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

Volume I Overview

Page No.

Tab 4: NIH Common Fund

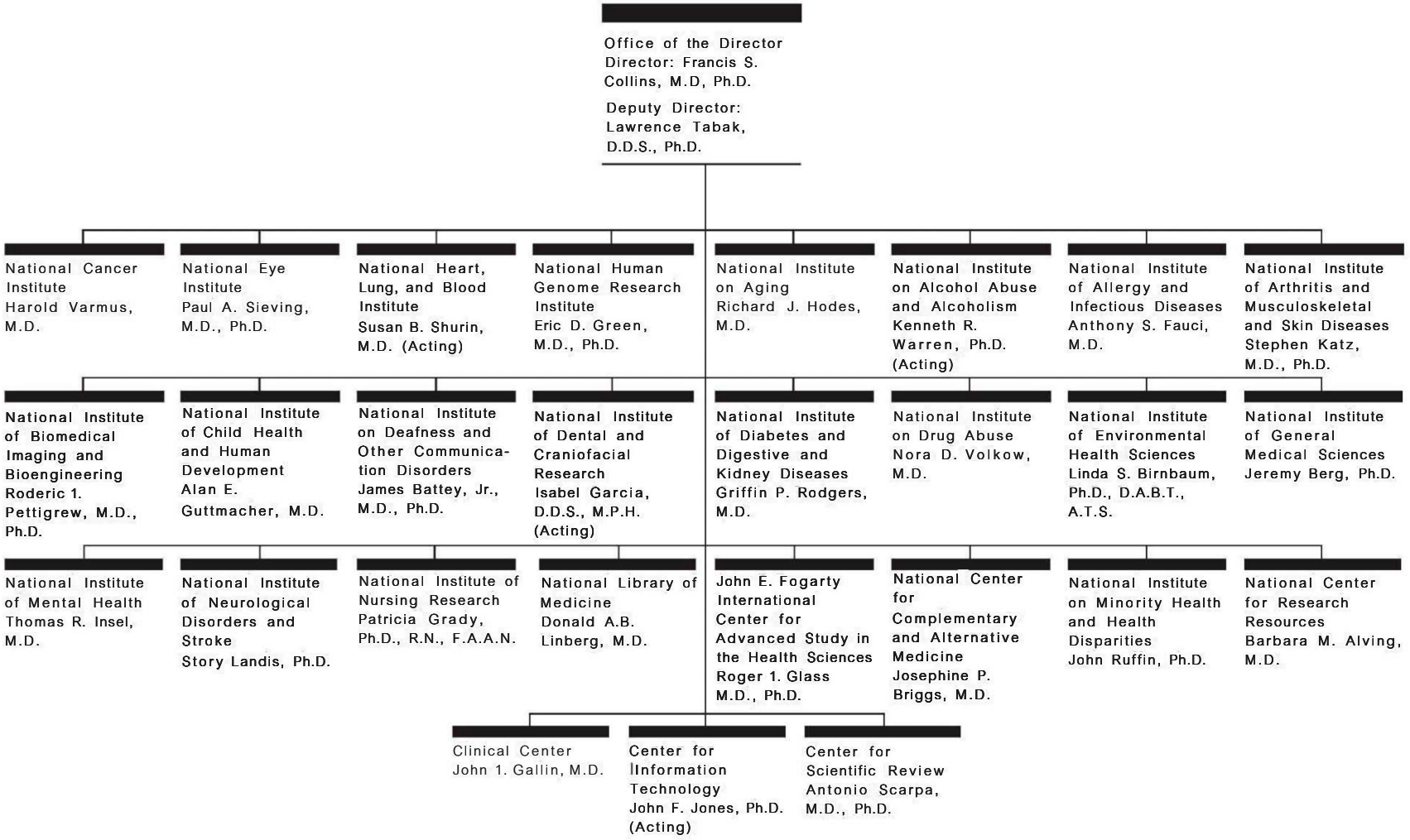
Tab 5: Office of AIDS Research

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Executive Summary

National Institutes of Health



FY 2012 Budget Request
National Institutes of Health

Introduction and Mission

The mission of the National Institutes of Health (NIH) is science in the pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy lives and to reduce the burdens of illness and disability. As a steward of public funds, NIH has a responsibility to ensure that the Nation's investment in biomedical research is fully leveraged to maximize its benefit not only to fundamental scientific understanding, but also to improvements in treatments and cures for disease, as well as the overall quality of life for Americans and other populations around the globe.

NIH supports a robust research enterprise that provides biomedical researchers with the tools and incentives that help foster discovery. These include state-of-the-art technologies and facilities for scientific investigation; mechanisms for data sharing and interdisciplinary collaboration; and, the means to translate fundamental research findings into clinically useful applications. NIH support of research and training stimulates the creativity of individual investigators, while fostering highly productive collaborations among disciplines.

FY 2012 Budget Request
National Institutes of Health

OVERVIEW OF BUDGET REQUEST

Total Budget Request

($ in millions)

	FY 2010 Actual	FY 2012 Budget Request
Total Program Level[1]	$31,243	$31,987
Change from FY 2010 Actual: Dollars	---	+$745
Change from FY 2010 Actual: Percent		+2.4%

[1] Reflects FY 2010 total program level on a comparable basis with FY 2012. Includes discretionary budget authority (appropriations from Labor/HHS and Interior Superfund), mandatory Type 1 Diabetes appropriations and Program Evaluation funds from HHS in the NLM..

Overview of NIH Budget Request

The President's Budget request for the National Institutes of Health (NIH) is a total program level of $31.987 billion for fiscal year (FY) 2012—an increase of $745 million or 2.4 percent from the FY 2010 Actual funding level. This funding level invests in areas of extraordinary promise for biomedical science and its supporting infrastructure, while achieving efficiencies to maintain fiscal constraint. Investments in biomedical and behavioral research will increase the understanding of disease and generate tangible progress toward solving the Nation's most pressing health challenges. Through these investments, NIH will help improve the health of the American people, as well as the long-term economic health of the Nation.

Recent progress in genomics and biotechnology has advanced the development of new treatments for a wide range of diseases, such as Alzheimer's, cancer, autism, diabetes, and obesity. NIH-funded researchers have contributed to the identification of more than 800 genetic variants identified in the last five years alone. These discoveries can now be translated into new and improved diagnostics and novel drug targets, a critical task that will most effectively be accomplished through a new model for therapeutics development. The new model will marshal the relevant NIH programs in a concerted effort and draw upon the respective strengths of the public and private sectors.

Progress in stem cell biology is also opening doors to the development of new treatments for a wide range of devastating diseases. In the last three years, NIH-supported researchers have developed and refined methods to reprogram adult human cells to assume a stem cell-like state. These cells, called "induced pluripotent stem cells," are being used to make rapid advances in the study of disease. The next step is to translate these ground-breaking basic discoveries into clinical applications that lead to health improvements and new diagnostic and treatment advances

for patients, as has already begun for products derived from human embryonic stem cells. Three clinical trials of therapeutic products derived from human embryonic stem cells have already received approval from the Food and Drug Administration (FDA) to begin enrolling patients. The first trial, a phase I safety trial sponsored by Geron Corporation to treat spinal cord injury, has already been initiated.

Advances like these are creating exciting opportunities in biomedical research. Through the agency's continuous evaluation and careful management of its research portfolio, NIH focuses funding on those areas of greatest promise. This portfolio management approach ensures the most effective use of funding to achieve the greatest results within fiscal constraints. With continued support, NIH will help to revolutionize patient care, reduce health care costs, and generate economic growth.

Benefits of Biomedical Research

NIH-driven advances have had profound effects on the health and quality of life for all Americans. Since 1970, life expectancy in the United States has risen from 71 years to 78 years. Similarly, the percentage of the elderly with chronic disabilities has declined from 27 percent in 1982 to 19 percent in 2005. NIH-supported research contributed significantly to these improvements by helping reduce deaths from heart disease, stroke, HIV/AIDS, cancer, and other diseases, and by developing innovative treatments for cardiovascular disease, age-related macular degeneration, musculoskeletal conditions, and other chronic conditions. NIH-supported research has led to dramatic improvements in many areas, including:

- Minimally invasive techniques funded by NIH to prevent heart attacks and highly effective drugs to lower cholesterol, control high blood pressure, and break up artery-clogging blood clots have dramatically reduced the death rate by 60 percent for coronary heart disease and by 70 percent for stroke since 1970.

- Over the past 15 years, cancer death rates have dropped 13.5 percent among women and 21.2 percent among men, which translates into some 800,000 lives saved.

- NIH's leadership and financial support to determine how HIV causes illness, develop rapid HIV tests, identify a new class of HIV-fighting drugs, and, ultimately, combine those drugs in life-saving ways have yielded extraordinary results and benefits. Today, HIV-infected men and women in their 20s who receive combination therapy may expect to live to age 70 or beyond.
- Research supported by NIH has spurred innovation in the biotech and pharmaceutical industries and contributed to 58 percent of new molecular entities approved by the Food and Drug Administration (FDA) from 1982 through 2006.

These are but a few of the many, tangible examples of NIH's contributions to the Nation's health. NIH's contributions also generate a wide range of secondary benefits that enhance the Nation's economic well-being and global competitiveness. The aggregate economic gains from the increased life expectancy between 1970 and 2000 are estimated at $95 trillion.[2] One study conducted by a research advocacy group estimates that each dollar invested in NIH research generates about $2.21 in state economic output annually, while each grant awarded by NIH generates about seven jobs. The reduction in chronic disability has helped to restrain long-term health care costs for the elderly. Dramatic improvements in disease treatments based on U.S. research breakthroughs have helped to maintain overall U.S. productivity and global competitiveness.

Exceptional Scientific Opportunities

These are extraordinarily exciting times for the biomedical research community. Through the application of genomic research and high throughput technologies, breakthroughs in our understanding of the causes of many diseases and the identification of new targets and pathways for the development of new therapeutics are within reach. What makes these opportunities so extraordinary is that they enable a truly comprehensive approach to human biology. For example, a decade ago, diagnosis of cancer was based on the organ involved and treatment depended on broadly aimed therapies that often greatly diminished a patient's quality of life. Today, research in cancer biology is moving treatment toward more effective and less toxic therapies tailored to the genetic profile of each patient's cancer. NIH-funded researchers are also uncovering information about genes and the environment that will help point the way toward more personalized, targeted treatments for other diseases. New insights into molecular mechanisms represent new opportunities for NIH to straighten and shorten the pathway from discovery to health. This expectation is grounded in several recent developments: the dramatic acceleration of our basic understanding of hundreds of diseases; the establishment of NIH-supported centers that enable academic researchers to use such understanding to screen thousands of chemicals for potential drug candidates; and, the emergence of public-private partnerships to aid the movement of drug candidates identified by academic researchers into the commercial development pipeline. The new National Center for Advancing Translational Sciences (NCATS) will provide the infrastructure and technologies to bring these critical basic discoveries to fruition through new diagnostics and therapeutics.

Scientific Preparedness in Public Health Emergencies

NIH also is positioned to take a lead role in the rapid response to public health emergencies. This has been particularly evident in the last year with the H1N1 pandemic, where the National Institute of Allergy and Infectious Diseases (NIAID) led the effort to conduct clinical trials on the new vaccine with record quality and speed. Even more recently, the National Institute of Environmental Health Sciences (NIEHS) committed to measure the health effects of the Deepwater Horizon oil spill in the Gulf, through a cohort study of 50,000 workers and controls.

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[2] Murphy, K. M., & Topel, R. H. (2006). The value of health and longevity. *Journal of Political Economy, 114(5),* 871-904.

FY 2012 Budget Request

The FY 2012 Budget Request reflects NIH's strong commitment to advance biomedical research. NIH will support many of its ongoing research efforts, will curtail other lower priority activities, and will make strategic investments in the key scientific opportunities. The budget request reflects the high priority placed on biomedical research within the current budget climate as an engine promising both better health and economic growth in the future.

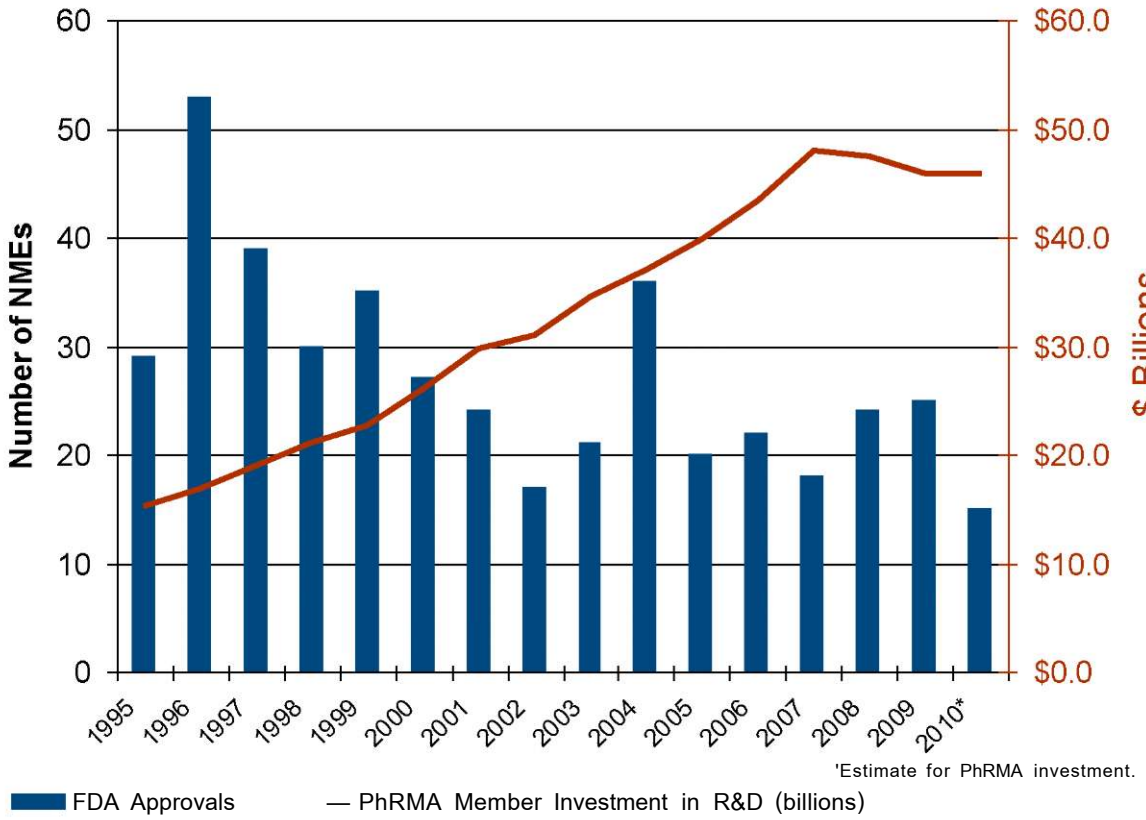
Priority Initiatives

Within the FY 2012 Budget Request, NIH plans to emphasize a groundbreaking new program to optimize and accelerate translational sciences and therapeutics development and three other themes that are exceptionally ripe for investment - technologies to accelerate discovery; the evidence base for health care decisions; and new investigators and new ideas. These four critical areas hold promise for advancing the health of the American people.

Optimizing and Accelerating Translational Sciences and Therapeutics Development: The National Center for Advancing Translational Sciences (NCATS)

Opportunities: NIH-supported basic biomedical research has been successful in deciphering the physiological processes that underpin health and disease. For example, we now understand—at the molecular level—the basis for thousands of diseases, both common and rare. This knowledge, combined with advanced technologies for rapidly screening thousands of molecules for therapeutic potential, has generated a rich inventory of potential new targets and candidates for therapeutic drug development.

Challenges: Translating basic discoveries into new and better diagnostics and treatments has historically been the province of the private sector. Developing new therapeutics, however, has become an exceedingly complex, costly, and risk-laden endeavor. Only a few compounds out of hundreds or thousands will ultimately prove safe and effective and make it to the medicine cabinet. According to research in 2004 and 2008 on the drug discovery process, 90-95 percent of new compounds entering clinical testing do not succeed. The cost of developing a new drug is estimated to range from $500 million to $2 billion, when all of the failures are taken into account. Moreover, in spite of significant investments in research and development, the number of FDA-approved new molecular entities (NMEs) has declined by 49 percent in recent years—from an average of 37 per year between 1995 and 1999 to an average of 21 per year between 2000 and 2010. These two trends are illustrated below in a chart that maps investments by pharmaceutical companies in drug research and development against the annual number of FDA approvals for NME drugs, excluding new biologic approvals, in the period from 1995 to 2010.



Note: Data on FDA approvals obtained from: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDeveloped andApproved/DrugandBiologicApprovalReports/ucm121136.htm. Data on Pharma Investment from the Pharmaceutical Research and Manufacturers of America, Profile 2010, pages 24-25 (http://www.phrma.org/sites/default/files/159/2010 phrma annual report.pdf)

The staggering development costs and failure rates have become a potent disincentive for pharmaceutical and biotechnology companies. In the last decade, for example, industry efforts to develop new antibiotics for multidrug-resistant organisms such as methicillin-resistant *Staphylococcus aureus* have declined significantly. According to 2007 research on the drug market, since 1999, 10 of the 15 largest companies have fully abandoned, or cut down significantly, discovery efforts in this field. In 2010, two pharmaceutical companies decided to end drug discovery work on pain, depression, anxiety, schizophrenia, and bipolar disorder. As another potential missed opportunity of significant consequence, the genetic bases of more than 2,000 rare diseases have now been identified, but effective therapies are available for only about 200 of those diseases. The limited economic incentive for such small markets means that roughly 20 million Americans affected by these rare diseases may have little hope of a new therapeutic - unless NIH gets involved.

A New Role for NIH in Therapeutics Development: The cost and amount of time required for developing new therapies has increased the risk associated with this research in the private sector. NIH is uniquely positioned to catalyze progress in therapeutics development by capitalizing on new and emerging scientific opportunities, leveraging new biomedical discoveries and existing scientific resources, and forging new partnerships with diverse organizations and sectors.

To do so, however, certain translational sciences programs at NIH must be more effectively organized in order to maximize synergy and efficiency. Although not yet reflected in the present FY 2012 Budget Justification documents, NIH is proposing to establish the National Center for Advancing Translational Sciences (NCATS) at the beginning of FY 2012 to catalyze improvements in therapeutics discovery and speed the development of new, urgently needed diagnostics and drugs. In December 2010, the Scientific Management Review Board (SMRB), which was established by Congress to advise the NIH Director on organizational issues, recommended the creation of a new NIH Center with the mission of supporting and strengthening translational medicine and therapeutics development. The SMRB reached its conclusions about the need for a new center after considering the views of internal and external experts and stakeholders, and analyzing a range of organizational alternatives. NIH's proposal is consistent with the advice of the SMRB. Budget details for transitioning to this new Center will be provided this spring.

NCATS would be responsive to the need for innovative strategies for therapeutics development, a need recognized as never before—by the public, government, academic institutions, pharmaceutical and biotechnology companies, and venture capitalists. The recognition of this need and the mounting interest in these strategies are outgrowths of several forces. One is intense interest from the public, whom NIH serves, in development of new treatments for both rare and common diseases. Another is investor-generated pressures on the private sector to speed the pace of therapeutics discovery and reap more rapid returns on the billions of dollars that pharmaceutical and biotechnology companies invest in R&D. Another force is widespread dissatisfaction with the traditional model of therapeutics discovery and its low success rate. Every quarter of the enterprise is calling for approaches that are both *modular* and *integrative,* that enable each sector to deploy its strengths to the component of the process at which it excels, and that foster coordination by bringing the efforts and strengths of the sectors together through public-private partnerships.

A Bird's Eye View of Drug Development

Therapeutics development involves many phases, beginning with basic research to illuminate the cause and natural history of disease and preclinical studies to identify a disease target i.e. an aspect of the disease process that might be discoverable for diagnostic purposes and susceptible to intervention for therapeutic purposes. The target must then be validated, another complex and pivotal process. Compounds that hit the target are screened to identify promising candidates for further assessment of their therapeutic potential. The most promising candidates will undergo painstaking preclinical research involving animal models of disease to assess the safety, toxicity, pharmacokinetics, and metabolic properties of the candidate compounds, only a few of which will ultimately prove to be safe or promising enough for clinical studies in humans. Such studies are conducted in a three-phase process of clinical trials, which are expensive and laden with challenges. A final step is FDA approval.

An illustrative example of how productive these approaches can be is the recent collaborative effort between several components of NIH (including the National Heart, Lung, and Blood Institute; the NIH Clinical Center; and the Therapeutics for Rare and Neglected Diseases Program) and a private sector company (AesRx) to develop a new therapy for sickle cell disease (SCD). Sickle cell disease is the most common inherited blood disorder in the United States, affecting approximately 70,000 to 100,000 Americans, primarily those of African descent. It affects 1 in every 500 African American newborns.

Sickle cell disease is caused by a defect in the oxygen carrying capacity of red blood cells. Affected individuals face a lifetime of episodes of pain, chronic anemia, severe infections, and multi-organ damage, usually beginning in early childhood. As yet, there is no cure for SCD; a combination of fluids, painkillers, antibiotics and transfusions are used to treat symptoms and complications. The new investigational sickle cell drug acts by increasing the red cell oxygen carrying capacity. It has been designated by the FDA as an orphan drug for the treatment of sickle cell disease. The collaborative effort between NIH and AesRx will carry out both the pre-clinical development activities necessary for Investigational New Drug (IND) application, as well as the clinical trials following IND approval. The result will potentially lead to a major advance toward a safe and effective therapy for SCD -- a disease affecting approximately 13 million people worldwide.

NIH has the capacity to conduct and to support research in the early, preclinical stages of therapeutics discovery and development—research that industry and venture capital are increasingly reluctant to pursue. NIH also has a key role to play in identifying new techniques and technologies that enhance the predictive value of work done at the preclinical stages of therapeutics discovery. As such, NIH can both conduct the essential preclinical work and help prevent the attrition of compounds and failure at later, more expensive, stages of clinical testing by discovering and disseminating innovative approaches to preclinical development.

By establishing NCATS, NIH is positioning itself to assume a greater and more focused role in the therapeutics discovery and development enterprise. The intent is not to assume a role more appropriate for the private sector, rather, through the marshalling and concentration of expertise, technologies, and resources, to fill gaps in the early developmental phases that biotechnology and pharmaceutical corporations are not equipped to fill, and to "de-risk" projects for future commercial investment. NCATS will work synergistically with the private sector and enable NIH to help bridge the translational divide by accelerating, improving, and streamlining a newly collaborative process for realizing the promise of translational medicine and science.

Components, Functions, and Focus of the New Center

NCATS will align and bring together in one organization a number of trans-NIH programs that are inherently cross-cutting (i.e. they do not have a specific disease focus) and are ideally suited for incorporation into the new Center. NCATS programs are expected to include the following components:

The ***Molecular Libraries Program (MLP)*** provides academic researchers with access to technology for assay development, so that the discovery of a new drug target can be developed into an assay amenable to high throughput screening of chemical libraries. More than 100 potential lead compounds relevant to a long list of rare and common diseases have been identified, and many of these are poised for further development. Under the auspices of the new Center, MLP will continue to grow and gain more attention from potential investigators engaged in a wide variety of research areas. One program funded by MLP is the ***NIH Chemical Genomics Center (NCGC),*** which provides robotic high-throughput screening services and a library of more than 350,000 compounds for use in basic discoveries and as probes of cellular pathways, and provides medicinal chemistry support to identify initial hits and lead compounds for preclinical testing.

The ***Therapeutics for Rare and Neglected Diseases (TRND)*** program is designed to bridge the gap that often exists between basic research discovery and the testing of a new drug in humans, as in the example of SCA mentioned above. Leveraging expertise and investments from both the public and the private sectors, TRND strives to encourage and speed the development of drugs for rare and neglected diseases—an area where limited market and commercial potential may discourage others from pursuing critical, life-saving research. This unique program moves candidate drug compounds forward until they meet FDA requirements for an Investigational New Drug (IND) application, at which point they will be attractive to biotechnology and pharmaceutical companies willing to carry them through clinical development and subsequent commercialization. In addition, the TRND program also offers a laboratory for research on the development process itself with a specific focus on improving success rates in the crucial preclinical stage.

The ***NIH Rapid Access to Interventional Development (RAID)*** program helps fill the gap and reduces some of the common barriers that block progress of therapeutic discoveries from the bench to the bedside. The program makes available critical resources that are needed to develop new therapeutic agents, including ones that can generate bulk amounts of the drug candidate or test its stability or toxic effects. It also provides researchers with access to expertise at the FDA on document preparation and submission.

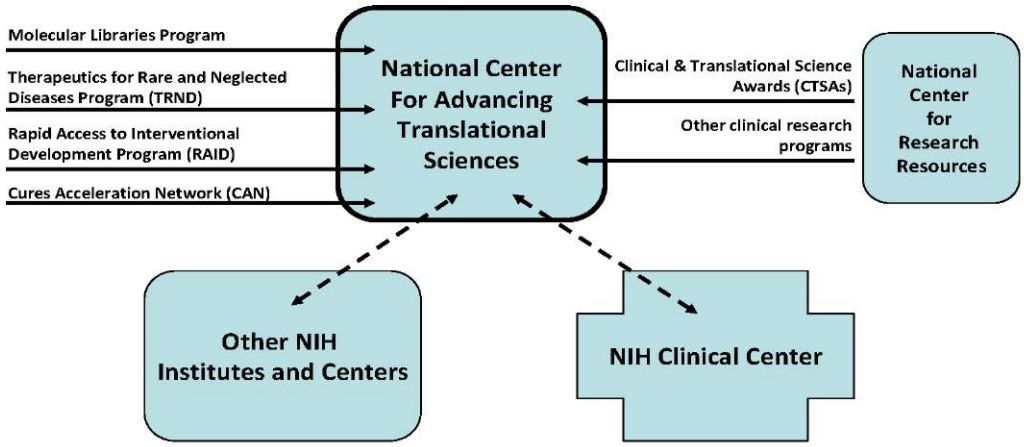
NCATS will be involved in a new ***NIH-FDA Partnership*** formed in 2010 to foster regulatory science, a specialized and interdisciplinary area of biomedical research that generates new knowledge and tools for assessing experimental therapies, preventatives, and diagnostics. A key goal of the partnership is to accelerate the development and use of new tools, standards, and approaches to enhance the efficiency of product development and the effectiveness of product review for safety, efficacy, and quality. Through a funding initiative begun in FY 2010, *Advancing Regulatory Science through Novel Research and Science-Based Technologies,* the agencies are supporting four regulatory science grants to advance nanoparticle characterization, adaptive trial design, development of a heart-lung micromachine for safety and efficacy testing, and toxicology testing strategies that will reduce dependency on the use of animals in toxicology testing.

The ***Cures Acceleration Network (CAN)*** will also be part of NCATS. CAN will advance the development of "high need cures" through the reduction of barriers between research discovery and clinical trials. Authorized by the Affordable Care Act of 2010 (P.L. 111-148), CAN includes flexible authorities to conceptualize and execute projects that will enable transactions other than contracts, grants, and cooperative agreements to achieve the goals and objectives of CAN, where, in the Director's determination, these standard mechanisms are not adequate. Contracts require the agency to envision and establish the project at the beginning, direct the project, and receive a deliverable. Grants require the recipient to envision and direct the project and report results after completion of the project. NIH will use the flexible research authority to work collaboratively with individual experts and teams in order to envision and identify new opportunities, and then fund exactly what is needed to overcome scientific and developmental hurdles. The authority allows NIH, on a project-by-project basis, to act quickly to capitalize on scientific opportunities and to direct the project, set and monitor specific milestones, and stay involved from both the scientific and administrative aspects, as well as to terminate the project as

necessary. This sort of flexibility has been essential to the success of DARPA, and will also be critical in translational medicine, where product development is the goal and where the exact needs to meet this specific goal cannot be fully anticipated in advance.

NCATS will become the new home of the ***Clinical and Translational Science Awards (CTSAs).*** Originally administered under the auspices of the National Center for Research Resources, the CTSAs provide funding for a nationwide consortium of biomedical research institutions. Consortium members are united around the goals of accelerating therapeutics development, engaging communities in clinical research efforts and training clinical and translational investigators. Launched in 2006, the CTSA program now includes 55 medical research institutions in 28 states and the District of Columbia.

NCATS



These programs and other components will enable NCATS to perform a range of critical functions in translational science and medicine. These include:

- Conducting and supporting translational research throughout the process of therapeutics development, but especially in the early phases of fundamental discovery and application;

- Providing a visible, central focus for broader access to scientific and technological resources, tools, and expertise in translational science and medicine;

- Streamlining and improving therapeutics development by facilitating effective handoffs between steps; learning from successes and failures of each project, enhancing the feedback loop; and designing innovative approaches to product development;

- Serving as a resource for NIH by augmenting the strengths and experience of current Institute/Center (IC)-based activities providing services and expertise to ICs, and informing the development of trans-NIH strategies and initiatives;

- Serving as a catalyst, resource, and convener for collaborative interactions by developing and providing scientific resources (e.g., assay development, chemical libraries, high-throughput screening, databases, repositories, data-sharing infrastructures, unique research facilities); promoting and facilitating open exchange of information; supporting novel and innovative partnerships; providing a means of "de-risking" projects that currently seem economically unattractive to the private sector; and developing creative intellectual property frameworks that provide a "win-win" outcome for public-private partnerships;

- Addressing the needs for education and training in translational science and medicine;

- Enhancing communication among all stakeholders in the enterprise of translational medicine.

NCATS will focus research efforts in high-need areas that attract insufficient commercial interest, areas that will not detract from the agency's emphasis on fundamental knowledge but rather stimulate the pursuit of new avenues of scientific inquiry. The scientific agenda of the new Center will evolve to meet the emerging needs of the field, but initial opportunities will include the rescue of abandoned drug products that have not been approved but hold promise, and the repurposing of approved products for new indications (i.e. applying them for other preventative, diagnostic, and therapeutic purposes). Rescue and repurposing offer a major short cut in getting a product into clinical trials, saving years of work and hundreds of millions of dollars.

NCATS will move quickly to conceptualize, incubate, and launch new partnerships among the various sectors engaged in therapeutics discovery and development. As previously noted, no one entity or sector can pursue all the opportunities available in translational medicine, nor can any single organization or sector tackle the myriad, inherent challenges and risks. A model that relies to a greater extent on cross-sector and interdisciplinary collaborations will distribute risks and capitalize on diverse perspectives and expertise. Public-private partnerships to advance biomedical science and translational medicine are not new. There is, however, a growing recognition on the part of all those involved in translational medicine that the current model for development is not sustainable and that novel partnerships and collaborations are critical to progress. Especially in this tight budget climate, the limits of any one sector are well recognized, as is the need for approaches that integrate and coordinate the respective strengths of multiple sectors.

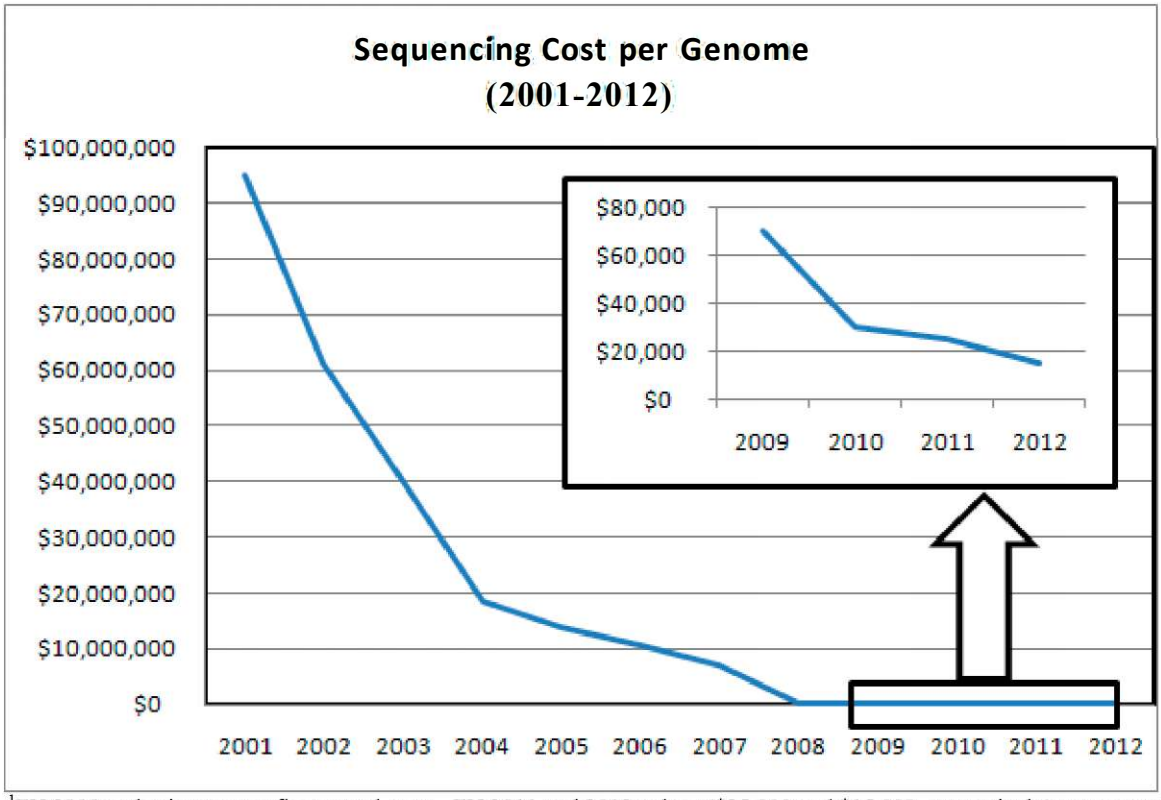
By virtue of its role in funding biomedical research and training—and thereby shaping the landscape of biomedical science and public health in the U.S.—NIH has the singular capacity to convene government, academia, and industry around common goals in translational medicine and science, in ways that would not have been possible a few years ago. The agency can develop and provide platforms for sharing data, including both positive and negative results, and it is

equipped to incentivize the sharing of this information. Through establishment of the new National Center for Advancing Translational Sciences, NIH will employ its convening power to facilitate the sharing of scientific ideas that are foundational to new collaborations. Success on this front will depend on other efforts, including building bridges between and among different disciplinary cultures and addressing administrative and legal hurdles presented by such issues as intellectual property and conflicts of interest. But, more than ever before, all sectors of the enterprise are committed to working together to achieve the promise of translational medicine and advance the development of effective treatments and cures for patients.

Technologies to Accelerate Discovery

In the past, most basic science projects in biomedicine required investigators to limit the scope of their studies to some single aspect of cell biology or physiology. The revolution now sweeping the field is the ability to be comprehensive (i.e. to define ***all*** of: the genes of the human or a model organism, the human proteins and their structures, the common variations in the genome, the major pathways for signal transduction in the cell, the patterns of gene expression in the brain, the steps involved in early development, and the components of the immune system). Technologies contributing to these advances, many of which have moved from the development stage to broad use across the research community only in the last few years, include DNA sequencing, microarray technology, nanotechnology, new imaging modalities, and computational biology.

Advances in DNA sequencing make it possible to both obtain the complete genome sequence of thousands of individuals and address comprehensive questions about hereditary factors in cancer, autism, heart disease, diabetes, and many other disorders. The Cancer Genome Atlas (TCGA), led jointly by the National Cancer Institute and the National Human Genome Research Institute, is a sweeping effort to accelerate understanding of the molecular basis of cancer through DNA sequencing, gene expression profiling, and epigenetic technologies. TCGA recently identified distinct molecular subtypes for a deadly brain cancer, for ovarian cancer, and for adult leukemia, providing a foundation for more effective personalized treatments across diseases and disorders. For efforts like these to succeed, additional major investments are needed in hardware and software for data analysis. The recent rapid reduction in genome sequencing cost has led to a gratifying increase in sequence information, but that is outpacing computing memory capacity and processing speed. Powerful new and creative methods are needed to mine the nuggets of biological revelation from the massive volumes of genomic information being produced.

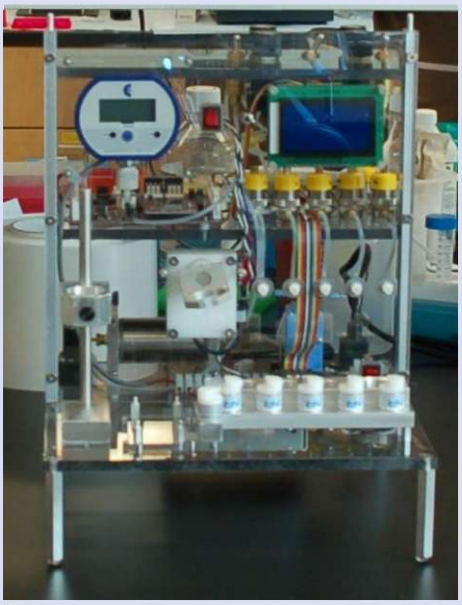


[1]FY 2009 and prior years reflect actual costs. FY 2011 and 2012 values ($25,000 and $15,000, respectively) represent targets for this NIH high priority performance goal.

