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

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Summary

The National Institutes of Health is the focal point for federal health research. An agency of the Department of Health and Human Services (HHS), it uses its \$28.5 billion budget to support more than 200,000 scientists and research personnel working at over 3,100 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.

The NIH appropriation in the past three years has shifted from marked growth to low or no increases. Congress doubled the budget in five years, from \$13.6 billion in FY1998 to \$27.1 billion in FY2003. Since then, growth has slowed to below the rate of inflation. The budget request for FY2007 is for \$28.5 billion, roughly the same as the FY2006 level and a decrease of 0.2% below FY2005. In inflation-adjusted (2006) dollars, the FY2007 request is 8.7% below the FY2003 level. The House Appropriations Committee matched the request for NIH, and the Senate bill provided \$200 million more (0.8% over FY2006). The only major increases in the proposals are for research related to pandemic influenza and to biodefense drugs and vaccines. The request would support some 650 fewer research project grants. The success rate for competing grant applications getting funded would be an estimated 19%, the same as FY2006, compared with 22% in FY2005 and 30%-32% during the doubling years. Currently, FY2007 funding is continued at the FY2006 rate.

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. A reauthorization bill addressing some of these issues (H.R. 6164) passed the House in September 2006. Congress also monitors ethics rules on conflicts of interest and tracks the efficacy of procedures intended to make results of NIH-sponsored research accessible to the public.

NIH's Internet home page is at [<http://www.nih.gov>]; budget information is at [<http://officeofbudget.od.nih.gov/ui/HomePage.htm>]; disease funding estimates are at [<http://www.nih.gov/news/fundingresearchareas.htm>]; and legislative issues tracking is at [<http://olpa.od.nih.gov>]. This report will be updated as events warrant.

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

Overview of the National Institutes of Health

Introduction

The National Institutes of Health 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. 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).¹ For FY2006, it had a total budget of \$28.5 billion and total employment of more than 18,000 people. The President's FY2007 budget requests level funding.

Congress maintains a high level of interest in NIH for a variety of reasons:

- The NIH budget is by far the largest and most visible component of federal civilian research and development spending. It 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 funds extramural researchers in every state, and widespread constituencies contact Congress about funding for particular diseases and levels of research support in general.
- NIH has increasingly come to the attention of Congress and the American people in the last decade, thanks to greater awareness of science advances (for example, the Human Genome Project and its potential for guiding more personalized medicine) and public policy debates (for instance, the use and regulation of embryonic stem cells). Special interest surrounded the five-year doubling of the agency's budget between FY1999 and FY2003. Since then, during three years of low or no growth, Congress has increasingly scrutinized how NIH is using its expanded resources, how it can

¹ 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).

most efficiently adapt to budgetary constraints, and whether its current structure of 27 semi-autonomous institutes and centers may be too “stovepiped” to identify and respond nimbly to important public health challenges.

- The last major reauthorization of NIH was in 1993, although a number of laws focusing on individual NIH-related topics have amended the Public Health Service Act since then. Most policy changes have come in the appropriations arena, or through agency initiatives under its broad research authority. Some in Congress feel that the authorizing committees (the House Committee on Energy and Commerce and Senate Committee on Health, Education, Labor, and Pensions) should reassert their role in shaping the agency’s structure and policies. After many hearings, the Energy and Commerce Committee reported H.R. 6164, the NIH Reform Act of 2006, which the House passed on September 26, 2006. Draft legislation had been circulated starting in the summer of 2005 to solicit comments and reactions from the disparate stakeholders of the medical research community, including those in academia, government, industry, the nonprofit sector, patient advocacy groups, and the general public. H.R. 6164 focuses on enhancing the authority and tools for the NIH Director to do strategic planning, especially to facilitate and fund cross-institute research initiatives.

Other issues of concern to Congress and the research community include:

- clinical research, and more broadly, translational research, meaning the movement of discoveries of basic science into new preventives, diagnostics, therapies, and cures. Initiatives are under way to make the process quicker and more efficient, and to encourage more medically trained young scientists to work in clinical research;
- helping young investigators (both basic and clinical) obtain their first independent research grants faster;
- congressional and/or administrative restrictions on types of research funded, particularly human embryonic stem cell research, and concerns over certain areas of mental health and sexuality research;
- conflict-of-interest regulations for NIH scientists and other employees concerning their financial holdings and their freedom to consult with industry and outside colleagues, including questions of impact on recruitment and retention; and
- development of policies for free public access to journal articles stemming from NIH-supported research, and weighing that access against the interests of publishers, including scientific societies. (A new NIH voluntary policy for NIH-funded authors to submit their articles to the National Library of Medicine within 12 months of publication has had little participation.)

This report provides background and analysis on the organization, mission, budget, and history of NIH as an agency, outlines its major responsibilities and methods of fulfilling them, and discusses the issues facing Congress as it debates reauthorization legislation and works to guide and monitor the nation’s investment in medical research. This report will be updated as events warrant.

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 lab 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.

Structure. Today, NIH consists of the Office of the Director and 27 components — 19 institutes, 4 research centers, the National Library of Medicine, and 3 other centers that provide central services (for details, see **Table 1**, below, and **Table 5**, at the end of the report). 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 the Office of the Director. Congress provides separate appropriations to 24 of the 27 ICs, to OD, and to a buildings and facilities account (see the budget discussion later).² NIH occupies a 317-acre main campus in Bethesda, Maryland, as well as numerous off-campus sites, including locations in Maryland, North Carolina, and Montana.

Authority. The agency derives its statutory authority from the Public Health Service Act of 1944, as amended (42 U.S.C. § 201 through §300hh-11).³ 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 responsibilities, activities, and functions of the NIH Director and the institutes and centers. All of the institutes and centers are covered by specific provisions in the PHS Act, but only nine ICs, plus a variety of individual programs, have time-and-dollar limits on their authorizations of appropriations, most of which have expired. The other institutes and centers and most NIH programs do not require periodic reauthorization by Congress. Even when specific authorities have expired, the agency can fall back on its Section 301 authority. The annual appropriations statute becomes the authority for that fiscal year.

² 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’s information technology services; and the Clinical Center (CC), NIH’s hospital and outpatient facility for clinical research. Those centers are funded through the NIH Management Fund, which is financed by taps on other NIH appropriations. For further information on each component, see the *NIH Almanac, 2005-2006*, at [<http://www.nih.gov/about/almanac/about.htm>].

³ For a compilation of the Public Health Service Act as amended through December 31, 2004, see [http://energycommerce.house.gov/108/pubs/109_health.pdf].

Table 1. Components of the National Institutes of Health (NIH)(for additional details on the history and major research focus of each component, see **Table 5** at the end of the report)

Component	Website	FY2006 rev. IC Budget (Program Level) & Percent of Total NIH Budget (\$ in millions)	
Office of the Director (OD) — includes program coordination offices for research on AIDS, Disease Prevention (including Dietary Supplements, and Rare Diseases), Behavioral and Social Sciences, and Women’s Health	[http://www.nih.gov/icd/od]	\$478	1.7%
INSTITUTES			
National Cancer Institute (NCI)	[http://www.nci.nih.gov]	\$4,790	16.8%
National Eye Institute (NEI)	[http://www.nei.nih.gov]	\$666	2.3%
National Heart, Lung, and Blood Institute (NHLBI)	[http://www.nhlbi.nih.gov]	\$2,920	10.3%
National Human Genome Research Institute (NHGRI)	[http://www.nhgri.nih.gov]	\$486	1.7%
National Institute on Aging (NIA)	[http://www.nia.nih.gov]	\$1,046	3.7%
National Institute on Alcohol Abuse and Alcoholism (NIAAA)	[http://www.niaaa.nih.gov]	\$436	1.5%
National Institute of Allergy and Infectious Diseases (NIAID)	[http://www.niaid.nih.gov]	\$4,331	15.2%
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)	[http://www.niams.nih.gov]	\$508	1.8%
National Institute of Biomedical Imaging and Bioengineering (NIBIB)	[http://www.nibib.nih.gov]	\$297	1.0%
National Institute of Child Health and Human Development (NICHD)	[http://www.nichd.nih.gov]	\$1,264	4.4%
National Institute on Deafness and Other Communication Disorders (NIDCD)	[http://www.nidcd.nih.gov]	\$393	1.4%
National Institute of Dental and Craniofacial Research (NIDCR)	[http://www.nidcr.nih.gov]	\$389	1.4%
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)	[http://www.niddk.nih.gov]	\$1,854	6.5%

Component	Website	FY2006 rev. IC Budget (Program Level) & Percent of Total NIH Budget (\$ in millions)	
National Institute on Drug Abuse (NIDA)	[http://www.nida.nih.gov]	\$999	3.5%
National Institute of Environmental Health Sciences (NIEHS)	[http://www.niehs.nih.gov]	\$720	2.5%
National Institute of General Medical Sciences (NIGMS)	[http://www.nigms.nih.gov]	\$1,934	6.8%
National Institute of Mental Health (NIMH)	[http://www.nimh.nih.gov]	\$1,403	4.9%
National Institute of Neurological Disorders and Stroke (NINDS)	[http://www.ninds.nih.gov]	\$1,534	5.4%
National Institute of Nursing Research (NINR)	[http://www.ninr.gov]	\$137	0.5%
National Library of Medicine (NLM)	[http://www.nlm.nih.gov]	\$323	1.1%
CENTERS			
John E. Fogarty International Center (FIC)	[http://www.fic.nih.gov]	\$66	0.2%
National Center for Complementary and Alternative Medicine (NCCAM)	[http://www.nccam.nih.gov]	\$121	0.4%
National Center on Minority Health and Health Disparities (NCMHD)	[http://www.ncmhd.nih.gov]	\$195	0.7%
National Center for Research Resources (NCRR)	[http://www.ncrr.nih.gov]	\$1,098	3.9%
Center for Information Technology (CIT)	[http://www.cit.nih.gov]	(\$33*)	
Center for Scientific Review (CSR)	[http://www.csr.nih.gov]	(\$54*)	
Warren G. Magnuson Clinical Center (CC)	[http://www.cc.nih.gov]	(\$334*)	
* Funded through the NIH Management Fund from taps on IC budgets			
Total, NIH Program Level		\$28,468	100%

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 200,000 scientists and research personnel working in over 3,100 universities, academic health centers, hospitals, and independent research institutions in the United States and abroad.⁴ About 84% of the overall NIH budget, some \$24 billion, is spent on extramural awards in the form of research grants, research and development contracts, training awards, and a few smaller categories such as grants for construction, facilities renovation, and medical libraries. The “research grants” category, by far the largest, includes research project grants 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. Nearly three-fourths of NIH’s extramural funds go to researchers working in institutions of higher education, particularly the nation’s 125 medical schools.⁵ Data on awards and recipients by state, by congressional district, by type of institution, by subject of the research, and by a variety of other groupings may be accessed from the website of the NIH Office of Extramural Research at [<http://grants1.nih.gov/grants/award/award.htm>].

