# National Institutes of Health American Recovery and Reinvestment Act (Recovery Act)

# Implementation Plan on Scientific Research

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

# A. Funding Table:

(dollars in millions)

|   | Total        | Estimated Planned Obligations |           |
|---|--------------|-------------------------------|-----------|
|   | Appropriated | FY 2009                       | FY 2010   |
| National Cancer Institute   | \$1,256.5    | \$587.2                       | \$669.3   |
| National Heart, Lung and Blood Institute                              | \$762.6      | \$384.9                       | \$377.6   |
| National Institute of Dental and Craniofacial Research                | \$101.8      | \$50.8                        | \$51.0    |
| National Institute of Diabetes and Digestive and Kidney Diseases      | \$445.4      | \$245.4                       | \$200.0   |
| National Institute of Neurological Disorders and Stroke               | \$402.9      | \$277.6                       | \$125.3   |
| National Institute of Allergy and Infectious Diseases                 | \$1,113.3    | \$556.6                       | \$556.7   |
| National Institute of General Medical Sciences                        | \$505.2      | \$239.4                       | \$265.8   |
| National Institute of Child Health and Human Development              | \$327.4      | \$161.8                       | \$165.7   |
| National Eye Institute  | \$174.1      | \$92.3                        | \$81.8    |
| National Institute of Environmental Health Sciences 1/                | \$187.4      | \$103.7                       | \$83.7    |
| National Institute on Aging   | \$273.3      | \$133.0                       | \$140.3   |
| National Institute of Arthritis and Musculoskeletal and Skin Diseases | \$132.7      | \$69.0                        | \$63.7    |
| National Institute on Deafness and Other Communication Disorders      | \$103.0      | \$73.8                        | \$29.2    |
| National Institute of Mental Health                                   | \$366.8      | \$217.3                       | \$149.5   |
| National Institute on Drug Abuse                                      | \$261.2      | \$139.1                       | \$122.1   |
| National Institute on Alcohol Abuse and Alcoholism                    | \$113.9      | \$65.3                        | \$48.6    |
| National Institute of Nursing Research                                | \$35.9       | \$23.4                        | \$12.5    |
| National Human Genome Research Institute                              | \$127.0      | \$63.5                        | \$63.5    |
| National Institute of Biomedical Imaging and Bioengineering           | \$77.9       | \$40.4                        | \$37.5    |
| National Center for Research Resources                                | \$310.1      | \$141.6                       | \$168.5   |
| National Center for Complementary and Alternative Medicine            | \$31.7       | \$16.0                        | \$15.7    |
| National Center on Minority Health and Health Disparities             | \$52.1       | \$52.1                        | \$0.0     |
| Fogarty International Center  | \$17.4       | \$13.3                        | \$4.1     |
| National Library of Medicine  | \$83.6       | \$39.7                        | \$43.9    |
| Common Fund   | \$136.8      | \$72.9                        | \$63.9    |
| Office of the Director  | \$800.0      | \$238.6                       | \$561.4   |
| Scientific Research Total   | \$8,200.0    | \$4,098.7                     | \$4,101.3 |

<sup>1/</sup> Includes Superfund

### B. Objectives:

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 the public and health care providers; 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 an array of Institutes and Centers (ICs), which support and conduct research through an extensive extramural research community and the intramural research program. The NIH objectives specifically support HHS strategic plan goal 4<sup>1</sup>: advance scientific and biomedical research and development related to health and human services.

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.

### C. Activities:

NIH plans several major activities, such as:

- 1. Expand the pay line for highly meritorious applications (total RPG's are an estimated \$5.7 billion): NIH will provide 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 would not otherwise likely be funded in FY 2009 or FY 2010.
- 2. Competitive Revisions (NOT-OD-09-058) and Administrative Supplements (NOT-OD-09-056) (approximately \$1 billion): NIH will support 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 that \$100,000) and personnel support for new types of activities that fit into the structure of the Recovery Act. NIH plans to make over 4,600 awards.
- 3. <u>Challenge Grants (NOT-OD-09-058)</u> (at least \$200 million): The new NIH Recovery Act Challenge Grant program will focus on health and science problems, to include cancer and autism, where significant progress can be made in a two year time frame. NIH plans to award at least 200 grants.
- 4. <u>Grand Opportunity Program, or "GO grants" (RFA-OD-09-004)</u> (at least \$200 million): 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.