Other exciting opportunities to gather comprehensive information in systems biology have recently emerged. One such opportunity is metabolomics - the ability to measure cellular levels of sugars, lipids, amino acids, nucleotides, and ions sensitively and cost-effectively, and to see how these metabolites are altered in the presence of disease. The field of proteomics (i.e. measurement and functional assessment of all the proteins in a tissue or cell type) also is poised to move into a new and more comprehensive mode, if appropriate resources are invested in technology development. These advances in systems biology will be particularly powerful if the technology is advanced to the point where measurements can be reliably made on single cells.

Understanding environmental contributions to health and disease has never been more important, but current technologies only detect a small fraction of the substances whose impact may be important to understand. Thus, the development and deployment of sensitive technologies to assess potential toxins in the air, water, and food are high priorities. New engineering approaches, aided by real time cell phone transmission, make major advances possible.

The development of new molecular imaging techniques has arrived at an important juncture. New positron emission tomography (PET) ligands, further advances in magnetic resonance imaging (MRI) scanning resolution, and more accurate ultrasound methods for vascular assessment are needed. There is a need to develop and implement new methods with high sensitivity and specificity to detect the presence of diseases like prostate cancer at the earliest possible moment.



A fully automated bench top CTC processing machine, which connects the CTC-chip to a pneumatic pump to push blood through the device.

Early detection of cancer is critical to provide effective therapy. Supported through the National Institute of Biomedical Imaging and Bioengineering, investigators recently reported the detection of *a single metastatic cell* from lung cancer in one billion normal blood cells. These circulating tumor cells (CTCs) may also be released into the bloodstream of patients with invasive but localized cancers. The presence of CTCs may be an early indicator of tumor invasion into the bloodstream long before distant metastases are detected. Identifying CTCs may be viewed as performing liquid biopsies, which can be especially advantageous for prostate cancer. Researchers plan to extend their work to develop a point-of-care microchip that would allow non-invasive isolation of CTCs from patients with many different types of cancer, to improve the management and treatment of this devastating disease.

Through this investment in technologies for discovery in FY 2012, NIH will support the development and application of state-of-the art technologies including computational biology, proteomics, genomics, metabolomics, single cell biology, stem cell biology, environmental technology, and new imaging technologies.

Enhancing the Evidence Base for Health Care Decisions

NIH's long-term investment in Comparative Effectiveness Research (CER) has informed the clinical guidelines used by doctors in consultation with their patients to select the most effective care. Knowledge from NIH-supported CER has changed the way diabetes, atrial fibrillation, hypertension, HIV/AIDS, schizophrenia, and many other conditions are treated. In addition to diagnostic and treatment trials, knowing more about the performance of disease prevention initiatives and medical care delivery will improve health. For example:

- *Comparing the effectiveness for anti-seizure drugs for childhood epilepsy.* NIH conducted the first comprehensive comparative clinical trial of three widely used anti-seizure drugs for the most common form of childhood epilepsy, which is absence epilepsy, and established an evidence-based approach for initial treatment. This form of epilepsy is characterized by short seizures of 10 seconds or so when the child stares and is unaware or unresponsive. The study showed that ethosuximid, one of the oldest available anti-seizure medications in the U.S., provided the best combination of seizure control and fewest side effects over the initial 16- to 20-week period after starting therapy.

- ***Comparing the effectiveness of tamoxifen and raloxifene for breast cancer prevention.*** Results from a long-term study of tamoxifen and raloxifene showed lower toxicities of raloxifene. Analysis of more than 19,000 participants who were monitored for nearly seven years after initiation of treatment showed that raloxifene was modestly less effective than tamoxifen in reducing risk of both invasive and noninvasive breast cancer. However, raloxifene was found to be markedly safer than tamoxifen. Women who had taken raloxifene showed a 45 percent reduced risk of endometrial cancer and a 25 percent lower risk of serious blood clots compared with women who had taken tamoxifen.

CER methodologies will also be important to advancing personalized medicine. Advances in pharmacogenomics, for instance, are moving clinical care away from "one-size-fits-all-medicine" toward individually-tailored treatments. The capacity to predict accurately which drugs may be safe and effective or, on the other hand, unsafe or ineffective for certain individuals, can go far to ensure the safety and value of medical interventions. Key to developing personalized treatments is testing candidate therapies in a real-world setting. Toward this end, NIH plans to fund a Health Maintenance Organization (HMO) Research Network Collaboratory, made up of HMOs currently caring for more than 13 million patients. The Collaboratory will accelerate science across three high-priority areas: large epidemiology studies, clinical trials, and electronic-health-record (EHR)-enabled health care delivery.

New Investigators, New Ideas Initiative

NIH plays a central role in the vitality of the biomedical research community in the United States and globally. The agency must continue to place a high priority on funding innovative people and ideas, providing support for the next generation of scientists, and ensuring support for early stage investigators.

Through the New Investigators, New Ideas initiative, NIH will empower and reinvigorate the biomedical research community. The initiative will enable NIH to award research project grants to first-time, early-stage investigators with new ideas and new perspectives and continue two programs - the NIH Director's New Innovator Award and the Pathway to Independence Award. These awards are designed to support and enable our brightest young scientists to pursue innovative research, and participate and thrive in the biomedical research community. The NIH Director's New Innovator Awards supports exceptionally creative new investigators who propose highly innovative projects that have the potential for unusually high impact. It is designed specifically to support creative investigators with highly innovative ideas at an early stage of their career when they may lack data required to compete successfully for an R01 grant. The Pathway to Independence Award provides a unique opportunity for highly promising scientists to transition from a mentored postdoctoral fellowship to their first independent research support. The program facilitates the ability of new investigators to complete their supervised research work, establish independence, publish results, obtain an independent research position, and prepare an application for other NIH grant support.

Over the past decades, young scientists are spending longer and longer periods of time as postdoctoral fellows. The average age of a scientist at his/her first independent award from NIH has risen to 42 years (from 36 years in 1981). In FY 2012, the new Director's Early Independence Award Program will encourage and support the most talented young scientists to

move directly from a doctoral degree to an independent career. A selected group of scientists who recently completed their graduate work will be provided resources, support, and mentorship to pursue independent projects. This will eliminate the increasingly elongated period of postdoctoral training, and it will jump-start the independent research contributions from these exceptionally creative and independent young investigators.

The development of physician scientists is a critical priority given longstanding concerns about the many barriers that physicians face in becoming clinical investigators and given their critical role in advancing translational science. The new Lasker Clinical Research Scholars program, a public-private partnership with the Lasker Foundation, will enable NIH to step up efforts to facilitate the training of clinical researchers. Lasker Scholars are drawn from the Nation's most talented clinically trained scientists who are in the early stages of research careers. The program provides them with research experience as a tenure-track principal investigator within the NIH Intramural Research Program, as well as additional years of independent research support, either through intramural support or at an extramural institution.

NIH will provide an across-the-board increase of four percent for stipends under the Ruth L. Kirschstein National Research Service Award training program.

Impact on the Biomedical Research Enterprise

This budget request reflects the agency's emphasis on areas of exceptional opportunity for advancing biomedical knowledge and the application of this knowledge to improve health. Of the $745 million increase over FY 2010, NIH will invest $100 million in the Cures Acceleration Network. Other programs and objectives cited above also will receive additional funding. The grant application and peer review process will focus funding on these objectives, while leaving intact the investigator-initiated nature of NIH-funded research projects. Thus, although specific funding levels for each investment area are not specified in advance, these areas will be supported heavily in FY 2012.

Policies also have been established to guide investments, while limiting inflationary cost increases. These policies for FY 2012 include: a one percent increase in the average cost of competing and non-competing Research Project Grants (RPGs); a one percent increase in Research Centers and Other Research; and a one percent increase for Intramural Research and Research Management and Support. Staffing levels also have been constrained. These policies were necessary to enable expanded support for critical areas of opportunity.

NIH estimated funding for the individual funding delivery mechanisms (e.g., competing research project grants, training), taking into account the NIH-wide investment policies and the current NIH research portfolio. As the NIH-wide policies are applied to the budgets and research portfolios of each institute and center, other factors (e.g., multiple grant cohorts, exceptionally large single grants and assessments to support cross-NIH requirements) come into play. The resulting funding estimates by mechanism, therefore, do not correspond solely to the inflation policy limitations.

For example, this budget request protects critical activities, including new and competing research project grants (RPGs), to the extent possible within overall funding constraints and requirements to support extramural commitments and NIH's infrastructure. However, since 75-80 percent of the RPG budget in any given year is committed to multi-year grants, the funds available for new and competing grants are limited. From FY 2010 to FY 2011 these factors, combined with the overall funding level, resulted in a decrease of 652 in the number of competing RPGs. However, for FY 2012, NIH again will focus funding on RPGs, resulting in an increase over the FY 2011 level of 424 competing RPGs. Overall, from FY 2010 to FY 2012, the number of competing RPGs, nonetheless, decline by 228.

The FY 2012 NIH Budget Request reflects changes in the distribution of funding by funding mechanism, as noted in the summary table below. A detailed funding mechanism table is provided following the All Purpose Table later in this section. A more detailed discussion of the impact of the Request by funding mechanism is provided in the Narrative by Activity section below.

Summary of Impacts on Mechanism Funding and Key Program Measures

($ in millions, except where noted)

	FY 2012 President's Budget	Change from FY 2010
Research Project Grants:		
Competing Average Cost ($ in 000s)	$433	$16
Number of Competing Awards (whole number)	9,158	-228
Estimated Competing RPG Success Rate: Absolute Rate	19%	-2%
Total Funding, All RPGs	$16,909	$436
Research Centers	$3,036	-$41
Other Research	$1,820	$25
Training	$794	$19
Research & Development Contracts	$3,545	$89
Intramural Research	$3,382	$50
Research Management and Support	$1,538	$30
Common Fund [1]	*$557*	*$13*
Buildings and Facilities	$134	$26
Other Mechanisms [2]	$831	$111
Total, Program Level	**$31,987**	**$745**

[1]Common Fund support also is represented within the relevant funding delivery mechanisms and appears separately here in italics as a "non-add."

[2]Includes budget authority identified for Office of the Director-Other and Superfund Research account, as well as transfer-in resources provided for National Library of Medicine (NLM) Program Evaluation.

Other NIH-Supported Initiatives

Presidential Initiatives

Autism, Cancer and Alzheimer's Disease Research

NIH will continue support for cancer, autism and Alzheimer's research in FY 2012. Consistent with the Administration's priority to both advance research and improve the outcomes for individuals suffering from these debilitating and costly illnesses, NIH will expand efforts that focus on the most promising avenues for discovery and translation of scientific understanding into effective prevention and treatment.

- Autism: NIH will continue to support a study of the health outcomes of children with ASD and their families. The study is the first of its kind to analyze existing administrative medical claims data to describe health trajectories and the utilization of health care services among children with ASD and their families compared with demographically matched control families. NIH will continue to support the Autism Centers of Excellence (ACE) program, which comprises 11 research centers and networks at major research institutions across the country, focusing on identifying the causes of ASD and developing new and improved treatments. Initially funded in FY 2007 and FY 2008, these centers will be supported through FY 2013. NIH is currently planning to issue a funding opportunity announcement to renew the ACE program in FY 2012 and beyond.

- Cancer: NCI is using new technologies to develop a deeper understanding of the molecular and genetic mechanisms that cause cancer and is establishing the Center for Cancer Genomics to coordinate activities related to genome structure and function across the Institute. The major component of this Center, The Cancer Genome Atlas, is a multi-institutional, collaborative study, conducted jointly with the NHGRI. It has recently cataloged the genetic alterations in two important cancers for which early diagnostic methods, broadly applicable prevention strategies, and effective therapies are not yet available: the uniformly lethal brain cancer, glioblastoma multiforme (GBM), and serous ovarian carcinoma.

  NCI is implementing changes to its Cooperative Groups Clinical Trials Program that will improve efficiency, oversight, and collaboration of trials, as recommended in an April 2010 Institute of Medicine report. These changes include: consolidation of the adult clinical trials groups; standardization of clinical trials data management software for NCI-sponsored multi-site trials; acceleration of clinical trial activation through the implementation of a real-time, internet-based dashboard containing clinical trial information for all parties involved in the process; collaboration with the Food and Drug Administration (FDA) by involving FDA scientists in NCI's disease-specific scientific steering committees; standardization of language for clinical trial and intellectual property agreements; improving funding of studies and increasing incentives for patient and physician participation by increasing per case reimbursement rates and developing a credentials registry for investigators and clinical trial sites.

- Data recently announced by the NCI-sponsored National Lung Screening Trial indicate that screening with low-dose computed tomography (CT) results in twenty percent fewer lung cancer deaths among current and former heavy smokers. This development marks the first time that a screening test has been found to reduce mortality from lung cancer, the most common cause of cancer deaths in the United States and the world.

- Alzheimer's Disease: NIH plans an expanded initiative to stimulate and advance research on the discovery and development of new preventive and therapeutic interventions for Alzheimer's Disease (AD), mild cognitive impairment, and age-related cognitive decline. This initiative will continue to support studies that lead to the submission of Investigational New Drug (IND) applications to the Food and Drug Administration, a prerequisite for beginning human trials of potential new therapies. It is anticipated that the program will support the development of an estimated 25 to 50 compounds over the continuation period.

  In addition, NIH will renew support for the Alzheimer's Disease Cooperative Study (ADCS), the Nation's preeminent clinical trials consortium devoted to the discovery, development and testing of new interventions for the prevention and treatment of AD. Building on recent exciting discoveries from the Alzheimer's Disease Neuroimaging Initiative, the ADCS will focus on new trial approaches using imaging and other biomarkers in cerebrospinal fluid and plasma to identify participants with AD pathology and to track disease progression and treatment response. ADCS investigators will place an increased emphasis on prevention studies, particularly in at-risk but presymptomatic individuals.

  Moreover, NIH will develop the AD Genetics Data Warehouse, a web-based repository of genetic data from a variety of AD studies. Warehouse data will be available to qualified investigators worldwide for use on basic science and clinical research studies. This initiative will speed the pace of discovery by providing a centralized resource through which investigators can access, study, and share their own high-quality data relevant to AD.

Recognizing the enormous and as yet untapped potential of human induced pluripotent stem (iPS) cells as models of human disease, NIH plans to support a ground-breaking initiative on the development of iPS cells and other reprogrammed cells for aging and Alzheimer's disease modeling. The use of human iPS cells would facilitate study of the genetic, molecular, and cellular mechanisms underlying human aging and AD and would provide a platform for drug screening and toxicity testing, and iPS cells would serve as a versatile complement to the cell lines and animal models currently in use.

Sustainability

In accordance with Executive Order (E.O.) 13514 - Federal Leadership in Environmental, Energy and Economic Performance - NIH has developed an inventory of its investments in sustainable resource use. This inventory demonstrates NIH's longstanding commitment to the responsible use of resources. Based on this inventory, NIH will provide an estimated $118 million in FY 2010-FY 2011 to implement the E.O. For example, NIH will invest approximately $4 million in FY 2010-FY 2011 in facility remediation and decommissioning

to address hazardous contaminants and minimize construction and demolition waste. Also, NIH has conducted a number of sustainability assessments, including an analysis of features to be incorporated into the design of the Porter Neuroscience Research Center Phase II project. Using a portion of the building and facilities funding in FY 2012, NIH will continue to invest in the E.O.'s objectives.

Administrative Cost Reductions

NIH is continuing to pursue every viable opportunity to reduce administrative costs and expand contracting and grant-making efficiencies. The agency is reviewing several proposals under the President's SAVE initiative. One such proposal may significantly reduce the travel costs associated with NIH's grant proposal peer review process by implementing more advanced communications technologies. In addition, NIH is continuing to implement more competitive and performance-based contracting approaches to ensure contracts provide high quality and cost-effective products and services. Overall, NIH estimates additional administrative cost savings in FY 2012 of over $15 million.

Other Priorities

Type 1 Diabetes

The Medicare and Medicaid Extenders Act of 2010 extended through FY 2013 the authorization for the mandatory appropriation of $150 million a year for the special research program on Type 1 diabetes.

HIV/AIDS

NIH will continue support in FY 2012 for its HIV/AIDS research. This research is discussed in greater detail in the Office of AIDS Research section in Tab 5 below.

High Priority Performance Goal

NIH will continue to focus on achieving the High Priority Performance Goal (HPPG) to reduce the fully loaded cost of sequencing a human genome to $15,000 in FY 2012 from the FY 2010 target of $50,000 and the FY 2011 target of $25,000. The reduction of sequencing costs will stimulate ground-breaking research ranging from studies aimed at understanding the human genome to those intended to lead to improvements in the prevention, diagnosis, and treatment of human illness.

FY 2012 Budget Request
National Institutes of Health

OVERVIEW OF PERFORMANCE

NIH supports a wide spectrum of scientific endeavors and engages in a full range of activities that enable research, its management, and the communication of research results. Because of this diversity and complexity, NIH uses a set of performance measures that are representative of its activities and that are useful for tracking progress in achieving performance priorities. By assessing the progress and results of its activities, NIH is positioned to respond effectively to new scientific opportunities and emerging public health needs.

Many of the NIH performance measures support the four initiatives, as described in the previous pages. In addition to aligning with these initiatives, NIH's performance priorities support the goals and objectives of the new HHS Strategic Plan 2010-2015. In particular, NIH substantially contributes to the HHS Strategic Goal 2 - Advance Scientific Knowledge and Innovation (Objective A: Accelerate the process of scientific discovery to improve patient care). For example, in FY 2012 NIH will:

- Apply innovative high-throughput technologies to understanding health and disease - by making freely available to researchers the results of 300 high-throughput biological assays, screened against a library of 300,000 unique compounds that are expected to provide a scientific resource that will accelerate the discovery of protein functions that control critical processes such as development, aging, and disease.

- Implement personalized medicine - by identifying and characterizing two molecular pathways of potential clinical significance that may serve as the basis for discovering new medications for preventing and treating asthma exacerbations.

Moreover, in support of the President's goal of transforming and modernizing the U.S. health care system and the HHS Strategic Goal 1 - Transform Health Care (Objective C: Emphasize primary and preventive care linked with community prevention services), NIH will:

- Identify three key factors influencing the scaling up of research-tested interventions across large networks of services systems such as primary care, specialty care and community practice.

NIH uses performance data to inform strategic decision-making. Effective performance measures have allowed NIH to monitor progress towards achieving its goals, to adjust its activities to increase efficiency and effectiveness, and to identify and promote evidence-based approaches in managing its programs. However, a number of challenges must be addressed to develop useful performance measures to track progress of scientific programs. In many instances, research outcomes cannot be foreseen with certainty, but progress may be captured with milestones toward the planned objectives. Unplanned results also are common in scientific studies. At times they can provide new information to redirect the course of research. Moreover, the full value of any given research finding may not be apparent at the time of

discovery. The implications or applications of some findings often only occur after many years or in combination with other advances. In some cases, the downstream impact of scientific knowledge generated by basic research is not known without further development by the private sector, public agencies, universities, or other research institutions.

NIH strives to achieve transparency and accountability to the American people by regularly reporting results, achievements, and the impact of its activities. By using a set of measures that are representative of its activities, NIH has successfully implemented an approach to actively measure its performance priorities and share this information with HHS, the rest of the Executive Branch, the Congress, and the general public. Detailed information on all of NIH's performance measures is available in the NIH Online Performance Appendix.

Summary of Targets and Results Table

NIH tracks its performance against a set of performance measures with targets for each measure specified for each fiscal year. As appropriate, the measures are retired when they are no longer relevant and new measures are added. The following table provides summary data on NIH's overall performance against its established targets. For example, of the 89 measures applicable to FY 2010, there were 99 performance targets. NIH met 91 of these targets, or 92 percent of the targets for which data were available.

Fiscal Year	Total Targets	Targets with Results Reported	Percent of Targets with Results Reported	Total Targets Met	Percent of Targets Met
2007	76	74	97%	66	87%
2008	80	79	99%	72	90%
2009	85	84	99%	74	87%
2010	99	99	100%	91	92%
2011	94	N/A	N/A	N/A	N/A
2012	74	N/A	N/A	N/A	N/A

NATIONAL INSTITUTES OF HEALTH

AH Purpose Table [1]

(Dollars in thousands)

	FY 2010 Actual	FY 2011 CR[1]	FY 2012 Estimate	Change from FY 2010 Actuals
Labor/HHS Discretionary Budget Authority (B.A.)	**$31,005,201**	**$30,705,788**	**$31,747,915**	**$742,714**
Interior B.A.	$79,212	$79,212	$81,085	$1,873
Total Discretionary B.A.	**$31,084,413**	**$30,785,000**	**$31,829,000**	**$744,587**
Type I Diabetes Initiative	$150,000	$150,000	$150,000	$0
Total B. A.	$31,234,413	$30,935,000	$31,979,000	$744,587
NIH Program Level [2]	$31,242,613	$30,943,200	$31,987,200	$744,587
Number of Competing RPGs	*9,386*	*8,734*	*9,158*	*-228*
Total Number of RPGs	*36,809*	*36,328*	*36,852*	*+43*
FTEs	*18,362*	*18,412*	*18,412*	*+50*

[1] The 2010 Labor, HHS, and Education Appropriations Act included a total of $4,818,275,000 for NIAID, of which $304,000,000 was transferred from the Biodefense Countermeasures account in the Department of Homeland Security. Since there are no funds remaining in that account in 2011, under the current law continuing resolution (P.L. 111-317), there can be no transfer to NIAID. The Administration supports replacing this transfer with budget authority for NIAID in 2011. Includes $1 million transfer from GDM for the Interagency Autism Coordinating Committee in FY 2010 and FY 2011.

[2] Includes NLM Program Evaluation of $8.2 million in each year.

NATIONAL INSTITUTES OF HEALTH

Budget Mechanism - Total [1]

(dollars in thousands)

MECHANISM	FY 2010 Actual [7]		FY 2011 CR [7]		FY 2012 PB		Change	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants:								
Research Projects:								
Noncompeting	25,738	$11,732,029	25,936	$11,871,057	26,019	$12,135,448	281	$403,419
Administrative Supplements	*1,517*	174,393	*1,378*	164,699	*1,282*	154,923	(235)	(19,470)
Competing:							0	0
Renewal	2,537	1,249,215	2,429	1,207,457	2,429	1,233,106	(108)	(16,109)
New	6,792	2,650,274	6,258	2,495,690	6,681	2,721,759	(111)	71,485
Supplements	57	15,347	47	14,168	48	14,197	(9)	(1,150)
Subtotal, Competing	9,386	$3,914,836	8,734	$3,717,315	9,158	$3,969,062	(228)	$54,226
Subtotal, RPGs	35,124	$15,821,258	34,670	$15,753,071	35,177	$16,259,433	53	$438,175
SBIR/STTR	1,685	$651,519	1,658	$637,161	1,675	$649,370	(10)	($2,149)
Research Project Grants	36,809	$16,472,777	36,328	$16,390,232	36,852	$16,908,803	43	$436,026
Research Centers:								
Specialized/Comprehensive	1,197	$2,294,986	1,201	$2,227,367	1,198	$2,242,880	1	($52,106)
Clinical Research	79	435,787	74	434,148	71	443,844	(8)	8,057
Biotechnology	109	153,412	100	147,078	100	148,574	(9)	(4,838)
Comparative Medicine	50	133,062	49	139,631	49	141,018	(1)	7,956
Research Centers in Minority Institutions	23	60,452	22	59,455	22	60,024	(1)	(428)
Research Centers	1,458	$3,077,699	1,446	$3,007,679	1,440	$3,036,340	(18)	($41,359)
Other Research								
Research Careers	4,049	$649,044	4,025	$651,467	4,007	$651,917	(42)	$2,873
Cancer Education	91	35,444	89	34,944	89	34,944	(2)	(500)
Cooperative Clinical Research	332	430,727	386	458,598	412	464,209	80	33,482
Biomedical Research Support	134	67,626	133	66,305	123	61,958	(11)	(5,668)
Minority Biomedical Research Support	371	107,035	372	106,009	378	107,232	7	197
Other	1,706	504,286	1,718	495,543	1,678	499,241	(28)	(5,045)
Other Research	6,683	$1,794,162	6,723	$1,812,866	6,687	$1,819,501	4	$25,339
Total Research Grants	44,950	$21,344,638	44,497	$21,210,777	44,979	21,764,644	29	$420,006
Research Training:	FTTPs		FTTPs		FTTPs			
Individual Awards	3,071	$125,301	3,084	$129,510	3,104	$134,661	33	$9,360
Institutional Awards	14,090	649,916	13,947	652,527	13,727	659,743	(363)	9,827
Total Research Training	17,161	$775,217	17,031	$782,037	16,831	$794,404	(330)	$19,187
Research & Development Contracts	2,508	$3,455,571	2,518	$3,257,522	2,519	$3,544,551	11	$88,980
(SBIR/STTR)	*129*	*$39,438*	*135*	*$45,039*	*127*	*$44,749*	*(2)*	*$5,311*
Intramural Research		$3,331,414		$3,342,540		$3,381,705		$50,291
Research Management and Support		1,507,640		1,522,721		1,537,588		29,948
Extramural Construction		0		0		0		0
Office of the Director - Appropriation [3]		*$1,176,844*		*$1,176,299*		*$1,298,412*		*$121,568*
Office of the Director - Other		632,816		632,271		741,522		109,251
Bridge Awards [3]		*0*		*0*		*0*		*0*
Common Fund [3]		*544,028*		*544,028*		*556,890*		*12,862*
Buildings and Facilities [4]		107,905		107,920		133,501		25,596
Appropriation		*125,581*		*100,000*		*125,581*		*0*
Type 1 Diabetes [5]		(150,000)		(150,000)		(150,000)		(0)
Subtotal, Labor/HHS Budget Authority		**$31,005,201**		**$30,705,788**		**$31,747,915**		**$742,714**
Interior Appropriation for Superfnd Res.		79,212		79,212		81,085		1,873
Total, NIH Discretionary B.A.		**$31,084,413**		**$30,785,000**		**$31,829,000**		**$744,587**
Type 1 Diabetes [6]		150,000		150,000		150,000		0
Total, NIH Budget Authority		**$31,234,413**		**$30,935,000**		**$31,979,000**		**$744,587**
NLM Program Evaluation		8,200		8,200		8,200		0
Total, Program Level		**$31,242,613**		**$30,943,200**		**$31,987,200**		**$744,587**
Grand Total, BA		**$31,242,613**		**$30,943,200**		**$31,987,200**		**$744,587**

[1] All items in italics are "non-adds"; items in parenthesis are subtractions.

[2] Flexible Research Authority is noted as a non-add since the funding is accounted for within the Office of the Director (OD) - Other line.

[3] Number of grants and dollars for The Common Fund are distributed by mechanism and are noted here as a non-add. The Office of the Director - Appropriations also is noted as a non-add since these funds are accounted for under OD - Other and Common Fund within the above mechanism distribution.

[4] Includes B&F appropriation plus construction dollars appropriated to NCI.

[5] Number of grants and dollars for Type I Diabetes are distributed by mechanism above; therefore, Type I Diabetes amount is deducted to provide subtotals only for th Labor/ HHS Budget Authority.

[6] Reflects HHS ASFR specified treatment of mandatory Type 1 Diabetes funding from the U.S. Treasury.

[7] FY 2010 reflects Secretary's 1% Transfer ($4.587 million), as well as $1 million transfer from HHS for the Interagency Autism Coordinating Committee. FY 2011 also reflects the $1 million transfer.

Summary of Recovery Act Performance

Buildings and Facilities Implementation Plan

Performance Measure	FY 2009 Result	FY 2010 Result	FY 2011 Target/Date	FY 2012 Target/Date
Number of capital facility project awards completed	6	18	-	-
Reduction in the backlog of maintenance and repairs	$ 23.0 M	$ 157.7 M	-	-
Condition Index improvement	0.5	3.1	-	-

Implementation Data Source: Deputy Director, Office of Research Facilities for ARRA Oversight; ARRA contract oversight specialists; and ARRA Contract and Project Officers.

NIH's Building and Facilities program received $500 million of Recovery Act funding to obligate during FY 2009 and FY 2010 by awarding 24 pre-approved capital facility projects. The first six projects were awarded in FY 2009, and the remaining 18 project awards were successfully completed during FY 2010. Awarding these 24 projects reduced NIH's backlog of maintenance and repairs by $180.7 million. Awards made in FY 2009 reduced the backlog by $23.0 million, and awards completed during FY 2010 further reduced the backlog by $157.7 million. In addition, successfully awarding these 24 projects improved NIH's Condition Index by 3.6 points. Awards made in FY09 improved the Condition Index by 0.5 points, and awards completed during FY 2010 improved the Condition Index by an additional 3.1 points. The remaining funding, $319.3 million, was used to support new construction efforts, including the new PNCR II building for $175.7 million and the construction of a new west utility tunnel for $22.3 million, thus helping to meet some of NIH's most critical construction needs.[3]

Comparative Effectiveness Research (CER) Implementation Plan

Performance Measure	FY 2009 Result	FY 2010 Result	FY 2011 Target/Date	FY 2012 Target/Date
Number of Meritorious Grants Awarded	166	214	N/A	N/A
Number of CER Meetings	27	34	46	58

Implementation Data Source: RePORTer

NIH received $400 million to support expanded comparative effectiveness research. For the performance measure, number of meritorious grants awarded, the 214 awards allowed NIH to expand its portfolio of landmark clinical effectiveness trials to fund additional comparisons within ongoing clinical trials, support new CER projects, and compare the effectiveness of

[3] The ARRA measurement data reported here is consistent with all prior ARRA reporting where the Condition Index and Backlog of Maintenance and Repair methodology recognized improvements when an award was made.

dissemination and translation techniques to facilitate the use of CER by patients, clinicians, payers, and others. ARRA funding also addressed a critical need for CER, namely developing and optimizing methods to design, implement, analyze, and report CER. Moreover, ARRA funds bolstered CER infrastructure and training—all in a trans-agency context.

For the performance measure, the number of CER meetings, the meetings included both the NIH CER Coordinating Council meetings, which occur monthly, and related meetings that included other Federal agencies (e.g., Agency for Healthcare Research and Quality, Food and Drug Administration, U.S. Department of Veterans Affairs) and the Federal Coordinating Council (FCC - CER), as well as national CER meetings focused on CER methodology research or the interface of CER and personalized medicine.

Extramural Construction Implementation Plan

Performance Measure	FY 2009 Result	FY 2010 Result	FY 2011 Target/Date	FY 2012 Target/Date
Number of grantees that have completed the final design phase	0	10	146	147

Implementation Data Source: The data comes from NIH internal databases that receive the design documents and track when design submissions occur.

NIH received $1 billion to support extramural construction programs. This performance measure reports the number of extramural construction awards that have completed the final design phase. Once final designs have been reviewed and approved, funds are released to allow the awardees to begin their construction/renovation project.

Shared Instrumentation Implementation Plan

Performance Measure	FY 2009 Result	FY 2010 Result	FY 2011 Target/Date	FY 2012 Target/Date
Shared instrumentation projects complete	0	128	150	200

Implementation Data Source: The data comes from recipient 1512 reports.

To support shared instrumentation programs, NIH received $300 million. This performance measure reports the number of major scientific research instruments that have been purchased and installed. Generally, it is expected that recipients will only mark their project as complete when the instrument has been delivered and has passed the benchmarks that demonstrate that the equipment is functioning correctly.

Performance Measure	FY 2009 Result	FY 2010 Result	FY 2011 Target/Date	FY 2012 Target/Date
Take advantage of advances in genomics research and high-throughput technologies to understand the fundamentals of biology and the causes of specific diseases.	N/A	Four of five FY 2010 targets were met.	Use the newly developed tools and resources to advance the research into the underlying causes of prevalent diseases. (12-2011)	N/A
Use new discoveries about health and disease to develop diagnostics, prevention, and therapies.	N/A	FY 2010 targets were met.	Demonstrate the therapeutic feasibility of the identified strategies and refine the stem cell models for future use in therapeutics. (12-2011)	N/A
Put science to work for the benefit of health care and reform.	N/A	FY 2010 targets were met.	Finalize development and begin testing the tools and resources identified in 2010. (12-2011)	N/A

Implementation Data Source: Complete descriptions of each performance measure and corresponding targets are available on the web at http://officeofbudget.od.nih.gov/index.htm

To support expanded scientific research, NIH received $8.2 billion. There were fourteen FY 2010 targets planned under the three performance objectives to gauge the performance of the scientific research implementation plan. Thirteen of the targets were met; however, the plan to analyze oral cancer genomes using high throughput methods to develop a blueprint of genetic

alterations is behind schedule. The rigorous screening protocol resulted in a lower than expected yield of analyzable specimens in the first year, and future targets have been adjusted to permit an expected 94 matched oral cancer specimens to be analyzed. This revised schedule will still permit the goal of developing a blueprint of genetic alterations for oral cancer to be realized. The 2011 target has been adjusted to reflect these technological improvements in genomic analysis.

FY 2012 Budget Submission
National Institutes of Health

Recovery Act Outlays
(dollars in millions)

ARRA Implementation Plan	Total Resources Available	FY 2009/ FY 2010 Outlays	FY 2011 Outlays	FY 2012 Outlays
Scientific Research	8,200.0	2,948.0	2,795.0	2,253.0
Comparative Effectiveness Research	400.0	88.0	150.0	145.0
Shared Instrumentation	300.0	96.0	113.0	60.0
Extramural Construction	1,000.0	18.0	82.0	100.0
Building and Facilities	500.0	50.0	123.0	145.0
Total Outlays	10,400.0	3,200.0	3,263.0	2,703.0

NIH ARRA APPROPRIATED FUNDS
(dollars in thousands)

	Scientific Research	Shared Instrumentation	Extramural Construction	B&F	Comparative Effectiveness Research[1]	Lotal
National Cancer Institute	$1,256,500					$1,256,500
National Heart, Lung and Blood Institute	762,600					762,600
National Institute of Dental and Craniofacial Research	101,800					101,800
National Institute of Diabetes and Digestive and Kidney	445,400					445,400
National Institute of Neurological Disorders and Stroke	402,900					402,900
National Institute of Allergy and Infectious Diseases	1,113,300					1,113,300
National Institute of General Medical Sciences	505,200					505,200
National Institute of Child Health and Human Development	327,400					327,400
National Eye Institute	174,100					174,100
National Institute of Environmental Health Sciences[2]	187,400					187,400
National Institute on Aging	273,300					273,300
National Institute of Arthritis and Musculoskeletal and Skin	132,700					132,700
National Institute on Deafness and Other Communication	103,000					103,000
National Institute of Mental Health	366,800					366,800
National Institute on Drug Abuse	261,200					261,200
National Institute on Alcohol Abuse and Alcoholism	113,900					113,900
National Institute of Nursing Research	35,900					35,900
National Human Genome Research Institute	127,000					127,000
National Institute of Biomedical Imaging and Bio engineering	77,900					77,900
National Center on Minority Health and Health Disparities	52,100					52,100
National Center for Research Resources	310,100	$300,000	$1,000,000			1,610,100
National Center for Complementary and Alternative Medicine	31,700					31,700
Fogarty International Center	17,400					17,400
National Library of Medicine	83,600					83,600
Common Fund	136,800					136,800
Office of the Director	800,000				$400,000	1,200,000
Buildings and Facilities:				$500,000		500,000
NIH ARRA Total:	**$8,200,000**	**$300,000**	**$1,000,000**	**$500,000**	**$400,000**	**$10,400,000**

[1] ARRA funding for NIH included a $400 million transfer from the Agency for Healthcare Research and Quality for patient-centered/comparative effectiveness health research.

[2] Includes funds for the Superfund program.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Overall Appropriation

FY 2012 Budget Request
National Institutes of Health

FY 2012 APPROPRIATIONS LANGUAGE

NATIONAL CANCER INSTITUTE

For carrying out section 301 and title IV of the Public Health Service Act with respect to cancer, $5,196,136,000 of which up to $8,000,000 may be usedfor facilities repairs and improvements at the National Cancer Institute-Frederick Federally Funded Research and Development Center in Frederick, Maryland.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

For carrying out section 301 and title IV of the Public Health Service Act with respect to cardiovascular, lung, and blood diseases, and blood and blood products, $3,147,992,000.

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

For carrying out section 301 and title IV of the Public Health Service Act with respect to dental disease, $420,369,000.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

For carrying out section 301 and title IV of the Public Health Service Act with respect to diabetes and digestive and kidney disease, $1,837,957,000.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

For carrying out section 301 and title IV of the Public Health Service Act with respect to neurological disorders and stroke, $1,664,253,000.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (INCLUDING TRANSFER OF FUNDS)

For carrying out section 301 and title IV of the Public Health Service Act with respect to allergy and infectious diseases, $4,915,970,000: Provided, That $300,000,000 may be made available to International Assistance Programs „ 'Global Fund to Fight HIV/AIDS, Malaria, and Tuberculosis," to remain available until expended.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

For carrying out section 301 and title IV of the Public Health Service Act with respect to general medical sciences, $2,102,300,000.

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

For carrying out section 301 and title IV of the Public Health Service Act with respect to child health and human development, $1,352,189,000.

NATIONAL EYE INSTITUTE

For carrying out section 301 and title IV of the Public Health Service Act with respect to eye diseases and visual disorders, $719,059,000.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (Labor/HHS Appropriation)

For carrying out sections 301 and title IV of the Public Health Service Act with respect to environmental health sciences, $700,537,000.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (Interior Appropriation)

For necessary expenses for the National Institute of Environmental Health Sciences in carrying out activities set forth in section 311(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, and section 126(g) of the Superfund Amendments and Reauthorization Act of 1986, $81,085,000.