Peer Review. All applications for extramural research support are considered under a two-tiered system of peer review. First, they are reviewed for scientific and technical merit by committees (scientific review groups known as “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. 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. The solicitations are known as RFAs and RFPs (for grants, Requests for Applications, and for contracts, Requests for Proposals); applications responding to them 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

⁴ NIH, *Justification of Estimates for Appropriations Committees, FY2007, Vol. I, Overview*, pp. 1-2 [<http://officeofbudget.od.nih.gov/FY07/Performance%20Budget%20Overview.pdf>].

⁵ NIH, Office of Extramural Research, *Characteristics of Awardee Organizations* [<http://grants1.nih.gov/grants/award/trends/awdorg.htm>].

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.

In FY2005, just over 43,000 new and renewal applications competed for research project grants (RPGs), and 9,599 received funding, for a “success rate” of 22.3%.⁶ Some researchers submit more than one proposal; the 43,000 applications in FY2005 were submitted by about 31,800 individual applicants, of whom 8,783, or 27.6%, received funding.⁷ Applicants who are not approved for funding, and who wish to try to improve their scores based on comments from the reviewers, are allowed to revise and resubmit their proposals twice.

Awards. The average length of an RPG 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 choose to compete for a renewal of the project. In FY2005, in addition to awarding 9,599 new or competing renewal awards, NIH awarded more than 27,000 noncompeting awards and nearly 2,000 small business awards, for a total of nearly 39,000 RPGs. The average annual cost of an RPG award is about \$400,000, including both direct and indirect costs.⁸ The direct costs, averaging 72% of the total award, cover project-specific expenses, while the indirect costs, averaging 28%, pay for facilities and administration costs (i.e., overhead) of the institution where the research is conducted.⁹

⁶ NIH, Office of Extramural Research, “Success Rates by Institute” (data are available for FY1970-FY2005) [http://grants1.nih.gov/grants/award/success/Success_ByIC.cfm].

⁷ NIH, Office of Extramural Research, “NIH Investment in Extramural Research and Training Programs” [http://grants1.nih.gov/grants/award/NIH_Investment.ppt#257,24,Slide24]. (For slides with charts and data tables; access from [<http://grants1.nih.gov/grants/award>].)

⁸ NIH, *Justification of Estimates for Appropriations Committees, FY2007, Vol. I, Overview*, table on “Research Project Grants: Total Number of Awards and Dollars,” p. NIH-86 [<http://officeofbudget.od.nih.gov/FY07/Tabular%20Data.pdf>].

⁹ NIH, *Justification of Estimates for Appropriations Committees, FY2007, Vol. I, Overview*, table on “Statistical Data — Grants, Direct and Indirect Costs Awarded,” p. NIH-85 [<http://officeofbudget.od.nih.gov/FY07/Tabular%20Data.pdf>].

Intramural Research. The NIH intramural research program accounts for about 10% of the budget. It includes more than 6,500 scientists and technical support staff who are government employees, and several thousand additional scientific fellows, 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. Many intramural scientists are based in the Clinical Center, which facilitates interdisciplinary collaboration and the direct clinical application of new knowledge derived from basic research.

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. Programs offered on the NIH campus range from summer internships for high school students to employment 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 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 (many of them available on the Internet); supporting information clearinghouses and running public information campaigns on various diseases; and making specialized databases available. Free searching of MEDLINE citations and other NLM databases, together with resources for health questions, is available at [<http://www.medlineplus.gov>] and at [<http://health.nih.gov>].

Budget

Recent History. At \$28.5 billion for FY2006, NIH's budget (see **Table 2**) represents nearly 50% of federal civilian (i.e., nondefense) spending for research and development (R&D).¹⁰ It also constitutes some 38% of all the discretionary spending of the Department of Health and Human Services.¹¹ The agency has enjoyed strong bipartisan support from Congress, reflecting the interest of the American public in promoting medical research. Even in the face of pressure to reduce the deficit, Congress approximately doubled NIH's appropriation in the decade between FY1988 and FY1998. At that point, a coordinated lobbying effort in support of NIH and an improved budget and economic outlook led Congress to start on a new path of doubling the NIH budget during the following five years. The base at the time was the FY1998 appropriation of \$13.6 billion, and the target was \$27.2 billion for FY2003. The commitment was essentially accomplished, although the makeup of the budget changed somewhat over the five years.

¹⁰ See CRS Report RL33345, *Federal Research and Development Funding: FY2007*, by Michael E. Davey et al.

¹¹ Department of Health and Human Services, *FY2007 Budget in Brief* (Feb. 2006), p. 14 [<http://www.hhs.gov/budget/07budget/2007BudgetInBrief.pdf>].

In the post-doubling years, the pattern has been markedly different. The annual increases for FY1999 through FY2003 were in the 14%-15% range each year. For FY2004 and FY2005, Congress and the President, faced with competing priorities and a changed economic climate, gave increases of between 2% and 3%, levels that were below the then-estimated 3.5% and 3.3% biomedical inflation index for those two years (see the discussion below). The final appropriation for FY2006 was \$67 million (0.2%) below the FY2005 level, marking the first time that the NIH appropriation had decreased since 1970. (A few months later, the FY2006 budget dropped another \$19.5 million because of a transfer within HHS — see the discussion of the FY2007 budget request below.) The FY2007 budget requested a program level of \$28.487 billion, an amount essentially equal to the FY2006 appropriation. See **Figure 1**, which charts NIH appropriations from FY1994 through the FY2007 request.

Figure 2 portrays the NIH appropriation adjusted for inflation (in constant 2006 dollars) using the Biomedical Research and Development Price Index (BRDPI).¹² The index, developed each year for NIH by the Bureau of Economic Analysis (BEA) 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.

With the projected value of the BRDPI at 3.5% for FY2006 and 3.4% for FY2007, the NIH budget has been losing ground in real terms each year since the end of the doubling in FY2003. In constant 2006 dollars, the FY2003 NIH budget was \$30.2 billion, FY2004 was \$30.0 billion, FY2005 was \$29.6 billion, FY2006 was \$28.5 billion, and the FY2007 request level is \$27.5 billion. In inflation-adjusted terms, the FY2006 budget was 5.7% below the FY2003 level, and the FY2007 request is 8.7% below the FY2003 level.¹³

¹² See NIH Price Indexes [http://officeofbudget.od.nih.gov/UI/GDP_FromGenBudget.htm].

¹³ A note of caution regarding the BRDPI and calculations from earlier in 2006: the inflation rate is not as steep as NIH had earlier reported. On July 24, 2006, NIH posted a notice announcing a revision of the BRDPI because of an error made by BEA in its previous calculations. The calculation of how much purchasing power the NIH budget has lost since FY2003 is affected by this revision. Using the previous BRDPI value, some observed in the first months of 2006 that the level of the FY2007 NIH budget request represented a decrease of nearly 11% in real terms compared to the end of the doubling period. As discussed above, the revised estimate is 8.7%. (See “July 2006 Revision of Biomedical Research and Development Price Index: Revised FY2005 Update and Projections for FY2006-2016” [http://officeofbudget.od.nih.gov/PDF/BRDPI_Proj_Revised_July_2006v3.pdf].) Earlier, in February 2006, NIH had reported the estimated increase in the BRDPI as 5.5% for FY2005, in July it revised the estimate to 3.8%. The projected future-year values had to be revised accordingly. For FY2006, the estimate is now 3.5% instead of 4.1%, and for FY2007, it is 3.4% instead of 3.8%.

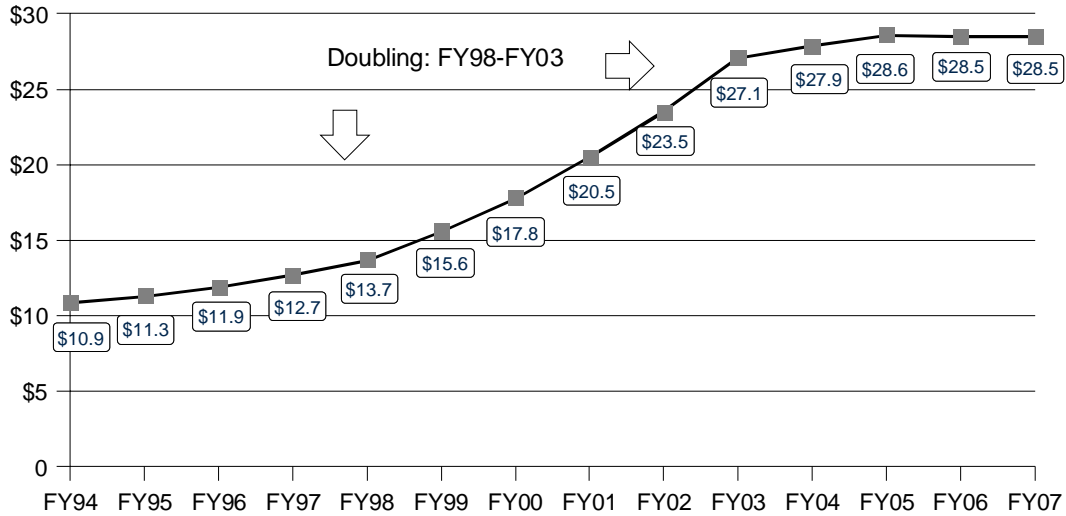
Table 2. National Institutes of Health (NIH) Appropriations
(dollars in millions)

