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

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

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 $29.2 billion budget to support more than 300,000 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.

FY2003 was the final year of a five-year undertaking by Congress to double the NIH budget from its FY1998 base of $13.7 billion to the FY2003 level of $27.1 billion. Since then, the growth rate has fallen to below the rate of inflation. In FY2008, NIH funding was increased by 0.5% above FY2007. The President requested an essentially flat budget of $29.2 billion for NIH for FY2009, while the advocates in the research community recommended a 6.5% increase. The projected increase in the inflation index is 3.5% for both FY2008 and FY2009. In inflation-adjusted terms, the FY2008 funding level represents an estimated 11% decrease from FY2003, while the FY2009 request level would be 14% below FY2003. The request planned to support about the same number of grants as the FY2008 estimate. The success rate for competing grant applications getting funded would be an estimated 18%, compared with 25% in FY2004 and 30%-32% during the doubling years.

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. In December 2006, Congress passed the NIH Reform Act (P.L. 109-482), addressing many of these issues through changes to NIH authorities. Implementation of the law's provisions is under way on a number of fronts. Congress also monitors ethics rules on conflicts of interest and tracks the efficacy of procedures intended to make results of NIH-sponsored research publicly accessible. 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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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 FY2008, it has a total budget of $29.2 billion and total employment of more than 18,000 people. The President's FY2009 budget requested 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 human embryonic stem cells). Special interest surrounded the five-year doubling of the agency's budget between FY1999 and FY2003. Since then, during five years of low or no growth, Congress has increasingly scrutinized

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[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). For further information, see CRS Report RL34098, *Public Health Service (PHS) Agencies: Background and Funding*, by Pamela W. Smith et al.

how NIH has used its expanded resources, how it can most efficiently adapt to budgetary constraints, and how its 27 semi-autonomous institutes and centers can best coordinate their efforts in order to identify and respond nimbly to important public health challenges.

- At the end of the 109th Congress, the House and Senate agreed on the first NIH reauthorization statute enacted since 1993, the NIH Reform Act of 2006 (P.L. 109-482). For more than a dozen years, most policy changes had come in the appropriations arena or through agency initiatives under its broad research authority. Work by the authorizing committees (the House Committee on Energy and Commerce and Senate Committee on Health, Education, Labor, and Pensions) had led to passage of a number of laws focusing on individual diseases or other NIH-related topics, but no comprehensive consideration of the agency's structure and policies had been undertaken. In the fall of 2006, after many hearings and solicitation of comments and reactions from the disparate stakeholders of the medical research community, Congress passed H.R. 6164, which the President signed on January 15, 2007. The act focused 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 more quickly;
- congressional and/or administrative restrictions on types of research funded, particularly human embryonic stem cell 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 voluntary policy for submission of articles had little participation, so Congress made it mandatory.)

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 in considering authorization legislation and its implementation, and as it 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** and **Table 4**). The Office of the Director (OD) sets overall policy for NIH and coordinates the programs and activities of all NIH components, particularly trans-institute research initiatives and issues. The individual institutes and centers (ICs), each of which focuses on particular diseases, areas of human health and development, or aspects of research support, plan and manage their own research programs in coordination with 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 §300ii-4).[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 activities, functions, and responsibilities of the NIH Director and the institutes and centers. All of the institutes and centers are covered by specific provisions in the PHS Act. Prior to passage of the NIH Reform Act of 2006 (P.L. 109-482), nine of the ICs and a variety of individual programs had time-and-dollar limits on their authorizations of appropriations. Most of the authorizations had expired, but § 301 provided authority for the programs. The other institutes and centers and most NIH programs did not require periodic reauthorization by Congress, and there was no overall authorization for the agency. The NIH Reform Act authorized total funding levels for NIH

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[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, 2006-2007*, 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].

appropriations for FY2007 to FY2009, and eliminated all of the other specific authorizations in Title IV.

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 4**)

Component	Website	FY2008 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]	$1,109	3.8%
INSTITUTES			
National Cancer Institute (NCI)	[http://www.nci.nih.gov]	$4,805	16.5%
National Eye Institute (NEI)	[http://www.nei.nih.gov]	$667	2.3%
National Heart, Lung, and Blood Institute (NHLBI)	[http://www.nhlbi.nih.gov]	$2,922	10.0%
National Human Genome Research Institute (NHGRI)	[http://www.nhgri.nih.gov]	$487	1.7%
National Institute on Aging (NIA)	[http://www.nia.nih.gov]	$1,047	3.6%
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]	$4,266	14.6%
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)	[http://www.niams.nih.gov]	$509	1.7%
National Institute of Biomedical Imaging and Bioengineering (NIBIB)	[http://www.nibib.nih.gov]	$299	1.0%
National Institute of Child Health and Human Development (NICHD)	[http://www.nichd.nih.gov]	$1,255	4.3%
National Institute on Deafness and Other Communication Disorders (NIDCD)	[http://www.nidcd.nih.gov]	$394	1.4%
National Institute of Dental and Craniofacial Research (NIDCR)	[http://www.nidcr.nih.gov]	$390	1.3%
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)	[http://www.niddk.nih.gov]	$1,857	6.4%

Component	Website	FY2008 IC Budget (Program Level) & Percent of Total NIH Budget ($ in millions)	
National Institute on Drug Abuse (NIDA)	[http://www.nida.nih.gov]	$1,001	3.4%
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]	$1,936	6.6%
National Institute of Mental Health (NIMH)	[http://www.nimh.nih.gov]	$1,405	4.8%
National Institute of Neurological Disorders and Stroke (NINDS)	[http://www.ninds.nih.gov]	$1,544	5.3%
National Institute of Nursing Research (NINR)	[http://www.ninr.nih.gov]	$137	0.5%
National Library of Medicine (NLM)	[http://www.nlm.nih.gov]	$329	1.1%
CENTERS			
John E. Fogarty International Center (FIC)	[http://www.fic.nih.gov]	$67	0.2%
National Center for Complementary and Alternative Medicine (NCCAM)	[http://www.nccam.nih.gov]	$122	0.4%
National Center on Minority Health and Health Disparities (NCMHD)	[http://www.ncmhd.nih.gov]	$200	0.7%
National Center for Research Resources (NCRR)	[http://www.ncrr.nih.gov]	$1,149	3.9%
Center for Information Technology (CIT)	[http://www.cit.nih.gov]	($39*)	
Center for Scientific Review (CSR)	[http://www.csr.nih.gov]	($105*)	
Warren G. Magnuson Clinical Center (CC)	[http://www.cc.nih.gov]	($361*)	
* Funded through the NIH Management Fund from taps on IC budgets (non-add)			
Total, NIH Program Level (includes Buildings and Facilities appropriation: $119m, 0.4% of total)		**$29,171**	**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 300,000 scientists and research personnel affiliated with over 3,100 universities, academic health centers, hospitals, and independent research institutions in the United States and abroad.[4] More than 82% 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. 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. Over 70% of NIH's extramural funds go to researchers working in institutions of higher education, particularly the nation's 129 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