NATIONAL INSTITUTE ON AGING

For carrying out section 301 and title IV of the Public Health Service Act with respect to aging, $1,129,987,000.

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

For carrying out section 301 and title IV of the Public Health Service Act with respect to arthritis and musculoskeletal and skin diseases, $547,891,000.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

For carrying out section 301 and title IV of the Public Health Service Act with respect to deafness and other communication disorders, $426,043,000.

NATIONAL INSTITUTE OF MENTAL HEALTH

For carrying out section 301 and title IV of the Public Health Service Act with respect to mental health, $1,517,006,000.

NATIONAL INSTITUTE ON DRUG ABUSE

For carrying out section 301 and title IV of the Public Health Service Act with respect to drug abuse, $1,080,018,000.

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

For carrying out section 301 and title IV of the Public Health Service Act with respect to alcohol abuse and alcoholism, $469,197,000.

NATIONAL INSTITUTE OF NURSING RESEARCH

For carrying out section 301 and title IV of the Public Health Service Act with respect to nursing research, $148,114,000.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

For carrying out section 301 and title IV of the Public Health Service Act with respect to human genome research, $524,807,000.

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

For carrying out section 301 and title IV of the Public Health Service Act with respect to biomedical imaging and bioengineering research, $322,106,000.

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

For carrying out section 301 and title IV of the Public Health Service Act with respect to minority health and health disparities research, $214,608,000.

NATIONAL CENTER FOR RESEARCH RESOURCES

For carrying out section 301 and title IV of the Public Health Service Act with respect to research resources and general research support grants, $1,297,900,000.

NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

For carrying out section 301 and title IV of the Public Health Service Act with respect to complementary and alternative medicine, $131,002,000.

JOHN E. FOGARTY INTERNATIONAL CENTER

For carrying out the activities of the John E. Fogarty International Center (described in subpart2 of part E of title IV of the Public Health Service Act), $71,328,000.

NATIONAL LIBRARY OF MEDICINE

For carrying out section 301 and title IV of the Public Health Service Act with respect to health information communications, $387,153,000, of which $4,000,000 shall be available until expended for improvement of information systems: Provided, That in fiscal year 2012, the National Library of Medicine may enter into personal services contracts for the provision of services in facilities owned, operated, or constructed under the jurisdiction of the National Institutes of Health: Provided further, That in addition to amounts provided herein, $8,200,000 shall be available from amounts available under section 241 of the Public Health Service Act to carry out the purposes of the National Information Center on Health Services Research and Health Care Technology established under section 478A of the PHS Act and related health services.

OFFICE OF THE DIRECTOR
(INCLUDING TRANSFER OF FUNDS)

For carrying out the responsibilities of the Office of the Director, National Institutes of Health ("NIH"), $1,298,412,000, of which up to $25,000,000 shall be used to carry out section 212 of this Act: Provided, That funding shall be available for the purchase of not to exceed 29 passenger motor vehicles for replacement only: Provided further, That the NIH is authorized to collect third party payments for the cost of clinical services that are incurred in NIH research facilities and that such payments shall be credited to the NIH Management Fund: Provided further, That all funds credited to such Fund shall remain available for one fiscal year after the fiscal year in which they are deposited: Provided further, That up to $193,880,000 shall be available for continuation of the National Children's Study: Provided further, That $556,890,000 shall be available for the Common Fund established under section 402A(c)(1) of the Public Health Service Act ("PHS Act"): Provided further, That of the funds provided $10,000 shall be for official reception and representation expenses when specifically approved by the Director of the NIH: Provided further, That the Office of AIDS Research within the Office of the Director of the NIH may spend up to $8,000,000 to make grants for construction or renovation of facilities as provided for in section 2354(a)(5)(B) of the PHS Act: Provided further, That up to $100,000,000 shall be available to implement section 402C of the PHS Act, relating to the Cures Acceleration Network.

BUILDINGS AND FACILITIES

For the study of; construction of; renovation of; and acquisition of equipment for, facilities of or used by the National Institutes of Health, including the acquisition of real property, $125,581,000 to remain available until expended.

GENERAL PROVISIONS FOR THE NIH

SEC. 203. None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse and Mental Health Services Administration shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II.

(TRANSFER OF FUNDS)
SEC. 207. The Director of the National Institutes of Health, jointly with the Director of the Office of AIDS Research, may transfer up to 3 percent among institutes and centers from the total amounts identified by these two Directors as funding for research pertaining to the human immunodeficiency virus: Provided, that the Committees on Appropriations of the House of Representatives and the Senate are notified at least 15 days in advance of any transfer.

(TRANSFER OF FUNDS)
SEC. 207. Of the amounts made available in this Act for the National Institutes of Health, the amount for research related to the human immunodeficiency virus, as jointly determined by the Director of the National Institutes of Health and the Director of the Office of AIDS Research, shall be made available to the ''Office of AIDS Research" account. The Director of the Office of AIDS Research shall transfer from such account amounts necessary to carry out section 2353(d)(3) of the Public Health Service Act.

SEC. 212. (a) AUTHORITY.—Notwithstanding any other provision of law, the Director of the National Institutes of Health may use funds available under section 402(b)(7) and 402(b)(12) of the Public Health Service Act to enter into transactions (other than contracts, cooperative agreements, or grants) to carry out research pursuant to such section 402(b)(7) (pertaining to the Common Fund) or research and activities described in such section 402(b)(12).
(b) PEER REVIEW.—In entering into transactions under subsection (a), the Director of the National Institutes of Health may utilize such peer review procedures (including consultation with appropriate scientific experts) as the Director determines to be appropriate to obtain assessments of scientific and technical merit. Such procedures shall apply to such transactions in lieu of the peer review and advisory council review procedures that would otherwise be required under sections 301(a)(3), 405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and 494 of the Public Health Service Act.

SEC. 215. Not to exceed $35,000,000 of funds appropriated by this Act to the Institutes and Centers of the National Institutes of Health may be used for alteration, repair, or improvement of facilities, as necessary for the proper and efficient conduct of the activities authorized herein, at not to exceed $2,500,000 per project.

(TRANSFER OF FUNDS)
SEC. 218. Of the amounts made available for the National Institutes of Health, 1 percent of the amount made available for National Research Service Awards ('NRSA') shall be made available to the Administrator of the Health Resources and Services Administration to make NRSA awards for research in primary medical care to individuals affiliated with entities who have received grants or contracts under Section 747 of the Public Health Service Act, and 1 percent of the amount made available for NRSA shall be made available to the Director of the Agency for Healthcare Research and Quality to make NRSA awards for health service research.

National Institutes of Health
Authorizing Legislation
($ in thousands)

	FY 2010 Actual	FY 2011 CR	FY 2012 Budget Request
National Institutes of Health:			
Section 301 and Title IV of the Public Health Service Act	$31,005,201	$31,009,788	$31,747,915
Section 330B(b)(2)(c) of the Public Health Service Act	$150,000	$150,000	$150,000
Section 311(a) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended, and Section 126(g) of the Superfund Amendments and Reauthorization Act of 1985	$79,212	$79,212	$81,085

NATIONAL INSTITUTES OF HEALTH

Appropriation History[1]

Fiscal Year	Budget Request to Congress	House Allowance	Senate Allowance	Appropriation
2001	18,812,735,000 [2]	20,512,735,000	20,512,735,000	20,458,130,000 [3]
2002	23,112,130,000	22,945,199,000	23,765,488,000	23,296,382,000 [4]
2003	27,343,417,000 [5]	27,351,717,000	27,369,000,000	27,066,782,000 [6]
2004	27,892,765,000	28,043,991,000	28,369,548,000	27,887,512,000 [7]
2005	28,757,357,000	28,657,357,000	28,901,185,000	28,495,157,000 [8]
2006	28,740,073,000	28,737,094,000	29,644,804,000	28,461,417,000 [9]
2007	28,578,417,000	28,479,417,000 [10]	28,779,081,000 [10]	29,030,004,000 [11]
2008	28,849,675,000	29,899,004,000	30,129,004,000	29,312,311,000 [12]
2008 Supp.				150,000,000
2009	29,457,070,000	30,607,598,000	30,404,524,000 [13]	30,545,098,000
2009 ARRA				10,400,000,000 [14]
2010	30,988,000,000	31,488,000,000	30,988,000,000	30,934,413,000 [15]
2011	32,136,209,000		31,989,000,000	
2012	31,979,000,000			

[1] Does not include comparability adjustments. Superfund and Type 1 diabetes are included except where indicated. Separate appropriation for Superfimd Research activities at NIEHS beginning in FY 2001. Includes amounts authorized to the NIDDK for Type 1 diabetes research beginning with the FY 2002 Appropriation.

[2] Reflects: $2,111,224,000 for HIV research in the NIH Office of AIDS Research.

[3] Reflects: a) $2,244,987,000 appropriated to the ICs for HIV research, b) across-the-board reduction of $8,666,000 and c) $5,800,000 transferred to the DHHS.

[4] Reflects: $2,535,672,000 appropriated to the ICs for HIV research and $10.5 million appropriated from the Emergency Relief Fund, b) across-the-board reduction of $9,273,000, c) rescissions for Labor/HHS ($22,946,000) and government-wide ($34,243,000) and d) transfer of $100M to the Global Fund for HIV/AIDS, malaria, and tuberculosis.

[5] Excludes $583,000 transferred to the Department of Homeland Security.

[6] Reflects: a) $2,747,463,000 appropriated to the ICs for HIV research and NIH's share of across-the-board reduction of $177,085,000, b) transfers of $99,350,000 to the Global Fund for HIV/AIDS, malaria, and tuberculosis, and $583,000 to the Department of Homeland Security.

[7] Reflects: a) $2,850,581,000 appropriated to the ICs for HIV research, b) across-the-board reduction of $165,459,000, c) Labor/HHS rescission of $17,492,000, and d) transfer of $149,115,000 to the Global Fund for HIV/AIDS, malaria, and tuberculosis.

[8] Reflects: a) $2,920,551,000 appropriated to the ICs for HIV research, b) aross-the-board reduction of $229,390,000, b) Labor/HHS rescission of $6,787,000, c) transfer of $99,200,000 to the Global Fund for HIV/AIDS, malaria, and tuberculosis

[9] Reflects: a) $2,903,664,000 appropriated to the ICs for HIV research, b) NIH share of Government-wide rescission of $287,356,000, and c) transfer of $99,000,000 to the Global Fund for HIV/AIDS, malaria, and tuberculosis.

[10] Reflects funding levels approved by the Appropriations Committees.

[11] Reflects: a) $2,905,802,000 appropriated to the ICs for HIV research, b) add-on for pay cost of $18,087,000, c) transfer of $99,000,000 to the Global Fund, and d) Supplemental Bill transfer of $99,000,000.

[12] Reflects: $2,928,345,000 appropriated to the ICs for HIV research, b) NIH share of the Government-wide rescission of $520,929,000, c) transfer of $294,759,000 to the Global Fund, and d) a supplemental appropriation of $150,000,000.

[13] Excludes funding for Superfimd Research activities which the Appropriations Committee did not make available.

[14] Provided under P.L. 111-5.

[15] Reflects Labor/HHS appropriation of $30,705,201,000; transfer of $300,000,000 to Global AIDS fimds; $1,000,000 transfer from HHS for the Interagency Autism Coordinating Committee and Secretary's 1% transfer to HHS of $4,587,000.

Expired Authorizations

Program	Last Year of Authorization	Authorization Level in Last Year of Authorization	Appropriations in Last Year of Authorization	Appropriations in FY 2011
National Institutes of Health, NIH[1]	2009	Section 103(b), P.L. 109-482, National Institutes of Health Reform Act of 2006, (Section 402A(b), PHSA)	$30,545,098	N/A

[1] No appropriation has been enacted for FY 2011.

FY 2012 HHS Enterprise Information Technology and Government-Wide E-Gov Initiatives

NIH Allocation Statement:

NIH will use $12,667,274 of its FY 2012 budget to support Department-wide enterprise information technology and government-wide E-Government initiatives. Operating Divisions help to finance specific HHS enterprise information technology programs and initiatives, identified through the HHS Information Technology Capital Planning and Investment Control process, and the government-wide E-Government initiatives. The HHS enterprise initiatives meet cross-functional criteria and are approved by the HHS IT Investment Review Board based on funding availability and business case benefits. Development is collaborative in nature and achieves HHS enterprise-wide goals that produce common technology, promote common standards, and enable data and system interoperability.

Of the amount specified above, $772,836 is allocated to developmental government-wide E-Government initiatives for FY 2012. This amount supports these government-wide E-Government initiatives as follows:

FY 2012 Developmental E-Gov Initiatives*	
Line of Business - Human Resources	$35,644
Line of Business - Grants Management	$131,963
Line of Business - Financial	$18,063
Line of Business - Budget Formulation and Execution	$13,263
Disaster Assistance Improvement Plan	$38,803
Federal Health Architecture (FHA)	$535,100
Line of Business - Geospatial	$0
FY 2012 Developmental E-Gov Initiatives Total	**$772,836**

* Specific levels presented here are subject to change, as redistributions to meet changes in resource demands are assessed.

Prospective benefits from these initiatives are:

Line of Business - Human Resources (HR) Management: Provides standardized and interoperable HR solutions utilizing common core functionality to support the strategic management of human capital.

Line of Business - Grants Management (GMLoB): Supports end-to-end grants management activities promoting improved customer service; decision making; financial management

processes; efficiency of reporting procedure; and, post-award closeout actions. The Administration for Children and Families (ACF) is a GMLoB consortia lead, which has allowed ACF to take on customers external to HHS. These additional agency users have allowed HHS to reduce overhead costs for internal HHS users. Additionally, NIH is an internally HHS-designated Center of Excellence. This effort has allowed HHS agencies using the NIH system to reduce grants management costs. Both efforts have allowed HHS to achieve economies of scale and efficiencies, as well as streamlining and standardization of grants processes, thus reducing overall HHS costs for grants management systems and processes.

Line of Business - Financial Management: Supports efficient and improved business performance while ensuring integrity in accountability, financial controls and mission effectiveness by enhancing process improvements; achieving cost savings; standardizing business processes and data models; promoting seamless data exchanges between Federal agencies; and, strengthening internal controls.

Line of Business - Budget Formulation and Execution: Allows sharing across the Federal government of common budget formulation and execution practices and processes resulting in improved practices within HHS.

Disaster Assistance Improvement Plan (DAIP): Assists agencies with active disaster assistance programs such as HHS to reduce the burden on other Federal agencies which routinely provide logistical help and other critical management or organizational support during disasters.

Line of Business - Federal Health Architecture: Creates a consistent Federal framework that improves coordination and collaboration on national Health Information Technology (HIT) solutions; improves efficiency, standardization, reliability and availability to improve the exchange of comprehensive health information solutions, including health care delivery; and, to provide appropriate patient access to improved health data. HHS works closely with Federal partners, state, local and tribal governments, including clients, consultants, collaborators and stakeholders who benefit directly from common vocabularies and technology standards through increased information sharing, increased efficiency, decreased technical support burdens and decreased costs.

In addition, $3,889,669 is allocated to ongoing government-wide E-Government initiatives for FY 2012. This amount supports these government-wide E-Government initiatives as follows:

FY 2012 Ongoing E-Gov Initiatives*	
E-Rule Making	$22,191
Integrated Acquisition Environment	$775,034
GovBenefits	$88,519
Grants.Gov	$3,003,925
FY 2012 Ongoing E-Gov Initiatives Total	**$3,889,669**

* Specific levels presented here are subject to change, as redistributions to meet changes in resource demands are assessed.

NARRATIVE BY ACTIVITY

NATIONAL INSTITUTES OF HEALTH

(dollars in thousands)

	FY 2010 Actual	FY 2011 CR[2]	FY 2012 PB	Change from FY 2010 Actual
BA (in thousands)[1]	$31,234,413	$30,935,000	$31,979,000	$744,587
FTEs	*18,362*	*18,412*	*18,412*	*+50*

'includes Labor/HHS Budget Authority, Interior Superfund Appropriation, and the mandatory appropriations funded for type 1 diabetes research. In FY2010 and FY2011, also reflects $1 million transfer from HHS for the Interagency Autism Coordinating Committee. In FY2010, also reflects transfer to HHS of $4,587,000 under the Secretary's 1 percent transfer authority.

[2]The $304,000,000 transfer from Homeland Security's Biodefense Countermeasures account is not included in FY 2011. Since there are no funds remaining in that account in FY 2011, under current law continuing resolution (P.L.111-317), there can be no transfer. The Administration supports replacing this transfer with budget authority in FY 2011.

Authorizing Legislation: Section 301 and Title IV of the Public Health Act, as amended.

Allocation Method.....Competitive Grant
Allocation Method.....Contract
Allocation Method.....Intramural
Allocation Method.....Other

Program Description and Accomplishments

Several major organizational initiatives and reforms either have been accomplished or are underway at NIH. On September 27, 2010, the National Center on Minority Health and Health Disparities was officially redesignated as the National *Institute* on Minority Health and Health Disparities. Authorized by the Affordable Care Act of 2010, the transition of the Center to Institute status signals an enhanced Federal focus on research on health disparities and elevates the Nation's emphasis on minority health and health disparities research activities.

In addition to the creation of the new National Center for Advancing Translational Science, as discussed in the Executive Summary, two other significant organizational changes are underway at NIH: 1) a new vision, role, governance and budget for the NIH Clinical Center; and 2) establishment of an institute focused on substance use, abuse, and addiction research. These organizational changes were informed by the recommendations of the Scientific Management Review Board (SMRB), a 21-member Federal advisory commission established by the NIH Reform Act of 2006 to advise the NIH Director on the use of certain organizational authorities, including the authorities to establish or abolish institutes or centers, to reorganize or alter functions of the Office of the Director, and to reorganize or alter the functions of administrative units within institutes or centers. The SMRB operates through extensive public consultation and open deliberations, and all of its recommendations are the product of extensive fact-finding, analysis, and consideration of wide-ranging public perspectives.

A New Vision, Role, Governance and Budget for the NIH Clinical Center. NIH will make several interrelated changes to enhance the programmatic and fiscal vitality of the NIH Clinical Center (CC). CC will become a *national* resource for clinical investigators both internal and external to the NIH. The technical resources and infrastructure, along with the programmatic potential of CC provide great promise for advancing clinical research on a national scale—an aim that is well aligned with the agency's goals for translational science and medicine. To facilitate the realization of this vision, in FY2012 the governance of CC will be streamlined to permit a clearer, more expeditious process of priority setting and implementation.

Establishment of an Institute on Substance Use, Abuse, and Addiction Research. NIH is considering the establishment of a new institute in FY 2013 focused on substance use, abuse, and addiction research and public health initiatives to capitalize on scientific opportunities and to promote synergies and collaborative efforts. Establishment of the new institute would involve several steps, including the integration of the relevant portfolios of the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), and other NIH institutes and centers, the transfer of the remaining portfolios from NIAAA and NIDA to other institutes and centers, the dissolution of NIAAA and NIDA, and the recruitment of a new director for the new institute.

National Center for Research Resources (NCRR). NIH is committed to re-evaluating and readjusting its activities and organizational structure to ensure that it can pursue the most promising biomedical research in an efficient and effective way. A final example of this effort is NIH's proposal to eliminate NCRR as an organizational unit in FY 2012 while maintaining its programs. It is likely that the Clinical and Translational Sciences Award (CTSA) program,

which comprises a large part of NCRR, will be better aligned with the new National Center for Advancing Translational Sciences (NCATS), and the organizational structure will likely reflect this. NIH plans to maintain all of the other programs currently funded under NCRR, but those that do not go to NCATS will be shifted to other parts of NIH. NIH will provide further details on this proposal in the Spring.

Long Range NIH Research Contributions to Improvements in Health Care and Public Health: Selected Examples

In the last 25 years, the NIH extramural and intramural biomedical research communities have made significant strides in scientific discoveries directly leading to human health benefits that both extend lifespan and reduce illnesses. Data from the National Long-term Care Survey shows that from 1982 to 2004, the age-standardized prevalence of reported chronic disability among American seniors (age 65 and older) dropped nearly 30 percent. A major component of this drop comes from improvements in prevention and treatment of heart attacks and strokes, including control of cholesterol levels and hypertension with pharmaceuticals, as well as improvements in materials and devices such as drug-eluting stents. NIH played a large role in creating these improvements. Other specific advances include treatment of arthritis with pharmaceuticals and joint replacements, and improvement in technologies, such as safe and effective outpatient cataract surgery.

Other examples of health improvements over the last several decades that originated from NIH-funded research are:

Age-RelatedMacular Degeneration (AMD): Forty years ago there was little or nothing one could do to prevent or treat advanced AMD and blindness. Because of new treatments and procedures based on NIH research, 750,000 Americans who would have gone blind over the next five years instead will continue to have useful vision.

Breast Cancer: The five-year survival rate for women diagnosed with breast cancer was 75 percent in the mid-1970s. Because of NIH-supported research, the five-year survival rate has risen to over 90 percent.

Cervical Cancer: Cervical cancer is the fifth most deadly cancer in women. Due to groundbreaking NIH research, an FDA-approved vaccine now is available to prevent the development of cervical cancer.

Colon Cancer: From 1974-1976, in an NIH-sponsored study, the five-year survival for patients with colon cancer was 50 percent. In 2009, based on NIH-supported clinical trials using new diagnostics and treatments, a comparable patient group has a five-year survival rate of over 70 percent.

Cochlear Implants: Because of NIH-supported research, profoundly deaf children that receive a cochlear implant within the first two years of life now have the same skills, opportunities, and potential as their normal-hearing classmates.

Type 1 Diabetes: Thirty to forty years ago, 30 percent of patients died within 25 years of a diagnosis of type 1 diabetes. Today, due to tight blood glucose control, heart disease and stroke in type 1 diabetics have been reduced by over 50 percent.

Heart Disease: The over one million annual deaths from coronary heart disease seen 30-40 years ago now have been cut by more than half due to new drugs, procedures, and prevention programs developed through NIH research.

Hepatitis B: In the mid-1980s, hepatitis B infection caused untreatable and fatal illness. Due to intensive vaccination programs based on NIH research, the rate of acute hepatitis B has fallen by more than 80 percent.

HIV/AIDS: In the 1980s, the diagnosis of HIV infection was a virtual death sentence. Due to antiviral drugs developed by NIH, today an HIV-positive 20-year-old can be expected to reach the age of 70.

Infant Health: In 1976, the infant mortality rate was 15.2 infant deaths per 1,000 live births. By 2006, that rate had fallen to 6.7 deaths per 1,000 live births. Much of this progress can be attributed to NIH research in the areas of maternal and pre-natal health care, neonatal care unit procedures and new drugs administered to women at risk for premature birth.

Science Advances in 2009-2010

NIH funded research leads to thousands of new findings every year. While it can take more time for new scientific and technological developments to bring about significant improvements in health, important scientific discoveries are made every day. These incremental advances are the building blocks on which further progress is made. Highlighted below are just a few of the many recent accomplishments from NIH's extramural and intramural research programs:

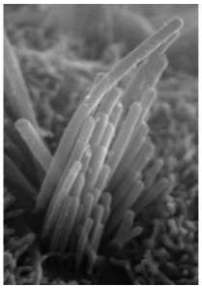
- The first results from a large clinical trial testing candidate microbicides that use anti-retrovirals (ARVs) found that the incorporation of an ARV into a vaginal gel was more than 50 percent protective against HIV infection. This advance is a key step toward empowering women with a safe and effective HIV prevention tool.

- NIH-supported research at General Electric supported the development of a low-cost, portable, high-quality ultrasonic imager. In the last year, this advance was extended even further with GE's production of "Vscan." This pocket-sized device makes medical ultrasound even more accessible and has enabled wireless imaging, patient monitoring, and prenatal care applications.

- The National Lung Screening Trial found that screening with low-dose computed tomography (CT) can decrease lung-cancer deaths among current and former heavy smokers by 20 percent. This was the first time that screening was found to reduce mortality from lung cancer, the most common cause of cancer deaths.

- Vaccines developed to combat drug addictions work by generating drug-specific antibodies that bind the drug while in the bloodstream and prevent its entry into the brain. A nicotine vaccine recently found to improve smoking quit rates is now in phase III trials to evaluate continued abstinence at 12 months.

- In mammals, mechanically-sensitive "hair cells" in the inner ear, which are essential for hearing and balance, cannot regenerate when they die or are damaged. NIH-supported scientists have used mouse embryonic stem cells as well as induced pluripotent stem cells, and generated hair cells that respond to mechanical stimulation, offering a new avenue for treatment of deafness.



- Carbon nanotubes have been used to deliver chemotherapeutic agents specifically to head and neck cancer cells, causing rapid death of the cancer cells, but leaving non-cancerous cells unharmed.

- Researchers have demonstrated in animal models that certain lipids called resolvins, which shut down inflammation, are more potent than morphine in controlling pain.

- A comparative effectiveness study for diabetic macular edema found that combined treatment with the drug ranibizumab and laser therapy was substantially better at improving vision in diabetic patients than laser therapy alone, and better than laser therapy with a different drug (triamcinolone).

- Intramural researchers discovered that ketamine, an anesthetic medication, provides rapid and effective treatment for depressive symptoms among bipolar disorder patients. While ketamine's side effects make it impractical for long-term use, this class of drugs may be invaluable for treating severe depressive symptoms in these patients during the weeks it usually takes for typical antidepressants to take full effect.

- Significant progress was made toward the development of a universal flu vaccine that would confer longer term protection against multiple influenza virus strains. NIAID-supported researchers have identified the regions of influenza viral proteins that remain unchanged among seasonal and pandemic strains. These findings will inform the development of influenza vaccines that might one day provide universal protection against the broad range of influenza strains. Such a universal influenza vaccine would make yearly flu shots a thing of the past.

BUDGET REQUEST

I. Summary of Priority Funding

For FY 2012, the National Institutes of Health (NIH) requests $31.979 billion in budget authority, an increase of $745 million or 2.4 percent over the FY 2010 Actual funding level. This budget request invests in areas of extraordinary promise for biomedical science and its supporting infrastructure, while achieving efficiencies to maintain fiscal constraint. Investment in biomedical and behavioral research will increase understanding of disease and generate tangible progress toward solving the Nation's most pressing health challenges. Through these investments, NIH will help improve the health of the American people, as well as the long-term economic health of the Nation.

NIH will support many of its ongoing research efforts, will curtail other lower priority activities, and will make strategic investments in key areas of scientific opportunity in FY 2012. In particular, NIH will emphasize:

- Translational sciences and therapeutics development;
- Technologies to accelerate discovery;
- Enhancement of the evidence-base for health care decisions; and,
- New investigators, new ideas.

These areas of exceptional opportunity for advancing biomedical knowledge and the application of this knowledge to improve health are described in detail in the Executive Summary of this document.

Funding will be focused specifically toward these areas of opportunity. For example, NIH will invest $100 million in the Cures Acceleration Network. Other high-priority programs and objectives also will receive additional funding, primarily through research project grants. The grant application and peer review process will focus on these objectives, while leaving intact the investigator-initiated nature of NIH-funded research projects. Thus, although specific funding levels for each investment area are not specified in advance, these areas will be supported heavily in FY 2012.

Policies also have been established to guide investments, while limiting inflationary cost increases. These policies for FY 2012 include: a one percent increase in the average cost of competing and non-competing Research Project Grants (RPGs); a one percent increase in Research Centers and Other Research; and, a one percent increase for Intramural Research and Research Management and Support. Staffing levels also have been constrained. These policies are necessary to enable expanded support for critical areas of opportunity.

Estimated funding for the individual funding delivery mechanisms (e.g., competing research project grants, training) takes into account the NIH-wide investment policies and the current NIH research portfolio. As the NIH-wide policies are applied to the budgets and research portfolios of each Institute and Center, other factors (e.g., multiple grant cohorts, exceptionally large single grants and assessments to support cross-NIH requirements) come into play. The resulting

funding estimates by mechanism, therefore, do not correspond solely to the inflation policy limitations. For example, this budget request protects critical activities, including new and competing research project grants (RPGs), to the extent possible within overall funding constraints and requirements to support extramural commitments and NIH's infrastructure. However, since 75-80 percent of the RPG budget in any given year is committed to multi-year grants, the funds available for new and competing grants are limited. From FY 2010 to FY 2011, these factors, combined with the overall funding level, resulted in an estimated decrease of 652 in the number of competing RPGs. However, for FY 2012, NIH again will focus funding on RPGs, resulting in an increase over the FY 2011 level of 424 competing RPGs. Overall, from FY 2010 to FY 2012, the number of competing RPGs declines by 228.

II. Explanation by Mechanism

Funding levels and related increases/decreases from FY 2010 to FY 2012 are provided in the mechanism tables that follow this discussion of each mechanism and associated budget policies.

Research Project Grants: Research project grants (RPGs) are the primary mechanism for funding of investigator-initiated biomedical research. These grants support new and experienced investigators in broad-based research programs. The use of RPGs as a mechanism of support covers the entire medical research continuum, from basic scientific research at the molecular and cellular levels to studies of human beings in both healthy and diseased states. Most grant applications originate with individual investigators who develop proposals for research in their areas of interest. Research project grants awarded to institutions on behalf of a principal investigator support medical research activities in the areas of both the specific interests and competence of the principal investigators and in areas identified as high priority by the NIH Institutes and Centers.

NIH uses several RPG activities to support the best research applications from the most talented researchers. The most common, the traditional R01 grant (including R37's), accounts for nearly 66 percent of the number of competing RPGs awarded and approximately 66 percent of competing RPG funding (FY 2010 data). The R01 supports a single project with a principal investigator or co-investigators. Another frequently used award is the program project (P01), a multi-project grant, which supports a variety of broad-based multi-disciplinary projects conducted by numerous investigators working on various aspects of a specific major research objective or theme.

Budget Policy: NIH established limitations on inflationary cost increases for RPGs of one percent average cost increase in FY 2012 for both competing and non-competing grants. In total, funding for RPGs will increase by $436 million to $16.909 billion, and the number of RPGs will increase by 43 grants to 36,852. These net effects over the two-year period result from the interaction of the outstanding research portfolio, the available funding and the prioritization placed by NIH on maintaining support for RPGs.

Research Centers: Research center grants are awarded to institutions on behalf of a program director and a group of collaborating investigators to: (1) provide long-term support for leading-edge research; (2) conduct multi-disciplinary programs of biomedical research; and

(3) develop research resources. The Research Centers program integrates basic research with applied research and transfer activities; promotes research in the areas of clinical applications with an emphasis on intervention, including prototype development and refinement of products, techniques, processes, methods, and practices; develops and maintains the biotechnology and research model resources needed by NIH-supported biomedical investigators to conduct research; and, assists minority institutions to improve their research infrastructure.

Budget Policy: The budget includes $3,036 million for Research Centers, a decrease of $41 million from FY 2010 to FY 2012. This reduces the number of such awards by 18.

Other Research: NIH will continue to support a variety of investigator-initiated activities through other types of research grants. Through the Research Careers program, NIH provides increased career opportunities in medical research to scientists of superior potential. The program supports young investigators who desire advanced development and scientists who need experience to qualify for senior positions. Other Research mechanisms include support for research initiatives in the cooperative clinical research sub-mechanism to encourage regionally-based clinical evaluations of methods of therapy and prevention strategies. Minority Biomedical Research Support Grants support research that enriches the biomedical research environment at undergraduate institutions. Moreover, these grants strengthen the research training capabilities of minority faculty and students. Other Research grants also provide funding for: shared resources at grantee institutions; purchase of equipment; implementation of the nanotechnology program of the Common Fund; and, conference grants to support investigator-initiated meetings, conferences or workshops to promote sharing of scientific knowledge and address specific issues.

Budget Policy: The budget includes $1,820 million for Other Research, an increase of $25 million from FY 2010 to FY 2012.

Research Training: The purpose of the Ruth L. Kirschstein National Research Service Awards (NRSA) program is to replenish the Nation's corps of biomedical and behavioral research investigators. Through institutional awards and individual fellowships, NIH supports both basic and applied research training in the biomedical and behavioral sciences. Institutional awards provide the foundation for the manpower development effort by supporting the national capacity for excellent, up-to-date training in a variety of institutional settings. They enable NIH to aid institutions in maintaining vigorous and effective research training programs and, in particular, to support research training programs in areas of national need. Funds are awarded for predoctoral and postdoctoral stipends and for tuition where warranted, with a modest allocation to the institution to defray training-related expenses not covered by tuition. NRSAs also include funds for travel, fees, indirect costs, and other expenses. Stipend levels constitute the largest dollar portion of NRSAs.

Budget Policy: At the FY 2012 request level, NIH will provide stipend increases of four percent. This will supplement the 2 percent increase in stipends included in NIH's FY 2011 estimate. Enhanced stipends will improve NIH's ability to attract high-quality research investigators to the field of biomedical research. In order to achieve the NIH's research

objectives, it is essential to ensure that highly trained scientists will be available to address the Nation's biomedical, behavioral and clinical research needs, especially as the current workforce ages and begins to retire. NRSA awards will receive $794 million in FY 2012, an increase of $19 million over the FY 2010 Actual level. This funding will support about 16,831 Full-Time Training Positions (FTTPs), a decrease of 330 FTTPs from the FY 2010 level. This decrease in FTTPs results from the planned phase-out of Common Fund support for NRSA training by FY 2012.

Research and Development Contracts: NIH awards Research and Development (R&D) contracts to acquire specific products, services or studies from academic institutions and non-profit and commercial organizations. This mechanism also includes collaborative research efforts with other agencies, small business innovation research and architect-engineering services contracts.

Budget Policy: Although NIH is working to constrain contract costs through a greater emphasis on performance-based contracting and careful evaluation of functions more appropriately performed by Federal employees and contractors, overall funding for this budget mechanism will increase by $89 million in FY 2012 compared with FY 2010. These funds also will support the increased use of interagency agreements and intra-agency funding arrangements.

Intramural Research: The Intramural Research Program (IRP) supports vital research conducted at NIH by some of the Nation's top scientists. This powerful network of investigators is an integral part of the greater national research network devoted to advancing the knowledge needed to develop treatments, tests, and prevention strategies to benefit the public as quickly as possible. A strong intramural program at NIH complements and reinforces the work being carried out in the extramural biomedical research community. Through IRP, NIH conducts basic and clinical research at its on-campus research facilities in Bethesda, Maryland, and at off-campus locations such as the Gerontology Research Center in Baltimore, Maryland; Research Triangle Park, North Carolina; the Rocky Mountain laboratories in Hamilton, Montana; Phoenix, Arizona; and, Frederick, Maryland. Fundamental research performed by intramural scientists provides the basis upon which advances in medical care are built. An important byproduct of this research is the cadre of young physicians and basic scientists trained in the techniques and approaches of intramural scientists. Many of these young researchers become future extramural and intramural principal investigators. An invaluable and unique feature of IRP is the Clinical Research Center. This world-class national resource promotes translational research -- that is, the transference of scientific laboratory research into applications that benefit patient health and medical care. The "bench-to-bedside" approach adopted in 1953, locates patient care units in close proximity to cutting-edge laboratories conducting related research; this facilitates interaction and collaboration among clinicians and researchers.

Budget Policy: The budget includes $3,382 million for Intramural Research, an increase of $50 million above the FY 2010 level.

Research Management and Support (RMS): This mechanism supports many functions, including: scientific direction and management by NIH staff in the review, award, and performance monitoring of extramural awards (i.e. research grants, training awards, and research and development contracts); administrative and technical support for congressionally-mandated review groups and advisory councils; liaison among NIH and Departmental components, as well as among applicants, grantees, advisory bodies, and special interest organizations; and, monitoring of advances emerging from basic science laboratories to determine possible clinical applications for treatment and prevention. Management and administrative functions for each Institute and Center (IC) also are supported by this mechanism. Examples of such functions include: interpreting, analyzing, and implementing new legislation and administrative orders; formulating and executing IC budgets; performing management evaluation studies; determining manpower requirements; assessing the condition of both NIH and extramural grantee laboratory facilities and equipment; supporting prevention and education activities, including development of educational and informational materials for both the medical community and the general public; and providing the leadership and business functions for the ICs.

Budget Policy: The budget includes $1,538 million for RMS, $30 million above the FY 2010 level.

Office of the Director: The Office of the Director (OD) provides leadership, coordination, and guidance in the formulation of policy and procedures related to biomedical research and research training programs. To provide this direction, OD centrally coordinates NIH's extramural and intramural research activities; science policy and related social, ethical, and legal issues; technology transfer and intellectual property protection policies; health information dissemination and public education functions; legislative activities; and, oversight of the agency's stewardship of public funds.

OD encourages and fosters cross-IC research and research training efforts in the prevention and treatment of disease through program coordination offices. These offices focus on Acquired Immune Deficiency Syndrome (AIDS); women's health; disease prevention; science education; dietary supplements; rare diseases and disorders; and, behavioral and social sciences research. While OD provides the overall direction, coordination and oversight of these programs, the ICs manage the actual research operations.