Institutes and Centers (ICs)	FY2005 actual ^a	FY2006 rev appr ^b	FY2007 request	FY2007 H.Comm.	FY2007 S.Comm.
Cancer (NCI)	\$4,828.2	\$4,790.1	\$4,753.6	\$4,753.6	\$4,799.1
Heart/Lung/Blood (NHLBI)	2,941.2	2,919.8	2,901.0	2,901.0	2,924.3
Dental/Craniofacial Res (NIDCR)	391.8	389.1	386.1	386.1	389.7
Diabetes/Diges/Kidney (NIDDK)	1,713.6	1,703.8	1,694.3	1,694.3	1,707.8
Neuro. Disorders/Stroke (NINDS)	1,539.4	1,533.7	1,524.8	1,524.8	1,537.7
Allergy/Infectious Dis (NIAID) ^c	4,402.8	4,380.3	4,395.5	4,270.5	4,395.5
General Medical Sci (NIGMS)	1,944.1	1,934.3	1,923.5	1,923.5	1,934.9
Child Health (NICHD)	1,270.3	1,263.9	1,257.4	1,257.4	1,264.5
Eye (NEI)	669.1	666.3	661.4	661.4	666.9
Environ Health Sci (NIEHS)	644.5	640.7	637.3	637.3	641.3
Aging (NIA)	1,052.0	1,045.9	1,039.8	1,039.8	1,048.9
Arthritis/Musculo/Skin (NIAMS)	511.2	507.6	504.5	504.5	508.6
Deafness/Comm'n Dis (NIDCD)	394.3	393.2	391.6	391.6	395.2
Nursing Research (NINR)	138.1	137.2	136.6	136.6	137.8
Alcohol Abuse (NIAAA)	438.3	435.6	433.3	433.3	436.6
Drug Abuse (NIDA)	1,006.4	999.3	994.8	994.8	1,000.3
Mental Health (NIMH)	1,411.9	1,402.6	1,394.8	1,394.8	1,403.6
Human Genome Res (NHGRI)	488.6	485.7	482.9	482.9	486.3
Bio Imaging/Bioengrg (NIBIB)	298.2	296.6	294.9	294.9	297.6
Research Resources (NCRR)	1,115.1	1,098.3	1,098.2	1,123.2	1,104.3
Complemnt/Alt Med (NCCAM)	122.1	121.4	120.6	120.6	122.0
Minority Hlth/Disparity (NCMHD)	196.2	195.3	194.3	194.3	196.8
Fogarty International Center (FIC)	66.6	66.3	66.7	66.7	66.8
Library of Medicine (NLM)	315.1	314.7	313.3	313.3	315.3
Office of Director (OD) ^d	405.1	527.2	667.8	667.8	687.8
Buildings & Facilities (B&F)	110.3	81.0	81.1	81.1	81.1
<i>Subtotal, Labor-HHS-ED Approp</i>	<i>\$28,414.5</i>	<i>\$28,329.8</i>	<i>\$28,350.0</i>	<i>\$28,250.0</i>	<i>\$28,550.7</i>
Superfund (Interior/Env Approp) ^e	79.8	79.1	78.4	79.4	79.4
Total, NIH discr budget auth	\$28,494.4	\$28,409.0	\$28,428.4	\$28,329.4	\$28,630.1
Pre-approp Type 1 diabetes ^f	150.0	150.0	150.0	150.0	150.0
NLM program evaluation ^g	8.2	8.2	8.2	8.2	8.2
Total, NIH program level	\$28,652.6	\$28,567.2	\$28,586.6	\$28,487.6	\$28,788.3
Global HIV/AIDS Fund transfer ^c	-99.2	-99.0	-100.0	0.0	-100.0
Total, NIH prog level w/ transfer	\$28,553.4	\$28,468.2	\$28,486.6	\$28,487.6	\$28,688.3

Sources: FY2007 NIH budget justification, H.Rept. 109-515, and S.Rept. 109-287.

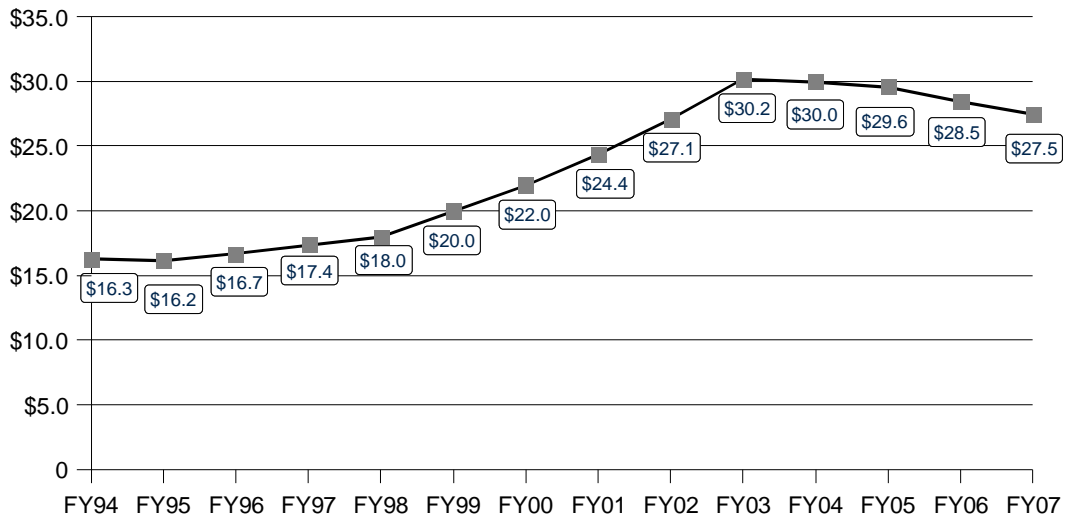
- a. Reflects across-the-board reduction (0.8%) of \$229.390m, Labor-HHS-ED reduction of \$6.787m for salaries and expenses, and an additional \$2.987m from NCI breast cancer stamp funds.
- b. Reflects across-the-board rescission (1%) of \$285.974m, Interior/Env reduction of \$0.382m, and HHS transfer of \$19.462m to Centers for Medicare and Medicaid Services (mid-June 2006).
- c. NIAID totals include funds for transfer to Global Fund to Fight HIV/AIDS, TB, and Malaria (not in FY2007 House bill). FY2006 includes \$18.0m supplemental funding from Public Health and Social Services Emergency Fund (PHSSEF) for pandemic flu (P.L. 109-148), and a comparable transfer of \$49.5m from NIAID to OD for Advanced Development of countermeasures.
- d. OD has Roadmap funds for distribution to ICs (FY2005, \$59.520m; FY2006, \$82.170m; FY2007, \$110.700m). FY2005 includes \$47.021m transferred from PHSSEF for nuclear/radiological countermeasures. FY2006 includes the \$49.5m comparable transfer from NIAID.
- e. Separate account in the Interior/Environment/Related Agencies appropriation for NIEHS research activities mandated in Superfund legislation (formerly in VA/HUD appropriation).
- f. Funds available to NIDDK for diabetes research (P.L. 106-554 and P.L. 107-360).
- g. Funds from PHS program evaluation set-aside (§ 241 of the PHS Act), \$8.2m for NLM each year.

Figure 1. NIH Appropriations FY1994-FY2007 Request
 Program Level (\$ in billions)



Source: Figure prepared by the Congressional Research Service (CRS).

Figure 2. Effect of Inflation on NIH Budget
 FY1994-FY2007 Program Level
 Purchasing Power in 2006 Dollars (Billions)
 Using Biomedical R&D Price Index (BRDPI)



Source: Figure prepared by CRS.

Sources of Funding. NIH's budget comes from four sources: the bulk through the annual Labor-HHS-Education (Labor-HHS-ED) appropriation, with an additional small amount for Superfund-related environmental work coming from the Interior, Environment, and Related Agencies (Interior/Environment) appropriation. Those two sources constitute NIH's discretionary budget authority. To reach the "program level" budget, other funds are counted that are added to or transferred from NIH. NIH annually receives \$150 million for the Type 1 Diabetes Initiative appropriated by P.L. 107-360, and in recent years has received an extra \$8.2 million for the National Library of Medicine from a "program evaluation" transfer within the Public Health Service (PHS) (see below). Also, in recent years, about \$100 million of the appropriation to the National Institute of Allergy and Infectious Diseases (NIAID) has been transferred out to the Global Fund to Fight HIV/AIDS, Tuberculosis, and Malaria.¹⁴

The NIH and other Public Health Service agencies within HHS are subject to a budget "tap" called the PHS Program Evaluation Transfer, 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. The FY2005 and FY2006 L-HHS-ED appropriations set the tap at 2.4%, as does the FY2007 Senate bill. The House bill returns the maximum tap to 1.0%, the level specified in the PHS Act. Since NIH has the largest budget among the PHS agencies, it becomes the largest "donor" of program evaluation funds and is a relatively minor recipient.

FY2007 Request and Appropriations Actions. For FY2007, the President requested a total program level of \$28.487 billion for NIH, including \$28.350 billion in the L-HHS-ED appropriation and \$78 million in the Interior/Environment appropriation (see **Table 2**). At the time of the request (February 2006), that amount represented the same overall level of funding for NIH as in FY2006. Subsequently, in mid-June 2006, the HHS Secretary exercised his transfer authority to give the Centers for Medicare and Medicaid Services (CMS) a total of \$40 million from other HHS discretionary accounts (to augment the funding for the Medicare prescription drug benefit call center). NIH's share of the transfer was \$19.5 million, dropping the FY2006 program level to \$28.468 billion.

In the request, most of the IC budgets decreased by 0.5%-0.8% below their FY2006 levels. The major increases, in the Office of the Director and in NIAID, were related to increases for biodefense and pandemic influenza research. For more details on the request and subsequent congressional actions, see the NIH section of CRS Report RL33345, *Federal Research and Development Funding: FY2007*, by Michael E. Davey, et al. Highlights are covered below.

¹⁴ The "NIH program level" cited in the Administration's budget documents, however, does not reflect the Global Fund transfer.

The House and Senate Appropriations Committees have reported their Labor-HHS-ED bills, but neither chamber has brought its bill to the floor. The Interior/Environment bill (H.R. 5386, H.Rept. 109-465 and S.Rept. 109-275) has passed the House and been reported in the Senate, with \$79 million for NIH, \$1 million above the request. Currently, NIH is operating at FY2006 funding levels under a continuing resolution.