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[4] NIH, *Justification of Estimates for Appropriations Committees, FY2009, Vol. I, Overview*, p. O-7, at [http://officeofbudget.od.nih.gov/ui/2008/Overview.pdf#page=6].

[5] NIH, Office of Extramural Research, *Characteristics of Awardee Organizations*, at [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 FY2007, over 47,400 new and renewal applications competed for research project grants (RPGs), and 10,100 received funding, for a "success rate" of 21.3%.[6] Some researchers submit more than one proposal; the 47,455 applications in FY2007 were submitted by 33,886 individual applicants, of whom 9,233, or 27.2%, 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 FY2007, in addition to awarding over 10,000 new or competing renewal awards, NIH awarded more than 26,700 noncompeting awards and nearly 1,800 small business awards, for a total of over 38,800 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]

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[6] NIH, Office of Extramural Research, "Success Rates by Institute" (data are available for FY1997-FY2007) [http://grants1.nih.gov/grants/award/success/Success_ByIC.cfm].

[7] NIH, Office of Extramural Research, *NIH Extramural Data Book 2007*. (Choose "Research Projects Grants (RPGs)," then go to slide RPG-3.) [http://grants.nih.gov/grants/award/Research_Training_Investment/Research_Training_Investment.cfm].

[8] NIH, *Justification of Estimates for Appropriations Committees, FY2009, Vol. I, Overview*, table on "Research Project Grants: Total Number of Awards and Dollars," p. TD-15, at [http://officeofbudget.od.nih.gov/ui/2008/tabular%20data.pdf#page=14].

[9] NIH, *Justification of Estimates for Appropriations Committees, FY2009, Vol. I, Overview*, table on "Statistical Data — Grants, Direct and Indirect Costs Awarded," p. TD-14 (continued...)

Intramural Research. The NIH intramural research program accounts for nearly 11% 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://medlineplus.gov] and at [http://health.nih.gov].

Budget

Recent History. At $29.2 billion for FY2008, NIH's budget (see **Table 2**) represents about 20% of total federal funding for research and development (R&D) and about half of federal civilian (i.e., nondefense) spending for 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

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[9] (...continued)
[http://officeofbudget.od.nih.gov/ui/2008/tabular%20data.pdf#page=13].

[10] See CRS Report RL34448, *Federal Research and Development Funding: FY2009*, by John F. Sargent et al.

[11] Department of Health and Human Services, *FY2009 Budget in Brief* (February 2008), p. 12, at [http://www.hhs.gov/budget/09budget/2009BudgetInBrief.pdf#page=15].

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.

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). Final funding for FY2006 was $82 million (0.3%) below the FY2005 level, marking the first time that the NIH appropriation had decreased since 1970. The FY2007 final level was a 2.0% increase over FY2006, and the final FY2008 funding level was 0.5% above FY2007. The FY2009 President's budget requested a program level of $29.165 billion, an amount essentially equal to the FY2008 appropriation. See **Figure 1**, which charts NIH appropriations from FY1994 through the FY2009 request.

Figure 2 portrays the NIH appropriation adjusted for inflation (in constant 2008 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 FY2008 and FY2009, the NIH budget has been losing ground in real terms each year since the end of the doubling in FY2003. In constant 2008 dollars, the FY2003 NIH budget was $32.8 billion. It fell to $32.6 billion in FY2004, and has decreased steadily to the FY2008 level of $29.2 billion, which is lower than the constant-dollar level of FY2002. The FY2009 request level is $28.2 billion in 2008 dollars. In inflation-adjusted terms, the FY2008 funding level represents an estimated 11% decrease from FY2003, while the FY2009 request level would be 14% below FY2003.

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

Table 2. National Institutes of Health (NIH) Appropriations

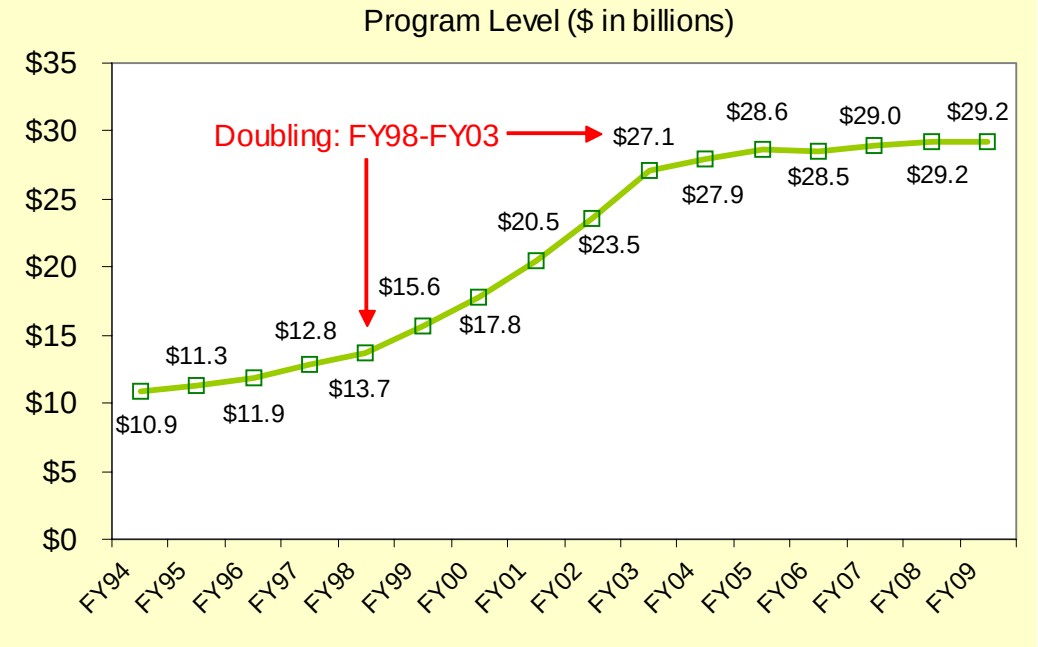
(dollars in millions)

