



# **National Institutes of Health: Scientific Research**

The Recovery Act directly provided \$10 billion to the National Institutes of Health (NIH). This Implementation Plan focuses on the \$8.2 billion of Recovery Act funds provided to NIH to support the Scientific Research program.

# A. Funding Table

(Dollars in millions)

Program/ Project/Activity	Total Appropriated	FY 2009 Actual Obligations	FY 2010 Estimated Obligations	
National Cancer Institute	\$1,256.5	\$830.0	\$426.5	
National Heart, Lung and Blood Institute	\$762.6	\$415.1	\$347.5	
National Institute of Dental and Craniofacial Research	\$101.8	\$53.2	\$48.6	
National Institute of Diabetes and Digestive and Kidney Diseases	\$445.4	\$196.3	\$249.1	
National Institute of Neurological Disorders and Stroke	\$402.9	\$223.7	\$179.2	
National Institute of Allergy and Infectious Diseases	\$1,113.3	\$526.1	\$587.2	
National Institute of General Medical Sciences	\$505.2	\$303.7	\$201.5	
National Institute of Child Health and Human Development	\$327.4	\$136.0	\$191.4	
National Eye Institute	\$174.1	\$93.3	\$80.8	
National Institute of Environmental Health Sciences 1	\$187.4	\$102.9	\$84.5	
National Institute on Aging	\$273.3	\$149.4	\$123.9	
National Institute of Arthritis and Musculoskeletal and Skin Diseases	\$132.7	\$73.7	\$59.0	
National Institute on Deafness and Other Communication Disorders	\$103.0	\$73.5	\$29.5	
National Institute of Mental Health	\$366.8	\$200.9	\$165.9	
National Institute on Drug Abuse	\$261.2	\$135.9	\$125.3	
National Institute on Alcohol Abuse and Alcoholism	\$113.9	\$57.5	\$56.4	
National Institute of Nursing Research	\$35.9	\$17.0	\$18.9	
National Human Genome Research Institute	\$127.0	\$68.7	\$58.3	
National Institute of Biomedical Imaging and Bioengineering	\$77.9	\$41.5	\$36.4	
National Center for Research Resources	\$310.1	\$240.1	\$70.0	
National Center for Complementary and Alternative Medicine	\$31.7	\$16.8	\$14.9	
National Center on Minority Health and Health Disparities	\$52.1	\$32.1	\$20.0	
Fogarty International Center	\$17.4	\$10.3	\$7.1	
National Library of Medicine	\$83.6	\$37.7	\$45.9	
Common Fund	\$136.8	\$68.3	68.5	
Office of the Director	\$800.0	\$215.2	\$584.8	
Total	\$8,200.0	4,318.9	\$3,881.1	

<sup>1</sup> Includes Superfund





# **B.** Objectives:

Program Purpose: The National Institutes of Health (NIH) accomplishes its mission through one overarching program: research. NIH probes the unknown to gain new knowledge; communicates and transfers new knowledge to health care providers and the public; trains investigators; and manages and supports the people, systems, and facilities necessary to carry out this work. These activities are integral elements of the research enterprise with the goal of adding to the body of knowledge that will help prevent, detect, diagnose, and treat disease and disability. The NIH research mission is pursued by its Institutes and Centers (ICs), which support and conduct research in partnership with an extensive extramural research community and the NIH intramural research program.

Public Benefits: Recovery Act funds will produce benefits to the economy, to scientific knowledge, and ultimately aid in improving the health of the Nation through the award of grants, contracts and other activities that support biomedical research. The NIH Recovery Act Implementation Plan was developed to accomplish these objectives through a three-tiered approach; 1) NIH has developed new Recovery Act funding opportunity announcements to target specific areas of health research which exploit new technologies and other timely opportunities for growth and to cultivate a stronger biomedical research infrastructure; 2) additional resources have been devoted to NIH's established research programs, including meritorious research programs that previously could not be supported by NIH's base appropriation, to accelerate the pace of ongoing research; and 3) new investments have been made in programs that offer potentially transformative approaches to address major challenges in biomedical research.