The House committee's Labor-HHS-ED bill (H.R. 5647, H.Rept. 109-515) would provide \$28.250 billion for NIH, with the same distribution as in the request, except for a \$25 million shift of construction money from NIAID to the National Center for Research Resources (NCRR) and the omission of the \$100 million to NIAID for transfer to the Global Fund. Counting the extra funding for diabetes as well as the transfers, the program level from the House bill would be \$28.488 billion, essentially the same as the request and \$19.5 million higher than the FY2006 revised funding level, because of the transfer to CMS.

The Senate committee's Labor-HHS-ED bill (S. 3708, S.Rept. 109-287) would provide \$28.551 billion, for a program level of \$28.688 billion. The increase is about \$220 million (0.8%) over the revised FY2006 amount and \$200 million above the request and the House amount. The Senate committee gave every NIH account a modest increase over FY2006, reversing the cuts to IC budgets proposed in the request. The committee gave an extra \$20 million to the Office of the Director beyond the large boost already in the request. It included the \$100 million to NIAID for transfer to the Global Fund that the House had omitted, and did not shift \$25 million in construction funds from NIAID to NCRR as in the House bill.

Specific priorities highlighted in the budget request include several trans-NIH initiatives involving multiple institutes with coordination by OD:

- Biodefense activities would receive a total of \$1.9 billion, a net increase of \$110 million (6.2%) over FY2006, including a new push for advanced product development of vaccines and drugs that are priority targets for acquisition by Project BioShield.¹⁵
- Support for the NIH Roadmap for Medical Research initiatives (discussed later in this report) would increase 34%, to \$443 million. The ICs and OD share funding of 28 NIH-wide initiatives under themes of new paths to biological discovery, building multidisciplinary research teams, and improving the clinical research enterprise.
- The Genes, Environment, and Health initiative and the long-term National Children's Study are looking for genetic and environmental influences on health. The Administration had proposed terminating the multi-agency National Children's Study, but both the House and Senate committees have directed NIH to continue supporting it.
- Two new NIH programs will support additional training and mentoring of new investigators (Pathway to Independence Awards) and transdisciplinary clinical research and training (Clinical and Translational Science Awards).

¹⁵ See CRS Report RS21507, *Project BioShield*, by Frank Gottron.

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.” 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, comprehensive research centers, agency-directed research contracts, research career training, facilities construction, research management costs, etc. **Table 3** and **Figure 3** show the distribution of the NIH budget by the major funding mechanisms. Although the President’s request indicates proposed spending by mechanism, including estimated numbers of awards to be supported in each category, the appropriators do not specify in their reports how the budget should be allocated by mechanism. FY2006 numbers in **Table 3** are not adjusted for the June 2006 CMS transfer.

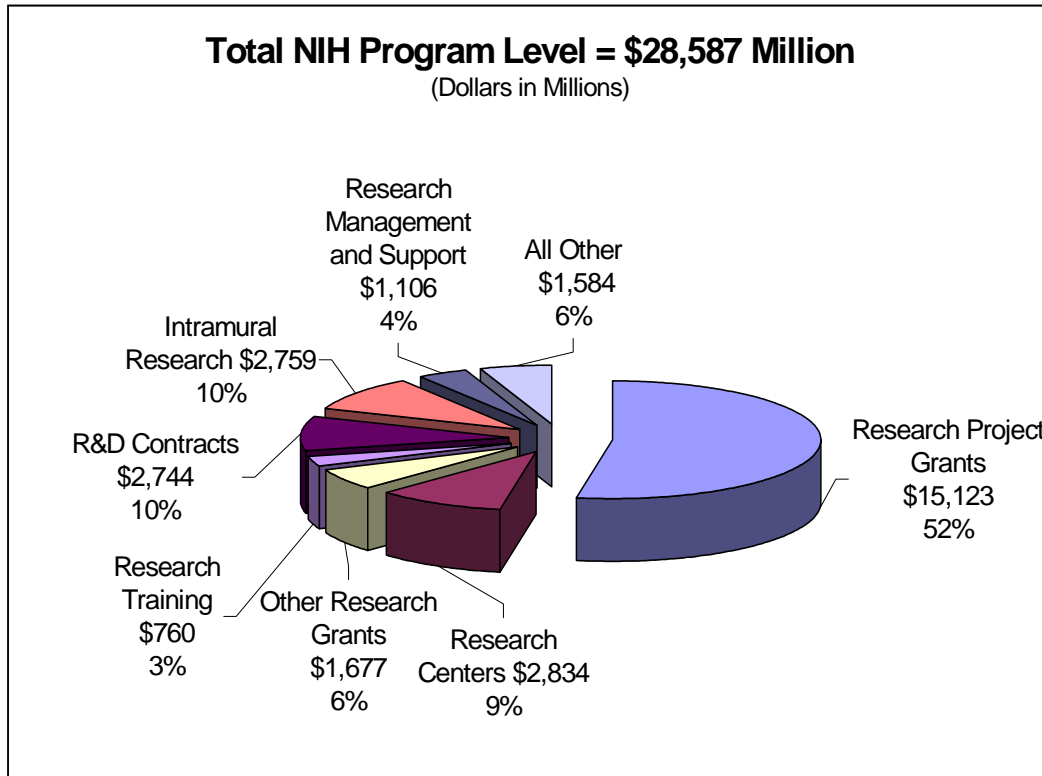
The major changes to note between FY2006 and FY2007 are (1) an increase in the number of new and competing renewal research project grants; (2) a decrease in the number of noncompeting grants (because a large number of grants that were started toward the end of the doubling years are completing their funding cycles in FY2006); (3) a resulting net decrease in total RPGs; (4) modest increases in research centers, other research grants, R&D contracts, and research management and support; (5) small decreases in research training and intramural research; and (6) a \$100 million increase in the “All Other” grouping, due to biodefense funding in OD.

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

Mechanism	FY2005 actual	FY2006 approp	FY2007 estimate	% change 2007/2006
Research Project Grants (RPGs)	\$15,484	\$15,355	\$15,123	-1.5%
Research Centers	\$2,731	\$2,771	\$2,834	+2.3%
Other Research Grants	\$1,636	\$1,656	\$1,677	+1.3%
Research Training	\$756	\$761	\$760	-0.1%
R&D Contracts	\$2,641	\$2,700	\$2,744	+1.6%
Intramural Research	\$2,756	\$2,768	\$2,759	-0.3%
Res. Management & Support	\$1,079	\$1,092	\$1,106	+1.3%
All Other ^a	\$1,570	\$1,484	\$1,584	+6.7%
Total, NIH Program Level	\$28,653	\$28,587	\$28,587	0.0%
# new/competing renewal RPGs	9,599	9,062	9,337	+275 grants
# noncompeting RPGs	27,385	27,385	26,468	-917 grants
# small business grants	1,924	1,880	1,866	-14 grants
Total # of RPGs	38,908	38,327	37,671	-656 grants

Source: NIH: *Summary of the FY2007 President’s Budget*, February 6, 2006, p. 10.
[<http://officeofbudget.od.nih.gov/pdf/Press%20info%20final.pdf>]

a. “All Other” includes Cancer Prevention and Control, Extramural Construction, NLM, OD, Buildings and Facilities, Superfund, and NLM Program Evaluation.

Figure 3. FY2007 NIH Budget Request by Funding Mechanism

Source: Adapted from *NIH: Summary of the FY2007 President's Budget*, February 6, 2006, p. 6 [<http://officeofbudget.od.nih.gov/pdf/Press%20info%20final.pdf>].

Issues for Congress

Congress has devoted considerable attention to NIH for decades, spurred by constituents who have voiced 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 fired the public's imagination, generating much hope and anticipation of further advances. More recently, however, budgetary realities and various issues facing the research enterprise are challenging NIH and Congress to rethink some approaches to NIH's traditional mission. Congress is confronting those challenges in the three spheres of appropriations, authorizations, and oversight.

Appropriations: Budgeting within Constraints

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 inflationary 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.

Setting Research Priorities. Some people feel that the main role of the Congress in regard to NIH should be to provide money with as few strings attached as possible. They favor trusting the creativity of investigator-initiated research and the NIH priority-setting process (to the extent that “good science” is driving research priorities), with funding targeted toward the maximum exploitation of scientific opportunity, as defined by the peer review system. They object to influences that skew research priorities in directions they would judge not scientifically sound. In support of that general philosophy, appropriators have traditionally tried to minimize congressional micromanagement of NIH’s budget, and have avoided specifying dollar amounts for particular fields of research or mechanisms of funding below the level of the Institute and Center accounts.

At the same time, it is recognized that both Congress and NIH do weigh numerous other factors when they make priority-setting decisions. NIH has laid out its considerations and processes for setting research priorities in a document on its website.¹⁶ Of paramount importance are judgments about public health needs, which may reflect, for example, information on the health and/or economic burdens posed by particular diseases, the populations affected, and the degree of threat to the general public. Another factor may be the potential applicability of research on one medical condition to broader, related fields.

¹⁶ NIH, “Setting Research Priorities at the National Institutes of Health” [<http://www.nih.gov/about/researchpriorities.htm>].

Advocacy Groups. In Congress, the annual appropriations process has always been a magnet for those seeking to bolster funding for biomedical research generally or to influence research priorities in favor of some disease or field of science. Every congressional district includes multiple parties with an interest in NIH. Patient advocacy organizations, sometimes termed “disease lobby groups,” are active in sending information to their members by mail and over the Internet. Advocacy groups have become more organized, and more demanding of a role in setting research priorities. They educate their contacts and the interested public about the latest developments in research and new therapies in their disease area. They frequently track federal and state legislation pertaining to health research and health care, and urge their members to contact their representatives for action in their areas of interest, including support of funding for NIH. Appropriators often use report language directing NIH to pay more attention to research on particular diseases as a way of responding to the public’s requests.