Institutes and Centers (ICs)	FY2007 actual[a]	FY2008 enacted[b]	FY2009 request	% change FY09 vs. FY08
Cancer (NCI)	4,795.5	4,805.1	4,809.8	0.1%
Heart/Lung/Blood (NHLBI)	2,919.2	2,922.1	2,924.9	0.1%
Dental/Craniofacial Research (NIDCR)	389.8	390.2	390.5	0.1%
Diabetes/Digestive/Kidney (NIDDK)	1,706.0	1,706.7	1,708.5	0.1%
Neurological Disorders/Stroke (NINDS)	1,534.9	1,543.9	1,545.4	0.1%
Allergy/Infectious Diseases (NIAID)[c,d]	4,366.4	4,560.7	4,568.8	0.2%
General Medical Sciences (NIGMS)	1,935.6	1,935.8	1,937.7	0.1%
Child Health/Human Development (NICHD)	1,254.1	1,254.7	1,255.9	0.1%
Eye (NEI)	666.7	667.1	667.8	0.1%
Environmental Health Sciences (NIEHS)	641.8	642.3	642.9	0.1%
Aging (NIA)	1,046.5	1,047.3	1,048.3	0.1%
Arthritis/Musculoskeletal/Skin (NIAMS)	508.1	508.6	509.1	0.1%
Deafness/Communication Disorders (NIDCD)	393.5	394.1	395.0	0.2%
Nursing Research (NINR)	137.3	137.5	137.6	0.1%
Alcohol Abuse/Alcoholism (NIAAA)	436.1	436.3	436.7	0.1%
Drug Abuse (NIDA)	1,000.0	1,000.7	1,001.7	0.1%
Mental Health (NIMH)[e]	1,403.6	1,405.5	1,406.8	0.1%
Human Genome Research (NHGRI)	486.4	486.8	487.9	0.2%
Biomedical Imaging/Bioengineering (NIBIB)	298.4	298.6	300.3	0.5%
Research Resources (NCRR)	1,143.8	1,149.4	1,160.5	1.0%
Complementary/Alternative Med (NCCAM)	121.4	121.6	121.7	0.1%
Minority Health/Health Disparities (NCMHD)	199.4	199.6	199.8	0.1%
Fogarty International Center (FIC)	66.4	66.6	66.6	0.1%
National Library of Medicine (NLM)	319.8	320.5	323.0	0.8%
Office of Director (OD)[d]	1,047.5	1,109.1	1,056.8	-4.7%
Common Fund (non-add)	*(483.0)*	*(495.6)*	*(533.9)*	*7.7%*
Buildings & Facilities (B&F)	81.1	119.0	125.6	5.6%
Subtotal, Labor/HHS Appropriation	**28,899.3**	**29,229.5**	**29,229.5**	**0.0%**
Superfund (Interior approp to NIEHS)[f]	79.1	77.5	77.5	0.0%
Total, NIH discretionary budget authority	**28,978.5**	**29,307.1**	**29,307.1**	**0.0%**
Pre-appropriated Type 1 diabetes funds[g]	150.0	150.0	150.0	0.0%
PHS Evaluation Tap funding[h]	8.2	8.2	8.2	0.0%
Global Fund transfer (AIDS/TB/Malaria)[c]	-99.0	-294.8	-300.0	1.8%
Total, NIH program level	**29,037.7**	**29,170.5**	**29,165.3**	**0.0%**

Source: Adapted by CRS from NIH, *Justification of Estimates for Appropriations Committees, Fiscal Year 2009*, Tabular Data, p. TD-1, at [http://officeofbudget.od.nih.gov/UI/2008/tabular%20data.pdf]. Details may not add to totals due to rounding.

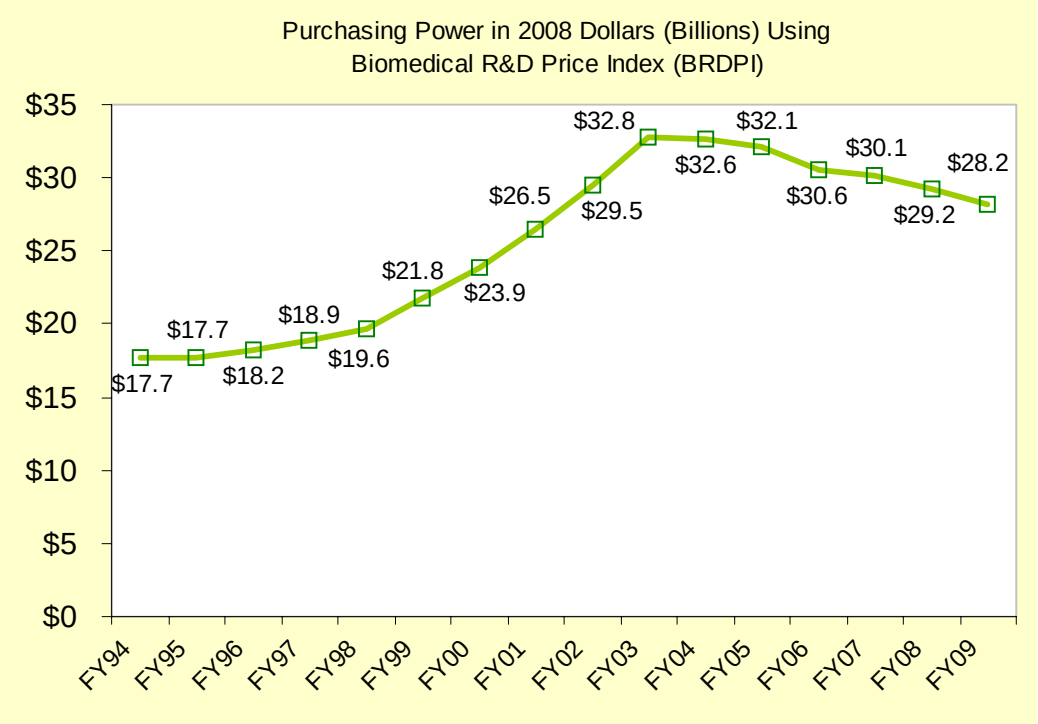
a. FY2007 reflects transfer of $99.0 million from NIH to Office of the Secretary, per P.L. 110-28 (see note d). FY2007 also reflects comparative transfers to HHS ($0.542m) and among NIH ICs.
b. The FY2008 program level is an increase of $132.8 million (0.5%) over FY2007. FY2008 includes comparative IC transfers from NHLBI to NIDDK ($0.816 million) and from NLM to NIDCR ($0.455 million).
c. NIAID totals include funds for transfer to the Global Fund to Fight HIV/AIDS, TB, and Malaria.
d. For FY2007, the emergency supplemental appropriations act (P.L. 110-28) transferred funding for the Advanced Development of Medical Countermeasures to Office of the Secretary ($49.5m each from NIAID and OD).
e. FY2008 NIMH has $0.983m from Office of the Secretary to administer Interagency Autism Coordinating Committee.
f. Separate account in the Interior/Environment appropriation for NIEHS research activities related to Superfund.
g. Funds available to NIDDK for diabetes research under PHS Act § 330B (authorized by P.L. 106-554, P.L. 107-360, and P.L. 110-173).
h. Additional funds for NLM from PHS Evaluation Set-Aside (§ 241 of PHS Act).

