

NCI Guidelines for ARRA Research and Research Infrastructure Grand Opportunities: Comparative Effectiveness Research in Cancer Prevention, Screening and Treatment

Announcement Number: [RFA-OD-09-004](#)

Title: Recovery Act Limited Competition for NIH Grants: Research and Research Infrastructure “Grand Opportunities” (RC2)

The NCI is participating in the Research and Research Infrastructure Grand Opportunities (GO) Program ([RFA-OD-09-004](#); RC2 grant), which has been issued by the NIH to support research on high impact ideas that lend themselves to short-term, non-renewable funding, and may lay the foundation for new fields of investigation. Through its participation on this and other related funding initiatives, the NCI is committed to fulfilling the goals of the American Recovery and Reinvestment Act (ARRA) to help stimulate the economy through support of biomedical and behavioral research. Additional information the Recovery Act and related NIH opportunities is available through the [Office of Extramural Research](#).

Areas of Scientific Priority:

A wide range of clinically-based preventive, screening and treatment interventions have been shown to be efficacious for many types of cancer. However, evidence is less complete on the effectiveness of these interventions in actual community practice, among populations and treatment settings and using techniques and practices that may differ markedly from those of initial controlled clinical trials. Effectiveness includes not just the standard “core” clinical outcomes such as survival, adverse clinical events, quality of life and symptoms, but also domains that affect the use of the treatment, or health care strategy. Factors that affect how treatment is used, and whether one treatment is preferred over another include patient-reported outcomes, acceptability and adherence to treatment, patient-physician communications, health system capacity and organization factors, medical and other resource use, economic cost, financial stress and broader impacts on the family, work and community, such as impacts on economic productivity and the ability to return to work and resume other normal social functions. Some of these domains have been investigated by NCI, but research in these areas remains underdeveloped in terms of data resources, methodology and research personnel. Also the field remains fragmented in terms disciplinary areas, phases of the cancer continuum explored, and cancer sites investigated.

For the purposes of this announcement, comparative effectiveness research (CER) is defined as a rigorous evaluation of the impact of different options that are available for treating or preventing a given medical condition for a particular set of subjects. Such a study may compare similar treatments or other interventions, such as competing drugs, or it may analyze very different approaches, such as surgery, drug therapy and behavioral interventions. Such research may include the development and use of clinical and

population level registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data as they apply to CER.

This funding opportunity will support two year efforts to build capacity and accelerate scientific progress in the area of cancer comparative effectiveness research (CCER). It will sponsor efforts to build coherent teams of interdisciplinary researchers, to leverage and integrate existing data and health system research resources, and to advance measurement techniques and methodology.

In order to accomplish these goals some or all of the following aims could be addressed:

Health Technology Monitoring and Assessment:

- Develop and apply innovative methods of information acquisition and analysis to augment existing methods of establishing a prioritized agenda of comparative effectiveness trials and other studies.

The Evaluation, Development, Validation and Integration of Comparative Effectiveness Data Resources and Informatics Resources:

- Develop and demonstrate valid methods of integrating data from electronic medical records, healthcare encounters and other information systems on diagnosis, service use, quality of care, and outcomes for patients across multiple integrated healthcare systems.
- Develop and demonstrate processes for creating pooled clinical data across multiple healthcare systems to analyze characteristics of patient populations, clinicians and healthcare settings, to develop and demonstrate the use of innovative technologies (e.g. patient web portals, handheld devices, secure messaging) to monitor quality of care, provide clinician feedback, and deliver interventions to improve outcomes for patients.

The Development of Comparative Effectiveness Trials Resources and Operating Procedures:

- Develop and deploy innovative, viable methods for efficiently identifying, recruiting, and enrolling, with random individual or provider cluster assignment, well characterized patients, including patients often enrolled in conventional efficacy trials at low levels because of age, comorbidity status, racial-ethnicity or low socioeconomic status.
- Explore how the innovative use of existing and developing health system information systems, health informatics tools, health system web portals and other novel communication systems can be used for these purposes.
- Develop operating procedures related to IRB approval, patient consent, recruitment and accrual, data safety monitoring, and stopping rules and to develop and evaluate intermediate and other novel outcomes.

The Development, Evaluation and Validation of Statistical, Psychometric, Econometric, Informatics and Modeling Methods for Comparative Effectiveness Research:

- Develop, evaluate and validate statistical, psychometric, econometric and informatics tools, techniques and methods that would ensure that the most appropriate methods are used, that the capabilities and limitations of these methods are well characterized and the standardization, transparency and ability to replicate studies becomes established in the field of comparative effectiveness research.

Comparative Effectiveness Studies:

- Conduct descriptive and evaluative studies, such as patterns of care studies, including prevalence of, variations in and disparities of medical practices and procedures, studies that examine factors that influence these patterns, such as patient and provider preferences and knowledge, health system organization, private and public sector education and promotion, clinical recommendations and guidelines, health insurance coverage policies and other economic incentives.

Funding Priorities:

We expect to make 3-5 awards for a period of 2 years.

The budget cap for each award proposal is 2 million dollars in total costs per year.

Applications would be expected to address selected comparative effectiveness issues across one or more domains the cancer continuum. The grant awards will be located at a University or other research organization but would be expected to have appropriate collaborative alliances with healthcare delivery systems or networks that would provide the community-based population laboratories for the conduct of comparative effective studies. Awardees will be expected to assemble a multidisciplinary team which would include the spectrum of knowledge area expertise and leadership necessary to advance this field. Relevant disciplines might include, but would not be limited to, clinical trialists, epidemiologists, statisticians, informaticians, psychometricians, geneticists, pharmacologists, economists, psychologists, sociologists, anthropologists, political scientists and public policy experts. These teams would function to develop multi-level and systems approaches to build CER capacity and tools in cancer prevention, screening and treatment, and define a new future for CER using accelerated timelines to transform clinical and public health practice.

Application Guidelines:

Applications for NCI funds supporting the scientific areas listed above **MUST** follow the guidelines listed in [RFA-OD-09-004](#).

Key Dates (RFA-OD-09-004):

Letters of Intent Receipt Date:	April 27, 2009
Application Receipt Date:	May 27, 2009
Peer Review Date:	June/July 2009
Council Review Date:	August 2009

Earliest Anticipated Start Date: September 30, 2009
Expiration Date: May 28, 2009

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