



The National Institutes of Health (NIH): Organization, Funding, and Congressional Issues

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March 16, 2011

Congressional Research Service

7-5700

www.crs.gov

R41705

Summary

The National Institutes of Health (NIH) is the focal point for federal health research. An agency of the Department of Health and Human Services (HHS), it uses its \$31 billion budget to support more than 325,000 scientists and research personnel working at over 3,000 institutions across the U.S. and abroad, as well as to conduct biomedical and behavioral research and research training at its own facilities. The agency consists of the Office of the Director, in charge of overall policy and program coordination, and 27 institutes and centers, each of which focuses on particular diseases or research areas in human health. A range of basic and clinical research is funded through a highly competitive system of peer-reviewed grants and contracts.

Congress doubled the NIH budget over a five-year period from its FY1998 base of \$13.7 billion to the FY2003 level of \$27.1 billion. Since then, the growth rate of the NIH budget has been below the rate of inflation, which for biomedical research in FY2011 is estimated to be 2.9%. The American Recovery and Reinvestment Act (ARRA) provided NIH with an additional \$10.4 billion to be spent over the two-year period of FY2009 through FY2010. The Continuing Appropriations Act, 2011 (P.L. 111-242), as amended, provides temporary FY2011 funding through March 18, 2011, at the FY2010 rate of operations. H.R. 1, the Full Year Continuing Appropriations Act, 2011, would provide funding for NIH for the remainder of the fiscal year. According to the House Appropriations Committee, the bill would reduce the NIH budget by \$1.63 billion compared to the FY2010 level and by \$1.57 billion compared with the FY2011 request. For FY2012, the Obama Administration has requested \$32 billion for NIH, an increase of \$745 million (2.4%) over FY2010.

Appropriators and authorizers face many issues in working with NIH to set research priorities in the face of tight budgets. Congress accepts, for the most part, the priorities established through the agency's complex process of weighing scientific opportunity and public health needs. While the Public Health Service Act (PHSA) provides the statutory basis for NIH programs, it is primarily through appropriations report language, not budget line items or earmarks, that Congress gives direction to NIH and allows a voice for advocacy groups. Challenges facing the agency and the research enterprise, all aggravated by restrained budgets, include attracting and keeping young scientists in research careers; improving the translation of research results into useful medical interventions through more efficient clinical research; creating opportunities for transdisciplinary research that cuts across institute boundaries to exploit the newest scientific discoveries; and managing the portfolio of extramural and intramural research with strategic planning, openness, and public accountability.

The last time Congress addressed NIH with comprehensive legislation was in December 2006 when it passed the NIH Reform Act (P.L. 109-482). Congressional oversight of NIH activities may focus on pending financial conflicts of interest regulations and proposals to reorganize the institutes and centers, such as the new National Center for Advancing Translational Sciences (NCATS). Also, health reform legislation (P.L. 111-148) requires NIH to implement the Cures Acceleration Network (CAN). The purpose of CAN is to support revolutionary advances in basic research and facilitate FDA review of CAN-funded cures. However, although P.L. 111-148 authorizes \$500 million for CAN in FY2010, CAN would be funded via a specific appropriation—not through the general NIH appropriation. If CAN receives an appropriation, NIH would determine which medical products are “high need cures,” and then make awards to research entities or companies in order to accelerate the development of such high need cures.

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Introduction

The National Institutes of Health (NIH) is the primary agency of the federal government charged with the conduct and support of biomedical and behavioral research. It also has major roles in research training and health information dissemination. 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 the burdens of illness and disability.”¹

NIH basic research is valued as a source of new and improved treatment and prevention measures but may also be used as a basis for policy decisions, economic development, and potentially new commercial products. The primary rationale for a federal government role in funding basic research is that private firms do not perform enough such research relative to the needs of society.² Private firms may lack the incentive to adequately support basic research because firms cannot ensure that they will capture all the benefits of such support.³ There is some concern that, given the size of federal research funding, without careful decision making, some of the federal funding could possibly “crowd out private-sector investment in R&D.”⁴ The federal government tends to focus on basic research and private firms concentrate on applied research and development, which may lower the risk of overlap or crowd out. However, the line between basic and applied research can be difficult to define. This is especially true when basic life-science research may be profitable.⁵

Federal support of basic research not only *directly* stimulates industry spending on applied research and development (R&D) through scientific discoveries that expand industry R&D opportunities but also *indirectly* stimulates industry R&D by training many of the researchers that are hired by industry.⁶ The training provided by NIH programs “enhances the productivity and profitability of the companies’ R&D investments.”⁷ In contrast, NIH funding may indirectly affect the number of researchers available for the private sector, this can indirectly affect the salaries of these researchers.

One recent study found that in 2007, industry accounted for 58% of all expenditures on biomedical research, followed by NIH (27%), state and local governments (5%), and private not-for-profit support (4%).⁸

Congress maintains a high level of interest in NIH for a variety of reasons. NIH funds extramural researchers in every state, and widespread constituencies contact Congress about funding for

¹ National Institutes of Health, About the National Institutes of Health, at <http://www.nih.gov/about/mission.htm>.

² Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, Washington, DC, October 2006, p. 3.

³ Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards*, Washington, DC, February 1993, p. 201.

⁴ Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, Washington, DC, October 2006, p. 3.

⁵ See for example the “Issues for Congress” section in general and the “Financial Conflicts of Interest” section in particular in this report.

⁶ *Ibid.*

⁷ *Ibid.*

⁸ E. Ray Dorsey, Jason de Roulet, and Joel P. Thompson, et al., “Funding of US Biomedical Research, 2003-2008,” *Journal of the American Medical Association*, vol. 303, no. 2 (January 13, 2010), pp. 137-143.

particular diseases and levels of research support in general. NIH is the largest and most visible contributor to the federal biomedical research effort, accounting for 84% of total federal funding in 2007.⁹ In both budget and personnel, it is the largest of the eight health-related agencies that make up the Public Health Service (PHS) within the Department of Health and Human Services (HHS).¹⁰ For FY2010, NIH had a total budget of \$31 billion and total employment of about 18,000 people. The President's FY2012 budget requested \$32.0 billion in funding for NIH. The agency garners great interest during deliberations on the annual appropriations bill for the Departments of Labor, Health and Human Services, and Education and Related Agencies.

NIH increasingly comes to the attention of Congress and the American people due to greater awareness of science advances. Examples include the Human Genome Project and its potential for guiding more personalized medicine, public policy debates on topics such as the use and regulation of human embryonic stem cells, and the potential for research advances to improve quality and lower costs of medical care.

Congress doubled the NIH budget between FY1998 and FY2003 and more recently provided a temporary two-year funding increase through the American Recovery and Reinvestment Act of 2009 (P.L. 111-5) after several years of low or no growth in the post-doubling period. In health reform legislation (P.L. 111-148), the 111th Congress directed NIH to implement the new Cures Acceleration Network (CAN) in order to support ground-breaking advances in basic research and facilitate FDA review of CAN-funded cures. However, the legislation mandates that CAN be funded via a specific appropriation—not through the general NIH appropriation—and the current budget outlook has worsened in the new Congress, especially for discretionary programs.

The 2010 election sent to Congress more fiscal conservatives, particularly in the House, who have promised to focus on deficit reduction and shrinking the federal budget during the 112th Congress. Some Members have suggested rolling back federal funding for many discretionary programs to FY2008 levels—this would change the NIH budget from current funding of \$30.9 million to \$29.3 million. According to the House Appropriations Committee, H.R. 1, the Full Year Continuing Appropriations Act, 2011, would reduce the NIH budget by \$1.63 billion compared to the FY2010 level and by \$1.57 billion compared with the FY2011 request. In the State of the Union speech, however, President Obama indicted his unwillingness to scale back the national investment in research and development, and said that “maintaining our leadership in research and technology is crucial to America’s success.” The speech specifically stated that in the budget proposal for FY2012, “we’ll invest in biomedical research.” For FY2012 the Obama Administration has requested \$32 billion for NIH, an increase of \$745 million (2.4%) over FY2010.

Other issues of concern to Congress and the research community include

- increasing the movement of basic science discoveries, via translational research, into new preventives, diagnostics, therapies, and cures;

⁹ Ibid.

¹⁰ The Public Health Service also includes the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Agency for Healthcare Research and Quality (AHRQ), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Indian Health Service (IHS), and the Agency for Toxic Substances and Disease Registry (ATSDR). For further information, see CRS Report RL34098, *Public Health Service (PHS) Agencies: Background and Funding*, coordinated by Pamela W. Smith.

- helping young investigators obtain their first independent research grants;
- congressional restrictions on research funding, such as work involving human embryos or human sexuality;
- development of NIH financial conflict-of-interest regulations; and
- proposals to reorganize some NIH institutes and centers, specifically the December 2010 recommendation for the new National Center for Advancing Translational Sciences (NCATS) put forward by the NIH Director and an NIH advisory board.

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

Organization of NIH

History

NIH traces its roots to 1887, when a one-room Laboratory of Hygiene was established at the Marine Hospital in Staten Island, New York. Relocated to Washington, DC, in 1891, and renamed the Hygienic Laboratory, it operated for its first half century as an intramural research lab for the Public Health Service. Congress designated the research laboratory the National Institute of Health in 1930 (P.L. 71-251). It moved to donated land in the Maryland suburbs in 1938. By 1948, several new institutes and divisions had been created, and the agency became the National Institutes of Health (P.L. 80-655). Congress has continued to create new institutes and centers, most recently in 2000 when it created the National Center on Minority Health and Health Disparities (NCMHD) (P.L. 106-525) and the National Institute of Biomedical Imaging and Bioengineering (NIBIB) (P.L. 106-580). In March 2010, Congress redesignated NCMHD as the National Institute on Minority Health and Health Disparities via the health reform legislation (Section 10334 of P.L. 111-148). NIH occupies a 322-acre main campus in Bethesda, Maryland, and several off-campus sites, including locations in Maryland, North Carolina, Montana, and elsewhere.

Selected NIH Resources <http://www.nih.gov>

Background: <http://www.nih.gov/about/index.html>
Budget: <http://officeofbudget.od.nih.gov/index.htm>
Spending estimates: <http://report.nih.gov/rcdc/categories/>
Health Information: <http://health.nih.gov>
Office of the Director, Institutes & Centers: <http://www.nih.gov/icd>
Grants: <http://grants.nih.gov/grants/oer.htm>
Grants searchable by topic: <http://projectreporter.nih.gov/reporter.cfm>
Grants searchable by recipient: <http://report.nih.gov/index.aspx>
Peer review: <http://enhancing-peer-review.nih.gov/>
Chronologies: <http://www.nih.gov/about/almanac/index.html>
Legislative summaries: <http://olpa.od.nih.gov>
Congressional Liaison: 301-496-3471

Structure

Today, NIH consists of the Office of the Director and 27 components—20 institutes, 3 research centers, the National Library of Medicine (NLM), and 3 other centers that provide operational support to the rest of NIH (for details, see **Table 1** and **Table 4**). The Office of the Director (OD) sets overall policy for NIH and coordinates the programs and activities of all NIH components, particularly trans-institute research initiatives and issues. The individual institutes and centers (ICs), each of which focuses on particular diseases, areas of human health and development, or aspects of research support, plan and manage their own research programs in coordination with OD. Congress provides separate appropriations to 24 (all 20 institutes, NLM, and the 3 research centers) of the 27 ICs, to OD, and to a buildings and facilities account (see “Budget”).¹¹ Only the institutes and the three research centers have the authority to award research grants; the three operational support centers do not award research grants.

In 2000, Congress requested a National Academy of Sciences (NAS) study of the structure and organization of NIH.¹² According to NAS, “the most common mechanism of origin of the institutes has been the congressional mandate responding to the health advocacy community.”¹³ The first institute to be established was the National Cancer Institute (NCI) in 1937. “From the middle 1940s to 1974, health advocates were successful in persuading Congress to establish additional institutes, often against the wishes of administrations, which generally opposed creation of new categorical institutes.”¹⁴ More recently, following the success of AIDS activists, health advocacy “groups have continued the long established pattern of pushing for creation of named entities at NIH to create focal points for developing more research funding for particular diseases. That has often resulted in the establishment by Congress of a named program at the office level. Through continued pressure, offices may then be elevated to centers and, in some cases, to institute status.”¹⁵

The 2003 NAS report suggested potential mergers, but said that any proposals for changing the number of ICs or OD program offices should be subject to a public evaluation process.¹⁶ The report also 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 councils are more independent, and protected from political influences.

¹¹ The three centers that do not receive their own appropriations are the Center for Scientific Review (CSR), which receives, refers, and reviews research and training grant applications; the Center for Information Technology (CIT), which coordinates NIH information technology services; and the Clinical Center (CC), NIH’s hospital and outpatient facility for clinical research. Funding is through the NIH Management Fund, which is financed by taps on other NIH appropriations. For further information, see the *NIH Almanac* at <http://www.nih.gov/about/almanac/about.htm>.

¹² U.S. Congress, Senate Committee on Appropriations, *Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriation Bill, 2001*, Report to Accompany S. 2553, 106th Cong., 2nd sess., May 21, 2000, S.Rept. 106-293, p. 179.

¹³ National Research Council and Institute of Medicine, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges* (Washington: National Academies Press, 2003), <http://www.nap.edu/catalog/10779.html>.

¹⁴ *Ibid.*, p. 46.

¹⁵ *Ibid.*

¹⁶ *Ibid.*, p. 7.

Authority

NIH derives its statutory authority from the Public Health Service Act of 1944, as amended (42 U.S.C. §§ 201-300ll-9). Section 301 of the PHS Act (42 U.S.C. § 241) grants the Secretary of HHS broad permanent authority to conduct and sponsor research. In addition, Title IV, “National Research Institutes” (42 U.S.C. §§ 281-290b), authorizes in greater detail various activities, functions, and responsibilities of the NIH Director and the institutes and centers. All of the institutes and centers are covered by specific provisions in the PHS Act. Prior to passage of the NIH Reform Act of 2006 (P.L. 109-482), nine of the ICs and a variety of individual programs had time-and-dollar limits on their authorizations of appropriations. Most of the authorizations had expired, but annual appropriations acts together with § 301 provided authority for the programs. The other institutes and centers and most NIH programs did not require periodic reauthorization by Congress, and there was no overall authorization of appropriations for the agency. The NIH Reform Act authorized total funding levels for NIH appropriations for FY2007 through FY2009, and eliminated all of the other specific authorizations in Title IV. Since 2006, a few specific authorizations have been added to Title IV; overall authorization expired at the end of FY2009.

