

## NARRATIVE BY ACTIVITY

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

### National Institutes of Health

( dollars in millions)

	<b>FY 2009 Omnibus</b>	<b>FY 2009 Recovery Act</b>	<b>FY 2010 Enacted</b>	<b>FY 2011 Estimate</b>	<b>Change from FY 2010 Enacted</b>
<b>Labor/HHS Discretionary Budget Authority (B.A.)</b>	<b>\$30,318</b>	<b>\$10,381</b>	<b>\$31,010</b>	<b>\$32,007</b>	<b>\$997</b>
Interior B.A.	\$78	\$19	\$79	\$82	\$3
<b>Total Discretionary B.A.</b>	<b>\$30,396</b>	<b>\$10,400</b>	<b>\$31,089</b>	<b>\$32,089</b>	<b>\$1,000</b>
Type I Diabetes Initiative	\$150	\$0	\$150	\$150	\$0
Total B. A.	\$30,546	\$10,400	\$31,239	\$32,239	\$1,000
NIH Program Level 1/	\$30,554	\$10,400	\$31,247	\$32,247	\$1,000
<i>Number of Competing RPGs</i>	<i>9,111</i>	<i>7,741</i>	<i>9,251</i>	<i>9,052</i>	<i>-199</i>
<i>Total Number of RPGs</i>	<i>37,068</i>	<i>13,226</i>	<i>36,806</i>	<i>37,001</i>	<i>195</i>
<i>FTEs</i>	<i>17,922</i>	<i>N/A</i>	<i>17,886</i>	<i>18,784</i>	<i>+898</i>

1/ Includes NLM Program Evaluation of \$8.2 million each year.

This document provides justification for the fiscal year (FY) 2011 activities of the National Institutes of Health. Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/ Intramural and Other.

### General Overview

Major advances in science are occurring more rapidly than ever before, and hold the promise to provide solutions to a long list of problems that confront our Nation and our world. Nowhere are the opportunities more compelling than in biomedical research; and, nowhere are the capabilities of making major biomedical advances stronger than at the National Institutes of Health (NIH).

The unprecedented power of the molecular approach to health and disease has steadily gained momentum over the past several decades, and is now poised to catalyze a true revolution in medicine with profound consequences for diagnosis, prevention, and treatment of virtually all diseases. The success of the Human Genome Project and several follow-on projects provided a powerful foundation for a new level of understanding of human biology. The revelation of hundreds of previously unknown risk factors for cancer, diabetes, heart disease, hypertension, and a long list of other common illnesses now make effective treatments more approachable. A new ability to achieve comprehensive understanding of the

mechanisms responsible for cancer has already provided insights into diagnostics and a new array of drug targets.

Recent breakthroughs in stem cell research hold great promise for applications to diseases like Parkinson's disease, type-1 diabetes, and spinal cord injury. New partnerships between academia and industry are revitalizing the flagging drug development pipeline. All these advances are leading to an era of personalized medicine, where prevention, diagnosis, and treatment of disease can be individualized, instead of using the existing, imprecise, one-size-fits-all approach. Vigorous U.S. support of biomedical research in all these areas promises to save lives, reduce the burden of chronic illness, stimulate the economy, empower new and more effective prevention strategies, and reduce health care costs.

## **The NIH Budget Request**

### ***Explanation by Scientific Opportunities***

The FY 2011 Discretionary Budget Authority request for NIH is \$32.089 billion, an increase of \$1 billion and 3.2 percent above the FY 2010 appropriation. Of this amount, \$32.007 billion is requested through the Labor/HHS/Education appropriation bill and \$81.8 million for Superfund Research activities through the Interior bill. These FY 2011 funds will enable the nationwide biomedical research community to pursue a number of substantial opportunities for major scientific and health advances. Five major areas build on NIH's recent advances that could reap substantial downstream benefits for the diagnosis, prevention, and treatment of a long list of diseases, both rare and common. These areas and specific increases for programs that fit within them are:

**Genomics and Other High Throughput Technologies:** In the past, most basic science projects in biomedicine required investigators to limit the scope of their studies to some aspect of genetics, cell biology, or physiology. The revolution now sweeping the field is the ability to be comprehensive – for example, to define *all* of the genes of the human or a model organism, *all* of the human proteins and their structures, or *all* of the major pathways for signal transduction in the cell. Technologies contributing to these advances, many of which became practical at scale only in the last few years, include DNA sequencing, microarray technology, nanotechnology, small molecule screening capabilities, new imaging modalities, and computational biology. These comprehensive approaches now hold the promise of major advances in the understanding of disease.

In FY 2011, NIH will direct \$382 million, a 6.0 percent increase, to the Administration's National Nanotechnology Initiative for efforts such as expanding nanomaterial characterization, broadening data dissemination, and optimizing scalable designs of nanosystems. This includes a unique NIH Nanomedicine Roadmap effort to analyze the nanoscale machinery in living cells with the explicit goal of using that information to

manipulate cellular networks for highly targeted correction of disease states. These projects engage engineers, physical scientists, biologists, clinical investigators and physicians to collaboratively conceptualize and implement novel strategies to mitigate disease and disability. NIH's investment will be one component of a Federal government effort to apply technological advancements to a wide array of human health, environmental protection, and safety issues and concerns.