The OD request also includes the NIH Common Fund that supports crosscutting, trans-NIH programs that require participation by at least two ICs. The Common Fund encourages collaboration across the ICs, while providing NIH with flexibility to determine priorities for Common Fund support.

Budget Policy: At the FY 2012 request level, OD will be funded at $1.298 billion, which is an increase of $122 million, or 10.3 percent, over the FY 2010 Actual level. The majority of this increase, $100 million, will support the newly authorized Cures Acceleration Network. The Common Fund will receive $557 million, an increase of $13 million over the FY 2010 Actual level. A total of $194 million will be provided for the National Children's Study, which is the same amount as in the FY 2010 Actual level.

Buildings and Facilities: The NIH buildings and facilities (B&F) program is responsible for the design, construction, improvement, and major repair of clinical and laboratory buildings and supporting facilities essential to NIH's research mission. Funds support two major needs: the design and construction of new facilities for NIH research programs; and, the continuing repair and improvement of existing facilities.

Budget Policy: The FY 2012 request level provides a total of $133.5 million for this mechanism total, which includes $125.6 million for the B&F appropriation account, an increase of $25.6 million over FY 2010, and a request for $7.9 million in building and facilities funds within the NCI appropriation account for facilities repair and improvements at the federally-funded research and development center in Frederick, MD. This increase over the FY 2010 level continues NIH's commitment to sustain its facilities and improve the overall B&F Condition Index (CI).

Other Trans-NIH Funding: NIH also funds several trans-NIH initiatives that benefit all or most of the Institutes and Centers (ICs) through assessments of the ICs, typically based on their proportion of the overall NIH budget, or their estimated use of the activity or equipment being funded through the initiative.

Budget Policy: For FY 2012, NIH will continue to fund several such initiatives, including support for the new synchrotron under development at the Department of Energy's Brookhaven National Laboratory ($15 million), and the OppNet program which focuses on behavioral research ($10 million). Funding associated with these assessments is incorporated within each ICs' budget.

NATIONAL INSTITUTES OF HEALTH

Budget Mechanism - Total [1]

(dollars in thousands)

MECHANISM	FY 2010 Actual [7]		FY 2011 CR [7]		FY 2012 PB		Change	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants:								
Research Projects:								
Noncompeting	25,738	$11,732,029	25,936	$11,871,057	26,019	$12,135,448	281	$403,419
Administrative Supplements	*1,517*	174,393	*1,378*	164,699	*1,282*	154,923	(235)	(19,470)
Competing:							0	0
Renewal	2,537	1,249,215	2,429	1,207,457	2,429	1,233,106	(108)	(16,109)
New	6,792	2,650,274	6,258	2,495,690	6,681	2,721,759	(111)	71,485
Supplements	57	15,347	47	14,168	48	14,197	(9)	(1,150)
Subtotal, Competing	9,386	$3,914,836	8,734	$3,717,315	9,158	$3,969,062	(228)	$54,226
Subtotal, RPGs	35,124	$15,821,258	34,670	$15,753,071	35,177	$16,259,433	53	$438,175
SBIR/STTR	1,685	$651,519	1,658	$637,161	1,675	$649,370	(10)	($2,149)
Research Project Grants	36,809	$16,472,777	36,328	$16,390,232	36,852	$16,908,803	43	$436,026
Research Centers:								
SpecializEd/Comprehensive	1,197	$2,294,986	1,201	$2,227,367	1,198	$2,242,880	1	($52,106)
Clinical Research	79	435,787	74	434,148	71	443,844	(8)	8,057
Biotechnology	109	153,412	100	147,078	100	148,574	(9)	(4,838)
Comparative Medicine	50	133,062	49	139,631	49	141,018	(1)	7,956
Research Centers in Minority Institutions	23	60,452	22	59,455	22	60,024	(1)	(428)
Research Centers	1,458	$3,077,699	1,446	$3,007,679	1,440	$3,036,340	(18)	($41,359)
Other Research:								
Research Careers	4,049	$649,044	4,025	$651,467	4,007	$651,917	(42)	$2,873
Cancer Education	91	35,444	89	34,944	89	34,944	(2)	(500)
Cooperative Clinical Research	332	430,727	386	458,598	412	464,209	80	33,482
Biomedical Research Support	134	67,626	133	66,305	123	61,958	(11)	(5,668)
Minority Biomedical Research Support	371	107,035	372	106,009	378	107,232	7	197
Other	1,706	504,286	1,718	495,543	1,678	499,241	(28)	(5,045)
Other Research	6,683	$1,794,162	6,723	$1,812,866	6,687	$1,819,501	4	$25,339
Total Research Grants	44,950	$21,344,638	44,497	$21,210,777	44,979	21,764,644	29	$420,006
Research Training:	FTTPs		FTTPs		FTTPs			
Individual Awards	3,071	$125,301	3,084	$129,510	3,104	$134,661	33	$9,360
Institutional Awards	14,090	649,916	13,947	652,527	13,727	659,743	(363)	9,827
Total Research Training	17,161	$775,217	17,031	$782,037	16,831	$794,404	(330)	$19,187
Research & Development Contracts	2,508	$3,455,571	2,518	$3,257,522	2,519	$3,544,551	11	$88,980
(SBIR/STTR)	*129*	*$39,438*	*135*	*$45,039*	*127*	*$44,749*	*(2)*	*$5,311*
Intramural Research		$3,331,414		$3,342,540		$3,381,705		$50,291
Research Management and Support		1,507,640		1,522,721		1,537,588		29,948
Extramural Construction		0		0		0		0
Office of the Director - Appropriation [3]		*$1,176,844*		*$1,176,299*		*$1,298,412*		*$121,568*
Office of the Director - Other		632,816		632,271		741,522		109,251
Bridge Awards [3]		*0*		*0*		*0*		*0*
Common Fund [3]		*544,028*		*544,028*		*556,890*		*12,862*
Buildings and Facilities [4]		107,905		107,920		133,501		25,596
Appropriation		*125,581*		*100,000*		*125,581*		*0*
Type 1 Diabetes [5]		(150,000)		(150,000)		(150,000)		(0)
Subtotal, Labor/HHS Budget Authority		**$31,005,201**		**$30,705,788**		**$31,747,915**		**$742,714**
Interior Appropriation for Superfnd Res.		79,212		79,212		81,085		1,873
Total, NIH Discretionary B.A.		**$31,084,413**		**$30,785,000**		**$31,829,000**		**$744,587**
Type 1 Diabetes [6]		150,000		150,000		150,000		0
Total, NIH Budget Authority		**$31,234,413**		**$30,935,000**		**$31,979,000**		**$744,587**
NLM Program Evaluation		8,200		8,200		8,200		0
Total, Program Level		**$31,242,613**		**$30,943,200**		**$31,987,200**		**$744,587**
Grand Total, BA		**$31,242,613**		**$30,943,200**		**$31,987,200**		**$744,587**

[1] All items in italics are "non-adds"; items in parenthesis are subtractions.

[2] Flexible Research Authority is noted as a non-add since the funding is accounted for within the Office of the Director (OD) - Other line.

[3] Number of grants and dollars for The Common Fund are distributed by mechanism and are noted here as a non-add. The Office of the Director - Appropriations also is noted as a non-add since these funds are accounted for under OD - Other and Common Fund within the above mechanism distribution.

[4] Includes B&F appropriation plus construction dollars appropriated to NCI.

[5] Number of grants and dollars for Type I Diabetes are distributed by mechanism above; therefore, Type I Diabetes amount is deducted to provide subtotals only for th Labor/ HHS Budget Authority.

[6] Reflects HHS ASFR specified treatment of mandatory Type 1 Diabetes funding from the U.S. Treasury.

[7] FY 2010 reflects Secretary's 1% Transfer ($4.587 million), as well as $1 million transfer from HHS for the Interagency Autism Coordinating Committee. FY 2011 also reflects the $1 million transfer.

NIH Outcomes and Outputs Table

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
SRO-1.3: By 2010, develop an experimental robotic exoskeleton that can be tested for clinical rehabilitation of upper extremity movement. (Outcome)	FY2010: Developed a portable pneumatic robotic exoskeleton for clinical rehabilitation of upper extremity movement in stroke patients, and completed safety and feasibility testing to enable use in a home or clinical setting. (Target Met)	Complete goal of developing an experimental robotic exoskeleton that can be tested for clinical rehabilitation of upper extremity movement.	N/A	N/A
SRO-1.4: By 2012, identify signatures of gene expression in peripheral tissues that are associated with alcohol-induced disorders. (Outcome)	FY2010: Standardized cell culture techniques were established, validated and refined. (Target Met)	Establish cell culture standardization techniques to enable initiation of gene expression analyses of cell lines derived from individuals with and without AUDs.	Complete gene expression studies with peripheral tissues and identify signature gene expression profiles.	N/A
SRO-1.5: (RA) By 2012, develop a comprehensive IT platform that can facilitate evaluation of diverse behavioral interventions to promote health (Outcome)	FY2010: The design phase of this project was completed and the development phase is well underway. (Target Met)	Complete concept (design phase) for an IT platform to facilitate evaluation of behavioral interventions.	Conduct at least 1 pilot project to test the functionality of the IT platform.	N/A
SRO-1.6: (RA) By 2012, present preliminary findings from the three-pronged approach to curtail the HIV pandemic. (Outcome)	FY2010: Enrollment was completed for HPTN 061 and HPTN 064. HPTN 061 enrolled 1,548 participants and HPTN 064 enrolled 2,099 participants. (Target Met)	Complete enrollment of two important studies that will support the "Test and Treat" approach - HPTN 061 and HPTN 064.	Present preliminary findings from the three-pronged approach to curtail the HIV pandemic, which includes Test, Link to Care, Plus Treat (TLC-Plus) and Pre-Exposure Prophylaxis (PrEP) studies, and basic research to eliminate HIV reservoirs.	N/A
SRO-1.7: (RA) By 2012, incorporate scientific human development concepts, in order to develop and rigorously test at least 2 childhood learning approaches that can be integrated into science, technology, engineering and mathematics (STEM) K-12 educational programs. (Outcome)	FY2010: A rigorous study protocol of STEM learning in at-risk children was developed and 50% of the 300 participants needed were enrolled. (Target Met)	Develop a rigorous study protocol, and enroll 50% of the participants needed, in at least 1 study of STEM learning in at-risk children.	Complete testing of at least 2 childhood learning approaches for integration into science, technology, engineering and mathematics (STEM) K-12 educational programs.	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
SRO-1.8: (RA) By 2012, identify three research findings that will advance understanding of the biological basis underlying the heterogeneity of autism spectrum disorder (ASD) and conduct initial testing of three treatment or service delivery strategies. (Outcome)	FY2010: Researchers initiated testing of more than six novel treatment or service delivery approaches to address symptoms or improve functioning for individuals with Autism Spectrum Disorder (ASD). (Target Met)	Initiate testing of at least three novel treatment or service delivery approaches to address symptoms or improve functioning for individuals with ASD.	Build upon research findings to advance understanding of the biological basis underlying the heterogeneity of autism spectrum disorder (ASD) and complete initial testing of three treatment or service delivery strategies	N/A
SRO-2.1: By 2015, evaluate islet transplantation in combination with immune modulation strategies for the treatment of type 1 diabetes in clinical trials. (Outcome)	FY2010: 303 subjects have been enrolled for assignment into 5 Phase II clinical trials and 2 Phase III clinical trials. (Target Met)	Continue to enroll subjects in trials, and follow enrolled subjects to endpoints.	Complete data collection for Phase II studies.	N/A
SRO-2.5: By 2011, identify and evaluate 5 novel molecular-targeted interventions for cancer, and determine suitability for use in early phase clinical trials. (Outcome)	FY2010: NIH investigators identified three novel targeted cancer interventions: HLI373, englerin, and Tdp1 inhibitors. (Target Met)	Identify 3 novel targeted cancer interventions.	N/A	N/A
SRO-2.6: By 2011, develop one field deployable sensor device for use in human studies and develop one biomarker to characterize the impact of environmental exposures on biological pathways. (Outcome)	FY2010: A wearable sensor measuring personal exposure to total hydrocarbon and total acid was validated and a high-throughput assay for detecting DNA damage in blood and buccal cells is being validated. (Target Met)	Sensors and candidate biomarkers will undergo benchmark testing prior to population level analyses.	N/A	N/A
SRO-2.7: By 2011, complete clinical testing of one candidate medical countermeasure that could be used to diagnose or treat victims of a chemical terrorist attack or accident, and complete preclinical testing for two others. (Outcome)	FY2010: Completed preclinical studies for the approval of an intramuscular formulation of midazolam for chemical agent induced seizures. (Target Met)	Complete preclinical tests of one chemical agent therapy	N/A	N/A
SRO-2.8: By 2013, advance two emerging new strategies for treating muscular dystrophy to the point of preparedness for clinical trials. (Outcome)	FY2010: Multiple small molecules have been shown to be efficacious and result in functional improvement in animal models. (Target Met)	Assess the activity of two promising small molecule drugs in cell and animal models	Test an antisense oligonucleotide-based therapeutic strategy that could be applicable to multiple MD-causing mutations that require exon skipping.	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
SRO-2.9: By 2015, advance understanding of social determinants of health and health disparities using multilevel, transdisciplinary team science approaches by developing intervention models of how various factors affect individual health outcomes and their distribution in populations. (Outcome)	FY2010: NIH funded 10 new Centers for Population Health and Health Disparities grant awards at academic institutions across the United States. (Target Met)	Fund up to ten new Centers for Population Health and Health Disparities, with each center including teams of scientists from the following disciplines: basic, clinical, and social sciences.	Build teams of transdisciplinary scientists, including those newly trained, to conduct cross-center analysis to understand and address health inequities.	N/A
SRO-2.10: By 2014, identify three clinical candidate compounds for rare or neglected diseases. (Outcome)	N/A	N/A	Begin pilot projects on the selected rare disease lead compound series to assess their capabilities as potential therapeutics.	N/A
SRO-2.11: By 2016, conduct studies of young children to determine whether the plant estrogens in soy formula produce hormone-like effects. (Outcome)	N/A	N/A	Enroll an additional 112 mothers prenatally or at birth. Complete 70 prenatal visits, 80 birth visits and 80 2-week examinations. Enroll an additional 200 Toddlers and complete their 1 year evaluations.	N/A
SRO-3.1: By 2013, identify at least one clinical intervention that will delay the progression, delay the onset, or prevent Alzheimer's disease (AD). (Outcome)	FY2011: NIH established a phase III clinical trial of intravenous immunoglobulin (IVIg) for the treatment of mild to moderate Alzheimer's disease. (Target Exceeded)	Identify at least one imaging or biological marker and/or clinical or neuropsychological evaluation method that will help researchers perform less expensive, shorter, and more efficient drug trials for AD.	Complete baseline imaging studies to facilitate analysis of the effects of IVIg on relevant biomarkers of AD.	N/A
SRO-3.2: By 2010, develop one universal antibiotic effective against multiple classes of biological pathogens. (Outcome)	FY2010: Conducted Phase Ib study of DAS181-F02 and determined it was safe and well-tolerated in healthy adults. (Target Met)	Clinically evaluate a compound with demonstrated broad spectrum activity in a Phase I (safety) trial.	N/A	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
SRO-3.3: By 2013, determine the efficacy of using salivary diagnostics to monitor health and diagnose at least one systemic disease. (Outcome)	FY2010: A validation study of salivary samples from 102 patients was completed. Salivary protein biomarkers and mRNA biomarkers were confirmed to discriminate Sjogren's Syndrome from systemic lupus erythematosus and healthy saliva. (Target Met)	Initiate pre-clinical trials to test the compact device that will perform diagnostic evaluation of saliva specimens	Demonstrate the clinical value of the compact instrument by collecting and testing saliva samples from 80 patients with head or neck cancer against 120 control samples.	N/A
SRO-3.4: By 2015, evaluate an HIV vaccine candidate in a test of concept (phase IIB) efficacy trial in order to move towards an HIV/AIDS vaccine. (Outcome)	FY2010: Researchers initiated three phase I studies of new HIV vaccine approaches: a DNA vaccine, an adenovirus-based HIV vaccine regimen, and a novel, preventive HIV vaccine. (Target Met)	Initiate studies of the human immune response to three new prototype HIV vaccines to begin to determine their promise as HIV preventive vaccines.	Develop one or more alternative macaque models that more accurately reflect human exposure and that can be used to determine the ability of candidate vaccines to provide protection against challenge viruses that are genetically distinct from the vaccine (i.e., a heterologous challenge)	N/A
SRO-3.5: By 2013, identify and characterize at least 2 human candidate genes that have been shown to influence risk for substance use disorders and risk for psychiatric disorders using high-risk family, twin, and special population studies. (Outcome)	FY2010: Functional differences were characterized for sequence variations in genes encoding serotonin receptors and transporters, the oxidative stress enzyme SOD2, and nicotinic receptor subunits. (Target Met)	Characterize and continue to validate the functional differences identified from previous fine mapping studies.	Initiate replication and refinement of genome wide association and functional analysis data.	N/A
SRO-3.6: By 2012, develop and apply clinically one new imaging technique to enable tracking the mobility of stem cells within cardiovascular tissues. (Efficiency) (Outcome)	FY2010: Encapsulated and non-encapsulated mesenchymal stem cell (MSC) survival was tested in a rabbit model. (Target Met)	(FY10) Test the hypothesis that encapsulated MSCs will provide increased MSC survival in normal animals.	Develop and apply clinically one new imaging technique to enable tracking the mobility of stem cells within cardiovascular tissues.	N/A
SRO-3.7: By 2019, develop at least two novel therapies for immune-mediated disease. (Outcome)	FY2010: Marked differences in cytokine profiles were observed between patients treated with two types of ATG, and antibody levels were correlated with serum sickness. (Target Met)	Analyze the biological effect of rabbit ATG on patients with aplastic anemia to determine the mechanism of action as an immunosuppressive or immunoregulatory drug and agent.	Complete data analysis of the study of rabbit and horse ATG in the treatment of severe aplastic anemia and publish results.	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
SRO-3.8: By 2017, determine the optimal tailored treatment regimen for patients with early stage breast cancer that maximizes the benefits of chemotherapy while minimizing the side-effects of unnecessary treatment. (Outcome)	FY2010: Completed accrual of additional patients per the amended protocol for a total of 6908 randomized participants. (Target Met)	Complete accrual of additional patients per the amended protocol. *Previous target: Perform central testing of hormone receptors per protocol.*	Complete hormone receptor scoring for 30% of all cases	N/A
SRO-3.9: By 2020, identify two molecular-targeted therapies for disorders of the immune system in children. (Outcome)	FY2010: Two cohorts are being accrued by NIH investigators - one with neonatal-onset multisystem inflammatory disease and another with systemic-onset juvenile idiopathic arthritis. (Target Met)	Begin accrual of two patient cohorts presenting in childhood, one with a monogenic autoinflammatory disorder and one with a genetically complex autoinflammatory disorder.	Complete genetic, biochemical, or cellular studies aimed at identifying a molecular pathway underlying the disease in each of the two patient cohorts.	N/A
SRO-3.10: By 2017, advance two candidate medications for treatment of substance use disorders to clinical studies in humans. (Outcome)	FY2010: Researchers identified a candidate compound for treatment of fatty liver and one new molecular target for treatment of problem drinking. (Target Met)	Identify one potential molecular target and/or potential candidate compound.	Test one compound in proof-of-concept trials.	N/A
SRO-3.11: By 2015, advance the discovery of high need cures through the development of novel compounds, the repurposing of abandoned products, and innovations in the therapeutics discovery and development process. (Outcome)	N/A	N/A	Establish mechanisms to operationalize the Cures Acceleration Network	N/A
SRO-4.4: By 2011, identify or study additional genes involved in communication disorders in humans and animal models. (Outcome)	FY2010: Scientists successfully mapped a new locus on chromosome 9q34.3 and identified a new gene (TPRN) important for hearing. (Target Met)	Map one new location (locus) on the human chromosome that contains a human deafness gene and identify one new human deafness gene.	N/A	N/A
SRO-4.5: By 2011, identify genetic and environmental factors which predispose to three complex diseases. (Outcome)	FY2010: Genome-wide association studies identified variation in the TERT gene and in the CHRNA5 nicotine receptor as related to lung cancer. (Target Met)	Identify genetic and environmental factors which predispose to one complex disease	N/A	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
SRO-4.6: (RA) By 2012, develop a technology to facilitate patient-controlled, secure image sharing between medical centers and at least one clinic operating in an underserved community. (Outcome)	FY2010: Researchers demonstrated a patient-controlled, secure, storage system-diagnostic infrastructure that will support exchange of medical image information between medical facilities. (Target Met)	Develop a patient-controlled, secure, storage system-diagnostic infrastructure to support exchange of medical image information between medical facilities.	Complete need analysis surveys in underserved areas and based on these identified needs develop at least one feasibility test of technology to facilitate patient-controlled, secure image sharing between medical centers and a clinic operating in an underserved community.	N/A
SRO-4.7: (RA) By 2011, evaluate at least one novel animal model of type 1 diabetes. (Outcome)	FY2010: NOD-scid IL2rynull embryonic stem cells were generated. (Target Met)	NOD-scid IL2rynull embryonic stem cells will be generated as a resource for rapidly generating knock-in and knock-out mice on the immunodeficient NOD-scid IL2rynull background.	N/A	N/A
SRO-4.8: (RA) By 2011, develop and/or test at least one strategy for improving end-of-life care or palliative care. (Outcome)	FY2010: A national Palliative Care Research Cooperative was supported to conduct innovative research to improve end-of-life and/or palliative care. (Target Met)	Identify at least one strategy, and its core elements, for improving end-of-life care and/or palliative care.	N/A	N/A
SRO-4.9: (RA) By 2011, enhance the capacity of researchers to investigate genetic causes of disease by DNA sequencing of participants in well-phenotyped cohorts. (Outcome)	FY2010: The study protocol has been developed and the sequencing of participants in the well-phenotyped cohorts has begun. (Target Met)	Develop the study protocol and begin the DNA sequencing of participants in well-phenotyped cohorts.	N/A	N/A
SRO-4.10: (RA) By 2011, accelerate progress toward identifying relevant genomic alterations in 10 tumor types. (Outcome)	FY2010: NIH began the identification of genomic alterations in an additional 8 tumor types. (Target Met)	Begin identification of genomic alterations in an additional 8 tumor types.	N/A	N/A
SRO-4.11: (RA) By 2011, analyze oral cancer genomes using high throughput methods to develop a blueprint of genetic alterations. (Outcome)	FY2010: 137 tissue samples were subjected to initial screening and only 53 of these passed the quality control screen, Thirty-three specimens have been subjected to sequencing studies. (Target Not Met)	Analyze and annotate the genome sequences of 124 samples taken from oral and tongue cancers and normal human tissue.	Analyze and annotate the genome sequences of 94 samples taken from oral and tongue cancers and compare with matched normal human tissue (total of 188 samples).	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
SRO-4.12: (RA) By 2011, demonstrate the feasibility of a new therapeutic strategy in a preclinical model of a neurological disease. (Outcome)	FY2010: Completed the preclinical optimization of a gene therapy for spinal muscular atrophy (SMA), a neurodegenerative disease. (Target Met)	Optimize a new treatment regimen for spinal cord injury, a neurodegenerative disease, or posttraumatic seizures.	N/A	N/A
SRO-5.2: By 2010, determine the efficacy of statins in preventing progression of atherosclerosis in children with systemic lupus erythematosus (SLE, or lupus). (Outcome)	FY2010: The final analysis showed that there was no significant difference between the atorvastatin group and placebo group in preventing the progression of atherosclerosis in pediatric lupus patients. (Target Met)	Determine the efficacy of statins in preventing progression of atherosclerosis in children with systemic lupus erythematosus (SLE, or lupus).	N/A	N/A
SRO-5.7: By 2010, validate and compare 3 imaging methods that could offer increased sensitivity over computed tomography (CT) as a means of assessing lung cancer response to therapy. (Outcome)	FY2010: Three imaging methods were compared, including FDG-PET, FLT-PET, and DCE-MRI. The 3 methods could offer increased sensitivity over computed tomography (CT) as a means of assessing lung cancer response to therapy. (Target Met)	Validate and compare 3 imaging methods of assessing lung cancer response to therapy.	N/A	N/A
SRO-5.8: By 2012, improve device(s) to measure hot flashes and test in clinical studies of hot flash therapies. (Outcome)	FY2010: 141 women have been successfully enrolled in the trial (78% of target enrollment). (Target Exceeded)	Complete 40% of planned study subject accrual and collect data on hot flash frequency, duration, and impact on daily activities.	Device to measure hot flashes developed and tested in clinical studies is improved compared to other devices.	N/A
SRO-5.9: By 2010, establish the role of genetic factors in three major diseases for which health disparities are noted between populations. (Outcome)	FY2010: The role of genetic factors was established in Type 2 diabetes, prostate cancer, and hypertension, for which health discrepancies are noted between populations. (Target Met)	Establish the role of genetic factors in three major diseases for which health discrepancies are noted between populations.	N/A	N/A
SRO-5.10: By 2011, conduct studies of girls aged 6 through 8 years to determine the associations between the age of onset of puberty and progression through puberty with 12 environmental exposures. (Outcome)	FY2010: Conducted year 4 follow-up clinical exams and data collection on approximately 90% of the cohort, and chemical analysis for biomarkers were also performed. (Target Met)	Conduct year 4 follow-up clinical exams and data collection for at least 75% of the cohort to examine the presence of specific markers of exposure and correlate with signs of puberty. Perform chemical analyses of year 1 samples to assess levels of biomarkers in blood and urine.	N/A	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
SRO-5.11: By 2012, develop and test at least two behavioral strategies for the management of symptoms to reduce the effects of disease, disability, or psychological distress on quality of life and outcomes. (Outcome)	FY2010: Assessments identified a that an intervention for caregivers of individuals with Alzheimer's disease improved health outcomes, including sleep quality, and that another intervention reduced pain and improved cardiovascular fitness in patients receiving cancer therapy. (Target Met)	Assess the impact on patient health outcomes of a cohort of behavior-based symptom management strategies designed to manage candidate symptoms identified in FY 2008 analysis.	Test at least two behavior-based strategies that manage at least one candidate symptom and improve quality of life and health outcomes.	N/A
SRO-5.12: By 2013, identify several potential targets and/or molecules that modulate or enhance the extinction of learned behaviors and conditioned associations supporting addiction, compulsion, or anxiety disorders. (Outcome)	FY2010: Two compounds were tested in animal models of relapse, i.e., reinstatement of drug seeking behavior: D-serine enhanced the extinction of cocaine reinforced behavior and modafini enhanced extinction of methamphetamine reinforced behavior. (Target Met)	Test an additional compound in animal models of extinction of drug-seeking behavior.	Test one additional compound in animal models of extinction of drug seeking behavior and confirm in replication studies the effectiveness of compounds reported to date	N/A
SRO-5.13: By 2015, establish and evaluate a process to prioritize compounds that have not yet been adequately tested for more in-depth toxicological evaluation. (Outcome)	FY2010: 7,000 compounds were selected and collected as an establishment of the compound library. A subset of this library, "the 1408 library compound library," has screened an additional 20 qHTS assays. 50 compounds were identified for testing in 50 mid-throughput assays but testing was not conducted and was rescheduled for 2011. (Target Not Met)	Establish a >7000 compound library for testing in quantitative high throughput screens (qHTS) and test in >20 qHTS, test >50 compounds (a subset of the main library) in at least 50 mid-throughput assays.	Test 10,000 compound main library in 50 qHTS and test 50 compounds in mid-throughput assays.	N/A
SRO-5.14: By 2013, reduce tobacco prevalence among youth by preventing initiation and increasing rates of cessation. (Outcome)	FY2010: NIH has developed and tested smokeless tobacco use prevention interventions for youth and smoking cessation interventions in low income populations. These studies are ongoing. (Target Met)	Develop and/or test a smokeless tobacco use prevention intervention for youth, and a study to improve the effectiveness of smoking cessation interventions in low income youth and adult populations.	Based on results of preliminary analysis, implement evidence-based behavioral cessation programs, and continue to assess the efficacy of cessation medicines in low income youth and adult populations.	N/A
SRO-6.1: By 2012, identify the genes that control the risk of development of age-related macular degeneration (AMD) and glaucoma in humans. (Outcome)	FY2010: Researchers elucidated mechanisms of AMD neovascularization by exploring the biological roles of newly identified genetic variants of growth factors, complement components, SERPING1, CCR3, and HTRA1. (Target Met)	Explore genetic factors involved in neovascularization related to AMD.	Complete goal of identifying the genes that control the risk of development of age-related macular degeneration (AMD) and glaucoma in humans.	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
SRO-6.2: By 2011, assess the efficacy of at least three new treatment strategies to reduce cardiovascular morbidity/mortality in patients with type 2 diabetes and/or chronic kidney disease. (Outcome)	FY2010: The primary results of the BARI 2D study showed that neither prompt revascularization vs. delayed revascularization nor insulin sensitization vs. insulin provision was superior in terms of mortality. (Target Met)	Report findings of the primary results of the Bari2D Trial.	N/A	N/A
SRO-6.4: By 2015, identify and characterize two molecular pathways of potential clinical significance that may serve as the basis for discovering new medications for preventing and treating asthma exacerbations. (Outcome)	FY2010: Histoblood group antigens were explored as susceptibility factors for asthma exacerbations.' O-secretor mucin glycan phenotype was identified as a risk factor for asthma exacerbations. (Target Met)	(FY10) Describe phenotypic characteristics of a group of asthma patients prone to exacerbations.	Investigate the role of mucus gel formation in healthy controls and asthma patients.	N/A
SRO-6.5: By 2014, develop and evaluate two new interventions for the prevention and/or treatment of HIV disease utilizing the newly restructured HIV/AIDS clinical trials networks. (Outcome)	FY2010: Initiated the Promoting Maternal-Infant Survival Everywhere (PROMISE) study to examine strategies to prevent antepartum, intrapartum and postpartum (breastfeeding) transmission while promoting maternal and infant health worldwide. (Target Met)	By 2010, initiate studies to evaluate strategies to protect HIV-infected pregnant women from disease progression and protect their babies from becoming infected in utero, at delivery or during breastfeeding.	Complete enrollment into a comparative study of three non-nucleoside reverse transcriptase inhibitor (NNRTI)-sparing antiretroviral regimens for treatment-naíve HIV-1-infected individuals.	N/A
SRO-6.6: By 2015, provide at least one new or significantly improved minimally-invasive treatment for clinical use in patients using image-guided interventions. (Outcome)	FY2010: New feasibility studies have begun on three IGI technologies for the diagnosis of skin and lymph node cancer and for ultrasound-based treatment of cardiac arrhythmias. One IGI system for prostate biopsy is being tested in human studies. (Target Met)	Conduct feasibility testing of at least two additional new image-guided interventions. At least one IGI system will be developed to the point of "first in human" pilot studies.	Support clinical studies in at least one IGI system.	N/A
SRO-7.7: By 2011, assess community-based methods for facilitating cancer research and providing patients access to optimal cancer care. (Outcome)	FY2010: Data from the 10 funded NCCCP hospitals was collected, analyzed, and compiled, including: case studies/site visits, cancer registry reports on adherence to evidence based practice, patient surveys, and a micro-cost survey. (Target Met)	(FY10) Begin implementation of the assessment of community-based research program components	N/A	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
SRO-7.8: (RA) By 2011, create genomic resources to identify rare genetic variants that contribute to primary open angle glaucoma. (Outcome)	FY2010: The NEIGHBOR consortium conducted SNP-based GWAS on 2,507 glaucoma patients and 2,901 controls, far exceeding initial goals in the largest GWAS to date. (Target Met)	Complete SNP-based GWAS from 2,000 POAG patients and 2,000 healthy controls.	N/A	N/A
SRO-7.9: (RA) By 2011, enhance understanding of the characteristics of differentiated heart, lung, and blood cells derived by reprogramming human embryonic and induced pluripotent stem cells. (Outcome)	FY2010: Four research teams initiated characterization studies of stem and progenitor cells. (Target Met)	Initiate characterization studies of stem and progenitor cells.	N/A	N/A
SRO-7.10: (RA) By 2011, create a publically accessible database of novel and highly-detailed cell images, videos, and animations from a variety of organisms. (Outcome)	FY2010: Developed the infrastructure, software and hardware, for the Image Library database. Established submission pipeline. Populated the site with images and videos. Added Annotation fields. (Target Met)	Create a comprehensive, publicly available database (i.e. Image Library) of images, videos and animations of cells from a variety of organisms.	N/A	N/A
SRO-7.11: (RA) By 2012, gather sufficient data to support the development of a national standard for normal fetal growth. (Outcome)	FY2010: The study protocol has been expanded to recruit twin pregnancies, in addition to singleton pregnancies, to conduct a series of ultrasound exams, nutrition surveys, body measurements, and blood collection. (Target Met)	Expand the study protocol and recruitment to include twin pregnancies, in addition to singleton pregnancies, to conduct a series of ultrasound exams, nutrition surveys, body measurements, and blood collection.	Complete data collection to support the development of a national standard for normal fetal growth.	N/A
SRO-8.6: By 2011, develop stable national estimates of vision impairment by extending the vision component of the National Health and Nutrition Examination Survey (NHANES). (Outcome)	FY2010: NHANES vision data released to public was used to estimate prevalence of diabetic retinopathy and is being analyzed to establish baselines for HHS Healthy People 2020 goals. (Target Met)	Conduct initial analysis of data to determine estimates of the extent and nature of vision impairment.	N/A	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
SRO-8.7: By 2015, identify three (3) key factors influencing the scaling up of research-tested interventions across large networks of services systems such as primary care, specialty care and community practice. (Outcome)	FY2010: Three intervention studies that utilize implementation mechanisms, strategies, or techniques were identified to improve the uptake of effective interventions for mental health services, HIV and drug use disorders, and alcohol screening and treatment in healthcare or community settings. (Target Met)	Identify at least three systemic (or services) intervention studies which utilize implementation mechanisms, strategies or techniques to improve the uptake of effective interventions in healthcare settings	Complete target by identifying three effective implementation strategies that enhance the uptake of research-tested interventions in service systems such as primary care, specialty care and community practice.	N/A
SRO-8.8: By 2012, identify at least one candidate intervention that extends median lifespan in an animal model. (Outcome)	FY2010: Phase II testing began on rapamycin and NDGA. (Target Met)	Begin Phase II testing of the most promising potential interventions from Phase I.	Identify one candidate intervention that extends median life span in an animal model.	N/A
SRO-8.9: By 2014, identify 12 pathogen and/or host factors critical for understanding the molecular and cellular basis of pathogenesis of Category A-C biodefense pathogens and/or pathogens causing emerging infectious diseases. (Outcome)	N/A	N/A	Identify three pathogen and/or host factors.	N/A
SRO-9.1: By 2010, demonstrate through research a capacity to reduce the total years lost to disability (YLDs) in the United States by 10% by (1) developing treatment algorithms to improve the management of treatment-resistant and recurrent depression and (2) elucidating the mechanisms by which depression influences at least two comorbid physical illnesses (e.g., heart disease, cancer, Parkinson's disease, or diabetes). (Outcome)	FY2010: NIH-supported research has generated a body of knowledge to demonstrate a capacity to reduce the total years lost to disability (YLDs) among persons in the United States with major depressive disorders by (1) developing treatment algorithms to improve the management of treatment-resistant and recurrent depression and (2) elucidating the mechanisms by which depression influences co-morbid illnesses including Alzheimer's Disease, cancer, and chronic obstructive pulmonary disease, and alcohol use. (Target Met)	Complete goal by demonstrating through research a capacity to reduce the total years lost to disability (YLDs) in the United States by 10% by (1) developing treatment algorithms to improve the management of treatment-resistant and recurrent depression and (2) elucidating the mechanisms by which depression influences at least two comorbid physical illnesses (eg., heart disease, cancer, Parkinson's disease, or diabetes)	N/A	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
SRO-9.2: By 2018, identify culturally appropriate, effective stroke prevention/intervention programs in minority communities. (Efficiency) (Outcome)	FY2010: Established a framework for the pilot stroke prevention program for the Alaska Native population. (Target Met)	Develop a pilot stroke prevention program for the Alaska Native population	Complete 75% of patient recruitment for testing an educational intervention and a secondary stroke prevention program in underserved, African American, urban communities.	N/A
SRO-9.3: By 2011, characterize the progression of normal, healthy brain development in a nationally representative sample of children in the United States by creating a database of MRI and clinical/behavioral data and analytical software. (Efficiency) (Outcome)	FY2010: Maintained the BIRN and disseminated imaging and clinical information to support the development of analytical software tools. (Target Met)	Continue to maintain database of information collected from approximately 500 children that includes repeated anatomic magnetic resonance imaging scans and clinical data via BIRN. Disseminate with the database, complete with processed diffusion tensor imaging and magnetic resonance spectroscopy data.	N/A	N/A
SRO-9.4: By 2013, develop and evaluate the efficacy of neonatal screening for congenital cytomegalovirus (CMV) infection to permit identification of infants who will develop CMV-induced hearing loss in the first years of life. (Outcome)	FY2010: Scientists determined that 0.45 percent of enrolled children have congenital CMV infection. (Target Met)	Begin analyses to determine the percentage of enrolled children that have congenital CMV infection.	Begin hearing testing on asymptomatic children who test positive for CMV infection.	N/A
SRO-9.5: By 2014, assess the efficacy of long-term oxygen treatment in patients with COPD and moderate hypoxemia. (Outcome)	FY2010: Achieved cumulative enrolment of 244 subjects. (Target Not Met)	Continue recruitment to 476 subjects.	Continue recruitment to 899 subjects.	N/A
CTR-1: By 2014, reduce the disparity between African American and white infants in back sleeping by 50% to further reduce the risk of sudden infant death syndrome (SIDS). (Efficiency) (Outcome)	FY2010: Presentations on SIDS risk reduction were presented at four national meetings for health professionals who can spread the Back to Sleep message to African American parents, caregivers, and health care providers. (Target Exceeded)	Develop and present two communication programs at national conferences for health professionals who can further disseminate the Back to Sleep message among African American parents, caregivers, and health care providers.	Conduct 23 SIDS risk reduction activities for African Americans caregivers and health providers serving African Americans across all of the nine health districts in Mississippi.	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
CTR-6: By 2010, improve the efficiency and reduce the unit cost of producing authoritative serials cataloging records used to improve access to the biomedical literature in libraries worldwide. (Outcome)	FY2010: The time to catalog an item has been reduced by 7 minutes per title, from 95 minutes to 88 minutes, and a savings of 0.10 FTE has been realized. (Target Met)	Reduce cataloging time by 7 minutes per title and realize an additional savings of 0.10 FTE.	N/A	N/A
CTR-7: By 2010, establish the feasibility of sharing information from already-conducted scientific studies of warfarin (coumadin^{R}) anti-coagulation, through the knowledge base PharmGKB. (Outcome)	FY2010: Sharing from already-conducted scientific studies of warfarin (Coumadin) anti-coagulation, through knowledge base PharmGKB was feasible and other consortia have used this data-sharing model. (Target Met)	Establishing the feasibility of sharing from already-conducted scientific studies of warfarin (Coumadin) anti-coagulation, through knowledge base PharmGKB.	N/A	N/A
CTR-8: By 2012, increase communication efforts and enhance centralized outreach strategies regarding extramural research funding policy, compliance and administration as demonstrated by the type and frequency of communications and related activities. (Outcome)	FY2010: NIH identified that existing grants process resources were primarily text based, and developed eight new multimedia outlets including online seminars and videos, podcasts, and twitter feeds. (Target Met)	Measure the breadth and number of centrally maintained multi-media outlets to expand usage to describe the grants process, and utilize at least one new technology to reach audience.	Incorporate at least one new social networking technology as a modality for NIH stakeholders to obtain information on new grants initiatives, policies and/or processes	N/A
CTR-9: By 2012, increase awareness of the NIH SBIR and STTR funding opportunities available for women-owned and socially and economically disadvantaged small business concerns (SBCs). (Outcome)	FY2010: NIH conducted and/or participated in three outreach activities in 2010 at regional or national conferences. (Target Met)	Conduct or participate in at least two outreach activities (i.e., local, regional or national conferences) that specifically target women-owned or socially and economically disadvantaged small businesses to communicate SBIR and STTR opportunities and how to apply for them.	Partner with a minimum of 2 regional groups dedicated to women-owned or socially and economically disadvantaged small businesses to enable knowledge transfer, increase awareness, and increase access to SBIR/STTR opportunities	N/A
CTR-10: By 2014, expand the scope of the Hazardous Substances Data Bank to include 14 nanomaterials. (Outcome)	N/A	N/A	Augment the Hazardous Substances Data Bank with comprehensive records for 4 nanomaterials and review initial database specifications.	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
CBRR-1.1: By 2012, ensure that the proportion of pre-doctoral trainees and fellows applying for and receiving subsequent NIH support exceeds the relevant comparison groups within 10 years of graduation. (Output)	FY2010: Award rate to comparison group reached 12%. (Target Met)	N ≥ 12%	N ≥ 12%	N/A
CBRR-1.2: By 2012, ensure that the proportion of post-doctoral fellows applying for and receiving subsequent NIH support exceeds relevant comparison groups within 10 years of fellowship completion. (Output)	FY2010: Award rate to comparison group reached 14% and exceeded the target by at least 2%. (Target Met)	N ≥ 12%	N ≥ 12%	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
CBRR-2: Promote data sharing and provide information in real time through the NIH Business System (NBS) by developing, integrating, deploying and maintaining business modules. (By FY 2014, the NBS will be in an ongoing status) (Output)	FY2010: Initiated development of planned business module, NIH Grants Interface Module (Target Not Met) FY2010: Completed integration activities for for NIH Grants Interface Module (Target Met) FY2010: Conducted priority deployment activities for GovTrip Phase II Travel Module (Target Met) FY2010: Maintained post deployment support for GovTrip and Phase II (Pilot) Travel Module (Target Met)	(Development [Dev]) Initiate development of planned business modules to build capacity and functionality of the NIH Business System. * Planned - NIH Grants Interface Module (ERA) [Int.2010] * Planned - Oracle 12i Upgrade [Int.2011] (Integration [Int]) Complete integration activities for full functionality and usability of priority modules for successful development efforts within 3 years of initiated development. * * Planned -NIH Grants Interface Module (ERA)[Dev2010/Dep.2011] (Deployment [Dep]) Conduct priority deployment activities to enable user accessibility and skill development within 2 years from the onset of integration. * Planned - GovTrip Phase II Travel Module [Int.2009/Mat.2011] (Maintenance [Mat]) Maintain deployed business modules. * Planned - GovTrip and Phase II (Pilot) Travel Module [Dep.2010]	(Development [Dev]) Initiate development of planned business modules to build capacity and functionality of the NIH Business System. * No Development activity for FY12 (Integration [Int]) Complete integration activities for full functionality and usability of priority modules for successful development efforts within 3 years of initiated development. * Planned - Service and Supply Activities Fund Module [Dev.2011/Dep.2012] * Planned - Oracle 12i Upgrade [Dev.2011/Dep.2013] (Deployment [Dep]) Conduct priority deployment activities to enable user accessibility and skill development within 2 years from the onset of integration. * Planned - Service and Supply Activities Fund Module [Int.2012/Mat.2012] (Maintenance [Mat]) Maintain deployed business modules. * Planned - Service and Supply Activities Fund Module [Dep.2012] * Planned - NIH Grants Interface Module (ERA) [Dep.2011]	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
CBRR-4: By 2013, provide greater functionality and more streamlined processes in grants administration by continuing to develop the NIH electronic Research Administration (eRA) system. (Efficiency) (Output)	FY2010: Approximately 89% of all grant business transactions are currently being done electronically and the Electronic Tracking and Analysis module was added to eRA. (Target Met)	Continue conversion of business processes: 87% of business processes being done electronically by FY 2010. *(Previous Target):* 85% electronic business processing	Continue conversion of business processes: 98% of business processes being done electronically by FY 2012.	N/A
CBRR-6.1: By 2011, construct or renovate 153 biomedical research facilities in order to build the capacity to conduct the proposed research. (Output)	FY2010: All 12 construction grants were completed either early or on time. (Target Met)	Complete 12 facilities	N/A	N/A
CBRR-6.2: By 2015 complete construction/commissioning of 15 biocontainment facilities to support biodefense and emerging infectious disease research needs, including research on Category A-C Priority agents and newly emerging infectious diseases. (Output)	FY2010: NIH completed construction of three (3) extramural biocontainment facilities. (Target Met)	Complete 1 facility	Conduct design development	N/A
CBRR-7: By 2010, utilize enhanced ARIS database to more efficiently conduct portfolio analysis to invest in priority AIDS research. (Output)	FY2010: 100% of the 572 expiring grants eligible for renewal or recompetition were reviewed. (Target Met)	Track, monitor, and budget for trans-NIH AIDS research, utilizing the enhanced ARIS database, to more efficiently conduct portfolio analysis of 100% of expiring grants to determine reallocation of resources for priority research.	N/A	N/A
CBRR-8: By 2012, ensure that 100% of trainee appointment forms are processed electronically, to enhance program management. (Output)	FY2010: Introduced a policy requiring all appointment forms to be processed electronically as of January 2011, and implemented essential xTrain system improvements and training. (Target Met)	Enhance system usability, capacity, and functionality, and promote use. *(Previous Target):* Ensure that 50% of trainee appointment forms are processed electronically.	Ensure that 100% of trainee appointment forms are processed electronically	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
CBRR-9: By 2011, achieve average annual cost savings of managing construction grants by expanding the use of electronic project management tools that enhance oversight and 20 year usage monitoring. (Output)	FY2010: Achieved an average annual cost of $36,703 per grant. (Target Met)	Achieve average annual cost of managing construction grants	N/A	N/A
CBRR-10: By 2015, make freely available to researchers the results of 300 high-throughput biological assays screened against a library of 300,000 unique compounds, and the detailed information on the molecular probes that are developed through that screening process. (Outcome)	FY2010: 98 new high-throughput assays were added to the MLP Portfolio. (Target Exceeded)	Establish 35 new assays in the Molecular Libraries Program (MLP) Portfolio	Deposit chemical structure and biological data for 175 new small molecule probes in PubChem	N/A
CBRR-11: (RA) By 2010, determine the number of shared instrumentation grants awarded that will contribute to the success of many NIH-funded research projects. (Output)	FY2010: Three hundred and seventy-four (374) shared instrumentation grant awards were made to domestic public and nonprofit institutions. (Target Exceeded)	350 shared instrumentation grants awarded with sample shared usage.	N/A	N/A
CBRR-12: (Priority Goal) By 2012, reduce the fully loaded cost of sequencing a human genome to $15,000. (Efficiency) (Outcome)	FY2010: New sequencing machines are in routine production at centers and are on track to meet sequencing targets. (Target Met)		Reduce the fully-loaded cost of sequencing a human genome to $15,000.	N/A
SMHC-4: By 2012, ensure NIH reports tracked commercial functions and cost savings from completed commercial services studies efficiently and on time. (Efficiency) (Output)	FY2010: FAIR Act inventory and Post-Competition Accountability were completed and submitted to HHS (Target Met)	Complete FAIR Act Inventory and Post-Competition Accountability reporting.	Complete FAIR Act Inventory and Post-Competition Accountability reporting.	N/A
SMHC-5: By 2011, improve and monitor the use of human resource services by providing real-time access to tools via the NIH portal. (Efficiency) (Output)	FY2010: Conducted usability testing with HR and non-HR IC users. Monitored satisfaction and usage of portal community pages, portlets, and projects and improved the portal usability by implementing changes to the information architecture. Consulted with Content Managers to improve the HR content on the NIH Portal. (Target Met)	Continuously monitor satisfaction and usage of human resources content on the NIH Portal against the established baseline.	Determine pathway for upgrading Portal technology	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
SMHC-6: Provide opportunities for enhanced leadership skills to meet the challenges of workforce management and/or individual advancements. (Ongoing) (Output)	FY2010: A study was done looking at best practices in supervisory development in the literature and in similar organizations. In addition, a committee was formed with cross-NIH membership to determine which base skills should be required of all new supervisors in a mandatory training. A draft policy was created and an SOW submitted to begin development of a course. (Target Exceeded) FY2010: The first session of NIH Executive Leadership Program (ExLP) was developed, launched, and completed. 20 participants were selected via a competitive NIH-wide process. They attended sessions offered by Brookings, Washington University Olin Business School, and current and former NIH senior leaders. (Target Exceeded)	Examine [EX] key area to enhance leadership skills * Conduct studies of leadership training to develop NIH leaders with a focus on moving people from individual performer into supervisory roles and enhancing skills for new supervisors.[IM.2011] Implement [IM] recommendation from prior year assessments * Create and implement a leadership development program to prepare high potential leaders for top 5 positions. [EX.2009/AS.2011]	Examine [EX] key area to enhance leadership skills * Study best practices in supervisory training for federal populations and conduct competency gap analysis at NIH to determine if there are better ways to implement basic mandatory training for all new and existing supervisors [IM 2013] Implement [IM] recommendation from prior year assessments * Create and implement an executive on-boarding program. [EX.2011/AS.2013] Assess [AS] results of implementation * Assess results from leadership development program for new supervisors and individual performers preparing for supervisory roles. [IM 2011]	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
SMHC-7: Address diverse workforce recruitment needs to ascertain highly qualified staff to conduct or support biomedical research. (Ongoing) (Output)	FY2010: 58 series, 86 titles, and 363 PDs in HR CARDS. The number of PDs in HR CARDS increased by 53%. (Target Met) FY2010: Posted the standard operating procedure (SOP) for Shared Certificates, Drafted the SOP for Global Recruitment (GR). Briefed Branchs, ICs and other communities on the GR Process. Disseminate the NIH recruitment brand internally and externally through the Corporate Recruitment Unit. (Target Met)	Examine [EX] key area to enhance recruitment * Incorporate useful varied disciplined position descriptions into the position description library. [IM.2011] Implement [IM] recommendation from prior year assessments * Implement NIH recruitment brand, reengineering communication plan/strategy, and standard operating procedure to improve hiring efficiency through global recruitment strategies and sharing of certificates [EX.2009 /AS.2011]	Examine [EX] key area to enhance recruitment *Develop corporate recruitment strategy to focus on diversity recruiting, student recruiting, and trans-NIH hiring. [IM. 2013/ AS. 2014] Implement [IM] key area to enhance recruitment *Implement re-engineering strategies for existing HR policies and procedures, to support the 80 day hiring timeline instituted by OPM.[EX 2011] [AS 2013] Assess [AS] results of implementation *Results from the use of Human Resources Classification and Recruitment Document System (HR CARDS). [IM 2011]	N/A
SMHC-8: Address areas to facilitate retention of highly qualified staff to conduct or support biomedical research. (Ongoing) (Output)	FY2010: Administered a baseline survey of NIH Telework Coordinators to assess telework participation rates and hoteling efforts. (Target Met) FY2010: Implemented internal communication strategy by developing telework marketing/outreach materials, publishing an article in the Administrative newsletters, and soliciting best practices from key members within the NIH leadership group through strategic telework partnerships (Target Met)	Examine [EX] key area to enhance retention * Study teleworking participation [IM.2011] Implement [IM] recommendation from prior year assessments * Implement Telework Communications Plan [EX.2009/AS.2011]	Examine [EX] key area to enhance retention * No new key areas to date Implement [IM] recommendation from prior year assessments * No new key areas to date Assess [AS] results of implementation *Results from implemented telework study participation program [EX 2010 / IM 2011]	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
POI-2: Utilize performance-based contracting (PBC). (ongoing) (Output)	FY2010: Obligated 41% of the eligible service contracting dollars through performance-based contracts. (Target Not Met)	Obligate the FY 2010 OMB/OFPP goals of eligible service contracting dollars to PBC	Obligate the FY 2012 OMB/OFPP goal of eligible service contracting dollars to PBC.	N/A
POI-5: By 2010, enhance NIH's ability to demonstrate benefits resulting from extramural research investments through changes to policy and information systems. (Output)	FY2010: Deployment of ExPORTER provides the public the ability to download information on science, funding and results, including references to the resulting publications, for all NIH supported research projects. (Target Met)	Complete goal of enhancing NIH's ability to demonstrate benefits resulting from extramural research investments through changes to policy and information systems.	N/A	N/A
POI-6.1: Improve facility conditions in order to reach and maintain a Condition Index (CI) weighted average of 85 or above (CIwa≥85). (Ongoing) (Efficiency) (Output)	FY2010: Recovery Act projects did not improve the CIwa of the portfolio above the 74.1 threshold reached in FY09. (Target Not Met) FY2010: The condition of the portfolio (Not including the RA Program) reached CIwa of 74.1 (Target Met)	(2010 RA) Improve CIwa by an additional 2.2 points through Recovery Act projects CIwa = 73.6	CIwa = 76.3 (Tentative)	N/A
POI-6.2: By 2017, maintain the annual condition of buildings and facilities portfolio so that no less than 95% of occupied gross square feet (GSF) will have a CI greater than 65. (Ongoing) (Efficiency) (Output)	FY2010: The FY10 target of 69.3% of occupied GSF was met. 72.6% of the space reached a CI > 65 (Target Met)	Target = 69.3%	Target= 73.0%	N/A
POI-7.1: Manage all Buildings and Facilities (B&F) line item projects so it is completed within 100% of the final approved project cost. (Ongoing) (Output)	FY2010: 24 Recovery Act funded projects were active.. Fifteen (15) active Recovery Act funded projects were initiated within the approved budget. Nine (9) projects were added to the portfolio and were also initiated (Target Exceeded) FY2010: Twelve (12) of the sixteen (16) active projects were initiated: within the approved budget. Two (2) projects were shifted to the Recovery Act Program, one (1) was cancelled due to program changes, and one (1) delayed for further study. (Target Not Met)	(2010 RA) Manage 15 active Recovery Act funded projects. 16 active projects initiated.	12 active Recovery Act funded projects (Tentative) 8 active projects (Tentative)	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
POI-7.2: Manage design and construction of capital facility projects funded by B&F so that no more than 10% of the projects may incorporate plus or minus 10% adjustments of the approved scope. (Ongoing) (Output)	FY2010: 24 Recovery Act funded projects were initiated. Fifteen (15) active Recovery Act funded projects were managed within the approved scope. Nine (9) projects were added to the portfolio and also managed within scope (Target Exceeded) FY2010: Eleven (11) of the fifteen (15) active projects were managed within the approved scope. Two (2) or 13% of the active projects were shifted to the Recovery Act Program for execution, one (1) was cancelled due to programmatic changes and one (1) deferred for further study. (Target Not Met)	(2010 RA) Manage 15 active Recovery Act funded projects / 10% < 1 15 active projects / 10% < 1	(2012 RA) 12 active Recovery Act funded projects (Tentative) / 10% ≤ 1 8 active projects (Tentative) / 10% < 1	N/A
POI-8.1: By 2013, ensure that 100% of grantees have met all construction requirements, including NIH approved design and construction documents that ensures proposed research in the space is feasible, and ensures that grantees will take action to file or record a Notice of Federal Interest that ensures grantees cannot lease, sell or mortgage property without NIH approval. (Output)	FY2010: AWARDED 110 extramural construction grants for Core Facility Renovation, Repair, and Improvement (G20) and Extramural Research Facilities Improvement Program (C06). (Target Exceeded)	(2010 RA) AWARD 110 extramural construction grants in 2010 with construction requirements met by 2013, as specified in the measure.	(2012RA) Ensure that 100% of 50 grantees have met all construction requirements.	N/A
POI-8.2: By 2015, report the percent of extramural construction projects that are in compliance with the post award 20 year usage requirement to conduct research. (Output)	FY2010: 100% of the extramural construction projects were in compliance with the post award 20 year usage requirement. (Target Met)	95% of 196 projects are in compliance	95% of 177 projects are in compliance	N/A
POI-9: By 2015, reallocation of laboratory resources based on external reviews by Boards of Scientific Counselors. (Output)	FY2010: 25% of Principal Investigators reviewed resulting in 25% of resources recommended to be reallocated. (Target Met)	Conduct BSC reviews of 25% of Principal Investigators to assess quality of science in order to prioritize resources.	Conduct BSC reviews of 25% of Principal Investigators to access quality of science in order to prioritize resources.	N/A
Program Level Funding ($ in millions)	$31,242	$30,943	$31,987	+$745