#### C. Activities:

The three-tiered approach outlined above allowed NIH to begin distributing the Recovery Act appropriation in a thoughtful and deliberate manner within only four months of the Act's passage, achieving immediate economic relief for the biomedical research community and the vendors, manufacturers and other technical professionals reliant upon the Nation's thriving biomedical research industry for their livelihoods. The American biomedical research community responded to a series of ARRA funding announcements issued by the NIH Office of the Director with an overwhelming number of meritorious grant applications. NIH included in each of the funding announcements, and in the FY 2009 implementation plan, a conservative estimate of the minimum amount that would be awarded under each of these funding announcements from the ARRA funds appropriated to the Office of the Director (OD). In many cases, because of the large number of highly meritorious applications, the individual Institutes also elected to pay applications relevant to their specific missions. As a result, the funds awarded surpassed the original conservative estimates, particularly for the Competitive Revisions and Administrative Supplements, Summer Research Experiences for Students and Science Educators, Challenge Grants, and Grand Opportunity grants programs...





# In March 2009, NIH announced four programs to provide immediate benefits through Recovery Act funds:

- ARRA Payline Extension: Awarding highly meritorious applications (approximately \$1.4 billion awarded in FY 2009; additional awards will be made in FY 2010): NIH has provided funding support for peer-reviewed and approved, highly meritorious grant applications from investigators across the nation that were not funded in FY 2008, as well as grant applications that were not otherwise likely to be funded in FY 2009 or FY 2010.
- Competitive Revisions (NOT-OD-09-058) and Administrative Supplements (NOT-OD-09-056) (approximately \$1.7 billion awarded in FY 2009; additional awards will be made in FY 2010): NIH is expanding the scope and accelerating the tempo of ongoing science via NIH's supplement programs, through support of additional infrastructure (e.g., equipment costing less than \$100,000) and personnel support for new types of activities that fit into the structure of the Recovery Act.
- Summer Research Experiences for Students and Science Educators (NOT-OD-09-060) (approximately \$45 million awarded in FY 2009): This program provides summer jobs for high school/college students and teachers to work in science labs.

**NIH** also worked to develop new research programs specifically tailored to foster new research infrastructure and to achieve high-impact results within the short timeline of the Recovery Act initiative. Examples of the newly developed activities supported through the NIH Recovery Act programs include:

- Challenge Grants (RC1: RFA-OD-09-003) (\$371 million awarded in FY 2009; additional awards will be made in FY 2010): The NIH Recovery Act Challenge Grant program focuses on health and science problems, to include cancer and autism, where significant progress can be made in a two-year time frame.
- Grand Opportunity Program, or "GO grants" (RC2: RFA-OD-09-004) (\$550 million awarded in FY 2009; additional awards will be made in FY2010): The purpose of this program is to support high-impact ideas that require significant resources for a discrete period of time to lay the foundation for new fields of investigation.
- New Faculty Recruitment to Enhance Research Resources through Biomedical Research Core Centers (RFA-OD-09-005) (\$80 million awarded in FY 2009; additional awards will be made in FY 2010): NIH will support the recruitment of new faculty to conduct research at institutions across the country.
- Enabling National Networking of Scientists and Resource Discovery (U24: RFA-RR-09-009; \$14 million awarded in FY 2009; additional awards will be made in FY 2010):
  NIH is developing, enhancing, or extending infrastructure for connecting people and resources to facilitate national discovery of individuals and of scientific resources by scientists and students to encourage interdisciplinary collaboration and scientific exchange.





- Small Business Catalyst Awards for Accelerating Innovative Research (R43: RFA-OD-09-009; \$5 million to be awarded in FY 2010): NIH will support entrepreneurs of exceptional creativity, drawn from scientific and technological environments beyond NIH, who propose pioneering and possibly transformative approaches to addressing major biomedical or behavioral challenges with the potential for downstream commercial development.
- NIH Directors Opportunity for Research in Five Thematic Areas (RC4: RFA-OD-10-005; at least \$80 million to be awarded in FY 2010): NIH will develop and implement critical research innovations in five thematic areas.
- Academic Research Enhancement Award (R15: RFA-OD-09-007; at least \$20 million to be awarded in FY 2010): NIH is stimulating research in educational institutions that provide baccalaureate or advanced degrees for a significant number of the Nation's research scientists, but that have not been major recipients of NIH support.
- The NIH Director's ARRA Funded Pathfinder Award to Promote Diversity in the
   <u>Scientific Workforce (DP4: RFA-OD-10-013; at least \$10 million to be awarded in FY 2010)</u>: NIH will encourage exceptionally creative individual scientists to develop highly innovative and possibly transforming approaches for promoting diversity within the biomedical research workforce.
- Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies (BRDG-SPAN) Pilot Program (RC3: RFA-OD-09-008; at least \$35 million to be awarded in FY 2010): NIH will address the funding gap between promising research and development (R&D) activities and transitioning to the market by contributing to the critical funding needed by applicants to pursue the next appropriate milestone(s) toward ultimate commercialization; i.e. to carry out later stage research activities necessary to that end.