## NANOTECHNOLOGY

(Dollars in Millions)

RCDC Category	FY 2009 Actual	FY 2010 Estimate	FY 2011 Estimate	FY 2009 Actual ARRA
<b>Nanotechnology</b> (published on RCDC web site) *	<b>\$ 342.7</b>	<b>\$360.6</b>	<b>\$ 382.4</b>	<b>\$ 73.4</b>
Nanotechnology - Fundamental nanoscale phenomena and processes	46.7	48.0	50.3	14.7
Nanotechnology - Instrumentation research, metrology, and standards for nanotechnology	17.5	18.0	18.6	4.4
Nanotechnology - Major research facilities and instrumentation acquisition	13.6	14.0	14.4	0.7
Nanotechnology - Nanomanufacturing	2.2	2.2	2.3	0.4
Nanotechnology - Nanomaterial	73.9	75.9	80.0	15.7
Nanotechnology - Nanoscale devices and systems	172.4	180.7	193.8	28.6
Nanotechnology - Societal Dimensions **	16.5	21.9	23.0	8.9
<i>Nanotechnology - Societal Dimensions - Environmental, Health and Safety Implications (non-add)</i>	<i>12.0</i>	<i>17.3</i>	<i>18.3</i>	<i>8.4</i>
<i>Nanotechnology - Societal Dimensions - Societal Dimensions other than EHS (non-add)</i>	<i>4.5</i>	<i>4.6</i>	<i>4.7</i>	<i>0.5</i>

\*/ Increase of a minimum of \$20.0 million over estimated FY 2010 level is reflected consistent with the Administration's government-wide nanotechnology investment plan.

\*\*/ The significant percentage increase in FY 2010 reflects the \$9.0 million increase specified in FY 2010 President's Budget. And supported through the overall FY 2010 appropriation.

### The Cancer Genome Atlas (TCGA) Reports First Results of Brain Tumor Analysis



Comprehensive genetic analysis of the most common and deadly brain tumor in adults, known as glioblastoma (GBM) successfully provided new insights into the roles of three cancer-related genes and the deregulation of major pathways in GBM, which may be informative in guiding future therapeutic decisions and approaches.

### Researchers use Nanotechnology to Make Synthetic HDL Cholesterol

Researchers engineered a synthetic HDL-like structure composed of a nanoparticle gold core bound by apolipoprotein A-I and phospholipids. The synthetic HDL is capable of binding cholesterol under physiologically relevant conditions and could



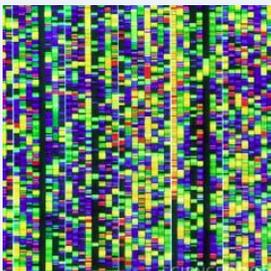
potentially be administered to patients to reduce cholesterol levels without the side-effects of current cholesterol lowering drugs.

**Translating Basic Science into New and Better Treatments:** Significant progress has been made in accelerating the discovery → development → treatment trajectory. Three major factors have contributed to this advancement: 1) the discovery of the fundamental basis of hundreds of diseases has advanced dramatically due to the application of new technologies; 2) academic investigators, supported by NIH, now can convert a fundamental observation about a disease to an assay used to screen hundreds of thousands of compounds for those most promising for drug development; 3) public-private partnerships in the drug development pipeline enable biotech and pharmaceutical companies to pursue promising compounds that have been effectively “de-risked” by expert academic NIH-supported investigators. Continued emphasis and funding are expected to reduce time limitations even further.

NIH will provide an additional \$26 million in FY 2011 to expand the *Therapeutics for Rare and Neglected Diseases (TRND)* program to a total of \$50 million. TRND will bridge the wide gap in time and resources that often exist between basic research and human testing of new drugs and encourage and speed the development of new drugs for rare and neglected diseases. This program is grounded in, but aims to improve upon, existing processes for drug development in the pharmaceutical industry.

The *Clinical and Translational Science Awards (CTSA)* award program will continue to see program growth for a total of \$500 million in FY 2011. The CTSA program originated in the NIH Common Fund and is currently administered/ funded by both the Common Fund and NCCR, which will assume sole responsibility by FY 2012.

#### **Determination of the First Complete DNA Sequence of a Human Cancer Genome**



Whole-genome sequencing was performed on tumor and normal tissue samples from a 50-year-old female acute myeloid leukemia (AML) patient. The study generated the first complete DNA sequence of a human cancer genome and identified new genes not previously associated with AML-demonstrating the utility of whole-genome tumor sequencing.

#### **Therapy for Fragile X Syndrome in Clinical Trial**

Children with fragile X syndrome have a variety of behavioral challenges including difficulties with attention, anxiety, and interpersonal relations. Based on early work that identified the protein that causes this disorder, a drug that blocks this protein's effect was identified and is now in a clinical trial as a potential therapy for this life-altering syndrome.



**Enable Health Reform:** Quality, affordable health care for all Americans cannot occur without significant advances in the underlying science that will enable better and more cost-effective treatments to be identified. Related projects that will be supported by NIH include: comparative effectiveness research; health disparities research; the identification of prevention and personalized medicine; pharmacogenomics; health economics research; and social and behavioral research.

The *Basic Behavioral and Social Sciences Opportunity Network (OppNet)*, launched by NIH in FY 2010 through funds provided by the American Recovery and Reinvestment Act, will receive \$20 million in FY 2011; these funds will be provided through 50 percent from the the Office of the Director and 50 percent across all the ICs. This trans-NIH initiative furthers our understanding of fundamental mechanisms and patterns of behavioral and social functioning relevant to the Nation's health and well-being, as they interact with each other, with biology, and the environment. Research results lead to new approaches for reducing risky behaviors and improving health.

**Focusing on Global Health:** NIH has a long and strong record in funding research efforts on AIDS, tuberculosis and malaria in order to reduce the enormous human toll from these common and life-threatening disorders. In FY 2011 NIH will provide \$300 million to the Global Fund for HIV/AIDs, Tuberculosis and Malaria, the same amount as the FY 2010 level. In addition, emphasis will be placed on research to develop strategies to affect the often neglected diseases of low-income countries that contribute to staggering levels of morbidity and mortality—diseases such as roundworm, elephantiasis, trachoma, leprosy, African sleeping sickness, and buruli ulcer. Collectively, these diseases affect about one billion people worldwide and result in almost a million deaths each year. In FY 2011, NIH, in partnership with other sources of support such as the Bill and Melinda Gates Foundation, will ramp up its efforts to facilitate advances in prevention, diagnostics, and therapeutics of diseases in the developing world.