Scientists working at universities and research institutions are also urged by their professional organizations to contact Congress in support of more funding for biomedical research and for federal science agencies generally. Their message is that many advances against disease can be traced back to NIH-funded research, and that continued improvements in human health require continued commitment to NIH. As an example, the Federation of American Societies for Experimental Biology (FASEB) recently provided its members with a slide presentation that they could customize with information from their own institutions.¹⁷

Scarce Resources. Congress’s flexibility in helping NIH respond to scientific opportunity and public health needs has been severely reduced since FY2004. The prior five years, when Congress provided for the doubling of the NIH budget, coincided with a time of economic expansion and federal budget surpluses. More recent years, on the other hand, have been characterized by a return to federal deficits and new commitments to spending on defense and homeland security. The result has been a tightening of funds available for domestic discretionary programs. Caps on spending in recent 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. NIH’s budget shifted from annual increases of around 6% to 7% before FY1999 to twice that (around 14% to 15%) during the doubling to between 0% and 3% since FY2003, levels below the rate of inflation. As demonstrated in **Figure 2**, above, if the amount proposed in the President’s FY2007 request were accepted by Congress, NIH would have 8.7% less purchasing power in 2006 dollars than in FY2003.

The extra resources provided during the doubling period allowed the number of new grants to be increased (though not doubled), the average dollar size of grants to go up to cover the needs of more sophisticated research projects, and research institutions, especially universities, to expand their research faculties and create more laboratory space. Such increases tend to drive the need for yet more resources in the future. It seems not to have been anticipated in some quarters that the NIH budget

¹⁷ Federation of American Societies for Experimental Biology, “FASEB Launches Grassroots Campaign for NIH, ‘Supporting Medical Research in Concept Is Not Enough,’” *FASEB News*, Aug. 9, 2006 [<http://opa.faseb.org/pdf/PowerpointLaunch8.9.06.pdf>].

increases might change so dramatically after the doubling. The research community had hoped for a “softer landing” after the doubling, with increases of perhaps 8% to 10% per year to maintain the momentum of their work. Recent NIH appropriations that have grown less than the rate of inflation have strained certain areas of the biomedical research enterprise, particularly investigator-initiated research.

Success Rates. A key marker for the research community of the adequacy of NIH grant funding is the “success rate” of research project grant applications, that is, the proportion of competing RPG applications that receive funding. NIH expects that under the FY2007 request, the success rate would be about 19%, the same as in FY2006, compared with 22% in FY2005. During the doubling years, the success rate averaged 30% to 32%.¹⁸ Changes in the success rate can be driven by changes in either the numerator (number of applications funded) or the denominator (number of applications reviewed). The rate has dropped in some years even when the number of competing awards increased, because the number of applications soared even more. The increase in the number of applications received in the two years following the doubling (FY2004 and FY2005) exceeded the increase of the previous four years, at a time when the number of competing awards was dropping.¹⁹ In other words, in those years, more and more applicants were chasing fewer and fewer awards. Projections for FY2006 and FY2007 are similar. The increase in applications stems from both the expanded research capacity at many academic medical centers and the increase in the number of applications submitted per applicant, as researchers try more than one route to obtain funding.

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. In January 2006, NIH announced a new “Pathway to Independence” program that increases support of young investigators in order to address the ever-lengthening time that it has been taking them to get their first grants. The new program will support promising postdoctoral scientists through five-year awards that will have a two-year mentored phase and a three-year independent phase.²⁰ NIH planned to support 150 to 200 awards beginning in fall 2006, and a similar number in each of the following five years, for a total commitment of almost \$400 million.

¹⁸ NIH, *Justification of Estimates for Appropriations Committees, FY2007, Vol. I, Overview*, table on “Research Project Grants: Success Rates, FY1998-FY2007,” p. NIH-87 [<http://officeofbudget.od.nih.gov/FY07/Tabular%20Data.pdf>].

¹⁹ NIH, Office of Extramural Research, “Success Rates by Institute” (data available for FY1970-FY2005) [http://grants1.nih.gov/grants/award/success/Success_ByIC.cfm].

²⁰ See [http://grants2.nih.gov/grants/new_investigators/pathway_independence.htm] for information on the new award, and [http://grants2.nih.gov/grants/new_investigators] for general information on NIH’s New Investigators Program.

Research Restrictions. Also generating uncertainty for some researchers are congressional and/or administrative restrictions on types of research funded. The major recent examples are controls on federal funding of research on human embryonic stem cells, and congressional concerns over grant awards in certain areas of behavioral research.

During more than 25 years of debate on the science and ethics of stem cell research, scientists have been able to get federal funding for only a limited number of avenues of basic research, despite what many experts feel are promising long-term prospects for advances against debilitating diseases. Current restrictions on funding of embryonic stem cell research involve both congressional limits in appropriations laws and an administration policy announced by President Bush in August 2001. Some scientists who want to work with a wide range of stem cells have sought support from private funding or from several new state research initiatives. For further information, see the following CRS Reports by Judith A. Johnson and Erin D. Williams: RL33540 (*Stem Cell Research: Federal Research Funding and Oversight*), RL33554 (*Stem Cell Research: Ethical Issues*), and RL33524 (*Stem Cell Research: State Initiatives*).

The research community is also troubled by congressional attempts to cancel funding for specific existing peer-reviewed grants.²¹ The targeted studies tend 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. In the House L-HHS-ED bill for FY2006 (H.R. 3010, §525), funding for two grants from the National Institute of Mental Health was canceled; the conferees on the appropriations bill, however, did not accept the provision (H.Rept. 109-337, p. 120).²²

New Approaches? While advocates warn that tight budgets will slow research advances on the major chronic conditions that burden American society, other commentators advise that coping with the reality of budget constraints will require NIH and the research community to rethink some of their traditional approaches to planning and organizing research. As NIH Director Dr. Elias Zerhouni has noted, “As science grows more complex, it is also converging on a set of unifying principles that link apparently disparate diseases through common biological pathways and therapeutic approaches. Today, NIH research needs to reflect this new reality.”²³ Scientific leaders in and out of NIH urge critical examination of the best ways to transform knowledge into medical applications and allocate resources into the most critical priorities to maximize return on the public’s investment.

²¹ Jocelyn Kaiser, “House ‘Peer Review’ Kills Two NIH Grants,” *Science*, vol. 309 (July 1, 2005), pp. 29-31; Shirley Haley, “Amendment to Defund Current NIH Mental Health Grants Added to House Labor-HHS Spending Measure,” *Research Policy Alert*, June 28, 2005.

²² For debate and inserted statements on the amendment that mandated the defunding of the grants, see *Congressional Record*, daily edition, vol. 151, no. 86 (June 24, 2005), pp. H5136-H5139.

²³ Elias Zerhouni, “The NIH Roadmap,” *Science*, vol. 302 (Oct 3, 2003), pp. 63-64, 72.

Authorizations: Structure and Program Direction

Organizational Complexity. A key element of such rethinking is consideration of NIH'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, with loose coordination 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 5**), each with its own mission, budget, staff, review office, and other bureaucratic apparatus. Many have wondered whether the agency has become too fragmented to be manageable, and whether NIH is able to respond appropriately to new scientific and public health challenges. Some have suggested consolidating the ICs into a smaller number of units encompassing broad areas of science.²⁴ Others have warned that such a move could prove politically unfeasible because of the loyalties of the constituencies of the individual ICs, and might result in a net loss of congressional and public support. Further, although NIH wishes to emphasize a culture of inter-disciplinary teamwork, many observers fear that the present structure of multiple independently operated institutes may undermine important initiatives in cross-disciplinary research, especially in fields such as the neurosciences.

The National Academies Study and Recommendations. As part of the FY2001 appropriation, Congress directed NIH to have the National Academy of Sciences study "whether the current structure and organization of NIH are optimally configured for the scientific needs of the Twenty-first Century" (S. Rept. 106-293, p. 179). The National Research Council (NRC) and the Institute of Medicine (IOM) of the National Academies formed a Committee on the Organizational Structure of the National Institutes of Health. The committee spent a year soliciting and assessing the views of the basic science, clinical medicine, and health advocacy communities, together with those of management experts and many current and former NIH leaders. It released its recommendations in a 2003 report, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*.²⁵

The committee did not think that wholesale consolidation of institutes and centers was the most useful approach to ensuring NIH's ability to meet future challenges. It did suggest a few possible consolidations, but said that those and any other proposals for increasing or decreasing the number of ICs or OD program offices should be subject to a public process for evaluating the scientific needs, consequences, available resources, and level of public support for the proposed changes. It strongly recommended mergers of some clinical research components of the extramural and intramural research programs to improve leadership, funding, and management of the NIH clinical research enterprise.

²⁴ Harold Varmus, "Proliferation of National Institutes of Health," *Science*, vol. 291 (Mar. 9, 2001), pp. 1903-1905.

²⁵ 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>].

The committee recommended that Congress strengthen the role of the NIH Director in strategic planning and budgeting for innovative, trans-NIH research. Referring to “vast changes in the landscape of science and the nation’s health concerns during the last half century,” the committee report noted in its executive summary the increasingly complex environment in which scientists operate: “In science, the importance of multi-institutional, multidisciplinary research that relies more and more on large infrastructural investments is ever more apparent.” At NIH, such crosscutting issues and initiatives go beyond the purviews of individual ICs. The committee felt that more initiatives were needed and that they would require more centralized leadership and budgeting. It recommended that the NIH Director present such trans-NIH initiatives to Congress, with proposed funding amounting to 5% of the NIH budget in the first year, and more in subsequent years. It also recommended that additional staff, budget, and reprogramming authority be provided for OD operations in managing its new responsibilities, and that funding for research management and support in all of NIH’s units be increased.

Other recommendations in the committee’s report addressed the need for more highly innovative, high-risk research projects with potentially great payoffs, both in extramural grants and in the intramural research program. It recommended that Congress create a Director’s Special Projects Program to fund such research, with a sustained commitment starting at \$100 million per year and growing to as much as \$1 billion per year. To enhance public accountability and transparency, the committee said that NIH should improve its data systems for tracking and reporting spending by areas of research. It faulted current information management systems and the lack of standardized coding across the ICs, and said that NIH should improve its reporting and analysis of research accomplishments of scientists trained and supported with NIH funds. A particular problem involves the question of how to count research that is related but not directly applicable to a specific topic. (Currently, NIH’s estimates of its funding for specific diseases and conditions may be found at [<http://www.nih.gov/news/fundingresearchareas.htm>].) Some final recommendations by the committee were to have more rigorous and frequent review of the performance of top NIH and IC leadership, including the possibility of term limits; that Congress reassess the special status of the National Cancer Institute in regard to appointments and budget authority; and that the advisory council system be reformed so that councils are more independent, protected from political influences, and more involved in priority setting and planning.

