grants Policy

NIH grantees must comply with NIH policies governing their award. NIH grant requirements are based in laws, regulations, and NIH-developed policies. As summarized in the "Authority" section above, NIH's statutory authorizations, especially in PHSA Title IV, form the statutory basis for NIH grant requirements along with other HHS and federal-wide requirements elsewhere in law. Key regulations underpinning NIH grants include general HHS award regulations (45 C.F.R. Part 75)[53] and NIH-specific regulations (42 Parts 50-52i and 59a, with variation by grant type).

NIH maintains an annually updated "Grants Policy Statement" on the standard terms and conditions of NIH grant awards.[54] Grantees are also informed of specific award requirements in their "Notice of Award." For the most part, extramural researchers must comply with the same

[53] These regulations reflect HHS's adoption of uniform federal award regulations promulgated by the Office of Management and Budget in 2 C.F.R. Part 200. (Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards). HHS follows the federal government-wide requirements with a few variations specific to the department.

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

research policy requirements as intramural researchers. Some of these policy requirements are summarized in the **Appendix**.

Selected NIH Grants Terminology

Authorized Organization Representative (AOR): The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards.

Grants Management Officer (GMO): An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. GMOs are delegated the authority from the Chief Grants Management Officer to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH IC that awards grants has one or more GMOs with responsibility for particular programs or awards.

Program Director/Principal Investigator (PD/PI): The individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. The applicant organization may designate multiple individuals as program directors/principal investigators (PD/PIs), who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PD/PIs are named, each is responsible and accountable to the applicant organization or, as appropriate, to a collaborating organization for the proper conduct of the project or program, including the submission of all required reports. The presence of more than one PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI.

Program Official/Program Officer/Project Officer (PO): The NIH official responsible for the programmatic, scientific, and technical aspects of a grant or cooperative agreement.

Source: NIH, "Grants-Glossary," https://grants.nih.gov/grants/glossary.htm.

Grants Administration and Oversight

While NIH-funded research projects are typically led by Program Directors/Principal Investigators (PD/PIs; see the **text box** above), grant awards are generally made to the institutions that employ those researchers. At funded institutions, an Authorized Organization Representative (AOR) is responsible for the administrative aspects of NIH grants. AORs are responsible for signing grant applications submitted by PD/PIs and, in doing so, ensure that the institution will comply with all applicable federal requirements. According to NIH, AORs, PD/PIs, and other research administration staff share overall responsibility for the successful implementation of an NIH grant.[55] If an NIH awardee collaborates with another research institution on the grant, the awardee is responsible for overseeing their collaborators (with prior approval required from NIH in some cases), regardless of whether the NIH awardee provides any funding or support to the collaborator.[56] The NIH Division of Grants Compliance and Oversight provides training and resources to grantees and institutions to ensure compliance.[57]

NIH monitors its awardees through reporting requirements, such as financial reporting and research progress reports.[58] Every funded NIH grant has an assigned Grants Management Officer (GMO) responsible for overseeing business and nonprogrammatic (e.g., financial) aspects of the grant, as well as a Program Official (PO) responsible for overseeing programmatic, scientific, and

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[55] NIH, *2.1.2 Roles and Responsibilities-Recipient Staff*, NIH Grants Policy Statement, April 2024, https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.1.2_recipient_staff.htm.

[56] See NIH, *2.15.1 Consortium Agreements: General*, NIH Grants Policy Statement, April 2024, https://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15.1_general.htm.

[57] NIH Grants & Funding, "Grants Compliance & Oversight," https://grants.nih.gov/policy/compliance.htm.

[58] NIH Grants & Funding, "Post-Award Monitoring and Reporting," https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm.

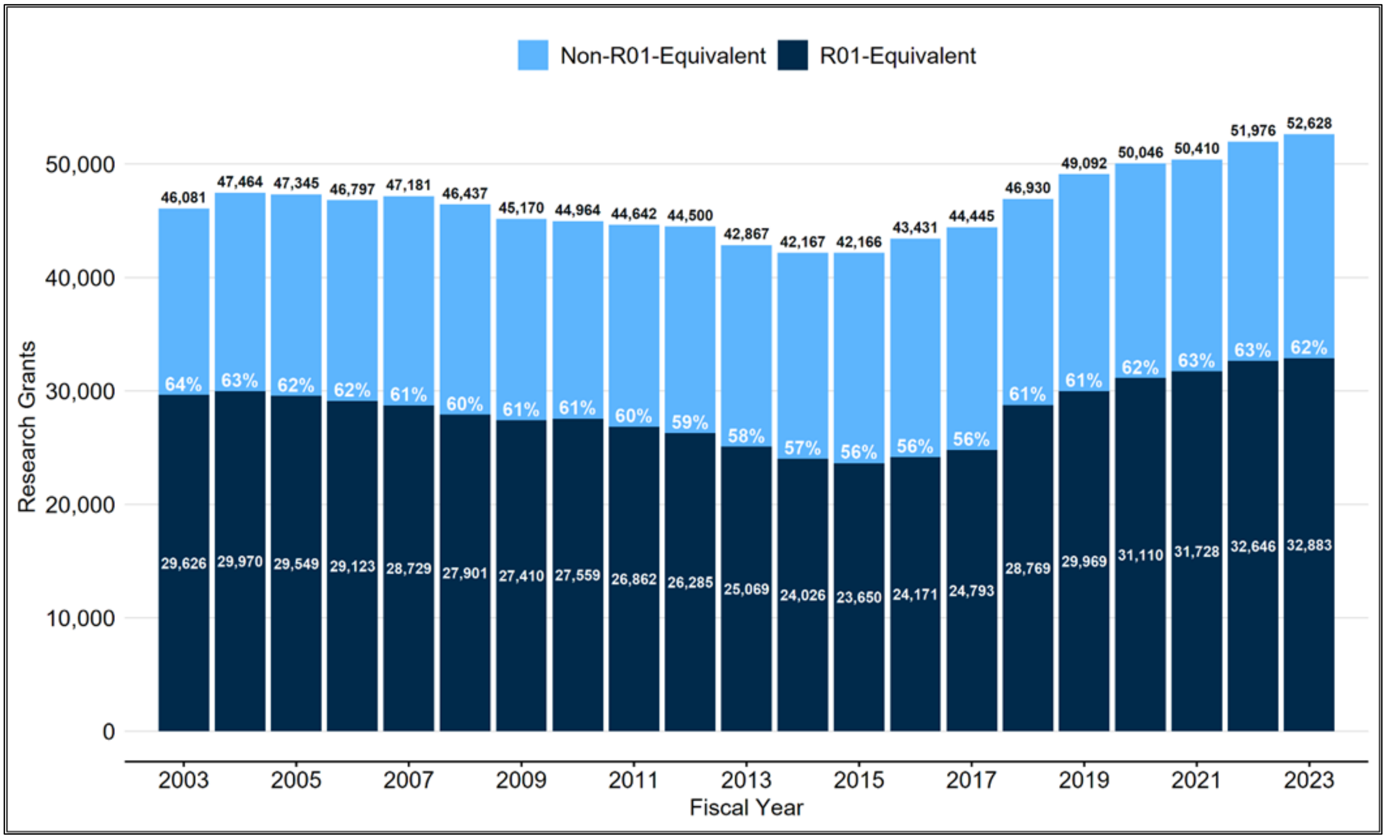
technical aspects of the grant (see the **text box** above).[59] NIH may also conduct site visits to ensure compliance as needed.[60] NIH and funded research institutions share responsibility for ensuring that NIH-funded research complies with federal requirements.[61]

Research Grants: By the Numbers

In FY2023, NIH funded over 52,000 research grants (including RPGs, center grants, and other research awards). **Figure 5** illustrates funding trends, showing the percentage of research grants each year for R01-equivalent awards.

Figure 5. Research Grants Awarded, by Fiscal Year, 2009-2023

Includes number and percentage of R01-equivalent grants of total research grants awarded



Source: CRS analysis of data from NIH Data Book, including "Research Grants: Awards, by Institute/Center," https://report.nih.gov/nihdatabook/report/205, and "R01-Equivalent Grants: Awards as a Percentage of All Research Grants," https://report.nih.gov/nihdatabook/report/32.

Notes: Research grants are defined as extramural awards made for Research Centers, Research Projects, Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Grants, and Other Research Grants. Research Grants are defined by the following NIH activity codes: R, P, M, S, K, U (excluding UC6), DP1, DP2, DP3, DP4, DP5, D42, and G12. R01-equivalent grants are defined as grants awarded under NIH activity codes DP1, DP2, DP5, R01, R37, R56, RF1, RL1, U01, and R35 from select NIGMS and NHGRI program announcements (PAs).

[59] NIH, *2.1.1 Roles and Responsibilities-NIH and HHS Staff*, NIH Grants Policy Statement, April 2024, https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.1.1_nih_and_hhs_staff.htm.

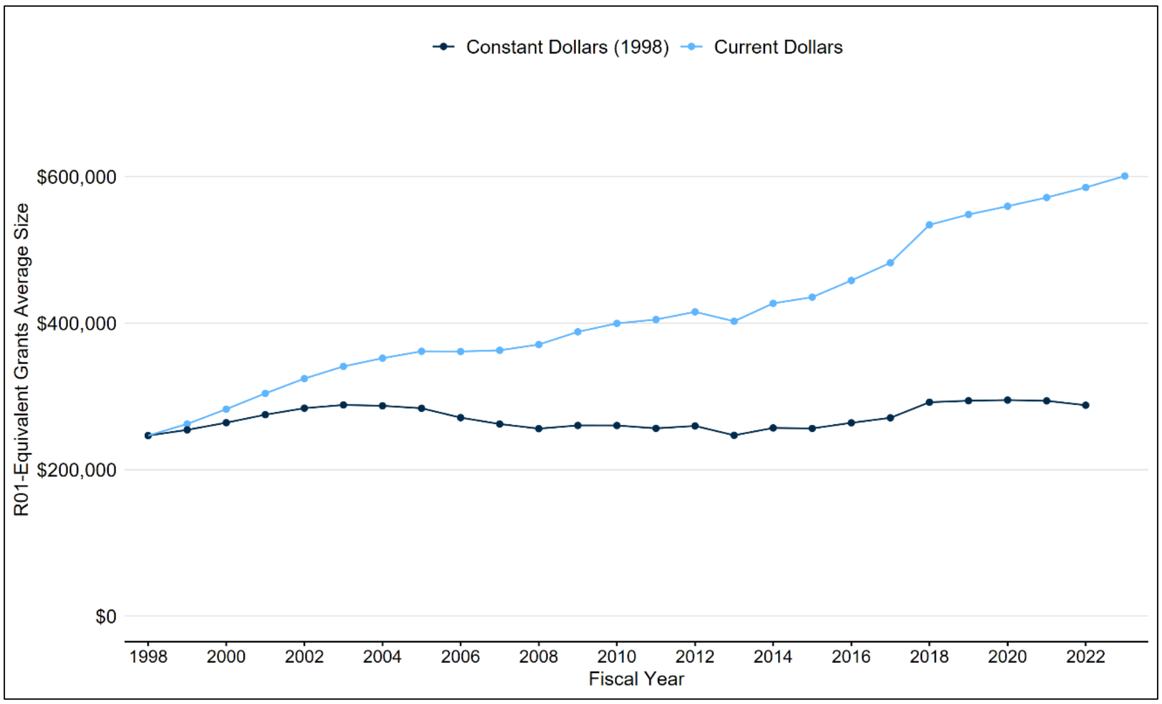
[60] NIH Grants & Funding, "Grants Compliance & Oversight," https://grants.nih.gov/policy/compliance.htm.

[61] Ibid.

As shown in **Figure 5**, the total number of grants rose slightly following the end of the NIH budget doubling period (FY2003) and then began to fall when NIH saw decreases in its purchasing power by FY2009 (see the "Budget" section). With funding increases, the total number of grants awarded began to increase in FY2016 and eventually exceeded the prior peak level in FY2004 (47,464 grants) by FY2019 (49,092). The majority of grants awarded are R01-equivalent independent research project grants, ranging from 56% to 64% of all grants awarded in any year.

In FY2022, the average cost of an R01-equivalent grant was $585,307.[62] Average costs vary by type of grant. For example, the average cost of research center grants in FY2022 was over $2.4 million.[63] As shown in **Figure 6**, while the average cost of an R01-equivalent grant rose in current dollars from FY2000 to FY2023, the average cost rose slightly when adjusting for inflation ($288 thousand in 2022 compared with $247 thousand in FY1998).

Figure 6. R01-Equivalent Grant Average Cost: 2000 to 2023



Source: NIH Data Book, "R01-Equivalent Grants: Average Size," https://report.nih.gov/nihdatabook/report/158.

Notes: Inflation adjustment used the Biomedical Research and Development Price Index (BRDPI).

Intramural Research

The NIH intramural research program (IRP), at about $5.0 billion in FY2023, accounts for approximately 11% of the total NIH budget.[64] IRP employs approximately 1,150 principal investigators and 6,000 trainees, ranging from high school students to postdoctoral and clinical

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[62] NIH Data Book, "R01-Equivalent Grants: Average Size," https://report.nih.gov/nihdatabook/report/158.

[63] NIH Data Book, "Research Center Grants: Average Size," https://report.nih.gov/nihdatabook/report/160.

[64] CRS analysis of data from NIH, "FY2025 Justification of Estimates for Appropriations Committees, Vol I: Overview–History of Obligations by Total Mechanism," p. 50, https://officeofbudget.od.nih.gov/pdfs/FY25/br/Overview%20of%20FY%202025%20Presidents%20Budget%20corrected%20Jul%2015.pdf.

fellows in NIH-operated laboratories.[65] 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.[66]

Almost all of the ICs have an intramural research program, but the size, structure, and activities of the programs vary greatly.[67] 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, allocating resources to certain laboratories and programs, and conducting reviews by panels of external experts. [68] In addition, intramural researchers are generally subject to the same research policy requirements as extramural researchers (see the **Appendix** section) but adhere to these requirements through internal NIH processes.[69] 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 also reviewed by an external panel every 10 years, concerning the entire research portfolio and impact of the research.[70]

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 solely to clinical research. Along with scientists, the Clinical Center employs over 1,000 nurses and allied health professionals to support its work.[71] Most ICs with intramural research programs fund research at the Clinical Center.

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."[72] Research training activities are designed to support every stage of a biomedical research career (see the "Stages of a Research Career" **text box** 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.[73] 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

[65] NIH, *Report of the Director of the National Institutes of Health: Fiscal Years 2019-2021*, p. 17, https://dpcpsi.nih.gov/sites/default/files/2023-09/FY19-21%20Triennial_Report_FINAL_508C.pdf.

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

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

[68] NIH, *Report of the Director of the National Institutes of Health: Fiscal Years 2019-2021*, p. 18, https://dpcpsi.nih.gov/sites/default/files/2023-09/FY19-21%20Triennial_Report_FINAL_508C.pdf.

[69] See NIH, "Policy Manual," https://policymanual.nih.gov/.

[70] NIH, *Report of the Director of the National Institutes of Health: Fiscal Years 2019-2021*, p. 18, https://dpcpsi.nih.gov/sites/default/files/2023-09/FY19-21%20Triennial_Report_FINAL_508C.pdf.

[71] Ibid, pp. 19-20.

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

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

postdoctoral research training awards to both institutions and individuals. In 2023, the NRSA program supported over 17,000 graduate students and postdoctoral fellows.[74]

Stages of a Scientific Research Career

- **Undergraduate and Postbaccalaureate**. Current students or recent recipients of bachelor's degrees who are studying 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 a career as an independent researcher.
- **Early Career Researcher.** 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. They often serve as mentors to trainees at undergraduate, predoctoral, and postdoctoral levels.

Source: NIH, "Research Training and Career Development- Career Path," at https://researchtraining.nih.gov/career-path.

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 health care professionals on the latest science.[75]

Budget

At roughly $47 billion for FY2024 (excluding ARPA-H funding), 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). In FY2023, about 32% of all discretionary HHS funding was provided to NIH.[76] Moreover, as of FY2023, NIH represented about one-fifth of total federal R&D funding and close to 45% of federal spending on R&D outside of the Department of Defense.[77]

NIH has seen budget fluctuations, as shown in **Figure 7**. 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

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[74] CRS analysis of numbers available in NIH, "Data Book- Kirschstein-NRSA Training Grants and Fellowships: Pre- and Post-Doctoral Full-Time Training Positions Awarded," https://report.nih.gov/nihdatabook/report/52.

[75] NIH, *Report of the Director of the National Institutes of Health: Fiscal Years 2019-2021*, pp. 50-53, https://dpcpsi.nih.gov/sites/default/files/2023-09/FY19-21%20Triennial_Report_FINAL_508C.pdf.

[76] Analysis of data used for CRS Report R48060, *Department of Health and Human Services: FY2025 Budget Request*.

[77] CRS analysis of federal research and development budget data provided by the Office of Management and Budget.

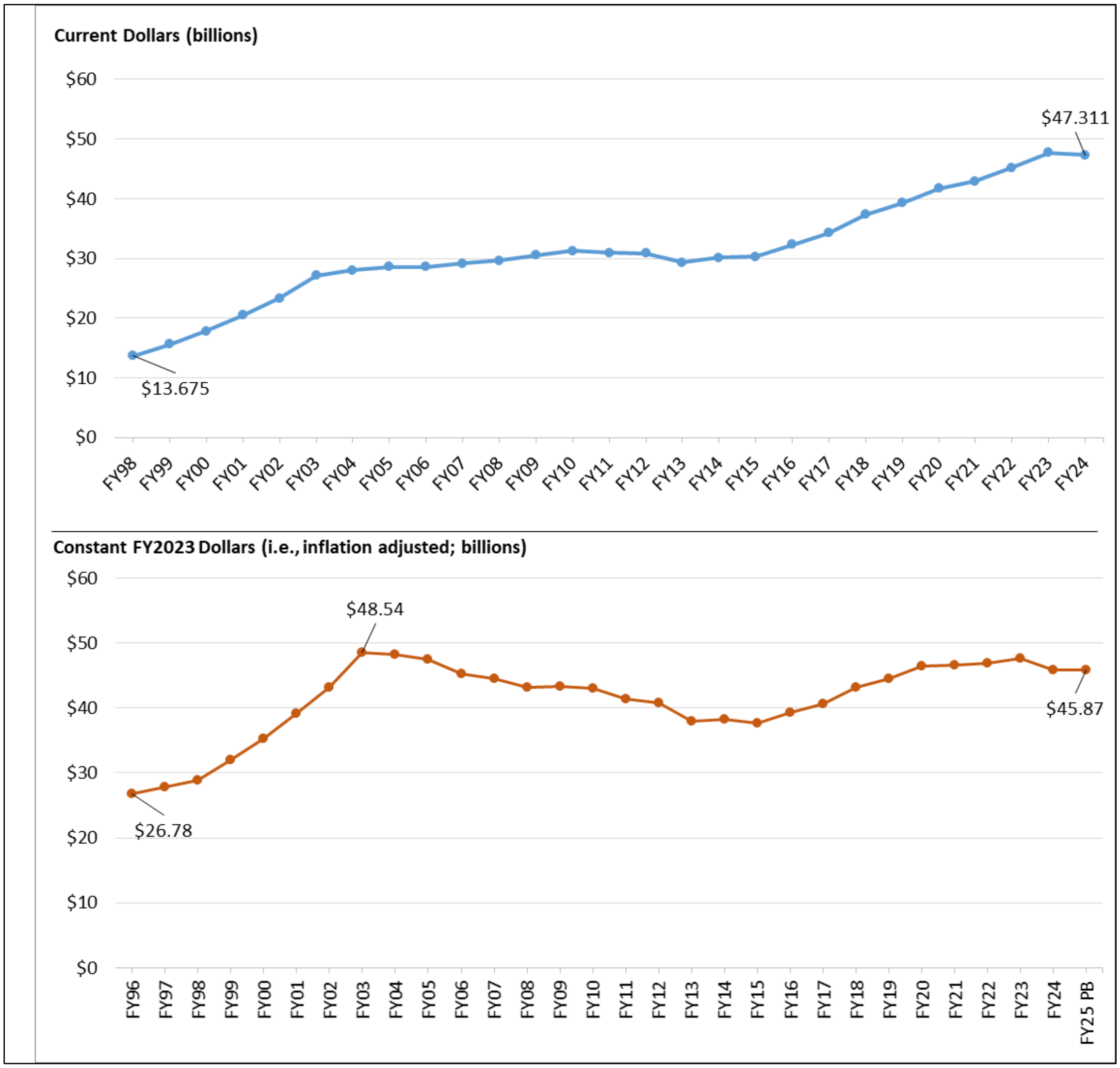
level of $27.2 billion. Subsequently, NIH experienced a decade of stagnant growth in the agency's budget. Congress provided budget increases generally around 1.0%-3.2% from FY2004 to FY2015, often lower than the rate of inflation for biomedical research, which resulted in reduced purchasing power for the agency. In some years (FY2006, FY2011, and FY2013), funding for the agency decreased in nominal dollars. Starting in FY2016 through FY2023, Congress provided NIH with funding increases each year, mostly over 5% annually, increasing the program level from $30.3 billion in FY2015 to $47.7 billion in FY2023.[78] NIH once again saw a slight reduction in its overall program level in FY2024, decreasing -0.7% compared with FY2023. In inflation-adjusted FY2023 dollars, the FY2024 NIH program level remains roughly 6% below the peak 2003 level.[79] For more information, see CRS Report R43341, *National Institutes of Health (NIH) Funding: FY1996-FY2025*.

[78] FY2023 level excludes funding for the Advanced Research Projects Agency for Health (ARPA-H).

[79] Analysis excludes funding for ARPA-H.

Figure 7. NIH Funding, FY1998-FY2024

Program Level Funding in Current and Constant (FY2023) Dollars



Source: FY2024 request and FY2024-enacted numbers from Congressional Record, daily edition, vol. 170, no. 51, Book 11, March 22, 2024, pp. H2022-H2025, accessed at https://www.congress.gov/118/crec/2024/03/22/170/51/CREC-2024-03-22-bk2.pdf, and P.L. 118-47. FY2023 final and FY2025 request numbers from NIH, Overview of FY2025 President's Budget, pp. 100, 101, at https://officeofbudget.od.nih.gov/pdfs/FY25/br/Overview%20of%20FY%202025%20Presidents%20Budget.pdf, and ARPA-H, Congressional Justification: FY2025, p. 9, accessed at https://arpa-h.gov/sites/default/files/2024-03/ARPA-H%20FY%202025.pdf. The FY2022 (and earlier) program levels are from NIH Budget Office, Appropriations History by Institute/Center (1938 to Present), at http://officeofbudget.od.nih.gov/approp_hist.html. Inflation adjustment reflects the Biomedical Research and Development Price Index (BRDPI), updated January 2024, at https://officeofbudget.od.nih.gov/gbiPriceIndexes.html.

