



I am pleased to present the Congressional Justification of the National Institutes of Health (NIH) Fiscal Year (FY) 2009 Budget Request, including the Annual Performance Plan and the Annual Performance Report. This budget supports the President's and Secretary's priority initiatives and the goals and objectives in the HHS FY 2004-2009 Strategic Plan.

The FY 2009 budget request is for a program total of \$29.465 billion, equal to the FY 2008 Enacted Level.

One of the greatest challenges facing our society is the skyrocketing growth of health care costs: health care currently accounts for more than \$2 trillion in expenditures. The Centers for Medicare and Medicaid Services project that by 2016, the Nation's health care costs will reach a staggering \$4.1 trillion. The most expensive way to practice medicine is to do it the way we do it now, where every interaction between patient and medical care system can involve as many as twenty people. Biomedical research supported by the NIH is an essential component in the effort to reduce this expense.

The Nation's return on investment in NIH includes declines in death rates for cardiovascular diseases and increase in cancer survivorship—only two examples of the many advances driven by NIH. These investments in NIH have brought us to where we can now clearly envision an era when the treatment paradigm of medicine will increasingly become more predictive, personalized, and preemptive, with greater participation by patients in the active management of their health. We expect to move away from today's costly and predominantly curative model of health care, which requires us to wait for the disease to occur before intervening, to a preemptive model.

As we reach that inflection point in our efforts to truly improve health, we must nurture a vibrant, creative research workforce, including sufficient numbers of new investigators with new ideas and new skills, such as interdisciplinary research skills. In FY 2007, we set a goal of sustaining 1500 new investigators each year—the NIH historical average from FY 2000 to FY 2005. I am happy to report we exceeded this goal. In FY 2008 and in the FY 2009 President's Budget, we will continue our support of new investigators. To help ensure the pipeline of future investigators is maintained as the current workforce ages and begins to retire, the first cohort of Pathway to Independence awardees will graduate to noncompeting Research Project Grant support, allowing a third cohort of entrants into the Pathway to Independence program in FY 2009. In FY 2009, we will continue the NIH Director's Bridge Award program, added by Congress in FY 2007 to support investigators, with the same level of support provided in the FY 2007 final appropriation. Finally, the FY 2009 request provides a modest stipend increase of 1 percent for pre- and post-doctoral research fellows in the Ruth L. Kirschstein National Research Service Award program, to help ensure the pipeline of future investigators is adequate as the current workforce reaches retirement age.

We plan to support the Common Fund in FY 2009 at a level of \$534 million, an increase of \$38 million over FY 2008, and will fund, as in 2007 and 2008, a third cohort of new Innovator Awards directed at our most creative early-career investigators. The Common Fund is an incubator for new ideas and initiatives that will accelerate the pace of discovery. NIH is preparing to launch its second cohort of Roadmap initiatives in the Common Fund during FY 2008 and FY 2009 with the selection of two new program areas. NIH is launching 5-year projects in the Microbiome—a project to characterize the microbial content of sites in the human body and their relationship to disease—and in Epigenomics—the study of stable genetic modifications and their relationship to disease. Funds are reserved in the FY 2009 Common Fund for the continuation of the Microbiome and Epigenetics projects and up to \$40

million for new projects that will be developed over the course of this year. These initiatives are focused on efforts that no single or small group of Institutes or Centers could conduct on their own. These initiatives are transforming; they have fostered synergies and led to other transforming initiatives within NIH.

To ensure an appropriate level of stewardship of our extensive buildings and facilities, in FY 2009 NIH will take the steps necessary to extend the life of some of its current facilities, provide necessary improvements to meet regulatory requirements, and increase overall condition index ratings.

The budget request supports the President's commitment to the Global Fund for HIV/AIDS, Tuberculosis, and Malaria with \$300 million in FY 2009.

The FY 2009 budget continues to support studies of the Genes, Environment and Health Initiative to accelerate discovery of the major genetic factors for diseases that have a substantial public health impact.