#### ***Global Health Breakthrough***

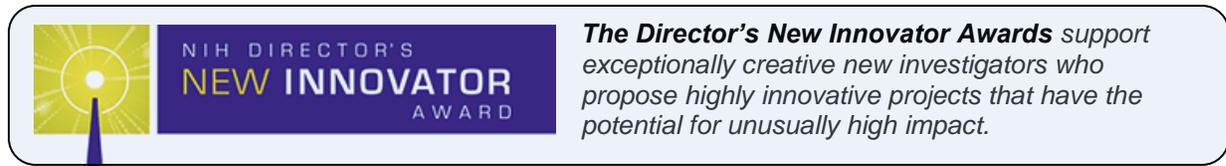


*NIH researchers have recently discovered a new potential drug to treat the parasitic disease, schistosomiasis, which causes chronic disease and impairs growth and development in children in tropical countries.*

#### **Reinvigorating the Biomedical Research Community**

Training a next generation of researchers: The lifeblood of biomedical research in the United States rests upon the talent and dedication of its scientists and the support of innovative research. Moreover, the success of biomedical research rests squarely on the robustness of NIH training programs for the next generation of scientists. These training programs must be managed effectively to support an evolving population of young scientists. Multiple issues must be addressed, which include enabling young scientists to pursue independent research, and redoubling minority training efforts to one day realize the goal of generating a scientific workforce that reflects the diversity of the nation.

The FY 2011 request includes an increase of 6.0 percent for training stipends, which translates into a total dollar level of \$824.4 million for *Ruth L. Kirschstein National Research Service Awards (NRSA)*.



**Essential Research Tools:** A promising tool for the biomedical research community is the *National Synchrotron Light Source-II (NSLS-II)*. NSLS-II will be a high-performance synchrotron light source — currently being constructed by the Department of Energy (DOE) Office of Basic Energy Sciences (DOE-BES) at the Brookhaven National Laboratory (BNL) — and it is expected to become operational around 2015. NIH has made a final commitment to DOE in the amount of \$45 million, and will focus its efforts on: 1) beam line optics and instrumentation specifications for future beam lines, and 2) management models on NSLS-II Life Sciences beam lines. In FY 2010, the National Center on Research Resources will provide \$12 million from their ARRA funds, and the remaining \$33 million will be contributed by NCRR in FY 2011.

NIH will also support the scientific research enterprise by providing inflationary increases of two percent for Research Project Grants (RPGs).

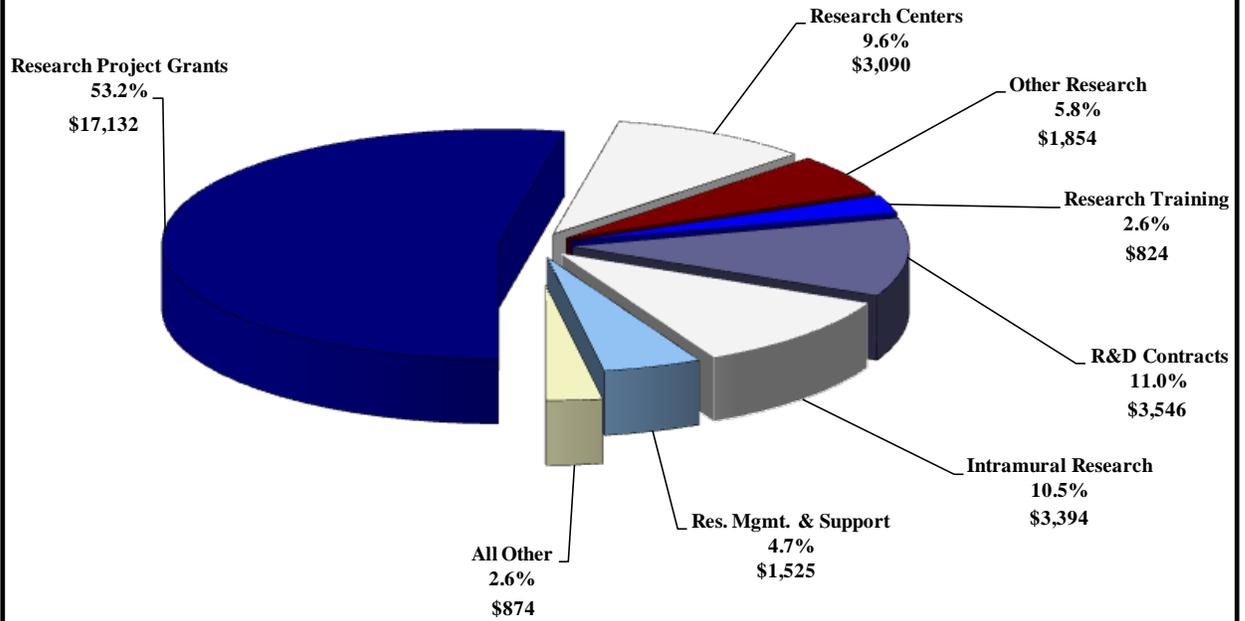
### **Cancer/Autism/HIV-AIDS Research Priorities**

**Cancer Research:** The NIH FY 2011 budget request will support a range of bold and innovative cancer research efforts, including the initiation of 30 new drug trials in FY 2011, and a doubling of the number of novel compounds in Phase 1 – 3 clinical trials by 2016. In addition, funds are provided for the completion of a comprehensive catalog of cancer mutations for the 20 most common malignancies, setting the stage for complete genomic characterization of every cancer as part of medical care within 10 years.