Figure 1. NIH Appropriations FY1994-FY2009 Request



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

Figure 2. Effect of Inflation on NIH Budget FY1994-FY2009 Program Level



Source: Figure prepared by CRS.

Sources of Funding. NIH's budget comes from four sources: the bulk is through the annual Labor-HHS-Education (Labor-HHS-ED) appropriation, with an additional small amount for environmental research and training related to Superfund 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 P.L. 110-173, 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). Conversely, NIH loses part of its appropriation to a transfer to the Global Fund to Fight HIV/AIDS, Tuberculosis, and Malaria. For several years, about $100 million of the annual appropriation to NIAID was transferred to the Global Fund. For FY2008, the amount was increased to $300 million in the request, and the final amount of the transfer from the NIH appropriation was $295 million. The FY2009 budget again proposed a transfer of $300 million to the Global Fund.[13]

The NIH and three of the other Public Health Service agencies within HHS are subject to a budget "tap" called the PHS Program Evaluation Set-Aside, authorized by section 241 of the PHS Act (42 U.S.C. § 238j). It is used to fund not only program evaluation activities, but also functions that are seen as having benefits across the Public Health Service, such as the National Center for Health Statistics in CDC and the entire budget of the Agency for Healthcare Research and Quality. These and other uses of the evaluation tap by the appropriators have the effect of redistributing appropriated funds among PHS agencies. The FY2008 appropriation kept the tap at 2.4%, the same as in FY2007. NIH, with the largest budget among the PHS agencies, becomes the largest "donor" of program evaluation funds, and is a relatively minor recipient. By convention, budget tables such as **Table 2** do not subtract the amount of the evaluation tap, or of other taps within HHS, from the agencies' appropriations.[14]

FY2009 Request. For FY2009, the President requested budget authority of $29.230 billion in the L-HHS-ED appropriation and $78 million in the Interior/Environment appropriation, for a total program level of $29.165 billion for NIH (see **Table 2**). The FY2008 level, provided by the Consolidated Appropriations Act, 2008 (P.L. 110-161), totaled $29.171 billion.[15] The FY2009 request represents a decrease of $5 million (-0.02%) below the FY2008 program level.

Within the FY2009 request, most of the institutes and centers would be approximately level-funded from their FY2008 amounts, receiving increases of 0.1% or 0.2%. Only the National Center for Research Resources (1.0%) and the National

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

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

[15] For information on the FY2008 appropriation, see the NIH section of CRS Report RL34048, *Federal Research and Development Funding: FY2008*, by John F. Sargent et al.

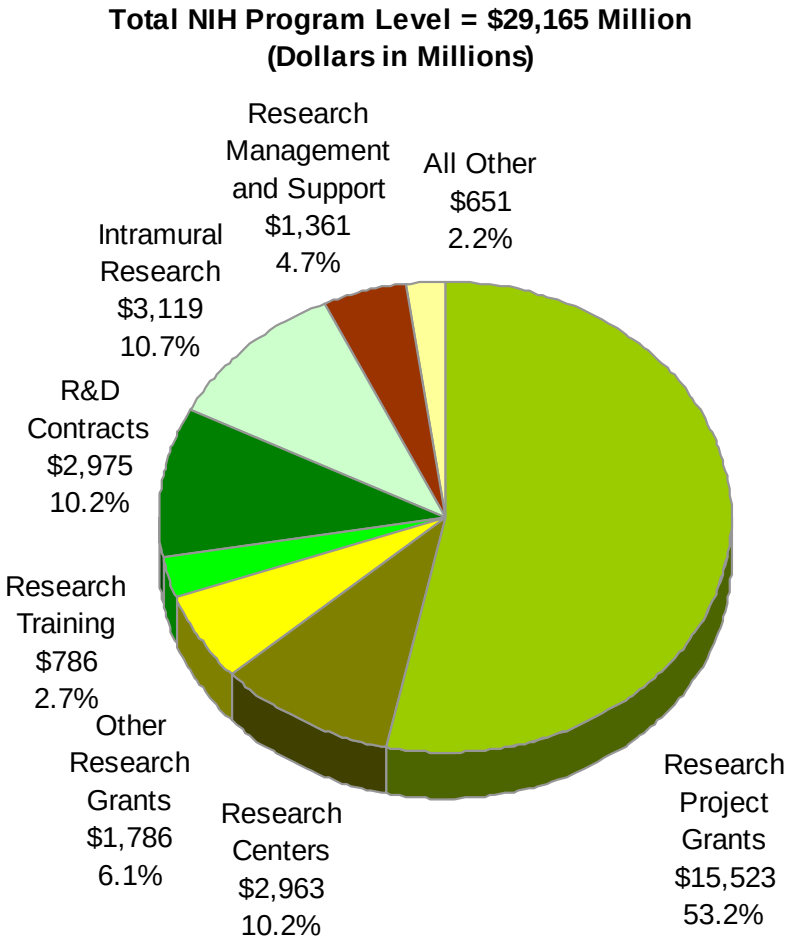
Library of Medicine (0.8%) would receive increases greater than 0.5%. The two biggest changes in the request are a 5.6% increase in the Buildings and Facilities account, and a 4.7% drop in funding for the Office of the Director. Many of the laboratories, animal facilities, and office buildings on the NIH campus are aging and are in need of upgrading to stay compliant with health and safety guidelines and to provide the proper infrastructure for the Intramural Research program. The budget requests $126 million for Buildings and Facilities, an increase of $7 million.