NATIONAL INSTITUTES OF HEALTH

Statistical Data - Grants, Direct and Indirect Costs Awarded

(Dollars In millions)

Fiscal Year	Direct Costs Awarded	Indirect Costs Awarded	Total Dollars Awarded	Percent To Total In Dollars		Percent Growth In Dollars	
				Direct	Indirect	Direct	Indirect
FY 2000	9,787	3,881	13,668	71.6%	28.4%	16.6%	13.5%
FY 2001	11,210	4,425	15,634	71.7%	28.3%	14.5%	14.0%
FY 2002	12,721	4,937	17,658	72.0%	28.0%	13.5%	11.6%
FY 2003	14,337	5,410	19,747	72.6%	27.4%	12.7%	9.6%
FY 2004	14,780	5,760	20,540	72.0%	28.0%	3.1%	6.5%
FY 2005	15,299	5,915	21,214	72.1%	27.9%	3.5%	2.7%
FY 2006	15,095	5,905	21,000	71.9%	28.1%	-1.3%	-0.2%
FY 2007	15,266	5,998	21,264	71.8%	28.2%	1.1%	1.6%
FY 2008	15,173	6,027	21,200	71.6%	28.4%	-0.6%	0.5%
FY 2009	15,652	5,981	21,633	72.4%	27.6%	3.2%	-0.8%
FY 2010	16,087	6,044	22,131	72.7%	27.3%	2.8%	1.1%
FY 2011 CR	16,016	6,009	22,026	72.7%	27.3%	-0.4%	-0.6%
FY 2012 President's Budget	16,339	5,979	22,318	73.2%	26.8%	2.0%	-0.5%

Note: FY 2011 and FY 2012 data represent estimates and will change as actual data is received.

NATIONAL INSTITUTES OF HEALTH
Research Project Grants
Total Number of Awards and Dollars

(Dollars in thousands)

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007 1/	FY 2008	FY 2009	FY 2010	FY 2011 Continuing Resolution	FY 2012 President's Budget
No. of Awards:										
Competing	10,411	10,025	9,481	9,085	9,872	9,737	9,111	9,386	8,734	9,158
Noncompeting	25,776	27,064	27,353	27,296	26,588	26,658	26,217	25,738	25,936	26,019
Subtotal	36,187	37,089	36,834	36,381	36,460	36,395	35,328	35,124	34,670	35,177
SBIR/STTR	2,032	2,190	1,934	1,835	1,792	1,849	1,740	1,685	1,658	1,675
Total	38,219	39,279	38,768	38,216	38,252	38,244	37,068	36,809	36,328	36,852
Average Annual Cost:										
Competing	$337.8	$355.3	$358.2	$369.6	$363.9	$378.1	$427.6	$417.1	$425.6	$433.4
Total RPGs 2/	$282.7	$297.6	$311.0	$311.6	$306.0	$313.7	$327.3	$339.0	$347.2	$349.4
Percent Change over prior year average costs:										
Competing RPGs	-0.3%	5.2%	0.8%	3.2%	-1.5%	3.9%	13.1%	-2.5%	2.0%	1.8%
Total RPGs	3.7%	5.3%	4.5%	0.2%	-1.8%	2.5%	4.3%	3.6%	2.4%	0.6%
Average Length of Award for Competing RPGs in Years	3.9	3.7	3.7	3.8	3.7	3.7	3.8	3.7	3.7	3.7

1/ Beginning in FY 2007, RPGs funded by the National Cancer Institute's Cancer Prevention & Control program and the National Library of Medicine are included in grant numbers and dollar amounts.

2/ Includes Noncompeting and Admin. Suppls. and excludes SBIR/STTR.

3/ The NIH policy for FY 2012 limits RPGs to an average cost increase of one point. However, when the policy is applied to the research portfolio of each Institute and Center, other factors (e.g., multiple grant cohorts, exceptionally large grants and assessments to support trans-NIH requirements) come into play, resulting in estimated average cost increases of 1.8 percent for competing RPGs and 0.6 percent for total RPGs.

Note: FY 2011 and FY 2012 are estimates and will change as actual data is received.

NATIONAL INSTITUTES OF HEALTH
Research Project Grants
Success Rates
FY 2003 - FY 2012 1/, 2

INSTITUTES & CENTERS	FY 2003	FY 2004	FY 2005	FY2006	FY2007	FY 2008	FY 2009	FY 2010	FY2011 CR	FY 2012 President's Budget	INSTITUTES & CENTERS
NCI	27%	24%	20%	19%	20%	21%	19%	17%	14%	15%	NCI
NHLBI	34%	29%	24%	20%	21%	22%	22%	20%	17%	18%	NHLBI
NIDCR	27%	30%	24%	19%	22%	20%	19%	22%	20%	19%	NIDCR
NIDDK	33%	27%	24%	21%	21%	25%	23%	26%	23%	22%	NIDDK
NINDS	30%	25%	22%	18%	19%	21%	21%	23%	23%	19%	NINDS
NIAID	35%	24%	25%	21%	23%	23%	19%	24%	19%	24%	NIAID
NIGMS	38%	30%	27%	26%	32%	27%	27%	27%	24%	25%	NIGMS
NICHD	27%	17%	18%	15%	21%	17%	15%	15%	16%	16%	NICHD
NEI	33%	30%	26%	23%	27%	30%	30%	27%	29%	32%	NEI
NIEHS	25%	19%	19%	22%	19%	18%	18%	25%	15%	20%	NIEHS
NIA	29%	21%	19%	17%	22%	20%	18%	15%	17%	18%	NIA
NIAMS	20%	20%	20%	19%	20%	21%	20%	21%	15%	16%	NIAMS
NIDCD	38%	35%	27%	28%	31%	29%	32%	30%	30%	32%	NIDCD
NIMH	27%	24%	21%	20%	22%	21%	22%	22%	17%	18%	NIMH
NIDA	35%	27%	22%	20%	23%	24%	22%	20%	15%	17%	NIDA
NIAAA	27%	29%	31%	27%	27%	26%	24%	27%	19%	25%	NIAAA
NINR	27%	21%	24%	18%	26%	20%	21%	13%	13%	15%	NINR
NHGRI	30%	23%	18%	34%	28%	32%	34%	34%	36%	35%	NHGRI
NIBIB	19%	17%	20%	17%	22%	19%	18%	16%	14%	14%	NIBIB
NIMHD 3/	N/A	N/A	N/A	N/A	N/A	N/A	11%	22%	5%	7%	NCMHD
NCRR	28%	21%	14%	13%	20%	15%	22%	11%	9%	4%	NCRR
NCCAM	14%	17%	17%	14%	11%	12%	12%	8%	16%	14%	NCCAM
FIC	19%	22%	24%	19%	25%	28%	21%	26%	26%	25%	FIC
NLM 4/	N/A	N/A	N/A	N/A	19%	21%	12%	21%	21%	11%	NLM
Common Fund 5/	N/A	13%	17%	10%	7%	12%	17%	11%	35%	32%	Common Fund
NIH	**30%**	**25%**	**22%**	**20%**	**21%**	**21%**	**21%**	**21%**	**19%**	**19%**	**NIH**

1/ Includes Biodefense and Type 1 Diabetes. Excludes NIEHS Superfund and ARRA applications and awards.

2/ Application success rates represent the percentage of applications that are awarded during the fiscal year.

3/ NIMHD (formally NCMHD) success rates are not available (NA) due to co-funding agreements with other ICs through FY 2008. NIMHD only co-funded competing RPGs with other ICs until FY 2009.

4/ NLM success rate is displayed for FY 2007 and forward due to change in the reporting requirements. As of FY 2007, NLM funding is no longer reflected as an individual line item on the NIH Budget Mechanism Table.

5/ Common Fund (formally Roadmap) did not fund competing RPGs until FY 2004.

Note: Success Rates identified in FY 2011 and FY 2012 are estimates, and will change as applications are received and selected for funding.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Supplementary Tables

NATIONAL INSTITUTES OF HEALTH
Budget Request by Institute/Center
FY 2012 Estimate
(dollars in thousands)

Institute/ Center	FY 2010 Actual	FY 2011 CR	FY 2012 Estimate	2012 PB +/- 2010 Actual
NCI[1]	$5,100,826	$5,099,047	$5,196,136	$95,310
NHLBI	3,095,271	3,094,282	3,147,992	52,721
NIDCR	413,009	412,885	420,369	7,360
NIDDK [2]	1,957,071	1,956,562	1,987,957	30,886
NINDS	1,635,448	1,634,979	1,664,253	28,805
NIAID [3]	4,816,055	4,510,177	4,915,970	99,915
NIGMS	2,050,581	2,050,053	2,102,300	51,719
NICHD	1,328,804	1,328,397	1,352,189	23,385
NEI	706,642	706,435	719,059	12,417
NIEHS	689,446	689,194	700,537	11,091
NIA	1,109,636	1,109,285	1,129,987	20,351
NIAMS	538,759	538,623	547,891	9,132
NIDCD	418,585	418,477	426,043	7,458
NIMH	1,489,540	1,489,105	1,517,006	27,466
NIDA	1,059,266	1,058,947	1,080,018	20,752
NIAAA	462,086	461,953	469,197	7,111
NINR	145,575	145,536	148,114	2,539
NHGRI	515,799	515,589	524,807	9,008
NIBIB	316,398	316,313	322,106	5,708
NIMHD	211,469	211,392	214,608	3,139
NCRR	1,268,323	1,267,817	1,297,900	29,577
NCCAM	128,767	128,734	131,002	2,235
FIC	69,993	69,991	71,328	1,335
NLM	351,023	365,716	387,153	36,130
OD	1,176,844	1,176,299	1,298,412	121,568
B&F	99,985	100,000	125,581	25,596
Type 1 Diabetes [2]	(150,000)	(150,000)	(150,000)	0
Subtotal, Labor/HHS	**$31,005,201**	**$30,705,788**	**$31,747,915**	**$742,714**
Interior/Superfund Research Program	$79,212	$79,212	$81,085	$1,873
Total, NIH Discretionary B.A.	**$31,084,413**	**$30,785,000**	**$31,829,000**	**$744,587**
Type 1 Diabetes	$150,000	$150,000	$150,000	$0
Total, NIH Budget Authority	**$31,234,413**	**$30,935,000**	**$31,979,000**	**$744,587**
NLM Program Evaluation	$8,200	$8,200	$8,200	$0
Total, Program Level	**$31,242,613**	**$30,943,200**	**$31,987,200**	**$744,587**

[1] Includes $7,920,000 in each year for facilities repairs and improvements at the NCI Frederick Federally Funded Research and Development Center in Frederick, MD.

[2] Type 1 Diabetes Initiative mandatory funds are included in NIDDK and subtracted in Type 1 Diabetes to ensure non-duplicative counting.

[3] Includes funds for transfer to the Global Fund for HIV/AIDS, Malaria, and Tuberculosis ($300 million in each year).

National Institutes of Health
FY 2012 Congressional Justification
Budget Authority: Appropriations Adjustments for FY2010
(dollars in thousands)

FY 2010 Budget Authority												
		Real Transfers						Comparable Adjustments				
IC	Enacted[1]	Type I Diabetes	Global AIDS	HHS IACC	Director's 1% Transfer[2]	Secretary's 1% Transfer	Enacted Budget Appendix	Director's 1% Transfer[2]	NCBI	Public Access	Global AIDS	Comparable Budget Authority
NCI	5,103,388				-4,459	-760	5,098,169	4,459	-1,214	-588		5,100,826
NHLBI	3,096,916				-2,845	-463	3,093,608	2,845	-737	-445		3,095,271
NIDCR	413,236				-637	-62	412,537	637	-98	-67		413,009
NIDDK	1,808,100	150,000			1,160	-270	1,958,990	-1,160	-430	-329		1,957,071
NINDS	1,636,371				-2,557	-244	1,633,570	2,557	-389	-290		1,635,448
NIAID	4,818,275		-300,000		-2,174	-675	4,515,426	2,174	-1,146	-399	300,000	4,816,055
NIGMS	2,051,798				-3,228	-307	2,048,263	3,228	-488	-422		2,050,581
NICHD	1,329,528				-1,942	-199	1,327,387	1,942	-316	-209		1,328,804
NEI	707,036				-1,130	-106	705,800	1,130	-168	-120		706,642
NIEHS	689,781				5,302	-103	694,980	-5,302	-164	-68		689,446
NIA	1,110,229				-1,792	-166	1,108,271	1,792	-264	-163		1,109,636
NIAMS	539,082				-866	-81	538,135	866	-128	-114		538,759
NIDCD	418,833				-676	-63	418,094	676	-100	-85		418,585
NIMH	1,489,372			1,000	3,361	-223	1,493,510	-3,361	-354	-255		1,489,540
NIDA	1,059,848				7,221	-158	1,066,911	-7,221	-252	-172		1,059,266
NIAAA	462,346				-704	-69	461,573	704	-110	-81		462,086
NINR	145,660				-216	-22	145,422	216	-35	-28		145,575
NHGRI	516,028				8,192	-77	524,143	-8,192	-123	-29		515,799
NIBIB	316,582				-507	-47	316,028	507	-75	-62		316,398
NIMHD	211,572				-337	-32	211,203	337	-51	-20		211,469
NCRR	1,268,896				-1,607	-190	1,267,099	1,607	-302	-81		1,268,323
NCCAM	128,844				-205	-19	128,620	205	-31	-27		128,767
FIC	70,051				-74	-10	69,967	74	-17	-31		69,993
NLM	339,716				720	-50	340,386	-720	7,272	4,085		351,023
OD	1,177,300				0	-176	1,177,124	0	-280	0		1,176,844
B & F	100,000				0	-15	99,985	0	0	0		99,985
Total NIH	**31,008,788**	**150,000**	**-300,000**	**1,000**	**0**	**-4,587**	**30,855,201**	**0**	**0**	**0**	**300,000**	**31,155,201**
Superfimd	79,212	0	0	0	0	0	79,212	0	0	0	0	79,212
Ttl, w/Supfnd	**31,088,000**	**150,000**	**-300,000**	**1,000**	**0**	**-4,587**	**30,934,413**	**0**	**0**	**0**	**300,000**	**31,234,413**
NLM Pgm. Eval.	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**8,200**
Tot. Pgm. Level	**31,088,000**	**150,000**	**-300,000**	**1,000**	**0**	**-4,587**	**30,934,413**	**0**	**0**	**0**	**300,000**	**31,242,613**

[1] As appropriated in P.L 111-117

[2] Genes, Environment and Health Initiative (GEI) transfer.

National Institutes of Health
FY 2012 Congressional Justification
Budget Authority: Appropriations Adjustments for FY 2011
(dollars in thousands)

	FY 2011 Budget Authority					
		Real Transfers			Comparable Adjustments	
IC	FY 2011 CR[1]	Type I Diabetes	HHS IACC	Non-Comparable Budget Authority	NCBI and PA	Comparable Budget Authority
NCI	$5,103,388			$5,103,388	-$4,341	$5,099,047
NHLBI	3,096,916			3,096,916	-2,634	3,094,282
NIDCR	413,236			413,236	-351	412,885
NIDDK	1,808,100	150,000		1,958,100	-1,538	1,956,562
NINDS	1,636,371			1,636,371	-1,392	1,634,979
NIAID	4,514,275			4,514,275	-4,098	4,510,177
NIGMS	2,051,798			2,051,798	-1,745	2,050,053
NICHD	1,329,528			1,329,528	-1,131	1,328,397
NEI	707,036			707,036	-601	706,435
NIEHS	689,781			689,781	-587	689,194
NIA	1,110,229			1,110,229	-944	1,109,285
NIAMS	539,082			539,082	-459	538,623
NIDCD	418,833			418,833	-356	418,477
NIMH	1,489,372		1,000	1,490,372	-1,267	1,489,105
NIDA	1,059,848			1,059,848	-901	1,058,947
NIAAA	462,346			462,346	-393	461,953
NINR	145,660			145,660	-124	145,536
NHGRI	516,028			516,028	-439	515,589
NIBIB	316,582			316,582	-269	316,313
NIMHD	211,572			211,572	-180	211,392
NCRR	1,268,896			1,268,896	-1,079	1,267,817
NCCAM	128,844			128,844	-110	128,734
FIC	70,051			70,051	-60	69,991
NLM	339,716			339,716	+26,000	365,716
OD	1,177,300			1,177,300	-1,001	1,176,299
B & F	100,000			100,000	+0	100,000
Total NIH	$30,704,788	**$150,000**	**$1,000**	$30,855,788	**$0**	$30,855,788
Superfund	79,212	0	0	79,212	0	79,212
Ttl, w/Supfnd	**$30,784,000**	$150,000	$1,000	**$30,935,000**	$0	**$30,935,000**
NLM Pgm. Eval.	$0	$0	$0	$0	$0	**$8,200**
Tot. Pgm. Level	**$30,784,000**	$150,000	$1,000	**$30,935,000**	$0	**$30,943,200**

[1] Assumes full year CR less $304 million for NIAID due to Bioshield transfer not provided in FY 2011.