Table I. Components of the National Institutes of Health (NIH)
(for additional details on the history and major research focus of each component, see **Table 4**)

Component	FY2010 IC Budget	
	Program Level \$ in Millions	Percent of Total NIH Budget
Office of the Director (OD)	\$1,177	3.8%
National Cancer Institute (NCI)	\$5,102	16.5%
National Eye Institute (NEI)	\$707	2.3%
National Heart, Lung, and Blood Institute (NHLBI)	\$3,096	10.0%
National Human Genome Research Institute (NHGRI)	\$516	1.7%
National Institute on Aging (NIA)	\$1,110	3.6%
National Institute on Alcohol Abuse and Alcoholism (NIAAA)	\$462	1.5%
National Institute of Allergy and Infectious Diseases (NIAID)	\$4,517	14.6%
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)	\$539	1.7%
National Institute of Biomedical Imaging and Bioengineering (NIBIB)	\$316	1.0%
National Institute of Child Health and Human Development (NICHD)	\$1,329	4.3%
National Institute on Deafness and Other Communication Disorders (NIDCD)	\$419	1.4%
National Institute of Dental and Craniofacial Research (NIDCR)	\$413	1.3%
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)	\$1,957	6.3%
National Institute on Drug Abuse (NIDA)	\$1,059	3.4%
National Institute of Environmental Health Sciences (NIEHS)	\$769	2.5%
National Institute of General Medical Sciences (NIGMS)	\$2,051	6.6%
National Institute of Mental Health (NIMH)	\$1,490	4.8%

Component	FY2010 IC Budget	
	Program Level \$ in Millions	Percent of Total NIH Budget
National Institute of Neurological Disorders and Stroke (NINDS)	\$1,636	5.3%
National Institute of Nursing Research (NINR)	\$146	0.5%
National Institute on Minority Health and Health Disparities (NIMHD) ^a	\$212	0.7%
National Library of Medicine (NLM)	\$359	1.2%
John E. Fogarty International Center (FIC)	\$70	0.2%
National Center for Complementary and Alternative Medicine (NCCAM)	\$129	0.4%
National Center for Research Resources (NCRR)	\$1,269	4.1%
Center for Information Technology (CIT)	(\$24) ^b	
Center for Scientific Review (CSR)	(\$111) ^b	
Warren G. Magnuson Clinical Center (CC)	(\$397) ^b	
Total, NIH Program Level (includes Buildings and Facilities, \$100m, 0.3% of total)	\$30,947	100%

Source: NIH FY2011 Justification, Tabular Data, p. TD-1, at <http://officeofbudget.od.nih.gov/pdfs/FY11/Tabular%20Data.pdf>, and Supporting Information, SI-8, at <http://officeofbudget.od.nih.gov/pdfs/FY11/Supporting%20information.pdf>. May not add to totals due to rounding.

- a. Redesignated as an Institute by P.L. 111-148; NIH implemented the change in September 2010.
- b. Funded through the NIH Management Fund from taps on IC budgets (non-add).

NIH Research Activities

Two categories of research are sponsored by the institutes and centers: *extramural research*, performed by non-federal scientists using NIH grant or contract money, and *intramural research*, performed by NIH scientists in the NIH laboratories and Clinical Center. In both the extramural and intramural programs, the research projects are largely investigator-initiated, and span all fields of basic and clinical medical and behavioral research. (Basic research is research in the fundamental medical sciences, sometimes called lab or bench research, while clinical research involves patients.) NIH also supports a range of extramural and intramural *research training programs* to prepare young investigators for research careers, and engages in a number of *information dissemination* activities to reach various audiences.

Extramural Research

The extramural research community includes more than 325,000 scientists and research personnel affiliated with over 3,000 universities, academic health centers, hospitals, and independent research institutions.¹⁷ More than 80% of the overall NIH budget is spent on extramural awards in the form of research grants, research and development contracts, training awards, and a few

¹⁷ Department of Health and Human Services, *FY2012 Budget in Brief*, February 14, 2011, p. 36, <http://www.hhs.gov/about/FY2012budget/fy2012bib.pdf>.

smaller categories. The “research grants” category, by far the largest, includes research project grants (RPGs) to individual investigators and small teams, as well as grants to groups of researchers who work in collaborative programs or in multidisciplinary centers that focus on particular diseases or areas of research. About 75% of NIH’s extramural funds go to researchers working in institutions of higher education, particularly the nation’s 131 medical schools.¹⁸ Data on awards and recipients by state, by congressional district, by type of institution, and by subject of the research may be accessed from the NIH website.¹⁹

Peer Review

Scientists who wish to compete for NIH extramural research funding, whether for totally new proposals or for renewal of previous grant awards, submit detailed applications that describe the research they plan to undertake. NIH considers the applications under a two-tiered system of peer review. First, the applications are reviewed for scientific and technical merit by committees called “study sections” composed primarily of nongovernment scientists who are experts in the relevant fields of research. Most applications for research project grants are investigator-initiated; they are assigned for review to study sections administered through the Center for Scientific Review (CSR). Some applications are submitted in response to solicitations by ICs for research areas the ICs wish to target and for which they have set aside funding. These solicitations are known as RFAs (for grants, Requests for Applications) and RFPs (for contracts, Requests for Proposals). RFA and RFP applications are reviewed by study sections within the ICs.

Three times a year, members of study sections convene to read, discuss, and score the most recent batch of submitted research proposals. Each application that appears strong enough upon first reading to have a chance of receiving funding is thoroughly discussed and given a “priority score” that represents the average of the scores assigned by the reviewers. That score becomes the main determinant in whether an applicant will eventually receive funding from an IC for the research proposal. For the most part, applications are funded in the order of their priority score percentile until the IC has committed all of its available resources.

The funding decisions, however, are fine-tuned by a second level of peer review in the ICs, when the applications are considered for program relevance by the National Advisory Councils or Boards of the ICs. Advisory Councils and Boards are composed of scientific and lay representatives. These groups sometimes recommend funding certain applications that fall just outside the normal cutoff if the research is of a type that an IC is particularly interested in promoting. IC staff make the final funding decisions among the top priority proposals.

Awards

The average length of a research project grant award is just under four years; hence, in any given year, about three-fourths of the grantees are in “noncompeting,” or “continuation,” status. Each noncompeting grantee has to submit a project report to the IC that supplied the funding, but the grantee does not have to compete for the second, third, and fourth year of funding—the IC considers the award a budgetary commitment. At the expiration of the award, the grantee may

¹⁸ NIH, Office of Extramural Research, “All extramural awards: Number of awards and organizations funded, by organization type” (Table #111), at http://report.nih.gov/funded_organizations/index.aspx.

¹⁹ See the NIH Research Portfolio Online Reporting Tools (RePORT) at <http://report.nih.gov/index.aspx>.

choose to compete for a renewal of the project. In FY2010, in addition to making almost 9,400 new and competing renewal awards, NIH made more than 25,700 noncompeting awards and almost 1,700 small business awards, for a total of about 36,800 RPGs.²⁰ The average annual cost of an RPG award is about \$426,000 in FY2011, including both direct and indirect costs.²¹ The direct costs, averaging 73% of the total award in FY2010, cover project-specific expenses, while the indirect costs, averaging 27%, pay for facilities and administration costs (i.e., overhead) of the institution where the research is conducted.²²

Intramural Research

The NIH intramural research program (IRP) accounts for approximately 10% of the budget. It includes about 5,300 scientists and technical support staff who are government employees, and another 5,000 young scientists at various stages of research training who come to NIH for a few years to work as non-employee trainees, including about 3,800 postdoctoral fellows.²³ Other IRP personnel include administrative support staff, guest researchers, and contractors.

Almost all of the ICs have an intramural research program, but the size, structure, and activities of the programs vary greatly.²⁴ Many 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. This arrangement facilitates interdisciplinary collaboration and the direct clinical application of new knowledge derived from basic research. Periodic reviews of IC intramural research programs are conducted by each IC's Board of Scientific Counselors, composed of external experts.

Research Training

Research training to prepare students and young scientists for research careers is supported through both the extramural and intramural research programs. Pre-doctoral and postdoctoral training opportunities are available for both basic and clinical scientists through a variety of training grants, fellowships, and loan repayment programs. The largest extramural program is called the Ruth L. Kirschstein National Research Service Awards (NRSA) program, authorized by § 487 of the PHS Act. Programs offered on the NIH campus range from summer internships for high school students to fellowships for postdoctoral scientists.

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 institutes

²⁰ NIH, *FY2012 Justification*, table on "Budget Mechanism—Total," p. OA-23, at <http://officeofbudget.od.nih.gov/pdfs/FY12/Tab%20%20Overall%20Appropriations.pdf>.

²¹ NIH, *FY2012 Justification*, table on "Research Project Grants: Total Number of Awards and Dollars," p. OA-46, at <http://officeofbudget.od.nih.gov/pdfs/FY12/Tab%20%20Overall%20Appropriations.pdf>.

²² NIH, *FY2012 Justification*, table on "Statistical Data—Grants, Direct and Indirect Costs Awarded," p. OA-45, at <http://officeofbudget.od.nih.gov/pdfs/FY12/Tab%20%20Overall%20Appropriations.pdf>.

²³ Personal communication with the NIH Office of Intramural Research, May 11, 2010.

²⁴ ICs that do not have an intramural research component are NIGMS, NCRR, FIC, CC, CIT, and CSR.

and centers 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 and mail inquiries; publishing physician and patient education materials on the Internet and in print; supporting information clearinghouses and running public information campaigns on various diseases; and making specialized databases available.²⁵

Budget

At \$31 billion for FY2010, NIH's budget constitutes more than a third of all HHS discretionary spending.²⁶ It also represents about half of federal spending for non-defense research and development (R&D) and about one-fifth of total federal R&D funding.²⁷ The following discussions, charts, and tables present information on the history of appropriations for NIH, both in current dollars and adjusted for inflation; the funding streams through which NIH receives its support; the process by which agency and Administration leaders formulate budget requests; and the content and status of the FY2012 request and congressional appropriations activity.

Appropriations History (Current Dollars)

Regular Appropriations

The NIH budget grew from about \$4 billion in FY1983 to nearly \$12 billion in FY1996.²⁸ **Figure 1** shows NIH appropriations (current dollars) from FY1994 through the FY2012 request. A relatively flat budgetary period (FY1994 through FY1997) is followed by a period in which Congress doubled the NIH budget in five years, from a base of \$13.65 billion in FY1998 to \$27.1 billion in FY2003. Annual increases in the 14%-15% range were the norm during the five-year doubling period. In contrast, over the seven year post-doubling period of FY2004 to FY2010 increases from regular appropriations have been between 1.0% and 3.2% each year. The one exception was in FY2006 when the total was 0.3% lower than the previous year, the first time that the NIH appropriation had decreased since FY1970. The NIH budget grew by a little over \$3 billion over the seven year post-doubling period, from \$27.9 billion in FY2004 to \$30.3 billion in FY2009 and \$30.9 billion in FY2010, not including ARRA funding. As discussed in more detail below, for FY2012 the President requested a 2.4% increase over FY2010, which would boost the NIH budget by \$745 million to \$32.0 billion.

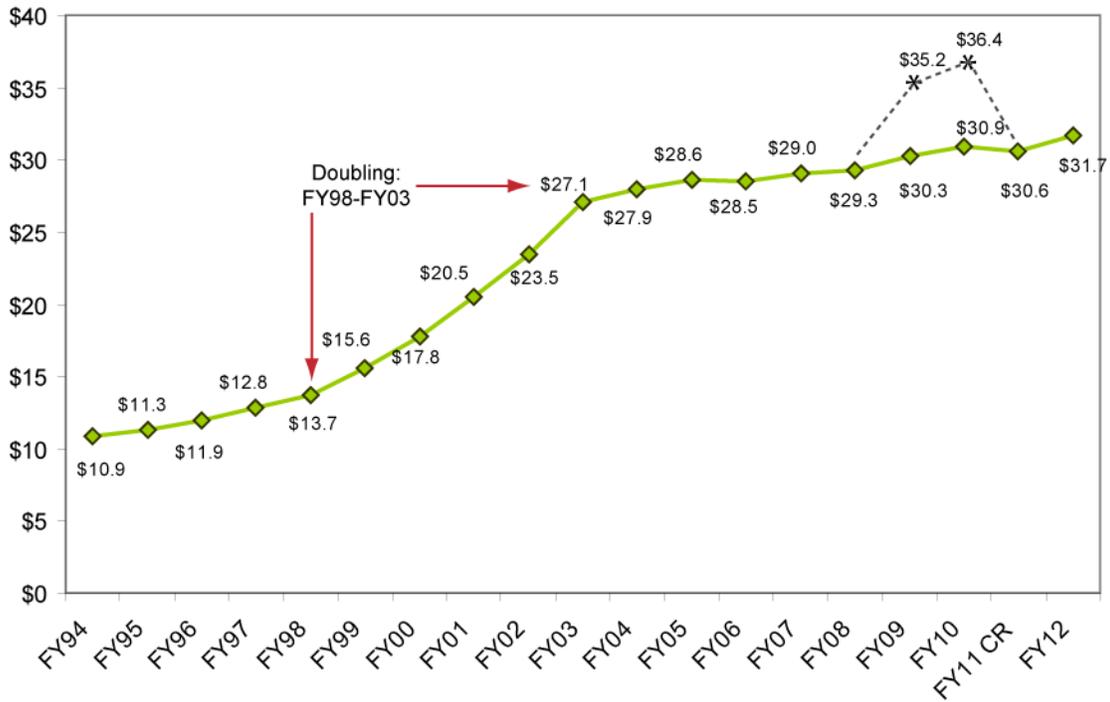
²⁵ Free searching of MEDLINE citations and other NLM databases, together with resources for health questions, is available at <http://medlineplus.gov> and at <http://health.nih.gov>.

²⁶ Department of Health and Human Services, *FY2012 Budget in Brief*, February 14, 2011, p. 11, <http://www.hhs.gov/about/FY2012budget/fy2012bib.pdf>.

²⁷ See CRS Report R41098, *Federal Research and Development Funding: FY2011*, coordinated by John F. Sargent Jr.

²⁸ NIH, Office of Budget, *Appropriations History by Institute/Center (1938 to Present)*, http://officeofbudget.od.nih.gov/approp_hist.html.

Figure I. NIH Funding, FY1994-FY2011 CR and FY2012 Request
 Program Level (\$ in billions)



Source: Figure prepared by the Congressional Research Service (CRS). Dotted lines and asterisks show the addition of ARRA funds in FY2009 and FY2010. FY2011 amount is based on the Continuing Appropriations Act, 2011 (P.L. 111-242) as amended, which provides temporary funding at the FY2010 rate of operations.

Supplemental ARRA Funding

NIH received a total of \$10.4 billion in emergency FY2009 supplemental appropriations in the American Recovery and Reinvestment Act of 2009 (P.L. 111-5).²⁹ ARRA funds were intended to create or save jobs by supporting scientists, providing research equipment, and repairing or constructing research facilities. The law specified that the National Center for Research Resources (NCRR) would receive \$1.3 billion, of which \$1 billion was used for extramural research facility construction, renovation, and \$300 million for shared instrumentation and equipment. P.L. 111-5 also provided \$8.2 billion to OD for scientific research; of this amount, \$7.4 billion was divided among the ICs in proportion to the appropriations made to the ICs in FY2009. OD also received \$400 million for comparative effectiveness research. Lastly, NIH buildings and facilities received \$500 million to fund high-priority repair, construction and improvement projects for the NIH campus in Maryland and other locations. ARRA funds were made available for obligation for two years; \$4.954 billion was obligated in FY2009, and \$5.446 billion in FY2010.³⁰

²⁹ For further details, see CRS Report R40181, *Selected Health Funding in the American Recovery and Reinvestment Act of 2009*, coordinated by C. Stephen Redhead.

³⁰ NIH, *FY2011 Justification*, table on “Budget Mechanism—Total,” p. TD-3, at <http://officeofbudget.od.nih.gov/pdfs/FY11/Tabular%20Data.pdf>.