Notes: Program level includes all budget authority, including transfers noted in budget documents. Amounts provided to NIH designated for emergency requirements are excluded from these totals (e.g., the FY2020 and FY2021 amounts do not include the amounts provided in the coronavirus supplemental appropriations acts).

Foundation for the NIH

NIH also works with the Foundation for the National Institutes of Health (FNIH), a 501(c)(3) charitable organization that raises private funding and manages public-private partnerships to support NIH's mission. FNIH was established by statute in 1990 (P.L. 101-613) and was amended in 1993 (P.L. 103-43). The organization initially began operations in 1996. FNIH supports research projects and programs, education and training, conferences and events, and other support activities for NIH.[80] 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.

As of 2023, FNIH has raised over $1.5 billion in support of NIH's mission.[81] FNIH also receives some transfers of NIH's appropriations for its administrative and operational expenses (averaging less than 0.01% of NIH's annual budget).[82] For more information on FNIH, see the relevant section in CRS Report R46109, *Agency-Related Nonprofit Research Foundations and Corporations*.

Setting NIH Research Priorities

NIH funds research on hundreds of diseases, conditions, and areas of human health.[83] NIH funding is highly competitive—21.4% of all research project grant applications were funded in FY2023.[84] 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;
- how to balance 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 or emerging health issues;
- how to allocate funding among established and successful scientists while enabling new scientists to enter the field;

[80] FNIH, "About Us," https://fnih.org/about, and FNIH, "Our Programs," https://fnih.org/our-programs/.

[81] FNIH, "FNIH Health Impact Report: 2023 Facts and Figures," https://fnih.org/story-2023-facts-figures/.

[82] CRS Report R46109, *Agency-Related Nonprofit Research Foundations and Corporations*.

[83] The NIH "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)" table includes over 280 categories of diseases, conditions, and research areas for which NIH categorizes its funding. The table is not comprehensive of all possible ways to categorize NIH research. See NIH, "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)" table, last updated May 14, 2024, https://report.nih.gov/funding/categorical-spending#/.

[84] NIH, "Justification of Estimates for Appropriations Committees FY2025, Overview Vol. I," p. 113.

- and how to determine the appropriate way to fund research among available mechanisms, including extramural grants, contracts, and intramural research.[85]

In recent decades, 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 other constituencies. At times, including in recent years, Congress has provided direction to NIH funding in both appropriations report language and legislation. The following sections summarize (1) NIH internal processes for setting research priorities through strategic planning and advisory groups, and (2) congressional involvement in NIH research priorities, including recent major efforts, legislation, and research restrictions.

NIH is not the only federal agency that supports biomedical and health research. The Department of Defense (DOD) and the Department of Veterans Affairs (VA) and others also support medical research programs.[86] In addition, other HHS agencies support health 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 research across the federal government.

NIH Process in Setting Research Priorities

Each NIH IC has separate research priorities, which are specified in statutory authority in varying levels of detail.[87] IC research priorities are also broadly captured by their mission statements.[88] 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. Per statute, the advisory councils consist of no more than 18 members appointed by the HHS Secretary. Two-thirds of the members represent leading representatives of the relevant health and scientific disciplines. One-third of the members are appointed from the general public and include leaders from other fields, such as law, health policy, economics, and management.[89] According to the agency, decisionmakers at NIH seek 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.[90]

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[85] See discussions in U.S. Congress, House Energy and Commerce Committee, Health Subcommittee, *Scientific Opportunities and Public Needs: Balancing NIH's Priority Setting Process*, 108th Cong., 2nd sess., June 2, 2004, and U.S. Congress, Senate Health, Education, Labor, and Pensions Committee, Labor Subcommittee, *Biomedical Research Priorities: Who Should Decide?*, 105th Cong., 1st sess., May 1, 1997.

[86] See CRS In Focus IF10349, *Congressionally Directed Medical Research Programs Funding for FY2024*, and section on "Medical Care and Medical Research Discretionary Programs Funding" in CRS Report R48056, *Department of Veterans Affairs FY2024 Appropriations*.

[87] Title IV of PHSA includes statutory authorities for all NIH ICs. See the "Authority" section of this report.

[88] NIH, "List of Institutes and Centers," last updated July 2023, https://www.nih.gov/institutes-nih/list-institutes-centers.

[89] Most NIH advisory councils are authorized in PHSA Section 406; 42 U.S.C. §284a. That section specifies membership and responsibilities for each advisory council.

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

Strategic Planning

For many years, most ICs have undergone a periodic strategic planning process to determine its funding priorities among the research areas in each IC's broadly defined mission and programmatic areas.[91] Statute 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."[92] The Cures Act (P.L. 114-255) added a requirement for an NIH-Wide Strategic Plan, in part to facilitate IC collaboration and coordination, to be updated every six years.[93] This followed a prior directive for NIH to develop an agency-wide strategic plan in the FY2015 appropriations law (P.L. 113-235).[94] (See the "Recent Major Legislative History" section.)

In the latest NIH-wide strategic plan for 2021-2025, NIH states that it seeks to meet its mission "by pursuing scientific opportunities when they arise, responding to ongoing and emerging public health needs, and addressing rare diseases." The plan specifies overarching agency objectives around advancing research, supporting research capacity, and ensuring research integrity. In addition, the plan names specific themes that NIH intends to support across its research portfolios. These include (1) Improving Minority Health and Reducing Health Disparities, (2) Enhancing Women's Health, (3) Addressing Public Health Challenges Across the Lifespan, (4) Promoting Collaborative Science, and (5) Leveraging Data Science for Biomedical Discovery.[95]

According to NIH, the Strategic Plan was developed with input from external stakeholders, including "members of the scientific and health care communities, professional societies, advocacy organizations, industry, other federal agencies, and the general public" and in collaboration with leadership and staff of NIH's Institutes, Centers, and Offices.[96]

Coordinating Across NIH

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 transdisciplinary, cross-institute research initiatives. The Reform Act also created a special office, the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), that "identifies important areas of emerging scientific opportunity or rising public health challenges to assist in the acceleration of research investments in these areas."[97] 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.[98]

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[91] Each individual IC strategic plan specifies its planning process; from NIH, "NIH Strategic Plans and Visions," at https://report.nih.gov/reports/strategic-plans.

[92] PHSA Section 402(b)(5); 42 U.S.C. §282(b)(5).

[93] 42 U.S.C. §282(m).

[94] See 128 STAT. 2475.

[95] NIH, "NIH-Wide Strategic Plan: Fiscal Years 2021-2025," p. 3, https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2021-2025-508.pdf.

[96] Ibid, pp. 44-45.

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

[98] NIH, "Office of Strategic Coordination—The Common Fund," https://commonfund.nih.gov/about.

Coordinating Across the Federal Government

As mentioned above, several agencies within and outside of HHS fund health research. NIH program staff use applicant information and other agencies' funding databases to avoid duplicating funding with another agency for the same recipient for the same project.[99] In addition, NIH holds regular meetings to collaborate and align priorities with other HHS research agencies, DOD, and VA.[100] NIH publishes an annual report and maintains a database of its collaborations with other HHS agencies.[101]

The executive branch and Congress have also established some interagency strategies and committees aimed at aligning research priorities across agencies, usually in an effort to ensure that funded research across agencies furthers overarching health goals. These strategies or committees are often specific to certain disease or research areas. The next section provides a few examples established by Congress.

Selected Examples of Interagency Coordinating Committees

Interagency Pain Research Coordinating Committee (IPRCC): The Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended) established the Interagency Pain Research Coordinating Committee,[102] which is now led by NIH.[103] The committee, made up of federal and nonfederal members, oversees scientific progress across the government under the Federal Pain Research Strategy, which focuses on advancing pain prevention and management, along with other efforts to advance pain research.[104]

Muscular Dystrophy Coordinating Committee (MDCC): As authorized in statute,[105] the Muscular Dystrophy Coordinating Committee coordinates research across NIH and with other federal agencies on all forms of muscular dystrophy. The committee, currently supported by National Institute of Neurological Disorders and Stroke (NINDS), includes both federal and nonfederal members and is tasked with developing a plan for research and education on muscular dystrophy across HHS to encompass health, psychosocial, public services, and rehabilitative issues related to the disease.[106]

Interagency Autism Coordinating Committee: As initially established by the Children's Health Act of 2000 (P.L. 106-310), the Interagency Autism Coordinating Committee (IACC), composed of federal and nonfederal public members, coordinates federal efforts related to autism spectrum

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[99] U.S. Government Accountability Office (GAO), *Biomedical Research: Actions Needed to Adopt Collaboration Practices to Address Research Duplication*, GAO-24-106757, February 2024, https://www.gao.gov/assets/870/866837.pdf, and GAO, *Biomedical Research: Observations on DOD's Management of Congressionally Directed Medical Research Programs*, GAO-22-105107, January 31, 2022, pp. 6-7, https://www.gao.gov/assets/gao-22-105107.pdf.

[100] Ibid.

[101] See NIH, "Report on NIH Collaborations with Other HHS Agencies for Fiscal Year 2022," https://crs.od.nih.gov/CRSPublic/.

[102] Authorized at PHSA Section 409J(b); U.S.C. 42 §284q.

[103] NIH, "About the NIH IPRCC," https://www.iprcc.nih.gov/about/nih-iprcc. Specifically, the Director of the National Center for Complementary and Integrative Health currently chairs the committee. See "Membership," https://www.iprcc.nih.gov/about/membership.

[104] NIH, "Federal Pain Research Strategy Overview," https://www.iprcc.nih.gov/federal-pain-research-strategy-overview.

[105] PHSA Section 404E(d); 42 U.S.C. §283g(d).

[106] PHSA Section 404E(e) and NIH, "Charter: Muscular Dystrophy Coordinating Committee," https://www.ninds.nih.gov/sites/default/files/documents/MDCC_Charter_508C.pdf.

disorder (ASD), including both research and services and supports activities.[107] The National Institute of Mental Health manages the committee and provides administrative support.[108]

Congressional Involvement in NIH Research Priorities

Congress has shaped NIH by establishing its overall authorizing statutes (see the "Authority" section), which govern the agency's overall structure, its award and review processes, and the responsibilities of each of its ICs. Congress also provides annual appropriations to the IC accounts, which drive NIH's overall research direction by setting different funding levels for ICs with different missions. From time to time, Congress has also authorized or funded specific research programs—often disease-specific research programs—either within or across NIH ICs. Congress has supported major large-scale research initiatives on specific diseases at NIH, including during the War on Cancer in the 1970s, for the HIV/AIDS epidemic in the 1980s and 1990s, and through several research initiatives discussed in the "Selected Recent Research Initiatives" section.[109] A long-standing debate has centered on whether and to what extent Congress should specify funding for certain diseases or programs within NIH, or whether Congress should allow the agency to determine research funding allocations through its own priority setting and review processes.[110] The following sections discuss how Congress has shaped NIH's research priorities through both appropriations and authorizations legislation. Congress at times has also enacted certain restrictions on NIH research.

Appropriations

For many years prior to FY2015, appropriators 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 were appropriated to each IC, and then funding was awarded through competitive grants, through contracts, or to intramural researchers.[111]

Changes in congressional practice have occurred most notably with research funding for Alzheimer's disease (discussed further in the "Alzheimer's Disease and Related Dementias Research" section). 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).[112] 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

[107] PHSA Section 399CC; 42 U.S.C. §280i-2.

[108] NIH, "Interagency Autism Coordinating Committee Charter," https://iacc.hhs.gov/about-iacc/charter/.

[109] NIH National Cancer Institute, "National Cancer Act of 1971," https://www.cancer.gov/about-nci/overview/history/national-cancer-act-1971, and Department of Health and Human Services (HHS), "A Timeline of HIV and AIDS," *HIV.gov*, https://www.hiv.gov/hiv-basics/overview/history/hiv-and-aids-timeline.

[110] Rachel Kahn Best, "Chapter 4: Ranking Diseases," in *Common Enemies: Disease Campaigns in America* (New York, NY: Oxford University Press, 2019), pp. 84-108.

[111] CRS review of appropriations documents.

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

> 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.[113]

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.[114] Then, in a departure from recent precedent, the explanatory statements accompanying FY2016 appropriations directed NIH to reserve a specific amount for Alzheimer's disease research.[115]

In recent years, appropriations reports for NIH have specified dollar amounts for some research related to certain diseases or topics, though annual appropriations have left most of each IC's funding flexible and untargeted. For example, the explanatory statement accompanying FY2024 appropriations for NIH included over 40 line items directing specific dollar amounts for certain research or program areas.[116] A Senate FY2024 appropriations report (S.Rept. 118-84) explained the committee's approach to targeting NIH funding as follows:

> As in previous years, the Committee has targeted NIH funding in areas of promise of scientific advancement and urgency, while allowing NIH to maintain flexibility to pursue unplanned scientific opportunities and address unforeseen public health needs.[117]

Authorizations

At times, Congress has enacted authorizations for specific programs or research areas within NIH ICs. Congress has, for example, enacted provisions targeting new types or approaches to research to be supported by NIH. For example, the Cures Acceleration Network (P.L. 111-148) in 2010 sought to advance technologies to improve drug development. Laws have also been enacted targeting specific disease or health program areas within NIH ICs. For example, since 2010, specific laws were enacted related to research on hearing loss screening and detection (P.L. 111-337), pancreatic and lung cancer (P.L. 112-239), pediatric cancer (P.L. 113-94, P.L. 115-180), muscular dystrophy (P.L. 113-166), and pain (P.L. 114-198), to name a few examples.

In some cases, these laws have provided NIH or its ICs with new authorities or funding sources for research and, at times, have included new requirements for NIH research (e.g., strategic planning or reporting requirements).[118] However, in many cases, NIH does not need a specific authorization to fund research on a certain health topic. NIH is able to support research on nearly all areas of human health through its existing authorizations.

Some policymakers have long questioned whether considering disease-specific legislation for NIH research is a productive use of limited committee and floor time, and whether such

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

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

[115] *Congressional Record*, December 17, 2015, vol. 161, no. 184—Book III, H10285.

[116] See Table A-1 in CRS Report R43341, *National Institutes of Health (NIH) Funding: FY1996-FY2025*. Includes funding directives incorporated by reference from S.Rept. 118-84.

[117] S.Rept. 118-84, p. 89.

[118] For example, the Gabriella Miller Kids First Research Act (P.L. 113-94) created a new funding source for research by directing transfers of certain amounts from the Presidential Election Campaign Fund to a new 10-Year Pediatric Research Initiative Fund to be made available for pediatric research as authorized by the law. The authorization for the Cures Acceleration Network (P.L. 111-148) granted NIH new authorities to support research, including through Other Transactions authority and through requiring matching funds from certain recipients under the program. P.L. 115-180 added new reporting requirements for NIH on childhood cancer research projects.

legislation leads to the best outcomes at NIH.[119] At the same time, Members of Congress frequently hear from stakeholders—particularly disease-specific advocates—calling for NIH research on certain topics.[120] These stakeholders may express concern that NIH is inadequately funding research in certain areas or that the agency's funded research approaches are not meeting health needs.[121] In an effort to be responsive to these stakeholders, Congress has sometimes considered and passed disease-specific legislation for NIH research. To illustrate, in 1993, an exchange between a House Representative and then-HHS Secretary during a hearing on the NIH Revitalization Act (H.R. 4, 103rd Congress) showed the considerations at hand with disease- and program-specific provisions in the bill:

> Rep Greenwood: "H.R. 4 is a nice, big, thick, 170-page bill that gives a lot of direction to the NIH with regard to research. The question I have is this: Is there anything in here that the institutes could not do without this legislation? Do you really need this kind of direction? Or, are we guilty of micro-managing in response to all of the well intentioned disease groups, if you will, pressuring for research funding."
>
> Sec. Shalala: "Of course, there is nothing that we could not do without those directives. The question is whether our own strategic planning process would produce that specific list which is what you are asking. My answer to this is that this is government money and those elected by the government have a right to give us-to nudge us, to set the standards for us, to give us a list of what they think is important. We also have a right to come back and argue what we think the priorities ought to be privately or publicly. It is just if I am going to keep my own integrity as part of this process, I am not going to pretend that we would not prefer to have more flexibility. I certainly wanted that as I headed any agency, but what I am suggesting to you is that this bill, as structured, is one that we believe on balance we can support. There are obviously parts of it that we might not think are terrific at this point in time."[122]

Research Restrictions

From time to time, Congress has placed restrictions on NIH research, often in annual appropriations legislation. Restrictions for FY2024 related to, for example, advocating or promoting gun control, payment for abortions, human embryo research, and promoting

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[119] See, for example, statement by Rep. Bliley in 1993 during consideration of the NIH Revitalization Act (H.R. 4, 103rd Congress), "I personally have serious reservations that world-renowned institution such as the NIH really needs this much detailed Congressional direction in order to conduct the best possible scientific research" (from U.S. Congress, House Energy and Commerce Committee, Health and Environment Subcommittee, *NIH Revitalization Act*, 103rd Cong., 1st sess., February 3, 1993), and statement by Senator Kennedy in 1997 hearing, "Setting research priorities, a complex process that must be informed by the concerns of many groups—the patients, women, children and the elderly. But the final judgment on the direction of the biomedical research must be left largely to NIH. They have the knowledge and experience to make the wisest decision" (from U.S. Congress, Senate Committee on Labor and Human Resources, Subcommittee on Public Health and Safety, *Biomedical Research Priorities: Who Should Decide?*, 105th Cong., 1st sess., May 1, 1997).

[120] To illustrate, an analysis found that beginning in the 1980s, witnesses representing disease-specific organizations or patient advocacy groups made up over 20% of all witnesses at annual House LHHS appropriations hearings that are open to all public witnesses. By the 1990s, such witnesses made up about one-third of all witnesses at such hearings. This is particularly notable because LHHS appropriations fund a wide a wide array of health, education, labor, social services, and other programs. See Rachel Kahn Best, "Chapter 4: Ranking Diseases," in *Common Enemies: Disease Campaigns in America* (New York, NY: Oxford University Press, 2019), pp. 87-88.

[121] Rachel Kahn Best, "Chapter 4: Ranking Diseases," in *Common Enemies: Disease Campaigns in America* (New York, NY: Oxford University Press, 2019), pp. 84-108.

[122] U.S. Congress, House Energy and Commerce Committee, Health and Environment Subcommittee, *NIH Revitalization Act*, 103rd Cong., 1st sess., February 3, 1993.

legalization of controlled substances.[123] In many cases, these restrictions reflected ethical and political decisions that Congress made about the types of research that NIH should support. As an example, the restriction on human embryo research dates back to FY1996 and prohibits HHS from creating human embryos for research purposes or "for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero" under referenced laws and regulations.[124]

Selected Recent Research Initiatives

Alzheimer's Disease and Related Dementias Research

As noted in the "Appropriations" section, Congress began directing specific funding levels for Alzheimer's and related dementias research in appropriations reports from FY2015 through FY2024, reflecting an overall recent change in congressional practice around specifying funding for certain diseases at NIH.

Table 1. NIH Alzheimer's Disease Research Funding Directed by Congress

Fiscal Year	Amount
FY2015	Increase of $25 million (no total specified)
FY2016	$926 million (+350 million)
FY2017	$1,391 million (+400 million)
FY2018	$1,828 million (+414 million)
FY2019	$2,340 million (+425 million)
FY2020	$2,818 million (+350 million)
FY2021	$3,118 million
FY2022[a]	Increase of $289 million
FY2023	Increase of $226 million
FY2024	Increase of $100 million

Source: Reports and explanatory statements accompanying annual Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations (LHHS) appropriations laws.

Notes: Amounts shown in parentheses from FY2016 to FY2020 show increases from the prior fiscal year. In some years, language directed funding for Alzheimer's disease research. In other years, language directed funding for Alzheimer's disease and related dementias research. The table does not show allocations to specific institutes and centers named in the directives.

a. Beginning in FY2022, the reports did not state a total provided for Alzheimer's disease and related dementias research, but rather stated that the appropriations law provided an increase for such research.

These funding increases have been driven by the National Plan to Address Alzheimer's Disease, first announced in 2012.[125] 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

[123] NIH, "Notice of Legislative Mandates in Effect for FY2024," from https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-110.html.

[124] Specifically, 45 C.F.R. §46.204(b) and PHSA Section 498(b) (42 U.S.C. §289g(b)). See Section 508 of Division D in Further Consolidated Appropriations Act, 2024 (P.L. 118-47), for current language of the restriction.

[125] 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.

Dementias by 2025" as the first of five key goals.[126] 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 budgeting process. 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 is to submit an annual independent Alzheimer's research budget request directly to Congress, pursuant to the National Alzheimer's Plan. 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 funding opportunity notices to solicit research proposals related to Alzheimer's disease from scientists.[127]

Alzheimer's disease research represents an area of major congressional involvement, in which large amounts of research funding are directed toward a specific disease. In recent years, some advances have been made in preventing, diagnosing, and treating Alzheimer's disease and related dementias, many of which have been linked to NIH research. For example, recent diagnostic advances in imaging and certain fluid-based tests have helped improve the ability to identify and diagnose Alzheimer's disease and related dementias in conjunction with other clinical evaluations.[128] NIH helped fund the development of the first blood test of amyloid, a biomarker (or biological indicator) of Alzheimer's disease.[129] NIH-funded research contributed to the imaging technologies used in clinical trials to assess the efficacy of drugs to treat Alzheimer's disease and related dementias.[130] In addition, NIH-funded research has contributed to an understanding of prevention; for instance, that controlling high blood pressure may reduce age-related cognitive impairment that may ultimately lead to Alzheimer's disease.[131] In recent years, the U.S. Food and Drug Administration has approved three drugs for treating mild or early-stage Alzheimer's disease.[132] NIH funded basic research into amyloid, the brain protein targeted by these drugs that helped inform their scientific basis.[133]

There is still much progress to be made in research on Alzheimer's disease and related dementias, including better understanding the contributions of genetics, environmental exposures, and life events to the disease and for improving diagnosis, including through digital tools or improved

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

[127] NIH, *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.

[128] W.M van der Flier, M.E de Vugt, E.M.A Smets, et al., "Towards a Future Where Alzheimer's Disease Pathology is Stopped Before the Onset of Dementia," *Nature Aging*, vol. 3 (May 18, 2023), pp. 494-505.

[129] National Institute on Aging (NIA), "Small Business Spotlight: C2N Diagnostics' Blood Test Detects Alzheimer's," November 1, 2022, https://www.nia.nih.gov/news/small-business-spotlight-c2n-diagnostics-blood-test-detects-alzheimers, and National Institute on Aging, "Biomarker Research," in *2020–2021 Report of Scientific Advances for the Prevention, Treatment, and Care of Alzheimer's Disease and Related Dementias*, https://nia.nih.gov/report-2020-2021-scientific-advances-prevention-treatment-and-care-dementia/biomarker-research.