NATIONAL INSTITUTES OF HEALTH

Object Classifications

Budget Authority by Object Including Type I Diabetes Funds*

(dollars in thousands)

Object Class	FY 2010 Actual	FY 2012 Estimate	Increase or Decrease
11.1 Full-time permanent	$861,127	$870,165	$9,038
11.3 Other than full-time permanent	470,569	473,751	3,182
11.5 Other Personnel Compensation	45,710	46,231	521
11.7 Military Personnel	23,250	24,119	869
11.8 Special personnel services payments	181,439	182,480	1,041
Total, Personnel Compensation	**$1,582,095**	**$1,596,746**	**$14,651**
12.0 Personnel Benefits	$385,727	$389,227	$3,500
12.2 Military Personnel Benefits	16,265	16,419	154
13.0 Benefits for Former Personnel	0	0	0
Subtotal, Pay Costs	**$1,984,087**	**$2,002,392**	**$18,305**
21.0 Travel and transportation of persons	58,801	60,024	1,223
22.0 Transportation of things	5,606	5,826	220
23.1 Rental payments to GSA	230	248	18
23.2 Rental payments to others	615	646	31
23.3 Communications, utilities and miscellaneous charges	25,071	25,593	522
24.0 Printing and reproduction	8,470	8,660	190
25.1 Consulting services	102,080	104,335	2,255
25.2 Other services	742,800	746,088	3,288
25.3 Purchase of goods and services from government accounts	3,077,402	3,341,503	264,101
25.4 Operation and maintenance of facilities	174,774	196,580	21,806
25.5 Research and development contracts	2,498,434	2,311,184	(187,250)
25.6 Medical care	18,219	18,688	469
25.7 Operation and maintenance of equipment	74,202	76,833	2,631
25.8 Subsistence and support of persons	10	10	0
25.0 Subtotal, Other Contractual Services	**$6,687,921**	**$6,795,221**	**$107,300**
26.0 Supplies and materials	$217,674	$223,779	$6,105
31.0 Equipment	$143,928	$148,573	$4,645
32.0 Land and structures	3	3	0
33.0 Investments and loans	0	0	0
41.0 Grants, subsidies and contributions	22,022,769	22,626,927	604,158
42.0 Insurance claims and indemnities	0	0	0
43.0 Interest and dividends	26	22	(4)
44.0 Refunds	0	0	0
Subtotal, Non-Pay Costs	29,171,114	29,895,522	724,408
Total Budget Authority	**$31,155,201**	**$31,897,914**	**$742,713**

*Excludes Superfund appropriation. NLM program evaluation funds are excluded from admin. costs; only the extramural portion of IMPAC II and ORI are excluded.

NATIONAL INSTITUTES OF HEALTH

Budget Authority by Object Including

Service and Supply Fund and Management Fund [1]

	Object Classes	FY 2010 Actual	FY 2012 Estimate	Increase or Decrease
	Personnel Compensation:			
11.1	Full-Time Permanent	$1,182,666	$1,201,243	$18,577
11.3	Other than Full-Time Permanent	590,791	597,539	6,748
11.5	Other Personnel Compensation	73,665	74,508	843
11.7	Military Personnel	32,781	33,932	1,151
11.8	Special Personnel Services Payments	186,674	187,775	1,101
	Total, Personnel Compensation	**2,066,577**	**2,094,997**	**28,420**
12.1	Civilian Personnel Benefits	515,921	523,832	7,911
12.2	Military Personnel Benefits	21,345	21,671	326
13.0	Benefits for Former Personnel	724	745	21
	Subtotal, Pay Costs	**2,604,567**	**2,641,245**	**36,678**
21.0	Travel & Transportation of Persons	63,087	64,406	1,319
22.0	Transportation of Things	6,920	7,160	240
23.1	Rental Payments to GSA	49,861	49,966	105
23.2	Rental Payments to Others	118,704	120,078	1,374
23.3	Communications, Utilities & Miscellaneous Charges	140,815	143,119	2,304
24.0	Printing & Reproduction	13,767	14,091	324
25.1	Consulting Services	278,301	285,722	7,421
25.2	Other Services	1,178,719	1,200,173	21,454
25.3	Purchase of Goods & Services from Government Accounts	3,389,425	3,666,125	276,700
25.4	Operation & Maintenance of Facilities	261,657	286,070	24,413
25.5	Research & Development Contracts	2,499,166	2,311,938	-187,228
25.6	Medical Care	23,095	23,687	592
25.7	Operation & Maintenance of Equipment	181,802	187,607	5,805
25.8	Subsistence & Support of Persons	10	10	0
25.0	**Subtotal, Other Contractual Services**	**7,812,175**	**7,961,332**	**149,157**
26	Supplies & Materials	340,589	349,281	8,692
31.0	Equipment	180,568	186,303	5,735
32.0	Land and Structures	14	14	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	22,022,769	22,626,927	604,158
42.0	Insurance Claims & Indemnities	1,953	1,963	10
43.0	Interest & Dividends	291	288	-3
44.0	Refunds	0	0	0
	Subtotal, Non-Pay Costs	**30,751,513**	**31,524,928**	**773,415**
	Total Budget Authority	**33,356,080**	**34,166,173**	**810,093**

[1] Reflects request to Labor/HHS/Education Subcommittee, and Type 1 Diabetes provided through P.L. 107-360. See pages SI-7 to SI-14 for additional information on the NIH Management Fund and Service and Supply Fund.

NATIONAL INSTITUTES OF HEALTH

LHHS Discrectionary including Type 1 Diabetes Mandatory Appropriation
Salaries and Expenses
(dollars in thousands)

OBJECT CLASSES	FY 2010 Actual	FY 2012 PB	Increase or Decrease
Personnel Compensation:			
Full-time permanent (11.1)	$861,127	$870,165	$9,038
Other than full-time permanent (11.3)	470,569	473,751	3,182
Other personnel compensation (11.5)	45,710	46,231	521
Military personnel (11.7)	23,250	24,119	869
Special personnel services payments (11.8)	181,439	182,480	1,041
Total Personnel Compensation (11.9)	**$1,582,095**	**$1,596,746**	**$14,651**
Civilian personnel benefits (12.1)	$385,727	$389,227	$3,500
Military personnel benefits (12.2)	16,265	16,419	154
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	**$1,984,087**	**$2,002,392**	**$18,305**
Travel (21.0)	$58,801	$60,024	$1,223
Transportation of things (22.0)	5,606	5,826	220
Rental payments to others (23.2)	615	646	31
Communications, utilities and miscellaneous charges (23.3)	25,071	25,593	522
Printing and reproduction (24.0)	8,470	8,660	190
Other Contractual Services:			
Advisory and assistance services (25.1)	102,080	104,335	2,255
Other services (25.2)	742,800	746,087	3,287
Purchases from government accounts (25.3)	2,094,925	2,150,403	55,478
Operation and maintenance of facilities (25.4)	153,854	180,821	26,967
Operation and maintenance of equipment (25.7)	74,202	76,833	2,631
Subsistence and support of persons (25.8)	10	10	0
Subtotal Other Contractual Services	**$3,167,871**	**$3,258,489**	**$90,618**
Supplies and materials (26.0)	$216,903	$222,988	$6,085
Subtotal, Non-Pay Costs	$3,483,337	$3,582,226	$98,889
Total, Administrative Costs	**$5,467,424**	**$5,584,618**	**$117,194**

Includes Type 1 Diabetes Mandatory Appropriations.
Excludes pruchases from government accounts (OC 25.3) related to Program Evaluations and Inter-agency Agremments related to the Research and Development Contracts mechanism

National Institutes of Health
Full-Time Equivalents

Institutes and Centers (ICs)	FY 2010 Actual	FY 2011 CR	FY 2012 PB
NCI	3,056	3,061	3,061
NHLBI	876	878	878
NIDCR	240	241	241
NIDDK	625	627	627
NINDS	497	499	499
NIAID	1,802	1,803	1,803
NIGMS	142	142	142
NICHD	612	614	614
NEI	250	251	251
NIEHS	666	667	667
NIA	415	416	416
NIAMS	245	245	245
NIDCD	144	145	145
NIMH	620	623	623
NIDA	396	397	397
NIAAA	224	224	224
NINR	70	71	71
NHGRI	338	340	340
NIBIB	97	98	98
NIMHD	30	30	30
NCRR	137	138	138
NCCAM	67	67	67
FIC	61	61	61
Subtotal, ICs	11,610	11,638	11,638
NLM	800	804	804
OD	667	672	672
Central Services	5,271	5,284	5,284
Subtotal, NIH	18,348	18,398	18,398
CRADA	10	10	10
Trust Fund	4	4	4
Total NIH	18,362	18,412	18,412

History of Obligations by Institute or Center*

Fiscal Years 2001 - 2012 [1]

(Dollars in Thousands)

Institutes and Centers	FY 2001 Actual	FY 2002 Actual	FY 2003 Actual	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual	FY 2009 Actual	FY 2010 Actual	FY 2011 CR	FY 2012 Estimate
NCI	$3,758,566	$4,177,830	$4,595,477	$4,727,365	$4,797,731	$4,754,121	$4,792,615	$4,827,552	$4,968,973	$5,100,826	$5,099,047	$5,196,136
NHLBI	2,298,035	2,569,794	2,793,681	2,882,601	2,922,573	2,893,527	2,922,323	2,937,333	3,015,689	3,095,271	3,094,282	3,147,992
NIDCR	306,152	342,292	371,630	382,013	389,346	385,589	389,060	391,136	402,652	413,009	412,885	420,369
NIDDK 3	1,302,184	1,463,013	1,615,959	1,679,473	1,702,592	1,688,511	1,702,990	1,712,188	1,761,338	1,957,071	1,956,562	1,987,957
NINDS	1,175,591	1,325,193	1,456,426	1,498,203	1,529,654	1,519,971	1,532,977	1,549,543	1,593,344	1,635,448	1,634,979	1,664,253
NIAID	2,041,311	2,339,779	3,606,789	4,141,769	4,276,433	4,274,201	4,264,034	4,286,410	4,702,572	4,816,055	4,814,177	4,915,970
NIGMS	1,535,056	1,722,890	1,846,917	1,915,130	1,931,690	1,916,927	1,932,481	1,942,783	1,997,801	2,050,581	2,050,053	2,102,300
NICHD	975,537	1,110,459	1,205,908	1,247,939	1,262,273	1,252,598	1,252,765	1,259,435	1,294,894	1,328,804	1,328,397	1,352,189
NEI	510,241	580,047	633,109	650,961	664,840	660,340	665,863	669,534	688,480	706,642	706,435	719,059
NIEHS	501,813	574,518	614,183	630,254	640,405	630,447	726,131	729,088	662,820	689,446	689,194	700,537
NIA	785,413	891,282	993,595	1,021,376	1,045,339	1,036,559	1,045,468	1,050,998	1,080,796	1,109,636	1,109,285	1,129,987
NIAMS	396,305	447,682	486,031	499,368	507,843	502,954	507,292	510,358	524,872	538,759	538,623	547,891
NIDCD	300,282	341,260	370,330	380,737	391,679	389,623	392,937	395,515	407,259	418,585	418,477	426,043
NIMH	1,106,095	1,245,292	1,341,014	1,379,225	1,403,007	1,390,009	1,402,385	1,414,541	1,450,491	1,489,540	1,489,105	1,517,006
NIDA	790,185	892,639	965,721	991,510	1,000,056	990,405	1,001,952	1,007,295	1,032,759	1,059,266	1,058,947	1,080,018
NIAAA	340,151	383,174	415,960	427,223	435,503	431,726	435,366	437,839	450,230	462,086	461,953	469,197
NINR	104,294	120,217	130,537	134,279	137,199	136,020	137,167	137,990	141,879	145,575	145,536	148,114
NHGRI	381,971	428,248	464,960	490,546	485,500	481,339	508,240	505,380	502,367	515,799	515,589	524,807
NIBIB	0	111,740	278,279	286,684	296,324	293,954	296,380	299,726	308,208	316,398	316,313	322,106
NIMHD	130,070	157,364	185,674	190,824	194,904	193,522	199,083	200,252	205,959	211,469	211,392	131,002
NCRR	817,098	1,010,169	1,138,820	1,191,556	1,108,028	1,088,500	1,131,618	1,153,911	1,226,263	1,268,323	1,267,817	214,608
NCCAM	89,120	104,334	113,405	116,590	121,333	120,294	121,369	122,013	125,471	128,767	128,734	1,297,900
FIC	50,430	56,787	63,425	65,160	66,164	65,726	66,348	66,828	68,691	69,993	69,991	71,328
NLM	239,068	275,395	299,771	310,165	312,980	311,721	321,354	323,385	330,771	351,023	365,716	387,153
OD	212,482	234,784	266,161	327,267	533,673	724,831	1,046,557	1,111,694	1,246,864	1,176,844	1,176,299	1,298,412
Subtotal	$20,147,450	$22,906,182	$26,253,762	$27,568,218	$28,157,069	$28,133,415	$28,794,755	$29,042,727	$30,191,443	$31,055,216	$31,059,788	$31,772,334
B&F [4]	205,756	114,839	305,628	303,254	239,246	170,456	89,114	127,227	125,581	99,985	109,223	125,581
TOTAL	$20,353,206	$23,021,021	$26,559,390	$27,871,472	$28,396,315	$28,303,871	$28,883,869	$29,169,954	$30,317,024	$31,155,201	$31,169,011	$31,897,915
Interior/Superfund	62,850	70,212	83,515	78,300	79,836	79,108	79,111	77,531	78,074	79,212	79,212	81,085
Type I Diabetes	*97,000*	*97,000*	*97,000*	*150,000*	*150,000*	*150,000*	*150,000*	*150,000*	*150,000*	*150,000*	*150,000*	*150,000*
Total, Budget Authority	$20,416,056	$23,091,233	$26,642,905	$27,949,772	$28,476,151	$28,382,979	$28,962,980	$29,247,485	$30,395,098	$31,234,413	$31,248,223	$31,979,000

[1] Obligations for actual years includes amounts that were lapsed

[2] Includes all comparable adjustments

[3] Include funds for Type I Diabetes Initiative

History of Obligations by Total Mechanism
Fiscal Years 2003 - 2012
(Dollars in Thousands)

Budget Mechanism [1] [2]	FY 2003 Actual	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual	FY 2009 Actual	FY 2010 Actual [3]	FY 2011 CR	FY 2012 PB
Res. Project Grants	$14,239,043	$15,165,836	$15,426,097	$15,313,663	$15,333,540	$15,688,339	$16,139,081	$16,472,777	$16,390,232	$16,908,803
Research Centers	2,425,448	2,545,972	2,647,355	2,659,653	2,709,259	2,946,346	3,018,711	3,077,699	3,007,679	3,036,340
Other Research	1,587,841	1,651,823	1,655,743	1,650,974	1,652,501	1,779,990	1,773,478	1,794,162	1,812,866	1,819,501
Flexible Research Authority	0	0	0	0	0	0	0	0	0	20,000
Subtotal Res. Grants	$18,252,332	$19,363,631	$19,729,195	$19,624,290	$19,695,300	$20,414,675	$20,931,270	$21,344,638	$21,210,777	$21,764,644
Research Training	711,441	740,506	743,861	731,121	763,797	770,480	776,313	775,217	782,037	794,404
R & D Contracts	2,299,140	2,691,897	2,516,611	2,582,606	2,693,443	2,934,858	3,056,888	3,455,571	3,257,522	3,544,551
Intramural Research	2,564,664	2,658,853	2,737,865	2,745,676	3,002,558	3,087,891	3,221,196	3,331,414	3,342,540	3,381,705
Res. Mgt. & Support	927,297	977,771	1,014,754	1,098,953	1,136,197	1,375,559	1,432,156	1,507,640	1,522,721	1,537,588
Cancer Control [4]	533,173	529,980	531,634	505,705	498,396					
Construction	496,782	118,148	178,560	29,700	14,100	0	0	0	0	0
Library of Medicine [4]	299,771	310,165	312,980	311,721	7,376					
Office of the Director	266,161	327,267	533,673	724,831	1,046,557	523,798	616,700	632,816	632,271	741,522
Subtotal	$26,350,761	$27,718,218	$28,299,133	$28,354,603	$28,857,724	$29,107,261	$30,034,523	$31,047,296	$30,747,868	$31,764,414
Buildings & Facilities [5]	305,628	303,254	247,182	178,376	97,034	135,147	133,501	107,905	107,920	133,501
Total	$26,656,389	$28,021,472	$28,546,315	$28,532,979	$28,954,758	$29,242,408	$30,168,024	$31,155,201	$30,855,788	$31,897,915
Interior - Superfund	$83,515	$78,300	$79,836	$79,108	$79,111	$77,546	$78,074	79,212	$79,212	$81,085
Total Budget Authority	$26,739,904	$28,099,772	$28,626,151	$28,532,979	$29,033,869	$29,319,954	$30,246,098	$31,234,413	$30,935,000	$31,979,000

[1] All amounts include funds for Type I Diabetes Initiative

[2] Obligations for actual years do not include lapses

[3] FY 2009 Comparable includes all transfers and comparable adjustments

[4] Beginning in FY 2008 NIH modified its traditional budget display by mechanism so that activities of the National Cancer Institute's Cancer Prevention and Control Program and the National Library of Medicine are allocated among the various

[5] Buildings & Facilities (B&F) includes B&F obligations, NCI obligations of $7,920,000 in FY 2008 - FY 2009, and estimated NCI obligations of $7,920,000 in FY 2010 - FY 2012

National Institutes of Health

Stem Cell Research - FY 2009 to FY 2012 Estimate

(Dollars in millions)[1]

	FY 2009	FY 2010	FY 2011	FY 2012	+/- FY10	FY2009 ARRA	FY 2010 ARRA
Human Embryonic Stem Cell Research	119.9	125.5	125.5	128.0	2.5	22.7	39.7
Non-Human Embryonic Stem Cell Research	148.1	175.3	175.3	178.8	3.5	29.1	19.6
Human, Non-Embryonic Stem Cell Research	339.3	340.8	340.8	347.6	6.8	57.9	73.6
Non-Human, Non-Embryonic Stem Cell Research	550.2	569.6	569.6	581.0	11.4	88.1	74.2
Stem Cell Research - Induced Pluripotent Stem Cell	27.2	108.2	108.2	110.4	2.2	30.3	53.5
Stem Cell Research - Induced Pluripotent Stem Cell Human	21.2	96.3	96.3	98.2	1.9	25.3	49.9
Stem Cell Research - Induced Pluripotent Stem Cell Non-Human	8.5	22.1	22.1	22.5	0.4	8.6	15.3
Total, NIH Stem Cell Research	1,044.4	1,099.1	1,099.1	1,121.1	22.0	186.9	186.8

[1] Figures for the various types of stem cells research do not add to the total due to overlap across types. NIH's new Research Conditions and Disease Category (RCDC) tracking system does not filter out such overlaps.

National Institutes of Health

Programs Proposed for Elimination

National Center for Research Resources (NCRR): NIH is committed to re-evaluating and readjusting its activities and organizational structure to ensure that it can pursue the most promising biomedical research in an efficient and effective way. A final example of this effort is NIH's proposal to eliminate NCRR as an organizational unit in FY 2012 while maintaining its programs. It is likely that the Clinical and Translational Sciences Award (CTSA) program, which comprises a large part of NCRR, will be better aligned with the new National Center for Advancing Translational Sciences (NCATS), and the organizational structure will likely reflect this. NIH plans to maintain all of the other programs currently funded under NCRR, but those that do not go to NCATS will be shifted to other parts of NIH. NIH will provide further details on this proposal in the Spring.

NATIONAL INSTITUTES OF HEALTH

Management Fund

General Statement

The NIH Management Fund (MF) was established on June 29, 1957, by Public Law 85-67. The MF was created to finance a variety of centralized support services and administrative activities that are required for the efficient and effective operation of all NIH programs and facilities. The services provided by the MF include a research hospital and outpatient clinic, receipt, review and referral of research and training grant applications, collaborative computer science research, police, fire, security and general administrative support services. Funds credited to the NIH Management Fund remain available for one fiscal year after the fiscal year in which they are deposited.

NATIONAL INSTITUTES OF HEALTH

MANAGEMENT FUND

Budget Authority by Activity

(Dollars in thousands)

	FY 2010 Actual		FY 2011 CR		FY 2012 Estimate		Change from FY 2010	
Extramural Research	**FTEs**	**Amount**	**FTEs**	**Amount**	**FTEs**	**Amount**	**FTEs**	**Amount**
Detail:								
Center for Information Technology	86	$21,474	86	$24,858	86	$25,653	0	$4,179
Clinical Center	1,896	399,347	1,897	$417,663	1,897	431,028	0	$31,681
Center for Scientific Review, SREA	289	110,624	289	$113,742	289	117,382	0	$6,758
Research Support and Administrative Services, OD	712	75,973	715	$69,667	715	71,896	0	($4,077)
Office of Research Services, Facilities, Development & Operations	577	93,167	597	$101,238	597	104,417	0	$11,250
TOTAL	3,560	**$700,585**	3,584	**$727,168**	3,584	**$750,376**	0	**$49,791**

Includes FTEs which are reimbursed from the NIH Common Fund for Medical Research

NATIONAL INSTITUTES OF HEALTH
MANAGEMENT FUND

Budget Authority by Object
(Dollars in Thousands)

	FY 2011 CR	FY 2012 Estimate	Increase or Decrease
Total compensable workyears:			
Full-time employment	3,584	3,584	0
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary	$177,588	$179,364	$1,776
Average GM/GS grade	11.0	11.0	0.0
Average GM/GS salary	$90,015	$90,915	$900
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$80,268	$81,070	$802
Average salary of ungraded positions	129,971	131,270	1,299

	OBJECT CLASSES	FY 2011 Estimate	FY 2012 Estimate	Increase or Decrease
	Personnel Compensation:			
11.1	Full-time permanent	$156,901,000	$161,556,000	$4,655,000
11.3	Other than full-time permanent	112,331,000	115,663,000	3,332,000
11.5	Other personnel compensation	17,305,000	17,504,000	199,000
11.7	Military personnel	7,512,000	7,735,000	223,000
11.8	Special personnel services payments	5,091,000	5,150,000	59,000
	Total, Personnel Compensation	**299,140,000**	**307,608,000**	**8,468,000**
12.0	Personnel benefits	77,768,000	80,394,000	2,626,000
12.2	Military personnel benefits	4,133,000	4,272,000	139,000
13.0	Benefits for former personnel	0	0	0
	Subtotal, Pay Costs	**381,041,000**	**392,274,000**	**11,233,000**
21.0	Travel and transportation of persons	2,998,000	3,088,000	90,000
22.0	Transportation of things	612,000	630,000	18,000
23.1	Rental payments to GSA	27,000	27,000	0
23.2	Rental payments to others	37,000	38,000	1,000
23.3	Communications, utilities and miscellaneous charges	4,906,000	5,063,000	157,000
24.0	Printing and reproduction	2,550,000	2,639,000	89,000
25.1	Consulting services	12,186,000	12,430,000	244,000
25.2	Other services	116,881,000	122,050,000	5,169,000
25.3	Purchase of goods and services from government accounts	93,270,000	97,081,000	3,811,000
25.4	Operation and maintenance of facilities	12,410,000	12,783,000	373,000
25.5	Research and development contracts	4,000	4,000	0
25.6	Medical care	4,501,000	4,613,000	112,000
25.7	Operation and maintenance of equipment	11,011,000	11,287,000	276,000
25.8	Subsistence and support of persons	0	0	0
25.0	**Subtotal, Other Contractual Services**	**250,263,000**	**260,248,000**	**9,985,000**
26.0	Supplies and materials	66,366,000	67,361,000	995,000
31.0	Equipment	18,325,000	18,966,000	641,000
32.0	Land and structures	9,000	9,000	0
33.0	Investments and loans	0	0	0
41.0	Grants, subsidies and contributions	0	0	0
42.0	Insurance claims and indemnities	0	0	0
43.0	Interest and dividends	34,000	34,000	0
44.0	Refunds	0	0	0
	Subtotal, Non-Pay Costs	**$346,127,000**	**$358,103,000**	**$11,976,000**
	Total Budget Authority by Object	**$727,168,000**	**$750,377,000**	**$23,209,000**

Includes FTEs which are reimbursed from the NIH Common Fund for Medical Research

NATIONAL INSTITUTES OF HEALTH
MANAGEMENT FUND

Detail of Positions

GRADE	FY 2010 Actual	FY 2011 CR	FY 2012 Estimate
Total, ES Positions	8	7	7
Total, ES Salary	1,403,238	1,243,115	1,255,546
GM/GS-15	130	134	134
GM/GS-14	231	241	242
GM/GS-13	267	268	269
GS-12	303	306	307
GS-11	255	257	259
GS-10	32	32	32
GS-9	147	148	149
GS-8	163	164	165
GS-7	459	464	470
GS-6	170	172	174
GS-5	66	67	66
GS-4	20	20	20
GS-3	6	6	6
GS-2	7	7	7
GS-1	1	1	1
Subtotal	2,257	2,287	2,302
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	3	3
Director Grade	19	19	19
Senior Grade	17	15	15
Full Grade	33	36	36
Senior Assistant Grade	15	12	12
Assistant Grade	13	13	13
Subtotal	97	98	98
Ungraded	1,297	1,313	1,308
Total permanent positions	2,408	2,425	2,425
Total positions, end of year	3,659	3,705	3,715
Total full-time equivalent (FTE) employment, end of year	3,560	3,584	3,584
Average ES salary	175,405	177,588	179,364
Average GM/GS grade	10.9	11.0	11.0
Average GM/GS salary	88,597	90,015	90,915

NATIONAL INSTITUTES OF HEALTH

Service and Supply Fund

General Statement

The NIH Service and Supply Fund (SSF) was established on July 3, 1945, under 42 U.S.C. 231. The SSF was created to finance a variety of centralized research support services and administrative activities that are required for the efficient and effective operation of all NIH programs and facilities. The SSF provides a single means for consolidating the financing and accounting of business-type operations, including the sales of services and commodities to customers. The services provided through the SSF include mainframe computing, enterprise IT software planning and development, facilities engineering, planning, and design, facility use and maintenance including leased buildings, printing, telecommunications, procurement, shipping and receiving, motor pool, research animals, fabrication and maintenance of scientific equipment, utilities and plant maintenance, finance and accounting operations, government-wide contracting for IT, biomedical engineering, security, consolidated human resources, and other administrative support services.

NATIONAL INSTITUTES OF HEALTH
SERVICE & SUPPLY FUND
Budget Authority by Activity
(Dollars in thousands)

	FY 2010 Actual		FY 2011 CR		FY 2012 Estimate		Change from FY 2010	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Detail:								
Research Support and Adminstrative	820	$658,852	823	$677,324	823	$708,754	0	$31,430
Office of Research Facilities	627	463,273	611	474,392	611	481,982	0	$7,590
Development & Operations							0	
Information Technology	263	314,279	264	321,822	264	326,971		$5,149
Clinical Center	2	169	2	173	2	175	0	$2
TOTAL	1,712	**$1,436,573**	1,700	**$1,473,711**	1,700	**$1,517,882**	0	**$44,171**

Includes FTEs which are reimbursed fo m the NIH Common Fund for Medical Research

NATIONAL INSTITUTES OF HEALTH
SERVICE & SUPPLY FUND

Budget Authority by Object
(Dollars in Thousands)

	FY 2011 CR	FY 2012 Estimate	Increase or Decrease
Total compensable workyears:			
Full-time employment	1,700	1,700	0
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary	$168,601	$170,961	$2,360
Average GM/GS grade	11.5	11.5	0.0
Average GM/GS salary	$115,556	$117,040	$1,484
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$82,327	$83,479	$1,152
Average salary of ungraded positions	111,889	113,007	1,118

	OBJECT CLASSES	FY 2011 Estimate	FY 2012 Estimate	Increase or Decrease
	Personnel Compensation:			
11.1	Full-time permanent	$164,638,000	$169,522,000	$4,884,000
11.3	Other than full-time permanent	7,891,000	8,125,000	234,000
11.5	Other personnel compensation	10,650,000	10,773,000	123,000
11.7	Military personnel	2,019,000	2,078,000	59,000
11.8	Special personnel services payments	144,000	145,000	1,000
	Total, Personnel Compensation	**185,342,000**	**190,643,000**	**5,301,000**
12.0	Personnel benefits	52,426,000	54,211,000	1,785,000
12.2	Military personnel benefits	947,000	980,000	33,000
13.0	Benefits for former personnel	724,000	745,000	21,000
	Subtotal, Pay Costs	**239,439,000**	**246,579,000**	**7,140,000**
21.0	Travel and transportation of persons	1,288,000	1,294,000	6,000
22.0	Transportation of things	702,000	704,000	2,000
23.1	Rental payments to GSA	49,604,000	49,691,000	87,000
23.2	Rental payments to others	118,052,000	119,394,000	1,342,000
23.3	Communications, utilities and miscellaneous charges	110,838,000	112,463,000	1,625,000
24.0	Printing and reproduction	2,747,000	2,792,000	45,000
25.1	Consulting services	164,035,000	168,957,000	4,922,000
25.2	Other services	319,038,000	332,035,000	12,997,000
25.3	Purchase of goods and services from government accounts	218,753,000	227,541,000	8,788,000
25.4	Operation and maintenance of facilities	74,473,000	76,707,000	2,234,000
25.5	Research and development contracts	728,000	750,000	22,000
25.6	Medical care	375,000	386,000	11,000
25.7	Operation and maintenance of equipment	96,589,000	99,487,000	2,898,000
25.8	Subsistence and support of persons	0	0	0
25.0	**Subtotal, Other Contractual Services**	**873,991,000**	**905,863,000**	**31,872,000**
26.0	Supplies and materials	56,549,000	58,141,000	1,592,000
31.0	Equipment	18,315,000	18,764,000	449,000
32.0	Land and structures	2,000	2,000	0
33.0	Investments and loans	0	0	0
41.0	Grants, subsidies and contributions	0	0	0
42.0	Insurance claims and indemnities	1,953,000	1,963,000	10,000
43.0	Interest and dividends	231,000	232,000	1,000
44.0	Refunds	0	0	0
	Subtotal, Non-Pay Costs	**1,234,272,000**	**1,271,303,000**	**37,031,000**
	Total Budget Authority by Object	**1,473,711,000**	**1,517,882,000**	**44,171,000**

Includes FTEs which are reimbursed from the NIH Common Fund for Medical Research

NATIONAL INSTITUTES OF HEALTH
SERVICE & SUPPLY FUND

Detail of Positions

GRADE	FY 2010 Actual	FY 2011 CR	FY 2012 Estimate
Total, ES Positions	3	3	3
Total, ES Salary	$493,243	$498,547	$503,533
GM/GS-15	70	71	71
GM/GS-14	201	203	203
GM/GS-13	403	406	406
GS-12	288	290	290
GS-11	116	117	117
GS-10	3	3	3
GS-9	86	87	87
GS-8	42	42	42
GS-7	88	89	89
GS-6	26	26	26
GS-5	28	28	28
GS-4	9	9	9
GS-3	5	5	5
GS-2	4	4	4
GS-1	0	0	0
Subtotal	1,369	1,380	1,380
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	7	7	7
Senior Grade	2	2	2
Full Grade	7	7	7
Senior Assistant Grade	1	1	1
Assistant Grade	2	2	2
Subtotal	19	19	19
Ungraded	360	360	360
Total permanent positions	1,709	1,714	1,714 1,709
Total positions, end of year	1,751	1,762	1,762
Total full-time equivalent (FTE) employment, end of year	1,712	1,700	1,700
Average ES salary	164,414	168,601	170,961
Average GM/GS grade	11.5	11.5	11.5
Average GM/GS salary	113,088	115,556	117,040

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Common Fund

NATIONAL INSTITUTES OF HEALTH
Common Fund
Budget Mechanism - Total [1]
Dollars in Thousands

MECHANISM	FY 2010 Actual No.	FY 2010 Actual Amount	FY 2011 CR No.	FY 2011 CR Amount	FY 2012 President's Budget No.	FY 2012 President's Budget Amount	Change No.	Change Amount
Research Grants								
Research Projects								
Noncompeting	210	$127,739	280	$149,107	267	$165,057	57	$37,318
Administrative Supplements	*35*	5,341	*9*	1,447	*9*	1447	*-26*	-3894
Competing:				0				
Renewal	0	0	0	0		0	0	0
New	198	152,299	211	165,806	226	179,345	28	27,046
Supplements	0	0	0	0		0	0	0
Subtotal, Competing	198	$152,299	211	$165,806	226	$179,345	28	$27,046
Subtotal, RPGs	408	$285,379	491	$316,360	493	$345,849	85	$60,470
SBIR/STTR	0	$0	0	$0	0	$0	0	$0
Research Project Grants	408	$285,379	491	$316,360	493	$345,849	85	$60,470
Research Centers								
Specialized/Comprehensive	36	$119,059	40	$113,767	40	$114,905	4	-$4,154
Clinical Research	9	7,003	9	6,606	9	6,672	0	-331
Biotechnology	20	7,231	13	4,749	13	4,796	-7	-2,435
Comparative Medicine	0	0	3	6,000	3	6,060	3	6,060
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	65	$133,293	65	$131,122	65	$132,433	0	-$860
Other Research								
Research Careers	32	$13,820	30	$14,929	0	$0	-32	-$13,820
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	0	0	0	0	0	0	0	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	23	23,758	22	19,827	28	25,000	5	1,242
Other Research	55	$37,578	52	$34,756	28	$25,000	-27	-$12,578
Total Research Grants	528	$456,250	608	$482,238	586	$503,282	58	$47,032
Research Training	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	0	$0	0	$0	0	$0	0	$0
Institutional Awards	336	12,160	200	8,713	0	0	-336	-12,160
Total Research Training	336	$12,160	200	$8,713	0	$0	-336	-$12,160
Research & Development Contracts	0	$29,396	0	$11,525	0	$11,640	0	-$17,756
(SBIR/STTR)	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*
	FTEs		FTEs		FTEs		FTEs	
Intramural Research	0	$34,617	0	$27,879	0	$28,158	0	-$6,459
Research Management and Support	0	11,605	0	13,673	0	13,810	0	2,205
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, Common Fund	0	$544,028	0	$544,028	0	$556,890	0	$12,862

1/ All items in italics are ""non-adds"; items in parenthesis are subtractions

Major Changes in the Fiscal Year 2012 Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail; these highlights will not sum to the total change for the FY 2012 budget request for the NIH Common Fund, which is $12.862 million more than the FY 2010 Enacted level, for a total of $556.890 million.

Research Project Grants (+$60.470 million, total $345.849 million): The NIH Common Fund expects to support a total of 493 Research Project Grant (RPG) awards in FY 2012. Noncompeting RPGs will increase by 57 awards and increase by $37.318 million. Competing RPGs will increase by 28 awards and increase by $27.046 million. Expansion of the High-Risk High-Reward program, including support for the new Early Independence Awards in FY 2012, accounts for most of this increase in funding. The NIH Budget policy for RPGs in FY 2012 includes a 1.0 percent inflationary increase in noncompeting awards and for the average costs in competing grants.

Research Centers (-$0.860 million, total $132.433 million): The NIH Common Fund plans to support a total of 65 Research Center Awards in FY 2011. The decrease in number and amount reflects a decrease in funding for the National Centers for Biomedical Computing (NCBCs), which are undergoing a planned transition from the Common Fund to the ICs as described in the original NCBC plan.

Research Careers (-$13.820 million, total $0 million): The Clinical and Translational Science Awards (CTSAs) transition from the NIH Common Fund to the NCRR in FY 2012. This transition eliminates Common Fund activity in Research Careers.

Other Research, Other (+$1.242 million, total $25.000 million): The increase in Common Fund support in FY 2012 reflects adjustments in the Nanomedicine Program following a program review in FY 2009. The requested level of funding allows the Common Fund to maintain use of $25.000 million in Flexibility Research Authority (FRA) and fund existing FY 2012 commitments. $16.000 million of the FRA will be used in FY2012 to fund ongoing projects within the Nanomedicine program. In addition, $9.000 million are requested to use as needed for New Programs to be developed. These funds provide a great deal of flexibility for application and review so will allow the NIH Director to respond rapidly to emerging needs and opportunities.

Institutional Training Awards (-$12.160 million, total $0 million): The decrease in funding reflects a planned transition of the Interdisciplinary Research program to the ICs in FY 2012.

Research and Development Contracts (-$17.756 million, total $11.640 million): The requested level of funding reflects a balance of adjustments involving expiration of the pilot phase of the Genotype-Tissue Expression (GTEx) initiative and funding of the Gulf Long-term Follow-up of Workers Study via contract in FY 2011 and FY 2012.

Intramural Research (-$6.459 million, total $28.158 million): The requested level of funding reflects a discontinuation of Common Fund support for the Molecular Libraries and Imaging Program's Core Synthesis Facility to Produce Imaging Probes in FY 2010 and a shift in support for the Gulf Long-term Follow-up of Workers Study from intramural research to research and development contract in FY 2011.