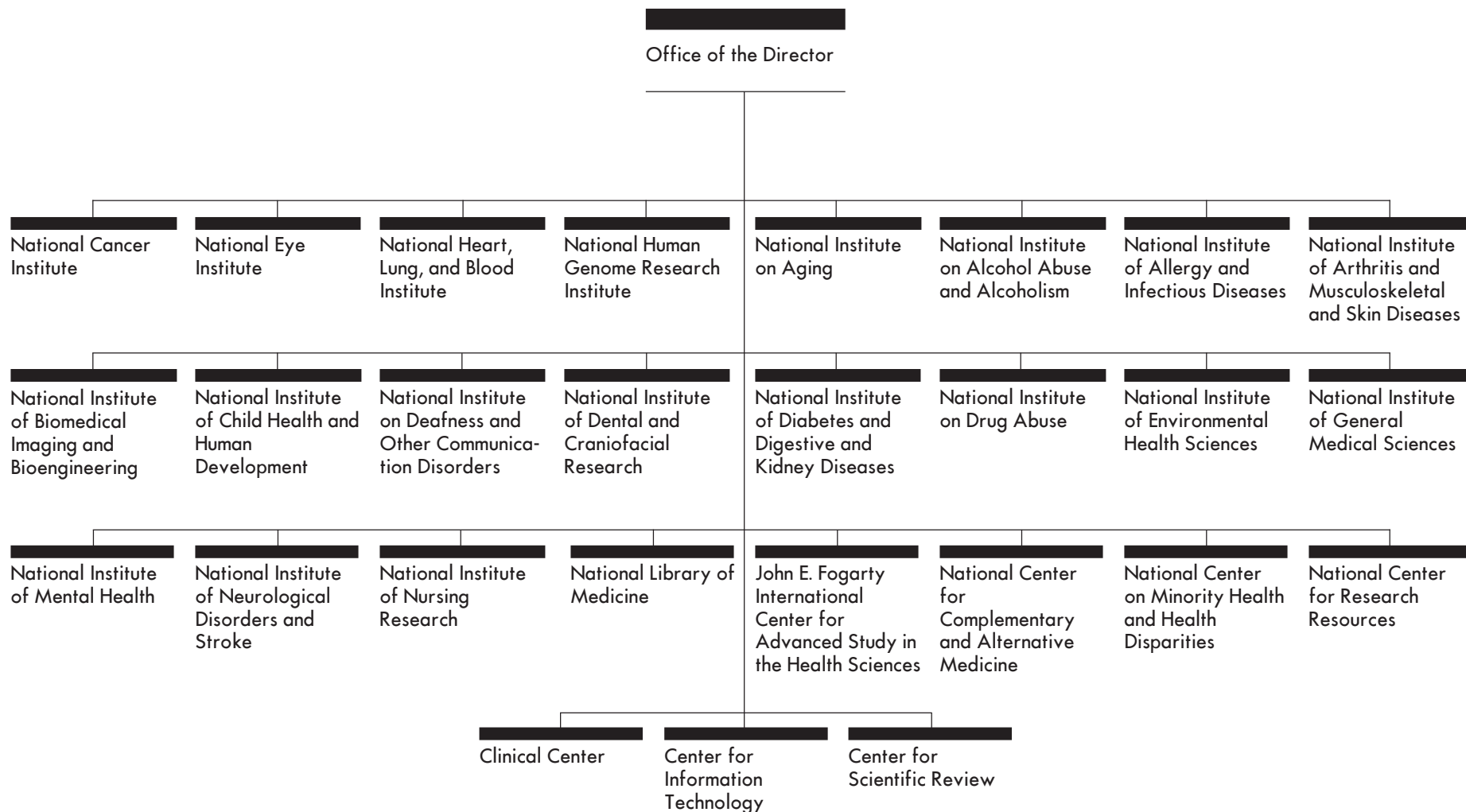
The development of this performance budget request is consistent with the Government Performance and Results Act (GPRA). NIH uses GPRA and many other performance monitoring tools, such as peer review, site visits, and performance-based contracting, to continually assess program performance and to plan future research programs. NIH's effectiveness is recognized by the Office of Management and Budget through the Performance Assessment Rating Tool (PART) in six NIH programs assessed to date that comprise over 95 percent of our budget—the AIDS Research Program and Extramural Construction Program, which were scored as moderately effective—and the Extramural Research Program, Intramural Research Program, Extramural Research Training and Research Career Development Program, and Buildings and Facilities Program, which were all scored as effective.