NIH Initiatives. In the past few years, under the leadership of current NIH Director Dr. Elias A. Zerhouni and with the concurrence of the appropriations committees, NIH has undertaken several new initiatives and organizational changes that address many of the issues highlighted by the NRC/IOM report.

NIH Roadmap. In September 2003, Dr. Zerhouni announced a series of initiatives known collectively as the NIH Roadmap for Medical Research [<http://nihroadmap.nih.gov>].²⁶ The Roadmap had been developed over the previous year and a half as a comprehensive plan to identify and address the major scientific opportunities and gaps in medical research that no single institute or center at NIH could tackle alone. NIH held meetings attended by more than 300 leaders in

²⁶ NIH, Office of the Director, “NIH Announces Strategy to Accelerate Medical Research Progress,” press release, Sept. 30, 2003 [<http://www.nih.gov/news/pr/sep2003/od-30.htm>].

academia, industry, government, and the public who had been invited to discuss today's most compelling scientific challenges and the most important knowledge gaps ("roadblocks") they felt were constraining rapid progress in research and its application to useful prevention, diagnostic, and treatment strategies. NIH leaders further refined the ideas and developed proposed initiatives and implementation plans. They ultimately identified 28 trans-NIH priorities and initiatives, grouped into three main themes.

The first theme, "New Pathways to Discovery," addresses the "daunting complexity of biological systems" and the need to know much more about networks of molecules and their interactions, together with the need to develop new technologies, databases, and other scientific "tools" to pursue research at the cellular and molecular level. Examples of resources to be established include libraries of chemical molecules, imaging probes, nanotechnology devices, and enhanced computational capability.

The second theme, "Research Teams of the Future," addresses collaborative team efforts in interdisciplinary research, high-risk research, and public-private partnerships. Modern biomedical science represents the convergence of biological, physical, and information sciences, and NIH wants to encourage investigators to break out of their traditional disciplines and take on new approaches. One new funding possibility for highly innovative researchers is the NIH Director's Pioneer Award [<http://nihroadmap.nih.gov/pioneer>], which seeks to support investigators who will "take on creative, unexplored avenues of research that carry a relatively high potential for failure, but also possess a greater chance for truly groundbreaking discoveries."²⁷

The third theme is "Re-engineering the Clinical Research Enterprise." NIH characterizes this as "undoubtedly the most challenging, but critically important, area identified through the NIH roadmap process."²⁸ Translating the findings of laboratory research into products and practices that improve people's health is the job of clinical researchers, and is the ultimate goal of performing fundamental research. Traditional methods of conducting clinical studies, however, are slow, complex, costly, and tend to be limited in the number of patients they can involve. To more quickly develop, test, and deliver new interventions, researchers could work in closer proximity to patients. The revamped clinical research enterprise will need integrated networks of academic centers linked to community-based health care providers and organized patient communities. It will also require new ways of handling information, developing research protocols, assessing clinical outcomes, harmonizing regulations, and training more people for the clinical research workforce. In 2005, NIH launched a new Clinical and Translational Science Awards (CTSA) program.²⁹ Administered by NIH's National Center for Research Resources, the program has been developed to foster transdisciplinary clinical research and training, with the goal of speeding the translation of the findings of "discovery" research into clinical practice.

²⁷ Ibid.

²⁸ NIH, Office of Portfolio Analysis and Strategic Initiatives, "Overview of the NIH Roadmap" [<http://nihroadmap.nih.gov/overview.asp>].

²⁹ NIH, National Center for Research Resources, "Clinical and Translational Science Awards" [<http://www.ncrr.nih.gov/clinicaldiscipline.asp>].

Roadmap initiatives are funded by a set-aside from the budgets of all the institutes and centers and from appropriations to the OD Director's Discretionary Fund. Congressional appropriators have approved the funneling of this money into a "Common Fund" for shared needs. As shown in **Table 4**, the amounts have increased each year, with the proposed contribution from each IC being 1.2% in FY2007, for a total Roadmap funding level that equals about 1.6% of the NIH budget.

Table 4. Funding for NIH Roadmap Initiatives
(dollars in millions)

	Roadmap Total	Office of Director Contribution	Institute/Center Contribution	Roadmap % of IC Budgets	Roadmap % of Total NIH Budget
FY2005	\$239.7	\$64.0	\$175.7	0.6%	0.8%
FY2006	\$329.5	\$82.2	\$247.3	0.9%	1.2%
FY2007	\$442.7	\$110.7	\$332.0	1.2%	1.6%

Source: NIH, *Justification of Estimates for Appropriations Committees, FY2007, Vol. I, Overview*, "Roadmap Contributions by Institute and Center," p. NIH-77 [<http://officeofbudget.od.nih.gov/FY07/Tabular%20Data.pdf>].

OPASI, a New Home for Trans-NIH Initiatives. Besides the Roadmap for Medical Research, NIH has organized other interdisciplinary, trans-institute initiatives in recent years, such as the Strategic Plan for Obesity Research, started in FY2005, and the Neurosciences Blueprint, commenced in FY2006. The Blueprint pools resources among 15 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. In September 2005, NIH established a new office within the Office of the Director to "identify and integrate information to support the planning and implementation of trans-NIH initiatives."³⁰ Called the Office of Portfolio Analysis and Strategic Initiatives (OPASI) [<http://opasi.nih.gov>], it is meant to give the agency "more transparent processes and cutting-edge tools to analyze, assess, and manage the array of research it supports, and provide better information to support planning and priority-setting in areas of shared Institute and Center interest."³¹ It is hoped that the office will achieve a "functional integration" of NIH (without the need for structural reorganization) by bringing together diverse components of the agency in pursuit of common scientific purposes. NIH leaders feel that the effectiveness of the Roadmap approach promises that OPASI will offer further "flexibility and nimbleness" in finding and funding cutting-edge research.³²

³⁰ HHS, NIH, "Statement of Organization, Functions, and Delegations of Authority," 70 *Federal Register* 56730, Sept. 28, 2005.

³¹ NIH, *Justification of Estimates for Appropriations Committees, FY2007, Vol. I, Overview*, p. NIH-56 [<http://officeofbudget.od.nih.gov/FY07/Narrative%20by%20Activity.pdf>].

³² Carla Garnett, "New NIH Portfolio Analysis Office To Provide 'Incubator Space' for Novel Ideas," *NIH Record*, vol. 62, no. 25 (Dec. 16, 2005), pp. 1, 6-7 [http://www.nih.gov/nihrecord/12_16_2005/story01.htm].

Two of the new OPASI divisions focus on (1) resource development (such as databases) and assessments to support priority setting among scientific areas and research portfolio analysis and management (for example, to improve the coding of disease-specific resources); and (2) program evaluations, both IC-specific and trans-NIH, and systematic assessments such as those required by the Government Performance and Results Act (GPRA) and the OMB Program Assessment Rating Tool (PART) — all in order to inform evaluation of the NIH research agenda and decisions about NIH-wide resource allocations. The third division, the Division of Strategic Coordination, manages the current trans-NIH initiatives, including the Roadmap, and coordinates the decision-making processes that lead to formulation of new trans-NIH strategic initiatives. OPASI does not have grant-making authority, but it manages the Common Fund monies to support time-limited (five to 10 years) priority projects that are administered by the ICs. Initiatives will be reviewed frequently for continuation, transfer to an IC, or completion, with no initiative to remain in OPASI more than 10 years. The budget for the Common Fund is planned to grow to 1.7% of the total NIH budget in FY2008, but will not go beyond that percentage unless the annual NIH appropriation grows by more than the inflation rate for biomedical research.³³

Congressional Activities on NIH Reauthorization (H.R. 6164). 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). Over the years 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. Systematic change to these authorities has 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 have not been updated. (The programs continue under NIH's general authority to conduct and sponsor research.) A number of additional laws enacted since 1993 have addressed particular areas of research; most of these authorities have also expired.³⁴ While Congress has rearranged the provisions of Title IV and added new program authorizations and reporting requirements, it has never initiated a major restructuring of the agency's organization, aside from the addition of institutes, centers, and offices.

The recommendations of the 2003 NRC/IOM report reawakened congressional interest in using the reauthorization process to improve NIH management and operations. The House Committee on Energy and Commerce, which had already

³³ Information for this paragraph was taken from an August 2006 "Fact Sheet" on OPASI, available at [http://opasi.nih.gov/documents/OPASI_FactSheet_Aug06.pdf].

³⁴ 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, 2005-2006*, at [<http://www.nih.gov/about/almanac/about.htm>], includes a comprehensive chronology of NIH-related legislation. 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 [<http://www.cbo.gov/publications/bysubject.cfm?cat=6>].

held a series of hearings on NIH and research-related issues, circulated a draft bill for discussion and held a hearing in July 2005, taking testimony from the NIH Director.³⁵ The disparate stakeholders of the medical research community, including those in academia, government, industry, the nonprofit sector, patient advocacy groups, and the general public, had opportunities during the following year to provide comments and reactions to the proposal, which resulted in changes in a number of provisions in the draft bill. On September 19, 2006, the committee held a legislative hearing on the third draft of the “National Institutes of Health Reform Act of 2006,” during which representatives of major stakeholder organizations expressed their support for the revised legislation.³⁶ An amended version of the draft was approved by the committee in a markup session the next day. The bill, H.R. 6164 (H.Rept. 109-687), was introduced by Chairman Barton on September 25, 2006, and was passed by the House under suspension of the rules on September 26, 2006, by a vote of 414-2.

The bill proposes managerial and organizational changes for NIH, with a focus on enhancing the authority and tools available to the NIH Director’s Office to do strategic planning, and especially to facilitate and fund transdisciplinary, cross-institute research initiatives. It contains no provisions relating to specific diseases or fields of research, and does not eliminate or consolidate any existing ICs.

The bill establishes a Division of Program Coordination, Planning, and Strategic Initiatives within the Office of the Director. The Division is similar to NIH’s OPASI (described in the previous section), except that the individual program offices in OD would be housed in the Division (such offices coordinate research on AIDS, women’s health, behavioral and social sciences, disease prevention, dietary supplements, and rare diseases). While not superseding the planning and priority-setting responsibilities of the individual institutes and centers, the bill charges the Director with overall program coordination of the entire research portfolio of NIH. It creates a comprehensive electronic reporting system to catalogue research activities from all of the ICs in a standardized format. Information from the tracking system is intended to assist the Director and the Division in planning trans-NIH research initiatives that cannot be handled within individual ICs.