About 40% of FY2009 ARRA funding was used to supplement existing projects and about 60% was used to support new science.³¹ The new science projects funded in FY2009 included previously reviewed, highly meritorious research proposals that could be accomplished in two years, as well as a number of types of projects submitted in response to ARRA-specific funding opportunity announcements. FY2010 ARRA funding was used for continuation of FY2009 grantees and for new awards in certain ARRA programs such as extramural construction grants. The project period for some types of ARRA grants spans more than two years, so obligated funds will continue to be paid out to some grantees over the next several years.

Appropriations History (Constant Dollars)

Figure 2 portrays the NIH appropriation adjusted for inflation (in constant 2011 dollars) using the Biomedical Research and Development Price Index (BRDPI).³² The index, developed each year for NIH by the Bureau of Economic Analysis of the Department of Commerce, reflects the increase in prices of the resources needed to conduct biomedical research, including personnel services, supplies, and equipment. It indicates how much the NIH budget must change to maintain purchasing power. Annual growth rates of the regular appropriations for FY2004 to FY2010 have been at or below the biomedical research inflation rates for their respective years. While growth rates were 3.2% or lower each year, changes in the BRDPI ranged between 2.8% and 4.7%.³³

In constant 2011 dollars, the NIH regular appropriations peaked at \$36.1 billion in FY2003, then decreased steadily. The constant-dollar funding levels for FY2008 (\$31.9 billion), FY2009 (\$32.0 billion), and FY2010 (\$31.8 billion) were lower than the FY2002 level of \$32.4 billion. Funding provided to NIH by ARRA as a supplement to regular appropriations increased the total budgets for FY2009 and FY2010 above the FY2003 level, as shown in **Figure 2**. The FY2012 NIH budget request was again below the FY2002 funding level in inflation-adjusted dollars. The projected changes in the BRDPI are 2.9% for FY2011 and 3.0% for FY2012. In inflation-adjusted terms, both the FY2010 appropriation and the FY2012 request represented estimated decreases of about 12% and 15% below FY2003. Still, the NIH budget is a considerable portion—more than one third—of all HHS discretionary spending, and is much larger than the budgets of other PHS agencies such as FDA (\$2.4 billion), CDC (\$6.5 billion), HRSA (\$7.5 billion), Indian Health Service (\$4.1 billion) and SAMHSA (\$3.4 billion).³⁴

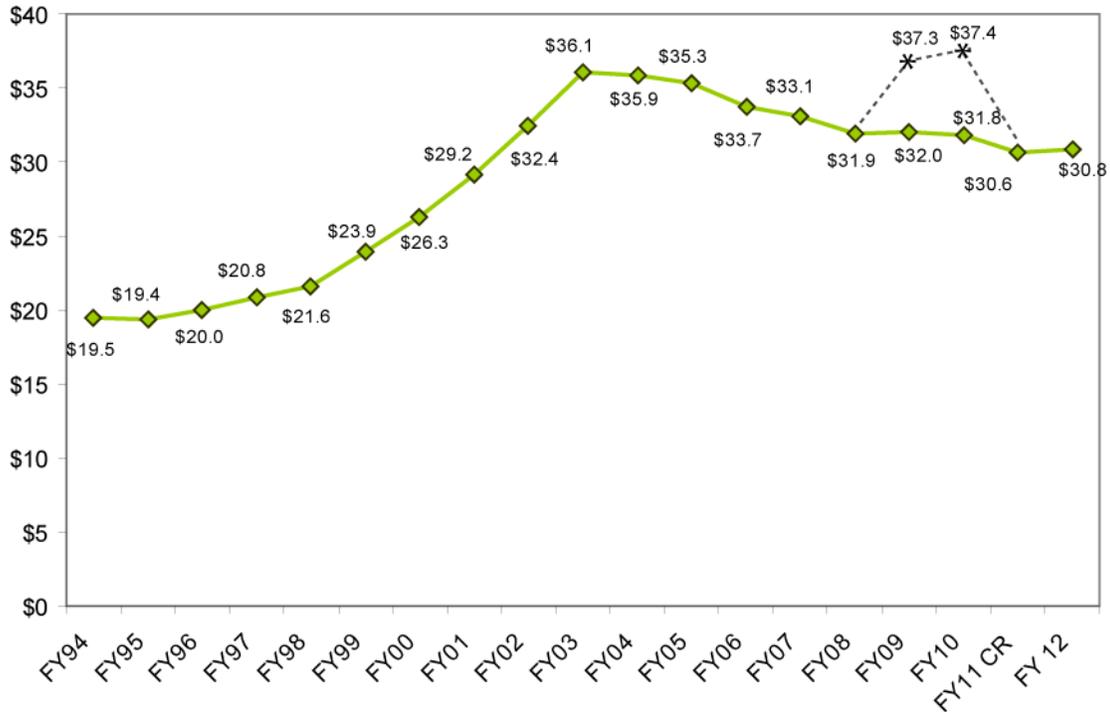
³¹ NIH ARRA FY2009 Funding, at http://report.nih.gov/UploadDocs/Final_NIH_ARRA_FY2009_Funding.pdf

³² See NIH Price Indexes, at <http://officeofbudget.od.nih.gov/gbiPriceIndexes.html>.

³³ NIH, Biomedical Research and Development Price Index (BRDPI): Fiscal Year 2010 Update and Projections for FY 2011-FY 2016, January 24, 2011, http://officeofbudget.od.nih.gov/pdfs/FY12/BRDPI_Proj_Jan_2011_Final.pdf.

³⁴ U.S. Department of Health and Human Services, *Fiscal Year 2012 Budget in Brief*, February 14, 2011, p. 11, <http://www.hhs.gov/about/FY2012budget/fy2012bib.pdf>.

Figure 2. NIH Funding in Constant Dollars, FY1994-FY2011 ICR and FY2012 Request
 Purchasing Power in 2011 Dollars Using Biomedical R&D Price Index (BRDPI), Program Level
 (\$ in billions)



Source: Figure prepared by CRS. Dotted lines and asterisks show the addition of ARRA funds in FY2009 and FY2010. FY2011 amount is based on the Continuing Appropriations Act, 2011 (P.L. 111-242) as amended, which provides temporary funding at the FY2010 rate of operations.

Sources of Funding

Table 2 shows the standard display of the NIH budget by institute and center and identifies the four main funding sources. The bulk of the budget is provided through the annual Labor-HHS-Education (Labor-HHS) appropriations act, which funds the agency through 26 separate accounts. An additional small amount for environmental research and training related to Superfund comes from the Interior, Environment, and Related Agencies (Interior-Environment) appropriations act. Those two sources constitute NIH’s discretionary budget authority. The “program level” budget takes into account other funds that are added to or transferred from NIH. NIH receives extra funding (currently \$150 million a year) for the Type 1 Diabetes Initiative; the funds are pre-appropriated in separate legislation, most recently by P.L. 110-275 and P.L. 111-309. Since FY2003, NIH has received an extra \$8.2 million each year for the National Library of Medicine from a “program evaluation” transfer within PHS (see below). Conversely, part of the NIH annual appropriation is transferred to the Global Fund to Fight HIV/AIDS, Tuberculosis, and Malaria.³⁵

³⁵ In FY2002-FY2007, about \$100 million of the annual appropriation to NIAID was transferred to the Global Fund (the FY2004 amount was \$149 million). For FY2008, the amount was increased to \$300 million in the request, and the final amount of the transfer from the NIH/NIAID appropriation was \$295 million. For FY2009 and FY2010, \$300 million of the NIH/NIAID appropriation was transferred to the Global Fund.

The Administration’s FY2012 budget again proposes a transfer of \$300 million to the Global Fund.³⁶

NIH and three of the other Public Health Service agencies within HHS are subject to a budget “tap” called the PHS Program Evaluation Set-Aside, authorized by section 241 of the PHS Act (42 U.S.C. § 238j). It is used to fund not only program evaluation activities, but also functions that are seen as having benefits across the Public Health Service, such as the National Center for Health Statistics in CDC and the entire budget of the Agency for Healthcare Research and Quality. These and other uses of the evaluation tap by the appropriators have the effect of redistributing appropriated funds among PHS agencies. Section 205 of the FY2010 Labor/HHS appropriations act capped the set-aside at 2.5%, replacing the 2.4% maximum that had been in place for several years. The FY2012 budget proposes increasing the set-aside to 3.2% of eligible appropriations. NIH, with the largest budget among the PHS agencies, becomes the largest “donor” of program evaluation funds, and is a relatively minor recipient. By convention, budget tables such as **Table 2** do not subtract the amount of the evaluation tap, or of other taps within HHS, from the agencies’ appropriations.³⁷

Table 2. National Institutes of Health (NIH) Funding
(dollars in millions)

Component	FY 2010 Actual ^a	FY 2011 CR ^b	FY 2012 Request	FY2012 +/- FY2010
Cancer (NCI)	5,101	5,099	5,196	95.3
Heart/Lung/Blood (NHLBI)	3,095	3,094	3,148	52.7
Dental/Craniofacial Research (NIDCR)	413	413	420	7.4
Diabetes/Digestive/Kidney (NIDDK)	1,807	1,807	1,838	30.9
Neurological Disorders/Stroke (NINDS)	1,635	1,635	1,664	28.8
Allergy/Infectious Diseases (NIAID) ^c	4,816	4,510	4,916	99.9
General Medical Sciences (NIGMS)	2,051	2,050	2,102	51.7
Child Health/Human Development (NICHD)	1,329	1,328	1,352	23.4
Eye (NEI)	707	706	719	12.4
Environmental Health Sciences (NIEHS)	689	689	701	11.1
Aging (NIA)	1,110	1,109	1,130	20.4
Arthritis/Musculoskeletal/Skin (NIAMS)	539	539	548	9.1
Deafness/Communication Disorders (NIDCD)	419	418	426	7.5
Mental Health (NIMH)	1,490	1,489	1,517	27.5
Drug Abuse (NIDA)	1,059	1,059	1,080	20.8

³⁶ The “NIH program level” cited in agency and OMB budget documents, however, does not reflect the Global Fund transfer.

³⁷ For further information on the Program Evaluation tap, see CRS Report RL34098, *Public Health Service (PHS) Agencies: Background and Funding*, coordinated by Pamela W. Smith.

Component	FY 2010 Actual ^a	FY 2011 CR ^b	FY 2012 Request	FY2012 +/- FY2010
Alcohol Abuse/Alcoholism (NIAAA)	462	462	469	7.1
Nursing Research (NINR)	146	146	148	2.5
Human Genome Research (NHGRI)	516	516	525	9.0
Biomedical Imaging/Bioengineering (NIBIB)	316	316	322	5.7
Minority Health/Health Disparities (NIMHD) ^d	211	211	215	3.1
Research Resources (NCRR)	1,268	1,268	1,298	29.6
Complementary/Alternative Medicine (NCCAM)	129	129	131	2.2
Fogarty International Center (FIC)	70	70	71	1.3
National Library of Medicine (NLM)	351	366	387	36.1
Office of Director (OD)	1,177	1,176	1,298	121.6
Common Fund (non-add)	544	544	557	12.9
Buildings & Facilities (B&F)	100	100	126	25.6
Subtotal, Labor/HHS Appropriation	31,005	30,706	31,748	742.7
Superfund (Interior approp to NIEHS) ^e	79	79	81	1.9
Total, NIH discretionary budget authority	31,084	30,785	31,829	744.6
Pre-appropriated Type I diabetes funds ^f	150	150	150	0
PHS Evaluation Tap fundings	8	8	8	0
Total, NIH program level	31,243	30,943	31,987	744.6
Total, NIH program level (less Global Fund)	30,943	30,643	31,687	744.6

Source: Adapted by CRS from NIH, *Justification of Estimates for Appropriations Committees, Fiscal Year 2012*, ST-2, at <http://officeofbudget.od.nih.gov/pdfs/FY12/Tab%203%20-%20Supplementary%20Tables.pdf>. Details may not add to totals due to rounding.

- a. FY2010 Comparable reflects real transfer of \$1 million from HHS/OS to NIMH as well as comparable adjustments for transfers of funds from ICs to NLM.
- b. FY2011 amount is based on the Continuing Appropriations Act, 2011 (P.L. 111-242) as amended, which provides temporary funding at the FY2010 rate of operations.
- c. Includes funds for transfer to the Global Fund for HIV/AIDS, Tuberculosis, and Malaria (\$300 million in each of FY2010, FY2011, and FY2012). Bioshield transfer of \$304 million was not provided in FY2011.
- d. A provision of the health reform legislation (P.L. 111-148) redesignated the Center as an Institute.
- e. Separate account in the Interior-Environment appropriations for NIEHS research activities related to Superfund.
- f. Funds available to NIDDK for diabetes research under PHS Act § 330B (provided by P.L. 110-275 and P.L. 111-309). Funds have been appropriated through FY2013.
- g. Additional funds for NLM from PHS Evaluation Set-Aside (§ 241 of PHS Act).

Background on Agency Budget Formulation

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

As a continuing process, IC leaders, with input from the scientific community, define the most important and promising areas in their respective fields. They consider whether the research portfolio they are already supporting needs any rebalancing, and they decide on possible new initiatives for the coming budget year. An annual budget retreat in May brings together the IC leaders with top NIH management to discuss policies and priorities under various budget scenarios. They might consider, for example, what the different emphases in their programs would be if the appropriation turned out to be a certain percent decrease, a flat budget, or an increase. The presentations and discussions allow NIH management to develop the budget request they will submit to HHS, taking into account the estimate of the amount of funding needed to support the “commitment base” of continuing awards, the funding desired for unsolicited new research proposals, the new initiatives that the Director wants to incorporate, and guidance from the department about the request (for example, there might be an instruction to pay no inflation increases on grants). At the HHS level, NIH’s request is considered in the context of the overall department budget, resulting in a notice back to NIH on the department’s allowance. There are usually appeals and adjustments made before the final HHS budget goes to OMB. The process of submission, passback, and appeals is repeated as OMB considers the entire federal budget and tells HHS what amounts and policy approaches are approved for incorporation into the President’s final budget that will be sent to Congress. Once the budget is made public in early February, all agency comments about the request are expected to support the President’s proposed levels.

FY2011 Administration Request and Congressional Action

For FY2011, the President requested budget authority of \$32.007 billion in the L-HHS-ED appropriation and \$82 million in the Interior/Environment appropriation, which would provide \$32.089 billion in discretionary budget authority for NIH. The addition of \$150 million in diabetes funds and \$8.2 million from the PHS Evaluation Tap would bring the NIH program level to \$32.247 billion, and \$31.947 billion after subtraction of \$300 million for the Global Fund transfer. The FY2010 program level, provided by the Consolidated Appropriations Act, 2010 (P.L. 111-117), totaled \$30.947 billion (after subtracting \$300 million for the Global Fund). The FY2011 program level request represents an increase of \$1 billion (3.2%) above the FY2010 program level.³⁸

³⁸ For further information on the FY2011 appropriation, see the NIH section of CRS Report R41098, *Federal Research and Development Funding: FY2011*, coordinated by John F. Sargent Jr..

The House Labor-HHS-Education Appropriations Subcommittee held a markup session in July 2010 but the full committee did not report a bill. The Senate Committee on Appropriations reported S. 3686 (S.Rept. 111-243) in August 2010 but the bill did not receive any further action. The Continuing Appropriations Act, 2011 (P.L. 111-242) as amended, provides temporary FY2011 funding through March 18, 2011, at the FY2010 rate of operations.

