

National Institutes of Health in the FY 2005 Budget

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HIGHLIGHTS

- The National Institutes of Health (NIH) would receive \$28.8 billion for its total budget in FY 2005, an increase of \$729 million (2.6 percent) over the FY 2004 estimate. NIH R&D would increase 2.6 percent to \$27.9 billion (see Table II-9).
- The budget request would support a record total of 39,986 research project grants, including 10,393 new and competing awards, an increase of 258 over FY 2004.
- The average cost of research project grants would increase by 1.3 percent. Non-competing continuation awards would receive 1.9 percent increases; new and competing awards would receive average cost increases of 1.0 percent.
- \$1.7 billion is proposed for NIH biodefense research, an increase of \$121 million (7.4 percent).
- The NIH Director's Roadmap initiative would receive \$237 million, an increase of \$109 million (85.2 percent).
- Individual NIH institutes and centers would receive increases ranging from 2.8 percent to 3.6 percent. One notable exception is the National Center for Research Resources (NCRR), which would see a decrease of 7.2 percent, mostly due to a reduction in facilities spending.
- Ruth L. Kirschstein National Research Service Awards will increase by 225; however, stipend levels will remain at the FY 2004 level.

BACKGROUND

The National Institutes of Health (NIH) is the world's premier medical research institution, supporting more than 212,000 research personnel at over 2,800 research universities, medical schools, teaching hospitals, independent research institutes and industrial organizations throughout the United States and the world. NIH is the second largest supporter of R&D in the federal government, after the Department of Defense (DOD). Located within the Department of Health and Human Services (HHS), the NIH is comprised of 27 distinct institutes and centers (ICs), each of which has an explicit mission directed to the advancement of an aspect of biomedical and behavioral sciences. An institute's focal point may be a particular disease, organ system, stage of development, or have a crosscutting mission such as developing research tools and other resources.

FY 2004 is the first budget year for the NIH following a five-year doubling of the agency's budget, which was completed between FY 1998 and 2003. During this doubling period, NIH received annual funding increases ranging from 14-16 percent and was able to expand both basic and applied research. The doubling provided new insights into human biology and behavior that have accelerated solutions to human disease and disability. However, there is concern that many policy makers see the completion of the doubling as a time to devote scarce resources to other agencies and provide inflationary future increases for the NIH, potentially impeding the NIH's ability to take full advantage of the recent investments. The relatively small increase afforded the agency in FY 2004, and the approximately 2 percent increases projected into the future, are below projected levels of biomedical research and development inflation, and provide the NIH with significant administrative and managerial challenges.

The NIH receives broad support from both chambers of Congress, particularly from the chairmen and ranking members of the House and Senate Labor, Health and Human Services, Education and Related Agencies Appropriations subcommittees. This is evidenced by the amendment to the Senate's FY 2004 budget resolution last year that would have added \$1.8 billion to the allocation for NIH and passed the Senate by a vote of 96-1, and the strong support given to an amendment to the FY 2004 Labor-HHS-Education Appropriations bill to add \$1.5 billion to the NIH that was ruled out of order because it was offset by

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emergency spending. However, even though there is strong support for the NIH, due to the large budget deficit and the continuing overseas military operations, Congress will be hard pressed to provide more funds than the President has recommended for FY 2005.

FY 2005 FUNDING REQUEST

The FY 2005 budget request of \$28.8 billion for the NIH is an increase of \$729 million (2.6 percent). Of this total, 97 percent or \$27.9 billion is classified as R&D; the remainder is for training and research, management and support (RMS). This reflects an increase in R&D of \$703 million (2.6 percent; see Table II-9). NIH estimates the Biomedical Research and Development Price Index (BRDPI) increase for FY 2005 at 3.5 percent.

The largest segment of the NIH budget is devoted to research project grants (RPGs). In FY 2005, the NIH proposes to allocate \$14.9 billion to RPGs, an increase of 2.7 percent, for a total of 37,744 RPGs, an increase of 515 over the FY 2004 estimate. RPGs are generally investigator-initiated awards that are peer-reviewed and awarded competitively based on the peer review score. The total number of grants includes 27,351 non-competing continuation grants, an increase of 257 or 0.9 percent, and 10,393 new competing awards, an increase of 258 or 2.5 percent. The NIH also plans to award 2,242 SBIR/STTR (Small Business Innovation Research and Small Business Technology Transfer) grants at a cost of \$618 million for a total of 39,986 grants (see Table II-10). The average cost of an RPG would increase by an average of 1.3 percent. Within this aggregate increase, non-competing continuation awards would receive increases of 1.9 percent and competing RPGs would receive average cost increases of 1.0 percent. NIH expects a success rate of 27 percent, the same level as FY 2004, but slightly lower than the 30 percent in FY 2003 and 31 percent in FY 2002.

In addition to RPGs, NIH also funds research through its intramural program, R&D contracts, and research centers. The NIH intramural program, which is conducted mostly at the Bethesda, Maryland campus by NIH's world-class scientists, accounts for 9.6 percent of the agency's total budget under the Administration's budget, an increase of \$106 million (4.0 percent). R&D contracts comprise approximately 9.4 percent of the agency's budget, a decrease of \$111 million or 3.9 percent from FY 2004. This decrease is due primarily to the large number of

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biodefense research contracts awarded in FY 2004. Research centers would receive \$2.7 billion, an increase of \$152 million (5.9 percent).