**Autism Spectrum Disorders (ASD):** In FY 2011 NIH will continue to pursue comprehensive and innovative approaches to defining the genetic and environmental factors that contribute to ASD, investigate epigenomic changes in the brain, and accelerate clinical trials of novel pharmacological and behavioral interventions by 2016.

**HIV/AIDS:** NIH has established the largest and most significant HIV/AIDS research program in the world. No other disease so thoroughly transcends every area of clinical medicine and basic scientific investigation, crossing the boundaries of the NIH Institutes and Centers. NIH will provide about \$3.2 billion for HIV/AIDS research, \$98.7 million or 3.2 percent above the 2010 enacted level. The Office of AIDS Research (OAR) has developed a distribution approach for these funds that reflects the most compelling scientific opportunities as determined by the NIH Working Groups and OAR's external advisors.

**FY 2011 President's Budget Request  
Total NIH Budget Authority  
\$32,239 Million**



## The NIH Budget Request

### Explanation by Mechanism

**Research Project Grants:** Research project grants (RPGs) are the primary mechanism for funding investigator-initiated biomedical research. These grants support new and experienced investigators in a wide array of research programs across 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 area of interest. Research project grants support medical research activities in areas of 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, accounts for 67 percent of RPGs awarded and approximately 66 percent of competing RPG funding (FY 2008 data). The R01 supports a single project with a principal investigator or co-investigators. Another frequently used award is the program project (P01), a multiproject 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: Support for RPGs remains a high priority in the FY 2011 Budget. This will enable NIH to maintain support for ongoing research and to support new researchers and new ideas to maintain the vitality of biomedical research.

The FY 2011 Budget would fund a total of 37,001 RPGs, an increase of \$ 533.3 million and 195 RPGs over the estimated FY 2010 level. Competing RPGs of 9,052 represent a decrease of 199 with a funding level of \$4.014 billion, a decrease of \$11.5 million or 0.3 percent below FY 2010. Due to the receipt of Recovery Act funds in FY 2009, NIH will temporarily suspend the NIH Director's Bridge Award program in FY 2011.

For noncompeting continuation awards, the FY 2011 Budget provides inflationary increases of 2.0 percent. The average cost of competing RPGs also increases by 2.0 percent over the FY 2010 level.

**Research Centers:** Research center grants are awarded to institutions on behalf of a program director and a group of collaborating investigators to provide long-term support for leading-edge research, to conduct multi-disciplinary programs of biomedical research, and to develop research resources. The centers program aims to integrate basic research with applied research and transfer activities; to promote research in the areas of clinical applications with an emphasis on intervention, including prototype development and refinement of products, techniques, processes, methods, and practices; to develop and maintain the biotechnology and research model resources needed by NIH-supported biomedical investigators for

conducting research; and to assist minority institutions in improving their research infrastructure.

Budget Policy: In the FY 2011 Budget, NIH proposes to increase support for research centers to \$3.090 billion, an increase of \$56.4 million or 1.9 percent above the FY 2010 level. NCRRC received \$10 million and will re-direct an additional \$10 million for the CTSA program. CTSA originated in the NIH Common Fund and is currently administered/funded by both the Common Fund and NCRRC, which will assume sole responsibility by FY 2012.

**Other Research:** NIH continues to support a variety of investigator-initiated activities through other research grants. Through the research careers program, NIH provides increased career opportunities in medical research to scientists of superior potential. The program provides support for 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 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 and serve to strengthen the research training capabilities of minority faculty and students. Other research funding also supports grants for shared resources for grantee institutions, for purchase of equipment, for implementation of the Nanotechnology program of the Common Fund using the flexible research authority, and for conference grants to support investigator-initiated meetings, conferences or workshops to promote sharing of scientific knowledge and to address specific issues.

Budget Policy: Support for Other Research increases by \$47 million, or 2.6 percent.

**Research Training:** The Ruth L. Kirschstein National Research Service Awards (NRSA) program serves 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. NRSA's also include funds for travel, fees, indirect costs, and other expenses. Stipend levels constitute the largest dollar portion of NRSA's.

Budget Policy: The FY 2011 budget request provides stipend increases of 6.0 percent resulting in a total of \$41.7 million over the FY 2010 level. At the FY 2011 budget request level, NIH will support 17,164 Full-Time Training Positions (FTTPs), 92 fewer than in FY 2010.

**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: R&D contracts increase by \$86.3 million, or 2.5 percent, compared to the FY 2010 level, for a total of \$3.546 billion. In FY 2009, NIH launched a new program called Therapeutic Rare and Neglected Diseases (TRND). This trans-NIH program will advance drug development for rare and neglected diseases by leveraging the chemical genomics centers created through the Common Fund. In FY 2011, funding increases by \$26 million, for a total program level of \$50 million in FY 2011. The Basic Behavioral and Social Sciences Opportunity Network (OppNet), launched by NIH in FY 2010 through funds provided by the American Recovery and Reinvestment Act, will receive \$20 million in FY 2011; these funds will be provided through a co-funding of 50/50 percent across all the ICs and the Office of the Director. NIH's contribution to the Department of Energy's construction of the National Synchrotron Light Source II will be \$33 million in FY 2011. The National Center on Research Resources provided \$12 million from their ARRA funds, and the remaining \$33 million contributed by the ICs in FY 2011 provides a total of \$45 million for this project. NIH will continue to provide \$300 million for the Global Fund for HIV/AIDS, Tuberculosis and Malaria. The FY 2011 budget increases the share of funds to be provided in the Department set-aside for Program Evaluation endeavors from 2.5 percent in FY 2010 to 2.86 percent in FY 2011.

