Operating Plan for American Recovery and Reinvestment Act Funds for Comparative Effectiveness Research at the Agency for Healthcare Research and Quality

1. Purpose of funding

The American Recovery and Reinvestment Act (ARRA) appropriated $1.1 billion for comparative effectiveness research (CER), of which $300 million is for the Agency for Healthcare Research and Quality (AHRQ), $400 million is for the National Institutes of Health (NIH), and $400 million is for allocation at the discretion of the Secretary of the Department of Health and Human Services.

The overarching goal of comparative effectiveness research 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 research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in “real world” settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other 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 and subgroups. Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies. This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness and actively disseminate the results.

With the $300 million made available through the American Recovery and Reinvestment Act (ARRA), the Agency for Healthcare Research and Quality (AHRQ) will conduct and support comparative effectiveness research, consistent with Titles III and IX of the Public Health Services Act; Part A of title XI of the Social Security Act; and Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. AHRQ will employ grants and contracts, to undertake this research.

AHRQ will use ARRA funds to expand and broaden pre-existing comparative effectiveness research activities initiated at the Agency in response to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, legislation designed to increase the availability of research that would inform the real-world decisions facing patients and clinicians. AHRQ’s investments using ARRA funds will expand its Effective Health Care (EHC) Program. This effort will increase the national output of comparative effectiveness research; in addition, it will build research infrastructure and capacity, allowing future studies to address questions where data are currently not sufficient to provide guidance about competing
alternatives and to improve the efficiency with which the research infrastructure is able to respond to pressing health care questions. Research activities will be performed using rigorous scientific methods within a previously-established process that emphasizes stakeholder involvement and transparency, that was designed to prioritize among pressing health issues, and whose products are designed for maximum usefulness for health care decision makers.

**Overview of Funding Proposals**

AHRQ conceptualizes the process of generating comparative effectiveness research as shown in Figure 1. Stakeholder input occurs through all steps of this process to ensure the relevance of the research to decision makers. ARRA funds will be allocated to all steps of the comparative effectiveness research process.

The process starts with horizon scanning, the identification of current or emerging medical interventions available to diagnose, treat, or otherwise manage a particular condition. Horizon scanning activities are vital for understanding the relevant healthcare context and landscape, as a basis for identifying and beginning to prioritize among research needs. Once options are identified, evidence synthesis focuses on the review and synthesis of current medical research, to provide rigorous evaluation of what is known on the basis of existing research about the comparative effectiveness of alternative approaches to the given clinical problem. Evidence synthesis involves the distillation of a body of evidence generally comprised of multiple studies and often including a combination of trials and non-experimental studies, to provide the most relevant information possible for clinicians and other decision makers.

To increase the impact of comparative effectiveness research in the U.S., it is vital to rigorously and systematically identify evidence needs and gaps, areas where new research conducted within a comparative effectiveness framework would contribute to bridging the gap between existing medical research and clinical practice. EPCs have been charged with identifying evidence gaps in their systematic reviews of the literature. ARRA funding will allow HHS to put greater emphasis on the identification of evidence needs in the systematic review process, which begins with the identification of evidence gaps that has been the purview of the EPCs. This effort will be designed to produce recommendations that further consider the timing, value and feasibility of research that would fill these gaps and will include coordination with other funders as well researchers able to conduct needed research.
Evidence generation, the conduct of new comparative effectiveness research, is essential to meeting the needs of clinical and health policy decision makers. It will include both efforts to build the infrastructure for conducting comparative effectiveness studies, and underwriting rigorous research with dedicated study designs and data collection to definitively address knowledge gaps that could not otherwise be addressed.

Dissemination and translation efforts will comprise the final link, ensuring that knowledge synthesized or generated within the comparative effectiveness research program is available to decision makers to better inform their decisions. AHRQ will increase efforts in this area, expanding the number of clinician- and consumer-oriented summaries of findings produced by the John M. Eisenberg Clinical Decisions and Communications Science Center (currently operated by Baylor College of Medicine). As the translation and dissemination component of the comparative effectiveness research initiative, the Eisenberg Center will continue to produce these products in partnership with specific stakeholder groups, including the general public, patients, providers, payers, and policy-makers, to generate information tailored to their circumstances. ARRA funds will also enable new investments in innovative research on incorporating comparative effectiveness research into decision making, such as integrating
clinical decision support tools into health information technologies, as health care system reforms are planned and implemented.

Finally, essential to the goal of building a comparative effectiveness program that will be capable of engendering real change in the healthcare system, is strengthening and capacity building within the research infrastructure. **Research training and career development** of researchers and clinicians will strengthen the research infrastructure and build the research infrastructure’s capacity through ensuring a sufficient pool of research expertise for national efforts in comparative effectiveness research.

ARRA funding will focus initially on 14 priority conditions established by the Secretary of the Department of Health and Human Services under Section 1013 of the Medicare Modernization Act. These priority conditions were identified through a process involving discussion with and extensive input from the public and Federal agencies and include conditions relevant to the Medicare, Medicaid and SCHIP programs. AHRQ will continue to review the currency of the priority list and make recommendations to the Secretary regarding updates. As additional priorities are identified through ongoing research at AHRQ and using recommendations from the Federal Coordinating Council and Institute of Medicine reports, funds will be allocated accordingly.