[130] NIH, "10 Years of Alzheimer's Disease and Related Dementias Research," September 2023, https://www.nia.nih.gov/10-years-alzheimers-disease-and-related-dementias-research.

[131] NIA, "Intensive Blood Pressure Control May Slow Age-Related Brain Damage," press release, August 13, 2019, https://www.nia.nih.gov/news/intensive-blood-pressure-control-may-slow-age-related-brain-damage.

[132] Alzheimer's Association, "FDA-Approved Treatments For Alzheimer's," https://www.alz.org/media/Documents/alzheimers-dementia-fda-approved-treatments-for-alzheimers-ts.pdf.

[133] NIH, "2024 NIH Alzheimer's and Related Dementias Research Progress Report: Advances and Achievements," https://www.nia.nih.gov/sites/default/files/2024-08/2024-alzheimers-progress-report.pdf.

fluid-based tests, among many other topics. In addition, while drugs for treating Alzheimer's disease are now available, they serve a relatively small patient population with early or mild disease and can have significant side effects.[134] As of March 2024, the National Institute on Aging reported funding 72 different clinical trials on potential pharmacological treatments for Alzheimer's disease and related dementias that take many different treatment approaches.[135] More broadly, as of January 2024, there were 171 clinical trials assessing 134 drugs for treating Alzheimer's disease (funded by both the public and private sectors). One expert has argued that this level of drug development is much less than the level of development for cancer drugs.[136]

It may take decades to see the full scientific and medical impact of recent NIH investments in Alzheimer's disease and related dementias research. New drugs for any given disease generally build upon a body of science that takes decades to fully develop and then translate to practical application. According to a 2015 study, some of the first drugs approved to treat symptoms associated with Alzheimer's disease were approved 22 years after the body of science underpinning those drugs became established.[137] For the recent FDA-approved drugs that target amyloid, the body of science underlying those technologies became established in the early 2000s, fitting the same general trend with the related drug approvals occurring in 2022 to 2024.[138]

21st Century Cures Act Innovation Projects

The 21st Century Cures Act (P.L. 114-255; the Cures Act), enacted in December 2016, authorized $4.8 billion for NIH for four specific innovation projects over a 10-year period (FY2017-FY2026), with varying amounts allocated each fiscal year (see **Table 2**). The Cures Act established the "NIH Innovation Account," to which specified amounts were transferred for each of FY2017 through FY2026 (see **Table 2**) for the purpose of carrying out the following four NIH Innovation Projects, with funds made available in subsequent appropriations acts:

- The *All of Us* Research Program ($1.5 billion for FY2017 through FY2026), which aims to collect clinical, environmental, lifestyle, and genetic data from a large patient cohort over many years—with a goal of recruiting over 1 million

[134] National Academies of Sciences, Engineering, and Medicine, "Preventing and Treating Alzheimer's Disease and Related Dementias: Promising Research and Opportunities to Accelerate Progress: Proceedings of a Workshop–in Brief," Washington, DC, 2024, https://nap.nationalacademies.org/catalog/27784/preventing-and-treating-alzheimers-disease-and-related-dementias-promising-research-and-opportunities-to-accelerate-progress.

[135] NIA, "NIA-Funded Active Alzheimer's and Related Dementias Clinical Trials and Studies," last updated March 2024, https://www.nia.nih.gov/research/ongoing-AD-trials.

[136] National Academies of Sciences, Engineering, and Medicine, "Preventing and Treating Alzheimer's Disease and Related Dementias: Promising Research and Opportunities to Accelerate Progress: Proceedings of a Workshop–in Brief," Washington, DC, 2024, https://nap.nationalacademies.org/catalog/27784/preventing-and-treating-alzheimers-disease-and-related-dementias-promising-research-and-opportunities-to-accelerate-progress.

[137] Jennifer M. Beierlein, Laura M. McNamee, Michael J. Walsh et. al, "Patterns of Innovation in Alzheimer's Disease Drug Development: A Strategic Assessment Based on Technological Maturity," *Clinical Therapeutics*, vol. 37, no. 8 (August 1, 2015).

[138] Jennifer M. Beierlein, Laura M. McNamee, Michael J. Walsh et. al, "Patterns of Innovation in Alzheimer's Disease Drug Development: A Strategic Assessment Based on Technological Maturity," and email communication with Dr. Fred Ledley, one of the study authors in September 2024.

participants[139] (formerly named the Precision Medicine Initiative Cohort Program).[140]

- The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative ($1.5 billion for FY2017 through FY2026), which involves developing and implementing 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.[141]
- The *Beau Biden Cancer Moonshot* ($1.8 billion for FY2017 through FY2023), which began in 2016 and sought to make a decade's worth of progress in preventing and treating cancer in just five years.[142]
- The Regenerative Medicine project ($30 million for FY2017 through FY2020), which supported clinical research using adult stem cells in coordination with FDA.[143]

To date, amounts authorized for the Innovation Projects shown in **Table 2** have been fully appropriated.

Table 2. Authorization of Appropriations for NIH Innovation Projects Under the Cures Act

Millions of dollars

Fiscal Year	PMI/*All of US*	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**	**4,796**

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

139 NIH, *Implementation of Funding Plan for the NIH Innovation Projects Under the 21st Century Cures Act*, https://www.nih.gov/sites/default/files/research-training/initiatives/nih-cures-innovation-plan.pdf, and NIH, "About," *All of Us Research Program*, https://allofus.nih.gov/about.

140 NIH, "PMI Cohort Program announces new name: the All of Us Research Program," October 13, 2016, https://allofus.nih.gov/news-events/announcements/pmi-cohort-program-announces-new-name-all-us-research-program.

141 NIH, *Implementation of Funding Plan for the NIH Innovation Projects Under the 21st Century Cures Act*, https://www.nih.gov/sites/default/files/research-training/initiatives/nih-cures-innovation-plan.pdf, and NIH, The BRAIN Initiative, "Overview," https://braininitiative.nih.gov/about/overview.

142 National Cancer Institute, "History of the Cancer Moonshot," December 2023, https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/history.

143 NIH, *Implementation of Funding Plan for the NIH Innovation Projects Under the 21st Century Cures Act*, https://www.nih.gov/sites/default/files/research-training/initiatives/nih-cures-innovation-plan.pdf.

Cures Act Innovation Project funding is unique from most of the funds NIH receives through the annual appropriations process. These funds are subject to different budget enforcement rules: for appropriated amounts to the account—up to the limit authorized for each fiscal year—the amounts are subtracted from any cost estimate for enforcing discretionary spending limits (i.e., the budget caps). In effect, appropriations to the NIH Innovation Account as authorized by the Cures Act are not subject to discretionary spending limits.[144] Therefore, Congress does not need to consider the Innovation Account funds when determining the amount of NIH funding within the discretionary spending allocations. The funds are also "no-year" funds that are available until expended. Most NIH appropriations are made available for one fiscal year.

As shown in **Table 2**, funding for each of the four different Innovation Projects was made in variable amounts across fiscal years. After the Cures Act was enacted, NIH was required to submit a workplan to Congress on how the agency planned to use Innovation Project funding and manage changes from year to year.[145] In its workplan, NIH set out plans to achieve scientific goals for each of the Innovation Projects, with different strategies to use the Innovation Account funding for each. For example, for the *All of Us* research program, NIH had planned to carry over certain funding from year to year to manage anticipated large year-to-year increases and decreases in funding authorized in the Cures Act. For the BRAIN initiative, NIH had estimated that the agency would need annual funds in addition to the authorized Cures Act funding in order to meet that program's scientific goals.[146]

As of this report's publication, two of the Innovation Project funding authorizations have expired: the Regenerative Medicine project in FY2020 and the Cancer Moonshot in FY2023. The Biden Administration proposed to reauthorize the Cancer Moonshot authorization in its FY2024 and FY2025 budget requests; to date, Congress has not adopted either of these proposals.[147] NIH continues to fund the *All of Us* research program and the BRAIN Initiative. Both programs have been supported by a combination of Cures Act Innovation funding and allocations from other NIH accounts.

Both the *All of Us* research program and the BRAIN initiative saw large decreases in FY2024 funding compared with FY2023 when accounting for Cures Act innovation funding and allocations from regular appropriations toward the programs. An overall decrease in NIH's regular budget authority in FY2024 may have affected the agency's ability to allocate resources to these programs. For the *All of Us* program, NIH had originally planned to carry over certain Cures Act funds from FY2023 to FY2024 to mitigate the effects of the decrease.[148] Both programs have reported consequences from the decrease in funding. The *All of Us* CEO reported that because of the funding decrease in FY2024, the program would reduce most program awards, which would result in a "decrease in the rate of new enrollments, a delay in the launch of pediatric enrollment, and a slowing of new data collection."[149] The BRAIN Initiative reduced

[144] CRS Report R45778, *Exceptions to the Budget Control Act's Discretionary Spending Limits*.

[145] Section 1001(c) of 21st Century Cures Act, P.L. 114-255.

[146] NIH, *Implementation of Funding Plan for the NIH Innovation Projects Under the 21st Century Cures Act*, https://www.nih.gov/sites/default/files/research-training/initiatives/nih-cures-innovation-plan.pdf, and NIH, The BRAIN Initiative, "Overview," https://braininitiative.nih.gov/about/overview.

[147] CRS Report R43341, *National Institutes of Health (NIH) Funding: FY1996-FY2025*.

[148] NIH, *Implementation of Funding Plan for the NIH Innovation Projects Under the 21st Century Cures Act*, https://www.nih.gov/sites/default/files/research-training/initiatives/nih-cures-innovation-plan.pdf, and NIH, The BRAIN Initiative, "Overview," https://braininitiative.nih.gov/about/overview.

[149] NIH, "From the All of Us CEO: Keeping Our Momentum Amidst Funding Uncertainties," April 23, 2024, https://allofus.nih.gov/news-events/announcements/all-us-ceo-keeping-our-momentum-amidst-funding-uncertainties.

some award amounts and cancelled several planned funding opportunities in FY2024, citing a 40% decrease to its budget.[150]

Looking forward, authorized Cures Act funding for both *All of Us* and the BRAIN Initiative will see significant decreases from FY2024 to FY2025, as shown in **Table 2**, and will expire in FY2026. Both programs were designed as long-term, multifaceted projects and have remaining scientific goals to achieve. For the *All of Us* research program, the program has so far made significant progress toward but ultimately fallen short of its goal to enroll and have data on 1 million participants. As of December 29, 2024, over 849,000 participants had consented to join the program and over 574,000 had completed all the initial steps to submit data.[151] Recruitment slowed during the COVID-19 pandemic when in-person enrollment activities were paused; the enrollment rate has since increased.[152] For the BRAIN initiative, the program has reported several major scientific milestones in 2023 and 2024, including the first complete cell atlas of a whole mammalian brain (the mouse brain), the most granular subcellular mapping of human brain tissues to date, and some of the first complete visualizations of brain neuron connections (in insects) and blood vessel networks (in mice).[153] Many of these recent developments are seen as "proof of concept" for further study. As the BRAIN Initiative Director stated in a blog post reflecting on 10 years of the initiative, "We are still just at the beginning of this neuroscience revolution." CRS could not identify independent (non-NIH) evaluations of either program and their scientific progress. Both programs have set short- and long-term goals throughout their history, but CRS could not identify an independent evaluation of whether the programs have met these goals, any challenges faced, and what, if any, further funding may be needed to achieve them.[154]

Coronavirus Disease 2019 (COVID-19) and Long COVID Research

NIH played a major role supporting COVID-19 research during the pandemic, alongside other agencies such as the Biomedical Advanced Research and Development Authority.[155] NIH's activities included efforts to better understand the fundamental biology of the virus, to better understand the epidemiology and clinical presentation of the disease, and to help develop new medical products such as tests, vaccines, and treatments.[156] NIH also published and maintained treatment guidelines for COVID-19 as scientific and medical understanding was evolving during

[150] NIH, "Notices of Change for Select BRAIN Initiative Funding Opportunities," May 14, 2024, https://braininitiative.nih.gov/news-events/blog/notices-change-select-brain-initiative-funding-opportunities.

[151] NIH All of Us Research Program, "Data Snapshots," https://www.researchallofus.org/data-tools/data-snapshots/.

[152] Geoffrey S. Ginsburg, Joshua C. Denny, and Sheri D. Schully, "Data-Driven Science and Diversity in the All of Us Research Program," *Science Translational Medicine*, vol. 15, no. 726 (December 13, 2023).

[153] See NIH, "The BRAIN Initiative Factsheet," https://braininitiative.nih.gov/sites/default/files/documents/brain_initiative_scientific_advancements_508c.pdf; NIH Director's Blog, "Most Detailed 3D Reconstruction of Human Brain Tissue Ever Produced Yields Surprising Insights," May 30, 2024, https://directorsblog.nih.gov/2024/05/30/most-detailed-3d-reconstruction-of-human-brain-tissue-ever-produced-yields-surprising-insights/; NIH, "Complete Wiring Map of the Insect Brain," March 28, 2023, https://www.nih.gov/news-events/nih-research-matters/complete-wiring-map-insect-brain; and NIH, "Blood Flow Makes Waves Across the Surface of the Mouse Brain," May 29, 2024, https://www.nih.gov/news-events/news-releases/blood-flow-makes-waves-across-surface-mouse-brain.

[154] NIH, *Implementation of Funding Plan for the NIH Innovation Projects Under the 21st Century Cures Act*, https://www.nih.gov/sites/default/files/research-training/initiatives/nih-cures-innovation-plan.pdf, and NIH, The BRAIN Initiative, "Overview," https://braininitiative.nih.gov/about/overview.

[155] For broader background, see CRS Report R46427, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions*.

[156] NIH COVID-19 Research, "NIH's Strategic Response," https://covid19.nih.gov/nih-strategic-response-covid-19.

the pandemic. (NIH stopped publishing these guidelines in 2024.)[157] NIH reports having received close to $4.9 billion for COVID-19 research.[158]

Much of NIH's COVID-19 research activities were supported through its regular and ongoing intramural and extramural research programs. Many of its COVID-19 research efforts built upon long-standing coronavirus, vaccine, and other infectious disease research programs. For example, since 2016, NIH and Moderna (a pharmaceutical and biotechnology company) have collaborated on mRNA vaccines.[159] In January 2020, scientists at the National Institute of Allergy and Infectious Diseases' intramural Vaccine Research Center shifted ongoing vaccine research to develop a new mRNA-based COVID-19 vaccine with Moderna in response to early clusters of the disease. This vaccine was ultimately authorized by FDA by the end of 2020.[160] This and other COVID-19 vaccines also drew upon prior NIH research on coronaviruses; specifically, research that determined how to potentially design coronavirus vaccines that would provide robust immunity.[161]

For extramural research, NIH also has specific authority to issue extramural supplemental research funding and to expedite the peer review process for research awards related to public health emergencies.[162] NIH used this authority to award COVID-19 research supplements and to issue new funding opportunities on an expedited basis.[163]

NIH also supported several large-scale and coordinated COVID-19 research initiatives. NIH participated in the federal government-wide Operation Warp Speed (OWS) partnership to develop COVID-19 vaccines and therapeutics. Specifically, NIH helped coordinate and oversee clinical trials on five of the six OWS vaccine candidates, among other activities.[164] Major NIH COVID-19 related programs included the following:

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[157] NIH stopped updating the treatment guidelines in February 2024 and then shut down the COVID-19 treatment guidelines website in August 2024. See Pien Huang, "In a Pandemic Milestone, the NIH Ends Guidance on COVID Treatment," March 19, 2024, https://www.npr.org/sections/health-shots/2024/03/19/1239276507/nih-covid-treatment-guidelines. For an archived version of the treatment guidelines, see https://web.archive.org/web/20231220204947/https://www.covid19treatmentguidelines.nih.gov/.

[158] NIH COVID-19 Research, "COVID-19 Funded Research Projects," https://covid19.nih.gov/funding. Some of the COVID-19 relief laws appropriated funds directly to NIH accounts, while others appropriated funding to HHS Secretary accounts with the ability to allocate funds to specific operating divisions such as NIH. For more information on COVID-19 relief appropriations to HHS public health agencies, see CRS Report R46711, *U.S. Public Health Service: COVID-19 Supplemental Appropriations in the 116th Congress*, and CRS Report R46834, *American Rescue Plan Act of 2021 (P.L. 117-2): Public Health, Medical Supply Chain, Health Services, and Related Provisions*.

[159] NIH COVID-19 Research, "COVID-19 Vaccine Development: Behind the Scenes," https://covid19.nih.gov/news-and-stories/vaccine-development; NIH, "Decades in the Making: mRNA COVID-19 Vaccines," https://www.niaid.nih.gov/diseases-conditions/decades-making-mrna-covid-19-vaccines; and Anthony Fauci, "The Story Behind COVID-19 Vaccines," *Science*, vol. 372, no. 6538 (April 9, 2021).

[160] NIH COVID-19 Research, "COVID-19 Vaccine Development: Behind the Scenes," https://covid19.nih.gov/news-and-stories/vaccine-development; NIH, "Decades in the Making: mRNA COVID-19 Vaccines," https://www.niaid.nih.gov/diseases-conditions/decades-making-mrna-covid-19-vaccines; and Anthony Fauci, "The Story Behind COVID-19 Vaccines," *Science*, vol. 372, no. 6538 (April 9, 2021).

[161] See patent on which many coronavirus vaccines are based: NIH Technology Transfer, "Prefusion Coronavirus Spike Proteins and Their Use," https://www.techtransfer.nih.gov/tech/tab-3261, and Anthony Fauci, "The Story Behind COVID-19 Vaccines," *Science*, vol. 372, no. 6538 (April 9, 2021).

[162] PHSA Section 494, 42 U.S.C. §289c.

[163] NIH Extramural Nexus, "COVID-19 Funding and Funding Opportunities," April 13, 2020, https://nexus.od.nih.gov/all/2020/04/13/covid-19-funding-and-funding-opportunities/.

[164] Francis Collins, Stacey Adam, Christine Colvis, et al., "The NIH-led Research Response to COVID-19," *Science*, vol. 379, no. 6631 (February 2, 2023), pp. 441-444, and Moncef Slaoui and Matthew Hepburn, "Developing Safe and (continued...)

Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Partnership: In April 2020, NIH launched ACTIV, a public-private partnership to coordinate research and clinical trials on new vaccines and therapeutics that involved several federal agencies, nonprofit organizations, and private companies, as facilitated by FNIH (see the "Foundation for the NIH" section). The initiative was designed to prioritize promising vaccine and therapeutic candidates, streamline clinical trials and their design, coordinate regulatory processes, and leverage resources among partners.[165] The initiative sought to create a national framework for coordinating among disparate entities that might otherwise compete with one another.[166] For example, as part of ACTIV, NIH helped coordinate and oversee clinical trials on 29 of the most promising potential COVID-19 therapeutic candidates, which ultimately led to six drugs being approved for clinical use as of February 2023.[167]

Rapid Acceleration of Diagnostics (RADx) Initiative: As funded by supplemental appropriations provided by Congress, NIH launched the RADx program in April 2020.[168] Prior to launch, two Senate committee chairs had proposed a competitive "shark tank" program to develop new COVID-19 tests.[169] The RADx initiative was different from many other NIH programs in that it was designed to facilitate commercialization and scale-up of new technologies. As stated by NIH officials, RADx represented a "dramatic extension of the usual NIH mode of supporting research."[170] RADx consisted of four components, the largest of which was the RADx Tech program that involved the "shark tank"-like three-phase process to rapidly develop and scale up new testing technologies. The program began with a solicitation of potential proposals, followed by an expert review of the technologies in Phase 0. Selected technologies then received further technical assistance and validation in Phase 1, and then a smaller group of technologies was selected for clinical testing and scale-up in Phase 2, with substantial financial assistance provided.[171] RADx helped develop the first FDA-authorized over-the-counter COVID-19 test in the United States and ultimately led to 55 FDA authorized COVID-19 tests.[172]

RECOVER Long COVID Initiative: In December 2020 (P.L. 116-260), Congress provided NIH with $1.15 billion in supplemental appropriations for research on the long-term health

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Effective Covid Vaccines—Operation Warp Speed's Strategy and Approach," *The New England Journal of Medicine*, vol. 383 (August 26, 2020), pp. 1701-1703.

[165] NIH, "NIH to Launch Public-Private Partnership to Speed COVID-19 Vaccine and Treatment Options," press release, April 17, 2020, https://www.nih.gov/news-events/news-releases/nih-launch-public-private-partnership-speed-covid-19-vaccine-treatment-options.

[166] Francis Collins and Paul Stoffels, "Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV): An Unprecedented Partnership for Unprecedented Times," *JAMA*, vol. 323, no. 24 (May 18, 2020).

[167] Francis Collins, Stacey Adam, Christine Colvis, et al., "The NIH-led Research Response to COVID-19," *Science*, vol. 379, no. 6631 (February 2, 2023), pp. 441-444.

[168] RADx was initially funded by $1.5 billion provided in the Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139); see CRS Report R46711, *U.S. Public Health Service: COVID-19 Supplemental Appropriations in the 116th Congress*. See also National Institute of Biomedical Imaging and Bioengineering (NIBIB), "RADx® Tech and ATP Programs," https://www.nibib.nih.gov/covid-19/radx-tech-program.

[169] Senator Lamar Alexander and Senator Roy Blunt, "Opinion: We Need More Covid-19 Tests. We Propose a 'Shark Tank' to Get Us There," *Washington Post*, April 20, 2020, https://washingtonpost.com/opinions/2020/04/20/how-speed-up-testing-shark-tank-government/.

[170] Bruce J. Tromberg, Tara A. Schwetz, Eliseo J. Pérez-Stable, et al., "Rapid Scaling Up of Covid-19 Diagnostic Testing—The NIH RADx Initiative," *The New England Journal of Medicine*, vol. 383, no. 11 (September 10, 2020), pp. 1071-1077.

[171] Ibid, pp. 1071-1077.