The pace of discovery in biomedical sciences has never been as rapid or as promising as in the recent past. Research institutions throughout the country have responded to the call for more research and have invested their own resources in facilities and new research faculty to address the growing scope and costs of health challenges. This has made NIH funding more competitive than ever. NIH continues to think creatively and strategically to sustain the successful research programs of our talented grantees and intramural scientists and to capitalize on the expanded opportunities and intellectual resources that the American public has already invested in the NIH. NIH faces many tough choices and we continue to make the difficult calls necessary to sustain to the greatest extent possible the vitality of our science in an increasingly competitive global environment.

The NIH is the world's greatest asset for progress in health through rigorous science and evidence-based knowledge. NIH represents an outstanding investment in the health of the Nation and its global competitiveness in a century characterized by the need to make rapid progress in the life sciences across all of its applications. In the upcoming budget hearings, I look forward to discussing how we can maintain the momentum of discovery and work with you to enact a budget that allows NIH to best continue its mission to uncover new knowledge that will lead to better health for everyone.

Elias A. Zerhouni, M.D.

National Institutes of Health



NATIONAL INSTITUTES OF HEALTH FY 2009 BUDGET OVERVIEW

Introduction

The FY 2009 Congressional Justification is one of several documents that fulfill the Department of Health and Human Services' (HHS') performance planning and reporting requirements. HHS achieves full compliance with the Government Performance and Results Act of 1993 and Office of Management and Budget Circulars A-11 and A-136 through HHS agencies' FY 2009 Congressional Justifications and Online Performance Appendices, the Agency Financial Report and the HHS Performance Highlights. These documents can be found at <http://www.hhs.gov/budget/docbudget.htm> and <http://www.hhs.gov/afr/>.

The Performance Highlights briefly summarizes key past and planned performance and financial information. The Agency Financial Report provides fiscal and high-level performance results. The FY 2009 Department's Congressional Justifications fully integrate HHS' FY 2007 Annual Performance Report and FY 2009 Annual Performance Plan into its various volumes. The Congressional Justifications are supplemented by the Online Performance Appendices. Where the Justifications focus on key performance measures and summarize program results, the Appendices provide performance information that is more detailed for all HHS measures.

The NIH Congressional Justification and Online Performance Appendix can be found at <http://officeofbudget.od.nih.gov/ui/HomePage.htm>

Statement of the National Institutes of Health Mission

The NIH mission is to uncover new knowledge that will lead to better health for everyone.

The National Institutes of Health (NIH) accomplishes its mission through one overarching program: Research. NIH probes the unknown to gain new knowledge; communicates and transfers new knowledge to the public and health care providers; trains investigators; and manages and supports the people, systems, and facilities necessary to carry out this work. These activities are integral elements of the research enterprise with the goal of adding to the body of knowledge that will help prevent, detect, diagnose, and treat disease and disability.

The NIH research mission is pursued by an array of Institutes and Centers (ICs), which support and conduct research through an extensive extramural research community and the intramural research program.

NIH Vision

The NIH Core Strategic Vision contains four pillars, known as the four Ps:

- Transform medicine and health from a Curative to a Preemptive paradigm (Preemptive)
- Support basic research to identify the earliest molecular stages of disease in complex biological systems (Predictive)
- Accelerate translation of findings from the bench to the bedside to the community (Personalized)
- Provide the evidence and knowledge base to allow for a rational transformation of our healthcare system to one that is patient-centered and pro-active (Participatory)

The four Ps promote an era of precision medicine by transforming medicine from the current practice of intervening too late in a disease process to a new era when medicine will be more predictive, personalized and preemptive. This will be accomplished through a broader scientific understanding of the fundamental mechanisms that lead to disease years before it strikes the patient. It will also require a transformation in the fundamental relationship between healthcare providers and patients, necessitating continuous participation of individuals, communities and healthcare institutions as early as possible in the natural cycle of a disease process.

For the purpose of planning and performance assessment, the NIH achieves its mission through one over-arching program—**Research**. Under this program, NIH carries out activities in five functional areas (Scientific Research Outcomes, Communication and Transfer of Results, Capacity Building and Research Resources, Strategic Management of Human Capital, Program Oversight and Improvement). They are described in the Performance Detail section available on-line.

In addition to supporting the Agency goals and vision, the NIH budget request supports the HHS Strategic Plan, the President's Management Agenda (http://www.whitehouse.gov/omb/budintegration/pma_index.html), HHS 20 Department-Wide Objectives, the Secretary's 500-Day Plan (<http://www.hhs.gov/500DayPlan/>), and Healthy People 2010 (<http://www.healthypeople.gov/>), (See Detailed Performance Tables). In particular, NIH substantially contributes to HHS Strategic Goal 4: Advance scientific and biomedical research and development related to health and human services.