**Intramural Research:** Through the intramural research program (IRP), the NIH conducts basic and clinical research at its on-campus research facilities in Bethesda, Maryland, and at such off-campus locations as the Gerontology Research Center in Baltimore, Maryland; Research Triangle Park, North Carolina; the Rocky Mountain laboratories in Hamilton, Montana; and Phoenix, Arizona. Fundamental research performed by intramural scientists provides the basis upon which advances in medical and dental care are built. An important byproduct of the research productivity is the cadre of young physicians and basic scientists who are trained in the techniques and approaches of intramural scientists. Many of these young researchers become extramural and intramural researchers. An invaluable and unique feature of the NIH 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 doing related research. This facilitates interaction and collaboration among clinicians and researchers. Most importantly, patients and families in the Clinical Center benefit from the cutting-edge technologies, research programs and the compassionate care, which are the signature of NIH.

The IRP supports vital research being conducted at the 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 complements and reinforces the work being carried out in the extramural program.

Budget Policy: In the FY 2011 budget, support for the NIH intramural research program would increase by 3.2 percent above the FY 2010 level, for a total of \$3.394 billion. This increase

maintains the intramural program to approximately 10 percent of NIH's overall budget. NIH's intramural research efforts have been responsible for countless medical advances, and NIH "in-house" scientists have received Nobel Prizes in recognition of their work.

**Research Management and Support:** This mechanism supports many functions, including scientific direction and management by NIH staff in the review, award, and performance monitoring of extramural awards (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; monitoring of advances emerging from basic science laboratories to determine possible clinical applications for treatment and prevention. Management and administrative functions for each IC are also supported by this mechanism. Examples of such functions include: interpreting, analyzing, and implementing new legislation, administrative orders; formulating and executing Institute budgets; performing management evaluation studies; determining manpower requirements; assessing the condition of both NIH and 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; providing the leadership and business functions for the IC.

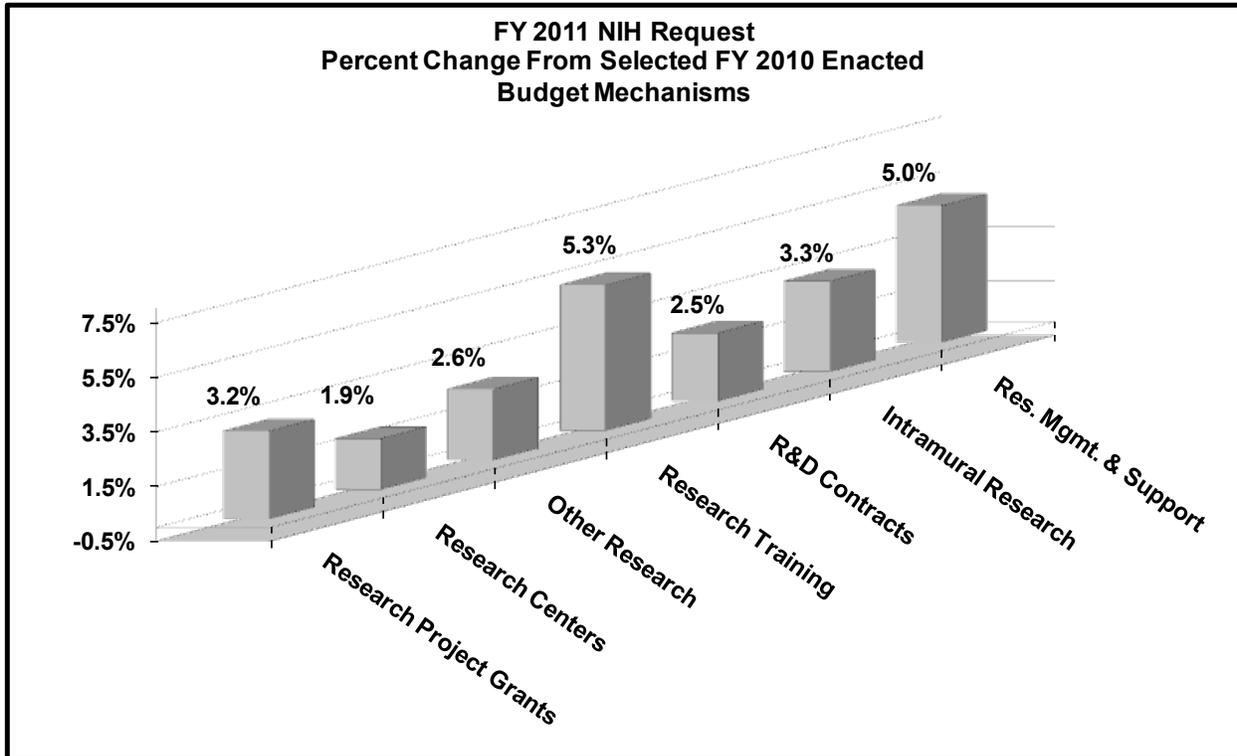
**Budget Policy:** For FY 2011, RMS would be funded at \$1.525 billion, an increase of \$72.6 million and 5.0 percent above the FY 2010 level. The complexity of science, e.g., genetic mapping, requires more high-level, hands-on, and state-of-the-art skilled managers of scientific portfolios. This increase will provide NIH with sufficient capacity to manage its research portfolios, and to improve stewardship of all funds. In addition, it will enable NIH to expand information technology infrastructure in support of scientific staff, support services for a prevention programs, and education initiatives.

**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, the 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 education functions; legislative activities; and oversight of the agency's stewardship of public funds.

The OD encourages and fosters NIH research and research training efforts in the prevention and treatment of disease through program coordination offices that complement the efforts of the NIH Institutes and Centers (ICs). 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 the OD provides the overall direction, coordination and oversight of these programs, the ICs manage the actual research operations.

Consistent with the FY 2010 Appropriation, the FY 2011 President's Budget for the OD reflects the total requested for the NIH Common Fund within this appropriation.