NATIONAL INSTITUTES OF HEALTH
Common Fund by Initiative
(Dollars in Thousands)

Title of Initiative	FY 2010 Actuals	FY 2011 CR	FY 2012 President's Budget	Change [1]
Bioinformatics and Computational Biology				
National Centers for Biomedical Computing	$19,361	$13,411	$8,500	-$10,861
Building Blocks, Biological Pathways and Networks				
National Technology Centers & Metabolomics Development	10,121	10,141	10,399	278
Epigenomics				
Mapping Centers	10,428	10,411	10,000	-428
Human Health and Disease	4,060	4,016	4,000	-60
Data Management Center for the Mapping Centers	2,906	2,905	3,000	94
Technology Development in Epigenetics	6,067	6,668	3,500	-2,567
Discovery of Novel Epigenetic Marks in Mammalian Cells	2,349	0	0	-2,349
Subtotal, Epigenomics	25,810	24,000	20,500	-5,310
Genotype-Tissue Expression (GTEx) Resources				
Genotype-Tissue Expression (GTEx) Resources	22,329	2,878	3,000	-19,329
Global Health				
Medical Eduction Partnership Initiative (MEPI)	3,000	3,000	3,000	0
Human Heredity and Health in Africa (H3Africa)	750	0	5,000	4,250
Subtotal, Global Health	3,750	3,000	8,000	4,250
Gulf Long-term Follow-up of Workers Study				
Gulf Long-term Follow-up of Workers Study	5,000	2,500	2,500	-2,500
Health Economics				
Changing Incentives for Consumers, Insurers, and Providers	0	2,486	2,443	2,443
Science of Structure, Organization, and Practice Design in the Efficient Delivery of Healthcare	0	1,336	3,268	3,268
Economics of Prevention	0	1,338	2,868	2,868
Data Infrastructure to Enable Research on Health Reform	0	121	3,043	3,043
Subtotal, Health Economics	0	5,281	11,622	11,622
High-Risk Research				
NIH Director's Pioneer Awards	37,430	40,400	40,600	3,170
NIH Director's New Innovator Awards	97,821	80,200	80,000	-17,821
Transformative R01's	39,644	75,000	100,000	60,356
NIH Director's Early Independence Award Program	0	4,000	8,400	8,400
Subtotal, High-Risk Research	174,895	199,600	229,000	54,105
HMO Research Network Collaboratory				
NIH-HMORN Coordinating Center	1,000	3,273	1,200	200
Expansion Activities	0	0	4,000	4,000
Subtotal, HMO Research Network Collaboratory	1,000	3,273	5,200	4,200
Human Microbiome				
Sequence a Reference Set of Genomes	9,952	3,239	1,980	-7,972
Demonstration Projects	16,088	13,259	11,517	-4,571
New Tools and Technologies for Metagenomic Analyses	9,467	5,621	7,000	-2,467
Data Coordination	2,187	2,562	2,606	419
Resource Repository for Materials & Reagents	0	0	400	400
ELSI Studies Unique to HMP	495	500	500	5
HMP Workshops	0	765	635	635
Subtotal, Human Microbiome	38,189	25,946	24,638	-13,551
Interdisciplinary Research				
Interdisciplinary Research Centers	42,179	42,199	0	-42,179
Interdisciplinary Research Training Initiative	0	0	0	0
Innovation in Interdisciplinary Technology and Methods	2,807	0	0	-2,807
Subtotal, Interdisciplinary Research	44,986	42,199	0	-44,986
Knockout Mouse Phenotyping Program				
Production, Characterization, and Cryopreservation	0	6,180	6,200	6,200
Phenotyping and Data Release	500	4,179	4,200	3,700
Data Coordination	0	641	600	600
Subtotal, Knockout Mouse Phenotyping Program	500	11,000	11,000	10,500

Title of Initiative	FY 2010 Actuals	FY 2011 CR	FY 2012 President's Budget	Change [1]
Library of Integrated Network-Based Cellular Signatures (LINCS)				
Large-Scale Production of Perturbation-Induced Gene Expression	3,000	5,349	5,350	2,350
New Laboratory-Based Technology Development	0	2,800	2,800	2,800
Computational Tool Development and Integrative Data Analysis	0	1,400	1,400	1,400
Integration of Existing Datasets	0	451	450	450
Subtotal, Library of Integrated Network-Based Cellular Signatures (LINCS)	3,000	10,000	10,000	7,000
Molecular Libraries and Imaging				
Creation of NIH Bioactive Small Molecule Library & Screening Centers	88,372	86,375	56,850	-31,522
Cheminformatics	4,100	3,900	3,700	-400
Technology Development	17,169	12,825	10,700	-6,469
Imaging Probe Database	600	0	500	-100
Core Synthesis Facility to Produce Imaging Probes	3,000	0	0	-3,000
Subtotal, Molecular Libraries and Imaging	113,241	103,100	71,750	-41,491
Nanomedicine				
Nanomedicine Development Centers	20,000	15,946	16,000	-4,000
NIH Center for Regenerative Medicine (NCRM)				
NIH Center for Regenerative Medicine (NCRM)	2,321	6,000	10,000	7,679
Protein Capture				
Antigen Production	980	870	900	-80
Production of anti-TF Antibodies	0	3,975	3,975	3,975
New Reagent Technology Development and Piloting	200	5,337	5,125	4,925
Subtotal, Protein Capture	1,180	10,182	10,000	8,820
Public-Private Partnerships				
Public-Private Partnerships	0	0	0	0
Re-engineering the Clinical Research Enterprise				
Clinical Research Policy Analysis and Coordination	0	0	0	0
Translational Research Core Services	5,848	5,000	5,000	-848
Dynamic Assessment of Patient-Reported Chronic Disease Outcomes	9,396	8,448	8,448	-948
Enhance Clinical Research Training via the National Multi-disciplinary CR Career Development Program and CRTP and MSTP Expansions	1,100	880	720	-380
Clinical and Translational Science Awards	25,245	22,703	0	-25,245
Subtotal, Re-engineering the Clinical Research Enterprise	41,589	37,031	14,168	-27,421
Regulatory Science				
Advancing Regulatory Science Through Novel Research and Science-Based Technologies	2,891	3,081	2,555	-336
Science of Behavior Change				
Mechanisms of Change	4,643	4,883	4,958	315
Structural Biology				
Membrane Protein Production	8,381	8,004	8,000	-381
Strategic Planning Funds	841	2,572	2,594	1,753
Subtotal Common Fund	544,028	544,028	484,384	-59,644
New Initiatives in Common Fund	**0**	**0**	**72,506**	**72,506**
Total Common Fund	**$544,028**	**$544,028**	**$556,890**	**$12,862**

[1] Comparison of FY 2012 to FY 2010

Justification of Budget Request

Common Fund

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended.

Budget Authority:

	FY 2010 Actual	FY 2011 CR	FY 2012 Budget Request	FY 2012 + / - FY 2011
BA	$544,028,000	$544,028,000	$556,890,000	$12,862,000
FTE	0	0	0	0

Director's Overview

The 2006 NIH Reform Act called for the NIH Common Fund to support important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between two or more national research institutes or national centers, or would otherwise benefit from strategic coordination and planning. To this end, the Common Fund programs encourage transformative research that tackles the most critical challenges in biomedical research and translation. These are short term (5-10 year) programs that are intended to solve problems or build resources that will then catalyze research throughout the entire biomedical research enterprise.

The catalytic nature of Common Fund programs often involves the generation, integration and an analysis of complex data sets using high-throughput tools and technologies for biological discovery related to health and disease. This category of program expanded in FY 2011. The Library of Integrated Network-Based Cellular Signatures (LINCS) program, launched in FY 2011, is using high-throughput approaches to develop a resource "library" for the biomedical community to determine how different types of cells respond to a variety of perturbing agents that may be related to disease. Also launched in FY 2011, the Knock-out Mouse Phenotyping ($KOMP^2$) program is providing resources to characterize an existing collection of mutant mice, in which most of the genes in the genome have been "knocked out," one gene at a time. This vast collection of mutant mouse strains will be much more useful to the community if the impact of each mutation is known. The Common Fund will therefore support fundamental characterization of each strain, to catalyze future investigator-initiated studies on how mammalian genes function.

The Common Fund also continues to support the Human Microbiome Program which is developing and applying high-throughput genomics and computational approaches to generate a reference set of genomes from the micro-organisms that inhabit various organs of the human body, the so-called human microbiome. These efforts will accelerate our understanding of the relationship between the human microbiome and health and disease. Researchers from the Human Microbiome Program have published the first reference set of 178 genomes from

microbes in or on the human body, revealing a vast amount of microbial diversity[1]. Similarly, the Epigenomics program is developing reference data pertaining to the human epigenome - the entire set of chemical and structural modifications to DNA that, although generally not inherited, determine which genes are active in a given cell type. These modifications can have profound effects on health and disease. Researchers in the Epigenomics program have discovered that a type of epigenetic modification differs between embryonic stem cells and adult, differentiated cells, which may help explain how stem cells maintain their ability to become any cell type in the body[2]. Finally, the Genotype-Tissue Expression (GTEx) project is using high-throughput genetic and genomic approaches to develop a set of reference gene expression profiles for specific human tissues that will greatly enhance our ability to characterize genetic variation as it relates to gene expression.

Common Fund programs also catalyze NIH-wide research through the provision of resources or development of novel technologies to advance the development of new and better drugs, biologics, and devices and bring new innovative treatments to patients. The Common Fund launched the NIH Center for Regenerative Medicine (NCRM) program in FY 2010 within the NIH Intramural Research Program (IRP). The program supports a collection of new intramural pilot projects that focus on induced pluripotent stem cells with the intent of building a cadre of investigators in the IRP focused on regenerative medicine. These pilot projects are intended to accelerate clinical applications of stem cells. The Common Fund also provides continued support for other programs that strengthen the therapeutics development pipeline. For example, the Molecular Libraries and Imaging program is identifying small molecules that may hold promise in the development of new disease therapies. Scientists in the Molecular Libraries and Imaging program have helped identify cellular pathways that contribute to insulin resistance, suggesting novel drug targets for the prevention or treatment of diabetes[3]. The NIH Rapid Access to Intervention Development (RAID) program is providing public sector researchers and small businesses with much needed resources to speed up the analysis, synthesis and formulation of potentially beneficial molecules through the valley of death phase of therapeutics development. RAID has supported the development of a drug currently in clinical trials as a potential treatment for Alzheimer's disease[4]. To hasten the development and testing of new designs, strategies and models for clinical trials of therapies, preventives, and diagnostics, the NIH is partnering with the Food and Drug Administration in the Common Fund's new Regulatory Science program.

Strategic planning in 2010 resulted in three new Common Fund programs in FY 2011 to to assist in reforming the health care system. The new Health Economics program supports a series of projects, some that build on the findings of comparative effectiveness research (CER), to identify and develop new approaches to improve health and increase the efficiency and quality of health care delivery. The HMO Research Network Collaboratory program was created in FY 2010 to leverage and expand existing information technology, electronic records systems, and scientific capacity within HMO health service networks to accelerate large

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[1] The Human Microbiome Jumpstart Reference Strains Consortium (2010). A catalogue of reference genomes from the human microbiome. Science, 328, 994-999.

[2] Lister R, Pelizzola M, Dowen RH, et al. (2009). Human DNA methylomes at base resolution show widespread epigenomic differences. Nature, 462, 315-322.

[3] Choi JH, Banks AS, Estall JL, et al. (2010). Anti-diabetic drugs inhibit obesity-linked phosphoylation of PPARy by Cdk5. Nature, 466, 451-456.

[4] Mithridion press release, http://mithridion.com/pr09.html.

epidemiology studies and clinical trials that address cross-cutting NIH priorities. Some of the projects funded through the High Risk/High Reward initiatives are enhancing the evidence base for clinical care by identifying and examining behavioral aspects of patient health, compliance and health costs. Specific projects are developing clinical markers for mood disorders as a way to design more effective treatments and monitor compliance and response to treatment, and assessing how the way health information is conveyed to patients affects their attitudes and prevention behavior related to cancer.

Recognizing the need for further stimulation of the biomedical workforce, specifically to support researchers at the beginning of their independent careers, the NIH Director expanded the High Risk/High Reward program in FY 2011 through the launch of the Early Independence Award (EIA) initiative. The EIA supports exceptionally creative individuals who are mature enough at the end of their graduate training to move directly into independent research careers and skip the traditional post-doctoral period. The Transformative Research Project (TR01) awards also expanded in FY 2011 to support the next cadre of highly innovative projects. Together with the Pioneer awards and the New Innovator awards, these initiatives allow creative investigators to define their own innovative, high-risk, original, and unconventional research projects without the need for extensive preliminary data required by traditional R01s.

Overall Budget Policy: The FY 2012 request for the Common Fund is $556.890 million, an increase of $12.862 million or 2.46 percent over the FY 2010 Actual level. The Common Fund plans to support a 1 percent inflationary increase for non-competing and competing grants. The Common Fund will continue to support research consistent with the NIH Director's Themes. As mature programs transition out of the Common Fund, new programs are being established through strategic planning activities that identify cross-cutting challenges and emerging scientific opportunities where short-term investment can have a catalytic impact. Programs that support regenerative medicine or that expand the clinical research networking capabilities of the HMO Research Network will expand. The Common Fund will also support the Director's Theme of Reinvigorating the Workforce through expanded funding of High Risk/High Reward research, emphasizing programs that foster the creativity and independence of exceptional early career investigators.

Program Descriptions and Accomplishments

Bioinformatics and Computational Biology: In an age where the ability to manage and organize large amounts of varied biomedical data is necessary for research, the need for informatics tools is critical. These tools must be adapted to handle data that are unique to studies of biological systems. The Bioinformatics and Computational Biology program, which supports the National Centers for Biomedical Computing (NCBCs), was funded beginning in 2003-2004 and has completed its first phase of funding through the Common Fund. The first phase established the utility of a network of integrated centers that collectively address a broad range of biological problems. In the second phase of the program, the network of centers will gradually transition to NIH's Institutes and Centers (ICs) support. The Centers will function as core resources for the development of novel software and computational tools that address IC-specific problems.

Budget Policy: The FY 2012 budget estimate of $8.500 million for this program represents a decrease of $10.861 million or 56.1 percent less than the FY 2010 Enacted level. This estimated decrease is consistent with the natural transition of NCBC support from the Common Fund to the ICs as described in the original NCBC plan.

Building Blocks, Pathways, and Networks: The basic building blocks of the human body, from individual genes to entire organs, work together to promote normal development and sustain health. This amazing feature of biological systems is accomplished mainly through ever-changing relationships between the proteins that make up biological pathways. Understanding how these pathways are interconnected and maintained, how they can become disturbed, and what might be done to restore disturbed pathways to their normal functions is key to understanding health and disease. Although scientists can currently study interactions between proteins within cells, their ability to do this is equivalent to taking a snapshot - looking at a single, isolated moment in time. The National Technology Centers for Networks and Pathways (TCNP) program supports the development of new technologies to help researchers view dynamic events, such as protein-protein interactions, in cells to better understand how these processes work under normal conditions and in disease. The centers serve as an important overall resource for NIH-supported investigators by promoting collaboration among biomedical researchers and speeding the transfer of new technologies to other laboratories.

Budget Policy: The FY 2012 budget estimate of $10.399 million for this program represents an increase of $0.278 million or 2.7 percent more than the FY 2010 Enacted level. FY 2012 funds will be used for continued development of new technology and dissemination of these research tools at the TCNPs.

Epigenomics: Epigenetics focuses on processes that regulate how and when certain genes are turned on and turned off, while epigenomics pertains to analysis of epigenetic changes across all of the genes in a cell. Some human diseases, such as cancer, are known to involve epigenetic changes; however, the role of epigenetics in other diseases is largely unknown and is difficult to study because researchers lack the tools to efficiently detect and correlate changes in the epigenome to specific diseases or health conditions. The Common Fund Epigenomics program includes a series of complementary initiatives to generate the research tools, technologies, and infrastructure needed to accelerate our understanding of the role of epigenomics in human health and disease. The Reference Epigenome Mapping Centers are developing maps of epigenetic changes in a specific cell type that can be used to identify epigenomic changes that underlie biology and disease, and may be targeted in new therapeutics. An Epigenomics Data Analysis and Coordination Center is developing standardized datasets from the Mapping Center studies that will be made available to the public. Two other initiatives support projects on Technology Development in Epigenetics and Discovery of Novel Epigenetic Marks in Mammalian Cells. A fourth initiative, the Epigenomics of Human Health and Disease, provides funds for investigators to determine how or whether epigenomic changes correlate with disease.

Budget Policy: The FY 2012 budget estimate of $20.500 million for this program represents a decrease of $5.310 million or 20.6 percent less than the FY 2010 Enacted level. The FY 2010 completion of several 2-year projects funded under the Discovery of Novel Epigenetic Marks in Mammalian Cells initiative and a reduction in funding of the Technology Development in

Epigenetics initiative in FY 2011, due to the completion of four-year grants awarded in FY 2008, accounts for this estimated decrease in funding.

Genotype-Tissue Expression (GTEx): Although genome-wide studies are an effective way to identify specific genes that may be associated with a disease, many diseases involve changes in DNA that lie outside of a specific gene region, making it difficult to study them using this approach. The Genotype-Tissue Expression (GTEx) project provides the scientific community with a much-needed resource with which to study how gene activity is controlled and how DNA variation correlates with variation in gene activity levels. The GTEx project was initiated in FY 2010 as a two-year pilot to test the feasibility of collecting high-quality RNA and DNA from multiple tissues from approximately 160 donors identified through autopsy or organ transplant. If the pilot phase proves successful, the project will be scaled up to involve approximately 1000 donors. The project involves consultation and research into the ethical, legal, and social issues raised by the research, support for new statistical methods, and creation of a database of genetic and clinical data generated by the program and obtained from other sources. The database allows users to view and download data about possible genomic regions that correlate with changes in gene activity while providing a controlled system to ensure privacy about genetic and clinical data. The tissue repository serves as a resource for conducting many kinds of follow-up analyses.

Budget Policy: The FY 2012 budget estimate of $3.000 million for this program represents a decrease of $19.329 million or 86.6 percent less than the FY 2010 Enacted level. Beginning in FY 2010, the pilot phase of the GTEx included a contract that incurred no costs in FY 2011. Support of a small grant program to analyze gene sequence and expression data as part of the pilot phase of GTEx continues in FY 2012.

Global Health: The NIH Common Fund Global Health Program is partnering with other NIH Institutes, Centers, and Offices as well as other Federal agencies and the UK Wellcome Trust to support two initiatives that will expand research capacity in Africa. The Medical Education Partnership Initiative (MEPI) is developing and strengthening models of medical education and building research and clinical capacity in countries of Sub-Saharan Africa that are part of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). The Human Heredity and Health in Africa (H3Africa) initiative involves collaboration with the Wellcome Trust to build research capacity in Africa for the study of the genetic and environmental contributions to health and disease. Both communicable and non-communicable diseases and conditions are being addressed through this initiative.

Budget Policy: The FY 2012 budget estimate of $8.000 million for this program represents an increase of $4.250 million or 113.3 percent more than the FY 2010 Enacted level. This estimated increase is due to the launch in FY 2012 of the Human Heredity and Health and Africa (H3Africa) initiative as a partnership between the NIH and the UK Wellcome Trust.

Gulf Long Term Follow-Up (GuLF) of Workers Study: The oil from the April 20, 2010 explosion on the Deepwater Horizon oil rig in the Gulf of Mexico contaminated the Gulf and has settled along the coastline and marshes of Alabama, Louisiana and Florida. In his testimony before the Senate Subcommittee on Health, Committee on Energy and Commerce on June 15, 2010, the NIH Director pledged support from the Office of the Director and the NIH Common Fund for research into the environmental health hazards posed by the Gulf oil spill. The Gulf

program, initiated with FY 2010 funds, includes a prospective study of clean-up workers, called the Gulf Long-term Follow-up (GuLF) study, and toxicological studies. Longer term requirements for funds from the Common Fund will be determined when information concerning the availability of additional funds from BP becomes available. The NIH efforts for Gulf program complement and are coordinated with response efforts of other federal, state, and local agencies and institutions working in the Gulf region.

Budget Policy: The FY 2012 budget estimate of $2.500 million for this program represents a decrease of $2.500 million or 50.0 percent less than the FY 2010 Enacted level. The decrease reflects additional sources of funding, in addition to the Common Fund, for the prospective study of clean-up workers.

Health Economics: This program, launched in the wave of national health care reform, addresses research needs identified through strategic planning conducted in FY 2010. In FY 2012, the program includes a series of developmental research projects intended to identify and develop approaches to improve health and increase efficiency in delivery of health care.

Budget Policy: The FY 2012 budget estimate of $11.622 million for this program represents an increase of $11.622 million or 100 percent more than the FY 2011 Enacted level. This new FY 2011 program supports initiatives investigating economics of prevention strategies, costs and outcomes of health care delivery, and improvement of data infrastructure resources.

Portrait of a Program: Health Economics

FY 2010 Level: $ 0 million
FY 2012 Level: $11.622 million

The Affordable Care Act of 2010 set in motion a major expansion of insurance coverage, testing of several approaches to controlling costs, and creation of a new long-term care insurance fund. With other recent legislation, it provides funding for an expansion of health information technology (IT) in primary care. These reforms constitute the largest changes to the health care system in the US since the enactment of Medicare and Medicaid in 1965. But reform is a work in progress. A major challenge is to slow the rate of cost growth without jeopardizing access to high-value care or slowing technological innovation. The Health Economics program was initiated in FY 2011. FY 2012 funds support a series of small developmental projects to examine:

-- Effects of changing incentives for consumers, providers and insurers
-- Scientific questions underlying supply-side changes in organization of health care
-- Economics of prevention
-- Data infrastructure needed for research to inform health care reform.

Expansion of the program in FY 2012 represents new initiatives to develop and analyze the economics of prevention strategies, evaluate costs and outcomes of health care delivery, and improve existing data resources to promote data sharing and linkage across data sets and researchers.

High-Risk High-Reward Investigator-Initiated Research: Research that aims to transform science is inherently difficult; if it was either obvious or easy, the need for transformation would not exist. A primary goal of the Common Fund is to provide opportunities for investigators to take risks when the potential impact is high, to think outside the box, and to try things that may

not fare well in standard peer review, which relies on solid preliminary data to support proposed hypotheses. Although all of the Common Fund programs encourage risk-taking to overcome significant challenges in research, most of them involve designated funds for particular high risk objectives (such as clinical applications of nanobiology) or approaches (such as screening for new drugs or probes in the Molecular Libraries Program.) However, four initiatives within the Common Fund foster innovation, risk-taking, and transformative research in any area of health research chosen by the investigators: the NIH Director's Pioneer Award Program, the NIH Director's New Innovator Award Program, the Transformative Research Projects (TR01) program, and the NIH Director's Early Independence Award program. These initiatives represent complementary approaches to foster innovation and promote transformation. In FY 2011, the Early Independence Awards program was launched with a goal of invigorating the workforce by fostering independence of exceptional young scientists immediately after completion of their doctoral degrees.

Budget Policy: The FY 2012 budget estimate of $229.000 million for this program represents an increase of $54.105 million or 30.9 percent more than the FY 2010 Enacted level. This estimated increase in funding is due to an expansion of the FY 2011 NIH Director's Early Independence Award program to support exceptional young scientists in independent research positions, as well as expansion of the TR01 program in FY 2011 and FY 2012 to support two new cohorts of investigators exploring bold, innovative, and high-risk research.

Portrait of a Program: NIH Director's Early Independence Award (EIA)

FY 2010 Level: $0 million
FY 2012 Level: $8.400 million

The Early Independence Award (EIA), launched by the NIH Director through the Common Fund, addresses a fundamental need to bolster the biomedical workforce in the United States by supporting a cadre of highly creative and mature scientists who are prepared to tackle biomedical research problems earlier in their career than is typically allowed. Recent trends show an increase in the length of the traditional scientific training period with a concomitant increase in the age at which scientists establish independent research careers. Although traditional post-doctoral training is likely most appropriate for the majority of new Ph.D.s and M.D.s, there is a pool of talented young scientists who have the intellect, scientific creativity, drive, and maturity to flourish independently without the need for traditional post-doctoral training. Reducing the amount of time these scientists spend in training would provide them the opportunity to start highly innovative research programs as early in their careers as possible. To facilitate this, the NIH Common Fund established the NIH Director's EIA to provide a mechanism for exceptional, early career scientists who are U.S. residents or permanent citizens to omit traditional post-doctoral training, and move into temporary, independent academic positions at U.S. institutions directly upon completion of their graduate degrees (Ph.D, M.D. or equivalent). This highly competitive program is being expanded in FY 2012 to support a second cadre of exceptional research scientists.

HMO Research Network Collaboratory (HMORC): In the context of health care reform activities, the Common Fund is leveraging prior investments from ICs in a network of 15 U.S. member health plans of the national HMO Research Network (HMORN), started in 2007. The research infrastructure and capacity of the HMORC are being expanded to extend utility of the network to all NIH ICs. The increased collaborative potential of the network is reflected in the Common Fund name of this effort as a Research Collaboratory. The HMORN research

organizations, because of their history of public sector research and their affiliation with leading-edge integrated healthcare delivery systems, are ideally positioned to lead new research efforts in a number of cross-cutting NIH interest areas, including Mega-Epidemiology Studies, Clinical Trial Enterprise, and Health Care Delivery.

Budget Policy: The FY 2012 budget estimate of $5.200 million for this program represents an increase of $4.200 million or 420.0 percent more than the FY 2010 Enacted level. This estimated increase in funding is a result of expansion of the HMORC program to explore current capabilities of the HMORN research organizations and define collaborative opportunities with these organizations.

Human Microbiome Project: Microbes such as bacteria, viruses, and fungi found naturally in the human body outnumber human cells 100 to 1. Most of the microbes living in our bodies are beneficial whereas others cause disease. Bacteria have been implicated in conditions as diverse as asthma, cancer and obesity; yet the great majority of bacteria and viruses that reside on and in people are unidentified and uncharacterized. The Common Fund Human Microbiome Project was launched in FY 2008 to leverage advances in high throughput genomic technologies to identify and characterize approximately 600 new human microbes and to establish causal links between specific bacteria and disease. The program is focusing on sampling microbes from several different body sites from many different individuals to determine whether there is a common set of microbes, or so-called microbiome, that is shared by all people or whether each person has a unique microbiome. In FY 2012, the program investigators will focus on sequencing and cataloging of the microbiome samples, establishing links between the microbiome and disease, developing technologies to identify unknown microbes.

Budget Policy: The FY 2012 budget estimate of $24.638 million for this program represents a decrease of $13.551 million or 35.5 percent less than the FY 2010 Enacted level. The estimated decrease in funding levels reflects the balance of adjustments to several individual initiatives, including a reduction in Sequence a Reference Set of Genomes and an increase in Data Coordination.

Interdisciplinary Research Consortia: A major focus of the NIH Common Fund has been to foster new modes of conducting research, with emphasis on the need for interdisciplinary approaches to address complex health problems. In FY 2007, the NIH awarded funds to nine Interdisciplinary Research Consortia to explore new ways to integrate different scientific disciplines to address critical health challenges. This program piloted new award mechanisms for Interdisciplinary Research and Training as well as new methods of review for Interdisciplinary Research. It also resulted in a change of policy within the NIH to recognize multiple Principal Investigators on NIH grants and developed new methods of inter-IC award management. Common Fund support of this program ends in FY 2011, with the expectation that ICs will continue to use the award mechanisms as needed to support interdisciplinary approaches, working together to foster research that cuts across IC mission boundaries.

Budget Policy: The Interdisciplinary Research Consortia will receive no funding in FY 2012 from the Common Fund. This reflects the planned transition of support from the Common Fund to individual ICs, as appropriate.

Knock-out Mouse Phenotyping Program: Recognizing the value and utility of a readily accessible, genome-wide collection of knockouts as the lynchpin to determine how mammalian genes function, several international programs were launched in 2006 to develop mutant mouse strains. Collectively, these programs have created almost 8,000 prototype knockout mice, and they are on track to complete the resource by the end of 2011. The new Common Fund program builds upon this resource by expanding the efforts to characterize the mutant strains. The data will be made rapidly available to the entire research community through an internationally-coordinated data coordinating center.

Budget Policy: The FY 2012 budget estimate of $11.000 million for this program represents an increase of $10.500 million or 2100 percent more than the FY 2010 Enacted level. New FY 2011 initiatives to characterize mutant strains of mice and disseminate data to the research community continue in FY 2012 and account for the increase in funding.

Library of Integrated Networks of Cellular Signatures (LINCS): The LINCS program aims to develop a "library" of molecular signatures based on gene expression and other cellular changes that describe the response that different types of cells elicit when exposed to various perturbing agents, including small interfering RNAs (siRNAs), which are short RNA molecules that can inhibit expression of specific genes, and small bioactive molecules. High-throughput screening approaches are used to interrogate the cells and mathematical approaches will be used to describe the molecular changes and patterns of response. The data are being collected in a standardized, integrated, and coordinated manner to promote consistency and comparison across different cell types.

Budget Policy: The FY 2012 budget estimate of $10.000 million for this program represents an increase of $7.00 million or 233.3 percent more than the FY 2010 Enacted level. New FY 2011 initiatives to support technology development and investigate molecular signatures of perturbation and provide insights about cellular changes in disease will continue in FY 2012 and account for the increase in funding.

Molecular Libraries and Imaging: The pharmaceutical industry has for years used a process known as high-throughput screening (HTS) to identify new small molecule probes that can be used for drug development and to study biological processes involved in disease. Prior to the launch of the Molecular Libraries and Imaging Program, HTS capabilities were not available to academic researchers. This program provides public sector, biomedical researchers much needed access to HTS approaches to develop small molecule probes. Data about the structure and function of the probes are deposited in a free, online public database called PubChem (http://pubchem.ncbi.nlm.nih.gov/), which was designed and implemented by the Molecular Libraries and Imaging program. The program has developed 87 compounds that are in pre-clinical tests as new leads for drug development. In FY 2012, the program begins its transition out of the Common Fund. Having been successfully launched, elements of the program will continue through IC funding and/or funding through the Therapies for Rare and Neglected Diseases (TRND) Program and the Cures Acceleration Network (CAN).

Budget Policy: The FY 2012 budget estimate of $71.750 million for this program represents a decrease of $41.491 million or 36.6 percent less than the FY 2010 Enacted level. This estimated

reduction is due to the transition of the Molecular Libraries and Imaging program from Common Fund support to IC support as planned.

Nanomedicine: Nanotechnology, the study and manipulation of molecules less than 100 nanometers in size, holds great promise for use in diagnosing and treating disease. Nanotechnology is currently being used to: deliver drugs to specific locations in the body, diagnose disease, and view inside the body through the use of imaging. The goal of this Common Fund program is to use nanotechnology to understand and manipulate biological processes in a cell for specific medical purposes. For example, nanoscale protein folding machines are being developed for the treatment of diseases such as Alzheimer's and Huntington's, where misfolded proteins are thought to play a role. In FY 2005, a network of eight Nanomedicine Centers at academic institutions across the country was established. The program underwent an extensive review in FY 2009 to inform the next phase, which is focusing on making the nanobiological structures developed in the first phase more clinically useful. The second phase of the program constitutes a more focused effort involving a smaller number of centers. This program uses the Flexible Research Authority, or Other Transaction Mechanism, which will continue in FY 2012.

Budget Policy: The FY 2012 budget estimate of $16.000 million for this program represents a decrease of $4.000 million or 20.0 percent less than the FY 2010 Enacted level. The estimated funding reflects an overall reduction in the number of funded centers and ongoing support of the selected centers following the FY 2009 review.

NIH Center for Regenerative Medicine (NCRM): This new program, housed in the NIH Intramural Research Program (IRP), will provide a national resource for stem cell science that is specifically focused on facilitating the development of medical applications and cell therapies.

Budget Policy: The FY 2012 budget estimate of $10.000 million for this program represents an increase of $7.679 million or 330.8 percent more than the FY 2010 Enacted level. This estimated increase reflects a planned scale-up to support increased cell production and research capacity in the intramural center.

Portrait of a Program: NIH National Center for Regenerative Medicine (NCRM)

FY 2010 Level: $2.321 million
FY 2012 Level: $10.000 million

The NIH Center for Regenerative Medicine (NCRM), initiated in FY 2010, is intended to accelerate the development of cell based therapies for regenerative medicine. Housed within the NIH Intramural program, this Center will provide research resources to intramural and extramural investigators. The program will:

-- Establish a stem cell core facility that will be a resource for the scientific community, providing reagents and technologies and establishing collaborative projects with both intramural and extramural partners
-- Establish a lab for the Director of the Center within the NIH IRP, with the expectation that the Center Director will be a leader in clinical application of stem cell technologies
-- Provide pilot funds to intramural investigators to launch clinically-driven regenerative medicine projects which will then feed into the collaborative projects funded through the core activities of the Center.

FY 2012 funds provide support for a new Center Director, a series of intramural pilot projects on clinical applications of induced pluripotent stem cells (iPSCs), and continued development of the NCRM as a national resource.

Protein Capture: This program is intended to develop a renewable resource of protein capture reagents specifically designed to meet research and clinical demands ranging from protein isolation and high-throughput assays to diagnostics and biomarker development. To have the maximum benefit, such reagents would need to include high quality, affordable, reliable monoclonal antibodies as well as other reagents that can collectively target the range of possible proteins within cells and tissues. This program provides support for the development of new technologies and for the provision of monoclonal antibodies.

Budget Policy: The FY 2012 budget estimate of $10.000 million for this program represents an increase of $8.820 million or 747.5 percent more than the FY 2010 Enacted level. The increase in funding reflects the new FY 2011 initiative to develop reagents for a specific class of human proteins called transcription factors, and increased funding for the Antigen Production and New Reagent Technology Development and Piloting initiatives as the Protein Capture program advances.

Re-engineering the Clinical Research Enterprise: This program seeks to enhance the efficiency and effectiveness of clinical research. The initiatives within Re-engineering the Clinical Research Enterprise strive to transform the entire system of clinical research in order to fulfill the potential of modern medicine. These initiatives will foster the creation of new partnerships and a higher level of institutional integration in order to improve the working relationships among the numerous entities that are part of the clinical research process.

Translational Research Core Services: NIH Rapid Access to Intervention Development (RAID): Many promising new therapeutics encounter roadblocks during clinical development. Especially vulnerable are therapeutic approaches that involve high risk ideas or therapies for uncommon disorders that cannot attract private sector investment. Where private sector support for drug development is limited or not available, the NIH Rapid Access to Intervention Development Pilot program (NIH-RAID) can help fill the gap and reduce some of the common barriers that block progress of therapeutic discoveries from the bench to the bedside. The NIH-RAID program is not a grant program. Instead, it makes available critical resources that are needed to develop new therapeutic agents, including ones that can generate bulk amounts of the drug candidate or test its stability or toxic effects. It also provides researchers with access to expertise at the Food and Drug Administration on document preparation and submission. This program forms a critical component of the therapeutics pipeline and will be closely coordinated with the Therapeutics for Rare and Neglected Diseases (TRND) and Cures Acceleration Network (CAN) programs.

Budget Policy: The FY 2012 budget estimate of $5.000 million for this program reflects a decrease of $0.848 million or 14.5 percent less than the FY 2010 Enacted level. The funds provide support for ongoing programs and outreach efforts enhance the use of resources developed through the program.

Dynamic Assessment of Patient-Reported Chronic Disease Outcomes: Patient-Reported Outcomes Measurements Information System (PROMIS): PROMIS is a revolutionary effort to enhance the precision of measures of patient-reported symptoms and function or outcomes. Patient-reported outcomes are essential for proper medical care but are often

difficult to collect reliably. The PROMIS program has developed an interactive, computerized testing system that accurately reports patient-reported outcomes by adapting questions to the responses of each individual patient. This standardized measurement tool will increase the comparability of studies while reducing the reporting burden on patients. The initial PROMIS network of seven research sites and one coordinating center developed questionnaires tailored to a number of symptoms of chronic diseases and conditions including anxiety, pain, and fatigue. In FY 2009, the second phase of the PROMIS program began with an expansion of the network to 14 research sites and three supporting centers to extend the PROMIS system to several new areas with an emphasis on questionnaires tailored to children, minorities, women and the underserved.

Budget Policy: The FY 2012 budget estimate of $8.448 million for this program represents a decrease of $0.948 million or 10.1 percent less than the FY 2010 Enacted level. This estimated funding reflects the continued support of PROMIS as this program continues to develop questionnaires tailored to underserved and minority populations.

Clinical and Translational Science Awards (CTSAs): The CTSA program was established through Common Fund support as an effort to is a unique and bold venture to restructure and improve the clinical research enterprise. The CTSA program is enabling researchers to provide and deliver new treatments more efficiently and quickly to patients. Common Fund support for this program has ended, with the final year of support being FY 2011. Funding and management have transitioned to NCRR.

Budget Policy: The CTSA program will receive no funds from the Common Fund in FY2012, as support for this program transition to NCRR in FY 2011.

Regulatory Science: The NIH and the U. S. Food and Drug Administration (FDA) have formed an interagency partnership to foster regulatory science, a specialized and interdisciplinary area of biomedical research that serves to generate new knowledge and tools for assessing experimental therapies, preventives, and diagnostics. A key goal of this new Regulatory Science program is to accelerate the development and use of new tools, standards, and approaches to develop products efficiently and to evaluate product safety, efficacy, and quality more effectively.

Budget Policy: The FY 2012 budget estimate of $2.555 million for this program represents a decrease of $0.336 million or 11.6 percent less than the FY 2010 Enacted level. This estimated funding reflects a planned decrease in funding for this program due to the completion of one of its four grant projects during FY 2011.

Science of Behavior Change: The Common Fund launched the Science of Behavior Change program to improve our understanding of human behavior change across a broad range of health-related behaviors. This is being accomplished by supporting basic research to improve our understanding of human motivation and the maintenance of behavior change across multiple diseases and conditions, and then using this knowledge to develop more effective and economical behavioral interventions.

Budget Policy: The FY 2012 budget estimate of $4.958 million for this program represents an increase of $0.315 million or 6.8 percent more than the FY 2010 Enacted level. This estimated

funding reflects continued support of grants investigating behavior change at the social, contextual, behavioral, psychological, neurobiological, or genetic level of analysis.

Structural Biology: The overall health of a cell is maintained by an important class of proteins called membrane-bound proteins that are strategically located at the boundary between the cell and the external environment. The Structural Biology initiatives aim to create new methods and approaches for producing membrane-bound proteins in sufficient quantity and quality for use in research studies. The ability to produce membrane-bound proteins to meet this need has led to major breakthroughs in biological sciences and disease research. In FY 2009, the Structural Biology Centers began a second five-year phase of support through the Common Fund. While the first five years of the program led to major breakthroughs in the ability to produce and analyze membrane proteins, it revealed that this class of proteins is highly variable - methods that work for one protein seem unlikely to work for many. Therefore, the second five years of this program are intended to discover unifying principles so that membrane proteins may be more broadly studied.