**Signature Initiatives:** NIH also identified a number of Signature Initiatives to support exceptionally creative and innovative projects and programs that represent potentially transformative approaches to major challenges in biomedical research. The initiatives cover new scientific opportunities in nanotechnology, genome-wide association studies, health disparities, arthritis, diabetes, autism, the genetic risk for Alzheimer's disease, regenerative medicine, oral fluids as biomarkers, and HIV vaccine research.

**Contract Actions:** NIH also is funding similar scientific research through contracts to help achieve the objectives of the Recovery Act, including accelerating the advance of scientific knowledge, achieving economic benefits and ultimately improving the health of the Nation. In FY 2009 NIH awarded \$360 million in competitive contracts, with additional contracts to be awarded in FY 2010.

#### D. Characteristics

NIH exploited a diverse array of funding mechanisms to execute the Recovery Act funds. The table below shows the estimated allocation of Recovery Act funding by mechanism.





(Note that this table includes only NIH Recovery Act funding related to scientific research.) NIH will obligate a significant amount through research project grant mechanisms and contracts. Over \$8 billion will be awarded extramurally by the end of FY 2010, primarily to universities, medical centers, hospitals and for-profit and non-profit research institutions throughout the country. NIH will allocate approximately \$335 million for administrative and intramural projects.

The NIH uses the peer review system to determine meritorious awards. NIH's peer-review policy is intended to ensure that grant applications submitted to the NIH are evaluated on the basis of merit. Various levels of review are utilized to show relevance to the scientific issue and the IC oversight.

Allocation of Recovery Act funding by Mechanism<sup>1</sup>

Allocation of Recovery Act funding by Mech		FY 2009/FY 2010			
	No.	Amount			
Research Grants					
Research Projects					
Noncompeting	4,543	\$2,035,989			
Administrative Supplements	(9,669)	1,459,433			
Competing	5,472	2,746,347			
Subtotal	10,015	6,241,769			
SBIR/STTR	159	64,624			
Subtotal, RPG	10,174	6,306,393			
Research Centers					
Specialized/Comprehensive	440	515,043			
Clinical Research	3	77,307			
Biotechnology	6	32,506			
Comparative Medicine	2	24,712			
Res. Centers in Minority Instit.	2	22,861			
Subtotal, Centers	453	672,429			
Other Research					
Research Careers	87	42,324			
Cancer Education	0	1,292			
Cooperative Clinical Research	43	35,270			
Biomedical Research Support	6	1,464			
Minority Biomed. Res. Support	0	16,163			
Other	128	121,891			
Subtotal, Other Research	264	218,404			
Total Research Grants	10,891	7,197,226			
Total Research Grants	10,091	7,197,220			
Training	FTTPs:				
Individual	177	6,935			
Institutional	213	23,522			
Total Training	390	30,457			
R&D Contracts	47	637,487			





	FY 2009/FY 2010		
	No.	Amount	
Intramural Research		81,594	
Res. Management & Support		253,236	
TOTAL		8,200,000	

# E. Delivery Schedule:

NIH published several major Funding Opportunity Announcements (FOAs) related to the Recovery Act by May 12, 2009. NIH began making Recovery Act awards for meritorious applications that were not funded in prior years beginning in April 2009, and will continue to make awards as meritorious applications are identified. NIH awarded Challenge Grants, GO grants and awards in August and September 2009. About half of the funding available for this activity was obligated in FY 2009, with the rest to be obligated in FY 2010.

