



As Director of National Institutes of Health (NIH), it is my honor to present the Congressional Justification of the NIH fiscal year (FY) 2011 Budget Request, including the Annual Performance Plan and the Annual Performance Report. I am pleased to state that this budget request reflects the President's firm commitment to America's leadership in biomedical research. In this time of challenging and competing priorities, the Administration held true to the promise of boosting the Federal government's investment in research and technology. It is a clear acknowledgment of the potential for science to address some of the major issues that face our Nation and the world.

The FY 2011 budget request is for a program total of \$32.2 billion, an increase of \$1 billion or 3.2 percent over the FY 2010 Enacted Level. It is predicated on the vision that human health can be vastly improved through major scientific advances and breakthroughs. Indeed, these funds will enable the biomedical medical community to focus their considerable energies on discovering new cures, advancing technology, and solving some of our greatest health challenges.

The \$1 billion increase in NIH funds will support scientific opportunities in several emerging areas. Innovative high throughput technologies, including DNA sequencing, imaging, and computational biology, represent areas of exceptional promise. The success of the Human Genome Project and several other subsequent major projects provides a powerful foundation for a new level of understanding of human biology, and has opened a new window into the causes of disease. That includes the revelation of hundreds of previously unknown risk factors for cancer, autism, diabetes, heart disease, hypertension, and a long list of other common illnesses that have previously been unapproachable. In the area of cancer, a new ability to achieve comprehensive understanding of the mechanisms responsible for malignancy has already provided insights into diagnostics, and pointed to a whole new array of drug targets. New stem cell research projects are underway, encouraged by the President's Executive Order on stem cell research, and hold out great promise for applications to diseases like Parkinson's disease, type 1 diabetes, and spinal cord injury. New partnerships between academia and industry promise to revitalize the flagging drug development pipeline. An era of personalized medicine is appearing, where prevention, diagnosis, and treatment of disease can be individualized, instead of using the one-size-fits-all approach that all too often falls short, wasting health care resources and potentially subjecting patients to unnecessary and dangerous medical treatments and diagnostic procedures. Global health research faces new and powerful opportunities to develop better diagnostics and therapeutics for both infectious and non-communicable diseases. Vigorous U.S. support of biomedical research in all these areas promises to save lives, reduce the burden of chronic illness, stimulate the economy, empower new and more effective prevention strategies, and reduce health care costs.

Based on scientific opportunity, increases will be targeted to many trans- NIH specific programs, including:

The *Therapeutics for Rare and Neglected Diseases (TRND) program*. This program directs \$50 million to bridge the wide gap in time and resources that often exist between basic research and human testing of new drugs and encourage and speed the development of new drugs for rare and neglected diseases. This program is grounded in, and is intended to complement, existing processes for drug development in the pharmaceutical industry.

*Clinical and Translational Science Awards (CTSA)*. CTSA's were developed and implemented to reduce the time it takes for laboratory discoveries to become treatments for patients, to engage communities in clinical research efforts, and to train a new generation of clinical and translational researchers. A total of \$500 million will be invested in this program.

The *Basic Behavioral and Social Sciences Opportunity Network (OppNet)*, launched by NIH in FY 2010 through funds provided by the American Recovery and Reinvestment Act, will be expanded in FY 2011. This trans-NIH initiative provides \$20 million to further our understanding of fundamental mechanisms and patterns of behavioral and social functioning relevant to the Nation's health and well-being, as they interact with each other, with biology, and the environment. Research results will lead to new approaches for reducing risky behaviors and improving health.

Training stipends provided by the *Ruth L. Kirschstein National Research Service Awards*, aptly named for a very committed and dedicated "in house" NIH scientist who passed away in 2009, will be increased by six percent in FY 2011. This increase sends a clear message to both existing and "would be" scientists that their efforts are valued.

Identified by the Administration as key areas of concern in 2010, the FY 2011 budget request will continue and reinforce cancer research and investigations into the causes of and treatments for autism spectrum disorders.