Budget Policy: The FY 2012 budget estimate of $8.000 million for this program represents a decrease of $0.381 million or 4.5 percent less than the FY 2010 Enacted level. This estimated funding reflects continued support of research about methods to produce and analyze a broad range of membrane proteins.

NIH Strategic Planning Funds: The core mission of the NIH Common Fund is to foster collaboration, coordination, and strategic planning activities across the NIH. New research opportunities that would benefit from Common Fund support are being envisioned for FY 2012. To facilitate these planning efforts, the NIH Director is convening a series of trans-NIH workshops and brainstorming sessions, beginning in FY2011, involving external and internal experts, public and private sector partners, and stakeholders. These planning efforts are being supported through the Common Fund Strategic Planning Funds. In keeping with the mission of the Common Fund, new programs initiated in FY 2012 will address emerging opportunities and public health challenges through the development of new tools, technologies, approaches, and research data needed to tackle pressing biological problems and accelerate the translation of research findings into new and better therapies.

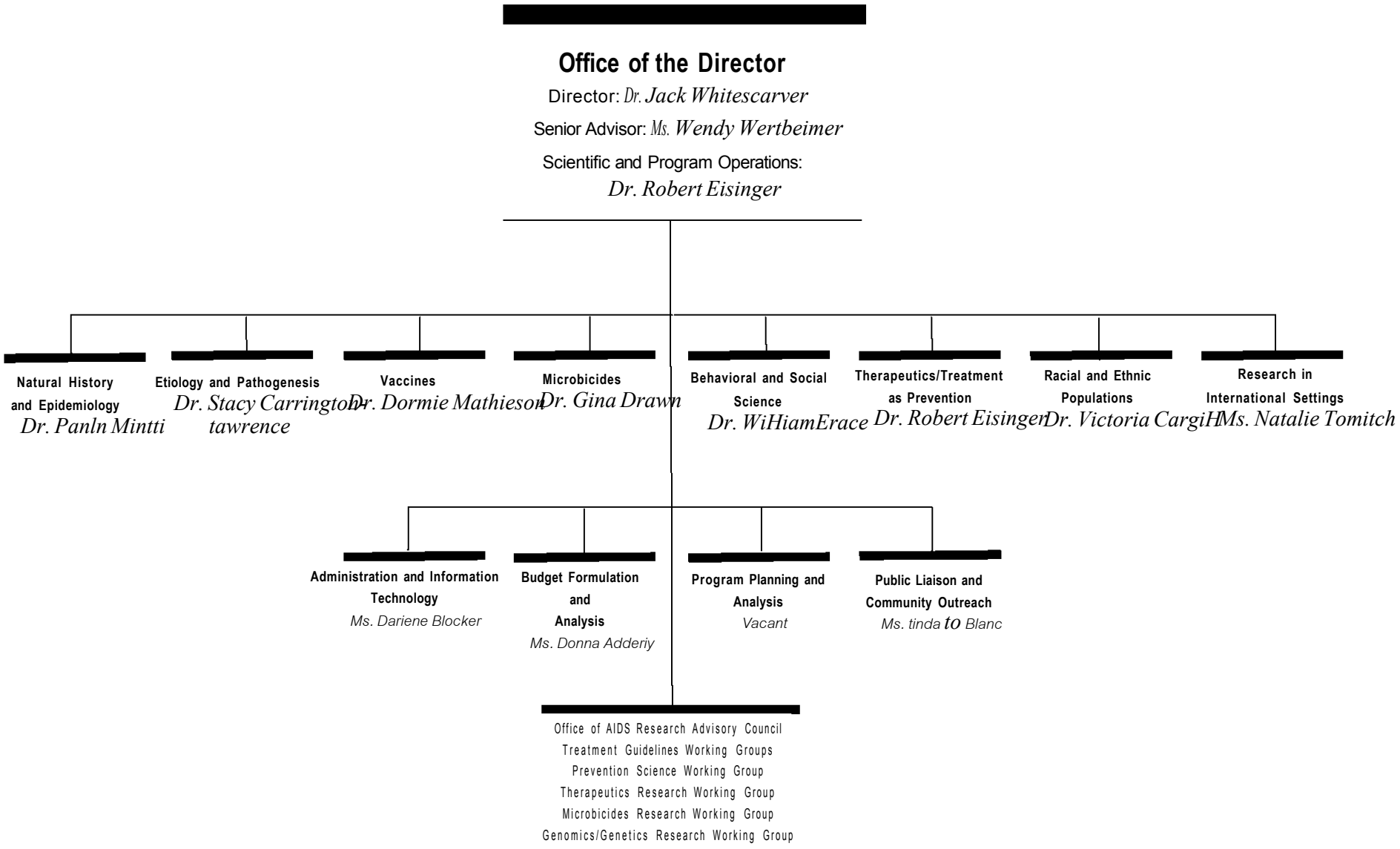
Budget Policy: The FY 2012 budget estimate of $2.594 million for this program represents an increase of $1.753 million or 208.4 percent more than the FY 2010 Enacted level. Strategic planning led to the development of several new programs launched in FY 2011. This level of funding reflects the Common Fund's commitment to design and implement a strategic planning process for gathering bold and innovative ideas to address cross-cutting challenges and promote emerging scientific opportunities.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research Trans-NIH AIDS Research Budget

FY 2012 Budget — Page No.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Program Planning and Analysis
Vacant
Public Liaison and Community Outreach
Ms. tinda to Blanc
Office of AIDS Research Advisory Council
Treatment Guidelines Working Groups
Prevention Science Working Group
Therapeutics Research Working Group
Microbicides Research Working Group
Genomics/Genetics Research Working Group

National Institutes of Health
Office of AIDS Research

Budget Authority by Institute and Center

Institute/Center	FY 2010 Actual	FY 2011 CR	FY 2012 PB 1/	Change FY 2010 Actual/ FY 2012 PB
NCI	$272,130,000	$272,130,000	$281,185,000	$9,055,000
NHLBI	68,206,000	68,206,000	68,206,000	–
NIDCR	20,251,000	20,251,000	20,251,000	–
NIDDK	31,031,000	31,031,000	31,389,000	358,000
NINDS	47,027,000	47,027,000	47,886,000	859,000
NIAID	1,577,322,000	1,577,547,000	1,615,016,000	37,694,000
NIGMS	57,334,000	57,334,000	57,847,000	513,000
NICHD	145,652,000	145,652,000	149,758,000	4,106,000
NEI	10,631,000	10,631,000	9,094,000	-1,537,000
NIEHS	5,347,000	5,347,000	5,347,000	–
NIA	5,645,000	5,645,000	5,645,000	–
NIAMS	4,938,000	4,938,000	4,938,000	–
NIDCD	1,880,000	1,880,000	1,788,000	-92,000
NIMH	191,025,000	191,051,000	195,443,000	4,418,000
NIDA	320,230,000	320,230,000	331,543,000	11,313,000
NIAAA	28,446,000	28,446,000	28,835,000	389,000
NINR	12,660,000	12,660,000	12,660,000	–
NHGRI	7,153,000	7,153,000	7,353,000	200,000
NIBIB	2,705,000	2,705,000	1,221,000	-1,484,000
NIMHD	6,000,000	6,000,000	6,000,000	–
NCRR	171,012,000	171,012,000	176,550,000	5,538,000
NCCAM	2,441,000	2,441,000	1,641,000	-800,000
FIC	24,356,000	24,356,000	25,932,000	1,576,000
NLM	7,683,000	7,683,000	8,243,000	560,000
OD	64,241,000	64,241,000	65,760,000	1,519,000
B&F	–	–	–	–
TOTAL, NIH	3,085,346,000	3,085,597,000	3,159,531,000	74,185,000

1/ Includes approximately $27 million to be provided to the Office of the Assistant Secretary of Health (OASH) in support of the National HIV/AIDS Strategy.

SUMMARY OF BUDGET BY MECHANISM

(Dollars in thousands)

MECHANISM	FY 2010 Actual		FY 2011 CR		FY 2012 PB 1/		Change vs. FY 2010	
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects								
Noncompeting	1,751	1,346,199	1,729	$1,274,937	1,708	$1,331,172	(43)	($15,027)
Administrative supplements	(24)	16,605	(5)	15,384	(8)	14,471	(32)	(2,134)
Competing	583	294,457	687	360,406	622	328,072	39	33,615
Subtotal, RPGs	2,334	1,657,261	2,416	1,650,727	2,330	1,673,715	(4)	16,454
SBIR/STTR	67	29,346	79	35,535	87	40,835	20	11,489
Subtotal, RPGs	2,401	1,686,607	2,495	1,686,262	2,417	1,714,550	16	27,943
Research Centers								
Specialized/comprehensive	66	143,547	69	132,944	87	133,104	21	(10,443)
Clinical research	0	55,027	1	55,127	1	55,127	1	100
Biotechnology	0	4,720	1	4,698	1	4,724	1	4
Comparative medicine	14	56,882	18	56,981	18	56,983	4	101
Research Centers in Minority Institutions	1	14,316	2	14,257	2	14,261	1	(55)
Subtotal, Centers	81	274,492	91	264,007	109	264,199	28	(10,293)
Other Research								
Research careers	248	42,364	237	41,385	237	41,726	(11)	(638)
Cancer education	0	0	0	0	0	0	0	0
Cooperative clinical research	13	20,687	12	18,326	20	20,239	7	(448)
Biomedical research support	0	1,717	1	1,710	1	1,710	1	(7)
Minority biomedical research support	1	140	1	141	1	142	0	2
Other	141	60,506	122	61,265	125	62,776	(16)	2,270
Subtotal, Other Research	403	125,414	373	122,827	384	126,593	(19)	1,179
Total Research Grants	2,885	2,086,513	2,959	2,073,096	2,910	2,105,341	25	18,828
Ruth L. Kirschstein Training Awards:	FTTPs		FTTPs				FTTPs	
Individual awards	86	3,541	86	3,528	86	3,568	0	27
Institutional awards	650	30,888	649	30,975	648	31,498	(2)	610
Total, Training	736	34,429	735	34,503	734	35,066	(2)	637
Research & development contracts	116	460,977	120	473,894	118	508,687	2	47,710
(SBIR/STTR)	(2)	(81,316)	(2)	(173)	(2)	(173)	(0)	(81,489)
Intramural research		313,648		314,147		317,749		4,101
Research management and support		125,538		125,716		126,928		1,390
Construction								0
Office of the Director		64,241		64,241		65,760		1,519
Total Budget Authority		3,085,346		3,085,597		3,159,531		74,185

1/ Includes approximately $27 million to be provided to the Office of the Assistant Secretary of Health (OASH) in support of the National HIV/AIDS Strategy.

Budget Authority by Activity

(Dollars in thousands)

Area of Emphasis	FY 2008 Actual	FY 2009 Actual	FY 2010 Actual	FY 2011 CR	FY 2012 PB 1/	Dollar Change
HIV Microbicides	$115,495	$128,670	$143,162	$143,162	$146,741	$3,579
Vaccines	556,139	560,956	534,972	534,972	551,021	16,049
Behavioral and Social Science	412,502	434,305	429,313	429,339	443,440	14,127
Therapeutics						
Treatment as Prevention	*74*	*85*	*68*	*65*	*69*	
Drug Discovery, Development, and Treatment	*698,387*	*670,476*	*684,923*	*685,151*	*699,983*	
Total, Therapeutics	698,461	670,561	684,991	685,216	700,052	15,061
Etiology and Pathogenesis	703,874	729,991	744,649	744,649	762,226	17,577
Natural History and Epidemiology	227,900	247,914	275,098	275,098	280,600	5,502
Training, Infrastructure, and Capacity Building	171,706	198,028	216,329	216,329	218,051	1,722
Information Dissemination	42,268	48,868	56,832	56,832	57,400	568
Total	2,928,345	3,019,293	3,085,346	3,085,597	3,159,531	74,185

1/ Includes approximately $27 million to be provided to the Office of the Assistant Secretary of Health (OASH) in support of the National HIV/AIDS Strategy.

World Health Organization

UNAIDS

Global estimates for adults and children, 2009

- **People living with HIV** **33.3 million** [31.4 million - 35.3 million]
- **New HIV infections in 2009** **2.6 million** [2.3 million - 2.8 million]
- **Deaths due to AIDS in 2009** **1.8 million** [1.6 million - 2.1 million]

Justification of Budget Request

OFFICE OF AIDS RESEARCH

Trans-NIHAIDS Research Budget Justification

Budget Authority:

FY 2010 Actual	FY 2011 Continuing Resolution	FY 2012 President's Budget	FY 2012+/- FY 2010
$3,085,346,000	$3,085,597,000	$3,159,531,000	$74,185,000

DIRECTOR'S OVERVIEW

New Scientific Advances and Opportunities: The past year has been a significant one for AIDS research. The NIH investment in the priority areas of HIV prevention research and in basic science over the past several years has reaped rewards resulting in important progress in critical areas of the NIH AIDS research program. Recent research advances by NIH intramural and extramural investigators have opened doors for new and exciting research opportunities in the search for strategies to prevent and treat HIV infection. All of these important advances, while preliminary and incremental, provide the groundwork for further scientific investigation and the building blocks for the development of this Trans-NIH AIDS research budget:

- An HIV vaccine clinical trial conducted in Thailand by NIH and the Department of Defense demonstrated the first indication of a modest but positive effect in preventing HIV infection. The trial marked the first step in proving the concept that a vaccine to prevent HIV infection is feasible.
- A team of scientists led by researchers at the NIAID Vaccine Research Center discovered two potent human antibodies that can stop more than 90 percent of known global HIV strains from infecting human cells in the laboratory and determined the structural analysis of how they work. The novel techniques used in this research may accelerate HIV vaccine research as well as the development of vaccines for other infectious diseases.
- A study conducted in South Africa with NIH infrastructure support demonstrated the first proof of concept for the feasibility of a microbicide gel that could prevent HIV transmission.
- A large international NIH clinical trial provided strong evidence that the use of pre-exposure prophylaxis, that is, the use of antiretroviral treatment before exposure to prevent infection, can reduce risk of HIV acquisition.
- Progress in both basic science and treatment research aimed at eliminating viral reservoirs has for the first time led scientists to plan and conduct research aimed at a cure.
- NIH-sponsored researchers made an important discovery related to the genetics of an individual's immune system that appear to offer some protection from disease progression among a group of individuals considered "elite controllers," who have been exposed to HIV

over an extended period, but whose immune systems have controlled the infection without therapy and without symptoms.

Mission: The Office of AIDS Research (OAR) coordinates the scientific, budgetary, legislative, and policy elements of the trans-NIH research program on AIDS and its wide spectrum of associated malignancies, co-infections, and clinical complications. OAR functions as an "institute without walls," vested with responsibility for all NIH AIDS-related research supported by every NIH Institute and Center. This diverse portfolio requires unprecedented trans-NIH planning, scientific priority setting, and resource management. OAR has established unique trans-NIH processes to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effectively to lead to the development of new tools for use in the global fight against AIDS.

The Pandemic: AIDS remains a global scourge that affects people in nearly every country worldwide. UNAIDS reports that in 2009, more than 33 million people were estimated to be living with HIV/AIDS; 2.6 million were newly infected; and 1.8 million people died of AIDS-related illnesses. In the U.S., more than 1.1 million people are estimated to be HIV-infected; and someone is infected with HIV every nine and a half minutes, disproportionately affecting racial and ethnic populations, women of color, young adults, and men who have sex with men. In 2008, an estimated 29 percent of HIV-infected adults in the U.S. were at least 50 years old, and individuals 50 years of age and older accounted for approximately 15 percent of all new HIV infections.

The National HIV/AIDS Strategy: In July 2010, the Administration released the first comprehensive *National HIV/AIDS Strategy for the United States.* The National HIV/AIDS Strategy (NHAS) was the result of unprecedented public input, including 14 HIV/AIDS community discussions held across the country, as well as an online suggestions process, various expert meetings and other inputs. Senior officials from the NIH were involved in the Federal interagency working group that reviewed recommendations from the public and worked with the Office of National AIDS Policy to develop the NHAS.

The National Strategy focuses on three overarching goals: reducing the number of new HIV infections, increasing access to care for people living with HIV and improving disease outcomes, reducing HIV-related health disparities, and achieving a more coordinated national response.

With the authority to direct and coordinate resources for HIV/AIDS research across NIH, OAR has a critical role to play in ensuring that NIH funding for domestic HIV/AIDS research focuses on projects that support the goals of the NHAS.

Trans-NIH Research Program: NIH has established the largest and most significant AIDS research program in the world, a comprehensive program of basic, clinical, translational, and behavioral and social sciences research in domestic and international settings. NIH-funded research has led to: the critical discovery of antiretroviral therapies and regimens that have resulted in improved life expectancy for those with access to and who can tolerate these drugs; the development of treatments for many HIV-associated co-infections, co-morbidities, malignancies, and clinical manifestations; advances in HIV prevention, including groundbreaking strategies for the prevention of mother-to-child transmission; safety of the blood

supply; and critical basic science discoveries that continue to provide the foundation for novel research. Despite these important advances, the epidemic continues to expand, and improved prevention strategies and therapeutic regimens are urgently needed.

The AIDS pandemic, the deadliest epidemic of our generation, will continue to wreak devastating consequences around the world for decades to come in virtually every sector of society. The OAR has utilized its unique authorities to shift AIDS research program priorities and resources to meet the changing epidemic and scientific opportunities. This investment in AIDS research has produced groundbreaking scientific advances. However, serious challenges lie ahead. NIH will continue to focus on the need for comprehensive strategies to decrease HIV transmission and improve treatment options and treatment outcomes in affected vulnerable populations in the U.S. and in international settings.

TRANS-NIH STRATEGIC PLAN AND BUDGET

OAR's trans-NIH planning process, involving both government and non-government experts, and representatives from community constituency groups results in the identification of clear, overarching AIDS-research priorities and specific research objectives and strategies. The priorities of the Plan guide the development of the trans-NIH AIDS research budget. OAR develops each IC's allocation based not on a formula but on the Plan, current scientific opportunities, and the IC's capacity to absorb and expend resources for the most meritorious science. This process reduces redundancy, promotes harmonization, and assures cross-Institute collaboration.

Critical AIDS Research Priorities: The overarching research priorities of the FY 2012 Trans-NIH Strategic Plan and this trans-NIH AIDS research budget request will establish the scientific foundation to achieve the goals of the President's National HIV/AIDS Strategy and also are aligned with the NIH Director's themes. They include:

- **Expanding Basic Discovery Research:** Research is needed to better understand the virus and how it causes disease, including studies to delineate how gender, age, ethnicity, and race influence vulnerability to infection and HIV disease progression. OAR will increase support for genetic studies and breakthroughs in sequencing the human genome, and for new opportunities to apply these valuable tools to the search for new HIV prevention and therapeutics strategies. OAR will also increase research on eliminating viral reservoirs toward identifying a cure.
- **Reducing New Infections:** Key prevention research areas include vaccines, microbicides, and behavioral and social science. Another critical area is the study of treatment strategies as a method to prevent new infections. These include: post-exposure prophylaxis, the use of treatment to prevent HIV infection after exposure, including in a healthcare environment; pre-exposure prophylaxis (PreP), the long-term use of treatment regimens for high-risk uninfected individuals to prevent HIV acquisition; and a potential prevention strategy known as "test and treat," to determine whether a community-wide testing program with immediate treatment can decrease the overall rate of new HIV infections in that community. A better understanding of biological-behavioral interactions will lead to the development of

combination prevention interventions that can be used in different populations, including adolescents and older individuals.

- **Improving Disease Outcomes:** A growing proportion of patients receiving long-term antiretroviral therapy (ART) are demonstrating treatment failure, experiencing serious drug toxicities and side effects, and developing drug resistance. Studies continue to show an increased incidence of malignancies, cardiovascular and metabolic complications, and premature aging associated with long-term HIV disease and ART. There is a need to develop better, less toxic treatments and to investigate how genetic determinants, sex, gender, race, age, nutritional status, treatment during pregnancy, and other factors interact to affect treatment success or failure and/or disease progression.
- **Reducing HIV-Related Disparities:** Research is needed to better understand the causes of HIV-related health disparities, their role in disease transmission and acquisition, and their impact on treatment access and effectiveness. These include disparities among racial and ethnic populations in the U.S.; between developed and resource-constrained nations; between men and women; between youth and older individuals; and disparities based on sexual identity. NIH will support research training for new investigators from racial and ethnic communities, development of research infrastructure, community outreach, information dissemination, and research collaborations to help reduce these disparities.
- **Translating Research from Bench to Bedside to Community:** Research will focus on analyses of the feasibility, effectiveness, and sustainability required for the scale-up and implementation of interventions from a structured behavioral or clinical study to a broader "real world" setting, including critical epidemiologic and natural history studies, collaborative networks, and specimen repositories to evaluate various operational strategies that can be employed to scale up and evaluate treatment programs and successful prevention interventions in communities at risk.

Global Impact of NIH AIDS Research: Research to address the global pandemic is essential. Since the early days of the epidemic, NIH has supported research efforts in countries affected by AIDS. Beginning in 1983 with a research project in Haiti, NIH has maintained a strong international AIDS research portfolio that now includes projects in approximately 100 countries around the world. AIDS research represents the largest component of the total NIH global research investment. NIH AIDS research studies are designed so that the results are relevant both to the host nation as well as for the U.S. Implementation studies are critical to translating clinical trial research results into community based interventions that can be operational in international settings. The development of research infrastructure, including training of scientists and healthcare providers, is an essential component of these research programs. Most of these grants and contracts are awarded to US-based investigators to conduct research in collaboration with in-country scientists; some are awarded directly to investigators in international scientific or medical institutions.

AIDS Research Conducted in International Settings
(Dollars in millions)

FY 2010 Actual	FY 2011 CR	FY 2012 PB
$485.607	**$485.607**	**$489.384**

Overall Budget Policy: To address these priorities, the OAR FY 2012 President's Budget request for the trans-NIH AIDS research program is $3,159,531,000 which represents an increase of $74,185,000 and 2.4% over the FY 2010 Actual. This amount includes the total trans-NIH support for intramural and extramural research for basic, clinical, behavioral, social science, and translational research on HIV/AIDS and the wide spectrum of AIDS-associated malignancies, opportunistic infections, co-infections, and clinical complications; as well as research management support; research centers; and training. Descriptions and accomplishments in each program area follow. Also included in this amount is about $27 million to be transferred to the Office of the Assistant Secretary of Health (OASH) in support of the National HIV/AIDS Strategy.

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HIV MICROBICIDES

Microbicides are antimicrobial and other products that could be applied topically or orally as pre-exposure prophylaxis (oral PrEP), alone or in combination with other strategies, for the potential prevention of HIV and other sexually transmitted infections. These products may represent promising primary prevention interventions. NIH supports a comprehensive and innovative microbicide research program that includes the screening, discovery, development, preclinical testing, and clinical evaluation of microbicide candidates; basic science aimed at understanding how HIV transverses mucosal membranes and infects cells; behavioral and social science research on adherence to and acceptability and use of microbicides among different populations; studies of the safety of microbicide use during pregnancy; and implementation research to better understand how to integrate a potential product into community prevention practices.

Budget Policy: The FY 2012 President's Budget request for Microbicides is $146,741,000 which represents an increase of $3,579,000 and 2.5% over the FY 2010 Actual for this high priority area of research. In FY 2012, NIH will continue to support the discovery, design, development, and evaluation of microbicide candidates. Key ongoing activities include support for the microbicide clinical trials network and the necessary infrastructure to conduct microbicide trials and oral PrEP trials, especially to build on recent research advances; development of innovative, novel, and high risk-high reward approaches for the development and testing of microbicide candidates; the development of criteria for selecting potential products to be evaluated in clinical trials and for advancing them through the different phases of preclinical and clinical studies; and research on ethical, adherence, and other behavioral and social science research issues that can impact these clinical trials. A number of trans-governmental working groups, non-governmental expert meetings, conferences, and workshops will be supported to foster coordination and collaboration in innovative microbicide research that will lead to the development and testing of novel potential candidates that prevent HIV transmission and acquisition.

VACCINES

The best long-term hope for controlling the AIDS pandemic is the development of safe, effective, and affordable AIDS vaccines that may be used in combination with other prevention strategies. AIDS vaccine research remains a high priority to ensure that new and innovative concepts continue to be tested. NIH supports a broad AIDS vaccine research portfolio encompassing basic, preclinical, and clinical research including studies to identify and better understand potentially protective immune responses in HIV-infected individuals and studies of

improved animal models for the preclinical evaluation of vaccine candidates. Information gained from these studies is being used to inform the design and development of novel vaccine strategies. The recent release of data from several vaccine clinical studies presents new scientific opportunities for investigation that will require realignment of resources.

Budget Policy: The FY 2012 President's Budget request for Vaccines is $551,021,000, an increase of $16,049,000 and 3.0% over the FY 2010 Actual. Basic research studies, particularly those using samples from the clinical trials, are critically needed on the virus and host immune responses that can inform the development of new and innovative vaccine concepts; as well as the development of improved animal models to conduct pre-clinical evaluations of vaccine candidates. In FY 2012, NIH will fund additional basic research on HIV and host immune responses, as well as the design and development of new vaccine concepts and the pre-clinical/clinical development of vaccine candidates in the pipeline. Resources will be directed toward the development and testing of improved products in additional clinical studies, both in the U.S. and abroad, building on the results of the recent Phase III vaccine trial in Thailand. This also includes support for new initiatives to integrate systems biology with HIV vaccine discovery and for additional research involving non-human primates.

BEHAVIORAL AND SOCIAL SCIENCE

NIH supports research to better understand how to change the risk behaviors that lead to HIV infection and disease progression, as well as how to maintain protective behaviors once they are adopted. Studies develop and evaluate interventions directly targeting the substance abuse and sexual behaviors associated with HIV transmission. Other research aims toward better understanding and changing the environmental, social and cultural factors associated with HIV infection and disease outcomes, including stigma. Determining effective strategies to test HIV-infected persons, link them to care, and promote adherence to antiretroviral therapy is another important area of research. Comprehensive approaches that integrate biomedical and behavioral science perspectives are necessary to develop the needed range of preventive and therapeutic strategies. NIH also supports research to improve behavioral methodologies, including ways to improve recruitment into clinical trials, to enhance statistical analysis of behaviors such as alcohol use that can affect medication studies, or to characterize behavioral traits relevant to genetic or genomic studies.

Budget Policy: The FY 2012 President's Budget request for Behavioral and Social Science is $443,440,000 which is an increase of $14,127,000 and 3.3% over the FY 2010 Actual. NIH will continue to fund research to develop and evaluate effective interventions to prevent HIV transmission and acquisition by reducing HIV-related risk behaviors and increasing protective behaviors. Resources will be directed toward several new prevention initiatives, including studies integrating behavioral and social science methods with biomedical prevention strategies, community-based approaches to engaging and retaining persons in care, and the impact of improved care on reducing HIV transmission.

THERAPEUTICS

Antiretroviral treatment (ART) has resulted in improved immune function in patients who are able to adhere to the treatment regimens and tolerate the toxicities and side effects associated with antiretroviral drugs; and it has delayed the progression of HIV disease to the development of AIDS. However, an increasing number of patients receiving long-term antiretroviral therapy are demonstrating treatment failure, experiencing serious drug toxicities, and developing drug resistance. Recent epidemiologic studies continue to show an increasing incidence of co-infections, co-morbidities, AIDS-defining and non-AIDS defining malignancies, and complications associated with long-term HIV disease and ART, including tuberculosis, Hepatitis C, metabolic disorders, cardiovascular disease, conditions associated with aging, and neurologic and neurocognitive disorders. NIH supports a comprehensive therapeutics research program to design, develop, and test drugs and drug regimens to maintain long-term undetectable viral load, overcome drug resistance and treatment failure, prevent and treat HIV-associated co-morbidities and complications, and eradicate persistent viral reservoirs that may lead to a potential or functional cure for HIV disease.

Budget Policy: The FY 2012 President's Budget request for Therapeutics is $700,052,000, which represents an increase of $15,061,000 and 2.2% over the FY 2010 Actual. The increase in funding for therapeutics research will be less than other areas to allow for increased funding for HIV prevention science research. A portion of the funds from expiring grants and contracts for therapeutics research will be re-allocated to studies on the treatment and prevention of HIV-associated co-infections and co-morbidities and to support crucial basic research on HIV, genomics studies on the host immune response to HIV, and development and clinical testing of potential microbicides and behavioral and social science interventions. Resources within the area of Therapeutics also will be directed to several new and/or expanded initiatives for developing innovative therapies to control and eradicate HIV infection that may lead to a cure; identifying new drug targets based on the structure of HIV/host complexes; delineating the interaction of aging and neuro-AIDS; and discovering the next generation of drugs that may be used in potential "treatment as prevention" strategies.

Treatment as Prevention: A critical new area of prevention research is the study of treatment strategies as a method to prevent new HIV infections. This approach builds on NIH-sponsored landmark clinical trials that successfully demonstrated that treatment of HIV-infected pregnant women could significantly reduce transmission of HIV from mother to child. Strategies currently being investigated include: post-exposure prophylaxis, the use of treatment to prevent HIV infection after accidental exposure, including in a healthcare environment; pre-exposure prophylaxis (PrEP), the long-term use of treatment regimens for high-risk uninfected populations

to prevent HIV acquisition; and a potential innovative prevention strategy known as "test and treat," to determine whether a community-wide HIV testing and counseling program with immediate treatment for HIV-infected individuals can decrease the overall rate of new HIV infections in that community.

ETIOLOGY AND PATHOGENESIS

NIH supports a comprehensive portfolio of research focused on gaining a better understanding of how HIV infection is established and maintained and what causes the associated profound immune deficiency and severe clinical complications. Research on basic HIV biology and AIDS pathogenesis has revolutionized the design of drugs, methodologies for diagnosis, and monitoring of the safety and effectiveness of antiviral therapies. Ground-breaking strides have been made towards understanding the fundamental steps in the life-cycle of HIV, the host-virus interactions, and the clinical manifestations associated with HIV infection and AIDS. Additional research is needed to further the understanding of the virus and how it causes disease, including studies to delineate how sex, gender, age, ethnicity, race, pregnancy, nutritional status, and other factors interact to affect treatment success or failure and influence vulnerability to infection and HIV-disease progression, including the development of HIV-associated comorbidities, malignancies and coinfections. Additional studies of the genetic determinants associated with HIV susceptibility, disease progression and treatment response may lead to the development of customized therapeutic and preventive regimens formulated for an individual patient based on his or her genetic sequence. A gene sequence associated with adverse reactions to the drug abacavir already has been identified. This finding led the FDA to recommend that doctors conduct genetic screening before prescribing abacavir to patients. Research examining the mechanisms by which HIV establishes and reactivates latent reservoirs of infection is a high priority for the NIH. A better understanding of these processes could lead to the development of therapies that eradicate persistent viral reservoirs. Some have speculated that the eradication of these reservoirs might provide a cure for HIV disease.

Budget Policy: The FY 2012 President's Budget request for Etiology and Pathogenesis is $762,226,000, which is an increase of $17,577,000 and 2.4% over the FY 2010 Actual. The results from recent microbicide and vaccine clinical studies have revealed gaps in knowledge and understanding of HIV etiology and pathogenesis, particularly with regard to host immune responses, how HIV interacts with and transverses mucosal surfaces, and the establishment and maintenance of latent viral reservoirs. The amount requested includes funding for research on the biology of HIV transmission and pathogenesis, including studies on co-infections, malignancies, premature aging, and other complications.

NATURAL HISTORY AND EPIDEMIOLOGY

Natural history and epidemiologic research is essential for monitoring epidemic trends, developing and evaluating prevention modalities, following the changing clinical manifestations of HIV disease in different populations, and measuring the effects of treatment regimens. NIH supports research in domestic and international settings to examine HIV transmission, HIV disease progression (including the occurrence of co-infections and opportunistic infections, malignancies, metabolic, cardiovascular, neurological, and other complications), the development of other HIV-related conditions, and improved methodologies to support this research. Epidemiologic research is instrumental in identifying and describing AIDS-related co-morbidities, disentangling effects related to treatment from those related to HIV disease itself. As the AIDS epidemic continues to evolve, there is a crucial need to continue to conduct epidemiologic studies in both domestic and international settings. These studies have delineated the significant health disparities that are critical factors in the epidemic. These include racial and ethnic disparities in the U.S.; disparities between developed and resource-constrained nations; disparities between men and women; disparities within younger and older age groups; and health disparities based on sexual identity. NIH will continue to place high priority on understanding the causes of HIV-related health disparities, both in the United States and around the world, their role in disease transmission and acquisition, and their impact on treatment access and effectiveness.

Budget Policy: The FY 2012 President's Budget request for Natural History and Epidemiology is $280,600,000, which represents an increase of $5,502,000 and 2.0% above the FY 2010 Actual. NIH will continue to provide support for high-priority epidemiology studies of groups and populations affected by HIV and at high risk of infection, including individuals over fifty years of age, men who have sex with men (MSM), especially MSM of color, and adolescents. NIH also will increase support for critical studies on the mechanisms of disease progression, the specific role of race and gender, the effects of increased HIV testing and linkage to care on HIV transmission and disease progression, the impact of therapy in changing the spectrum of HIV disease, and the causes of death. In addition, resources will be directed towards implementation/operational science including the evaluation of strategies to scale-up efficacious and cost-effective interventions to the community level.

TRAINING, INFRASTRUCTURE, AND CAPACITY BUILDING

NIH supports the training of domestic and international biomedical and behavioral AIDS researchers, and provides support for the equipment necessary for the conduct of AIDS-related research and clinical studies. The expansion of NIH-funded HIV research globally has necessitated the development of research infrastructure in many locations, including resource-

limited settings in Africa, the Caribbean, India, and Asia. Numerous NIH funded programs have increased the number of training positions for AIDS-related researchers, including programs specifically designed to recruit individuals from underrepresented populations into research careers and to build research infrastructure at minority-serving institutions in the United States.

Budget Policy: The FY 2012 President's Budget request for Training, Infrastructure, and Capacity Building is $218,051,000, which represents an increase of $1,722,000 and 0.8% above the FY 2010 Actual. NIH will continue to support ongoing efforts to increase the supply of non-human primates, particularly rhesus macaques, for AIDS research and other areas of biomedical research both in the United States and abroad. NIH also will support training programs for U.S. and international researchers to build the critical capacity to conduct AIDS research both in racial and ethnic communities in the United States and in developing countries. Support also will be provided for the NIH AIDS Research Loan Repayment Program and the Intramural AIDS Research Fellowship program that will help ensure an adequate number of trained AIDS researchers at NIH.

INFORMATION DISSEMINATION

Effective information dissemination approaches are integral to HIV prevention and treatment efforts and critical in light of the continuing advent of new and complex antiretroviral treatment regimens, issues related to adherence to prescribed treatments, and the need to translate behavioral and social prevention approaches into practice. The changing pandemic and the increasing incidence of HIV infection in specific population groups in the United States, such as racial and ethnic populations, men who have sex with men, and women, underscore the need to disseminate HIV research findings and other related information to communities at risk. The flow of information among researchers, health care providers, and the affected communities represents new opportunities to rapidly translate research results into practice and to shape future research directions. NIH supports initiatives to enhance dissemination of research findings; develop and distribute state-of-the art treatment guidelines; and enhance recruitment and retention of participants in clinical studies, including women, adolescents, and racial and ethnic populations.

Budget Policy: The FY 2012 President's Budget request for Information Dissemination is $57,400,000, which represents an increase of $568,000 and 1.0% above the FY 2010 Actual. As the number and complexity of clinical studies increases, resources must be invested in clinical trials-related information dissemination to ensure recruitment of an adequate number of participants, particularly from populations at risk, including women and racial and ethnic populations in the United States. In addition, funding will be provided to ensure that critical federal guidelines on the use of antiretroviral therapy, as well as guidelines for the management of HIV complications for adults and children, will be updated regularly and disseminated to healthcare providers and patients through the *AIDSinfo* website (www.aidsinfo.nih.gov).

Benefits to other areas of research: Because of the unique nature of HIV--the way the virus enters a cell, causes infection, affects every organ system, and unleashes a myriad of opportunistic infections, comorbidities, cancers, and other complications--and the pace at which the knowledge base has been expanded, AIDS research also is helping to unravel the mysteries surrounding many other infectious, malignant, neurologic, autoimmune, and metabolic diseases, as well as complex issues of aging and dementia. Basic knowledge of the biology of HIV infection and the processes by which it causes disease benefits other areas of basic research including immunology, virology, microbiology, molecular biology, and genetics. AIDS research has provided an entirely new paradigm for drug design, development, and clinical trials to treat viral infections and to address the special recruitment requirements of women, minorities, and other underserved and at-risk populations. Drugs developed to prevent and treat AIDS-associated opportunistic infections also now benefit patients undergoing cancer chemotherapy or receiving anti-transplant rejection therapy; and AIDS research is providing a new understanding of the relationship between viruses and cancer.