Building on the approach of the NIH Roadmap, such trans-NIH initiatives would be funded through a reserve account called the “Common Fund.” In any year in which the total NIH appropriation is greater than that of the previous year, the Common Fund is authorized to receive half of the increase until the Fund reaches 5% of the total NIH budget. The funding base would be the FY2006 total for trans-NIH initiatives. Proposals for trans-NIH research would be reviewed by a new advisory body, the “Council of Councils,” composed of representatives from the IC advisory councils. Proposals from investigators who are first-time applicants are to be given

³⁵ 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). For links to Energy and Commerce hearings (archived webcasts and printed transcripts), see [<http://energycommerce.house.gov/108/action.htm>].

³⁶ 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., Sept. 19, 2006. The archived webcast and testimony of the witnesses are available at [<http://energycommerce.house.gov/108/Hearings/09192006hearing2031/hearing.htm>].

“appropriate consideration,” and NIH’s traditional emphasis on peer-reviewed, investigator-initiated research is to be maintained.

The bill creates a “Scientific Management Review Board” charged with formally and publicly reviewing NIH’s organizational structure within 18 months of enactment, and at least once every seven years thereafter. The board may recommend restructuring, including the creation of new institutes, but the number of ICs is capped at the current 27. The bill sets out time frames for the Director to take action on such recommendations, including notice to Congress. Actual authority to reorganize ICs and the offices in OD resides with the Director, subject to approval by the Secretary.

The measure authorizes total funding levels for NIH, although not for the individual ICs, for FY2007-FY2009. This is the first time the PHS Act has specified a ceiling for overall NIH funding. From an FY2006 baseline of \$28.33 billion, funding increases 5% per year to \$29.75 billion for FY2007, \$31.24 billion for FY2008, and \$32.80 billion for FY2009. Within those amounts, appropriations are authorized for the Office of the Director at \$1.0 billion, \$1.05 billion, and \$1.1 billion for FY2007-FY2009, respectively. The bill eliminates a number of statutory authorizations of appropriations for specific programs (including those for several institutes), but does not change NIH’s authority to run the programs.

The bill 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. All other duplicative reporting requirements are eliminated. The bill adds new reporting requirements on clinical trials, human tissue storing and tracking, whistleblower complaints, and special consultant hires (all of those issues have been the subject of investigations by the committee in the past few years). Two demonstration programs are 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.

In the September 2006 hearing and markup session, some Members questioned provisions of the bill or offered amendments. A number of Members voiced unhappiness with the recent lack of growth in the NIH budget and the effect on IC research portfolios. Some thought the authorization levels in the bill should be set to grow at more than 5% per year, or should reflect the BRDPI (inflation) rate plus a growth factor, or should provide for growth in the IC budgets before funds are diverted to the Common Fund. Some objected to giving the Director authority to abolish institutes and centers that Congress had created. Some questioned the detailed reporting requirements on disease research, wondering whether the requirements would unduly burden NIH, or whether they might lead to deemphasizing basic research in favor of research with more tangible benefits. Several Members spoke about the nation’s problems with disparities in health and access to health care, especially among minorities, and expressed a desire that the bill addressed the issue more directly. An amendment to expand research on links between breast cancer and environmental factors was rejected.

Oversight: Maintaining Trust and Transparency

The same committees and subcommittees that handle authorizations and appropriations for NIH have also engaged in oversight activities as specific issues or problems have arisen. Two ongoing matters are discussed below.

Ethics Regulations for NIH Employees Regarding Conflicts of Interest. 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.³⁷ 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. Nonetheless, NIH Director Elias Zerhouni wrote to senior NIH staff in November 2003:

Recently Congress and the media have been scrutinizing the implementation of ethics rules at the NIH. They are reviewing a wide range of activities that are allowed under Federal regulations, including lecture awards, outside activities, consultant arrangements, and financial holdings. Care must be taken to ensure that we continue to adhere to strict ethical practices and that we avoid the perception of conflicts of interest, even in situations where remuneration or awards are considered permissible.³⁸

More studies and hearings on ethics policies, and investigations of individual cases, both by NIH and by Congress, ensued during 2004 and 2005.³⁹ 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.⁴⁰ Published as an interim final rule with a request for comments, the regulation strictly 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.

³⁷ 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*, Dec. 7, 2003, p. A1.

³⁸ Elias A. Zerhouni, “Awards, Travel, and Official Duty and Outside Activity Approvals,” memo to IC Directors and OD Senior Staff, Nov. 20, 2003 [<http://www.nih.gov/news/pr/nov2003/11202003drzerhounimemo.pdf>].

³⁹ 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].

⁴⁰ 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* 5543-5565, Feb. 3, 2005.

The final revised regulation, published in August 2005, covered reporting of certain financial interests, stock divestiture, outside activities, and awards.⁴¹ 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.⁴²

Implementation of the rules has largely quelled concern over new infractions. Controversy persists, however, over two intramural scientists who violated NIH's previous ethics rules by engaging in questionable consulting activities with outside parties without obtaining permission. One of the scientists also transferred human tissue samples from NIH to a private company without seeking approval (which, NIH says, would not have been granted). NIH has recommended terminating the two scientists from their positions, but does not have final personnel authority over them because they are officers in the Public Health Service Commissioned Corps. Action on the matter has been stalled at the HHS level far longer than anyone involved had anticipated, and the two men remain employed at NIH. The House Energy and Commerce Committee held hearings in June⁴³ and September⁴⁴ 2006 to investigate the status of proceedings in the two cases.

Public Access to Results of NIH-Sponsored Research. The Internet has given the general public unprecedented access to health and medical information. In fact, so much is available that consumers have had to learn to be discriminating about the reliability of what they retrieve. NIH tries to assist in this filtering effort by providing information, links, and search capability on many of its websites, all with the intent of helping people find information from accurate, current sources. A well-regarded starting point is MedlinePlus [<http://www.medlineplus.gov>], the consumer health site from the National Library of Medicine (NLM).

⁴¹ 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, Aug. 31, 2005.

⁴² NIH Office of the Director, "NIH Announces Final Ethics Rules," press release, Aug. 25, 2005 [<http://www.nih.gov/news/pr/aug2005/od-25.htm>].

⁴³ U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Human Tissue Samples: NIH Research Policies and Practices*, hearings, 109th Cong., 2nd sess., June 13-14, 2006. Archived webcasts and witness testimony available at [<http://energycommerce.house.gov/108/action.htm#June2006>].

⁴⁴ U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Continuing Ethics and Management Concerns at NIH and the Public Health Service Commissioned Corps*, hearing, 109th Cong., 2nd sess., Sept. 13, 2006. The archived webcast and testimony of the witnesses are available at [<http://energycommerce.house.gov/108/Hearings/09132006hearing2020/hearing.htm>].

Access to the professional literature of medicine and biomedical research remains limited, however. In the case of journal articles that stem from NIH-sponsored research, there is growing sentiment that taxpayers should have easy access to the results of that research. The public can search for journal articles on NLM's MEDLINE/PubMed database [<http://www.pubmed.gov>] and retrieve references from more than 16 million articles published in 4,800 biomedical journals dating back to the 1950s. Although the citation and an abstract are usually available, only occasionally will there be a link to the full article. Most often, the link leads to a publisher's website where a subscription to the journal is required for access to full-text articles. The alternative for most people is to visit a university, medical school, or hospital library to consult the hard-copy journals.

For several years, NLM has been building up a digital repository of full-text, peer-reviewed biomedical, behavioral, and clinical research journals called PubMed Central (PMC) [<http://www.pubmedcentral.gov>]. The aim is to have a publicly accessible, stable, permanent, and searchable electronic archive of life science literature, one separate from publishers' databases. A large number of journals already routinely deposit material in PMC, and generally make all of their published articles available. Many scientists with NIH grants, however, may publish the results of their research in journals that do not contribute articles to PMC.

In February 2005, NIH announced a new Public Access Policy [<http://publicaccess.nih.gov>], formally called the Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research.⁴⁵ The policy requests each NIH-funded investigator to submit an electronic version of a final, peer-reviewed manuscript to NLM's existing PubMed Central database at the time the article is accepted for publication in a journal. NIH encourages authors to make manuscripts available to other researchers and the public immediately after they have been published, but the policy allows a delay in releasing articles of up to 12 months.

NIH listed the following three goals on its website as an answer to the question, "Why should there be a public resource of published peer-reviewed research findings of NIH-funded research?":

- creating a stable archive of peer-reviewed research publications resulting from NIH-funded research to ensure the permanent preservation of these vital published research findings;
- securing a searchable compendium of these peer-reviewed research publications that the NIH and its awardees can use to manage more efficiently and to understand better their research portfolios, monitor scientific productivity, and ultimately, help set research priorities; and
- making published results of NIH-funded research more readily accessible to the public, health care providers, educators, and scientists.⁴⁶

⁴⁵ "Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research," *NIH Guide for Grants and Contracts*, Feb. 3, 2005, available at [<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html>].

⁴⁶ NIH Office of Extramural Research, "Questions and Answers: NIH Public Access (continued...)"

NIH implemented the policy in May 2005, when it activated a manuscript submission system for authors to deposit articles. Participation is voluntary, in deference to publishers' concerns about the loss of their proprietary content, and so far has been very low. NIH reported to the Appropriations Committees in January 2006 that, for the first eight months, the rate of submission to the system had been less than 4% of the total number of articles estimated to be eligible (1,636 new articles submitted out of an estimated 43,000 that could have been deposited).⁴⁷ In looking into reasons for the low submission rate, NIH said that its surveys indicate that the majority of NIH-funded scientists are aware of the Policy. It concluded the report by observing, "NIH continues to work with researchers, journal publishers, scientific societies, librarians, disease advocacy organizations and the general public to improve public access."⁴⁸

There have been calls to make the submission of manuscripts mandatory. The pending House Labor-HHS-ED Appropriations bill (H.R. 5647) includes a provision (§ 220) that states, "The Director of the National Institutes of Health (NIH) shall require that all investigators funded by the NIH submit an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication to the NIH National Library of Medicine's PubMed Central as soon as practicable but no later than 12 months after the official date of publication." The Senate Labor-HHS-ED Appropriations bill (S. 3708) has no similar provision. Both committees included report language commending NLM for developing PubMed Central. They encouraged NLM to work with health sciences librarians and the medical library community on issues related to copyright, fair use, peer review, and classification of information on PubMed Central.

