



As Director of the National Institutes of Health (NIH), I am pleased to present the Congressional Justification of the NIH fiscal year (FY) 2012 budget request, including the annual performance report and plan. This budget request for a \$31.987 billion total program level reflects an effort, amid economic uncertainty and fiscal constraint, to fulfill the President's unwavering commitment to international leadership in science and progress in biomedical research.

The requested funding will enhance NIH's ability to support research that prolongs life, reduces disability, and strengthens the economy.

NIH-funded research contributes to economic growth, produces well-paying jobs, and helps to keep the United States competitive on the global stage. This year NIH is proposing a new paradigm for turning lab discoveries into cures and treatments through targeted investments in translational science and medicine.

In FY 2012, NIH will target investments to selected areas of promise for biomedical science to advance public health. For the FY 2012 budget request, NIH has identified one major area of extraordinary opportunity and three other themes that are exceptionally ripe for investment and integral to improving the health of the American people.

***A groundbreaking new program at NIH -- The National Center for Advancing Translational Sciences:*** Recent insights into the molecular basis of disease have identified many promising new targets for therapeutic intervention and created the potential for the development of more effective diagnostics and therapeutics. Yet at the same time, the number of new molecular entities approved by the FDA has been paradoxically falling over the past decade. Recently, pharmaceutical companies have actually been cutting back in several areas of R&D, and biotechnology companies are finding it difficult to identify funds for projects with lead times of more than a few years. In order to address this situation, new public-private partnership paradigms are needed. Accordingly, NIH is proposing to establish a new National Center for Advancing Translational Sciences (NCATS), in order to place the agency in a pivotal position to contribute to re-engineering the pipeline for diagnostics and therapeutics discovery and development. The new Center will bring together resources and skilled scientists to serve as a focal point for innovation in medical product development. NCATS will catalyze innovation at key junctures in the pipeline, "de-risk" projects to the point where they become economically attractive for commercial investment, spur new public-private partnerships, and facilitate the regulatory review process through recent initiatives including the NIH-FDA Leadership Council and a research program in Regulatory Science. The Cures Acceleration Network (CAN), authorized by the Affordable Care Act of 2010, will help NIH to play a leading role in the effort to accelerate the development of "high need cures."

In FY 2012, NIH will also emphasize the following three scientific areas that the agency views as instrumental in paving the way for more rapid scientific advances across all areas of human health and disease, including global applications:

- ***First, technologies to accelerate discovery:*** The critical first step in developing more effective therapies for diseases that affect millions of Americans every day, such as heart disease, cancer, and Alzheimer's disease, is illuminating the complex causes of disease. This requires, in part, deciphering the roles and relative contributions of genetic and environmental factors. Investigators are better able to take this first step--and beyond--with such advanced technologies as DNA sequencing, microarray technology, nanotechnology, new imaging modalities, and computational biology. NIH must exploit the potential inherent in this extraordinary opportunity by supporting the development and application of these advanced technologies.
- ***Second, enhancing the evidence base for health care decisions:*** NIH will support rigorous studies for assessing the effectiveness of new therapies and health care interventions within populations and for individuals. Research in comparative effectiveness and personalized medicine is essential to the fulfillment of the agency's mission and will enhance the evidence base for decision making in clinical practice. For example, NIH will fund a Health Maintenance Organization Research Network Collaboratory. This landmark initiative will bring together HMOs caring for more than 13 million patients for the purpose of accelerating research in the high priority areas of epidemiological studies, clinical trials, and electronic-health-record-enabled health care delivery.
- ***Third, new investigators, new ideas:*** Attracting the best and brightest to biomedical research is vital to maintaining the pipeline of talented and innovative researchers. To help young scientists develop, NIH will support two programs: the NIH Director's New Innovator Award, which supports new investigators with potentially high-impact projects, and the Early Independence Award, which enables our most talented young scientists to move directly from a doctoral degree to an independent research career.

This budget reflects NIH's long-standing commitment to invest strategically using performance-based analysis, as required under the Government Performance and Results Act (GPRA). In particular, NIH's strong peer review process, site visits, performance monitoring, program evaluation and performance-based contracting enable NIH to ensure its investments generate the best possible results for the American people.

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 welcome the opportunity to discuss this budget request and NIH's plans for FY 2012 and the years ahead.

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

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NATIONAL INSTITUTES OF HEALTH**

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