March 2009	NIH began publishing Recovery Act-specific funding announcements
April 2009	NIH began awarding Recovery Act payline extension grants, supplements and competitive revisions
May-July 2009	Peer review was conducted for Challenge and GO Grants
August-Sept 2009	Council Review and awards issued for Challenge and GO Grants
January 2010	Council Review was carried out for the following Funding Opportunities:  BRDG-SPAN Pilot Program Small Business Catalyst Awards Recovery Act AREA Awards
Ongoing after March 2010	Awards issued for council reviewed and meritorious applications.  Progress reports received and reviewed for non-competing Recovery Act renewals; non-competing continuation awards obligated prior to the expiration of the initial award segment
May 2010 Council	Council Review for the following Funding Opportunities:  Building Sustainable Community-Linked Infrastructure
August 2010	Council Review for the following Funding Opportunities:  NIH Director's Pathfinder Award  NIH Director's Research in Five Thematic Areas





September 2010	Awards issued to obligate all remaining Recovery Act funds
	under the Scientific Research Appropriation

## F. Environmental Review Compliance

Consistent with the provisions of the National Environmental Policy Act (NEPA), NIH has procedures in place to ensure that Federal officials properly take into account potential environmental consequences when taking actions. Section 1609 (c) of the Recovery Act requires that the President report to the Senate Environment and Public Works Committee and the House Natural Resources Committee every 90 days following the date of enactment until September 30, 2011 on the status and progress of projects and activities funded by the Act with respect to compliance with NEPA requirements and documentation. The Council on Environmental Quality (CEQ) promulgated reporting requirements in a March 11, 2009 document that described specific procedures and a reporting template that NIH completes regularly and provides to the HHS Office of Facilities Management and Policy (OFMP).

Most research grants qualify for a categorical exclusion from detailed NEPA review, as promulgated in the Federal Register on January 19, 2000: "NIH is providing notice of the actions that will normally be categorically excluded from further environmental review because individually and cumulatively they will not have a significant effect on the human environment. If a proposed action is included in one of the categories but extraordinary circumstances as described in section D of this notice apply, an environmental review will be performed." In other words, whereas most research grants qualify for the categorical exclusion, NIH is required to conduct oversight to ensure that all proposals are reviewed for extraordinary circumstances or triggers that might warrant additional environmental review. To meet this responsibility, NIH has included NEPA related reviews in its award and progress reporting processes.

NIH has determined that the following are potential extraordinary circumstances:

- 1. Greater scope or size than other actions included within a category.
- 2. A threatened violation of a Federal, State, or local law established for protection of the environment or for public health and safety.
- 3. Potential effects of the action are unique or highly uncertain.
- 4. Use of especially hazardous substances or processes for which adequate and accepted controls and safeguards are unknown or not available.
- 5. Overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous wastes, etc)
- 6. Possible impact on endangered or threatened species.
- 7. Introduce new sources of hazardous/toxic wastes or require storage of wastes pending technology for safe disposal.
- 8. Introduce new sources of radiation or radioactive materials.
- 9. Substantial and reasonable controversy exists about the environment effects of the action.

In order to ensure a heightened awareness of the environmental aspects of Recovery Act, the Director of the Office of Research Facilities briefed the Extramural Program Management Committee on April 2, 2009; the Grants Management Advisory Committee





on June 17, 2009; and NIH Extramural Staff at large on July 31, 2009. The Categorical Exclusion is used for routine research grants, and we expect ARRA awards to follow a similar pattern.

#### G. Measures

This information will be available to the public on the Recovery Act website.

NIH is using the following measures for this program:

Outcome / Achievement	Units	Туре	9/30/09	12/31/09	3/31/10	6/30/10	9/30/10	Program End
Number of New and Competing Research	#	TARGET	6,722	5,053	5,116	5,315	7,679	
Project Grants (RPGs) awarded.		ACTUAL	5,071	5,079	5,159			
Number of administrative	#	TARGET	2,076	7,095	7,838	9,125	3,983	
supplement awards made.		ACTUAL	7,005	7,416	8,086			
Number of competitive.	#	TARGET	539	409	414	431	661	
revision awards made		ACTUAL	414	417	423			
Number of non competing.	#	TARGET			72	2,177	4,801	
continuation awards made		ACTUAL			61			
Number of	ш	TARGET	6,722				7,679	
Jobs Created or Retained	#	ACTUAL	4,921	12,338	16,953			