[172] NIBIB, *RADx Tech: Delivering COVID-19 Diagnostic Technologies at Unprecedented Speed and Scale*, March 2024, p. 4, https://www.nih.gov/sites/default/files/research-training/initiatives/radx/RADx-Tech-White-Paper-March-2024.pdf.

effects of COVID-19. NIH used these funds, in addition to later allocations, to establish the RECOVER Initiative for studying Long COVID, or the long-term health effects of COVID-19 infections. The initiative supports scientific networks of researchers who study the clinical presentation and biology of Long COVID along with clinical trials of potential treatments and data resources for research.[173]

Other major efforts included the NIH Community Engagement Alliance (CEAL) Against COVID-19 disparities, which helped recruit people from underserved communities to participate in COVID-19 clinical trials.[174] In addition, NIH developed many data resources for COVID-19 research, including the National COVID Cohort Collaborative, a nationwide repository of electronic health record (EHR) data that ultimately became one of the largest health research datasets on COVID-19 patients in the world.[175]

NIH saw some successes from its COVID-19 programs, including the vaccine and test development examples described above. NIH also faced some criticisms. In particular, NIH faced criticism for its perceived inability to generate robust evidence on potential COVID-19 treatments quickly.[176]As summarized above, NIH's ACTIV ultimately led to new COVID-19 treatments, but many of the clinical trials were not completed until 2022 or 2023.[177] The earliest FDA-authorized COVID-19 therapeutic drug in May 2020, remdesivir, had mixed evidence of its effectiveness in treating COVID-19 at the time of authorization, including one NIH-run clinical trial involving slightly over 1,000 patients.[178] In comparison, in June 2020, the United Kingdom's Randomized Evaluation of COVID-19 Therapy (RECOVERY) trial generated robust data on a highly effective drug to improve survival in hospitalized COVID-19 patients (the steroid dexamethasone), based on a trial involving several thousand patients. This drug quickly became the standard of care.[179] Some critiqued NIH for its inability to stand up clinical trials at a similar scale as quickly as the U.K. trials, despite the NIH's much larger budget.[180] One company reported pulling a COVID-19

[173] NIH, About RECOVER Funding, https://recovercovid.org/funding.

[174] Francis Collins, Stacey Adam, Christine Colvis, et al., "The NIH-led Research Response to COVID-19," *Science*, vol. 379, no. 6631 (February 2, 2023), pp. 441-444, and Michele P. Andrasik, Gail B. Broder, and Stephaun E. Wallace, "Increasing Black, Indigenous and People of Color Participation in Clinical Trials Through Community Engagement and Recruitment Goal Establishment," *PLoS One*, vol. 16, no. 10 (October 19, 2021).

[175] NIH, "NIH Launches Analytics Platform to Harness Nationwide COVID-19 Patient Data to Speed Treatments," press release, June 15, 2020, https://www.nih.gov/news-events/news-releases/nih-launches-analytics-platform-harness-nationwide-covid-19-patient-data-speed-treatments, and Cat Ferguson, "It Took a Pandemic, But the US Finally Has (Some) Centralized Medical Data," *MIT Technology Review*, June 21, 2021, https://www.technologyreview.com/2021/06/21/1026590/us-covid-database-n3c-nih-privacy/.

[176] Cary P. Gross and Ezekiel J. Emanuel, "The Missing Part of America's Pandemic Response," *The Atlantic*, June 5, 2022, https://www.theatlantic.com/ideas/archive/2022/06/nih-covid-vaccine-research-studies/661182/.

[177] NIH ACTIV, "COVID-19 Therapeutics Prioritized for Testing in Clinical Trials," https://www.nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials.

[178] FDA, "FDA Approves First Treatment for COVID-19," press release, October 22, 2020, https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19; FDA, "Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment," press release, May 1, 2020, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment; H. Clifford Lane and Anthony S. Fauci, "Research in the Context of a Pandemic," *The New England Journal of Medicine*, vol. 384, no. 8 (July 17, 2020); and Yeming Wang, Dingyu Zhang, Guanhua Du, et al., "Remdesivir in Adults with Severe COVID-19: A Randomised, Double-Blind, Placebo-Controlled, Multicentre Trial," *The Lancet*, vol. 395, no. 10236 (May 16, 2020), pp. 1569-1578.

[179] The RECOVERY Collaborative Group, "Dexamethasone in Hospitalized Patients with Covid-19," *New England Journal of Medicine*, vol. 384, no. 8 (July 17, 2020), pp. 693-704 and H. Clifford Lane and Anthony S. Fauci, "Research in the Context of a Pandemic," *The New England Journal of Medicine*, vol. 384, no. 8 (July 17, 2020).

[180] Cary P. Gross and Ezekiel J. Emanuel, "The Missing Part of America's Pandemic Response," *The Atlantic*, June 5, (continued...)

drug candidate out of the NIH-run trials, reportedly because of its slow progress (the drug was authorized by FDA a year later).[181] Many credit the U.K.'s clinical trial success in large part to its nationalized health system and associated clinical trial infrastructure, which was able to enroll 10% of all patients hospitalized with COVID-19 in the country in 2020.[182] Several U.S. federal agencies now have ongoing efforts to develop enhanced national clinical trial infrastructure that could be used in future public health emergencies.[183]

NIH has also received considerable scrutiny for its RECOVER Long COVID research initiative from certain patient advocates, policymakers, and researchers. NIH faced significant scientific challenges in studying and researching new treatments for Long COVID given that it is a new condition with hundreds of reported symptoms. NIH faced the challenge of working to characterize and understand the disease while also testing potential treatments on a rapid basis.[184] In particular, NIH has faced criticism about the Long COVID research initiative not being led by researchers with specific expertise in other post-infection syndromes. According to critics, the lack of relevant experts in leadership led to several challenges with the research questions explored, the design of the research, and the treatments tested in clinical trials. In addition, NIH was criticized because after three years, the NIH initiative still had not met many of its original research objectives and, in particular, faced slow enrollment in clinical studies. Patients also reported lack of meaningful engagement in the research plans and priorities.[185] Observers have also praised certain aspects of the initiative, for example, its pediatric research program and its data and biospecimen resources.[186] After receiving considerable criticism, in February 2024, NIH announced an additional $515 million allotted to the RECOVER Long COVID Initiative to

2022, https://www.theatlantic.com/ideas/archive/2022/06/nih-covid-vaccine-research-studies/661182/ and The COVID Crisis Group, "Chapter 9: Fighting Back with Drugs and Vaccines," in *Lessons from the COVID War: An Investigative Report* (New York, NY: PublicAffairs, 2023), pp. 225.

[181] Specifically, Merck pulled Molnupiravir from the NIH-run clinical trials in December 2020. The drug received FDA authorization in December 2021. See The COVID Crisis Group, "Chapter 9: Fighting Back with Drugs and Vaccines," in *Lessons from the COVID War: An Investigative Report* (New York, NY: PublicAffairs, 2023), pp. 225-226.

[182] H. Clifford Lane and Anthony S. Fauci, "Research in the Context of a Pandemic," *The New England Journal of Medicine*, vol. 384, no. 8 (July 17, 2020) and Derek C. Angus, Anthony C. Gordon, and Howard Bauchner, "Emerging Lessons From COVID-19 for the US Clinical Research Enterprise," *Journal of the American Medical Association*, vol. 325, no. 12 (February 26, 2021), pp. 1159-1161.

[183] See, for example, the Biomedical Advanced Research and Development Authority, "BARDA Launches the D-COHRe Program, Seeking to Enhance Clinical Innovation with Decentralized Care Capabilities," July 5, 2023, https://medicalcountermeasures.gov/newsroom/2023/d_cohre/ and Advanced Research Projects Agency for Health (ARPA-H), "ARPA-H Advances Initiative to Improve Clinical Trials," October 20, 2023, https://arpa-h.gov/news-and-events/arpa-h-advances-initiative-improve-clinical-trials.

[184] Department of Health and Human Services (HHS), "National Research Action Plan on Long COVID," August 2022, https://www.covid.gov/sites/default/files/documents/National-Research-Action-Plan-on-Long-COVID-08012022.pdf.

[185] Betsy Ladyzhets, "NIH Documents Show How $1.6 Billion Long Covid Initiative Has Failed so Far to Meet its Goals," *STAT*, May 31, 2024, https://www.statnews.com/2024/05/31/long-covid-nih-recover-initiative-falls-short-on-causes-treatments/ and Betsy Ladyzhets, "'They Bungled It:' NIH Documents Reveal how $1.6 Billion Long Covid Initiative has Failed so Far to Meet its Goals," *The Sick Times*, May 31, 2024, https://thesicktimes.org/2024/05/31/they-bungled-it-nih-documents-reveal-how-1-6-billion-long-covid-initiative-has-failed-so-far-to-meet-its-goals/, and Max Kozlov, "NIH Launches Trials for Long COVID Treatments: What Scientists Think," *Nature*, August 1, 2023.

[186] Betsy Ladyzhets, "NIH Documents Show How $1.6 Billion Long Covid Initiative Has Failed so Far to Meet its Goals," *STAT*, May 31, 2024, https://www.statnews.com/2024/05/31/long-covid-nih-recover-initiative-falls-short-on-causes-treatments/; Betsy Ladyzhets, "'They Bungled It:' NIH Documents Reveal how $1.6 Billion Long Covid Initiative has Failed so Far to Meet its Goals," *The Sick Times*, May 31, 2024, https://thesicktimes.org/2024/05/31/they-bungled-it-nih-documents-reveal-how-1-6-billion-long-covid-initiative-has-failed-so-far-to-meet-its-goals/;, and Max Kozlov, "NIH Launches Trials for Long COVID Treatments: What Scientists Think," *Nature*, August 1, 2023.

pursue further studies intended to be responsive to stakeholders.[187] NIH has defended some of its decisions and research progress while also acknowledging some of the challenges. As NIH Director Bertagnolli stated at a 2024 congressional hearing with respect to the program, "We are not where we want to be in terms of a rapid nimble clinical trials enterprise that's testing promising treatments very quickly. That is our focus right now moving forward to do that."[188]

Selected Issues for Congress

Changing NIH's Structure

NIH's large and decentralized organizational structure has been an issue of concern for decades.[189] There are costs and complexities of administering an agency comprising 27 ICs, each with its own mission, budget, staff, review office, and other organizational apparatuses. The resulting fragmentation may create potential for research overlap or gaps, and might adversely affect NIH's ability to respond appropriately to new scientific and public health challenges. At the same time, any large-scale reorganization could disrupt the agency's ongoing programs and activities. Some have argued that NIH's large and decentralized structure allows the agency to be responsive to the diverse constituencies interested in NIH's work.[190] Some laws have addressed organization and structure at NIH, including the NIH Reform Act of 2006 and the 21st Century Cures Act, but have stopped short of large-scale agency reorganization.

NIH's current structure evolved from a series of separate congressional and executive branch decisions made over the course of decades. After the National Cancer Institute was first established in 1937, Congress and the Administration established many specific institutes within NIH from the 1940s to 2011 (see **Table 3**). Several external reviews have examined NIH's organizational structure at points throughout its history.[191] A congressionally requested 2003 report that preceded the NIH Reform Act of 2006 examined NIH's structure and found that "the most common mechanism of origin of the institutes has been the congressional mandate responding to the health advocacy community."[192] A common pattern historically was that advocacy groups pushed for an NIH office on a certain disease or health topic that was ultimately

[187] NIH, "NIH to Bolster RECOVER Long COVID Research Efforts Through Infusion of $515 Million," press release, February 13, 2024, https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-bolster-recover-long-covid-research-efforts-through-infusion-515-million.

[188] U.S. Congress, Senate Appropriations Committee, *Review of the President's FY2025 Budget Request for the National Institutes of Health*, 118th Cong., May 23, 2024.

[189] Many prior reports have explored NIH's structure and the need for reform, including Institute of Medicine, *Responding to Health Needs and Scientific Opportunity: The Organizational Structure of the National Institutes of Health*, October 1984, and National Research Council and Institute of Medicine, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*, 2003. 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.

[190] See discussion in Chapter 1 of National Research Council and Institute of Medicine, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*, 2003.

[191] See, for example, Institute of Medicine, *Responding to Health Needs and Scientific Opportunity: The Organizational Structure of the National Institutes of Health*, October 1984, and National Research Council and Institute of Medicine, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*, 2003.

[192] National Research Council and Institute of Medicine, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*, 2003.

created, then elevated to a center, and then, in some cases, to an institute.[193] At the same time, the report noted that NIH's many different ICs have "provided for the expression of a broader set of priorities and expanded political support and budget success both for the specific interests involved and for NIH in the aggregate."[194] This report ultimately did not find a compelling argument for major reorganization and consolidation of NIH's ICs and instead proposed several reforms to improve agency coordination and management.[195]

As discussed in the "Recent Major Legislative History" section, the NIH Reform Act of 2006 ultimately established a Scientific Management Review Board to conduct public reviews of NIH's organizational structure and processes and to recommend reforms. 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."[196] Instead, SMRB proposed a framework for considering and evaluating potential organizational changes at NIH.[197] This was the last report that SMRB published on NIH's overall structure. Although SMRB is required by statute to review NIH's overall organizational structure every seven years,[198] media reporting and congressional investigations have found that SMRB had not convened since 2015.[199] NIH reestablished SMRB in 2024.[200]

In 2024, some leaders in committees of jurisdiction for NIH published white papers or proposals for NIH reform. For example, in the Senate, then-ranking member Cassidy of the Senate Committee on Health, Labor, Education and Pensions (HELP) proposed reforms in a white paper published in May 2024, which included proposals to reduce redundancies and find efficiencies within and across NIH ICs. The paper did not propose a specific NIH restructuring.[201] On the House side, then-House Energy and Commerce committee chair Rodgers proposed restructuring NIH's current 27 ICs into 15, with overall policy goals to reduce duplication and silos, and to "ensure each IC is considering the whole individual and all populations across the entire lifespan"; this proposal was announced in June 2024.[202] The House FY2025 Departments of Labor, Health and Human Services, and Education, and Related Agencies (LHHS) appropriations bill (H.R. 9029 , 118th Congress) included a new NIH account structure that reflected the proposed reorganization. It is unclear what, if any, practical effect this account structure would

193 Ibid.

194 Ibid.

195 Ibid.

196 Scientific Management Review Board, *Report on Deliberating Organizational Change and Effectiveness*, November 2010, p. 4, https://web.archive.org/web/20240801213248/https:/smrb.od.nih.gov/documents/announcements/DOCE_112010.pdf.

197 Ibid.

198 PHSA Section 401(e)(2)(A) and 42 U.S.C. §281(e)(2)(A).

199 Lev Facher, "The Panel Was Supposed to Improve Efficiency at the NIH. It Hasn't Even Met for 7 Years," *STAT*, May 9, 2022, and U.S. Congress House Energy and Commerce Committee, "E&C Committee Probes NIH for Failing to Convene Scientific Management Review Board," press release, March 13, 2023, https://energycommerce.house.gov/posts/e-and-c-committee-probes-nih-for-failing-to-convene-scientific-management-review-board.

200 See HHS NIH, "Charter: Scientific Management Review Board," filed April 11, 2024, available at https://www.facadatabase.gov/.

201 Senator Bill Cassidy, ranking member, *NIH in the 21st Century: Ensuring Transparency and American Biomedical Leadership*, Senate Committee on Health, Education, Labor and Pensions, May 2024, https://www.help.senate.gov/imo/media/doc/nih_modernization_5924pdf.pdf.

202 U.S. Congress House Energy and Commerce Committee majority, "Reforming the National Institutes of Health: Framework for Discussion," June 2024, https://energycommerce.house.gov/posts/chair-rodgers-unveils-framework-for-nih-reform-requests-stakeholder-input.

have had on NIH's organizational structure if adopted, particularly since the bill would not have amended PHSA Title IV, which currently governs NIH's structure and organization.

Reactions to the House-proposed changes were mixed. Some agreed with all or some aspects of the reorganization plan or with the underlying intention to reform NIH. Others disagreed with certain aspects of the reorganization proposal. Many voiced concerns about the process, especially the choice to reflect the proposed reorganization in the House LHHS FY2025 appropriations bill.[203] A letter signed by 223 stakeholder organizations argued that "a policy of this magnitude—and one affecting one of our nation's preeminent research institutions—should not be included in an appropriations bill. It must be considered by an authorizing body through an open, transparent process that includes input from a variety of key stakeholders and follows a thorough review of NIH operations and portfolios."[204]

Moving forward, if Congress considers reorganizing NIH a priority, Congress might consider how to structure a process for determining NIH's new structure with input from relevant stakeholders. Congress might also consider what, if any, evidence might inform how NIH could best be structured to achieve its mission.

Determining NIH's Research Priorities

How should NIH prioritize its research funding across diseases, population groups, scientific fields, technologies, and many other possible categories? To what extent should Congress weigh in on NIH's research priorities and how? How can Congress ensure that diverse constituencies have input into NIH's research priorities? Members of Congress, NIH leaders, and outside stakeholders such as scientists and patient advocates have debated these questions since NIH was first founded.[205]

As mentioned above, Congress has set NIH's overall statutory authorizations and provides annual funding to each of its ICs, but otherwise, it has predominately deferred to NIH's internal priority-setting and award processes to determine research funding allocations. These appropriations levels ultimately drive NIH's overall research priorities as some ICs receive more funding than others. In recent years, Congress has mostly followed a practice of setting funding levels and authorizations for certain priority diseases and health issues within ICs (e.g., Alzheimer's disease, ALS) but has otherwise left most of each IC's funding untargeted (see the "Congressional Involvement in NIH Research Priorities" section). As detailed further in the next section, most of NIH's annual budget is already committed for multiyear projects in any given fiscal year.

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[203] Sarah Owermohle, "With Sweeping NIH Reform on the Table, GOP Previews New Era of Research Scrutiny," *STAT*, June 18, 2024, https://www.statnews.com/2024/06/18/nih-reform-proposal-gop-reaction-analysis/ and Max Kozlov, "Major Biomedical Funder NIH Poised for Massive Reform Under Trump 2.0," *Nature*, vol. 635 (November 28, 2024).

[204] Letter from NIH Stakeholder Organizations to Representatives Tom Cole and Rosa DeLauro, chair and ranking member of House Appropriations Committee, July 9, 2024, https://d3dkdvqff0zqx.cloudfront.net/groups/apaadvocacy/attachments/LHHSFY25RestructuringSignOnLetter_7.9.24.pdf.

[205] For related histories, see Stephen P. Strickland, *Politics, Science, and Dread Disease: A Short History of United States Medical Research Policy* (Cambridge , MA: Harvard University Press, 1972), and Bhaven Sampat, *The History and Political Economy of NIH Peer Review*, The Brookings Institution, May 2023, https://www.brookings.edu/wp-content/uploads/2023/05/SampatFinal-3.pdf. See also discussions in congressional hearings, for example, U.S. Congress, House Energy and Commerce Committee, Health Subcommittee, *Scientific Opportunities and Public Needs: Balancing NIH's Priority Setting Process*, 108th Cong., 2nd sess., June 2, 2004, and U.S. Congress, Senate Labor and Human Resources Committee, Subcommittee on Public Health and Safety, *Labor Subcommittee, Biomedical Research Priorities: Who Should Decide?*, 105th Cong., 1st sess., May 1, 1997.

Therefore, in general, only a fraction of NIH's budget can support new research in any given year, limiting the agency's flexibility to quickly shift its overall research priorities and direction.

Members of Congress frequently hear from stakeholders who advocate for NIH research on certain disease or health topics.[206] Understandably, patients and their families facing diseases that lack adequate preventive, diagnostic, and treatment options may advocate for health and medical advancements with respect to those conditions. In addition, Members of Congress and other stakeholders sometimes raise concerns about NIH's relative investment in or research approaches to certain diseases.[207] There is evidence that sustained federal funding focused on a specific disease (or disease type) has led to better health outcomes associated with that disease, according to a 2024 National Academy of Medicine report.[208]

At the same time, it is not clear that allocating funding by disease is the best way to prioritize NIH research. For example, setting funding priorities based solely on disease advocacy may not prioritize research funding for the diseases that pose the greatest health burden or risk. To illustrate this, one 2019 analysis by a sociologist found mismatches between the level of advocacy surrounding a particular disease and the overall health impact of the given disease (as measured by mortality and disability-adjusted life years).[209] As an example, lung cancer is one of the leading causes of death in the United States (131,889 deaths in 2022),[210] but the analysis found relatively few organizations and lobbying expenditures dedicated to lung cancer advocacy compared with other diseases. On the other hand, Alzheimer's disease has caused a similar number of deaths (120,122 deaths in 2022),[211] but the disease has a much greater number of dedicated advocacy organizations and lobbying expenditures. Overall, the analysis found that there is less advocacy for mental illness and preventable or infectious diseases.[212]

Further, much of NIH research funding may not be easily targetable by disease. NIH in large part supports basic research—research that explores the fundamental nature of biology and behavior. It is inherently difficult to categorize such research by disease or health area. To illustrate, a study on the mechanisms of neurons in the brain could have implications for many conditions: mental health conditions, Alzheimer's disease and dementias, and traumatic brain injury, along with

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[206] See footnote 119.

[207] See, for example, discussions in U.S. Congress, House Energy and Commerce Committee, Health Subcommittee, *Scientific Opportunities and Public Needs: Balancing NIH's Priority Setting Process*, 108th Cong., 2nd sess., June 2, 2004, and media reporting such as Betsy Ladyzhets, "NIH Documents Show How $1.6 Billion Long Covid Initiative Has Failed so Far to Meet its Goals," *STAT*, May 31, 2024, https://www.statnews.com/2024/05/31/long-covid-nih-recover-initiative-falls-short-on-causes-treatments/, and Betsy Ladyzhets, "'They Bungled It:' NIH Documents Reveal how $1.6 Billion Long Covid Initiative has Failed so Far to Meet its Goals," *The Sick Times*, May 31, 2024, https://thesicktimes.org/2024/05/31/they-bungled-it-nih-documents-reveal-how-1-6-billion-long-covid-initiative-has-failed-so-far-to-meet-its-goals/.

[208] National Academy of Medicine, *The State of the U.S. Biomedical and Health Research Enterprise: Strategies for Achieving a Healthier America*, Washington, DC, 2024, p. 14, https://nap.nationalacademies.org/read/27588/chapter/3#14.

[209] In this case, the level of advocacy is based on an advocacy score, an index of standardized measures of lobby expenditures, organizations, and congressional testimony related to a given disease from Best, *Common Enemies: Disease Campaigns in America*, p. 79.

[210] Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System, Mortality 2018-2022 on CDC WONDER Online Database, released in 2024. Data are from the Multiple Cause of Death Files, 2018-2022, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program, accessed at http://wonder.cdc.gov/mcd-icd10-expanded.html on December 11, 2024.

[211] CDC National Center for Health Statistics, "Alzheimer's Disease," https://www.cdc.gov/nchs/fastats/alzheimers.htm.

[212] Rachel Kahn Best, "Chapter 3: Deserving Patients," in *Common Enemies: Disease Campaigns in America* (New York, NY: Oxford University Press, 2019), pp. 69-76.

many others. In NIH's funding categorization system, the agency could count such a research project as relating to all of those diseases and conditions.[213] Therefore, some studies have found that disease-specific research grant programs often lead to "spillover" publications, or publications related to other diseases in addition to the specific disease for which the research is funded.[214] As another consideration, prioritizing research based on *current* health burden of diseases may not relate to the future or potential burden of certain diseases. As a key example, coronaviruses were not a major heath issue until the COVID-19 pandemic.

In addition, broader fundamental scientific and technological advances can have major impacts on medical advances, sometimes in unexpected ways. For example, NIH has highlighted that a study of how microbes protect themselves led to the discovery of a gene-editing technology known as CRISPR, which now serves as a basis for many gene therapies in development. As another example, innovations in imaging technologies are important for drug discovery and medical science, and therefore have implications across diseases.[215] NIH has therefore historically argued that scientific and technological considerations should guide funding decisions in addition to health considerations.