The net $52 million drop in the OD account, from $1,109 million in FY2008 to $1,057 million in the request, represents the proposed cancellation of a study combined with increases for several other OD activities. The National Children's Study was funded at $111 million in FY2008. It is a long-term (25+ year), multi-agency environmental health study that was mandated by the Children's Health Act of 2000 (P.L. 106-310). It plans to examine the effects of environmental influences on the health and development of more than 100,000 children across the United States, following them from before birth until age 21. The overall projected cost for the whole study is about $2.7 billion. Starting with the FY2007 request, when the study moved from the planning phase to the more costly implementation phase, the Administration has proposed each year to end its funding. Congress has continued to support the study.

Proposed increases within the OD account total $59 million, including a $38 million increase (7.7%) for the NIH Roadmap initiatives funded through the Common Fund. The NIH Roadmap for Medical Research, discussed in more detail below, is a set of trans-NIH research activities designed to support high-risk/high-impact research in emerging areas of science or public health priorities. For FY2009, planned funding for the Roadmap/Common Fund totals $534 million, up from $496 million in FY2008. The other major increase requested for OD is an additional $19 million (19.9%) for research on medical countermeasures against nuclear, radiological, and chemical threats, increasing that program to $113 million from $94 million in FY2008. That is the only significant increase for NIH's biodefense portfolio, which totals $1,748 million in the President's FY2009 request (up 1.2%).

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. **Figure 3** and **Table 3** show the distribution of the NIH budget by the major funding mechanisms.

Figure 3. FY2009 NIH Budget Request by Funding Mechanism



Source: Adapted from *NIH: Summary of the FY2009 President's Budget*, February 4, 2008, p. 5 [http://officeofbudget.od.nih.gov/ui/2008/Summary%20of%20FY%202009%20Budget-Press%20Release.pdf]. That document presents NIH Budget Authority, totaling $29,457 million, whereas this chart shows NIH Program Level. Program level excludes $300 million from the R&D Contracts mechanism for the Global HIV/AIDS Fund transfer, and includes $8 million in the All Other category for NLM Program Evaluation funds. See **Table 2**.

The NIH's two major concerns in the face of tight budgets are maintaining support of investigator-initiated research through research project grants, and continuing to nourish the pipeline of new investigators. Total funding for RPGs, at $15.5 billion, represents about 53% of NIH's budget. The FY2009 request would support an estimated 38,257 awards, about the same as in FY2008, but with $19 million less in funding. Within that total, 9,757 would be competing RPGs, 14 fewer than in FY2008. No inflationary increases are proposed for noncompeting (continuation) RPGs, and the average annual cost of competing RPGs would remain at the FY2008 level, about $361,000. The expected "success rate" of applications

receiving funding would decline to about 18% from the estimated rate of 19% for FY2008. Estimated success rates for the various ICs would range from 8% to 26%.[16]

Table 3. NIH Budget by Funding Mechanism

(dollars in millions)

Mechanism	FY2007 actual	FY2008 enacted	FY2009 estimate	% change 2009/2008
Research Project Grants (RPGs)	$15,627	$15,543	$15,523	-0.1%
Research Centers	$2,934	$2,943	$2,963	0.7%
Other Research Grants	$1,793	$1,809	$1,786	-1.3%
Research Training	$782	$782	$786	0.6%
R&D Contracts[a]	$2,886	$2,947	$2,975	1.0%
Intramural Research	$3,035	$3,069	$3,119	1.6%
Res. Management & Support	$1,317	$1,341	$1,361	1.5%
All Other[b]	$664	$736	$651	-11.6%
Total, NIH Program Level	**$29,038**	**$29,171**	**$29,165**	**-0.02%**
# new/competing renewal RPGs	10,323	9,771	9,757	-14 grants
# noncompeting RPGs	26,741	26,728	26,759	+31 grants
# small business grants	1,781	1,740	1,741	+1 grants
Total # of RPGs	**38,845**	**38,239**	**38,257**	**+18 grants**

Source: Adapted from NIH FY2009 Budget Justification, *Tabular Data*, p. TD-4, February 4, 2008 [http://officeofbudget.od.nih.gov/ui/2008/tabular%20data.pdf#page=4]. Details may not add to totals due to rounding.

a. Program level excludes funds from the R&D Contracts mechanism to be transferred to the Global HIV/AIDS Fund (FY2007: $99 million; FY2008: $294.759 million; FY2009: $300 million). See **Table 2**.

b. "All Other" includes Extramural Construction, Buildings and Facilities, Superfund, NLM Program Evaluation, and OD funding that is not for Roadmap or Director's Bridge Awards (that funding is distributed by mechanism).

Several efforts are focused on supporting new investigators, to encourage young scientists to undertake careers in research and to help them speed their transition from training to independent research. The Pathway to Independence program would support approximately 500 awardees, including 170 new awards, for a total of $71 million. Regular training mechanisms such as the National Research Service Awards are proposed for an increase of $5 million (0.6%) to $786 million, including stipend increases of 1% for both pre- and post-doctoral fellows. Clinical research training, including the Clinical and Translational Science Awards, would be funded at a total of $475 million. The request would support about 25 New Innovator Awards for a total of $56 million in the Common Fund. The NIH Director's Bridge Award is a

[16] NIH, *Justification of Estimates for Appropriations Committees, FY2009, Vol. I, Overview*, table on "Research Project Grants: Success Rates, FY2000-FY2009," p. TD-16, at [http://officeofbudget.od.nih.gov/ui/2008/tabular%20data.pdf#page=15].

program that can give short-term funding to established, meritorious investigators who have just missed the funding cutoff for a renewal application and who have little other support, giving them time to resubmit without disrupting the operation of their laboratory. The request includes $91 million for 244 awards, an increase of $1.6 million.

