# **CRS** Report for Congress

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### The National Institutes of Health: An Overview

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#### Summary

The National Institutes of Health (NIH) is the focal point for federal health research. An agency of the Department of Health and Human Services, it uses its \$13.65 billion budget to support more than 50,000 scientists working at 2,000 institutions across the United States, as well as to conduct biomedical and behavioral research and research training at its own facilities. Components of the agency include 21 institutes and centers, each with a focus on particular diseases or research areas in human health. Recent budget growth has been kept well above inflation levels despite caps on discretionary spending. The FY1998 appropriation gave NIH a 7.1% increase, and the FY1999 request is for an unprecedented \$1.15 billion increase (8.4%) as part of the proposed Research Fund for America. Reauthorization legislation is expected in the second session. NIH's Internet home page is at <a href="http://www.nih.gov">http://www.nih.gov</a>.

#### Background

NIH is the primary agency of the federal government charged with the conduct and support of biomedical and behavioral research. It also has major roles in research training and health information dissemination. 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 (DHHS).<sup>1</sup> For FY1998, it has a total budget of over \$13.6 billion and total employment of about 17,000 people.

NIH derives its statutory authority from the Public Health Service Act of 1944, as amended numerous times in the last half century (42 U.S.C. 201-300gg). Section 301 of the PHS Act grants the Secretary of DHHS broad permanent authority to conduct and

<sup>&</sup>lt;sup>1</sup>The Public Health Service also includes the Agency for Health Care Policy and Research (AHCPR), the Agency for Toxic Substances and Disease Registry (ATSDR), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

sponsor research. In addition, Title IV authorizes in greater detail various responsibilities, activities, and functions of the NIH Director and the institutes. Several of the NIH institutes have specific time-and-dollar authorizations that require periodic renewal by Congress, as do selected other activities such as the programs for training grants and facilities construction awards. Authorizing committees with jurisdiction over NIH are the Senate Labor and Human Resources Committee and the House Commerce Committees. Appropriations are handled by the House and Senate Appropriations Subcommittees on Departments of Labor, Health and Human Services, and Education and Related Agencies.

#### Organization

Begun in 1887 as a one-room Marine Hospital laboratory, NIH spent its first half century operating as an intramural research lab for the Public Health Service. It became the National Institute of Health in 1930, and the National Institutes of Health in 1948. Today, NIH comprises 18 institutes, 2 centers, and the National Library of Medicine (see **Table 1**). Each has a specialized focus on particular diseases, areas of human health and development, or aspects of research support, and each receives a separate appropriation.<sup>2</sup> NIH has 77 buildings on a 300-acre main campus in Bethesda, Maryland, and also occupies off-campus sites in Maryland, North Carolina, Montana, and other locations.

#### Activities

Two categories of research are sponsored by the institutes and centers (I/Cs): extramural research, performed by scientists working in universities, academic health centers, hospitals, and independent research institutions using NIH grant or contract money; and intramural research, performed in the NIH laboratories and Clinical Center by NIH scientists. In both programs, the research projects are largely investigator-initiated, and span all fields of basic and clinical medical research. (Basic research is research in the fundamental medical sciences, sometimes called lab or bench research, while clinical research involves patients.) NIH also supports both extramural and intramural research training programs to prepare young investigators for research careers.

In FY1997, about 82% of the overall NIH budget went for extramural awards in the form of research grants, research and development contracts, training awards, and a few smaller categories such as construction grants, facilities renovation grants, and medical library grants.<sup>3</sup> The "research grants" category, by far the largest, includes traditional research project grants to individual investigators, as well as grants to groups of researchers working in collaborative programs or in multidisciplinary centers that focus

<sup>&</sup>lt;sup>2</sup>Three research divisions are also components of NIH: the Center for Scientific Review (formerly the Division of Research Grants), which receives, reviews, and refers research and training grant applications; the Division of Computer Research and Technology, which conducts research in computer science and biomedical engineering; and the Clinical Center, NIH's hospital and outpatient clinic. These divisions do not receive their own appropriations, but 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*, *1997* (NIH Pub. No. 97-5).

<sup>&</sup>lt;sup>3</sup>Information from the NIH Office of Extramural Research. The intramural research program accounts for about 11% of the budget, with the remaining 7% for management costs, buildings and facilities, interagency agreements, etc.