**Budget Policy:** The OD increases by \$43.5 million or 3.7 percent. The FY 2011 Request does not include funds for the NIH Director's Bridge Award program, as Recovery Act funds enabled NIH to support additional awards just missing the nominal payline. The NIH CF increases by \$17.5 million. A total of \$194 million is provided for the National Children's Study. Funds in the amount of \$10 million are included in the Office of Behavioral and Social Sciences Research to provide the OD's 50 percent of funding support for the Basic Behavioral and Social Sciences Opportunity Network (OppNet).



**Full Time Equivalents (FTEs)**

The workforce at NIH is one of its greatest assets and constitutes the largest collection of the brightest scientists and science managers in the world. This array of talent and systematic interdependence of scientific, programmatic, and administrative staff and missions have helped create NIH's success and its reputation as one of the world's leading biomedical research organizations. As the nature of science continues to change, the tools of administering that science must also change. NIH must ensure that it continues to meet these new opportunities with the best tools to attract and retain its staff, ensure the needed talent and skills, and plan for its future workforce needs. NIH will continue to require personnel to manage the research portfolio and recruit the best scientists to conduct world-class research.

	FY 2009 Actual	FY 2010 Enacted	FY 2011 President's Budget	Change FY 10/ FY11 P.B.
<b>Ceiling</b>	17,922	17,876	18,773	897
<b>Ceiling Exempt</b>	0	10	11	1
<b>Total NIH</b>	17,922	17,886	18,784	898

### Other Key Issues

#### **NCBI and Public Access Comparable Adjustments**

The FY 2009 and FY 2010 columns reflect base adjustments in the Institutes and Centers to centralize the public access and National Center for Biotechnology Information (NCBI) support in the National Library of Medicine (NLM). The NLM has operated these programs with additional support from the Institutes and Centers to enable NIH-funded authors to electronically submit their manuscripts, convert them to web-formatted documents and make them publicly available through the PubMed Central archive, as well as to keep pace with the increasing volume of genomic data and to support specific trans-NIH projects. NIH leadership believes that locating these program costs entirely within the NLM will allow for greater oversight and management of these vital programs.

#### **Science, Technology, Engineering, Mathematics (STEM) Education**

The Science, Technology, Engineering, and Mathematics (STEM) Education Coalition works to support STEM programs for teachers and students at the U. S. Department of Education, the National Science Foundation, and other agencies that offer STEM-related programs.

The STEM Education Coalition is composed of advocates from over 1,000 diverse groups representing all sectors of the technological workforce – from knowledge workers, to educators, to scientists, engineers, and technicians. The participating organizations of the STEM Education Coalition are dedicated to ensuring quality STEM education at all levels.

The table below represents the contributions of the National Institutes of Health to this program, which will help to both foster increased interests in the sciences and develop the next generation of researchers.

<b>FY 2009 - 2011 Budget Resources for STEM</b>			
(Dollars in Thousands)			
Program Title	2009 Actual Funding	2010 Appropriation Funding	2011 Estimate Funding
Science Education Drug Abuse Partnership Award	\$2,988	\$2,628	
Mind Over Matter on Prescription	80		

## FY 2009 - 2011 Budget Resources for STEM

(Dollars in Thousands)

Program Title	2009 Actual Funding	2010 Appropriation Funding	2011 Estimate Funding
Drugs			
Small Business Innovation Research Contracts	100	375	375
R25 Science Education Partnership Award (SEPA) [allocated 69% education	12,426	12,644	12,851
Mathematics and Science Cognition and Learning: Development and Disorders	9,483	9,739	10,031
Media-Smart Youth	400	400	400
OSE K-12 Science Education Program [budget less FTE payroll costs for 07-09]	2,717	2,742	2,977
Rx for Science Literacy	9	9	9
Summers of Discovery	242	242	250
STEER	571	570	577
Summer Supplements for HS Students and Undergraduates	-	34	35
Environmental Health Perspectives Student Edition	125	125	125
Diabetes-Based Science Education in Tribal Schools (DETS)	1,014	-	-
Diabetes Education Curriculum K-12 Schools	-	2,514	2,514
Short-Term Education Program for Minority Students (STEP-UP)	1,777	1,777	1,777
MedMyst Grant to Rice University (R25 AI062762; "MedMyst II: Middle School Infectious Disease Materials;" Leslie Miller, Principal Investigator - currently re-competing in FY08	230	223	-
Supplements to Promote Diversity in Biomedical Research	6,000	6,000	6,000
NIAID Science Education Award (R25)	123	123	-
R25 Science Education Partnership Award (SEPA) [allocated 31% outreach]	5,582	5,680	5,773
<b>TOTAL</b>	<b>\$43,867</b>	<b>\$45,825</b>	<b>\$43,694</b>
<b>Education</b>	<b>\$38,285</b>	<b>\$40,145</b>	<b>\$37,921</b>
<b>Outreach</b>	<b>\$5,582</b>	<b>\$5,680</b>	<b>\$5,773</b>

**FY 2011 HHS Enterprise Information Technology and  
Government-Wide E-Gov Initiatives**

**OPDIV Allocation Statement**

The **NIH** will use **\$12,483,803** of its **FY 2011** 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, **\$730,554** is allocated to developmental government-wide E-Government initiatives for **FY 2011**. This amount supports these government-wide E-Government initiatives as follows:

<b>FY 2011 Developmental E-Gov Initiatives*</b>	
Line of Business - Human Resources	\$34,579
Line of Business - Grants Management	\$55,911
Line of Business - Financial	\$18,063
Line of Business - Budget Formulation and Execution	\$12,000
Disaster Assistance Improvement Plan	\$75,000
Federal Health Architecture	\$535,000
<b>FY 2011 Developmental E-Gov Initiatives Total</b>	<b>\$730,554</b>

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

Prospective benefits from these initiatives are:

**Lines of Business-Human Resources Management:** Provides standardized and interoperable HR solutions utilizing common core functionality to support the strategic management of Human Capital. HHS has been selected as a Center of Excellence and will be leveraging its HR investments to provide services to other Federal agencies.