Changes proposed in the request for other funding mechanisms within the NIH budget include increased support for research centers, up $20 million (0.7%) to $2,963 million; a $28 million (1.0%) increase to $2,975 million for R&D contracts (excluding the funding to be transferred for the Global HIV/AIDS Fund); $50 million more (1.6%) for the NIH intramural research program, for a total of $3,119 million; an increase of $20 million (1.5%) to a total of $1,361 million for research management and support; and a decrease of $23 million (1.3%) for other research grants totaling $1,786 million.

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 made information about setting research priorities and other aspects of research planning available on its website at [http://www.nih.gov/about/researchplanning.htm]. 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.

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) provides advocacy information on legislative issues as well as materials that scientists can customize with facts 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 indicated in **Figure 2**, above, if the amount proposed in the President's FY2009 request were to be accepted by Congress, NIH would have about 14% less purchasing power 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 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. In more recent years, the advocates have urged Congress to again provide increases in the neighborhood of 6.5%. NIH appropriations that have consistently 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

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[17] FASEB, Office of Public Affairs, Legislative Action Center at [http://capwiz.com/faseb/home/]; and "FASEB Launches Grassroots Campaign for NIH, 'Supporting Medical Research in Concept Is Not Enough,'" *FASEB News*, August 9, 2006, at [http://opa.faseb.org/pdf/PowerpointLaunch8.9.06.pdf].

is, the proportion of competing RPG applications that receive funding. NIH expects that under the FY2009 request, the success rate would be at a historic low of about 18%, compared with 25% in FY2004. 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, more and more applicants were chasing fewer and fewer awards, a pattern which has continued. 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 to increase support of young investigators in order to address the ever-lengthening time that it has been taking them to get their first grants. The program supports promising postdoctoral scientists through five-year awards that have a two-year mentored phase and a three-year independent phase.[20] Starting with FY2007, NIH planned to support 150 to 200 awards each year for five years.

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.

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[18] NIH, *Justification of Estimates for Appropriations Committees, FY2009, Vol. I, Overview*, table on "Research Project Grants: Success Rates, FY2000-FY2009," p. TD-16 [http://officeofbudget.od.nih.gov/ui/2008/tabular%20data.pdf#page=15].

[19] NIH, Office of Extramural Research, "Success Rates by Institute" (data are available for FY1997-FY2007), at [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 this award, and [http://grants2.nih.gov/grants/new_investigators/index.htm] for general information on NIH's New Investigators Program.

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: CRS Report RL33540, *Stem Cell Research: Federal Research Funding and Oversight*; CRS Report RL33554, *Stem Cell Research: Ethical Issues*; and CRS Report RL33524, *Stem Cell Research: State Initiatives*. For legal issues, see CRS Report RS21044, *Background and Legal Issues Related to Human Embryonic Stem Cell Research*, by Edward C. Liu.

From time to time, the research community has also been troubled by congressional attempts to cancel funding for specific existing peer-reviewed grants.[21] The targeted studies have tended to be in fields of behavioral research, including some in mental health and human sexuality research. Sponsors and supporters of such amendments to the L-HHS-ED appropriations bills say that NIH should not be devoting scarce resources to research studies whose value they question. Researchers, however, including NIH leadership, have expressed alarm at what they view as an assault on the peer review system, saying that such studies were funded because of their technical merit and the important research questions they addressed.

New Approaches? While advocates warn that tight budgets will slow research advances on the major chronic conditions that burden American society, other commentators note that coping with the reality of budget constraints has increasingly required NIH and the research community to rethink some of their traditional approaches to planning and organizing research. As NIH Director Dr. Elias Zerhouni has advised, "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."[22] 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.

Authorizations: Structure and Program Direction

Organizational Complexity. A key element of such rethinking has been consideration of NIH's organizational structure, which 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

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

[22] Elias Zerhouni, "The NIH Roadmap," *Science*, vol. 302 (Oct 3, 2003), pp. 63-64, 72.

have multiplied as new entities have been created by Congress (seven of them between 1985 and 2000; see **Table 4**), each with its own mission, budget, staff, review office, and other bureaucratic apparatus. Over the years, many observers had wondered whether the agency had become too fragmented to be manageable, and whether NIH was able to respond appropriately to new scientific and public health challenges. Some commentators suggested consolidating the ICs into a smaller number of units encompassing broad areas of science.[23] Others 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 felt that the structure of multiple independently operated institutes might 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*.[24]

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.

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,

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[23] Harold Varmus, "Proliferation of National Institutes of Health," *Science*, vol. 291 (March 9, 2001), pp. 1903-1905.

[24] 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].

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 NIH's 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. 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. A number of these were put in place prior to the major congressional response to the 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].[25] 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 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

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[25] NIH, Office of the Director, "NIH Announces Strategy to Accelerate Medical Research Progress," press release, September 30, 2003 [http://www.nih.gov/news/pr/sep2003/od-30.htm].

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. Additional cohorts of new initiatives have been developed through subsequent planning processes.

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. For example, two programs are meant to stimulate highly innovative researchers. The NIH Director's Pioneer Award [http://nihroadmap.nih.gov/pioneer] 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."[26] The NIH Director's New Innovator Award [http://grants.nih.gov/grants/new_investigators/innovator_award/] offers support to extraordinarily creative new investigators who have never had a traditional research project grant.

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."[27] 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.[28]

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[26] Ibid.

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

[28] NIH, National Center for Research Resources, "Clinical and Translational Science (continued...)

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.