The actual number of awards reported above reflect data on awards made by the specific issuance date in NIH's Information for Management, Planning, Analysis and Coordination System v.2 (IMPAC2) database. Targets reflect analysis of actual awards made to date by type of grant award, as well as detailed reporting by individual Institute/Center on anticipated awards by grant type for the remainder of FY 2010. The actual average size of ARRA awards made in FY 2009 was larger than the standard award size NIH used when calculating the original targets, resulting in a downward adjustment in the number of awards anticipated for research project grants and competing revision awards. The increased average size of ARRA awards acknowledges





the loss of purchase power experienced in prior years when NIH experienced increasing differences between the inflation rate and annual budget increases. NIH will obligate all ARRA funds by 9/30/10 by issuing new and competing awards in response to the FY 2010 FOAs, continuing to award highly meritorious applications received in response to non-ARRA FOA's, as well as making additional administrative supplement and competing revision awards.

NIH has also developed the following outcome performance objectives, set forth in GPRA plans, to assess the performance of Recovery Act activities beyond 2010. Given the breadth of science covered in the Scientific Research program, these outcome measures are illustrative of the program.

Performance Objectives				FY 2010	
	Type	Frequency	Unit	Target	Target
Take advantage of advances in genomics research and high-throughput technologies to understand the fundamentals of biology and the causes of specific diseases.	Outcome	Yearly	GPRA Performance Target	Develop tools and resources for the study of prevalent diseases using genetic and genomic methods.	Use the newly developed tools and resources to advance the research into the underlying causes of prevalent diseases.
Use new discoveries about health and disease to develop diagnostics, prevention, and therapies.	Outcome	Yearly	GPRA Performance Target	Identify therapeutic strategies and initiate characterization of stem cell models for the treatment of major diseases such as diabetes, cardiovascular disease, autism spectrum disorders and neurodegenerative diseases.	Demonstrate the therapeutic feasibility of the identified strategies and refine the stem cell models for future use in therapeutics.
Put science to work for the benefit of health care and reform	Outcome	Yearly	GPRA Performance Target	Initiate development of at least five tools and resources to facilitate health care throughout the course of a patient's life.	Finalize development and begin testing the tools and resources identified in 2010.

Examples of specific performance targets related to the performance objective listed under advances in genomics include:

- Initiate genome sequencing of 10,000 well-phenotyped patients with various diseases and their matched controls (12/31/10);
- Deposit the results of the high-throughput genome sequencing for 10,000 patients and their matched controls in a publicly accessible database (12/31/11);
- Begin identification of genomic alterations in nine tumor types (12/31/10):





- Complete the identification of the genomic alterations in the nine tumor types 12/31/11);
- Create an image library (e.g., images, videos and animations) of cells from a variety of organisms (12/31/10); and,
- Populate the image library with approximately 15,000 cell images (12/31/11).

Examples of specific performance targets listed under the performance objective related to using new discoveries to develop diagnostics, prevention and therapies include:

- Identify at least four therapeutic strategies and initiate characterization of two stem cell models for the treatment of major diseases (12/31/10);
- Demonstrate the therapeutic feasibility of the identified strategies and refine the stem cell models for future use in therapeutics (12/31/11);
- Characterize two stem cell models (12/31/10); and,
- Refine two stem cell models (12/31/11).

Examples of specific performance targets listed under the performance objective related to putting science to work for the benefit of health care reform include:

- Design an IT system to support exchange of medical images and another to evaluate behavioral interventions (12/31/10);
- Demonstrate sharing of medical images among at least four medical centers and develop the IT infrastructure resource to support secure information sharing (12/31/11);
- Expand a study aimed at developing a national standard for normal fetal growth study (12/31/11);
- Recruit at least 50 percent of the participants required for the fetal growth study (12/31/11);
- Expand studies aimed at gathering information to be used in curtailing the HIV pandemic (12/31/10);
- Identify at least one new strategy to target residual HIV in treated patients (12/31/11);
- Identify at least one new strategy for improving end-of-life and/or palliative care (12/31/10); and,
- Complete the development and/or testing of at least one strategy for enhancing quality of life through improved end-of-life and/or palliative care 12/31/11).

More complete descriptions of each measure and corresponding targets are available on the web at <a href="http://officeofbudget.od.nih.gov/pdfs/FY11/FY11\_Online\_Performance\_Appendix-NIH.pdf">http://officeofbudget.od.nih.gov/pdfs/FY11/FY11\_Online\_Performance\_Appendix-NIH.pdf</a>.