NIH leaders, some biomedical research advocates, and some Members of Congress have historically argued that NIH funding should be left untargeted and that the agency should have flexibility to determine its priorities by balancing health considerations with pursuing scientific opportunity and investing in emerging areas.[216] This line of reasoning has long asserted that NIH's peer review process—its two-tier, committee-based process to evaluate research proposals—is the best way to solicit untargeted research proposals from researchers and then formally weigh whether to fund such proposals based on complex scientific, technical, and health priorities and considerations.[217] This view was what led to the initial establishment of NIH's peer review system.[218] On the other hand, some research has raised questions about whether the peer review process leads NIH to fund the best science or to adequately boost innovation. Evidence is currently mixed regarding whether the NIH peer review process ultimately funds the best

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[213] See NIH, "RCDC: Categorization Process," https://report.nih.gov/funding/categorical-spending/rcdc-process.

[214] Josie Coburn, Ohid Yaqub, Ismael Rafols, et al., "Cross-Disease Spillover from Research Funding: Evidence from Four Diseases," *Social Science and Medicine*, vol. 349, no. 116883 (May 2024), and Yasemin Aslan, Ohid Yaqub, Bhaven N. Sampat, et al., "Unexpectedness in Medical Research," *Research Policy*, vol. 53, no. 105075 (October 2024).

[215] NIH, "Basic Research—Digital Media Kit," last reviewed June 2022, https://www.nih.gov/news-events/basic-research-digital-media-kit.

[216] See footnote 149 and statement from former NIH Director Harold Varmus at a 1997 hearing: "the inherent ability to plan science is limited. Science attempts to discover what is unknown. It's inherently unpredictable. History has shown time and again … how the benefits of allowing much of our research activity to be governed by the imagination of an individual scientist has had benefits for the public health. Much of the research done by our institutes may be difficult or impossible to explain as part of a research plan against a specific disease. Nevertheless, such work—whether it be on the three- dimensional structure of proteins or the way in which cells die—could ultimately form the basis for very practical advances against any of several diseases." From U.S. Congress, Senate Labor and Human Resources Committee, Subcommittee on Public Health and Safety, *Biomedical Research Priorities: Who Should Decide?*, 105th Cong., 1st sess., May 1, 1997.

[217] See statements in U.S. Congress, Senate Labor and Human Resources Committee, Public Health and Safety Subcommittee, *Biomedical Research Priorities: Who Should Decide?*, 105th Cong., 1st sess., May 1, 1997; U.S Congress House Energy and Commerce Committee, Health Subcommittee, *Scientific Opportunities and Public Needs: Balancing NIH's Priority Setting Process*, 108th Cong., 2nd sess., June 2, 2004; *Congressional Record*, Volume 160, Issue 9, Book II (January 15, 2014), pp. H1037; and Bhaven Sampat, *The History and Political Economy of NIH Peer Review*, The Brookings Institution, May 2023.

[218] C.J. Van Slyke, "New Horizons in Medical Research," *Science*, vol. 104, no. 2711 (December 13, 1946), pp. 559-567.

scientific proposals.[219] Some studies suggest that the process disfavors scientific innovation or has become more risk-averse in recent years.[220]

In addition to questions about *what* research to fund at NIH, Congress could also consider questions about *how* NIH could fund research. Some have voiced concerns about the administrative burdens on researchers of regularly applying for funding through the peer review process, suggesting, in particular, that this burden takes time away from research and science.[221] Many have proposed that NIH could experiment with different models of funding research, including a shift to funding more "people not projects," where NIH funds specific researchers (rather than their research proposals) and allows them freedom to pursue scientific questions and ideas.[222] On the other hand, some NIH funding models where the agency has a more directive and hands-on approach with researchers have shown some success, such as the RADx initiative discussed in the "Coronavirus Disease 2019 (COVID-19) and Long COVID Research" section. Several academic researchers have proposed that NIH could more systematically experiment with different approaches of funding research and evaluate outcomes in order to build an evidence base around NIH research policy.[223]

Balancing New and Existing Funding Commitments

Because of variation in annual appropriations, NIH cannot support the same number and size of research projects from year to year. In years with large funding increases, the agency may proportionally increase research awards. When funding is cut, the agency may limit the number and size of research grants awarded. Given that most grants are multiyear awards (often three to five years) that have "noncompeting" status during the duration of the project performance period, 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 8 shows NIH research project grant (RPG) numbers and success rates for new grant applications annually from FY2003 to FY2023. NIH supported about the same total number of RPGs each year from FY2003 to FY2008, but it supported fewer RPGs after FY2008. To maintain existing funding commitments, NIH mostly maintained the number of noncompeting

[219] Danielle Li and Leila Agha, "Big Names or Big Ideas: Do Peer-Review Panels Select the Best Science Proposals?," *Science*, vol. 348, no. 6233 (April 24, 2015), pp. 434-38, and Ferric C. Fang, Anthony Bowen, and Arturo Casadevall, "NIH Peer Review Percentile Scores are Poorly Predictive of Grant Productivity," *Elife*, vol. 16, no. 5 (February 16, 2016).

[220] Mikko Packalen and Jay Bhattacharya, "NIH Funding and the Pursuit of Edge Science," *PNAS*, vol. 117, no. 22 (May 19, 2020), pp. 12011-12016, Chiara Franzoni, Paula Stephen, and Reinhilde Veugelers, "Funding Risky Research," *Entrepreneurship and Innovation Policy and the Economy*, vol. 1, no. 1 (2022), pp. 103-22, and Pierre Azoulay, "Scientific Risk-Taking and Grant Funding: A "Risky Research" Agenda for NIH," *Building a Better NIH Project*, May 2023, https://www.brookings.edu/wp-content/uploads/2023/05/AzoulayFinal-2.pdf.

[221] Good Science Project, "The Burden of Administrative Compliance," June 2, 2022, https://goodscienceproject.org/articles/the-burden-of-bureaucratic-compliance/, and Matt Faherty, *New Science's Report on the NIH*, New Science, April 2022, https://newscience.org/nih/#grant-writing-and-maintenance.

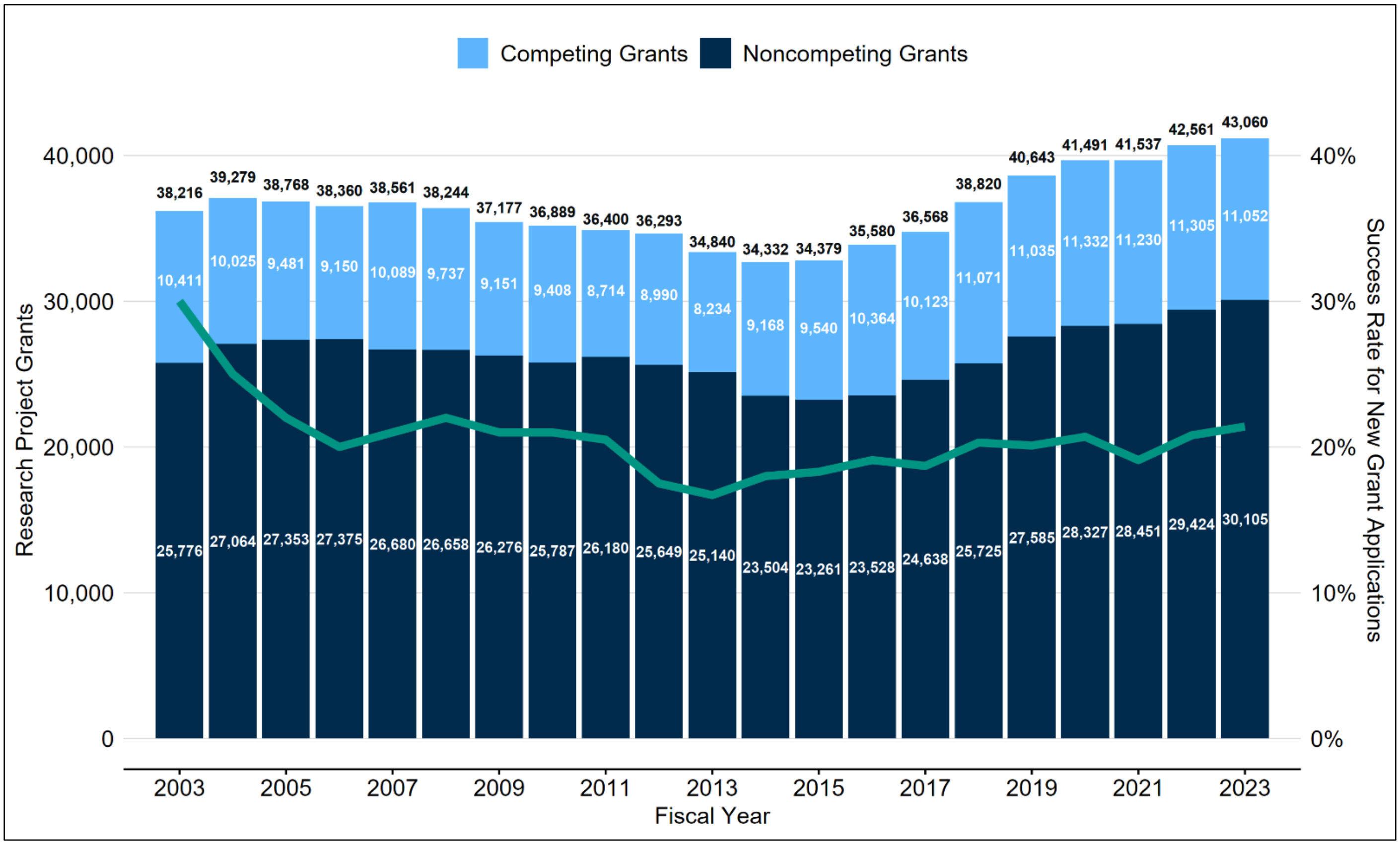
[222] John P. A. Ioannidis, "Fund People not Projects," *Nature*, vol. 477 (September 28, 2011), pp. 529-531, Good Science Project, "The NIH Should Expand Its "Person Not Project" Funding," February 21, 2023, https://goodscienceproject.org/articles/the-nih-should-expand-its-person-not-project-funding/.

[223] Pierre Azoulay, "Scientific Risk-Taking and Grant Funding: A "Risky Research" Agenda for NIH," *Building a Better NIH Project*, May 2023, https://www.brookings.edu/wp-content/uploads/2023/05/AzoulayFinal-2.pdf, and Kyle R. Myers, "Experimentation at NIH," *Building a Better NIH Project*, May 2023, https://www.brookings.edu/wp-content/uploads/2023/05/MyersFinal-3.pdf.

grants from year to year, while cutting back on awarding competing project grants from FY2009 to FY2015—grants that fund new research projects.

Figure 8. Research Project Grants (RPG) Awarded by NIH and Success Rates for New Grant Applications

FY2003-FY2023



Source: Developed by CRS using data from NIH, "Research Project Grants (RPG): Number of Awards, FY1999-FY2023", https://officeofbudget.od.nih.gov/pdfs/FY25/spending_hist/Number%20of%20RPG%20Awards%20FY%201999%20-%20FY%202023%20(V).pdf; NIH, "Overview of FY2024 President's Budget", p. 114, https://officeofbudget.od.nih.gov/pdfs/FY24/br/Overview%20of%20FY%202024%20Presidents%20Budget.pdf; NIH, "FY2016 Budget Request—Summary Tables", https://officeofbudget.od.nih.gov/pdfs/FY16/Supplementary%20Tables.pdf; and NIH, "FY2011 Budget Request–Tabular Data," https://officeofbudget.od.nih.gov/pdfs/FY11/Tabular%20Data.pdf.

Success rates for grant applications (i.e., 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 8**, the success rate for new grant applications was 30% in FY2003, fell to a low of 17% in FY2013, and rose to 21% in FY2023. 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. 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 from FY2016 to FY2023 than it was 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 peaked at

58,872 in FY2021, a 70% increase in applications from FY2003. The number of applications for FY2023 was 51,883 and represents a roughly 50% increase between FY2003 and FY2023. [224]

To increase the number of available grants for competition, one policy option is for Congress to increase NIH's budget. However, the ability to provide NIH with a funding increase may be constricted during times of budgetary pressures and competing policy priorities. Some have proposed measures to reduce the overall size of NIH research awards in order to save money while still funding the same or increased numbers of research projects. For example, during the Trump Administration, some budget requests for NIH included several different proposals to reduce the amount spent on each research award.[225] One proposal from FY2018 would have capped the indirect costs that could be covered by NIH grants (facilities and administrative, or F&A, costs) at 10% of the total costs, to reduce the overall size of an RPG (at the time, NIH reported spending 28% of its extramural budget on indirect costs).[226] In FY2018, both the House and Senate Appropriations Committees did not adopt the proposal to cap F&A costs. The report accompanying the Senate bill (S.Rept. 115-150), in rejecting the policy, stated,

> The methodology for negotiating indirect costs has been in place since 1965, and rates have remained largely stable across NIH grantees for decades. The Administration's proposal would radically change the nature of the Federal Government's relationship with the research community, abandoning the Government's long-established responsibility for underwriting much of the Nation's research infrastructure, and jeopardizing biomedical research nationwide. The Committee has not seen any details of the proposal that might explain how it could be accomplished without throwing research programs across the country into disarray.[227]

Another proposal in FY2019 would have capped the total amount of researcher salaries that could be paid for with NIH grants.[228] At the request of the House Appropriations committee, an NIH analysis found that "no previous research examines the impact of reducing the salary cap on the number of grants and the average cost per grant."[229] NIH found one potentially illustrative example where a salary cap reduction in FY2011 did not reduce the average cost of NIH grants and that the number of NIH grants awarded decreased in that year, though other factors may have affected grant numbers and average costs. NIH also noted that an unintended consequence of the salary cap policy could be that institutions will have to supplement the remaining portion of researchers' salaries, which "may limit the number of applicants with sufficient resources to participate in Federally-funded research."[230]

To consider policies to cut costs, Congress could pursue rigorous independent analyses of the impacts on researchers of cost reduction measures, such as caps on F&A costs and researcher salaries. Any measure to cut costs associated with NIH grants could be disruptive for the research community. Congress might consider how to introduce reforms in ways that are less disruptive

[224] NIH, "NIH Data Book—Success Rates: R01-Equivalent and Research Project Grants," 2024, https://report.nih.gov/nihdatabook/category/10.

[225] See NIH Congressional Justifications for FY2018, FY2019, and FY2020, available at NIH Office of the Budget, "National Institutes of Health Historical Budget Requests," https://officeofbudget.od.nih.gov/history_budget_req.html.

[226] NIH, *Congressional Justification FY2018*, pp. 3-4, https://officeofbudget.od.nih.gov/pdfs/FY18/Overview%20of%20FY%202018%20President's%20Budget.pdf.

[227] S.Rept. 115-150, p. 109.

[228] NIH, *Congressional Justification FY2019*, https://officeofbudget.od.nih.gov/pdfs/FY19/br/Overview.pdf.

[229] NIH, *Congressional Justification FY2020—Significant Items*, p. 33, https://officeofbudget.od.nih.gov/pdfs/FY20/br/FY-2020-NIH-CJ-Significant-Items.pdf.

[230] NIH, *Congressional Justification FY2020—Significant Items*, p. 33, https://officeofbudget.od.nih.gov/pdfs/FY20/br/FY-2020-NIH-CJ-Significant-Items.pdf.

for researchers. Congress might also consider the costs and sustainability of the overall NIH grants portfolio, or even overall federal health research portfolio, in any broader policy review.

NIH and the Research Workforce Pipeline

NIH funding and policy has considerable influence on the overall U.S. biomedical research workforce. The agency has therefore maintained an interest in the research workforce pipeline. 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.[231] 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 (see the "Postdoctoral Workforce" section).[232] 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."[233] From FY1985 to FY2020, the proportion of researchers receiving NIH research project grants (RPGs) classified as late-career (58 years of age or older) increased, while the proportion classified as early career (less than 46 years of age) decreased.[234] Given that some research suggests that scientists tend to be more productive and innovative at earlier ages (before the age of 40 or 50), this aging workforce could have implications for U.S. biomedical innovation more broadly.[235]

From 1995 to 2003, the average age at which a new investigator first obtained a R01 grant (independent research project grant; see the "Types of Extramural NIH Grants" **text box** above) increased from 39 years for PhDs and 41 years for MDs to 43 years for PhDs and 46 years for MDs, respectively.[236] The percentage of the NIH workforce made up of first-time principal investigators peaked at 39% in FY2010 and decreased to 34% in FY2023.[237] In addition, the success rate for new investigators (for R01 research grants) fell from 25% in FY1998 to 14% in FY2012 and FY2013 but increased to 20% in FY2023.[238] NIH has attributed the relatively low success rates for new investigators to a "hypercompetitive" environment for NIH grant dollars.[239]

Further, evidence shows increasing inequality in the distribution of NIH grants among researchers and organizations over time. An NIH analysis of research project grants (RPG) data from 1995 to 2020 found that the proportion of NIH funding going to the top 1% of researchers (in terms of total NIH funding) increased from 14.3% to 18.7% during that period. In terms of institutions, the

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231 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.

232 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://nap.nationalacademies.org/read/25008/chapter/4#27.

233 Ibid.

234 Michael S. Lauer and Deepshikha Roychowdhury, "Inequalities in the Distribution of National Institutes of Health Research Project Grant Funding," *eLife*, 2021, p. 2, https://doi.org/10.7554/eLife.71712.

235 Kirstin R. W. Matthews et al., "The Aging of Biomedical Research in the United States," *PLOS ONE*, vol. 6, no. 12 (December 28, 2011) p. 3.

236 Ibid.

237 CRS Analysis of NIH Data Book, "Research Project Grant Investigators: Number Supported on Competing Awards, by Career Stage of Investigator," https://report.nih.gov/nihdatabook/report/167.

238 NIH Data Book, "R01-Equivalent Grants, New (Type 1): Competing Applications, Awards, and Success Rates, by Career Stage of Investigator," https://report.nih.gov/nihdatabook/report/136.

239 Michael Lauer, Lawrence Tabak, and Francis Collins, "The Next Generation Researchers Initiative at NIH," *PNAS*, vol. 114, no. 45 (November 7, 2017), pp. 11801-03.

top 10% of institutions (in terms of total NIH funding) received 70% of NIH RPG grant funding, whereas the bottom 50% of institutions received under 5%. Other inequalities exist in terms of race and gender. For example, the proportion of investigators who identified as Black remained below 2% of all funded investigators throughout the study period.[240] By gender, the percentage of NIH-funded female investigators receiving RPGs increased from 22% in FY1998 to 37% in FY2023 but was still not at parity with men.[241]

Next Generation Researchers Initiative

In June 2017, NIH launched the Next Generation Researchers Initiative (NGRI) aimed at increasing funding opportunities for early- and mid-career investigators. Authorized in the 21st Century Cures Act (P.L. 114-255), NGRI was established to coordinate policies and programs focused on promoting and providing opportunities for new researchers and earlier research independence across NIH.[242] NIH has implemented NGRI, in part, by establishing a new Early Stage Investigator (ESI) designation and by tasking the NIH ICs with devising strategies to increase the number of funded ESIs.[243] ESIs have finished their terminal research degree or clinical training within the past 10 years and have not previously competed successfully as a Principal Investigator (or Program Director) for a substantial NIH independent research award (e.g., a R01 research project grant).[244] In the review and award process, NIH policy is to prioritize ESI-designated applications for review and to consider application information differently than for established investigators.[245] Since NGRI implementation, NIH has reported a 62% increase in funded ESIs, from 978 ESIs in FY2016 (one year prior to NGRI) to 1,587 ESIs in FY2023, five years after NGRI was established.[246] NIH also saw funding increases in this same time period, which may explain some of the trends.

Initially, some were concerned that the ESI funding policies could decrease funding for established investigators.[247] However, established investigators have not seen decreased funding since NGRI was implemented. In FY2023, one institute reported that its NGRI programs had

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240 Michael S. Lauer and Deepshikha Roychowdhury, "Inequalities in the Distribution of National Institutes of Health Research Project Grant Funding," *eLife*, 2021, p. 4, https://doi.org/10.7554/eLife.71712.

241 NIH Data Book, "Research Project Grants: Awards, by Gender," https://report.nih.gov/nihdatabook/report/218.

242 PHSA Section 404M, 42 U.S.C. §283o.

243 See NIH, *Policy Supporting the Next Generation Researchers Initiative*, NOT-OD-17-101, August 31, 2017, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-101.html, and NIH, *Update on NIH's Next Generation Researchers Initiative (NGRI) Policy on Early Established Investigators (EEIs)*, NOT-OD-18-214, July 26, 2018, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-214.html.

244 NIH, "NIH Early Stage Investigators Policy," https://grants.nih.gov/policy-and-compliance/policy-topics/early-stage-investigators/policy. Initially NIH also established. Early Established Investigators (EEIs), seeking to target midcareer investigators at risk of losing funding. Based on advisory committee and stakeholder input, NIH ultimately did not move forward with the EEI designation in its final NGRI policy. NIH instead created an interim strategy to identify "at-risk investigators" until the advisory committee working group deliberations were complete. See NIH, *Update on NIH's Next Generation Researchers Initiative (NGRI) Policy on Early Established Investigators (EEIs)*, NOT-OD-18-214, July 26, 2018, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-214.html.

245 NIH, "NIH Early Stage Investigators Policy," https://grants.nih.gov/policy-and-compliance/policy-topics/early-stage-investigators/policy#what-is-the-benefit-of-having-esi-status?.

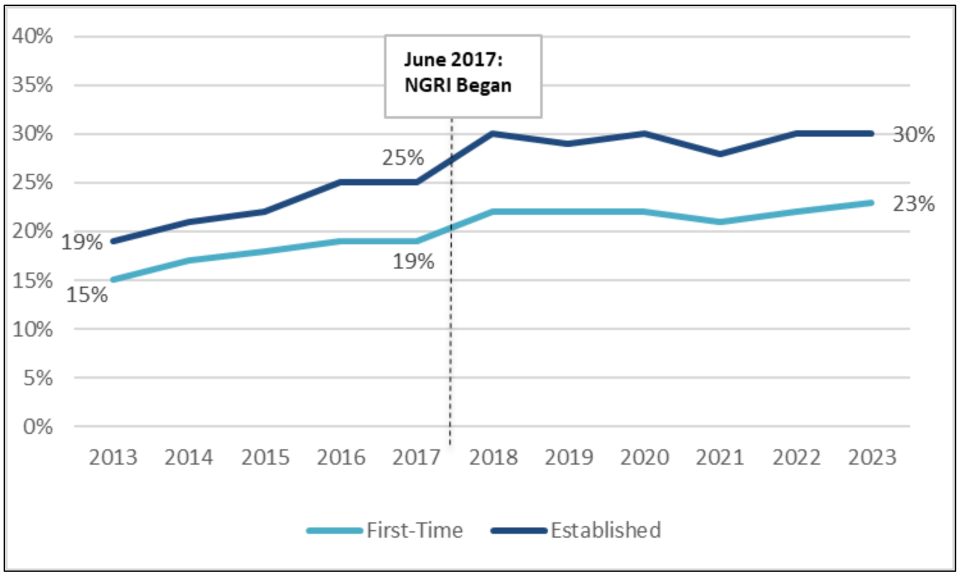
246 Based on investigators receiving R01-equivalent awards. From Mike Lauer, "Data on Implementing NIH's Next Generation Researchers Initiative," *NIH Extramural Nexus*, https://nexus.od.nih.gov/all/2021/07/12/data-on-implementing-nihs-next-generation-researchers-initiative/, and NIH Data Book, "R01-Equivalent Investigators, New (Type 1): Number of Early Stage Investigators (ESIs)," https://report.nih.gov/nihdatabook/report/304.