H.R. 1 (Rogers), the Full Year Continuing Appropriations Act, 2011, would provide funding for NIH for the remainder of the fiscal year. From the FY2010 level, the bill would reduce NIH overall by \$639.5 million, the Common Fund by \$48.5 million, non-competing research grants by \$260 million, and NIH buildings and Facilities by \$77.3 million. The bill would eliminate the transfer of \$304 million from the Project Bioshield Special Reserve Fund to NIH and would eliminate \$300 million in funding for the Global AIDS Transfer. An amendment to H.R. 1, H.Amdt. 99 (Hastings), reallocates \$14 million from the FY2011 administrative budget of NIH to the HRSA Ryan White AIDS Drug Assistance Program; the amendment was adopted by voice vote.³⁹

H.R. 1 also specifies that the average total cost of a new (competing) research grant must not be more than \$400,000 and that at least a total of 9,000 such grants are to be awarded in FY2011. The current average total cost of a new (competing) research grant is about \$426,000; NIH was planning on awarding about 8,700 such grants in FY2011.⁴⁰

FY2012 Administration Request

For FY2012, the President requested budget authority of \$31.748 billion in the L-HHS-ED appropriation and \$81 million in the Interior/Environment appropriation, which would provide \$31.829 billion in discretionary budget authority for NIH. The addition of \$150 million in diabetes funds and \$8.2 million from the PHS Evaluation Tap would bring the NIH program level to \$31.987 billion, and \$31.687 billion after subtraction of \$300 million for the Global Fund transfer.

The FY2012 request of almost \$32 billion for NIH is a 2.4% increase (\$745 million) over FY2010. The agency will focus on implementing a new translational medicine program in FY2012 as well as emphasize three other broad scientific areas including advanced technologies, comparative effectiveness research, and support for young investigators.

For the new program, NIH is proposing to establish a new center, the National Center for Advancing Translational Sciences (NCATS) to catalyze the development of new diagnostics and

³⁹ The House-passed H.R. 1 would appropriate a total of \$29.366 billion for NIH, which would be \$1.643 billion less than the FY2010 enacted level of \$31.009 billion. However, in FY2010 (and several previous years), \$300 million of the NIH appropriation was transferred out of HHS to the US Agency for International Development to support the Global Fund for HIV/AIDS, Malaria, and TB. H.R. 1 would eliminate both the \$300 million appropriation to NIH and the requirement for the transfer to the Global Fund. Therefore, in terms of NIH's own resources, the FY2010 level was \$30.709 billion compared to the proposed level of \$29.366 billion in H.R. 1 (a cut of \$1.343 billion). These amounts refer to NIH appropriations that are part of the Labor-HHS-Education appropriations. They do not take into account additional funds totaling about \$236 million that NIH receives from other sources, including the Special Diabetes Program (\$150 million each year), some Superfund appropriations (\$79 million in FY2010 and \$78 million in H.R. 1), and the Public Health Service Evaluation Tap (\$8 million each year).

⁴⁰ NIH, *Justification of Estimates for Appropriations Committees, FY2012, Vol. I, Overview*, table on "Research Project Grants: Total Number of Awards and Dollars," p. OA-46.

therapeutics.⁴¹ To do so, NIH proposes to abolish the existing National Center for Research Resources (NCRR) and transfer its Clinical and Translational Science Awards (CTSA) program to NCATS.⁴² The FY2012 request proposes \$485 million for CTSA, a program which funds a national consortium of medical research institutions that work together to accelerate treatment development, engage communities in clinical research efforts and train clinical and translational researchers. Another component of NCATS will be the Therapeutics for Rare and Neglected Diseases (TRND) program; the request would double support for TRND in FY2012 to \$50 million. TRND is currently funded on an NIH-wide basis.

NCATS may also incorporate the new Cures Acceleration Network (CAN), which was authorized but not funded, in the new health reform law (P.L. 111-148).⁴³ The purpose of CAN is to support the development of high need cures and facilitate their FDA review. P.L. 111-148 authorized \$500 million for FY2010 and such sums as may be necessary for subsequent fiscal years for CAN. The law also specified that other funds appropriated under the Public Health Service Act may not be allocated to CAN. The NIH request proposes \$100 million for CAN in FY2012. If CAN receives funding, NIH would determine which medical products are “high need cures,” and then make awards to research entities or companies in order to accelerate the development of such high need cures.

In addition to the new program, NIH will emphasize three scientific areas in FY2012.

1. Technologies to Accelerate Discovery. NIH will support further development and application of advanced technologies (such as DNA sequencing, microarray technology, nanotechnology, new imaging modalities, and computational biology) to further the understanding of complex diseases, such as cancer and Alzheimer’s disease, in order to develop more effective therapies.
2. Enhancing the Evidence Base for Health Care Decisions. NIH plans to use comparative effectiveness research methodologies to assist in developing individually-tailored treatments (personalized medicine) by testing candidate therapies in a group of Health Maintenance Organizations (HMOs) caring for more than 13 million patients.
3. New Investigators, New Ideas. NIH will emphasize two of its programs that support young scientists. The NIH Director’s New Innovator Award program provides first-time independent awards to outstanding investigators; the Administration requests \$80 million to support these awards in FY2012. The second program, announced in October 2010, called the Early Independence Program, will support talented junior scientists, allowing them to by-pass the traditional postdoctoral training period and move directly to an independent research career. NIH requests \$8.4 million for this program in FY2012.

The NIH Common Fund, funded through the OD, supports emerging areas of scientific opportunity, public health challenges or knowledge gaps that deserve special emphasis and might

⁴¹ See the section entitled “Scientific Management Review Board (SMRB) and the National Center for Advancing Translational Sciences (NCATS)” in this report.

⁴² NIH, *Justification of Estimates for Appropriations Committees, FY2012, Vol. I, Overview*, p. ES-12.

⁴³ See the section entitled “Cures Acceleration Network” in this report.

benefit from collaboration between two or more institutes or centers.⁴⁴ For FY2012, the President requests \$556.9 million for the Common Fund, up \$12.9 million from FY2010.

FY2012 Budget Discussion by Funding Mechanism

In addition to showing the appropriation by institute, the other common way to describe the NIH budget is by “funding mechanism,” meaning grants, contracts, training, research centers, etc., as shown in **Figure 3** and **Table 3**. Displaying budget data by mechanism reveals the balance between extramural and intramural funding, as well as the relative emphasis on support of individual investigator-initiated research versus funding of larger projects.

The NIH’s two major concerns in light of current funding trends are maintaining support of investigator-initiated research through research project grants, and continuing to sustain the pipeline of new investigators. Total FY2012 funding for RPGs, at \$16.9 billion, a 2.6% increase, represents about 53% of NIH’s budget. The FY2012 request would support an estimated 36,852 awards, 43 more grants than in FY2010. Within that total, 9,158 would be competing RPGs, 228 fewer than in FY2010. For noncompeting (continuation) RPGs, the FY2012 budget provides an inflation-adjustment increase of 1%.⁴⁵ The average annual cost of a competing RPG for FY2012 is about \$433,000.⁴⁶ The expected “success rate” of applications receiving funding would be 19% for FY2012 compared with 21% for FY2010; the success rate was 30% at the end of the doubling period in FY2003.⁴⁷ Estimated success rates for the various ICs in FY2012 would range from 4% to 35%.⁴⁸

⁴⁴ See the section entitled “The NIH Common Fund” in this report.

⁴⁵ NIH, *Justification of Estimates for Appropriations Committees, FY2012, Vol. I, Overview*, p. ES-18.

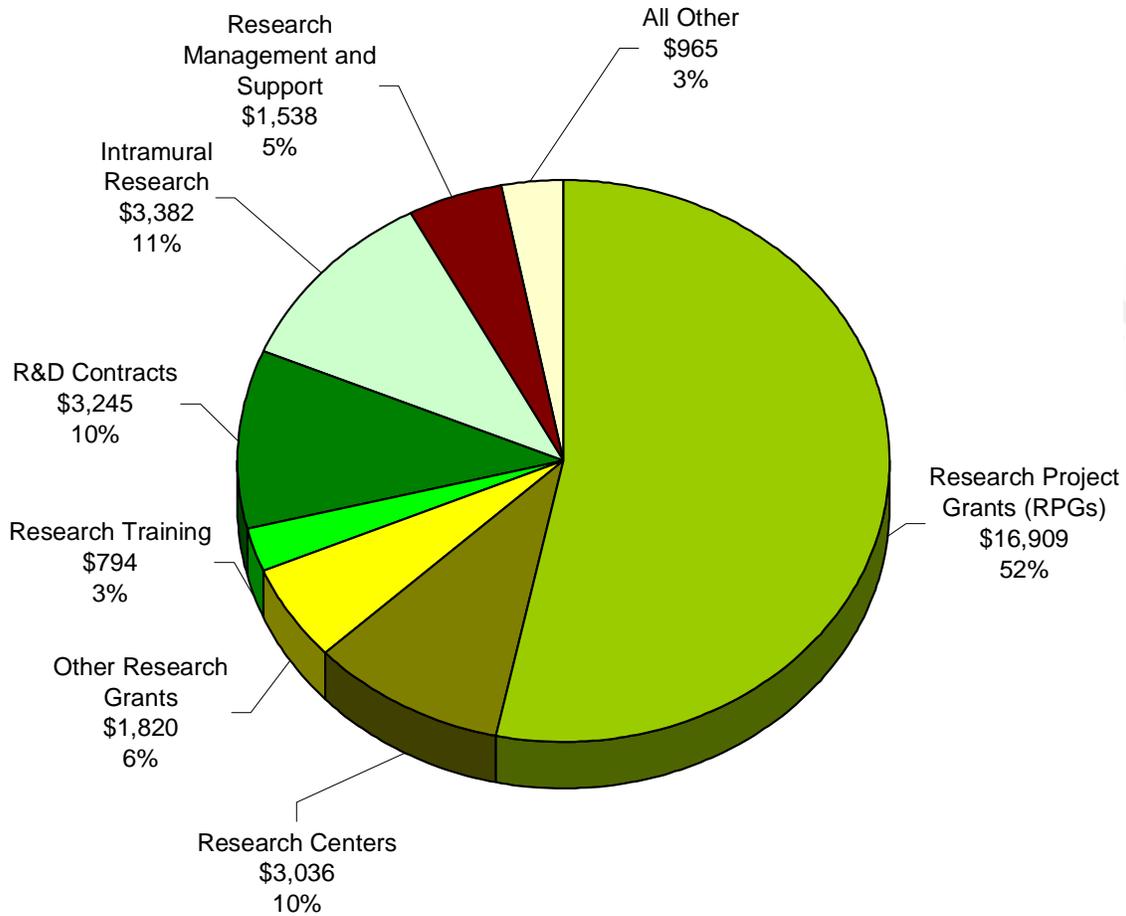
⁴⁶ NIH, *Justification of Estimates for Appropriations Committees, FY2012, Vol. I, Overview*, table on “Research Project Grants: Total Number of Awards and Funding,” p. OA-46, at <http://officeofbudget.od.nih.gov/pdfs/FY12/Tab%202%20Overall%20Appropriations.pdf>.

⁴⁷ NIH provides statistics on the “success rate” of research project grant (RPG) applications—the number of competing RPG applications funded *divided by* the number of applications reviewed. NIH, *Justification of Estimates for Appropriations Committees, FY2012, Vol. I, Overview*, table on “Research Project Grants: Success Rates, FY2003-FY2012,” p. OA-47, at <http://officeofbudget.od.nih.gov/pdfs/FY12/Tab%202%20Overall%20Appropriations.pdf>.

⁴⁸ *Ibid.*

Figure 3. FY2012 NIH Budget Request by Funding Mechanism

Total NIH Program Level = \$31,687 Million
(\$ in millions)



Source: Adapted from NIH FY2012 Budget Justification, p. ES-26. NIH Program Level excludes \$300 million from the R&D Contracts mechanism for the Global HIV/AIDS Fund transfer, and includes \$8 million in the All Other category for NLM Program Evaluation funds. See **Table 2** and **Table 3**.

Table 3. NIH Budget by Funding Mechanism
(dollars in millions)

Mechanism	FY2010 actual	FY2011 CR	FY2012 Request	change 2012/2010
Research Project Grants (RPGs)	\$16,473	\$16,390	\$16,909	2.6%
Research Centers	\$3,078	\$3,008	\$3,036	-1.3%
Other Research Grants	\$1,794	\$1,813	\$1,820	1.4%
Research Training	\$775	\$782	\$794	2.5%
R&D Contracts ^a	\$3,156	\$2,958	\$3,245	2.8%
Intramural Research	\$3,331	\$3,343	\$3,382	1.5%
Res. Management & Support	\$1,508	\$1,523	\$1,538	2.0%
Extramural Construction	\$0	\$0	\$0	0%
Office of the Director ^b	\$633	\$632	\$742	17.2%
Buildings and Facilities ^c	\$108	\$108	\$134	23.7%
Other ^d	\$87	\$87	\$89	2.3%
Total, NIH Program Level	\$30,943	\$30,643	\$31,687	2.4%
# new/competing renewal RPGs	9,386	8,734	9,158	-228 grants
# noncompeting RPGs	25,738	25,936	26,019	+281 grants
# small business grants	1,685	1,658	1,675	-10 grants
Total # of RPGs	36,809	36,328	36,852	+43 grants

Source: Adapted from NIH FY2012 Budget Justification, p. ES-26. Details may not add to totals due to rounding.

- a. Program level excludes funds from the R&D Contracts mechanism to be transferred to the Global HIV/AIDS Fund (FY2010-FY2012 regular appropriation: \$300 million each year). See **Table 2**.
- b. Excludes Roadmap/Common Fund and Director’s Bridge Awards, which are distributed by mechanism.
- c. Includes B&F appropriation plus \$8 million for NCI intramural construction in each regular appropriation.
- d. “Other” includes Interior appropriation for Superfund research and NLM Program Evaluation.

The FY2012 request includes an increase of 4% for training stipends for individuals supported by the Ruth L. Kirschstein National Research Service Awards program.⁴⁹ The budget request would raise funding for the program by \$19 million to \$794 million, a 2.5% increase, which would allow NIH to support 16,831 full-time training positions, 330 fewer than in FY2010.⁵⁰

Changes proposed in the request for other funding mechanisms within the NIH budget include a decrease in support for research centers, down \$41 million (-1.3%) to \$3,036 million; an increase of \$25 million (1.4%) for other research grants totaling \$1,820 million; an \$89 million (2.8 %) increase to \$3,245 million for R&D contracts (excluding the funding to be transferred for the

⁴⁹ NIH, *Justification of Estimates for Appropriations Committees, FY2012, Vol. I, Overview*, p. ES-18.

⁵⁰ NIH, *Justification of Estimates for Appropriations Committees, FY2012, Vol. I, Overview*, p. ES-26.

Global HIV/AIDS Fund); \$50 million more (1.5%) for the NIH intramural research program, for a total of \$3,382 million; an increase of \$30 million (2.0%) to a total of \$1,538 million for research management and support; and an increase of \$109 million (17.2%) for the Office of the Director, for a total of \$742 million. Buildings and Facilities would increase by almost \$26 million (23.7%) to \$134 million.