**Lines of Business-Grants Management:** 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.

**Lines 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.

**Lines 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):** The DAIP, managed by Department of Homeland Security, 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.

**Lines 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, **\$3,889,130** is allocated to ongoing government-wide E-Government initiatives for **FY 2011**. This amount supports these government-wide E-Government initiatives as follows:

<b>FY 2011 Ongoing E-Gov Initiatives*</b>	
Grants.Gov	\$3,225,282
Integrated Acquisition Environment	\$534,328
GovBenefits	\$129,520
<b>FY 2011 Ongoing E-Gov Initiatives Total</b>	<b>\$3,889,130</b>

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

**National Institutes of Health**  
**High-Priority Performance Goal**

**Biomedical Research**

**GOAL:** By 2011, reduce the fully-loaded cost of sequencing a human genome to \$25,000.

NIH conducts research to reduce the cost of genomic DNA sequencing which supports the use of advanced approaches in the comprehensive study of normal and disease-associated genetic variation in people. Research advances have enabled scientists to produce a reference sequence of the human genome (a map containing 99 percent of human genes), and to obtain the genomes of thousands of people to support genomic variation studies. Genomic DNA sequencing has become a core technology in contemporary biomedical research with many different applications. Sequencing the human genome would not have been possible without major reductions in the cost of DNA sequencing during the 1990s. In the 2000s, the continued decline in sequencing costs and the increased flexibility of next-generation technology have allowed many new uses for genomic sequencing in biomedical research. The National Institutes of Health (NIH) is committed to further reducing the cost of genomic DNA sequencing and enabling studies across the spectrum of human disease with the ability to identify important genomic variants underlying disease. This research may also support genome sequencing as a part of individual medical care to understand disease susceptibilities and to optimize treatment.

**Quarterly Measures and Milestones\***

Year	Baseline	Q1	Q2	Q3	Q4
<b>FY 2010</b>	Fully-loaded cost of sequencing a human genome is \$50,000			Increased data output from Illumina GA DNA sequencer from 50 gigabases/run to 100.	Increased data output from Applied Biosystems SOLiD DNA sequencer from 50 gigabases/run to 100.
<b>FY 2011</b>					Reduce the fully-loaded cost of sequencing a human genome to \$25,000

*\*milestones may be process or output indicators*

## National Institutes of Health

### American Recovery and Reinvestment Act (ARRA)

#### Summary of Obligations and Performance

The American Reinvestment and Recovery Act (Recovery Act) of 2009 is an effort to jumpstart our economy and create or save millions of jobs. NIH has received \$10.4 billion in total Recovery Act funding to foster research and infrastructure development through Scientific Research Programs, Extramural Construction Programs, Shared Instrumentation, Intramural Buildings and Facilities Programs, and Comparative Effectiveness Research Programs. NIH is committed to implementing the best possible approaches to ensure progress in an accelerated time frame with the most efficient and effective use of resources.

- Scientific Research Programs received \$8.2 billion in Recovery Act funds. NIH supports science advances through diverse programmatic strategies. These strategies stimulate science and provide resources for scientists across many areas of research. One strategy was to support meritorious applicants that previously could not be supported due to insufficient funds. Another strategy entailed Institutes identifying scientific priorities that can be funded through administrative supplements, which allows for accelerating the progress of a promising grant.

Finally, NIH has created new programs to spur novel areas of research. Challenge grants address specific scientific and health research challenge areas that will benefit from significant 2-year jumpstart funds. Challenge areas, defined by the NIH, focus on specific knowledge gaps, scientific opportunities, new technologies, data generation, or research methods that would benefit from an influx of funds to quickly advance the area in significant ways. Research in these areas should have a high impact in biomedical or behavioral science and/or public health.

Another new program is the Grand Opportunity Program, or “GO grants.” The GO program supports large-scale research projects that accelerate critical breakthroughs, early and applied research on cutting-edge technologies, and new approaches to improve the synergy and interactions among multi-disciplinary and interdisciplinary research teams. Applicants addressed either a specific research question or proposed the creation of a unique infrastructure/resource designed to accelerate scientific progress. These new programs and supplements seek to promote job creation and retention, as well as scientific progress by providing researchers the means to employ additional research staff.

- The Extramural Construction Program will award \$1 billion Recovery Act funds in FY 09-FY 10 to institutions that propose to construct, expand, remodel, renovate, or alter biomedical or behavioral research facilities. The improvements to the facilities will foster state of the art research. In addition, the awards are expected to create jobs for construction workers, engineers, architects, administrators, and scientists. Further job creation would include

industries that provide the materials (steel, brick, equipment, etc.) required to complete the construction project.

- The Shared Instrumentation program received \$300 million in Recovery Act funds to provide grants to academic institutions for advanced research tools, and capital equipment. The equipment is to be shared in order to utilize resources and to reduce waste. This enables more scientists to have current technologies which will likely enhance scientific discovery and support collaboration in ways that may accelerate research.
- The Buildings and Facilities Program received \$500 million in Recovery Act funds that will be used for high priority repair, construction and improvement projects on NIH research facilities to enable the highest quality science to be conducted. These activities will foster new jobs as well.
- Comparative Effectiveness Research received \$400 million in Recovery Act funds that will be used to support rigorous evaluation of different treatment option for a given medical condition for particular sets of patients. NIH supports this activity, but is not the lead agency.