247 Michael Lauer, Lawrence Tabak, and Francis Collins, "The Next Generation Researchers Initiative at NIH," *PNAS*, vol. 114, no. 45 (November 7, 2017), pp. 11801-03.

succeeded in balancing available funding between new and established investigators.[248] NIH data also show that the success rates for established investigators in receiving NIH funding has not changed since the ESI policies have been in place as shown in **Figure 9**. The number of established investigators funded has increased at a similar or greater rate than the number of ESIs funded since NGRI was established.[249] If NIH sees budget decreases or flat funding in future years, the agency may face challenges in continuing to increase its ESI workforce while maintaining funding for established investigators.

Figure 9. R01-Equivalent Grant Application Success Rates for First-Time and Established Investigators

From FY2013 to FY2023



Source: NIH Data Book, "R01-Equivalent Investigators, New (Type 1): Funding Rates, by Career Stage of Investigator," https://report.nih.gov/nihdatabook/report/166

Notes: R01 equivalent grants defined as grants with activity codes DP1, DP2, DP5, R01, R37, R56, RF1, RL1, U01 and R35 from select NIGMS and NHGRI program announcements (PAs). NGRI is the Next Generation Researchers Initiative.

Postdoctoral Workforce

NIH policy has considerable influence on the U.S. postdoctoral workforce. Postdoctoral fellowships are temporary training positions following a medical or doctoral degree, and they are commonly seen as required for independent academic biomedical research positions. Postdoctoral scholars are often responsible for much of the research and innovation in scientific laboratories.[250]

[248] Ariel C. Zane, James Onken, Marie B. Parker, et al., "An Evaluation of Programs to Support New Investigators at the National Institute of Allergy and Infectious Diseases: Striking a Balance with Funding for Established Investigators," *Evaluation and Program Planning*, vol. 98 (June 2023), p. 102218.

[249] NIH Data Book, "The NIH-Funded Research Workforce- Investigator Career Stage," https://report.nih.gov/nihdatabook/category/15.

[250] NASEM, *Breaking Through: The Next Generation of Biomedical and Behavioral Sciences Researchers*, National Academies of Science, Engineering, and Medicine, Washington, DC, 2018, pp. 21-29. Advisory Committee to the Director Working Group on Re-envisioning NIH-Supported Postdoctoral Training, *Report to the NIH Advisory Committee to the Director*, December 15, 2023, https://acd.od.nih.gov/documents/presentations/12152023_Postdoc_Working_Group_Report.pdf.

NIH's flagship program, the Ruth L. Kirschstein National Research Service Award (NRSA) program, directly supported 5,389 postdoctoral positions in 2023.[251] The NRSA program provides set stipends and other benefits for funded fellows each year.[252] Many other postdoctoral fellows' salaries are paid, at least in part, by their supervisors' NIH grant funding. According to NIH-published data, of the over 40,000 U.S. postdoctoral fellows in 2022, 41% reported federal research grants as their primary source of support (e.g., research project grants), whereas 9% reported federal training fellowships or awards as a primary source of support (such as NRSA; other fellows reported other sources of funding).[253] In general, research institutions have latitude to set non-NRSA postdoctoral salaries and to supplement NRSA stipends that postdoctoral fellows receive. However, some analyses have found that research institutions use NRSA stipend levels to set postdoctoral salaries for all fellows in their institutions. For example, one 2017 analysis found that the median salary for postdoctoral fellows at 52 U.S. research institutions was very similar to the lowest NIH NRSA stipend level, suggesting that institutions use the NRSA stipend levels as a benchmark for all postdoctoral fellow compensation.[254]

Reports have acknowledged that the postdoctoral workforce faces challenges of low compensation, job instability, uncertain career prospects, and increased time spent in positions before obtaining independent research scientist positions.[255] In December 2023, an NIH advisory committee working group published a report with recommendations for NIH-supported postdoctoral training policy. Among other recommendations, the report recommended increasing pay and improving benefits for all NIH-supported postdoctoral scholars.[256] In April 2024, NIH announced an 8% stipend increase for NRSA postdoctoral scholars, with expected future year increases depending on available funding.[257] In July 2024, NIH published a notice soliciting input on other committee recommendations and whether to adopt these recommendations as NIH policy; it remains to be seen whether the NIH will implement additional changes.[258]

[251] NIH Data Book, "Kirschstein-NRSA Training Grants and Fellowships: Pre- and Post-Doctoral Full-Time Training Positions Awarded," https://report.nih.gov/nihdatabook/report/52.

[252] NRSA stipends are governed by statute and regulation at PHSA Section 487 (42 U.S.C. §288) and 42 C.F.R. Part 66. NIH publishes annual stipend amounts each year. For FY2024, see NIH, "Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2024," NOT-OD-24-104, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-104.html.

[253] Based on data from the NSF-NIH Survey of Graduate Students and Postdoctorates in Science and Engineering. See NIH Data Book, "National Statistics: Primary Source of Support for Postdoctorates," https://report.nih.gov/nihdatabook/report/263.

[254] Rodoniki Athanasiadou, Adriana Bankston, McKenzie Carlisle, et al., "Assessing the Landscape of US Postdoctoral Salaries," *Studies in Graduate and Postdoctoral Education*, vol. 9, no. 2 (December 1, 2017), pp. 217-242.

[255] NASEM, *Breaking Through: The Next Generation of Biomedical and Behavioral Sciences Researchers*, National Academies of Science, Engineering, and Medicine, Washington, DC, 2018, pp. 21-29. Advisory Committee to the Director Working Group on Re-envisioning NIH-Supported Postdoctoral Training, *Report to the NIH Advisory Committee to the Director*, December 15, 2023, https://acd.od.nih.gov/documents/presentations/12152023_Postdoc_Working_Group_Report.pdf.

[256] Advisory Committee to the Director Working Group on Re-envisioning NIH-Supported Postdoctoral Training, *Report to the NIH Advisory Committee to the Director*, December 15, 2023, https://acd.od.nih.gov/documents/presentations/12152023_Postdoc_Working_Group_Report.pdf.

[257] NIH, "NIH to Increase Pay Levels for Pre- and Postdoctoral Scholars at Grantee Institutions," press release, April 23, 2024, https://www.nih.gov/news-events/news-releases/nih-increase-pay-levels-pre-postdoctoral-scholars-grantee-institutions.

[258] NIH, "Request for Information (RFI) on Recommendations on Re-envisioning U.S. Postdoctoral Research Training and Career Progression within the Biomedical Research Enterprise," NOT-OD-24-150, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-150.html.

Geopolitical and Security Dimensions of NIH Research

NIH is the largest single public funder of biomedical research in the world.[259] In 2021, the United States accounted for two-thirds of the $69 billion total public spending on health-related R&D among Organization for Economic Cooperation and Development (OECD) member countries with reported data. The United States government also spent the most on health-related R&D as a share of gross domestic product compared with other OECD member countries.[260] (China's government health research investments are not included in the OECD data.)

While the United States remains a lead funder of health-related R&D, other countries—particularly China—have increased their R&D funding in recent years.[261] One prominent analysis of high-quality research publications found that, in 2022, China-based researchers for the first time surpassed U.S.-based researchers in their share of all natural science publications globally, though still ranked second behind the United States in terms of biological and health sciences publications.[262]

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. This growth has contributed to a surge in research produced outside of the United States, as well as increased collaboration between U.S. and international institutions.[263] Policy and culture around U.S. academic science has historically fostered openness and collaboration.[264] NIH has actively encouraged international collaboration through some of its grant opportunities.[265] In addition, many scientists from other countries have spent time studying or working in the United States. They may continue to collaborate with international partners while in the United States or may continue collaborations with U.S. partners when they return to their home countries.[266]

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[259] NIH, "Impact of NIH Research: Serving Society: Direct Economic Contributions," last updated December 2023, https://www.nih.gov/about-nih/what-we-do/impact-nih-research/serving-society/direct-economic-contributions.

[260] Organization for Economic Cooperation and Development (OECD), "Pharmaceutical Research and Development," *Health At A Glance 2023: OECD Indicators*, 2023, https://doi.org/10.1787/0bdf62a7-en.

[261] National Science Foundation, *The State of U.S. Science and Engineering 2024*, March 2024, https://ncses.nsf.gov/pubs/nsb20243/discovery-u-s-and-global-r-d#global-r-d.

[262] Simon Baker, "China Overtakes United States on Contribution to Research in Nature Index," *Nature*, May 19, 2023, https://www.nature.com/articles/d41586-023-01705-7, and Nature Index, "Country/territory tables," https://www.nature.com/nature-index/country-outputs/generate/biological-sciences/global. The Nature Index tracks contributions to research articles published in high-quality natural-science and health-science journals, chosen based on reputation by an independent group of researchers. For more information, see "A Guide to the Nature Index," https://www.nature.com/articles/d41586-024-01601-8.

[263] To illustrate the collaborations, the Nature Index found the number of papers co-authored by researchers in the United States and China increased from 3,412 in 2015 to 5,213 in 2020, more than any other country pairing in the index. See James Mitchell Crow, "US–China Partnerships Bring Strength in Numbers to Big Science Projects," *Nature*, March 9, 2022, https://www.nature.com/articles/d41586-022-00570-0.

[264] As NIH has stated, "NIH and the biomedical research enterprise have a long history of international collaborations with rules of engagement that allow science to advance while assuring honesty, transparency, integrity, fair merit-based competition, and protection of intellectual capital and proprietary information." See NIH Grants and Funding, "Foreign Interference," last updated September 10, 2024, https://grants.nih.gov/policy/foreign-interference.htm.

[265] 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.

[266] James Mitchell Crow, "US–China Partnerships Bring Strength in Numbers to Big Science Projects," *Nature*, March 9, 2022, https://www.nature.com/articles/d41586-022-00570-0.

Biomedical research and development in other countries raises several geopolitical policy issues for NIH. One of the main policy concerns has centered around competition with other countries in biomedical R&D and innovation. Investment in NIH has been framed as a way of competing with other countries in biomedical innovation.[267]

In recent years, policy discussions have also centered around research security at NIH, particularly the issue of "undue foreign influence" at NIH. Since 2016, NIH investigations have found several issues, including (1) undisclosed sources of foreign research support, (2) undisclosed conflicts of interest associated with foreign countries and organizations, and (3) violations of the rules and integrity of the peer review process for NIH funding applications.[268] For example, in some cases, funding recipients received duplicative project funding from both NIH and a foreign country or organization; in other cases, peer reviewers shared confidential application information with scientists in foreign countries.[269] An NIH working group found that foreign talent recruitment programs—especially China's Thousand Talents program—have encouraged such actions and interference.[270] These cases represent a relatively small percentage of all NIH-funded researchers (less than 1% of all NIH-funded principal investigators).[271] Many NIH-funded researchers have international affiliations and collaborations that are in compliance with U.S. policy.

In light of these issues, Congress has funded the HHS Office of the Inspector General (OIG) to examine and provide recommendations on NIH's policies and practices with respect to foreign interference and security issues. To date, HHS OIG has explored issues related to controls for sensitive genomic research data,[272] the vetting process for peer reviewers,[273] financial conflicts of interest policies,[274] pre-award risk assessments,[275] and cybersecurity,[276] among others. These reports have highlighted potential weaknesses in NIH's ability to address security concerns associated with its funded research.

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[267] As an example, in the 114th Congress, H.Con.Res. 27, Section 809 ("Policy Statement on Medical Discovery, Development, Delivery and Innovation"), stated 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 "Organization for Economic Development and Cooperation predicts that China, for example, will outspend the United States in total research and development by the end of the decade."

[268] NIH, "About Foreign Interference," https://grants.nih.gov/policy/foreign-interference/about-foreign-interference.

[269] NIH, "About Foreign Interference," https://grants.nih.gov/policy/foreign-interference/about-foreign-interference.

[270] Lawrence A. Tabak and M. Roy Wilson, "Foreign Influences on Research Integrity," *117th Meeting of the Advisory Committee to the Director*, December 13, 2018, https://acd.od.nih.gov/documents/presentations/12132018ForeignInfluences.pdf.

[271] Michael S. Lauer and Patricia A. Valdez, "Safeguarding Integrity and Collaborations," *Science*, May 25, 2023, https://www.science.org/doi/10.1126/science.adi3894.

[272] HHS Office of the Inspector General (OIG), *Opportunities Exist for the National Institutes of Health to Strengthen Controls in Place to Permit and Monitor Access to Its Sensitive Data, Audit*, A-18-18-09350, February 5, 2019, https://oig.hhs.gov/oas/reports/region18/181809350.asp.

[273] HHS OIG, *Vetting Peer Reviewers at NIH's Center for Scientific Review: Strengths and Limitations*, OEI-01-19-00160, September 25, 2019, https://oig.hhs.gov/oei/reports/oei-01-19-00160.asp.

[274] HHS OIG, *The National Institutes of Health Has Limited Policies, Procedures, and Controls in Place for Helping to Ensure That Institutions Report All Sources of Research Support, Financial Interests, and Affiliations*, A-03-19-03003, September 25, 2019, https://oig.hhs.gov/oas/reports/region3/31903003.asp.

[275] HHS OIG, *The National Human Genome Research Institute Should Strengthen Procedures in Its Pre-Award Process to Assess Risk for Certain Foreign and Higher Risk Applicants*, A-05-20-00026, August 30, 2021, https://oig.hhs.gov/oas/reports/region5/52000026.asp.

[276] HHS OIG, *National Institutes of Health Grant Program Cybersecurity Requirements Need Improvement*, A-18-20-06300, September 19, 2022, https://oig.hhs.gov/oas/reports/region18/182006300.asp.

NIH has since amended some of its policies and raised awareness of the issues among funding recipients.[277] In addition, a 2021 presidential memorandum[278] and a provision of the National Defense Authorization Act for FY2021 (NDAA; P.L. 116-283, §223) required changes at all federal research agencies to address research security and disclosure of foreign ties. Congress also addressed cross-cutting federal research security issues through P.L. 117-167, commonly referred to as the CHIPS and Science Act, enacted in 2022.[279] NIH has made policy changes accordingly.[280] (For more information, see CRS In Focus IF12589, *Research Security Policies: An Overview*.)

At the same time, some have raised concerns that NIH investigations and actions related to foreign interference have unfairly targeted certain scientists, particularly scientists of Asian descent. One media investigation found that pressure associated with NIH's investigations into failures to disclose foreign funding or affiliations led some scientists to resign or to face adverse actions (e.g., termination) in a process they perceived as lacking transparency and fairness. Some of the scientists claimed to not know that their activities or collaborations needed disclosure. Others faced challenges while trying to dispute the evidence cited by NIH and perceived that their universities decided to take action against them rather than challenge NIH, a key source of research funding.[281] NIH has since defended its investigations, stating that the agency followed appropriate procedures and guidelines and provided as much transparency as possible given privacy considerations.[282]

Separately, issues surrounding the COVID-19 pandemic and investigations into the origins of the virus have focused attention on other potential security issues with NIH-funded research. For example, there has been increased attention on NIH's funding and oversight of so-called "gain-of-function" research, which can make a virus more transmissible or pathogenic.[283] Debates around this research have invoked broader discussions about the oversight of synthetic or other emerging biology research and its national security implications in general.[284] (For more information, see CRS Report R48155, *Oversight of Laboratory Biosafety and Biosecurity: Current Policies and Options for Congress*.) Another example is increased interest in NIH's ability to monitor subrecipients of grants located in foreign countries. For instance, HHS OIG has found that NIH did not effectively monitor funding awards made to EcoHealth Alliance and its funding subrecipient at the Wuhan Institute of Virology in China.[285] NIH has since announced new policy

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[277] NIH, "Foreign Interference," https://grants.nih.gov/policy/foreign-interference.htm.

[278] White House, *Presidential Memorandum on United States Government-Supported Research and Development National Security Policy*, National Security Presidential Memorandum - 33, January 14, 2021, https://trumpwhitehouse.archives.gov/presidential-actions/presidential-memorandum-united-states-government-supported-research-development-national-security-policy/.

[279] See Division B, Title VI, Subtitle D of P.L. 117-167.

[280] NIH, "Requirements for Disclosure of Other Support, Foreign Components and Conflicts of Interest," https://grants.nih.gov/policy/foreign-interference/requirements-for-disclosure.

[281] Jeffrey Mervis, "Pall of Suspicion," *Science*, March 23, 2023, https://www.science.org/content/article/pall-suspicion-nihs-secretive-china-initiative-destroyed-scores-academic-careers.

[282] Michael S. Lauer and Patricia A. Valdez, "Safeguarding Integrity and Collaborations," *Science*, May 25, 2023, https://www.science.org/doi/10.1126/science.adi3894.

[283] CRS Report R47114, *Oversight of Gain of Function Research with Pathogens: Issues for Congress*.

[284] CRS Report R47265, *Synthetic/Engineering Biology: Issues for Congress*.

[285] HHS OIG, *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, A-05-21-00025, January 25, 2023, https://oig.hhs.gov/oas/reports/region5/52100025.asp.

requirements for grants with foreign subrecipients or collaborators in an effort to enhance monitoring.[286]

As enacted in December 2022, the PREVENT Pandemics Act, part of Consolidated Appropriations Act, 2023 (P.L. 117-328, Division FF, Title II), included several provisions addressing research security policy broadly at NIH, including the following:[287]

- A prohibition on NIH intramural personnel from participating in foreign talent recruitment programs (with limited exemptions) and a requirement for extramural grantees to disclose foreign talent recruitment program participation.
- A requirement that HHS develops a comprehensive framework and controls for assessing and managing national security risks associated with funded research, including risks associated with access to genomic and other sensitive data.
- A requirement that the NIH Director addresses research security as part of the statutory duties of the position, including by regularly consulting with national security officials about potential national security implications of NIH research.
- A requirement that the HHS Secretary develops a set of strategies and frameworks to address many national and information security risks associated with federally funded biomedical R&D, including risks associated with sensitive or proprietary data, foreign talent programs, and emerging biological science.

Congress may continue to monitor implementation of these provisions and determine if further reforms are needed to address the security and geopolitical implications of NIH research. Congress might also consider whether certain policies intended to address research security concerns have secondary consequences for science and collaboration. As an example, NIH's 2023 policy requirements for grants with foreign subrecipients—intended to enhance monitoring of NIH-funded research in other countries—are viewed by some scientists as burdensome and may have the effect of reduced international collaborations in NIH-funded research.[288]

Balancing Federal and Industry Support of Research

Major debates around the federal government's appropriate role in medical research date back to the years following World War II. During the war, a large-scale federal contract funded medical research program demonstrated the potential of federally funded medical research: this effort resulted in discoveries such as penicillin and other drugs credited with saving hundreds of thousands of lives. After the war, many of the wartime research contracts were subsequently transferred to NIH and formed the agency's initial extramural research award program.[289] The end

[286] NIH policy available at "NIH Updated Policy Guidance for Subaward/Consortium Written Agreements," NOT-OD-23-133, Effective October 1, 2023, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-133.html.

[287] All provisions listed here are in Chapter 3 of Subtitle C of the PREVENT Pandemics Act (P.L. 117-328, Division FF, Title II).

[288] NIH policy available at "NIH Updated Policy Guidance for Subaward/Consortium Written Agreements," NOT-OD-23-133, effective October 1, 2023, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-133.html. For commentary on the policy, see Jocelyn Kaiser, "NIH Mandate that Foreign Partners of U.S. Scientists Regularly Submit All Data Stirs Outcry," *Science*, June 13, 2023, https://www.science.org/content/article/nih-mandate-foreign-partners-u-s-scientists-regularly-submit-all-data-stirs-outcry.

[289] Donald C. Swain, "The Rise of a Research Empire: NIH, 1930 to 1950," *Science*, vol. 138, no. 3546 (December 14, 1962), pp. 1233-1237; Stephen P. Strickland, "Chapter 2: The War Years and Reconversion," *Politics, Science, and Dread Disease: A Short History of United States Medical Research Policy*, p. 16-17 (Cambridge , MA: Harvard University Press, 1972); and Daniel P. Gross and Bhaven Sampat, "Crisis Innovation Policy from World War II to (continued...)

of the war generated policy debates about the federal government's appropriate role in funding science and medical research. Ultimately, the view that formed the primary basis for NIH research policy moving forward was that the NIH would focus on funding basic (fundamental) scientific research questions, while industry and other nongovernmental organizations would focus more on applied research and commercialization of technologies.[290] Around the same time, an increasing number of prominent civil society organizations emerged to advocate for increased federal research funding for specific diseases (e.g., the American Cancer Society and American Heart Association).[291] As a result of these two influences, NIH's budget grew over the following decades as Congress and the executive branch established many new NIH institutes and centers, often focused on specific diseases, yet with a primary research mission to advance fundamental science with respect to those diseases and conditions (see **Table 3**).[292]

There is a traditional economic view that science—especially basic science—is a public good: scientific knowledge may have widespread benefits that are difficult for an individual firm to "capture," so society may not produce enough of it through industry alone.[293] However, the line between basic and applied research is blurry. Some have concerns that, 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, the private sector industry would fund more research.[294]

In recent years, experience with medical innovation during the COVID-19 pandemic—where federal programs facilitated rapid development of new vaccines and treatments—has led to renewed policy discussions about the federal government's appropriate role in advancing medical research and technologies. Several economists and other experts have advanced the perspective that the federal government can play a more direct role in addressing market failures and in speeding up new medical innovation in partnership with industry.[295] Ultimately, this view

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COVID-19," *National Bureau of Economics Research Working Paper*, June 2021, https://www.nber.org/system/files/working_papers/w28915/w28915.pdf.

290 Stephen P. Strickland, "Chapter 2: The War Years and Reconversion," *Politics, Science, and Dread Disease: A Short History of United States Medical Research Policy*, p. 15-31 (Cambridge , MA: Harvard University Press, 1972), and Daniel P. Gross and Bhaven Sampat, "Crisis Innovation Policy from World War II to COVID-19," *National Bureau of Economics Research Working Paper*, June 2021, https://www.nber.org/system/files/working_papers/w28915/w28915.pdf.