NIH's HIV/AIDS research program funding will be increased to \$3.2 billion in FY 2011 and is the largest and most significant effort in AIDS research in the world. NIH Working Groups and the Office of AIDS Research's External Advisors will have a major role in determining the most compelling scientific opportunities - - both nationally and globally - - to address this disease.

NIH will direct \$382 million, \$22 million above last year, to the Administration's National Nanotechnology Initiative whose goal is to apply technological advancements to a wide array of human health, environmental protection, and safety issues and concerns.

NIH will provide funds to the Department of Energy's construction of a high performance synchrotron light source, which is a promising tool for use by the biomedical research community.

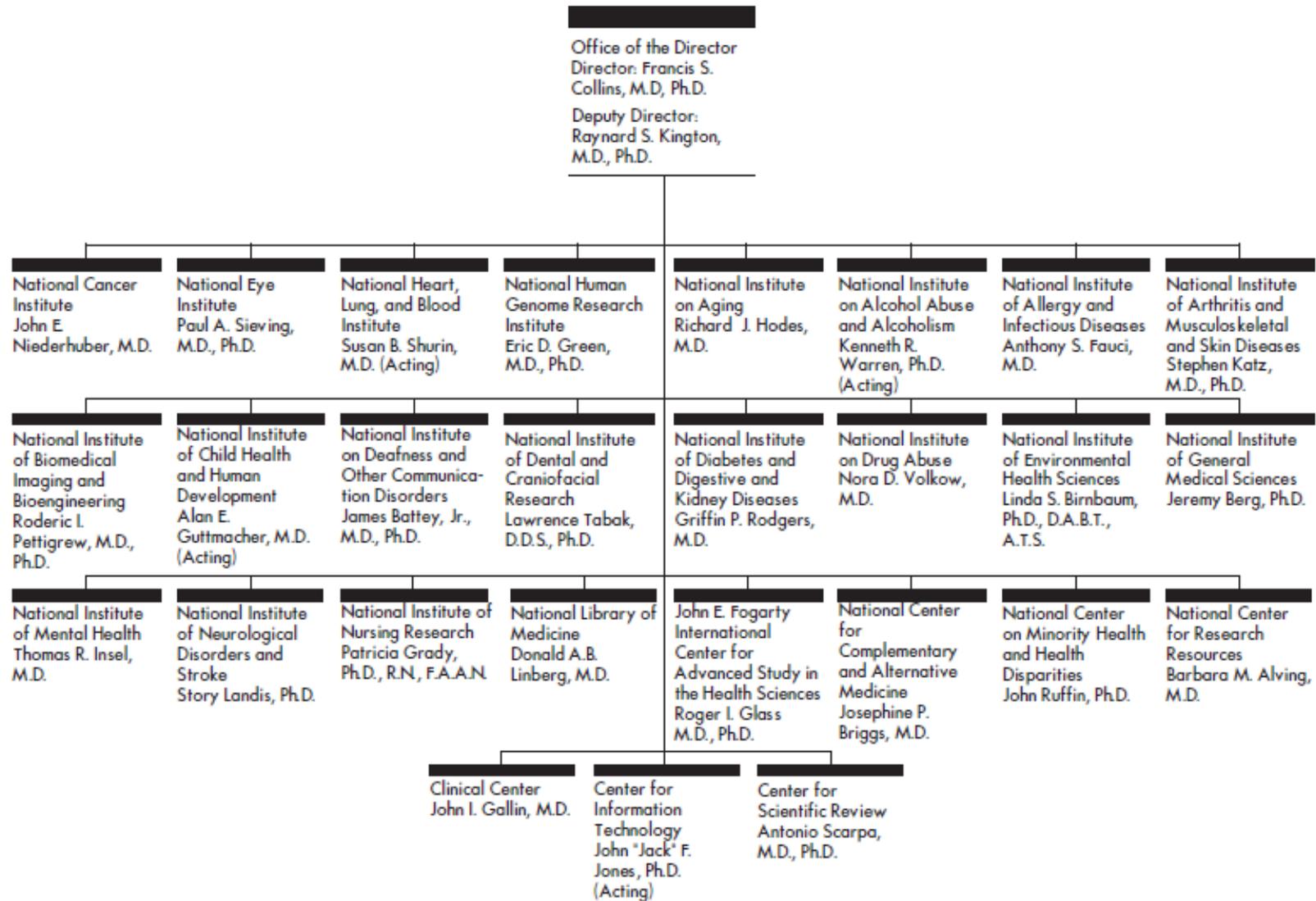
The budget request continues to support the Nation's commitment to the Global Fund for HIV/AIDS, Tuberculosis, and Malaria with \$300 million in FY 2011.