The agency also provides significant **training** opportunities for young researchers, and proposes a total of 17,791 individual and institutional awards under the Ruth L. Kirschstein National Research Service Awards (NRSA) program, an increase of 225 positions, while increasing the training budget by \$15 million to \$764 million (2.0 percent). The budget proposes to hold stipends for pre- and post-doctoral students at the FY 2004 level.

The NIH classifies 54.4 percent (\$15.2 billion) of the total spending on R&D as basic research, an increase of \$480 million (3.3 percent), making NIH the largest federal supporter of basic research with 57 percent of the nation's overall federal investment in basic research. The agency is also the largest federal supporter of applied research with over 43 percent of the total federal investment. Applied research comprises 44.7 percent of the NIH's R&D budget, an increase of \$191 million (1.6 percent). NIH does not classify any of its work as development (see Table II-1).

The remaining \$258 million of R&D funds at the NIH is classified as **facilities** (see Table II-1). \$150 million of this request is slated to fund an additional 20 biosafety level 3 (BSL-3) laboratories in metropolitan areas throughout the country. NIH estimates that once these facilities are completed, they will be able to support over 200 simultaneous research projects aimed at developing medical protection from bioterrorism. The remaining \$108 million would be for non-biodefense intramural facilities projects such as general repairs and improvements. The FY 2005 budget request does not include any funds for the extramural facilities construction program in the National Center for Research Resources (NCRR), which was funded at \$119 million in FY 2004.

FY 2005 PRIORITIES

The NIH budget mechanism table (see Table II-10) reflects a significant increase (10.0 percent) for the Office of the Director. A large portion of this increase would be targeted for **NIH Roadmap** proposal, the hallmark of NIH Director Elias Zerhouni, M.D.,'s vision for the agency. The \$237 million slated for this initiative would be distributed to the institutes and centers to address "critical roadblocks and knowledge gaps that currently constrain rapid progress in biomedical research." \$60

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million of the funding would come from the NIH Director's Discretionary Fund, and the remaining \$177 million would be funded through contributions from each of the component institutes and centers.

The NIH Roadmap targets research investments that promise to yield far-reaching dividends in medical research. Initiatives cut across NIH Institutes and Centers, and integrate the work of multiple disciplines, with the expectation that they will lead to advancements that address the most pressing health needs of Americans. The NIH Roadmap's three specific initiatives are:

- ▶ New Pathways to Discovery (\$137 million), which focuses on generating new knowledge and building a better "toolbox" for researchers in the 21st century including new technologies, databases and other resources;
- ▶ Multidisciplinary Teams of the Future (\$39 million), which establishes awards for centers and training, as well as for conferences aimed at building multidisciplinary research teams; and
- ▶ Re-engineering the Clinical Research Enterprise (\$61 million), which will facilitate the rapid translation of discoveries from the laboratory to the clinic, train a workforce of clinical investigators, create clinical research networks, and enhance the coordination of safety and ethics rules and regulations.

The NIH's number one priority in the area of **biodefense** is to support research needed in the war on terrorism. This includes basic research into the biology of microbial agents with bioterrorism potential, and applied research in the development of new vaccines, diagnostics and therapeutics. The FY 2005 budget request includes \$1.7 billion for NIH biodefense efforts, an increase of \$121 million. Planned initiatives for FY 2005 include completing the Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research; initiating the second phase of construction for specialized biosafety level 3 and 4 research laboratories; and undertaking clinical trials of plague, Ebola, and tularemia vaccine candidates. The NIH biodefense request includes \$47 million from the Public Health and Social Services Emergency Fund (PHSSEF) to develop drugs to prevent injury from radiological exposure, improve methods for measuring radiological exposure and contamination, and develop treatments or drugs to restore injured tissues.

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The FY 2005 NIH budget request includes \$2.9 billion for **HIV/AIDS-related research**, an increase of \$80 million (2.8 percent), including \$100 million provided through the National Institute of Allergy and Infectious Diseases (NIAID) for the Global Fund to Fight HIV/AIDS, Tuberculosis, and Malaria. Research in this area will be focused on developing vaccines, microbicides, and less toxic and cheaper drugs and regimens; strategies to prevent perinatal transmissions; international research; and research to target the disproportionate impact of this disease on racial and ethnic minorities.

The NIH is also concerned about the epidemic of **obesity** in the FY 2005 budget request. The agency proposes increasing spending on obesity research by 10 percent to \$440 million, including a specific \$22 million trans-NIH initiative to better understand the neurobiological, genetic, behavioral, and environmental basis of obesity.

OTHER HEALTH RESEARCH IN THE FEDERAL BUDGET

Although 95 percent of total R&D funding at the Department of Health and Human Services (HHS) comes from the NIH, there is also significant research conducted by several other agencies within HHS and by the Department of Veterans Affairs (VA; see Table II-8).

Under the President's budget, the **Agency for Healthcare Research and Quality (AHRQ)** would receive \$327 million for R&D purposes; however, the agency's entire budget would be funded through transfers from the Public Health Service Evaluation Fund. This represents the same level provided in FYs 2003 and 2004. AHRQ conducts and sponsors health services research to inform decision-making and improve clinical care and the organization and financing of health care.

Funding at the **Centers for Disease Control and Prevention (CDC)** is primarily aimed at non-R&D activities such as public health and health promotion activities, and more recently in biodefense for programs such as increasing state and local preparedness and improving security. The FY 2005 request provides for \$530 million in R&D activities, an increase of \$9 million (1.7 percent) from FY 2004.

(For information on VA medical research, see Chapter 13.)