# H. Monitoring/Evaluation





All Recovery Act programs are assessed for risk to ensure that appropriate internal controls are in place throughout the entire lifecycle of the program. These assessments are done consistent with the statutory requirements of the Federal Manager's Financial Integrity Act and the Improper Payments Information Act, as well as OMB's circular A-123 "Management's Responsibility for Internal Control" (including Appendices A, B & C).

NIH's risk management process fits within the overall governance structure established at HHS to address Recovery Act program risks. The HHS Risk Management and Financial Oversight Board provides executive leadership and establishes accountability for the risk assessment process related to internal controls over financial reporting, and the HHS Senior Assessment Team ensures that risk assessment objectives are clearly communicated throughout the Department. NIH's Senior Assessment Team in coordination with the NIH Risk Management Program carries out comprehensive annual assessments of its Recovery Act programs to identify risks and develop strategies to address them, including those associated with selecting recipients, awarding and overseeing funds, and achieving program goals. It meets quarterly to monitor and assess the effectiveness of mitigation strategies and identify emerging risks.

In addition, NIH has presented its high level risks to the Recovery Act Implementation Team. Chaired by the Deputy Secretary and comprised of senior policy officials from throughout the Department, the Implementation Team convenes monthly to monitor progress in carrying out Recovery Act programs and address the obstacles and risks that could impact on their success.

The National Institutes of Health through the Extramural Grants Management Advisory Committee (GMAC), and the Contract Management Advisory Committee (CMAC), has established policies and procedures to assure a consistent and integrated approach to oversight practices that monitor extramural grantee activities for NIH contracts, grants, and cooperative agreements. These committees meet approximately twice a month. Guidance for progress tracking, financial management, and administrative management of NIH grants and contracts includes OMB Circular A-110, OMB Circular A-123, *Management's Responsibility for Internal Control*, sections of the Recovery Act including Section 1512, the *Federal Acquisition Regulations* and the *Updated Implementing Guidance for the Recovery Act of 2009.* 

In addition, the NIH Office of Management Assessment (OMA) and the Office of Financial Management (OFM) have established the NIH risk management framework for identifying, assessing, and testing of operational and financial risks and internal controls associated with implementing Recovery Act requirements. OFM and OMA conduct risk and control assessments in compliance with the statutory requirements of the Federal Managers' Financial Integrity Act, the Improper Payments Information Act, and OMB's Circular A-123 *Management's Responsibility for Internal Control*. OMA will work with NIH offices that are responsible for implementing programs receiving Recovery Act funding to: identify and score the Recovery Act risks, assess controls related to the identified the Recovery Act risks, remediate controls as needed, monitor the inventory of Recovery Act





risks, and report on the risks and controls to NIH and HHS leadership. OFM uses its existing process for assessing internal control over financial reporting related to using and tracking Recovery Act funds and take into account any control deficiencies.

Progress reports are usually required for all active projects annually and report on scientific progress as well as administrative and fiscal compliance. The reports are reviewed by both program and grants management staff as required in the respective NIH Manual Chapters. The review process includes a project officer completing a review checklist for each project that covers: progress, scope, planning, any project changes, safety, outputs, and reporting requirement. The checklist requires additional information for identified compliance or risk areas. Mitigating or corrective actions are documented and trigger additional review as required. Outputs are reviewed by program officials to confirm appropriate progress. Progress standards are based on planned activities and milestones established by the terms of award of the funded grant application.

Grants management staff monitors the fiscal and administrative status using the progress report, the Financial Status Report and/or disbursements from the grantee project accounts as reported in the quarterly SF425 (Cash Transaction Report), and other pertinent information and correspondence. The administrative review is also documented through the completion of a checklist. When disbursements are materially outside of the parameters of the project, grants management staff contact the grantee for additional information, and confer with NIH program staff to determine whether the project may be at risk. Enforcement actions such as limiting disbursements based on actual charges to the project may be required, if project funds are determined to be at risk. Additional funds may be withheld if progress is not satisfactory, and continued concerns may lead to suspension or termination of award.

NIH routinely provides technical assistance and conducts technical assistance visits for oversight of grantee organizations when deemed necessary. Criteria that may trigger site visits include challenges or risk factors for progress, financial, or administrative management and other concerns regarding compliance the terms of award. Site visits and reviews are tailored to the specific circumstance of use for each Grantee Institution, with the participation of grant and / or program management as needed.