The National Institutes of Health is the world's greatest asset for progress in health through rigorous science and evidence-based knowledge. Research conducted and supported by NIH touches people's lives every day. NIH is the largest single engine for outstanding biomedical research in this country—and the world. Not only does NIH have an impact globally, it also has a lasting impact at the community level, bringing intellectual and economic growth to towns and cities across America. 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.

I look forward to discussing how we can maintain the momentum of discovery.

Francis S. Collins, M.D., Ph.D.

# National Institutes of Health



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President Obama's and Secretary Sebelius' visit to NIH in September 2009

# NATIONAL INSTITUTES OF HEALTH

## OVERVIEW

### Introduction

The FY 2011 Congressional Justification (CJ) 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 the HHS agencies' FY 2011 Congressional Justifications and Online Performance Appendices, the Agency Financial Report, and the HHS Summary of Performance and Financial Information. These documents are available at <http://www.hhs.gov/asrt/ob/docbudget/index.html>.

The FY 2011 CJs and accompanying Online Performance Appendices contain the updated FY 2009 Annual Performance Report and FY 2011 Annual Performance Plan. The Agency Financial Report provides fiscal and high-level performance results. The HHS Summary of Performance and Financial Information presents key past and planned performance and financial information.

The FY 2011 Department of Health and Human Services CJs fully integrate NIH's FY 2009 Annual Performance Report and FY 2011 Annual Performance Plan into its various volumes. The CJs are supplemented by the Online Performance Appendices, where its focus is on key performance measures and program results.

### **Vision**

*To uncover new knowledge that will lead to better health for everyone*

### **Mission Statement**

NIH's mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems, and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability. Molecular approaches to health and disease have steadily gained momentum over the past several decades and are now poised to catalyze a revolution in medicine. Increasingly, investigators are working in teams, accelerated by interdisciplinary approaches and empowered by open access to tools, databases, and technologies, so NIH will seek a careful balance between investigator-initiated projects and large-scale community resource programs.

## The Institutes and Centers

The NIH research mission is pursued by 27 Institutes and Centers (ICs), which support and conduct research through an extensive extramural research community and the intramural research program. These 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.

While some of the ICs focus on specific diseases (e.g., cancer, diabetes), others concentrate on organ systems (e.g., heart, eye, kidney); some examine 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.

### *Extramural Community*

The extramural community is composed of non-Federal scientists at universities, medical centers, hospitals, and research institutions throughout the country and abroad. With NIH support, these investigators and their institutions 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 also contributes to training the next generation of researchers, enhancing the skills and abilities of established investigators, and renewing the infrastructure for NIH-sponsored research.

More than \$8 out of every \$10 appropriated to NIH flows out to the scientific community at large. The extramural research community numbers more than approximately 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.

NIH funds are primarily awarded through a highly competitive process to the most promising and productive scientists. A two-tiered independent review system is critical to ensuring that the best proposals are funded. In FY 2009, NIH reviewed approximately 43,125 research project grant (RPG) applications, in addition to over 23,000 applications to the Grand Opportunity (GO) and Challenge grant programs made possible by awarded with American Reinvestment and Recovery Act (ARRA) funds.

### *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 in-house research program includes the

NIH Clinical Center and other resources 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.