



National Institutes of Health: Comparative Effectiveness Research

The Department of Health and Human Services (HHS) is currently developing a plan and a corresponding funding allocation for dollars appropriated to the Agency for Healthcare Research and Quality (AHRQ) for comparative effectiveness research (CER). The American Recovery and Reinvestment Act (Recovery Act) appropriated \$1.1 billion for CER, of which \$300 million is for AHRQ, \$400 million is for the National Institutes of Health (NIH), and \$400 million is for allocation at the discretion of the Secretary.

This implementation plan focuses on the \$400 million of funds in the Recovery Act for NIH as part of a trans-agency research effort in CER.

A. Funding Table

(Dollars in Millions)

	Total Appropriated	Planned Obligations FY 2009	Planned Obligations FY 2010
Comparative Effectiveness Research	\$400.0	*	*
Total	\$400.00		

*HHS is currently developing a plan that specifies the kind and scope of activities that will be funded to achieve the program's objectives. Planned obligations are not yet determined.

B. Objectives

The overarching goal of this program is to improve health outcomes by providing evidence to enhance medical decisions made by patients and their medical providers. The Department of Health and Human Services uses the definition of comparative effectiveness research as set forth by the Federal Coordinating Council for CER:

Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions. The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations. Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness.



Systematic research methods can include randomized controlled trials, meta-analyses, observational cohort analyses, and other new and emerging methodologies.

The National Institutes of Health's (NIH) objective is to target dollars to support scientific research opportunities that help support the goals of the Recovery Act. The projects will encompass NIH's mission by conducting CER that aims to enhance patient and clinician decision-making and to improve "real world" health outcomes for the nation. The NIH objective specifically supports HHS strategic plan goal 4¹: advance scientific and biomedical research and development related to health and human services.

C. Activities

NIH is currently developing a plan that specifies the kind and scope of activities that may be funded to achieve the program's objectives. As a member of the Federal Coordinating Council for Comparative Effectiveness Research (FCC), which was authorized by and established pursuant to the Recovery Act, NIH is coordinating its research plan with other agency members and consulting with the FCC to ensure consistency with the HHS-wide plan.

To support scientific research opportunities that help achieve the goals of the Recovery Act, NIH plans to obligate resources across several major activities. Such activities may include:

1. **Previously Peer-Reviewed and Approved Projects.** NIH will likely support peer-reviewed and approved, highly meritorious grant applications from investigators across the nation that were not funded in FY 2008 and grant applications that would not otherwise likely be funded in FY 2009 or FY 2010.
2. **New and Competing Research Efforts.** NIH may also provide support for new types of activities that fit into the structure of the Recovery Act. For example, the new NIH Challenge Grant and Grand Opportunities programs will focus on health and science problems where significant progress can be made within a two year time frame.
3. **Continuations.** NIH may support acceleration of the tempo of ongoing science via NIH's supplement programs known as "administrative supplements" or expansion of the scope of current research through "competitive revisions" for support of additional infrastructure (e.g., equipment costing less than \$100,000) and personnel.

D. Characteristics

The Recovery Act allows NIH to execute these funds via any NIH funding mechanism. NIH expects to obligate a significant amount through research awards based on peer review, scientific excellence and opportunity, and the potential impact of the proposal on biomedical research and public health priorities. 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

¹ HHS Strategic Plan Goals and Objectives - FY 2007-2012 available at http://www.hhs.gov/strategic_plan/



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issue and the IC oversight. The intended award recipients are primarily universities, medical centers, hospitals and research institutions throughout the country. At this time, fiscal year expenditure estimates are being considered with respect to NIH priorities, in consultation with the FCC CER, and in collaboration with other agency members on the Council.

E. Delivery Schedule

NIH is developing a schedule with milestones and planned delivery dates for major phases of the program's activities. NIH will likely focus initially on peer reviewed projects that were approved but were not funded in FY 2008 or approved but not likely to be funded in FY 2009 or FY 2010 within regular NIH appropriations related to CER. NIH issued a related Request for Application (RFA) for Challenge Grants and other NIH-wide solicitations such as Competitive Supplements, Grand Opportunities Grants to allow appropriate applicant response times to apply. NIH anticipates making the initial CER awards no later than September 2009.

As the Recovery Act requires, NIH will submit an operating plan for this program to the House and Senate Appropriation Committees prior to obligating the \$400 million not later than July 30, 2009. Detailed milestones and fiscal year expenditure estimates will be included in the July 30 submission.

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.



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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 is scheduled to brief 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

HHS is working to develop cross-cutting outcome measures for comparative effectiveness research activities across the Department. Initial outcome measures will be developed by December 1, 2009. In addition, the measures below will be reported quarterly and help HHS track progress toward the program's goals and objectives. Targets may change and additional measures may be developed given that priorities and a spending plan are not yet finalized.

NIH will use the following measures for this program:

Measure	Type	Frequency	Unit	2009			2010		
				Original Program Target	Revised Full Program Target	Target (incremental change in performance)	Original Program Target	Revised Full Program Target	Target (incremental change in performance)
Number of applications received	Output	Quarterly	Grants	TBD	TBD	TBD	TBD	TBD	TBD
Number of meritorious grants awarded	Output	Quarterly	Grants	TBD	TBD	TBD	TBD	TBD	TBD
Number of coordinating meetings, including FCC, AHRQ CER, VA CER	Output	Quarterly	Meetings	TBD	TBD	TBD	TBD	TBD	TBD



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

H. Monitoring and 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) are establishing a common 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 the 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



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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 grants competitions 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 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. 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.



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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 Effective Implementation

NIH does not anticipate any significant barriers to implementation.

NIH participates on the Federal Coordinating Committee for CER and has also reached out to other agencies within the FCC, including the FDA and the VA to ensure that research efforts are not duplicative and that research is pursued on topics of interest to stakeholders.

L. Federal Infrastructure

The infrastructure that may be supported through these funds will be primarily data bases, patient registries and other health information technologies, which are not subject to energy efficiency or green building requirements. No construction will be carried out with these funds.