## Table 1. Components of the National Institutes of Health (NIH) with year of establishment and major research focus

**INSTITUTES AND CENTERS (I/Cs)** National Cancer Institute (NCI) (1937). All aspects of cancer. National Heart, Lung, and Blood Institute (NHLBI) (1948). Diseases of the heart, blood vessels, blood, lungs, and the use of blood and the management of blood resources. National Institute of Dental Research (NIDR) (1948). Oral and dental diseases and conditions. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (1950). Diabetes, endocrinology, metabolic diseases; digestive diseases, nutrition; kidney, urologic, hematologic diseases. National Institute of Neurological Disorders and Stroke (NINDS) (1950). Convulsive, neuromuscular, demyelinating, and dementing disorders; fundamental neurosciences; stroke, trauma. National Institute of Allergy and Infectious Diseases (NIAID) (1955). Allergic, immunologic, and infectious diseases: research on the immune system. National Institute of General Medical Sciences (NIGMS) (1963). Research and research training in basic medical sciences, such as cellular and molecular biology, genetics, pharmacology, and physiology. Special focus on minority biomedical researchers. National Institute of Child Health and Human Development (NICHD) (1963). Reproductive biology; population issues; embryonic development; maternal, child, family health; medical rehabilitation. National Eve Institute (NEI) (1968). Diseases of the retina, cornea, and lens; cataract, glaucoma, visual processing, low vision. National Institute of Environmental Health Sciences (NIEHS) (1969). Interrelationships of chemical and physical environmental factors, individual genetic susceptibility, and age in affecting health. Environmental toxicology, pathology, mutagenesis, epidemiology, biostatistics. (Research Triangle Park, NC) National Institute on Aging (NIA) (1974). Biomedical, social, and behavioral research on the aging process; diseases, problems, and needs of the aged. National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) (1986). Arthritis; bone, joint, connective tissue and muscle disorders; skin diseases. National Institute on Deafness and Other Communication Disorders (NIDCD) (1988). Disorders of hearing, balance, smell, taste, voice, speech and language. National Institute of Nursing Research (NINR) (center status, 1986; became an institute in 1993). Acute and chronic illness, health promotion/disease prevention, nursing systems, clinical therapeutics. National Institute on Alcohol Abuse and Alcoholism (NIAAA) (first created in PHS in 1970; moved to NIH in 1992). Causes of alcoholism, how alcohol damages the body, prevention and treatment strategies. National Institute on Drug Abuse (NIDA) (first created in PHS, 1974; moved to NIH, 1992). Social, biological, behavioral, and neuroscientific bases of drug abuse; causes, prevention, and treatment strategies. National Institute of Mental Health (NIMH) (originally established in 1949; transferred out of NIH in 1967; transferred back in 1992) Brain research, mental illness, and mental health. National Human Genome Research Institute (NHGRI) (center, 1989; institute, 1997). Chromosome mapping, DNA sequencing, database development, ethical/legal/social implications of genetics research. National Center for Research Resources (NCRR) (1990, merged two research resources divisions). Extramural and intramural research resources and technologies: general clinical research centers, computers, instrument systems, animal resources and facilities, nonmammalian research models. John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) (1968). Focal point for NIH's international collaboration activities and scientific exchanges. National Library of Medicine (NLM) (established 1836; moved to NIH in 1968). Collects, organizes, and makes available biomedical information; sponsors programs to improve U.S. medical library services. **OTHER** Office of the Director (OD). Overall NIH leadership, liaison with DHHS. Several special research areas are represented by offices within OD: AIDS research (see OAR), women's health, minority health, alternative medicine, recombinant DNA activities, rare diseases, behavioral research, and dietary supplements. Office of AIDS Research (OAR) (established in OD in 1988). Plans and coordinates NIH's AIDS activities, including preparation of a comprehensive AIDS research plan; distributes funds to the I/Cs according to the plan (not in FY1996). Buildings and Facilities (B&F). Provides for the design, construction, improvement and repair of NIH

clinical and laboratory buildings.

on particular diseases or areas of research. Nearly three-fourths of NIH's extramural funds go to researchers working in institutions of higher education, with fully 50% going to the nation's 124 medical schools.<sup>4</sup> All applications for extramural research support are considered under a two-tiered system of peer review. First they are reviewed for scientific merit by "study sections" of nongovernment experts and given priority scores. Second, they are considered for program relevance by the appropriate National Advisory Councils or Boards of the I/Cs. I/C staff make the final funding decisions among the top priority proposals. The NIH Office of Extramural Research reports that over 24,200 applications for research project grants were reviewed in FY1997, with just over 30% receiving funding.