### **NIH Summary Of Recovery Act Obligations**

*(dollars in millions)*

<b>ARRA IMPLEMENTATION PLAN</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2009 – FY 2010</b>
Scientific Research	\$4,607.2	\$3,592.8	\$8,200.0
Extramural Construction	\$52.1	\$947.9	\$1,000.0
Shared Implementation	\$52.7	\$247.3	\$300.0
Buildings and Facilities	\$49.7	\$450.3	\$500.0
Comparative Effectiveness Research	\$191.8	\$208.2	\$400.0
<b>Total Obligations</b>	<b>\$4,953.5</b>	<b>\$5,446.5</b>	<b>\$10,400.0</b>

More information on these and other Recovery Act programs can be found at [www.hhs.gov/recovery](http://www.hhs.gov/recovery) and <http://www.nih.gov/recovery>.

## NIH Recovery Act Measure Reporting

NIH uses a representative portfolio of measures as part of its strategy for reporting performance. As a result of the additional resources provided by the Recovery Act, the NIH has established new measures and targets to represent Recovery Act activities, which has been integrated into routine performance reporting. These measures include Recovery Act only measures tracked through Recovery.Gov, GPRA only measures tracked through the Online Performance Appendix (OPA) report, and a combined Recovery Act and GPRA measures tracked through both Recovery.Gov and the OPA. The measures integrated into the OPA are indicated by an “RA” after the measure identifier.

MEASURE IDENTIFIER	MEASURE DESCRIPTION	RESULTS AND TARGETS	REPORTING MECHANISM	IMPLEMENTATION PLAN
<b>ARRA Funded Measures Tracked through GPRA ONLY</b>				
SRO-1.5 (RA)	By 2012, develop a comprehensive IT platform that can facilitate evaluation of diverse behavioral interventions to promote health.	See OPA Table of Contents	GPRA/OPA	Scientific Research
SRO-1.6 (RA)	By 2012, present preliminary findings from the three-pronged approach to curtail the HIV pandemic.	See OPA Table of Contents	GPRA/OPA	Scientific Research
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.	See OPA Table of Contents	GPRA/OPA	Scientific Research
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.	See OPA Table of Contents	GPRA/OPA	Scientific Research
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.	See OPA Table of Contents	GPRA/OPA	Scientific Research
SRO-4.7 (RA)	By 2011, evaluate at least one novel animal model of type 1 diabetes.	See OPA Table of Contents	GPRA/OPA	Scientific Research
SRO-4.8 (RA)	By 2011, develop and/or test at least one strategy for improving end-of-life care or palliative care.	See OPA Table of Contents	GPRA/OPA	Scientific Research
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.	See OPA Table of Contents	GPRA/OPA	Scientific Research
SRO-4.10 (RA)	(By 2011, accelerate progress toward identifying relevant genomic alterations in 10 tumor types.	See OPA Table of Contents	GPRA/OPA	Scientific Research
SRO-4.11 (RA)	By 2011, analyze oral cancer genomes using high throughput methods to develop a blueprint of genetic alterations.	See OPA Table of Contents	GPRA/OPA	Scientific Research
SRO-4.12 (RA)	By 2011, demonstrate the feasibility of a new therapeutic strategy in a preclinical model of a neurological disease.	See OPA Table of Contents	GPRA/OPA	Scientific Research
SRO-7.8 (RA)	By 2011, create genomic resources to identify rare genetic variants that contribute to primary open angle glaucoma.	See OPA Table of Contents	GPRA/OPA	Scientific Research
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.	See OPA Table of Contents	GPRA/OPA	Scientific Research

MEASURE IDENTIFIER	MEASURE DESCRIPTION	RESULTS AND TARGETS	REPORTING MECHANISM	IMPLEMENTATION PLAN	
SRO-7.10 (RA)	By 2011, create a publically accessible database of cell images, videos, and animations from a variety of organisms to better understand the molecular and biochemical activities of cells and subcellular components, as well as on the role of cellular dysfunction in disease.	See OPA Table of Contents	GPRA/OPA	Scientific Research	
SRO-7.11 (RA)	By 2012, gather sufficient data to support the development of a national standard for normal fetal growth.	See OPA Table of Contents	GPRA/OPA	Scientific Research	
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.	See OPA Table of Contents	GPRA/OPA	Shared Instrumentation	
<b>ARRA Funded Measures Tracked through GPRA and Recovery.gov</b>					
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) Includes RA measure – Condition Index (weighted average) of NIH Facilities	See OPA Table of Contents	Recovery.Gov and GPRA/OPA	Buildings and Facilities	
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) Includes RA measure – Number of capital facility projects completed	See OPA Table of Contents	Recovery.Gov and GPRA/OPA	Buildings and Facilities	
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) Includes RA measure – Percent of construction projects completed in accordance with 10% variance of contract schedules	See OPA Table of Contents	Recovery.Gov and GPRA/OPA	Buildings and Facilities	
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. Includes RA measure – Number of Extramural Construction grants awarded	See OPA Table of Contents	Recovery.Gov and GPRA/OPA	Extramural Construction	
MEASURE IDENTIFIER	MEASURE DESCRIPTION	FY 2009 RESULTS <sup>1</sup>	FY 2010 TARGET	REPORTING MECHANISM	IMPLEMENTATION PLAN
<b>ARRA Funded Measures Tracked through Recovery.gov</b>					
SR-1	Number of New and Competing Research Project Grants (RPGs) awarded	Target: 6,722 Results: 4,928	957	Recovery.Gov	Scientific Research
SR-2	Number of administrative supplement awards made	Target: 2,076 Results: 6,567	1907	Recovery.Gov	Scientific Research
SR-3	Number of competitive revision awards made	Target: 539 Results: 405	122	Recovery.Gov	Scientific Research
SI-1	Number of shared equipment and instrumentation grants awarded	Target: 75 Results: 84	350	Recovery.Gov	Shared Instrumentation
CER-1	Number of meritorious grants awarded	Target: N/A Results: 166	50	Recovery.Gov	Comparative Effectiveness Research

1. Data Source: The number of grants, supplements, and grants awarded was determined using the NIH's QVR data system