Issues for Congress

Congress has been supportive of NIH over the past several decades, in part due to a high level of constituent interest—voicing their expectation that the federal government would take the lead in cutting-edge research on prevention and treatment of disease. Since the mid-1990s, the doubling of the NIH budget and big projects like the sequencing of the human genome have allowed for the conduct of research in new areas and provided the opportunity for further advances. More recently, however, tight budgets and various issues facing the research enterprise have resulted in exploring new approaches to the agency's traditional mission. Congress has increasingly scrutinized how NIH has used its expanded resources, how it can most efficiently adapt to budgetary constraints, and how its 27 semi-autonomous institutes and centers can best coordinate their efforts in order to identify and respond to important public health challenges.

Setting NIH Research Priorities

Congressional involvement in NIH research priorities

Appropriators have traditionally avoided specifying dollar amounts for particular fields of research or mechanisms of funding aside from the level of the Institute and Center accounts. For example, the House and Senate reports that accompanied the FY2010 Labor-HHS appropriations bill stated the following on the Obama Administration's proposal to set specific funding levels for research:

The Committee is concerned by the harmful precedent established in the Administration's budget of setting specific funding levels for particular diseases. The Committee believes it is more appropriate to allocate funding in a way that permits scientific peer review to decide the most promising research to support. The serendipitous nature of science is documented each year, with breakthroughs in one disease area emanating from a finding in a completely unrelated field.⁵¹

The Committee rejects the administration's proposals to earmark an increase of \$268,000,000 for research on cancer and an increase of \$19,000,000 for research on autism. The devastating effects of cancer and autism are well known, and additional federally supported research in these areas is certainly warranted. However, the President's plan would set a dangerous precedent. The Committee has long subscribed to the view that funding levels for individual diseases should be determined without political interference. If Congress were to earmark funds for cancer and autism, advocates for a multitude of other health problems would justifiably demand similar treatment. In the long run, no one's

⁵¹ U.S. Congress, House Committee on Appropriations, *Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 2010*, report to accompany H.R. 3293, 111th Cong., 1st sess., July 22, 2009, H.Rept. 111-220 (Washington: GPO, 2009), p. 106.

interest would be served if Members of Congress with no professional expertise in medical research were asked to make funding decisions about hundreds of diseases and health conditions. The Committee also notes that the proposed increases for cancer and autism research total \$287,000,000 of the \$441,764,000 overall proposed increase for NIH. It is hard to justify to those whose lives have been touched by heart disease, diabetes, COPD, Alzheimer's disease and stroke, to name a few other high-morbidity diseases, that research in just two areas deserves almost two-thirds of all the new funding in fiscal year 2010.⁵²

However, appropriators often use report language directing NIH to focus research on particular diseases as a way of responding to constituent interests. For example, both House and Senate reports that accompanied the FY2010 Labor-HHS appropriations bill “encouraged NCI to study GI cancers in people age 40 and under, giving emphasis particularly to late-stage cancers for whom curative treatment options are unavailable. In addition, the Committee requests NCI to consider developing an interconnected gastrointestinal cancer biorepository with consistent, interoperable systems for collection, storage, annotation, and information sharing.”⁵³

Research Restrictions

From time to time, the research community has been unsettled by congressional attempts to cancel funding for specific existing peer-reviewed grants.⁵⁴ The targeted studies have tended to be in fields of behavioral research, including some in mental health and human sexuality research. Sponsors and supporters of such amendments to the L-HHS-ED appropriations bills say that NIH should not be devoting scarce resources to research studies whose value they question. Researchers, however, including NIH leadership, have expressed alarm at what they view as an assault on the peer review system, saying that such studies were funded because of their technical merit and the important research questions they addressed.⁵⁵ Perhaps the most prominent example is controls on federal funding of research on human embryonic stem cells. Although President Barack Obama signed an executive order in March 2009 that reversed the nearly eight-year-old George W. Bush Administration restriction on federal funding for human embryonic stem cell research, funding for some aspects of such research is still limited by a provision in the annual Labor-HHS appropriations act—the so-called Dickey amendment.⁵⁶

⁵² U.S. Congress, Senate Committee on Appropriations, *Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Bill, 2010*, report to accompany H.R. 3293, 111th Cong., 1st sess., August 4, 2009, S.Rept. 111-66 (Washington: GPO, 2009), p. 87.

⁵³ U.S. Congress, House Committee on Appropriations, *Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 2010*, report to accompany H.R. 3293, 111th Cong., 1st sess., July 22, 2009, H.Rept. 111-220 (Washington: GPO, 2009), p. 108; and, U.S. Congress, Senate Committee on Appropriations, *Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Bill, 2010*, report to accompany H.R. 3293, 111th Cong., 1st sess., August 4, 2009, S.Rept. 111-66 (Washington: GPO, 2009), p. 88.

⁵⁴ Jocelyn Kaiser, “House ‘Peer Review’ Kills Two NIH Grants,” *Science*, vol. 309 (July 1, 2005), pp. 29-31.

⁵⁵ *Ibid.*

⁵⁶ For further information, see CRS Report RL33540, *Stem Cell Research: Science, Federal Research Funding, and Regulatory Oversight*, by Judith A. Johnson and Erin D. Williams, and CRS Report RL33554, *Stem Cell Research: Ethical and Legal Issues*, by Erin D. Williams, Edward C. Liu, and Judith A. Johnson.

Cures Acceleration Network

Health reform legislation enacted in March 2010 (P.L. 111-148, the Patient Protection and Affordable Care Act, PPACA) amends the PHS Act requiring the NIH Director to implement the Cures Acceleration Network (CAN). The purpose of CAN is to support revolutionary advances in basic research and facilitate FDA review of CAN-funded cures. However, although PPACA authorizes \$500 million for CAN in FY2010 and such sums as necessary for subsequent fiscal years, CAN would be funded via a specific appropriation and cannot be funded using the general NIH appropriation.

If CAN receives an appropriation, the NIH Director would determine which medical products (drugs, devices, biological products, or combination products) are “high need cures,” based upon (1) their ability to diagnose, prevent, or treat harm from a disease or condition; and (2) the lack of market incentives for their adequate or timely development. NIH will then make awards to public or private research entities, medical centers, biotechnology or pharmaceutical companies, and patient advocacy groups in order to accelerate the development of such high need cures.⁵⁷ A CAN Review Board will advise the Director on the activities of CAN and on significant barriers to the translation of basic science into clinical applications. The CAN Review Board will submit reports to HHS regarding any barrier identified. The Director is required to respond to such recommendations in writing. Although advocacy groups, such as the Parkinson’s Action Network and the Council for American Medical Innovation, have voiced strong support for the creation of CAN, others have concerns about providing federal funds to industry without sufficient accountability to ensure that the taxpayer receives a return on the investment.⁵⁸

NIH Process in Setting Research Priorities

NIH weighs numerous factors when it makes research priority-setting decisions. In addition to advice from Congress and the Administration, NIH seeks input from the scientific community, NIH staff, patient organizations, voluntary health associations, the Advisory Councils for each NIH Institute and Center, and the Advisory Committee to the NIH Director.⁵⁹ Two relatively new entities, the NIH Director’s Council on Public Representatives and the Scientific Management Review Board, also provide NIH with advice and guidance.⁶⁰ Judgments about public health needs are most important; this may reflect, for example, information on the health and/or economic burdens posed by particular diseases, the populations affected, and the degree of threat

⁵⁷ The Cures Acceleration Partnership Awards provide up to \$15 million for the first year with a matching requirement; eligible entities must provide non-federal matching funds of \$1 for every \$3 funded by CAN. The Cures Acceleration Grant Awards are similar but have no matching requirement. The Cures Acceleration Flexible Research Awards would be available if the Director determined that the goals of CAN could not be met otherwise, and would consist of awards not to exceed 20% of the total funds appropriated for CAN.

⁵⁸ Alyah Khan, “Proposal to Expedite Product Development Makes Senate Health Bill,” *Inside Health Policy—Inside Health Reform*, January 6, 2010.

⁵⁹ The 2003 NAS report, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges* recommended that the NIH advisory councils become more involved in priority setting and planning.

⁶⁰ The NIH Director’s Council of Public Representatives (COPR) was established in 1998 following the release of the Institute of Medicine report, “Scientific Opportunities and Public Needs,” which urged the establishment of COPR “to facilitate interactions between NIH and the general public.” The Scientific Management Review Board was authorized by the NIH Reform Act of 2006 (P.L. 109-482) which provides certain organizational authorities to HHS and NIH officials regarding the NIH institutes and centers and the Office of the Director. The Scientific Management Review Board advises HHS and NIH officials on the use of these organizational authorities.

to the general public. Another factor may be the potential applicability of research on one medical condition to broader, related fields. The process of formulating the NIH budget provides a framework within which research priorities are identified, reviewed, and justified. Each NIH Institute determines how to allocate its funds among the many different research areas within its broadly defined mission.

The 2003 NAS report, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*, recommended that Congress strengthen the role of the NIH Director in strategic planning and budgeting for innovative, trans-NIH research. 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 trans-disciplinary, cross-institute research initiatives. The law also created a special office, the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) for large, complex research efforts that involve multiple Institutes. DPCPSI "identifies important areas of emerging scientific opportunity or rising public health challenges to assist in the acceleration of research investments in these areas."⁶¹ The Office of Strategic Coordination within DPCPSI manages the NIH Common Fund.

The NIH Common Fund

The NIH Common Fund supports large complex research efforts that involve the collaboration of two or more research institutes or centers, such as the Roadmap for Medical Research.⁶² Roadmap programs are expected to be supported by the Common Fund for 5-10 years, after which the research should transition to IC support.⁶³ Besides the Roadmap for Medical Research, NIH has organized other interdisciplinary, trans-institute initiatives, including the Strategic Plan for NIH Obesity Research started in FY2005⁶⁴ and the NIH Blueprint for Neuroscience Research begun in FY2006.⁶⁵ The Office of Strategic Coordination within DPCPSI works with staff and leadership across NIH to identify and promote NIH-wide scientific opportunities that receive Common Fund support.⁶⁶ To date, these have largely been Roadmap programs, but the Common Fund website notes, "As the Common Fund grows, and research opportunities and needs emerge in the scientific community, the portfolio of programs supported by the Common Fund will likely

⁶¹ See <http://www.nih.gov/about/researchplanning.htm>.

⁶² In September 2003, the former NIH Director, Dr. Elias A. Zerhouni, announced a series of initiatives known collectively as the NIH Roadmap for Medical Research. The Roadmap identified the most compelling scientific challenges and the most important knowledge gaps ("roadblocks") constraining progress in research and its application to prevention, diagnostic, and treatment strategies. NIH, Office of the Director, "NIH Announces Strategy to Accelerate Medical Research Progress," press release, September 30, 2003 <http://www.nih.gov/news/pr/sep2003/od-30.htm>. See also <http://nihroadmap.nih.gov/aboutroadmap.asp>.

⁶³ Initially, the budgets of the ICs were tapped for some of the contributions to the Common Fund, but since FY2007, all of the funding has been appropriated to OD. Funding for the Common Fund has increased from \$132 million in FY2004 to \$544 million in FY2010. For FY2009 and FY2010, the Common Fund also had supplemental funds provided by ARRA; about half of the \$137 million ARRA total was obligated in each of the two years. The FY2011 request proposes \$562 million for the Common Fund. NIH, *Justification of Estimates for Appropriations Committees, FY2011, Vol. I, Overview*, "NIH Common Fund/Roadmap," p. 4, at <http://officeofbudget.od.nih.gov/pdfs/FY11/Common%20Fund%20FY%202011%20CJ.pdf>.

⁶⁴ See <http://www.obesityresearch.nih.gov/about/strategic-plan.htm>.

⁶⁵ The Neuroscience Blueprint pools resources among 16 ICs with an interest in the nervous system for use in cooperative research, including development of research tools and infrastructure that serve the entire neuroscience community. See <http://neuroscienceblueprint.nih.gov/>.

⁶⁶ See <http://dpcpsi.nih.gov/osc/>.

evolve to encompass a diverse set of trans-NIH programs, although the NIH Roadmap is likely to remain a central component.”⁶⁷

Changes to the NIH Peer Review System

As mentioned earlier in this report, all investigator-initiated applications for NIH funding are peer reviewed by study sections, groups composed of scientists from outside NIH. The study section evaluates the scientific and technical merit in the research application and these evaluations are used by the NIH Institutes to determine which projects receive funding.⁶⁸

In June 2007 NIH began a year-long examination of the peer review process with the goal of funding “the best science, by the best scientists, with the least administrative burden.”⁶⁹ Two working groups, one internal and one external, sought input from the scientific community and received thousands of comments; a final plan was announced in June 2008 with an 18-month implementation period.

Changes to the peer review system included limiting the length of the research application (from 25 pages to 12 pages for many types of grants), a new 9-point grant scoring system, and a new format for reviewer critiques of each grant proposal. Under the old policy, applicants who were not approved for funding were allowed to revise (based on reviewer comments) and resubmit their proposals twice; under the new policy only one resubmission is allowed. NIH also announced a new policy of clustering the review of grant proposals from new scientists to help “level the playing field, allowing new investigators to achieve success rates comparable to those of established scientists.”⁷⁰ In order to better accommodate the schedules of reviewers, NIH is using high-bandwidth support for some review meetings as an alternative to in-person meetings.⁷¹

These peer review changes were implemented just prior to the huge increase in applications received in response to ARRA-specific funding opportunities—NIH received more than 20,000 applications in response to the Challenge Grant announcement and more than 2,000 applications for the Grand Opportunities (GO) grants.⁷² The large number of ARRA grant applications forced NIH to recruit an unprecedented number of scientific reviewers. Typically NIH reviews about 16,000 applications in each of its three rounds of review with the assistance of about 8,000 reviewers. The addition of ARRA required a total of 28,000 reviewers to evaluate 40,000

⁶⁷ See “About the NIH Common Fund” at <http://commonfund.nih.gov/about.asp>.

⁶⁸ NIH has developed a tracking system that reports spending on over 200 research, condition, and disease categories. Information on funding totals and on individual grants making up the categories is available to the public on the NIH website. See the table on “Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)” at <http://www.report.nih.gov/rcdc/categories>.

⁶⁹ National Institutes of Health, “NIH Director Announces Enhancements to Peer Review,” press release, June 6, 2008, <http://www.nih.gov/news/health/jun2008/od-06.htm>.

⁷⁰ National Institutes of Health, “New NIH Policy Establishes Goals to Support Scientists Early in Their Careers,” press release, October 31, 2008, <http://www.nih.gov/news/health/oct2008/od-31.htm>.

⁷¹ See http://enhancing-peer-review.nih.gov/engage_the_bestreviewers.html. For further information about changes to the NIH peer review process, see <http://enhancing-peer-review.nih.gov/index.html>.

