National Institutes of Health: Shared Instrumentation

The Recovery Act directly provided $10 billion to the National Institutes of Health (NIH). This Implementation Plan focuses on the $300 million of Recovery Act funds provided to the National Center for Research Resources (NCRR), a component of the National Institutes of Health (NIH), for the Shared Instrumentation program.

A. Funding Table

(Dollars in millions)

Program/ Project/Activity	Total Appropriated	FY 2009 Actual Obligations	FY 2010 Estimated Obligations
Shared Instrumentation	$300.0	$52.7	$247.3

B. Objectives

The Shared Instrumentation program provides grants to NIH-supported research institutions to purchase research instruments that will serve multiple researchers. It is a cost-effective mechanism to provide multiple investigators with technologically sophisticated equipment to support federally-sponsored research. The citizens of the United States will benefit from these awards through improved biomedical and behavioral research capacity.

The objectives of the Recovery Act Shared Instrumentation program align with the existing Shared Instrumentation program, in order to facilitate state of the art research as technologies advance to enable better images, diagnostics, data analysis, and new discovery tools. Innovative biomedical research requires access to the newest and most advanced technology.

C. Activities

The Shared Instrumentation program consists of two main activities:

1. **Shared Instrumentation Grants (SIG) (approximately $140 million)**: The SIG program supports grants to groups of three or more NIH-supported investigators at public and non-profit domestic institutions for the purchase of commercially available instruments costing from $100,000 to $500,000. Types of instruments supported include confocal and electron microscopes, biomedical imagers, mass spectrometers, DNA sequencers, biosensors, cell sorters, X-ray diffraction systems, and NMR spectrometers among others.
2. **High-End Instrumentation Grants (HEI) (approximately $160 million)**: The HEI program supports grants to groups of three or more NIH-supported investigators at public and non-profit domestic institutions for the purchase of a single major item of biomedical research equipment costing from $600,000 to $8,000,000. Examples of equipment that could be funded under this program are structural and functional imaging systems, macromolecular NMR spectrometers,

high-resolution mass spectrometers, cryoelectron microscopes, and supercomputers.

D. Characteristics

Eligible recipients include 1) Public/State Controlled Institution of Higher Education; 2) Private Institution of Higher Education; and 3) Nonprofit with or without 501(c)(3) IRS Status (Other than Institution of Higher Education).

Awards are made to public and non-profit domestic institutions only, including health professional schools, other academic institutions, hospitals, health departments, and research organizations. About $52.7 million was obligated in FY 2009, with the remaining $247.3 million to be obligated in FY 2010.

Institutions submit grant applications which are selected using NIH's standard, competitive, peer-reviewed process – a two level review process. Briefly, the first level of review for scientific and technical merit is conducted by expert peer review study sections convened by the NIH and comprised of external reviewers. The second level of review is conducted by the NCRR National Advisory Research Resources Council (NARRC). The final decisions are based on the scientific and technical merit of the application as determined by first and second level of peer review, the availability of funds, the relevance of the application to the NCRR/NIH program priorities, the national geographic distribution of awards, and the priorities specified in the Recovery Act, such as energy efficiency and job creation.

The table below provides a summary of key information about the Shared Instrumentation program.

Characteristics:	Shared Instrumentation Grant Program	High End Instrumentation Program
Funding Opportunity Announcement (FOA) #	PAR-09-028/ NOT-RR-09-008	PAR-09-118
Types of awards	Grants	Grants
Estimated size of awards	$100 - $500K	$600K - $8M
Targeted recipients/beneficiaries	Public and non-profit domestic institutions only	Public, private, and non-profit domestic institutions only
Methodology for award selection	Competitive, 2-tiered peer review	Competitive, 2-tiered peer review

E. Delivery Schedule

The following table depicts major milestones and their associated timelines for the Shared Instrumentation Program.

Milestones:	Shared Instrumentation Grant Program	High-End Instrumentation Program
Funding Opportunity Announcement (FOA) #	PAR-09-028/ NOT-RR-09-008	PAR-09-118

Milestones:	Shared Instrumentation Grant Program	High-End Instrumentation Program
FOA Released	March 5, 2009*	March 5, 2009
Applications Due (award size/due date)	March 23, 2009	May 6, 2009
Application Review	June – December 2009	June - October 2009
Earliest Anticipated Awards	September 2009	September 2009

* In addition, a FOA was released on November 14, 2008 and these applications will be considered for Recovery Act support.

Additionally, NIH funded a small number of previously peer-reviewed, meritorious (but unfunded) applications for the Shared Instrumentation Program. All of the Shared Instrumentation applications will have gone through two levels of peer-review.

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 heightened awareness of the environmental aspects of Recovery Act, the Director of the Office of Research Facilities briefed Program Officials on April 2, 2009 and briefed the Extramural Program Management Committee. The Categorical Exclusion is used for routine research grants, and we expect Recovery Act awards to follow a similar pattern.

G. Measures

NIH will use the following performance measures:

Outcome / Measure		9/30 2009	12/31 2009	3/31 2010	6/30 2010	9/30 2010	12/31 2010	3/31 2011	6/30 2011	9/30 2011	Program End
Number of shared equipment and	Target	75	130	190	270	450	450	450	450	450	450
instrumentation grants awarded.	Actual	84	110	215							
Shared Instrumentation	Projected	0	0	40	50	55	60	65	70	150	450
projects complete [1]	Actual	0	0	44							

[1] This information will be available to the public on the Recovery Act website. The data for the number of awards comes from the QVR system at NIH. The data for the number of awards that are complete come from recipient reporting required by section 1512 of the Recovery Act. The projections for the number of awards that are at various stages of completion take into account the date that each award was made as well as the quarterly reporting cycle for the section 1512 reports.

H. Monitoring and 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 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) 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 Recovery Act risks, assess controls related to the identified Recovery Act risks, remediate controls as needed, monitor the inventory of the 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.

NCRR is responsible for administering and overseeing the shared instrumentation program, while each grantee is responsible for ensuring that the awarded grant funds are used properly and as specified. NCRR works closely with the grantee to make sure the federal funds are expended appropriately. Additionally, NCRR is employing management tools to mitigate program risk through all program phases including grant review, award, and post-award monitoring.

I. Transparency

NIH is open and transparent in all of its contracting and grant competitions and regulations consistent with statutory and OMB guidance. To ensure recipient cost and performance requirements are reported on a quarterly basis, 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. More specifically, grants will include special terms and conditions based on guidance provided by OMB and HHS. 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 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.

NIH has 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 Shared Instrumentation 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 from the grantee 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.

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 will also be amended so that awardees are fully aware of the reporting requirements associated with these funds.

K. Barriers to Effective Implementation

NIH anticipates no significant barriers to implementation.

L. Federal Infrastructure

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)
- Adjusted activities funding (Section C. Activities)
  - Shared Instrumentation Grants from $200 million to $140 million
  - High- End Instrumentation Grants from $100 million to $160 million
  - These changes occurred in response to the relative number of applications submitted for each program.
- Updated award obligations (Section D. Characteristics)
  - Awards to public and non-profit domestic institutions from $50 million to $53 million in FY 2009
  - Awards to public and non-profit domestic institutions from $250 million to $247 million in FY 2010
- Updated program 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)