The Institutes and Centers

NIH is composed of 27 Institutes and Centers, whose research activities extend from basic research that explores the fundamental workings of biological systems and behavior, to studies that examine disease and treatments in clinical settings, to prevention, and population-based analyses of health status and needs. The Office of the Director, NIH, provides leadership, oversight, and coordination for the enterprise.

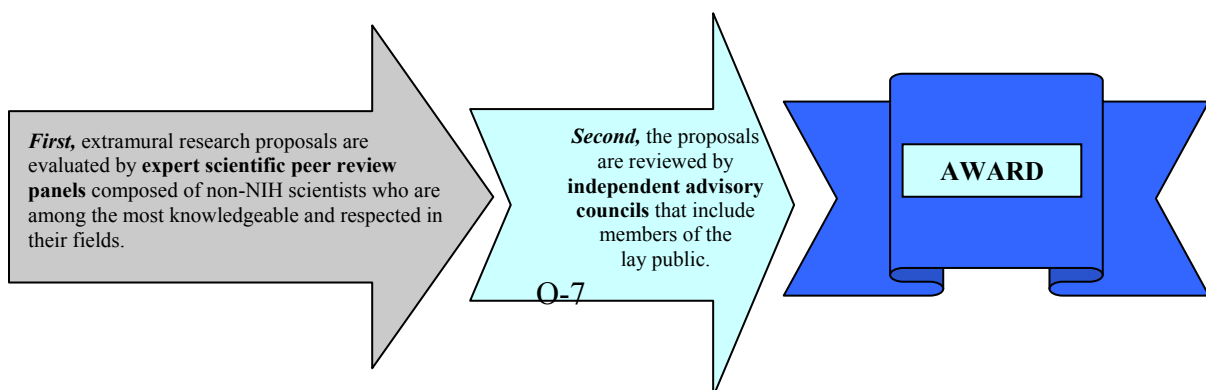
To most Americans, the ICs are the most “visible” NIH component. While some of the ICs focus on specific diseases (e.g., cancer, diabetes), others concentrate on organ systems (e.g., heart, eye, kidney); focus on a stage of life (e.g., children, the aging population); or address overarching opportunities (e.g., deciphering the human genome, understanding cellular biology) and technologies (e.g., biomedical imaging). ICs support research and training through extramural activities and also conduct “in-house” science and training through intramural activities.

The Extramural Community

The extramural community is composed of non-Federal scientists at universities, medical centers, hospitals, and research institutions throughout the country and abroad. NIH support allows these investigators and their institutions to conduct the vast majority of research that leads to improvements in the prevention, detection, diagnosis, and treatment of disease and disability. In tandem with the conduct of research, the extramural community trains the next generation of researchers, enhances the skills and abilities of established investigators, and provides our Nation with research infrastructure capacity.

More than \$8 out of every \$10 appropriated to NIH is provided to the extramural scientific community. This community includes more than 300,000 scientists and research personnel affiliated with over 3,100 organizations, including universities, medical schools, hospitals, and other research facilities located in all 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, and points abroad.

The majority of NIH funds are awarded through a highly competitive peer review process to the most promising and productive scientists as illustrated below. This two-tiered independent review system is critical to ensuring that the best proposals are funded. In FY 2006, NIH reviewed approximately 70,000 research and training applications.



NIH's Intramural Laboratories

A much smaller fraction of NIH funds, approximately 10 percent of the budget, supports a core program of basic and clinical research activities administered and staffed by NIH physicians and scientists known as the Intramural Research Program. Approximately 1,250 principal investigators lead intramural research projects. This includes the NIH Clinical Center, NIH research facilities in other states, and other collaborative efforts that provide scientific, clinical, and educational benefits to citizens of the United States and the world.

NIH ensures the research conducted in its intramural laboratories is of the highest caliber. Each IC maintains a board of scientific counselors, composed of external experts, that reviews the intramural programs and makes recommendations to the Institute Director. The Intramural program enables scientists to apply the results of laboratory research to patient care and to seek answers in the laboratory to questions that arise in the clinical setting, permitting a two-way process of the translation of scientific discovery to solving clinical problems and vice versa. This national resource permits NIH to respond rapidly to critical health problems and emergencies and take advantage of emerging opportunities.