Although science validates itself statistically, other forms of evaluations occur on a regular or as needed basis. The findings from evaluability assessments, evaluations and system assessments are used to improve or to eliminate activities. Assessment type activities often are conducted by external contractors; however, trained evaluation NIH staff separate from a project or program can conduct the assessment as well.

## I. Transparency

NIH is open and transparent in all of its contracting and grant competitions and regulations depending on what is appropriate for program activities that involve spending of Recovery Act funding consistent with statutory and OMB guidance. All funding opportunities for grant awards are available at Grants.gov and notification of contract request for proposals are available through FedBizOps.gov.





NIH ensures that recipient reports required by Section 1512 of the Recovery Act are submitted and reviewed for material omissions and significant errors that would mislead or confuse the public. NIH informs recipients of their reporting obligation through standard terms and conditions, grant announcements, contract solicitations, and other program guidance. In addition, NIH provides key award information to recipients and other technical assistance to grantees and contractors and fully utilizes Project Officers to ensure compliance with reporting requirements. NIH provides technical assistance to grantees and contractors, and fully utilizes Project Officers to ensure compliance with reporting requirements. To ensure recipient cost and performance requirements are reported, all awards issued with Recovery Act funds have special accounting numbers and codes to track the funds and awards. All Recovery Act funds must be awarded separately from the normal appropriation funds. The awards must comply with both existing NIH reporting requirements and the Recovery Act reporting requirements. Grants awards include special terms and conditions based on guidance provided by OMB and HHS.

NIH has a link to Recovery.gov on its website. Also, NIH provides a searchable summary of all funding awards, including ARRA awards at report.nih.gov.

## J. Accountability

To ensure that managers are held to high standards of accountability in achieving program goals under the Recovery Act, NIH has built upon and strengthened existing processes. Senior NIH and Science Implementation officials meet regularly with senior Department officials to ensure that projects are meeting their program goals, assessing and mitigating risks, ensuring transparency, and incorporating corrective actions. The personnel performance appraisal system has incorporated Recovery Act program stewardship responsibilities for program and business function managers.

The NIH staff annual review of progress reports is designed to identify risk or challenge areas. Mitigating factors or corrective actions are documented and may trigger more frequent progress and financial reports or special terms of award as required. Project outputs are reviewed by program officials to confirm appropriate progress. Grants Management reviews for fiscal and administrative compliance. Progress is assessed based on planned activities and milestones within the grant application. Grants management can limit disbursement of funds or withhold awards for non-compliance with the terms of award or if progress is not satisfactory.

The NIH Office of Management Assessment and Office of Financial Management are coordinating efforts to ensure that existing risk management processes are fully used as NIH implements the provisions of the Recovery Act. Terms and conditions of award notices have been amended so that awardees are fully aware of the reporting requirements associated with Recovery Act funds.

# K. Barriers to Implementation





NIH anticipates no significant barriers to implementation.

#### L. Federal Infrastructure Investments

This program does not include construction or renovations of federally owned assets or grant funded facilities.

#### Summary of Significant Changes:

- Expanded funding table to show three year obligations and outlays (Section A. Funding Table)
- Expanded "Public Benefits" to document focal areas for research (Section B. Objectives)
- Expanded discussion of planned activities to include actual funding in 2009 and additional areas of focus (Section C. Activities)
- Updated allocation of Recovery Act funding by mechanism (Section D. Characteristics)
- Expanded delivery schedule and updated accomplishments since inception (Section E. Delivery Schedule)
- Replacement of the listing of environmental review compliance "extraordinary circumstances" and
  efforts made to communicate compliance efforts to-date (May 2009) within NIH with the addition of
  National Environmental Policy Act (NEPA)-related reviews in awards and progress reports (F.
  Environmental Review Compliance)
- Updated performance *output* measures and added *outcome* performance measures (Section G. Measures)
- Added information on NIH's proactive risk assessment and mitigation efforts and their connection to OMB required internal controls (Section H. Monitoring and Evaluation)
- Expanded transparency efforts by making contractors and awardees aware of their transparency requirements under the Recovery Act; added link to recovery website (Section I. Transparency)
- Added explanation on the delays caused by added clearance levels to issue ARRA FOAs in
  publishing funding opportunities and the use of an accelerated awards process to offset the delay
  (Section K. Barriers to Implementation)