The NIH intramural research program includes more than 9,000 scientists and technical support staff. Each of the institutes has an intramural research program, but the structure and activities of the programs vary greatly. Many intramural scientists work in the Clinical Center, which facilitates interdisciplinary collaboration and the direct clinical application of new knowledge derived from basic research.

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 sponsor seminars, meetings, and consensus development conferences to inform health professionals of new findings; answer thousands of telephone and mail inquiries; publish physician and patient education materials (many of them available on the Internet); support information clearinghouses and run public information campaigns on various diseases; and make specialized databases available. Free Internet searching of Medline citations and other NLM databases is available at <a href="http://www.ncbi.nlm.nih.gov/PubMed">http://www.ncbi.nlm.nih.gov/PubMed</a> and <a href="http://igm.nlm.nih.gov/">http://igm.nlm.nih.gov/</a>.

#### Budget

At \$13.65 billion for FY1998, NIH's budget (see **Table 2**) represents over a third of federal civilian (i.e., nondefense) spending for research and development (R&D). 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 increasing pressure to reduce the deficit, Congress has nearly doubled NIH's appropriation in the last decade. In real terms, from FY1988 to FY1997, the budget stayed about 25% ahead of inflation as measured by the Biomedical Research and Development Price Index (BRDPI), a special inflation index developed for NIH to measure changes in the prices of items and services required for its R&D activities.<sup>5</sup>

For **FY1997**, Congress gave NIH a 6.9% increase to \$12.75 billion (P.L. 104-208). For **FY1998**, the President requested \$13.08 billion, a 2.6% increase over FY1997 compared with the estimated 3.1% biomedical inflation rate. The FY1998 Labor-HHS-

<sup>5</sup>NIH Office of Financial Management, "BRDPI Factors" (January 1998 revision), <a href="http://www.nih.gov/od/ofm/brdpi/">http://www.nih.gov/od/ofm/brdpi/</a> index.htm>, March 12, 1998.

<sup>&</sup>lt;sup>4</sup>National Institutes of Health, "NIH Extramural Data, Fiscal Year 1997,"

<sup>&</sup>lt;a href="http://silk.nih.gov/public/cbz2zoz.@www.contents.htm">http://silk.nih.gov/public/cbz2zoz.@www.contents.htm</a>, March 12, 1998. For more discussion of the research role of medical schools and academic health centers, see CRS Report 94-870, *Health Care Reform: Where Does Medical Research Fit In?* 

Education appropriations act (P.L. 105-78, H.R. 2264, conference report H.Rept. 105-390, signed November 13, 1997) gave NIH \$13.65 billion, a 7.0% increase over the revised FY1997 total. For **FY1999**, the Administration reversed the practice of recent years by proposing a large increase for NIH, requesting a total of \$14.8 billion, up \$1.15 billion or 8.4% over FY1998. NIH is the centerpiece of the proposed Research Fund for America, a 5-year effort that also includes increases for CDC and AHCPR; revenues for the increases are supposed to come from a tobacco settlement (not yet enacted). For further details, see the NIH section of CRS Issue Brief 98011, *Research and Development Funding: Fiscal Year 1999*.

#### **Issues for Congress**

Much of the congressional attention to NIH in the 105th Congress has focused on budgetary and appropriations issues. Reauthorization legislation to extend provisions that expired in FY1996 is also expected this session, and some hearings have been held.

The Administration's sizeable request for FY1999, at an 8.4% increase, is in line with legislative proposals that call for doubling the NIH budget in 5 to 10 years, requiring annual increases of between 7% and 15%. Examples of such proposals are S.Res. 15 (Mack), H.Res. 83 (Gekas), S.Res. 170 (Specter), and S. 1305 (Gramm/Lieberman). The funding source for such large increases can be problematic because of the budget caps on discretionary spending. Historically, within the appropriations bill for Labor-HHS-Education, support for biomedical research has been in perpetual competition with other discretionary programs, most of which have fared worse than NIH in recent years. The Administration's proposal to fund medical research increases from potential (but as yet uncertain) tobacco settlement revenues has been met with considerable skepticism. Several other bills have been introduced that seek to provide extra funding for NIH beyond its annual appropriation by establishing research trust funds in the Treasury, to be supported by income tax checkoffs, health plan premium set-asides, or tobacco settlement money. Meanwhile, during appropriations subcommittee hearings that began in early March, some questions have been raised about how NIH could responsibly spend such increases in funding.