A bill to require similar archiving and public access policies at other federal science agencies was introduced in May 2006, but has had no action. The Federal Research Public Access Act of 2006 (S. 2695) would require every federal agency with an extramural research budget of more than \$100 million to develop a public access policy that is consistent with and advances the purposes of the agency.

⁴⁶ (...continued)

Policy," February 24, 2005 [http://publicaccess.nih.gov/publicaccess_QandA.htm].

⁴⁷ NIH, "Report on the NIH Public Access Policy," January 2006, available at [http://publicaccess.nih.gov/Final_Report_20060201.pdf].

⁴⁸ *Ibid.*, p. 6.

Selected NIH Online Resources

NIH Home Page [<http://www.nih.gov>].

- health information [<http://health.nih.gov>];
- websites of the Office of the Director and each Institute and Center [<http://www.nih.gov/icd>];
- general information on grants [<http://grants1.nih.gov/grants>];
- grants searchable by topic [http://crisp.cit.nih.gov/crisp/crisp_query_generate_screen];
- grants searchable by recipient [<http://grants1.nih.gov/grants/award/awardtr.htm>];
- overview of the peer review system [<http://grants.nih.gov/grants/peer/peer.htm>];
- *Setting Research Priorities at NIH* [<http://www.nih.gov/about/researchpriorities.htm>];
- background on NIH [<http://www.nih.gov/about>], including organization and historical and legislative chronologies in the *NIH Almanac* [<http://www.nih.gov/about/almanac/index.html>]; and
- current news and medical research issues pages.

NIH Budget [<http://officeofbudget.od.nih.gov/ui/HomePage.htm>].

- Presidents' budget requests;
- budget justification documents prepared for the Appropriations Committees;
- appropriations history;
- estimates of NIH spending (FY2003-FY2007) on about 210 specific diseases, conditions, and research areas (note that these are estimates of research activity, *not* set-asides by NIH or line items from Congress) [<http://www.nih.gov/news/fundingresearchareas.htm>]; and
- information on the Biomedical Research and Development Price Index (BRDPI) and other measures of inflation, including tables [http://officeofbudget.od.nih.gov/UI/GDP_FromGenBudget.htm].

Legislation Affecting NIH [<http://olpa.od.nih.gov>].

- The NIH Office of Legislative Policy and Analysis (OLPA) in the Office of the Director produces and compiles summaries of major legislative issues relevant to NIH, and tracks pending legislation, public laws, and hearings.
- OLPA serves as the congressional liaison office for NIH (301-496-3471).

Table 5. Components of NIH, with History and Scope

Institute/Center (Statutory Authority in Public Health Service Act and <i>U.S. Code</i>)	Acronym	When and How Established; Chronology of Name Changes	Major Research Focus	FY2006 revised program level (\$ millions) (details, Table 2)
National Cancer Institute PHSA § 410-417D, 42 U.S.C. § 285-285a-10	NCI	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.	\$4,790
National Heart, Lung, and Blood Institute PHSA § 415-425, 42 U.S.C. § 285b-285b-8	NHLBI	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.	\$2,920
National Institute of Dental and Craniofacial Research PHSA § 453, 42 U.S.C. § 285h	NIDCR	1948 — National Dental Research Act (P.L. 80-755): National Institute of Dental Research. 1998 — NIDCR.	Oral, dental, and craniofacial diseases and disorders.	\$389
National Institute of Diabetes and Digestive and Kidney Diseases PHSA § 426-434A, 42 U.S.C. § 285c-285c-9	NIDDK	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.	\$1,854

Institute/Center (Statutory Authority in Public Health Service Act and <i>U.S. Code</i>)	Acronym	When and How Established; Chronology of Name Changes	Major Research Focus	FY2006 revised program level (\$ millions) (details, Table 2)
National Institute of Neurological Disorders and Stroke PHSA § 457-460, 42 U.S.C. § 285j-285j-3	NINDS	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.	\$1,534
National Institute of Allergy and Infectious Diseases PHSA § 446-447B, 42 U.S.C. § 285f-285f-3	NIAID	1955 — established under authority of Omnibus Medical Research Act (P.L. 81-692).	Allergic, immunologic, and infectious diseases.	\$4,331
National Institute of General Medical Sciences PHSA § 461, 42 U.S.C. § 285k	NIGMS	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.	\$1,934

Institute/Center (Statutory Authority in Public Health Service Act and <i>U.S. Code</i>)	Acronym	When and How Established; Chronology of Name Changes	Major Research Focus	FY2006 revised program level (\$ millions) (details, Table 2)
National Institute of Child Health and Human Development PHS § 448-452G, 42 U.S.C. § 285g-285g-10	NICHD	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.	\$1,264
National Eye Institute PHS § 455-456, 42 U.S.C. § 285i-285i-1	NEI	1968 — National Eye Institute Establishment Act (P.L. 90-489) (functions formerly in the institute for neurological diseases and blindness).	Eye diseases, visual disorders, visual function, preservation of sight, health problems of the visually impaired.	\$666
National Institute of Environmental Health Sciences (located in Research Triangle Park, NC) PHS § 463-463A, 42 U.S.C. § 285l-285l-1	NIEHS	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.	\$720
National Institute on Aging PHS § 443-445J, 42 U.S.C. § 285e-285e-11	NIA	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.	\$1,046

Institute/Center (Statutory Authority in Public Health Service Act and <i>U.S. Code</i>)	Acronym	When and How Established; Chronology of Name Changes	Major Research Focus	FY2006 revised program level (\$ millions) (details, Table 2)
National Institute of Arthritis and Musculoskeletal and Skin Diseases PHSA § 435-442A, 42 U.S.C. § 285d-285d-8	NIAMS	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.	\$508
National Institute on Deafness and Other Communication Disorders PHSA § 464-464F, 42 U.S.C. § 285m-285m-6	NIDCD	1988 — National Deafness and Other Communication Disorders Act of 1988 (P.L. 100-553) (functions formerly in the institute for neurological and communicative disorders and stroke).	Disorders of hearing, balance, smell, taste, voice, speech, and language.	\$393
National Institute of Nursing Research PHSA § 464V-464Y, 42 U.S.C. § 285q-285q-3	NINR	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.	\$137

Institute/Center (Statutory Authority in Public Health Service Act and <i>U.S. Code</i>)	Acronym	When and How Established; Chronology of Name Changes	Major Research Focus	FY2006 revised program level (\$ millions) (details, Table 2)
National Institute on Alcohol Abuse and Alcoholism PHSA § 464H-464J, 42 U.S.C. § 285n-285n-2	NIAAA	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.	\$436
National Institute on Drug Abuse PHSA § 464L-464P, 42 U.S.C. § 285o-285o-4	NIDA	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.	\$999

Institute/Center (Statutory Authority in Public Health Service Act and <i>U.S. Code</i>)	Acronym	When and How Established; Chronology of Name Changes	Major Research Focus	FY2006 revised program level (\$ millions) (details, Table 2)
National Institute of Mental Health PHSA § 464R-464U, 42 U.S.C. § 285p-285p-3	NIMH	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.	\$1,403
National Human Genome Research Institute PHSA § 485B, 42 U.S.C. § 287c	NHGRI	1989 — National Center for Human Genome Research (NCHGR) established. 1993 — NCHGR authorized (P.L. 103-43). 1997 — elevated to institute by the HHS Secretary.	Chromosome mapping, DNA sequencing, database development, ethical/legal/social implications of genetics research.	\$486
National Institute of Biomedical Imaging and Bioengineering PHSA § 464z, 42 U.S.C. § 285r	NIBIB	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.	\$297

Institute/Center (Statutory Authority in Public Health Service Act and <i>U.S. Code</i>)	Acronym	When and How Established; Chronology of Name Changes	Major Research Focus	FY2006 revised program level (\$ millions) (details, Table 2)
National Center for Research Resources PHSA § 479-481C, 42 U.S.C. § 287-287a-4	NCRR	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.	\$1,098
National Center for Complementary and Alternative Medicine PHSA § 485D, 42 U.S.C. § 287c-21	NCCAM	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.	\$121
National Center on Minority Health and Health Disparities PHSA § 485E-485H, 42 U.S.C. § 287c-31-287c-34	NCMHD	1990 — Office of Research on Minority Health (ORMH) created by NIH in OD. 1993 — ORMH authorized (P.L. 103-43). 2000 — NCMHD created (P.L. 106-525).	Research, training, and coordination on minority health conditions and populations with health disparities.	\$195

Institute/Center (Statutory Authority in Public Health Service Act and <i>U.S. Code</i>)	Acronym	When and How Established; Chronology of Name Changes	Major Research Focus	FY2006 revised program level (\$ millions) (details, Table 2)
John E. Fogarty International Center for Advanced Study in the Health Sciences PHSA § 482, 42 U.S.C. § 287b	FIC	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.	\$66
National Library of Medicine PHSA § 465-478A, 42 U.S.C. § 286-286d	NLM	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.	\$323
Office of the Director PHSA § 402, 42 U.S.C. § 282	OD	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).	\$478
Buildings and Facilities PHSA § 402(b), 42 U.S.C. § 282(b)	B&F	First separate appropriation FY1970.	Provides for the design, construction, improvement, and repair of NIH clinical and laboratory buildings.	\$81

Institute/Center (Statutory Authority in Public Health Service Act and <i>U.S. Code</i>)	Acronym	When and How Established; Chronology of Name Changes	Major Research Focus	FY2006 revised program level (\$ millions) (details, Table 2)
Total for appropriated accounts				\$28,468
Centers not receiving a separate appropriation (funded by taps from appropriated accounts listed above)				
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.	(\$334)
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.	(\$54)
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.	(\$33)

Sources: *NIH Almanac, 2005-2006* [<http://www.nih.gov/about/almanac/index.html>]. Budget figures from S. Rept. 109-287, FY2007 Labor-HHS-ED appropriation, and NIH FY2007 Budget Justification, vol. I, p. 91.