⁷² Challenge Grants are projects with budgets under \$500,000 per year in 15 broad areas of priority research. GO grants are large-scale, high-impact research projects with budgets over \$500,000 per year. Activities supported with NIH ARRA funds are tracked on the NIH Recovery website, <http://www.nih.gov/recovery/>. NIH implementation plans for the various funding categories are on the HHS Recovery Plans website, <http://www.hhs.gov/recovery/reports/plans/index.html>.

applications in half the usual amount of time, a difficult undertaking for the agency.⁷³ In 2009 NIH also created the “College of CSR Reviewers” to assist in the review of special sets of grant applications, such as occurred with ARRA.⁷⁴ The College consists of a pool of reviewers with broad expertise who are used primarily in the first stage of a two-stage review of complex research applications.⁷⁵

Balancing New and Existing Budget Commitments

Spending caps in congressional budget resolutions have left the Labor-HHS-ED appropriations subcommittees with difficult choices when allocating funds for a range of social and public health programs. The NIH budget shifted from annual increases of around 6% to 7% before FY1999, to twice that (around 14% to 15%) during the doubling period, to levels below the rate of inflation (between 0% and 3%) since FY2003, with a brief respite in FY2009 and FY2010 due to ARRA funds.

The FY1998 to FY2003 appropriations resulted in an increase in the number of new grants funded and the average dollar size of grants as well as an overall expansion of research facility construction. NIH appropriations since FY2003 have consistently grown less than the rate of inflation and have strained certain areas of the biomedical research enterprise, particularly investigator-initiated research. Similarly, the appropriations boost provided by ARRA for FY2009 and FY2010 will be largely gone in FY2011, creating another funding “cliff” on charts of dollars available and numbers of research projects supported.⁷⁶

Coping with the reality of budget constraints may require NIH and the research community to rethink the traditional approach to the way biomedical research is funded in the United States. For example, one observer notes that because of funding constraints and the accompanying lower success at obtaining grant funds, “biomedical researchers are spending far too much effort writing grant applications and reviewing those of others, leaving precious little time to do what they should be doing: reading the scientific literature and thinking deeply about their research and teaching.”⁷⁷ He goes on to say that this situation is due to “reliance on the NIH to pay not only the salaries of scientists but also the overhead (or indirect costs) of building and construction and maintenance. ... [This] “perverse incentive encourages U.S. universities, medical centers, and other research institutions to expand their research capacities indefinitely through funds derived from NIH research grants.”⁷⁸ One possible solution may be “for NIH to require that at least half of the salary of each principal investigator be paid by his or her institution, phasing in this requirement gradually over the next decade.”⁷⁹

⁷³ NIH Center for Scientific Review, “Challenge Grant Applications Challenge CSR,” press release, May 12, 2009, <http://cms.csr.nih.gov/nr/rdonlyres/e92a2d01-87f7-4fc8-bac1-7517ac116169/20856/challenge1.pdf>.

⁷⁴ NIH Center for Scientific Review, “College of CSR Reviewers’ to More Readily Match Reviewers and Applications,” press release, December 22, 2009, <http://cms.csr.nih.gov/nr/rdonlyres/28c73298-6090-4272-a4c3-099432058f7e/22199/reviewcollege.pdf>.

⁷⁵ For more information, see the FAQ and list of members in the College of CSR Reviewers on the NIH CSR webpage at <http://cms.csr.nih.gov/reviewerresources/collegecsrreviewers>.

⁷⁶ Jocelyn Kaiser, “Peering Over a Cliff at the Poststimulus World,” *Science*, vol. 328 (May 7, 2010), p. 676.

⁷⁷ Bruce Alberts, “Overbuilding Research Capacity,” *Science*, vol. 329 (September 10, 2010).

⁷⁸ *Ibid.*

⁷⁹ *Ibid.*

NIH Director Francis Collins alluded to this problem in a January 2010 interview, stating that universities are “becoming too reliant on NIH money, allowing faculty members to obtain all their income from federal research grants.”⁸⁰ Dr. Collins indicated that when faculty members run multiple research projects at the same time, “that turns that investigator into a grant-writing machine perhaps more than a doing-of-science machine.” However, he said, any new restrictions on NIH grants “would have to be phased in over a fairly long period of time because many universities and faculty members would find that quite disruptive.”⁸¹

NIH Initiatives to Assist Young Investigators

NIH is concerned that prospects for a lower number of grants and a lower success rate will further discourage young scientists from pursuing careers in medical research. New investigators with creative ideas are the lifeblood of the research enterprise, but the path to becoming an independent researcher is long and challenging. Many young doctoral students and postdoctoral scientists already observe that their more senior colleagues have had increasing trouble in getting funded. Especially if they are physicians with the option of going into clinical practice, they may wonder about the wisdom of devoting themselves to years of research training that may not lead to successful competition for independent grant support. Some may decide on other career paths, and some may choose to pursue research opportunities overseas.

Over the years, NIH has created a series of initiatives to assist new researchers in obtaining independent funding.⁸² Despite these efforts, the average age at which a new investigator first obtains an independent grant increased from 34 years in 1970 to 42 years in 2004.⁸³ In addition, the success rate for new investigators ranged between 40% and nearly 60% in the 1960s and fell to 23% in 2008.⁸⁴ On the other hand, some might argue that special efforts to retain new investigators in academia is unnecessary, that the problem may be driven by the doubling of the NIH budget, and that the correct number of new investigators is unknown.

Recent efforts undertaken by NIH to assist young investigators include introduction of the Pathway to Independence in 2006, the NIH Director’s New Innovator Award in 2007, and Early Stage Investigators in 2009. The Pathway to Independence program supports promising postdoctoral scientists through five-year awards that have a two-year mentored phase and a three-year independent phase.⁸⁵ NIH anticipates supporting 150 to 200 awards each year.

The NIH Director’s New Innovator Award aims to support highly innovative research that has been proposed by promising new investigators.⁸⁶ The program supports a small group of unusually creative new investigators with innovative research ideas at a stage in their career when they may not necessarily have the preliminary data required to fare well in the traditional NIH peer review system. NIH supported 30 New Innovator Awards in 2007, 31 in 2008, and 54 in

⁸⁰ Paul Basken, “NIH Will Give Less and Demand More in 2010, New Leader Says,” *The Chronicle of Higher Education*, January 17, 2010.

⁸¹ *Ibid.*

⁸² See “History of Commitment to New Investigators” at http://grants.nih.gov/grants/new_investigators/resources.htm#history.

⁸³ See http://grants.nih.gov/grants/new_investigators/Average_age_initial_R01.xls.

⁸⁴ See http://grants.nih.gov/grants/new_investigators/estimated_success_rates_1962-2008.xls.

⁸⁵ See http://grants.nih.gov/grants/new_investigators/#indaward for information on this award.

⁸⁶ See http://grants.nih.gov/grants/new_investigators/#award.

2009. NIH expects to make 33 such awards in 2011 “depending on the quality of the applications and the availability of funds.”⁸⁷

One of the changes made to the peer review system was a new policy of clustering the review of research applications submitted by Early Stage Investigators “with the expectation that they will be evaluated more effectively when judged against applications from scientists at the same stage of their careers.”⁸⁸ Early Stage Investigators are defined as “a New Investigator who has completed his or her terminal research degree or medical residency—whichever date is later—within the past 10 years and has not yet been awarded a substantial, competing NIH research grant.”⁸⁹

Organizational Complexity

Those who have examined ways to improve NIH operations have frequently considered the agency’s organizational structure, which has expanded markedly over time along with the growth in the budget. The institutes and centers, currently numbering 27, have always operated as a decentralized federation, coordinated by the Office of the Director. The costs and complexities of administering the enterprise have multiplied as new entities have been created by Congress (seven of them between 1985 and 2000; see **Table 4**), each with its own mission, budget, staff, review office, and other organizational apparatus.

Many observers have asked whether NIH had become too fragmented and if the agency was able to respond appropriately to new scientific and public health challenges. Some suggested consolidating the ICs into a smaller number of units encompassing broad areas of science.⁹⁰ Others warned that such a move could prove politically unfeasible, because of constituent loyalty to individual ICs, and might result in a net loss of congressional and public support.⁹¹ Further, although NIH wished to emphasize a culture of inter-disciplinary teamwork, many observers felt that the structure of multiple independently operated institutes might undermine important initiatives in cross-disciplinary research, especially in fields such as the neurosciences. In 2000, Congress requested that the National Academy of Sciences (NAS) study the structure and organization of NIH. Many of the recommendations in the 2003 NAS report, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*, were incorporated into the NIH Reform Act of 2006.

NIH Reform Act of 2006, P.L. 109-482

As discussed early in this report, statutory authority for NIH is found primarily in Title IV of the Public Health Service Act (42 U.S.C. § 281-290b). Since the PHS Act was first compiled in 1944, Congress has amended Title IV by adding numerous sections delineating specific responsibilities, activities, and functions of NIH. Before the 109th Congress, systematic change to those authorities

⁸⁷ See <http://commonfund.nih.gov/newinnovator/faq.aspx>.

⁸⁸ National Institutes of Health, “New NIH Policy Establishes Goals to Support Scientists Early in Their Careers,” press release, October 31, 2008, <http://www.nih.gov/news/health/oct2008/od-31.htm>.

⁸⁹ See http://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.htm.

⁹⁰ Harold Varmus, “Proliferation of National Institutes of Health,” *Science*, vol. 291 (March 9, 2001), pp. 1903-1905.

⁹¹ National Research Council, Institute of Medicine, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*, Washington, DC, 2003, p. p. 20.

had been undertaken only twice, in the Health Research Extension Act of 1985 (P.L. 99-158) and in the NIH Revitalization Act of 1993 (P.L. 103-43). Most of the specific authorities established or extended in the 1993 act expired in FY1996, and had not been updated. The programs continued under NIH's general authority to conduct and sponsor research. A number of additional laws enacted between 1993 and 2004 had addressed particular areas of research; most of those authorities had also expired.⁹² Congress has never initiated a major restructuring of NIH organization, aside from the addition of institutes, centers, and offices.

The recommendations of the 2003 NAS report, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*, reawakened congressional interest in using the reauthorization process to improve NIH management and operations. In 2006, after many hearings and solicitation of comments from various stakeholders in the medical research community, Congress passed the NIH Reform Act (H.R. 6164, P.L. 109-482).⁹³ The law made managerial and organizational changes in NIH. A major focus was enhancing the authority of the NIH Director's Office to perform strategic planning, especially facilitating and funding trans-disciplinary, cross-institute research initiatives. It contained no provisions relating to specific diseases or fields of research, and did not eliminate or consolidate any existing ICs.

The NIH Reform Act established the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the Office of the Director and moved a number of individual program offices in OD to DPCPSI (such offices coordinate research on AIDS, women's health, behavioral and social sciences, and disease prevention). While not superseding the planning and priority-setting responsibilities of the individual institutes and centers, the measure charged the Director with overall program coordination of the entire research portfolio of NIH.

The 2003 NAS report had recommended that NIH improve its data systems for tracking and reporting spending by areas of research. The Reform Act required the creation of a comprehensive electronic reporting system to catalogue research activities from all of the ICs in a standardized format. Information from the tracking system assists the Director and DPCPSI in planning trans-NIH research initiatives that cannot be handled within individual ICs. The new reporting system, called Research Portfolio Online Reporting Tools (RePORT), "provides access to reports, data, and analyses of NIH research activities, including information on NIH expenditures and the results of NIH-supported research."⁹⁴

⁹² Examples of such laws are the Women's Health Research and Prevention Amendments of 1998 (P.L. 105-340), Children's Health Act of 2000 (P.L. 106-310), Public Health Improvement Act of 2000 (P.L. 106-505), National Institute of Biomedical Imaging and Bioengineering Establishment Act of 2000 (P.L. 106-580), MD-CARE Act (Muscular Dystrophy Community Assistance, Research and Education Amendments of 2001, P.L. 107-84), and Rare Diseases Act of 2002 (P.L. 107-280), among others. The *NIH Almanac* includes a comprehensive chronology of NIH-related legislation (see <http://www.nih.gov/about/almanac/historical/index.htm>). The annual report by the Congressional Budget Office on *Unauthorized Appropriations and Expiring Authorizations* may be consulted for a chronological listing of public laws, arranged by authorizing committee, whose provisions have expired (see <http://www.cbo.gov/publications/bysubject.cfm?cat=6>).

⁹³ U.S. Congress, House Committee on Energy and Commerce, *Legislation to Reauthorize the National Institutes of Health*, hearing, 109th Cong., 1st sess., July 19, 2005, serial no. 109-40 (Washington: GPO, 2005), and U.S. Congress, House Committee on Energy and Commerce, *Improving NIH Management and Operation: A Legislative Hearing on the NIH Reform Act of 2006*, 109th Cong., 2nd sess., September 19, 2006.

⁹⁴ The home page for RePORT is at <http://report.nih.gov/index.aspx>. It includes links to a number of compiled tables, charts, and data sets, as well as sites for performing tailored searches on funded awards and other topics of interest. See <http://projectreporter.nih.gov/reporter.cfm> for grant searches and <http://report.nih.gov/rcdc/categories/> for "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)."

The Reform Act provided for funding of trans-NIH initiatives by enacting the Common Fund into law and requiring strategic planning for the Fund. The law established the Council of Councils to advise the NIH Director on the policies and activities of DPCPSI and to participate in developing proposals for trans-NIH research. The Council is composed of representatives from the IC advisory councils, OD offices, and the Council of Public Representatives. Proposals from investigators who are first-time applicants are to be given “appropriate consideration,” and NIH’s traditional emphasis on peer-reviewed, investigator-initiated research is to be maintained. The Council has held several meetings since it was organized in March 2008.⁹⁵

The Reform Act authorized total funding levels for NIH, although not for the individual ICs, for FY2007-FY2009. This was the first time the PHS Act had specified a ceiling for overall NIH funding. From an assumed FY2006 baseline of \$28.33 billion, authorized funding was increased by \$2 billion (7%) to \$30.33 billion for FY2007, \$2.5 billion (8.2%) to \$32.83 billion for FY2008, and was authorized for such sums as needed for FY2009. Within those amounts, appropriations were authorized for the Office of the Director at such sums as needed for FY2007-FY2009. The law eliminated a number of statutory authorizations of appropriations for specific programs (including those for several institutes), but did not change NIH’s authority to run the programs.

The law requires a biennial report from the Director to Congress assessing the state of biomedical research and reporting in detail on the research activities of NIH, including strategic planning and initiatives, and summaries of research in a number of broad areas.⁹⁶ 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). Two demonstration programs were authorized, one to award grants that “bridge the sciences” between the biological, behavioral, and social sciences and the physical, chemical, mathematical, and computational sciences, and the other to fund high-risk, high-reward research.⁹⁷

Scientific Management Review Board (SMRB) and the National Center for Advancing Translational Sciences (NCATS)

The NIH Reform Act provided certain authorities to HHS and NIH officials for making organizational changes to ICs and OD, and created the Scientific Management Review Board (SMRB) to advise the officials on the use of those organizational authorities.⁹⁸ SMRB is charged with formally and publicly reviewing NIH organizational structure at least once every seven years. SMRB may recommend restructuring but the number of ICs is capped at the current 27. The law set out time frames for the Director to take action on such recommendations, and provided for review by Congress.

⁹⁵ See links to Council materials at <http://dpcpsi.nih.gov/council/>.

⁹⁶ The first *Biennial Report of the Director, NIH*, covering FY2006-FY2007, was released in January 2008. See <http://report.nih.gov/biennialreport/>.

⁹⁷ A more detailed summary of the provisions of the NIH Reform Act may be found on the website of the NIH Office of Legislative Policy and Analysis (OLPA), at <http://olpa.od.nih.gov/legislation/109/publiclaws/reformact06.asp>. Dozens of bills and resolutions related to NIH, to disease research, or to other areas of public health were introduced in the 111th Congress, and a few had further action. See the OLPA website for its Bill Tracking pages and other links to congressional activity, at <http://olpa.od.nih.gov/tracking/>.