Roadmap initiatives are funded through a "Common Fund" for trans-NIH projects that is a separate line item in the appropriation for the Office of the Director. Initially, the budgets of the ICs were tapped for some of the contributions to the Common Fund, but since FY2007, all of the funding has been appropriated to OD. Since FY2004, funding for Roadmap has increased from $132 million to $496 million in FY2008, now representing 1.7% of the total NIH budget. The FY2009 request proposes $534 million for the Common Fund, equal to 1.8% of the budget.[29]

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 [http://www.obesityresearch.nih.gov/about/strategic-plan.htm], and the Neurosciences Blueprint [http://neuroscienceblueprint.nih.gov/], commenced in FY2006. The Blueprint pools resources among 16 ICs with an interest in the nervous system for use in cooperative research, including development of research tools and infrastructure that serve the entire neuroscience community. In September 2005, NIH administratively 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 was established to give the agency more capability in analyzing and managing its research portfolio, especially in planning and priority-setting for areas of interest to multiple ICs. The aim was to 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 felt that, building on the effectiveness of the Roadmap approach, OPASI would offer further "flexibility and nimbleness" in finding and funding cutting-edge research.[31]

Two of the 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

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[28] (...continued)
Awards," at [http://www.ncrr.nih.gov/clinical_research_resources/clinical_and_translational_science_awards/index.asp].

[29] NIH, *Justification of Estimates for Appropriations Committees, FY2009, Vol. I, Overview*, "NIH Common Fund/Roadmap," p. 4, at [http://officeofbudget.od.nih.gov/ui/2008/Final%20Roadmap.pdf#page=4].

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

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

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 are reviewed frequently for continuation, transfer to an IC, or completion, with no initiative to remain in OPASI more than 10 years.[32] With implementation of the NIH Reform Act of 2006 (P.L. 109-482) (see the next section), OPASI became an office within the new Division of Program Coordination, Planning, and Strategic Initiatives, and is leading several of the efforts required by the Act.

Congressional Activities on NIH Reauthorization (the NIH Reform Act of 2006, P.L. 109-482). As discussed early in this report, statutory authority for NIH is found primarily in Title IV of the Public Health Service Act (42 U.S.C. § 281-290b). 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. Before the 109th Congress, systematic change to those authorities had been undertaken only twice, in the Health Research Extension Act of 1985 (P.L. 99-158) and in the NIH Revitalization Act of 1993 (P.L. 103-43). Most of the specific authorities established or extended in the 1993 act expired in FY1996, and had not been updated. (The programs continued under NIH's general authority to conduct and sponsor research.) A number of additional laws enacted since 1993 had addressed particular areas of research; most of those authorities had also expired.[33] Over time, Congress has rearranged the provisions of Title IV and added new program authorizations and reporting requirements, but 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

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[32] 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].

[33] 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, 2006-2007*, 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.[34] 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.[35] 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 Joe 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. In the Senate, action on the bill was deferred until the last day of the 109th Congress. On December 8, 2006, the bill was discharged from the Senate Committee on Labor, Health, Education, and Pensions, and an amended version, the product of negotiations between the Senate and House authorizers and appropriators, passed the Senate by unanimous consent. The House agreed to the Senate amendment by voice vote. The measure was signed by President Bush on January 15, 2007, and became P.L. 109-482.

The law made managerial and organizational changes in 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 contained no provisions relating to specific diseases or fields of research, and did not eliminate or consolidate any existing ICs.

The law established a Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the Office of the Director, with many functions similar to those of OPASI (described in the previous section). The law moved a number of individual program offices in OD to the new Division (such offices coordinate research on AIDS, women's health, behavioral and social sciences, disease prevention, dietary supplements, and rare diseases). As noted earlier, OPASI also became an office in the Division. While not superseding the planning and priority-setting responsibilities of the individual institutes and centers, the measure charged the Director with overall program coordination of the entire research

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[34] 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/archives/archive_main.shtml]. This hearing is found at [http://energycommerce.house.gov/reparchives/108/Hearings/07192005hearing1590/hearing.htm].

[35] U.S. Congress, House Committee on Energy and Commerce, *Improving NIH Management and Operation: A Legislative Hearing on the NIH Reform Act of 2006*, 109th Cong., 2nd sess., September 19, 2006. The archived webcast and testimony of the witnesses are available at [http://energycommerce.house.gov/reparchives/108/Hearings/09192006hearing2031/hearing.htm].

portfolio of NIH. It required the creation of a comprehensive electronic reporting system to catalogue research activities from all of the ICs in a standardized format. Information from the tracking system 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, the act provided for funding of trans-NIH initiatives through the Common Fund. The law requires the NIH Director to reserve an amount for the Common Fund that, as a percentage of total NIH appropriations, is at least as great as in the previous year. A new Common Fund strategic planning report to the Congress is required; it is to estimate the funding needed for trans-NIH research. The law established a new advisory body, the "Council of Councils," to review proposals for trans-NIH research. The Council is composed of representatives from the IC advisory councils, OD offices, and the Council of Public Representatives. Proposals from investigators who are first-time applicants are to be given "appropriate consideration," and NIH's traditional emphasis on peer-reviewed, investigator-initiated research is to be maintained. The Council held its first meeting in March 2008.[36]

The law created a "Scientific Management Review Board" charged with formally and publicly reviewing NIH's organizational structure at least once every seven years. The board may recommend restructuring, including the creation of new institutes, but the number of ICs is capped at the current 27. The law set out time frames for the Director to take action on such recommendations, and provided for review by Congress.

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

The law requires a biennial report from the Director to Congress assessing the state of biomedical research and reporting in detail on the research activities of NIH, including strategic planning and initiatives, and summaries of research in a number of broad areas. All other duplicative reporting requirements were eliminated. The law added new reporting requirements on clinical trials, human tissue storing and tracking, whistleblower complaints, and special consultant hires (all of those issues had been the subject of investigations by the House Energy and Commerce Committee). Two demonstration programs were authorized, one to award grants that

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[36] NIH, Office of Extramural Research, "Appointment of Members to the NIH Council of Councils," *Extramural Nexus*, March 2008 (see also links to Council materials) [http://nexus.od.nih.gov/nexus/nexus.aspx?ID=29&Month=3&Year=2008].

"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.

A more detailed summary of the provisions of the NIH Reform Act may be found on the website of the NIH Office of Legislative Policy and Analysis (OLPA), at [http://olpa.od.nih.gov/legislation/109/publiclaws/reformact06.asp]. Information on NIH's progress in implementing various requirements of the law is included in the FY2009 budget justification narrative for the Office of the Director.[37]

Dozens of bills and resolutions related to NIH, to disease research, or to other areas of public health have been introduced in the 110th Congress, and a few have had further action. See the OLPA website for its Bill Tracking pages and other links to congressional activity, at [http://olpa.od.nih.gov/tracking/].