291 Rachel Kahn Best, "Chapter 1: Charitable Crusades," in *Common Enemies: Disease Campaigns in America* (New York, NY: Oxford University Press, 2019), pp. 23-42, and Stephen P. Strickland, "Chapter 3: The Rise of the Research Lobby: A New Mobilization," *Politics, Science, and Dread Disease: A Short History of United States Medical Research Policy*, p. 32-54, (Cambridge, MA: Harvard University Press, 1972).

292 Donald C. Swain, "The Rise of a Research Empire: NIH, 1930 to 1950," *Science*, vol. 138, no. 3546 (December 14, 1962), pp. 1233-1237.

293 Kyle R. Myers, "The Direction of Biomedical Science," *National Bureau of Economic Research*, November 29, 2016. CBO has stated, "The rationale for public investment in basic biomedical research is that private firms' incentives to invest in it are muted. Basic research generates knowledge (such as the identification of a disease target) that is not readily embodied in a marketable product (such as a drug). The more of that information a company could keep to itself, the greater its value to the company—and the stronger the company's incentive would be to invest in that research. But because information can be communicated at low cost, it can be difficult to contain within a firm." From Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, April 2021, https://www.cbo.gov/publication/57126.

294 Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, April 2021, https://www.cbo.gov/publication/57126, 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.

295 See, for example, Daniel P. Gross and Bhaven Sampat, "Crisis Innovation Policy from World War II to COVID-
(continued...)

contributed to the establishment of the Advanced Research Projects Agency for Health (ARPA-H) in FY2022, an independent agency within NIH focused on advancing health and medical innovation. For more background on ARPA-H, see CRS Report R47568, *Advanced Research Projects Agency for Health (ARPA-H): Overview and Selected Issues*. Given that ARPA-H is a new agency, it remains to be seen if ARPA-H will successfully advance new medical innovation.

ARPA-H's establishment also has raised questions about the types of research that NIH should fund moving forward. In recent years, NIH has shifted toward funding more applied research compared with basic research. **Figure 10** shows NIH's allocations of budget authority for basic research compared with applied research for fiscal years 2003 through 2023, which shows a trend of increased funding for applied research compared with basic research. (The FY2022 amount includes budget authority for ARPA-H, whereas the FY2023 amount does not.) As summarized in the "Types of Research at NIH" section, basic research encompasses research that explores the fundamental mechanisms of biology and behavior. Applied research, on the other hand, is research directed toward a specific practical aim or objective.[296] Applied research includes NIH's translational research focused on practical applications, such as developing new drugs and other medical products or services, as well as its clinical research with human subjects.[297]

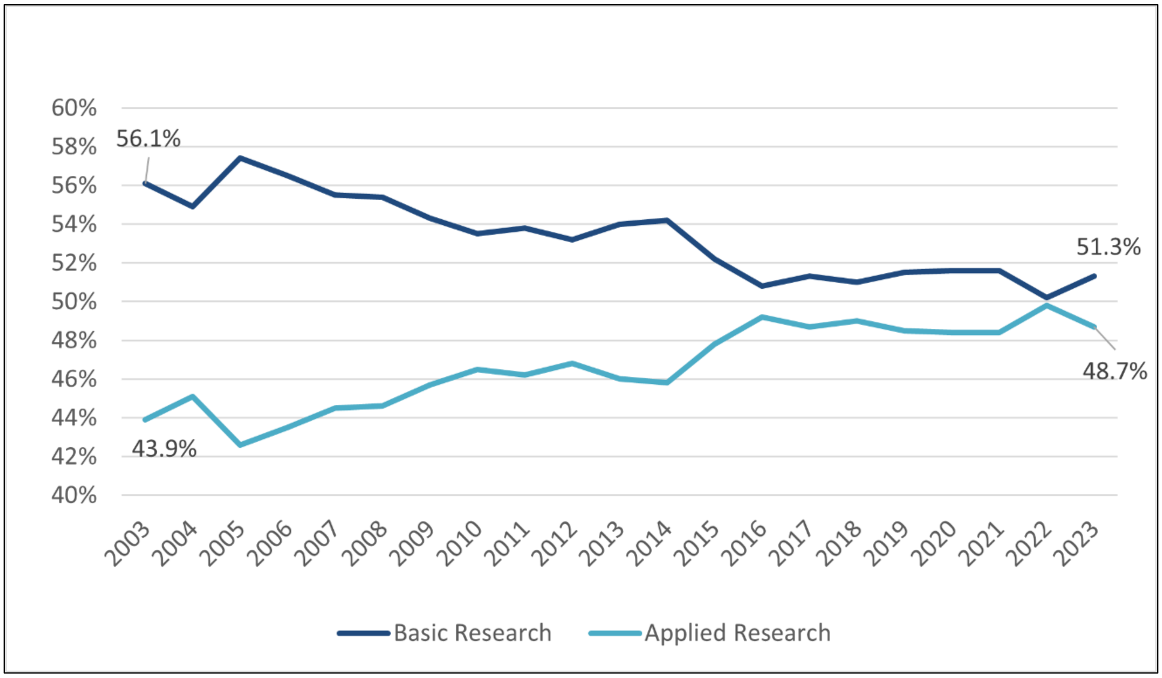
19," *National Bureau of Economics Research Working Paper*, June 2021, https://www.nber.org/system/files/working_papers/w28915/w28915.pdf, and Chiara Franzoni, Paula Stephan, and Reinhilde Veugelers, "Funding Risky Research," *National Bureau of Economic Research*, June 2021, https://www.nber.org/system/files/working_papers/w28905/w28905.pdf.

[296] See federal government-wide definitions discussed in Office of Management and Budget, *Chapter 6: Research and Development*, Analytical Perspectives, Budget of the U.S. Government, FY2025, p. 56, https://www.whitehouse.gov/omb/budget/analytical-perspectives/.

[297] Mike Lauer, "Trends in NIH-Supported Basic, Translational, and Clinical Research: FYs 2009-2022," *NIH Extramural Nexis*, October 31, 2023, https://nexus.od.nih.gov/all/2023/10/31/trends-in-nih-supported-basic-translational-and-clinical-research-fys-2009-2022/.

Figure 10. NIH Distribution of Budget Authority, Basic and Applied Research

FY2003-FY2023



Source: NIH Office of the Budget, "FY2003 - FY2023 Distribution of Budget Authority: Percentages for Basic and Applied Research," last updated March 8, 2024, https://officeofbudget.od.nih.gov/spending_hist.html.

Notes: All fiscal years exclude program evaluation tap budget authority for the National Institute of General Medical Sciences. FY2022 funding includes budget authority for ARPA-H, whereas FY2023 amounts exclude budget authority for ARPA-H, which may help explain changes in distribution of basic and applied funding for each year. FY2023 also accounts for recission of COVID-19 relief funding.

While most NIH funding continues to go to basic research, NIH's increased investment in applied research may reflect broader trends in the biomedical science field, including increasing collaborations between NIH-funded academic institutions and biopharmaceutical companies. Some attribute this increasing collaboration to NIH's flat or decreased budget after the budget doubling period ended in FY2003. In seeking new sources of funding for their work, academic scientists increasingly turned to industry.[298] As a result, academia may have shifted to focus on applied research in general. For example, one NIH Institute reported a decline in the number of basic science grant applications submitted from FY1997 to FY2012, which explained its decreased funding for basic science projects.[299] In addition, some major recent NIH initiatives have emphasized applied research, such as (1) the National Center for Advancing Translational Science, established in 2012; (2) some of the Cures Act Innovation Project research; and (3) some of the major research efforts focused on specific diseases, such as Alzheimer's disease and related dementias and COVID-19. Some policymakers and stakeholders have expressed concern about a shift away from funding basic science at NIH.[300] Others argue that making a dichotomy between

[298] See, for example, Marcus A. Banks, "Biopharma-Academic Collaborations in 2021," *Applied Clinical Trials*, November 12, 2021, https://www.appliedclinicaltrialsonline.com/view/biopharma-academic-collaborations-in-2021.

[299] Francis S. Collins, James M. Anderson, Christopher P. Austin, et al., "Basic Science: Bedrock of Progress," *Science*, vol. 351, no. 6290 (March 2016), p. 1405.

[300] See, for example, summary of stakeholder comments in Ranking Member Bill Cassidy, *NIH in the 21st Century: Ensuring Transparency and American Biomedical Leadership*, Senate Committee on Health, Education, Labor and (continued...)

basic and applied research is not useful, asserting that the actual conduct of science often reflects a complex nonlinear process that encompasses investigations into fundamental knowledge alongside an exploration of potential applications of such knowledge.[301]

In light of these trends and debates, Congress faces the question of what type of research NIH is best suited to support moving forward. Congress may consider whether basic research is still the best primary focus for NIH, or whether new categories or strategies should be devised to inform NIH and other federal research policy.

NIH Funded Research and Pharmaceutical Drug Development

In recent years, some policymakers have shown renewed interest in the role that NIH plays in funding research that leads to new pharmaceutical drugs.[302] In general, developing a new pharmaceutical drug typically requires several stages of research:[303]

- basic research to understand the fundamental mechanisms of a disease and how it might be treated;
- identification of a potential biological or chemical compound that could be the active ingredient in a drug;
- preclinical testing in the laboratory, often using animals, tissue samples, and/or computer models;
- clinical testing in several stages (typically three phases) of human clinical trials in progressively larger groups of human volunteers to assess the product's safety and effectiveness.

NIH-funded research is involved, both directly and indirectly, in pharmaceutical drug development. NIH funding *directly* contributes to pharmaceutical development when NIH-funded scientists develop or identify a compound or other invention that is patented and then licensed to the pharmaceutical industry to be incorporated as part of a new drug. NIH also funds some clinical research on new or existing pharmaceuticals to assess drug safety and effectiveness for FDA approval, though NIH-funded research institutions are usually not the main sponsors who submit such drugs for FDA approval. Since over 50% of NIH funding supports basic research, NIH funded research is, to a greater extent, *indirectly* involved in drug development—by generating scientific knowledge and innovations that later aid in pharmaceutical development.[304] For example, important basic advances in research, such as recombinant DNA, can lead to the

Pensions, p. 4, Washington, DC, May 9, 2024, https://www.help.senate.gov/ranking/newsroom/press/ranking-member-cassidy-releases-new-proposals-to-modernize-nih.

[301] See Venkatesh Narayanamurti, Tolu Odumosu, and Lee Vinsel, "RIP: The Basic/Applied Research Dichotomy," *Issues in Science and Technology*, vol. XXIX, no. 2 (Winter 2013), https://issues.org/venkatesh/.

[302] See, for example, Senate Committee on Health, Education, Labor and Pensions, Chair, "PREPARED REMARKS: Sanders Senate Floor Speech on the Need to Lower the Cost of Prescription Drugs and for Major NIH Reform," press release, November 7, 2023, https://www.help.senate.gov/chair/newsroom/press/prepared-remarks-sanders-senate-floor-speech-on-the-need-to-lower-the-cost-of-prescription-drugs-and-for-major-nih-reform.

[303] CRS Infographic IG10013, *The Pharmaceutical Drug Development Process*.

[304] NIH, "FY 2003–FY 2023 Distribution of Budget Authority Percentages for Basic and Applied Research," https://officeofbudget.od.nih.gov/pdfs/FY25/spending_hist/Basic%20and%20Applied%20FY%202003%20-%20FY%202023%20(V).pdf.

development of whole new classes of drugs.[305] NIH also supports the education and training of biomedical scientists, some of whom may eventually work for the pharmaceutical industry.[306]

In terms of NIH's total scientific contributions to drug development, one often cited study links NIH-funded research to every new molecular entity (NME) approved by the FDA from 2010 to 2019.[307] The study determined that the 356 new drugs approved by the FDA in this time period, as well as their biological targets, were associated with a body of research comprising 2 million publications—463 thousand of which cited NIH funding. The total NIH funding contribution to this body of research was determined to be $230 billion.[308] Other studies have used economic methods to quantify the overall impact of NIH funding on industry. For example, one 2019 study used patenting as an economic measure of the impact that NIH research funding had on the biopharmaceutical industry's productivity from 1980 through 2012. The study determined that NIH investments in a particular research area increased subsequent private-sector patenting: a $10 million increase in NIH funding for a given research area ultimately resulted in 2.7 additional patents. Alternatively phrased, one private-sector patent ultimately results from every two to three NIH grants. Though the authors faced difficulty measuring the economic value of such patents, they stated that "one rough calculation suggests that $1 in NIH funding generates around $2.34 in drug sales."[309]

Many economists and other experts consider NIH-funded research necessary, but not sufficient, for pharmaceutical drug development. In general, NIH tends to focus more on funding basic research and early-stage drug development than on late-stage R&D and other development activities required to bring a new drug to market (e.g., developing manufacturing capabilities).[310] As the Congressional Budget Office put it, "basic research creates knowledge that, in effect, reduces private companies' R&D costs and stimulates private investment in R&D, because it expands the set of potentially profitable drug development opportunities."[311] Even when NIH-funded research is directly involved in drug development, private-sector partners are involved in ultimately bringing the drug to market.[312]

[305] 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.

[306] National Academies of Sciences, Engineering, and Medicine, *The Role of NIH in Drug Development Innovation and Its Impact on Patient Access: Proceedings of a Workshop*, Washington, DC, 2020, https://nap.nationalacademies.org/catalog/25591/the-role-of-nih-in-drug-development-innovation-and-its-impact-on-patient-access.

[307] A new molecular entity (NME) is an active ingredient that contains no active moiety that has been previously approved by the FDA. The active moiety is the part of a molecule that is responsible for the physiological or pharmacological action of a drug.

[308] Ekaterina Galkina Cleary, Matthew J. Jackson, and Fred D. Ledley, "Government as the First Investor in Biopharmaceutical Innovation: 2010-2019," *Institute for New Economic Thinking- Working Papers*, July 20, 2021.

[309] 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.

[310] National Academies of Sciences, Engineering, and Medicine, *The Role of NIH in Drug Development Innovation and Its Impact on Patient Access: Proceedings of a Workshop*, Washington, DC, 2020, https://nap.nationalacademies.org/catalog/25591/the-role-of-nih-in-drug-development-innovation-and-its-impact-on-patient-access; Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, April 2021, https://www.cbo.gov/publication/57126; and Bhaven Sampat, "The Government and Pharmaceutical Innovation," *Journal of Law, Medicine, and Ethics*, vol. 49, no. 1 (2021), pp. 10-18.

[311] Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, April 2021, https://www.cbo.gov/publication/57126.

[312] Bhaven Sampat, "The Government and Pharmaceutical Innovation," *Journal of Law, Medicine, and Ethics*, vol. 49, no. 1 (2021), pp. 10-18.

In recent years, policy discussions concerning NIH's contributions to pharmaceutical drugs have centered primarily around direct contributions to pharmaceutical drugs resulting from NIH-funded research, especially drug-related patents derived from extramural and intramural researchers who received NIH funding for their work. In particular, in the 118th Congress, the Senate Committee on Health, Education, Labor, and Pensions (HELP) chair Senator Sanders had taken an interest in trying to ensure that drugs developed based on NIH-funded inventions are affordable to patients.[313] Other Members of Congress, such as 118th Congress Senate HELP Committee ranking member Senator Cassidy, have disagreed with drug-pricing control policies that they see as risking NIH's industry partnerships in advancing new medical innovations.[314] In general, studies find that at most a relatively small fraction (9%-14%) of new drugs approved by FDA in recent decades are associated with patents that have government assignees (i.e., intramural research) or have publicly funded researchers (including NIH-funded researchers) as the inventors.[315] Therefore, any policy targeted at drugs with patents derived from NIH-funded research would reach only a limited percentage of drugs.

Laws and policies governing patents resulting from federally funded research vary depending on whether the inventor was an intramural or extramural researcher. NIH and other federal agencies have recently announced policy changes aimed at addressing affordability of and access to inventions developed with federal support, as explained further in the next sections.

Intramural Research

In the course of their work, NIH intramural researchers sometimes develop potentially patentable inventions. Pursuant to federal law and policy, NIH may seek patent protection on an intramural invention when doing so would facilitate the commercial development of a product or service that would benefit public health or advance any other agency objective.[316] Once NIH patents an invention, the agency can issue licenses to third parties (such as pharmaceutical companies) for commercialization.[317] As of September 2024, NIH's website lists 15 vaccines and therapeutics

[313] See, for example, Senator Sanders' opening statement at U.S. Congress, Senate Health, Labor and Pensions Committee, *Nomination of Monica Bertagnolli to be Director of the National Institutes of Health*, 118th Cong., 2nd sess., October 18, 2023.

[314] See, for example, Senator Cassidy's opening statement at U.S. Congress, Senate Health, Labor and Pensions Committee, *Nomination of Monica Bertagnolli to be Director of the National Institutes of Health*, 118th Cong., 2nd sess., October 18, 2023.

[315] Studies vary depending on years of analysis, types of drugs included (new molecular entities only versus all approved drugs), and definition of public sector patent or intellectual property. See Bhaven N. Sampat and Frank R. Lichtenberg, "What are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?," *Health Affairs*, vol. 30, no. 2 (2011), pp. 332-339; Ashley J. Stevens, Jonathan J. Jensen, and Katrine Wyller, "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines," *New England Journal of Medicine*, vol. 364 (February 2011), pp. 535-541; Genia Long, "Federal Government-Interest Patent Disclosures for Recent Top-Selling Drugs," *Journal of Medical Economics*, vol. 22, no. 12 (2019), pp. 1261-67; Rahul K Nayak, Jerry Avorn, and Aaron S. Kesselheim, "Public Sector Financial Support for Late-Stage Discovery of New Drugs in the United States," *The BMJ*, vol. 367, no. 15766 (September 23, 2019); Ekaterina Galkina Cleary, Matthew J. Jackson, and Fred D. Ledley, "Government as the First Investor in Biopharmaceutical Innovation: Evidence From New Drug Approvals 2010-2019," Institute for New Economic Thinking- Working Papers, August 5, 2020; and Lisa Larrimore Ouellette and Bhaven N. Sampat, "The Feasibility of Using Bayh-Dole March-In Rights to Lower Drugs Prices," *National Bureau of Economic Research*, March 2024.

[316] U.S. Public Health Service, *Technology Transfer Policy Manual*, Chapter No. 200: Policy on Filing of Patent Applications for PHS Inventions, June 17, 2010, https://www.techtransfer.nih.gov/sites/default/files/documents/policy/pdfs/200-policy.pdf.

[317] U.S. Public Health Service, *Technology Transfer Policy Manual*, Chapter No. 300: PHS Licensing Policy, https://www.techtransfer.nih.gov/sites/default/files/documents/policy/pdfs/Chapter%20300%20-%20PHS%20Licensing%20Policy.pdf.

that have associated patents with active licenses from NIH.[318] Patentable discoveries may also result from collaborations or partnerships between intramural NIH researchers and industry researchers. In such cases, patent rights for such inventions may need to be negotiated. Typically, the specific terms of each contractual agreement signed by NIH and a collaborator informs patent ownership and licensing decisions related to any discoveries resulting from the joint research (in accordance with relevant governing laws and policies).[319] For example, Cooperative Research and Development Agreements (CRADAs) allow federal agencies and nonfederal partners to share facilities, resources, and personnel with one another as part of collaborative research efforts. Per statute, a CRADA will typically provide the collaborating party with an option to negotiate the license to any invention patented by NIH in the course of the collaborative research.[320]

In recent years, some stakeholders and policymakers have called for NIH to restore its "reasonable pricing" clauses in its agreements for its intramural technologies.[321] From FY1991 to FY1995, NIH included a reasonable pricing clause in its CRADAs, under which a company participating in the agreement taking exclusive license to bring an NIH invention to market could be compelled by NIH to submit documentation showing "reasonable relationship between the pricing of the product, the public investment in that product, and the health and safety needs of the public" ("reasonable relationship" was not defined). After reports about the negative impact of the clause, NIH held two public meetings in 1994, which according to NIH, "came to a consensus that companies were avoiding collaborations with the NIH because of the pricing clause." Subsequently, the NIH Director decided to discontinue the policy.[322] Following discontinuation of the policy, there was a fourfold increase in the number of CRADAs—a trend that NIH and other stakeholders point to as evidence that the clause had deterred industry collaboration.[323] Others have argued that the trend in CRADAs could be explained by factors other than the removal of the reasonable pricing clause.[324]

In May 2024, NIH announced a proposed policy for intramural inventions owned by the agency that would apply to commercial patent licenses that authorize commercialization of drugs,

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[318] NIH Office of Technology Transfer, "HHS License-Based Vaccines & Therapeutics," https://www.techtransfer.nih.gov/reports/hhs-license-based-vaccines-therapeutics.

[319] U.S. Public Health Service, *Technology Transfer Policy Manual*, Chapter No. 400, "PHS Cooperative Research and Development Agreement Policy," February 11, 2021, and NIH, *NIH Policy Manual, 1167 - Public–Private Partnerships*, September 25, 2007, https://policymanual.nih.gov/1167.

[320] 15 U.S.C. §3710a and U.S. Public Health Service, *Technology Transfer Manual*, "Chapter No. 400: PHS Cooperative Research and Development Agreement Policy," last updated February 2021, https://www.techtransfer.nih.gov/sites/default/files/Chapter%20400%20-%20PHS%20Cooperative%20Research%20and%20Development%20Agreement%20Policy%20.pdf?

[321] Public Citizen, *Public Citizen Comments to NIH: Proactively Support Access to Publicly Funded Medicines*, July 28, 2023, https://www.citizen.org/article/public-citizen-comments-to-nih-proactively-support-access-to-publicly-funded-medicines/, and Senator Sanders, chair, *Public Investment, Private Greed*, Senate HELP Committee Majority Staff, June 12, 2023, https://www.sanders.senate.gov/wp-content/uploads/Public-Medicines-Report-6.9.23.pdf.

[322] NIH, "The NIH Experience with the Reasonable Pricing Clause in CRADAs FY1990-1995," November 15, 2021, https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf.

[323] NIH, "The NIH Experience with the Reasonable Pricing Clause in CRADAs FY1990-1995," November 15, 2021, https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf, and National Academies of Sciences, Engineering, and Medicine, *The Role of NIH in Drug Development Innovation and Its Impact on Patient Access: Proceedings of a Workshop*, Washington, DC, 2020, https://nap.nationalacademies.org/catalog/25591/the-role-of-nih-in-drug-development-innovation-and-its-impact-on-patient-access.