Both the appropriations and the authorizing committees have conducted considerable debate and several hearings on NIH priority setting and resource allocation among the NIH institutes, among various disease categories, and between laboratory and clinical research (see CRS Report 97-917, *Disease Funding and NIH Priority Setting*). In response to a directive in the FY1998 Labor-HHS-Education appropriations act, NIH contracted with the Institute of Medicine of the National Academy of Sciences to do a 6-month study of NIH research priority setting. The study committee held its first meeting on March 6, 1998, and has an Internet site at <a href="http://www2.nas.edu/hsp/214e.html">http://www2.nas.edu/hsp/214e.html</a>.

A number of potential issues may arise in conjunction with expected reauthorization legislation, some of which were embodied in a Senate-passed bill from the 104<sup>th</sup> Congress ("NIH Revitalization Act of 1996," S. 1897, S.Rept. 104-364). They include extension of various program authorities, provisions for encouraging clinical research, additional focus on several research areas, including alternative medicine, women's health research, and bioengineering research, reductions in NIH administrative structure, and establishing a trust fund for biomedical research. There may also be debates over potentially contentious issues related to the use of human fetal tissue or human embryos in research

(see CRS Report 95-910, *Human Embryo Research*), and over attempts to prohibit human cloning research (see CRS Report 97-335, *Cloning: Where Do We Go From Here?*).

Institute or Center	FY1997 comp <sup>a</sup>	FY1998 comp <sup>b</sup> (% incr FY97-98)		FY1999 req. <sup>b</sup> (% incr FY98-99)	
Cancer	\$2,389.1	\$2,547.3	6.6%	\$2,776.3	9.0%
Heart/Lung/Blood <sup>c</sup>	1,488.2	1,585.8	6.6%	1,714.5	8.1%
Dental Research	197.1	209.4	6.3%	229.5	9.6%
Diabetes/Digestive/Kidney	813.1	873.9	7.5%	944.3	8.1%
Neurology/Stroke	729.3	780.7	7.1%	844.3	8.1%
Allergy/Infectious Diseases	1,257.8	1,351.7	7.5%	1,468.3	8.6%
General Medical Sciences	995.5	1,066.0	7.1%	1,145.4	7.5%
Child Health	631.6	674.8	6.8%	727.0	7.7%
Eye	331.6	355.7	7.3%	384.3	8.0%
Environmental Health	307.6	330.1	7.3%	354.8	7.5%
Aging	484.3	519.3	7.2%	558.0	7.5%
Arthritis	256.2	274.8	7.2%	295.6	7.6%
Deafness	188.3	200.7	6.6%	215.7	7.5%
Nursing Research	59.6	63.6	6.8%	68.3	7.5%
Alcohol Abuse/Alcoholism	211.3	227.2	7.5%	245.7	8.2%
Drug Abuse	499.7	527.2	5.5%	576.3	9.3%
Mental Health	700.7	750.2	7.1%	809.7	7.9%
Human Genome Research	189.0	217.7	15.2%	240.1	10.3%
Research Resources	414.0	453.9	9.6%	514.8	13.4%
Fogarty Center	26.5	28.3	6.7%	30.4	7.5%
Library of Medicine	150.4	161.2	7.2%	174.7	8.4%
Office of Director <sup>c</sup>	229.7	241.7	5.2%	254.7	5.4%
Buildings & Facilities	200.0	207.0	3.5%	225.0	8.7%
[AIDS/Office of AIDS	[1,501.1]	[1,607.1]	7.1%	[1,730.8]	7.7%
Research (non-add)] <sup>d</sup>					
Total, NIH	\$12,750.4	\$13,647.8	7.0%	\$14,797.8	8.4%

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

Source: NIH FY1999 Justification of Estimates for Appropriations Committees

<sup>a</sup> FY1997 reflects transfer of \$9.5 million to NIDA from the Office of National Drug Control Policy.

<sup>&</sup>lt;sup>b</sup> FY1998 and FY1999 do not reflect transfer of \$27 million for diabetes research for FY1998-FY2002 in accordance with the Balanced Budget Act.

<sup>&</sup>lt;sup>c</sup> FY1997 and FY1998 reflect comparable adjustments for transfer of the Women's Health Initiative from Office of the Director to National Heart, Lung, and Blood Institute.

<sup>&</sup>lt;sup>d</sup> All AIDS funding is shown distributed to the individual institutes, although the FY1999 request places the money in a consolidated OAR account. Total AIDS spending, as reported by NIH, is shown on the last line. The FY1997 and FY1998 appropriations acts did not specify amounts for AIDS.