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.

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).

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 17 million articles published in about 5,200 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

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[37] NIH, *Justification of Estimates for Appropriations Committees, FY2009, Vol. V, Office of the Director*, pp. OD-12 to OD-27 [http://officeofbudget.od.nih.gov/ui/2008/OD.pdf?ID=49&CT=1].

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.[38] The policy requested 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 was accepted for publication in a journal. NIH encouraged authors to make manuscripts available to other researchers and the public immediately after they have been published, but the policy allowed a delay in releasing articles of up to 12 months.

NIH listed the following three goals 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.[39]

NIH implemented the policy in May 2005, when it activated a manuscript submission system for authors to deposit articles. Participation was voluntary, in deference to publishers' concerns about the loss of their proprietary content. As time went on, however, the rate of submission to the system continued to be very low, and there began to be calls to make the submission of manuscripts mandatory. The FY2007 House Labor-HHS-ED Appropriations bill (H.R. 5647) included such a provision, although the Senate bill of that year did not. 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.

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

[39] NIH, Office of Extramural Research, "Questions and Answers: NIH Public Access Policy," February 24, 2005.

The FY2008 appropriation made the policy mandatory. NIH released its revised policy statement on January 11, 2008, with an effective date of April 7, 2008, saying: "In accordance with Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008), the NIH voluntary Public Access Policy (NOT-OD-05-022) is now mandatory. The law states: 'The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.'"[40]

NIH estimates that there are approximately 80,000 articles published each year that arise from NIH funds.[41] At a public meeting held March 20, 2008, to hear comments on the new policy, Dr. Zerhouni is reported as saying that if the policy remained voluntary, about 64,000 new research articles arising from NIH funds would not be available to the public each year.[42]

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.[43] 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.[44]

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[40] NIH, Office of Extramural Research, "Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research," Notice number NOT-OD-08-033, January 11, 2008 [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html].

[41] NIH, "Public Access Frequently Asked Questions," January 11, 2008 [http://publicaccess.nih.gov/FAQ.htm#f4].

[42] NIH, Office of Extramural Research, "NIH Hears Public Access Comments," *NIH Nexus*, March 2008 [http://nexus.od.nih.gov/nexus/nexus.aspx?ID=27&Month=3&Year=2008].

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

[44] Elias A. Zerhouni, "Awards, Travel, and Official Duty and Outside Activity Approvals," (continued...)

More studies and hearings on ethics policies, and investigations of individual cases, both by NIH and by Congress, ensued during 2004 and 2005.[45] 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.[46] 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.

The final revised regulation, published in August 2005, covered reporting of certain financial interests, stock divestiture, outside activities, and awards.[47] 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.[48]

Implementation of the ethics rules has largely quelled concern over new infractions. As a followup, NIH did some surveys and assessments of the impact of the rules on current employees, as well as on individuals who had left the agency or were potential employees. Some of the results of that process are posted at [http://www.nih.gov/about/ethics/10262006COImemo.htm], but no definitive trends were apparent.

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[44] (...continued)
memo to IC Directors and OD Senior Staff, November 20, 2003 [http://www.nih.gov/news/pr/nov2003/11202003drzerhounimemo.pdf].

[45] 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].

[46] 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, February 3, 2005.

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

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

Also of ongoing concern to NIH and the public is the possibility that research results will be biased because of financial conflicts of interest (FCOI) on the part of extramural grantees. Regulations setting forth requirements for researchers and their institutions are longstanding, but NIH recognizes that increasingly complex financial arrangements involving scientists are becoming more common, and might threaten objectivity in research. Reminders of the policies and answers to frequently asked questions are available to researchers and peer reviewers on the website of the Office of Extramural Research, at [http://grants.nih.gov/grants/policy/coi/index.htm].

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];
- 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 (FY2004-FY2009) 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 4. Components of NIH, with History and Scope

Institute/Center (Statutory Authority in Public Health Service Act and *U.S. Code*)	**Acronym**	**When and How Established; Chronology of Name Changes**	**Major Research Focus**	**FY2008 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.	$4,805
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.	$2,922
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.	$390
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.	$1,857

Institute/Center (Statutory Authority in Public Health Service Act and *U.S. Code*)	**Acronym**	**When and How Established; Chronology of Name Changes**	**Major Research Focus**	**FY2008 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.	$1,544
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.	$4,266
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.	$1,936
National Institute of Child Health and Human Development PHSA § 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.	$1,255

Institute/Center (Statutory Authority in Public Health Service Act and *U.S. Code*)	**Acronym**	**When and How Established; Chronology of Name Changes**	**Major Research Focus**	**FY2008 program level** ($ millions) (details, **Table 2**)
National Eye Institute PHSA § 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.	$667
National Institute of Environmental Health Sciences (located in Research Triangle Park, NC) PHSA § 463-463A, 42 U.S.C. § 285*l*-285*l*-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 PHSA § 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.	$1,047
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.	$509
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.	$394

Institute/Center (Statutory Authority in Public Health Service Act and *U.S. Code*)	**Acronym**	**When and How Established; Chronology of Name Changes**	**Major Research Focus**	**FY2008 program level** ($ millions) (details, **Table 2**)
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
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.	$1,001

Institute/Center (Statutory Authority in Public Health Service Act and *U.S. Code*)	**Acronym**	**When and How Established; Chronology of Name Changes**	**Major Research Focus**	**FY2008 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.	$1,405
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. 2007 — name officially changed in the PHS Act from NCHGR to NHGRI (P.L. 109-482)	Chromosome mapping, DNA sequencing, database development, ethical/legal/social implications of genetics research.	$487
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.	$299

Institute/Center (Statutory Authority in Public Health Service Act and *U.S. Code*)	**Acronym**	**When and How Established; Chronology of Name Changes**	**Major Research Focus**	**FY2008 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.	$1,149
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.	$122
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.	$200
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.	$67

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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.	$329
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).	$1,109
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.	$119
Total for appropriated accounts				$29,171
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.	($361)
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.	($105)

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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.	($39)

Sources: *NIH Almanac, 2006-2007* [http://www.nih.gov/about/almanac/index.html]. Budget figures from NIH FY2009 Budget Justification, vol. I, pp. TD-1 and SI-8