⁹⁸ See <http://smrb.od.nih.gov/index.asp>.

SMRB had its first meeting in April 2009 and several subsequent meetings have focused on the NIH reorganization issues. In November 2010, SMRB released a report recommending the merger of the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism.⁹⁹ This merger was recommended in the 2003 NAS report. A task force will produce a detailed reorganization plan for consideration by the NIH Director in the summer of 2011.

In December 2010, SMRB released a report recommending the creation of a new center focused on translation medicine and therapeutics, the National Center for Advancing Translational Sciences (NCATS).¹⁰⁰ On January 14, 2011, HHS Secretary Kathleen Sebelius sent a letter to Congress providing details of the plan for the new Center; the reorganization is scheduled to take effect on October 1, 2011.¹⁰¹ Congress has 180 days to comment on or take action on the proposal. NCATS would consist of programs focused on clinical research and drug discovery at NCRR, the NIH Common Fund, and the National Human Genome Research Institute.¹⁰² According to NIH, NCATS “would not compete with therapeutic development in the private sector, and would focus research efforts in areas that attract little commercial interest.”¹⁰³

Under the proposal for the new center, NCRR would be eliminated—its Clinical and Translational Science Awards (CTSA) programs would move to NCATS and the remaining NCRR program would move to other institutes.¹⁰⁴ In addition, the Therapeutics for Rare and Neglected Diseases (TRND) program would also become part of NCATS. The proposed reorganization is controversial, generating “more than 1200 comments on the NIH feedback site.”¹⁰⁵ The total budget for NCATS is estimated at \$632 million based on current funding for all transferred programs.¹⁰⁶ Another component of NCATS may be CAN, if Congress provides an appropriation for the new program.¹⁰⁷ Full funding for CAN would bring the NCATS budget to \$1.1 billion.

Public Access to Results of NIH-Sponsored Research

In May 2005, NIH implemented the “Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research” to allow taxpayers easy access to journal articles resulting from NIH support.¹⁰⁸ However, because submission of articles was voluntarily,

⁹⁹ National Institutes of Health, Scientific Management Review Board, *Report on Substance Use, Abuse, and Addiction Research at NIH*, November 2010, <http://smrb.od.nih.gov/announcements/SUAA-Report-Final-Nov15.pdf>.

¹⁰⁰ NIH Scientific Management Review Board, *Report on Translational Medicine and Therapeutics*, December 2010, http://smrb.od.nih.gov/announcements/TMAT_Report_FINAL.pdf

¹⁰¹ Gardiner Harris, “Federal Research Center Will Help Develop Medicines,” *The New York Times*, January 22, 2011.

¹⁰² NIH, Separating Fact & Fiction: News about the proposed National Center for Advancing Translational Sciences, http://feedback.nih.gov/index.php/ncats/fact_fiction/

¹⁰³ NIH, FAQ: Proposed National Center for Advancing Translational Sciences, <http://feedback.nih.gov/index.php/faq-ncats/>

¹⁰⁴ *Ibid.*

¹⁰⁵ Jocelyn Kaiser, “Collins Sparks Furor with Proposed NIH Reshuffling,” *Science*, January 28, 2011, p. 386.

¹⁰⁶ *Ibid.*

¹⁰⁷ NIH, Information on the Proposed National Center for Advancing Translational Sciences, <http://feedback.nih.gov/index.php/ncats/intro-read-more/>

¹⁰⁸ “Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research,” *NIH Guide for Grants and Contracts*, February 3, 2005, available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html>. See also <http://publicaccess.nih.gov>.

compliance with the policy was very low. In December 2007, the FY2008 appropriation made the policy mandatory. NIH released a revised policy statement in January 2008, with an effective date of April 7, 2008:

In accordance with Division G, Title II, Section 218 of P.L. 110-161 (Consolidated Appropriations Act, 2008), the NIH voluntary Public Access Policy (NOT-OD-05-022) is now mandatory. The law states: “The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine’s PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, that the NIH shall implement the public access policy in a manner consistent with copyright law.”¹⁰⁹

In the first year after the new mandatory submission policy was implemented, the number of articles submitted each month through PubMed Central (PMC) increased markedly. The count of original articles that were approved by their authors for processing by PMC rose from 1,852 in March 2008, before the policy was implemented, to 6,425 in March 2009.¹¹⁰ That same month, Congress made the policy permanent when it enacted the FY2009 Labor-HHS-ED appropriations act (Division F of P.L. 111-8, Omnibus Appropriations Act, 2009). In June 2010, the PMC archive received its two-millionth article.¹¹¹

Other organizations that support research also have demanded that resulting publications be publicly accessible, including the Howard Hughes Medical Institute in 2007 and the Wellcome Trust, the largest supporter of medical research in the United Kingdom, in 2006.¹¹² The Italian National Institute of Health, the European Research Council, and many others have implemented similar mandates, including all seven UK research councils.¹¹³ Other European funding sources—in France, Germany and elsewhere—have voiced support for enhanced public access.¹¹⁴ Disease advocacy groups, such as Autism Speaks, and universities, such as the Massachusetts Institute of Technology and the Faculty of Arts and Sciences at Harvard University, have also stated support for open access policies.¹¹⁵

At a September 2008 House Judiciary Committee hearing on the Fair Copyright in Research Works Act, some witnesses stated that the public access policy diminishes publishers’ rights to control dissemination of content in which they hold copyright and to which they have added value through peer review and final editing of articles.¹¹⁶ Witnesses projected that academic

¹⁰⁹ NIH, Office of Extramural Research, “Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research,” Notice number NOT-OD-08-033, January 11, 2008, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html>. For more information on the NIH policy, see <http://publicaccess.nih.gov/FAQ.htm>.

¹¹⁰ Meredith Wadman, “Open-Access Policy Flourishes at NIH,” *Nature*, April 9, 2009, pp. 690-691.

¹¹¹ See “New in PMC” at http://www.ncbi.nlm.nih.gov/pmc/about/new_in_pmc.html.

¹¹² Harold Varmus, “Science Publishing and Science Libraries in the Internet Age,” *Proceedings of the American Philosophical Society*, vol. 153, no. 2 (June 2009), pp. 160-184.

¹¹³ Meredith Wadman, “Open-Access Policy Flourishes at NIH,” *Nature*, April 9, 2009, p. 690.

¹¹⁴ Harold Varmus, “Science Publishing and Science Libraries in the Internet Age,” *Proceedings of the American Philosophical Society*, vol. 153, no. 2 (June 2009), p 181.

¹¹⁵ Meredith Wadman, “Open-Access Policy Flourishes at NIH,” *Nature*, April 9, 2009, p. 690.

¹¹⁶ U.S. Congress, House Committee on the Judiciary, Subcommittee on Courts, the Internet, and Intellectual Property, *Fair Copyright in Research Works Act*, Hearing on H.R. 6845, 110th Cong., 2nd sess., September 11, 2008, H.Hrg. 110-204 (Washington: GPO, 2009), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=\(continued...\)](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=(continued...))

libraries may cancel many journal subscriptions in favor of obtaining free access to articles, thereby reducing publishers' revenue. Others cited surveys indicating that there would not be significant loss of subscriptions. Some raised issues about potential conflicts with other countries' policies on protection of intellectual property. A bill introduced in the 111th Congress, H.R. 801 (Conyers), would have rolled back the NIH open access requirement. An oversight hearing on the topic of "Public Access to Federally-Funded Research" was held July 29, 2010, by the House Committee on Oversight and Government Reform, Subcommittee on Information Policy, Census and National Archives.

Financial Conflicts of Interest

There were few ties between academic researchers and industry prior to the 1980 passage of P.L. 96-517 (Amendments to the Patent and Trademark Act). The purpose of the law, often called the Bayh-Dole Act, is to promote the commercialization of new technologies through cooperative ventures between the research community, small business, and industry.¹¹⁷ Bayh-Dole encouraged universities to patent and commercialize the discoveries made by faculty who conducted research with federal funds. The law also led to the creation of technology transfer offices at universities and catalyzed the formation of many start-up companies and consulting relationships between faculty and industry. Although Bayh-Dole is viewed as being successful in meeting its objectives, some have voiced concern that the law may provide an increased opportunity for conflict of interest and redirection of research due to the possible influence of industry money on research results. In response to these concerns, NIH has made policy changes for scientists conducting intramural research and is currently considering changes for extramural scientists.

NIH Conflict of Interest Policy for Intramural Research

In late 2003, investigations by the *Los Angeles Times* indicated that some NIH scientists were earning outside income (including stock options in some cases) from consulting arrangements with drug and biotech companies.¹¹⁸ Earlier that year, questions had been raised about some top NIH scientists receiving honoraria for giving lectures at institutions that received NIH funding. Many of these arrangements were technically allowed under ethics rules that were in place at the time. More studies and hearings on ethics policies, and investigations of individual cases, both by NIH and by Congress, ensued during 2004 and 2005.¹¹⁹ Several dozen NIH scientists who had not complied with reporting requirements were disciplined.

In February 2005, to supplement existing ethics regulations, HHS published a new rule focusing on outside activities, financial holdings, and awards for all NIH employees, not just for scientists.¹²⁰ Published as an interim final rule with a request for comments, the regulation strictly

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110_house_hearings&docid=f:44326.pdf.

¹¹⁷ CRS Report RL32076, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*, by Wendy H. Schacht

¹¹⁸ David Willman wrote a series of articles for the *Times* over a number of months. The first was "Stealth Merger: Drug Companies and Government Medical Research," *Los Angeles Times*, December 7, 2003, p. A1.

¹¹⁹ Many pertinent documents can be found on NIH's "Conflict of Interest Information and Resources" web page http://www.nih.gov/about/ethics_COI.htm.

¹²⁰ U.S. Department of Health and Human Services, "Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements for Employees of the Department of Health and Human Services," 70 *Federal Register* 5543- (continued...)

limited interactions with pharmaceutical and biotechnology companies, grantee research institutions, and other entities, as well as investments in such companies for many NIH staff and their families. The rule was meant to create a substantially expanded system of oversight of employee activities to preserve the trust of the public in NIH. It was recognized, however, that the rule could have adverse impacts on recruitment and retention of employees, and that revisions of the rules might be desirable, especially for staff whose jobs did not involve decisions over research policies.

The final revised regulation, published in August 2005, covered reporting of certain financial interests, stock divestiture, outside activities, and awards.¹²¹ According to an NIH press release:

Three principles guided the crafting of the rules: (1) The public must be assured that research decisions made at NIH are based on scientific evidence and not by inappropriate influences; (2) Senior management and people who play an important role in research decisions must meet a higher standard of disclosure and divestiture than people who are not decision-makers; and (3) To advance the science and stay on the cutting edge of research, NIH employees must be allowed interaction with professional associations, participation in public health activities, and genuine teaching opportunities.¹²²

Implementation of the ethics rules has largely quelled concern over new infractions. As a follow-up, NIH performed surveys and assessments of the impact of the rules on current employees, as well as on individuals who had left the agency or were potential employees, but no definitive trends were apparent.¹²³

NIH Conflict of Interest Policy for Extramural Research

Concern has also been expressed about the possibility that the research results of extramural grantees could be biased because of financial conflicts of interest. As stated earlier in this report, more than 80% of the overall NIH budget is spent on extramural awards. Most of the grant award is used by the investigator to perform the research, but a significant portion (27% on average) goes to the grantee institution for overhead costs.¹²⁴ The current federal regulations were drafted in 1995 with the aim of ensuring that research funded by NIH grants would not be biased by the outside financial interests of an investigator.¹²⁵

Under the 1995 regulations, each institution that receives NIH funds must have in place “an appropriate written, enforced policy on conflicts of interest that complies with this subpart and

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5565, February 3, 2005.

¹²¹ U.S. Department of Health and Human Services, “Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements for Employees of the Department of Health and Human Services,” *70 Federal Register* 51559-51574, August 31, 2005.

¹²² NIH Office of the Director, “NIH Announces Final Ethics Rules,” press release, August 25, 2005, at <http://www.nih.gov/news/pr/aug2005/od-25.htm>.

¹²³ Some of the results of that process are posted at <http://www.nih.gov/about/ethics/10262006COImemo.htm>.

¹²⁴ NIH, *Justification of Estimates for Appropriations Committees, FY2011, Vol. I, Overview*, table on “Statistical Data—Grants, Direct and Indirect Costs Awarded,” p. TD-10, at <http://officeofbudget.od.nih.gov/pdfs/FY11/Tabular%20Data.pdf>.

¹²⁵ 42 C.F.R. § 50.601.

informs each investigator of that policy.”¹²⁶ A conflict of interest exists when the designated official(s) at the institution “reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting” of the NIH sponsored research.¹²⁷ A significant financial interest is defined as anything of monetary value, including but not limited to salary, consulting fees, honoraria, stock, stock options, patents, copyrights, and royalties; amounts under \$10,000 are excluded.¹²⁸ The institution must maintain records of all financial disclosures and any actions taken with respect to a conflict of interest, must establish adequate enforcement mechanisms and sanctions, and must certify to NIH that “there is in effect at the institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests.”¹²⁹ Before any grant funds are spent, the institution must report to NIH “the existence of a conflicting interest (but not the nature of the interest or other details) ... and assure that the interest has been managed, reduced or eliminated.”¹³⁰

In August 2007 Senator Charles Grassley announced an investigation of the financial dealings between pharmaceutical companies and biomedical researchers, especially physicians who work as academic researchers.¹³¹ The Grassley investigation led to introduction of legislation, the Physician Payments Sunshine Act, in the 110th Congress (S. 2029) and the 111th Congress (S. 301). Similar language was incorporated within the health reform legislation (P.L. 111-148). The law requires that as of March 2013, manufacturers of drugs and other medical products must report to the Secretary of HHS every payment to a physician that is greater than \$10, including cash, stock, gifts, entertainment, consulting and public speaking fees.¹³² Failure to comply will result in a civil monetary penalty. HHS will make the submitted information available to the public through a searchable website. Other states have passed similar measures (Minnesota, Vermont, West Virginia, Maine, Massachusetts, District of Columbia) or have considered such legislation (California, Texas, Illinois, New York).¹³³

In January 2008 the HHS Office of Inspector General (OIG) released a report on conflicts of interest in extramural NIH research.¹³⁴ The OIG report found that NIH could not provide an accurate count of the financial conflict of interest reports received from grantees during the period under study, FY2004 through FY2006, because the NIH database was incomplete. In addition, NIH was unaware of the details on the types of financial conflicts of interest within grantee institutions because the regulations do not require the details to be reported. Lastly, the primary method of oversight by NIH is reliance on grantee institutions’ assurances that the conflict of interest regulations are followed. The January 2008 OIG report recommended that NIH:

¹²⁶ 42 C.F.R. § 50.604(a).

¹²⁷ 42 C.F.R. § 50.605(a).

¹²⁸ 42 C.F.R. § 50.603.

¹²⁹ 42 C.F.R. § 50.604.

¹³⁰ 42 C.F.R. § 50.604(g)(2).

¹³¹ Sen. Charles Grassley, “Drug Company Payments to Physicians,” remarks in Senate, *Congressional Record*, August 2, 2007, pp. S10721-S10722.