<sup>1</sup> HHS Strategic Plan Goals and Objectives - FY 2007-2012 available at <a href="http://www.hhs.gov/strategic\_plan/">http://www.hhs.gov/strategic\_plan/</a>

- 5. New Faculty (RFA-OD-09-005) (approximately \$100 million): NIH will support the recruitment of new faculty to conduct research at institutions across the country.
- 6. Summer Research Experiences for Students and Science Educators (NOT-OD-09-060) (approximately \$20 million): This program will provide summer jobs for high school/college students and teachers to work in science labs.
- 7. <u>Signature Initiatives</u>: NIH will identify a number of Signature Initiatives that will support exceptionally creative and innovative projects and programs—and potentially transformative approaches to major challenges in biomedical research. The initiatives will 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.

#### D. Characteristics:

The Recovery Act allows NIH to execute these funds via any NIH funding mechanism. The table below shows the estimated allocation of Recovery Act funding by mechanism (note that this table includes NIH Recovery Act funding related to scientific research). NIH expects to obligate a significant amount through research project grant mechanisms and contracts. Over \$8 billion will be awarded extramurally, primarily to universities, medical centers, hospitals and research institutions throughout the country. NIH will allocate approximately \$122 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.

|                                  | FY 2009/ | FY 2009/FY 2010 |  |  |
|----------------------------------|----------|-----------------|--|--|
| Research Grants                  | No.      | Amount          |  |  |
| Research Projects                |          |                 |  |  |
| Noncompeting                     | 5,414    | \$1,963,566     |  |  |
| Administrative Supplements       | (3,983)  | 687,329         |  |  |
| Competing                        | 7,678    | 2,936,714       |  |  |
| New                              |          |                 |  |  |
| Supplements (Revisions)          | 661      | 206,447         |  |  |
| Renewals                         |          |                 |  |  |
| Subtotal                         | 13,092   | 5,587,609       |  |  |
| SBIR/STTR                        | 119      | 76,044          |  |  |
| Subtotal, RPG                    | 13,211   | 5,663,653       |  |  |
| Research Centers                 |          |                 |  |  |
| Specialized/Comprehensive        | 538      | 402,360         |  |  |
| Clinical Research                | 181      | 54,788          |  |  |
| Biotechnology                    | 70       | 21,000          |  |  |
| Comparative Medicine             | 61       | 20,200          |  |  |
| Res. Centers in Minority Instit. | 141      | 42,500          |  |  |
| Subtotal, Centers                | 991      | 540,848         |  |  |
| Other Research                   |          |                 |  |  |
| Research Careers                 | 348      | 62,874          |  |  |
| Cancer Education                 | 0        | 0               |  |  |
| Cooperative Clinical Research    | 45       | 53,609          |  |  |
| Biomedical Research Support      | 7        | 1,763           |  |  |
| Minority Biomed. Res. Support    | 20       | 5,000           |  |  |
| Other                            | 372      | 114,537         |  |  |
| Subtotal, Other Research         | 792      | 237,783         |  |  |
| Total Research Grants            | 14,994   | 6,442,284       |  |  |
| Training:                        |          |                 |  |  |
| Individual                       | 170      | 8,016           |  |  |
| Institutional                    | 525      | 39,000          |  |  |
| Total Training                   | 695      | 47,016          |  |  |
| R&D Contracts                    | 217      | 790,679         |  |  |
| Intramural Research              |          | 31,799          |  |  |
| Res. Management & Support        |          | 88,222          |  |  |
| Office of the Director           |          | 800,000         |  |  |
| TOTAL                            |          | 8,200,000       |  |  |
|                                  |          |                 |  |  |

These are initial estimates and the numbers WILL change.

### E. <u>Delivery Schedule:</u>

NIH published a majority of the 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 applications are reviewed over the next several months and into next fiscal year. NIH plans to award Challenge Grants and GO grants in August and September 2009. About half of the funding available for this activity will be obligated in FY 2009, with the rest obligated in FY 2010.

| March 2009    | Begin publishing Recovery Act specific funding    |
|---------------|---|
|               | announcements                                     |
| April 2009    | Begin awarding Recovery Act grants and obligating |
|               | funds   |
| May-July 2009 | Conduct peer review for Challenge and GO Grants   |
|               |   |

| August-Sept 2009       | Award Challenge and GO Grants                                   |
|------------------------|---|
| Ongoing after May 2010 | Review progress reports for non-competing Recovery Act renewals |

### F. Environmental Review Compliance:

National Environmental Policy Act (NEPA) Compliance under the Recovery Act in the area of Research Grants: Consistent with the provisions of NEPA in place since 1970, NIH has procedures in place to ensure that federal officials properly take into account potential environmental consequences when taking actions. Section 1609 (c) of 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 National Environmental Policy Act 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 fills in 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. 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 heighted awareness of the environmental aspects of Recovery Act, the Director of the Office of Research Facilities briefed Program Officials on April 2, 2009 and is scheduled to brief the Extramural Program Management Committee. The Categorical Exclusion is used for routine research grants, and we expect ARRA awards to follow a similar pattern.