[324] Ameet Sarpatwari, Alison K. LaPidus, and Aaron S. Kesselheim, "Revisiting the National Institutes of Health Fair Pricing Condition: Promoting the Affordability of Drugs Developed with Government Support," *Annals of Internal Medicine*, vol. 172, no. 5 (March 3, 2020), pp. 348-351, and James Love, *The Number of Standard and Material CRADAs Executed by The NIH from 1985 to 2020 and the Relationship to the NIH Reasonable Pricing Clause*, Knowledge Ecology International, April 5, 2021, https://www.keionline.org/wp-content/uploads/KEI-BN-2021-3.pdf.

biologics, vaccines, or devices. The policy would add language to NIH's standard (model) licensing agreements to require the licensee to anticipate the potential patient population for the licensed product and then develop one or more strategies to mitigate potential access challenges based on criteria such as affordability or availability. This access plan would be required within three months of a product entering a pivotal clinical trial (e.g., Phase III or equivalent), which are the large-scale clinical trials that typically provide final evidence for FDA regulatory submissions. The licensee must also agree to continued engagement with NIH on progress under the plan and to consider modifications proposed by the agency.[325]

Extramural Research

Given that over 80% of NIH's annual budget funds extramural research, most inventions that result from NIH-funded research are developed by extramural research institutions such as universities and medical centers. As mentioned above, studies find that a fraction (9%-14%) of new drugs approved by FDA in recent decades were based on patents or specific intellectual contributions of publicly funded researchers (including NIH-funded researchers).

The Bayh-Dole Act (P.L. 96-517, as amended) governs nonfederal organizations' patent ownership and licensing of inventions developed with federal support, which allows such private organizations to elect to retain patent rights to these inventions.[326] The federal government still retains a government-use license (ability to use the invention without paying a royalty) and authority to grant compulsory licenses to third parties in certain circumstances, known as "march-in rights." Circumstances for exercising march-in rights include conditions related to (1) practical application of the invention, (2) health and safety needs, (3) requirements for public use as specified by federal regulations, and (4) failure to comply with domestic manufacturing requirements. Since the Bayh-Dole Act was enacted, NIH has received several petitions to exercise its march-in rights based on the high prices of drugs that were developed, in part, with NIH-funded research.[327] In theory, if NIH exercised march-in rights over a drug, the pharmaceutical company would be required to grant a license to produce the drug to another manufacturer, potentially enabling price competition for the drug. NIH has rejected these petitions, mostly on the grounds that drug pricing alone was not sufficient to invoke march-in rights.[328] During proceedings regarding one petition in 2004, the then NIH Director stated,

> Finally, the issue of the cost or pricing of drugs that include inventive technologies made using Federal funds is one which has attracted the attention of Congress in several contexts that are much broader than the one at hand. In addition, because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively.[329]

[325] NIH, "National Institutes of Health (NIH) Office of Science Policy (OSP): Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning," 89 *Federal Register* 45003-45005, May 22, 2024.

[326] Originally titled the Patent and Trademark Act Amendments of 1980, but commonly referred to as the Bayh-Dole Act.

[327] This section was largely adapted from CRS In Focus IF12582, *Pricing and March-In Rights Under the Bayh-Dole Act*.

[328] CRS In Focus IF12582, *Pricing and March-In Rights Under the Bayh-Dole Act*.

[329] Elias A. Zerhouni, Director, NIH, In the Case of Norvir Manufactured by Abbott Laboratories, Inc., July 29, 2004, http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

The Biden Administration has taken policy action related to the Bayh-Dole Act and prices. In December 2023, U.S. Department of Commerce's National Institute of Standards and Technology (NIST, the lead agency for Bayh-Dole implementation) issued draft guidance on agencies' exercise of march-in rights. This followed a 2021 HHS comprehensive plan for addressing high drug prices, which stated that HHS would engage with other government agencies around issues related to march-in rights and government-funded inventions as one component of many strategies to address drug pricing.[330] The draft NIST guidance would allow considering price as a factor in determining whether to exercise march-in rights under the Bayh-Dole Act. It remains to be seen how this draft guidance, if finalized, would change NIH's consideration of march-in rights petitions related the price of drugs. For more information on the draft guidance, see CRS In Focus IF12582, *Pricing and March-In Rights Under the Bayh-Dole Act*.

Further, the number of drugs for which NIH could practically exercise march-in rights may be limited. A 2024 working paper by economists based on an analysis of patent data found that 9% of FDA-approved drugs from 1985 to 2022 had at least one public sector patent (meaning a patent with a statement indicating federal funding, a government assignee, or other government rights identified); however, most of these drugs were also covered by patents not covered by the Bayh-Dole Act (and therefore not subject to march-in rights). Only 2.5% of the drugs during that time period had only public sector patents. The authors of the paper posit that NIH may not be able to exercise march-in rights in a practically effective way unless the Bayh-Dole Act applies to all of the patents that cover the drug.[331]

Looking Ahead

It remains to be seen whether and how NIH and NIST finalize their draft policies and guidance. Some stakeholders have argued that NIH could do more to address the affordability of drugs developed with NIH support.[332] Others have argued that these policies could adversely affect federal (or academic)-industry research collaborations, lead to increased burdens on agencies, lead to industry reluctance to license federal funded inventions, or, in the case of march-in rights, lead to market volatility as companies file petitions to acquire others' products.[333] As noted, both of these policies would likely reach a limited number of FDA-approved drugs. Moving forward, Congress may consider how to appropriately balance innovation and commercialization with affordability for drugs developed with NIH support.

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330 Secretary Xavier Becerra, *Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy*, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, September 9, 2021, p. 22.

331 Lisa Larrimore Ouellette and Bhaven N. Sampat, "The Feasibility of Using Bayh-Dole March-In Rights to Lower Drugs Prices," *National Bureau of Economic Research*, March 2024.

332 See, for example, Letter from Public Citizen to Lawrence A. Tabak , Principal Deputy Director, NIH, July 22, 2024, https://www.citizen.org/wp-content/uploads/Public-Citizen.pdf, and Knowledge Ecology International, "KEI Submissions to the NIH on the Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning," July 23, 2024, https://www.keionline.org/40130.

333 See, for example, Letter from Gary Locke, Former Secretary of the Department of Commerce, Carlos Gutierrez, Former Secretary of the Department of Commerce, Andrei Iancu, Former Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office, et al. to President Biden, February 2, 2024, https://c4ip.org/wp-content/uploads/2024/02/Fmr-Commerce-Dept-Officials-Letter-to-President-Biden-re-Draft-Interagency-Guidance-Framework-for-Considering-the-Exercise-of-March-In-Rights.pdf, and Letter from Randall L. Rutta, Chief Executive Officer, National Health Council, to NIH Office of Science Policy, July 22, 2024, https://nationalhealthcouncil.org/letters-comments/nhc-comments-on-national-institutes-of-health-nih-office-of-science-policy-osp-request-for-information-on-draft-nih-intramural-research-program-policy-promoting-equity-through-access-planning/.

Table 3. Components of NIH, with History and Scope

Institute/Center Statutory Authority in Public Health Service Act and *U.S. Code*	When and How Established; Chronology of Name Changes	Major Research Focus Areas
Institutes		
National Cancer Institute (NCI) PHSA §410-417G, 42 U.S.C. §285-285a-13	1937—National Cancer Institute: National Cancer Institute Act (P.L. 75-244). 1944—under the PHS Act of 1944 (P.L. 78-410), NCI became a division of the National Institute of Health.	All types of cancer and aspects of cancer—cause, diagnosis, prevention, treatment, rehabilitation, and continuing care of patients.
National Heart, Lung, and Blood Institute (NHLBI) PHSA §418-425, 42 U.S.C. §285b-1-285b-9	1948—National Heart Institute.: National Heart Act (P.L. 80-655). 1969—National Heart and Lung Institute. 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) PHSA §453, 42 U.S.C. §285h	1948—National Institute of Dental Research: National Dental Research Act (P.L. 80-755): 1998—NIDCR.	Oral, dental, and craniofacial diseases and disorders.
National Institute of Allergy and Infectious Diseases (NIAID) PHSA §446-447D, 42 U.S.C. §285f-285f-5	1948—National Microbiological Institute. 1955—NIAID.	Allergic, immunologic, and infectious diseases.
National Institute of Mental Health (NIMH) PHSA §464R-464U, 42 U.S.C. §285p-285p-3	1949—NIMH: established under authority of the National Mental Health Act of 1946 (P.L. 79-487). 1967—transferred out of NIH to PHS. 1974—moved to Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA, P.L. 93-282). 1992—moved back to NIH (P.L. 102-321).	Brain research, mental illness, and mental health.
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) PHSA §426-434A, 42 U.S.C. §285c-285c-9	1950—National Institute of Arthritis and Metabolic Diseases: Omnibus Medical Research Act (P.L. 81-692): 1972—National Institute of Arthritis, Metabolism, and Digestive Diseases. 1981—National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. 1985—NIDDK: The Health Research Extension Act of 1985 (P.L. 99-158.	Diabetes, endocrine diseases, metabolic diseases; digestive diseases, nutrition; kidney, urologic, hematologic diseases.

Institute/Center Statutory Authority in Public Health Service Act and *U.S. Code*	When and How Established; Chronology of Name Changes	Major Research Focus Areas
National Institute of Neurological Disorders and Stroke (NINDS) PHSA §457-460, 42 U.S.C. §285j-285j-3	1950—National Institute of Neurological Diseases and Blindness: Omnibus Medical Research Act (P.L. 81-692). 1968—National Institute of Neurological Diseases and Stroke. 1975—National Institute of Neurological and Communicative Disorders and Stroke. 1988—NINDS.	Neurological diseases; fundamental neurosciences; stroke, trauma.
National Institute of General Medical Sciences (NIGMS) PHSA §461, 42 U.S.C. §285k	1963—NIGMS established under authority provided in PHS Act Amendment (P.L. 87-838), enacted in 1962	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) PHSA §448-452G, 42 U.S.C. §285g-285g-10	1963—NICHD established under authority provided in PHS Act Amendment (P.L. 87-838), enacted in 1962	Reproductive biology; population issues; embryonic development; maternal, child, and family health; medical rehabilitation.
National Eye Institute (NEI) PHSA §455-456, 42 U.S.C. §285i-285i-1	1968—NEI: 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) PHSA §463-463B, 42 U.S.C. §285*l*-285*l*-6	1965—National Environmental Health Sciences Center. 1969—NIEHS.	Interrelationships of environmental factors, individual genetic susceptibility, and age as they affect health.
National Institute on Alcohol Abuse and Alcoholism (NIAAA) PHSA §464H-464J, 42 U.S.C. §285n-285n-2	1970—NIAAA: Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act (P.L. 91-616) established NIAAA within NIMH in PHS. 1974—moved to ADAMHA (P.L. 93-282). 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) PHSA §464L-464P, 42 U.S.C. §285o-285o-4	1974—NIDA: established under authority of Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255). 1974—moved to ADAMHA (P.L. 93-282). 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.

Institute/Center Statutory Authority in Public Health Service Act and *U.S. Code*	When and How Established; Chronology of Name Changes	Major Research Focus Areas
National Institute on Aging (NIA) PHSA §443-445I, 42 U.S.C. §285e-285e-10a	1974—NIA: 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) PHSA §435-442A, 42 U.S.C. §285d-285d-8	1986—NIAMS: 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 of Nursing Research (NINR) PHSA §464V-464X, 42 U.S.C. §285q-285q-2	1986—National Center for Nursing Research established under authority of the Health Research Extension Act of 1985 (P.L. 99-158). 1993—NINR.	Basic and clinical nursing research; patient care research; health disparities; population and community health.
National Institute on Deafness and Other Communication Disorders (NIDCD) PHSA §464-464F, 42 U.S.C. §285m-285m-6	1988—NIDCD: 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).	Science as well as diseases and disorders of hearing, balance, smell, taste, voice, speech, and language.
National Human Genome Research Institute (NHGRI) PHSA §464z-1, 42 U.S.C. §285s	1990—National Center for Human Genome Research (NCHGR) established. 1993—NCHGR authorized (P.L. 103-43). 1997—NHGRI.. 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) PHSA §464z, 42 U.S.C. §285r	2000—NIBIB: NIBIB Establishment Act (P.L. 106-580).	Biomedical imaging, bioengineering and related technologies and modalities, including biomaterials and informatics.
National Institute on Minority Health and Health Disparities (NIMHD) PHSA §464z-3-464z-6, 42 U.S.C. §285t-285t-3	1990—Office of Research on Minority Health (ORMH) created by NIH in OD. 1993—ORMH authorized (P.L. 103-43). 2000—National Center on Minority Health and Health Disparities (NCMHD) created (P.L. 106-525). 2010—NIMHD (P.L. 111-148).	Minority health and populations with health disparities.

Institute/Center Statutory Authority in Public Health Service Act and *U.S. Code*	When and How Established; Chronology of Name Changes	Major Research Focus Areas
Centers and Other Components		
John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) PHSA §482, 42 U.S.C. §287b	1968—FIC. 1985—established in law (P.L. 99-158).	Global health research. Focal point for NIH's international collaboration activities and scientific exchanges.
National Center for Complementary and Integrative Health (NCCIH) PHSA §485D, 42 U.S.C. §287c-21	1992—Office of Alternative Medicine (OAM) created in OD. 1993—OAM authorized (P.L. 103-43). 1998—National Center for Complementary and Alternative Medicine (NCCAM) created (P.L. 105-277). 2014—NCCIH (P.L. 113-235).	Health and medical approaches outside of conventional or usual Western medical practice. Includes nutritional, psychological (e.g., mindfulness), and physical (e.g., massage) approaches to improving health and wellbeing.
National Center for Advancing Translational Sciences (NCATS) PHSA §479-481B, 42 U.S.C. §287-287a-3	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) PHSA §465-478A, 42 U.S.C. §286-286d	1836—established as the Library of the Office of the Surgeon General of the Army 1922—Army Medical Library. 1952—Armed Forces Medical Library. 1956—NLM: NLM Act (P.L. 84-941). 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) PHSA §401-402, 42 U.S.C. §281-282	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) PHSA §402(b), 42 U.S.C. §282(b)	First separate appropriation FY1970.	Provides for the design, construction, improvement, and repair of NIH clinical and laboratory buildings.
NIH Clinical Center (CC)	1944—authorized by the PHS Act (P.L. 78-410). 1953—first patient admitted.	NIH's hospital and outpatient facility for clinical research.

Institute/Center Statutory Authority in Public Health Service Act and *U.S. Code*	When and How Established; Chronology of Name Changes	Major Research Focus Areas
Center for Scientific Review (CSR)	1946—Division of Research Grants. 1997—CSR.	Receives, assigns, and reviews research and training funding applications.
Center for Information Technology (CIT)	1964—Division of Computer Research and Technology (DCRT) established. 1997—CIT formed (DCRT combined with other offices).	Provides, coordinates, and manages information technology for NIH.

Source: Public Health Service Act Title IV, NIH, "Chronology of Events," https://www.nih.gov/about-nih/what-we-do/nih-almanac/chronology-events, and NIH, "Legislative Chronology," https://www.nih.gov/about-nih/what-we-do/nih-almanac/legislative-chronology, and other NIH webpages and archived sources.

Notes: Throughout NIH's history, Congress has provided governing officials with certain general authorities to establish new NIH components or to reorganize the agency. Where the table does not list a specific legislative authority used to establish an NIH component, one of these general authorities was used. PHS=Public Health Service.

Appendix. Selected NIH Research Policies

NIH researchers, both extramural and intramural, must adhere to many policies as a condition of funding receipt or employment. The following summarizes selected NIH research policies of common congressional interest that inform the conduct of NIH research, as well as those that reflect certain broader ethical and scientific policy goals.

Animal Welfare

NIH research involving vertebrate animals must adhere to the *Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals*, developed based on statutory requirements in PHSA Section 495.[334] Grantees must also adhere to requirements in the Animal Welfare Act and U.S. Food and Drug Administration regulations, as applicable.[335] Together, these requirements seek to minimize suffering and distress among animals involved in research and to ensure best practices for their care. For more information, see CRS In Focus IF12002, *Animal Use in Federal Biomedical Research: A Policy Overview*.

Financial Conflict of Interest

Based in regulations for all U.S Public Health Service (PHS) grantees (42 C.F.R. Part 50, Subpart F) and statutory requirements in PHSA Section 493A, NIH award recipients are required to adhere to financial conflicts of interest (FCOI) policies. According to NIH, these FCOI policies seek to provide a "reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be free from bias by any conflicting financial interest of an Investigator."[336] Recipient institutions are required to comply with the FCOI policies and to ensure that funded researchers are in compliance. Recipient institutions must maintain an up-to-date and enforced institution-wide FCOI policy that requires NIH-funded investigators to disclose significant financial interests.[337] Based on the specific financial interests reported, institutions are to identify and mitigate any FCOIs and then report to NIH on disclosures and any actions taken in response.[338] NIH intramural researchers are subject to financial conflicts of interest policies specific to federal government employees.[339]

Human Subjects Protections

Any NIH research involving humans ("human subjects research") is subject to regulations in 45 C.F.R. Part 46, the Common Rule, which according to NIH, seeks to "safeguard the rights and welfare of individuals" who participate as subjects (or volunteers) in HHS and NIH research

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[334] 42 U.S.C. §289d.

[335] See CRS In Focus IF12002, *Animal Use in Federal Biomedical Research: A Policy Overview*.

[336] NIH, *4.1.10 Financial Conflict of Interest*, NIH Grants Policy Statement, April 2024, https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.10_financial_conflict_of_interest.htm.

[337] 42 C.F.R. §50.604. As defined in regulation, "significant financial interest" means any financial interest of the investigator or the investigator's immediate family generally with a value of $5,000 or more along with other intellectual property rights and interests (see regulatory language for further specifics).

[338] 42 C.F.R. Part 50, Subpart F.

[339] See NIH, "Ethics Program," https://ethics.od.nih.gov/. Federal government-wide requirements in 5 U.S.C. §13101-13112 (Ethics in Government Act); 5 C.F.R., Subchapter B, Part 2634 (Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture); and 5 C.F.R., Subchapter B, Part 2638 (Executive Branch Ethics Program). Regulations specific to NIH employees available at 5 C.F.R. Part 5501.

activities.[340] Under the Common Rule, each NIH-funded research institution must designate an Institutional Review Board (IRB) to review and approve all proposed human subjects research activities at the institution and to provide ongoing oversight of such research (unless determined exempt).[341] The IRB reviews proposed research to determine that risks to human subjects involved in research are minimized and are reasonable in relation to the anticipated benefits. A central goal of the Common Rule is to preserve research participant autonomy. This involves requiring that each participant gives informed consent to participate in a study, meaning that participants are given adequate information on the proposed research and its associated benefits and risks before providing written (or in some cases, verbal) consent to participate.[342] In addition, the IRB is to ensure that research participant selection is equitable and that participants are not subject to undue influence or coercion to participate.[343]

Inclusion Policies

NIH has two separate policies regarding inclusion of different populations in its human subjects research: (1) the inclusion across the lifespan policy, and (2) inclusion of women and minorities as subjects in clinical research policy:

- The **Inclusion Across the Lifespan Policy** seeks to ensure that NIH-funded research includes individuals of all ages, including children and older adults, unless there are scientific or ethical reasons not to include them. Any application or intramural research proposal involving human subjects research must include plans for including individuals across the lifespan and must provide a rationale for any age-related exclusion. The current policy went into effect for proposed research beginning in 2019 and expanded upon an earlier inclusion of children policy.[344] This policy change followed a provision of the 21st Century Cures Act (P.L. 114-255), which required NIH to seek input from experts on appropriate age groups to include in human subjects research and to update its policies as appropriate.[345]
- The **Inclusion of Women and Minorities Policy** seeks to ensure the inclusion of women and members of racial and ethnic minority groups in NIH-funded clinical research.[346] Any application or intramural research proposal involving clinical research must describe the proposed study population and the scientific or ethical rationale for any exclusion. Investigators must plan for appropriate outreach

[340] NIH, *4.1.10 Financial Conflict of Interest*, NIH Grants Policy Statement, April 2024, https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.10_financial_conflict_of_interest.htm.

[341] NIH, *4.1.15 Human Subjects Protections*, NIH Grants Policy Statement, April 2024, https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.15_human_subjects_protections.htm. Categories of research exempt from all or certain aspects of the Common Rule requirements are specified in 45 C.F.R. §46.104.

[342] 45 C.F.R. §46.116.

[343] 45 C.F.R. §46.111.

[344] NIH, "Inclusion Across the Lifespan in Human Subjects Research," https://grants.nih.gov/policy/inclusion/lifespan.htm. For Inclusion of Children policy, see NIH, "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects," 1998, https://grants.nih.gov/grants/guide/notice-files/not98-024.html.

[345] Section 2038(i) of the 21st Century Cures Act (P.L. 114-255); 42 U.S.C. §282 note.

[346] NIH defines clinical research as "research with human subjects that is (1) patient-oriented, meaning the research is conducted with human subjects or on materials of human origin (e.g., tissues) in which an investigator directly interacts with human subjects; (2) epidemiological and behavioral studies; and (3) outcomes research and health services research." See definition in NIH Grants and Funding, *Glossary*, https://grants.nih.gov/grants/glossary.htm#C.

programs and activities to recruit and retain the proposed study population.[347]
This policy is required by PHSA Section 492B.[348]

These inclusion policies generally seek to ensure that the findings of NIH-funded research can be generalizable to the broader population. Both policies involve ongoing reporting requirements to monitor inclusion in NIH-funded studies.[349] NIH also publishes an annual inclusion statistics report that provides median participation by demographic groups across types of NIH research (e.g., disease or condition areas) as required by the 21st Century Cures Act (P.L. 114-255).[350]

Data Sharing Policy

NIH has implemented a new Data Management and Sharing (DMS) policy, effective January 25, 2023. The new DMS policy applies to all NIH-funded research that results in the generation of scientific data.[351] (The previous DMS policy applied to a subset of funded projects.) Funding applications or intramural researchers must submit a DMS plan as part of their research proposal that outlines how scientific data from the funded research will be shared, taking into account any restrictions or limitations. ICs must assess the plan as part of proposal review. NIH expects researchers to maximize the appropriate sharing of scientific data, while acknowledging potential legal, ethical and technical constraints with data sharing.[352]

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[347] NIH, "Inclusion of Women and Minorities as Participants in Research Involving Human Subjects," https://grants.nih.gov/policy/inclusion/women-and-minorities.htm.

[348] 42 U.S.C. §289a-2.

[349] NIH, "Inclusion Across the Lifespan in Human Subjects Research," https://grants.nih.gov/policy/inclusion/lifespan.htm, and NIH, "Inclusion of Women and Minorities as Participants in Research Involving Human Subjects," October 11, 2022, https://grants.nih.gov/policy/inclusion/women-and-minorities.htm.

[350] NIH, "RCDC Inclusion Statistics Report," https://report.nih.gov/RISR/#/. For legislative requirement, see Section 2038 of P.L. 114-255.

[351] The policy defines scientific data as "the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens." See NIH, "Final NIH Policy for Data Management and Sharing," October 29, 2020, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html.

[352] NIH, "Final NIH Policy for Data Management and Sharing," October 29, 2020, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html.

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