¹³² CRS Report R40790, *Requiring Disclosure of Gifts and Payments to Health Care Professionals: A Legal Overview*, by Jennifer Staman and Brian T. Yeh.

¹³³ *Ibid.*, and Jill Wechsler, “Transparency Shapes Pharmaceutical R&D,” *Applied Clinical Trials*, vol. 18, no. 3 (March 2009), pp. 24-26.

¹³⁴ Daniel R. Levinson, Inspector General, *National Institutes of Health: Conflicts of Interest in Extramural Research*, Department of Health and Human Services, Office of Inspector General, Washington, DC, January 2008, <http://oig.hhs.gov/oei/reports/oei-03-06-00460.pdf>.

- Increase oversight of grantee institutions to ensure their compliance with federal financial conflict of interest regulations.
- Require grantee institutions to provide details regarding the nature of financial conflicts of interest and how they are managed, reduced, or eliminated.
- Require that each NIH Institute/Center forward to the NIH Office of Extramural Research (OER) all financial conflict of interest reports that are received from grantee institutions and ensure that the OER database contains information on all conflict of interest reports provided by grantee institutions.

In February 2008 the Association of American Medical Colleges and the Association of American Universities (AAMC/AAU) released a report that provided recommendations to strengthen the conflict of interest policies of academic institutions.¹³⁵ In April 2009, the Institute of Medicine (IOM) produced a comparable report.¹³⁶ Both reports state that researchers should be required to disclose all outside financial interests, no matter how small, that are directly or indirectly related to their work at the academic institution, and urge that a researcher with a conflict of interest should be restricted from participation in research involving human subjects.

In November 2009 the HHS OIG released a second report on conflicts of interest in extramural NIH research.¹³⁷ The report found that the most common conflict of interest among researchers funded by the NIH was equity ownership. Efforts to manage financial conflicts of interest by grantee institutions frequently involve requiring disclosure of the conflict in research publications, but the institutions rarely “reduce or eliminate” conflicts of interest. The report found a number of vulnerabilities in the identification, management, and oversight of financial conflicts of interest by grantee institutions. Examples include 90% of institutions rely solely on the researcher’s discretion to determine which financial interests are reported; institutions do not routinely verify the information submitted by researchers; about 50% of institutions do not require researchers to report specific amounts of equity or compensation on their disclosure forms; conflicts were not uniformly reported to NIH by the institutions; the institutions lack documentation to support their oversight of financial conflicts of interest; and, grantee institutions are not required to report to NIH the financial interests the institution itself has with outside companies. The November 2009 OIG report recommended that NIH:

- Request grantee institutions to provide the details of all reported financial conflicts of interest and how they are managed, reduced, or eliminated.
- Require grantee institutions to collect information on *all* financial interests held by researchers, including specific amounts of equity.

¹³⁵ AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research, Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research, February 2008, <http://www.aamc.org/research/coi/>.

¹³⁶ Bernard Lo and Marilyn J. Fields, editors, *Conflict of Interest in Medical Research, Education, and Practice*, Committee on Conflict of Interest in Medical Research, Education, and Practice; Institute of Medicine, Washington, DC, April 2009, <http://www.iom.edu/Reports/2009/Conflict-of-Interest-in-Medical-Research-Education-and-Practice.aspx>.

¹³⁷ Daniel R. Levinson, Inspector General, *How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health*, Department of Health and Human Services, Office of Inspector General, Washington, DC, November 2009, <http://oig.hhs.gov/oei/reports/oei-03-07-00700.pdf>.

- Develop guidance for grantee institutions on methods to verify researchers' financial interests.
- Ensure that grantee institutions maintain proper documentation as outlined in the federal regulations and take appropriate action against researchers who do not follow financial conflict of interest policies and procedures.
- Increase oversight of grantee institutions to ensure that financial conflicts of interest are reported and managed appropriately.
- Develop regulations that address institutional financial conflicts of interest.

In May 2009 NIH published an advance notice of proposed rule making, seeking comments on revising the conflict of interest regulations.¹³⁸ The deadline for submitting comments was July 2009. NIH had originally planned to publish the proposed rule in February 2010 and the final rule in July 2010.¹³⁹ That schedule was supposed to allow time for a 60 day comment period, analysis of the comments received, revision of the proposed rule, and review and clearance of the final regulations. The process proved considerably slower than anticipated. Following pressure from Congress over the delayed release, the proposed rule was published in May 2010, with a 60-day public comment period.¹⁴⁰ NIH later extended the comment period by 30 days to August 19, 2010, to solicit additional information on enforcement authorities and on situations where an investigator or a grant transfers from one institution to another.¹⁴¹

The May 2010 proposed rule “more precisely spells out the roles of NIH, of grantee institutions, and of investigators in disclosing, identifying and managing financial conflicts of interest.”¹⁴² The proposed rule would require investigators to report to their institution all significant outside income related to their institutional responsibilities, not just those related to NIH-funded work. It would lower the minimum threshold for significant outside income from \$10,000 to \$5,000 as well as require the reporting of any equity interest in a non-publicly traded company, in contrast to 5% equity under the 1995 rules. Institutions would be required to provide NIH with a detailed report on the value and nature of any financial conflicts of interest as well as the institution's management plan. Prior to spending any NIH grant funds, the institution would be required to post on a public website certain information on the financial conflicts of interest that the institution has determined to be related to NIH-funded research.

In contrast to the \$5,000 threshold in the May 2010 proposed rule, the IOM and the AAMC/AAU reports mentioned above recommended no minimum dollar threshold. Both reports also urged that a researcher with a conflict of interest should not participate in research involving human subjects; the May 2010 proposed rule is silent on this issue. Other observers point out that the

¹³⁸ Department of Health and Human Services, “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors; Request for Comments,” 74 *Federal Register* 21610-21613, May 8, 2009.

¹³⁹ NIH, Justification of Estimates for Appropriations Committees, FY2011, Vol. II, Overview—Significant Items, p. 207, at <http://officeofbudget.od.nih.gov/pdfs/FY11/Significant%20Items.pdf>.

¹⁴⁰ Department of Health and Human Services, “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors,” 75 *Federal Register* 28688-28712, May 21, 2010.

¹⁴¹ See 75 *Federal Register* 42362-42363, July 21, 2010.

¹⁴² Sally J. Rockey and Francis S. Collins, “Managing Financial Conflict of Interest in Biomedical Research,” *Journal of the American Medical Association*, May 24, 2010, pp. E1-E3.

required financial disclosure on the public website would allow the use of dollar ranges instead of specific amounts, which “means that the public won’t know if the amount is \$250,000 or \$2 million.”¹⁴³

The proposed rule also does not address concerns over institutional conflict of interest but it does invite additional public comment on this issue. A January 2011 report HHS OIG report again recommended that NIH “promulgate regulations that address institutional financial conflicts of interest.”¹⁴⁴ According to the January 2011 OIG report, “an institutional conflict may arise when an institution’s own financial interests (e.g., royalties, equity, stockholdings, and gifts) or those of its senior officials pose a risk of undue influence on decisions involving the institution’s research.”

As of the date of this CRS report, NIH has not published a final rule. Links to the May 21, 2010, proposed rule as well as information on the 1995 NIH financial conflict of interest policies that are currently in place and answers to frequently asked questions are available on the website of the NIH Office of Extramural Research.¹⁴⁵

¹⁴³ Jocelyn Kaiser, “Lowering the Boom on Financial Conflicts,” *Science*, vol. 328 (May 28, 2010), p. 1091.

¹⁴⁴ Daniel R. Levinson, Inspector General, *Institutional Conflicts of Interest at NIH Grantees*, Department of Health and Human Services, Office of Inspector General, Washington, DC, January 2011, <http://oig.hhs.gov/oei/reports/oei-03-09-00480.pdf>

¹⁴⁵ See <http://grants.nih.gov/grants/policy/coi/index.htm>.

Table 4. 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
National Cancer Institute (NCI) PHSA § 410-417D, 42 U.S.C. § 285-285a-10	1937—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 aspects of cancer—cause, diagnosis, prevention, treatment, rehabilitation, and continuing care of patients.
National Heart, Lung, and Blood Institute (NHLBI) PHSA § 415-425, 42 U.S.C. § 285b-285b-8	1948—National Heart Act (P.L. 80-655): National Heart Institute. 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 Dental Research Act (P.L. 80-755): National Institute of Dental Research. 1998—NIDCR.	Oral, dental, and craniofacial diseases and disorders.
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) PHSA § 426-434A, 42 U.S.C. § 285c-285c-9	1950—Omnibus Medical Research Act (P.L. 81-692): National Institute of Arthritis and Metabolic Diseases. 1972—National Institute of Arthritis, Metabolism, and Digestive Diseases. 1981—National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. 1985—NIDDK.	Diabetes, endocrinology, metabolic diseases; digestive diseases, nutrition; kidney, urologic, hematologic diseases.
National Institute of Neurological Disorders and Stroke (NINDS) PHSA § 457-460, 42 U.S.C. § 285j-285j-3	1950—Omnibus Medical Research Act (P.L. 81-692): National Institute of Neurological Diseases and Blindness. 1968—National Institute of Neurological Diseases and Stroke. 1975—National Institute of Neurological and Communicative Disorders and Stroke. 1988—NINDS.	Convulsive, neuromuscular, demyelinating, and dementing disorders; fundamental neurosciences; stroke, trauma.
National Institute of Allergy and Infectious Diseases (NIAID) PHSA § 446-447B, 42 U.S.C. § 285f-285f-3	1955—established under authority of Omnibus Medical Research Act (P.L. 81-692).	Allergic, immunologic, and infectious diseases.
National Institute of General Medical Sciences (NIGMS) PHSA § 461, 42 U.S.C. § 285k	1962—PHS Act Amendment (P.L. 87-838) authorized the Surgeon General to establish an institute for general (basic) biomedical sciences. 1963—NIGMS created in the Department of Health, Education, and Welfare (HEW).	Research and research training in basic biomedical sciences (cellular and molecular biology, genetics, pharmacology, physiology). Special focus on minority researchers.

Institute/Center Statutory Authority in Public Health Service Act and U.S. Code	When and How Established; Chronology of Name Changes	Major Research Focus
National Institute of Child Health and Human Development (NICHD) PHSA § 448-452G, 42 U.S.C. § 285g-285g-10	1962—PHS Act Amendment (P.L. 87-838) authorized the Surgeon General to establish an institute for research on child health and human development. 1963—NICHD created in HEW.	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—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 § 463-463A, 42 U.S.C. § 285l-285l-1	1969—The NIH Division of Environmental Health Sciences (established by the Surgeon General in 1965) was elevated to institute status by the Secretary of HEW.	Interrelationships of environmental factors, individual genetic susceptibility, and age as they affect health. NIEHS is located in Research Triangle Park, NC.
National Institute on Aging (NIA) PHSA § 443-445J, 42 U.S.C. § 285e-285e-11	1974—Research on Aging Act of 1974 (P.L. 93-296).	Biomedical, social, and behavioral research on the aging process; diseases, problems, and needs of the aged.
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) PHSA § 435-442A, 42 U.S.C. § 285d-285d-8	1986—Established under authority of the Health Research Extension Act of 1985 (P.L. 99-158). For earlier history, see NIDDK.	Arthritis; bone, joint, connective tissue and muscle disorders; skin diseases.
National Institute on Deafness and Other Communication Disorders (NIDCD) PHSA § 464-464F, 42 U.S.C. § 285m-285m-6	1988—National Deafness and Other Communication Disorders Act of 1988 (P.L. 100-553) (functions were formerly in the institute covering neurological and communicative disorders and stroke).	Disorders of hearing, balance, smell, taste, voice, speech, and language.
National Institute of Nursing Research (NINR) PHSA § 464V-464Y, 42 U.S.C. § 285q-285q-3	1986—National Center for Nursing Research established under authority of the Health Research Extension Act of 1985 (P.L. 99-158). 1993—NINR.	Acute and chronic illness, health promotion/disease prevention, nursing systems, clinical therapeutics.
National Institute on Alcohol Abuse and Alcoholism (NIAAA) PHSA § 464H-464J, 42 U.S.C. § 285n-285n-2	1970—Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act (P.L. 91-616) established NIAAA within NIMH in PHS. 1974—moved to Alcohol, Drug Abuse, and Mental Health Administration (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.

Institute/Center Statutory Authority in Public Health Service Act and U.S. Code	When and How Established; Chronology of Name Changes	Major Research Focus
National Institute on Drug Abuse (NIDA) PHSA § 464L-464P, 42 U.S.C. § 285o-285o-4	1974—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.
National Institute of Mental Health (NIMH) PHSA § 464R-464U, 42 U.S.C. § 285p-285p-3	1949—established under authority of National Mental Health Act of 1946 (P.L. 79-487). 1967—transferred out of NIH to PHS (P.L. 90-31). 1974—moved to ADAMHA (P.L. 93-282). 1992—moved back to NIH (P.L. 102-321).	Brain research, mental illness, and mental health.
National Human Genome Research Institute (NHGRI) PHSA § 464z-1, 42 U.S.C. § 285s	1989—National Center for Human Genome Research (NCHGR) established. 1993—NCHGR authorized (P.L. 103-43). 1997—designated an institute by the HHS Secretary. 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 Establishment Act (P.L. 106-580).	Research, training and coordination in 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—NCMHD redesignated as NIMHD (P.L. 111-148) (not yet implemented as of July 2010).	Research, training, and coordination on minority health conditions and populations with health disparities.
National Center for Research Resources (NCRR) PHSA § 479-481 C, 42 U.S.C. § 287-287a-4	1970—Division of Research Resources (DRR) moved to NIH from PHS. 1990—NCRR created by merging DRR and Division of Research Services (statutory authority in NIH Revitalization Act of 1993, P.L. 103-43).	Extramural and intramural research resources and technologies: general clinical research centers, computers, instrument systems, animal resources and facilities, nonmammalian research models.
National Center for Complementary and Alternative Medicine (NCCAM) PHSA § 485D, 42 U.S.C. § 287c-21	1992—Office of Alternative Medicine (OAM) created in OD. 1993—OAM authorized (P.L. 103-43). 1999—NCCAM created (P.L. 105-277).	Identifies, evaluates, and researches unconventional health care practices.

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John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) PHSA § 482, 42 U.S.C. § 287b	1968—established by HEW. 1985—established in law (P.L. 99-158).	Focal point for NIH’s international collaboration activities and scientific exchanges; provides leadership in global health.
National 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, later Army Medical Library (1922), Armed Forces Medical Library (1952), and NLM under PHS (1956, 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 § 402, 42 U.S.C. § 282	1930—Ransdell Act (P.L. 71-251) created the National Institute of Health.	Overall NIH leadership, and liaison with HHS. Includes special offices for research on AIDS, women’s health, behavioral and social sciences, and disease prevention (including rare diseases and dietary supplements)
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.
Center for Scientific Review (CSR)	1946—Division of Research Grants created. 1997—reorganized and renamed CSR.	Receives, assigns, and reviews research and training grant applications.
Center for Information Technology (CIT)	1964—Division of Computer Research and Technology (DCRT) established. 1998—CIT formed (DCRT combined with other offices).	Provides, coordinates, and manages information technology for NIH; research to advance computational science.

Sources: *NIH Almanac*, <http://www.nih.gov/about/almanac/index.html>.

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