### G. Measures:

NIH will develop the measures and targets set forth in GPRA plans to represent Recovery Act activities.

|  |        |           |        | 2009                          |                                      |  | 2010                          |                                      |  |
|--|--------|-----------|--------|-------------------------------|--------------------------------------|--|-------------------------------|--------------------------------------|--|
|  | Type   | Frequency | Unit   | Original<br>Program<br>Target | Revised<br>Full<br>Program<br>Target | Target (incremental change in performance) | Original<br>Program<br>Target | Revised<br>Full<br>Program<br>Target | Target (incremental change in performance) |
| Number of New<br>and Competing<br>Research<br>Project Grants<br>(RPGs)<br>awarded. | Output | Quarterly | Grants | 9,842                         | 16,564                               | 6,722                                      | 9,849                         | 10,806                               | 957  |
| Number of administrative supplement awards made.                                   | Output | Quarterly | Awards | 1,369                         | 3,445                                | 2,076                                      | 1,050                         | 2,957                                | 1,907                                      |
| Number of competitive revision awards made.  | Output | Quarterly | Awards | 37                            | 576                                  | 539  | 35                            | 157                                  | 122  |
| Number of jobs created/retained.   | Output | Quarterly | Jobs   |                               |                                      |  |                               |                                      |  |

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

### H. Monitoring/Evaluation:

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 includes OMB Circular A-110, OMB Circular A-123, *Management's Responsibility for Internal Control*, sections of the Recovery Act including Section 1512, 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) will use the established NIH risk management framework for identifying, assessing, and testing of operational and financial risks and internal controls associated with implementing Recovery Act requirements. 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. These assessments will be done consistent with the statutory requirements of the Federal Manager's Financial Integrity Act, which required managers to assess the effectiveness of management controls applicable to their responsibilities, and the Improper Payments Information Act, as well as OMB's circular A-123 *Management's Responsibility for Internal Control*, which strengthens financial management controls so that Federal agencies can better detect and prevent improper payments.

Progress reports are required for all active projects annually. 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 any identified risk or challenge 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 within the grant application.

Grants management specialists monitor disbursements from the grantee project accounts as reported in the quarterly SF272 (Cash Transaction Report) to assure that the drawdowns from the Division of Payment Management System are appropriate for the effort described in the application. When disbursements are outside of planned parameters, grants management specialists contact the grantee for additional information, and confer with NIH program staff to determine whether the project may be at risk. Decisions to limit 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 conducts technical assistance visits for oversight of grantee organizations when deemed necessary by the grants management specialist based on a GMAC Risk Assessment analysis. Criteria that trigger additional site visits can include challenges or risk factors for progress, financial, or administrative management. 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 will be open and transparent in all of its contracting and grant competitions and regulations that involve spending of Recovery Act funding consistent with statutory and

OMB guidance. NIH will ensure that recipient reporting required by Section 1512 of the Recovery Act and OMB guidance is made available to the public on Recovery.gov by October 10, 2009. NIH will inform recipients of their reporting obligation through standard terms and conditions, grant announcements, contract solicitations, and other program guidance. NIH will provide technical assistance to grantees and contractors and fully utilize 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 will include special terms and conditions based on guidance provided by OMB and HHS. NIH will have a link to Recovery.gov on its website.

### J. Accountability:

To ensure that managers are held to high standards of accountability in achieving program goals under the Recovery Act, NIH will build on and strengthen existing processes. Senior NIH and Science Implementation officials will 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 will also incorporate Recovery Act program stewardship responsibilities for program and business function managers.

The Project officer's annual review requires additional information for any identified risk or challenge 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 within the grant application. Grants management can limit disbursement of funds for any funding improprieties and if progress is not satisfactory.

NIH is coordinating efforts with its Office of Management Assessment and Office of Financial Management 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 will also be amended so that awardees are fully aware of the reporting requirements associated with these funds.

#### **K.** Barriers to Implementation:

NIH has not encountered any significant barriers to implementation.

# L. Federal Infrastructure Investments:

This program does not support Federally-owned assets. No intramural facilities renovations will be made.