1. Arthritis and nontraumatic joint disorders
2. Cancer
3. Cardiovascular disease, including stroke and hypertension
4. Dementia, including Alzheimer's Disease
5. Depression and other mental health disorders
6. Developmental delays, attention-deficit hyperactivity disorder, and autism
7. Diabetes mellitus
8. Functional limitations and disability
9. Infectious diseases including HIV/AIDS
10. Obesity
11. Peptic ulcer disease and dyspepsia
12. Pregnancy including preterm birth
13. Pulmonary disease/asthma
14. Substance abuse

HHS has established a team to promote and support ongoing policy coordination of comparative effectiveness research. This team includes a senior advisor from the Office of the Secretary, the Director of AHRQ, and the Director of NIH. This team will meet regularly to review policy issues related to comparative effectiveness research, including strategies to
effectively oversee and promote alignment with priority areas of all Recovery Act CER resources allocated to the Department, including AHRQ, NIH and OS; assure that they are synergistic with investments made with AHRQ and NIH regularly appropriated funds; and finally, assure related scientific issues across the Department are addressed. In addition, the team will ensure that all HHS Recovery Act CER funds are allocated based on a unified set of priority areas. There will be a consultative review process by the coordinating team to ensure: 1) CER gaps, needs, and priorities are being addressed, and 2) duplication is avoided to the extent possible. More details on the HHS CER framework and the coordination and priority-setting process will be included in the OS plan.
2. Specific Budget Proposals -

The proposal for ARRA funds is summarized in the table and the sections below. The AHRQ ARRA funding proposal represents an investment in creating the integrated components of a national comparative effectiveness activity in the United States, including the first coordinated prospective pragmatic comparative effectiveness clinical studies program. Additional ARRA investments will support the infrastructure, methods, and capacity necessary to sustain a vigorous national comparative effectiveness research enterprise in the United States.

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<tr>
<th>Research</th>
<th>Type of Financial Award</th>
<th>FY 09 Funding (M)</th>
<th>FY 10 Funding (M)</th>
<th>Total Funding (M)</th>
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<tr>
<td>I. Identification of New and Emerging Issues for Comparative Effectiveness (Horizon Scanning)</td>
<td>Contracts</td>
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<td>II. Evidence Synthesis</td>
<td>Task Order Contract</td>
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<td>III. Evidence Gap Identification</td>
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<td>IV. Evidence Generation</td>
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I. Identification of New and Emerging Issues for Comparative Effectiveness (Horizon Scanning): Total Expenditure $9.5 million (FY 09 - $0 M; FY 10 - $9.5 M)*

AHRQ proposes to use ARRA funding to establish an infrastructure to identify new and/or emerging issues for comparative effectiveness review investments. This investment will also address emerging technologies and their contextual role in health care.

* AHRQ scientific staff used its best judgment based on years of experience conducting related work to determine the funding amounts for each activity. In addition, the funding amounts are based on best government cost estimates for the type of work and tasks to be performed as well as the level of effort expected.
This horizon scanning approach is vital to understanding the relevant healthcare context and landscape, as a basis for identifying and beginning to prioritize among research needs. It will establish and use an efficient approach to investigate and prioritize areas for investigation relevant to the 14 priority conditions that guide AHRQ’s Effective Health Care Program and can be scaled for a national investment in comparative effectiveness research. AHRQ will work with stakeholders, including clinicians, to identify particularly valuable areas of research where the value of additional information is great; for example, stakeholders may be asked to provide input on emerging interventions and new technologies and how these new interventions fit/are likely to fit into current care pathways.

This new activity will track emerging clinical interventions and investigate key issues related to the intervention. Technical briefs will be produced to provide an overview of key issues related to the intervention -- for example, current indications for the intervention, relevant patient population and subgroups of interest, outcomes measured, and contextual factors that may affect decisions by reviewing the current literature regarding the intervention. Technical briefs generally focus on interventions for which there are limited published data (not enough to conduct a full systematic review) and too few completed protocol-driven studies to support definitive conclusions.

Some of the richest topics for comparative effectiveness research will likely be found at the frontier of new therapies, where there may be great promise but uncertain population benefits and risks. Priority setting activities will gather and present information for decisions on investments in the areas of impact on different populations, value of information, level and impact of uncertainty, and potential impact of the information. AHRQ will initiate a program dedicated to tracking emerging interventions and investigating ways in which these new interventions are likely to fit into current care pathways. This new effort will employ technical briefs, described above, that will provide a public framework of pertinent issues and identify significant or controversial questions of effectiveness that may be addressed by undertaking new evidence synthesis or generation and will be presented in formats conducive to priority setting activities.

In FY 2009, AHRQ will write the request for contract for Identification of New and Emerging Issues for Comparative Effectiveness (Horizon Scanning). Funds for this horizon scanning activity will be obligated in FY 2010 through a new, competitive, cost-based reimbursement contract. AHRQ plans to award one contract to establish an infrastructure for identifying new and/or emerging issues for comparative effectiveness review investments as opposed to making multiple awards to ensure consistency in the processes for horizon scanning and to prevent duplicative efforts and redundancy which may occur if multiple groups were to work on this activity. The information gathered from this program will help to inform the other processes for generating comparative effectiveness research as shown in figure 1 and described below.

The amount of staff time that will be used to administer the activity will vary. Key factors that will impact the amount of FTE on this activity include the availability and
expertise of staff and the phase of the project. An approximate FTE allocation to administer this activity is 1 FTE based on our current experience. Actual FTE utilization will not be available until all projects are solicited, reviewed approved and completed.

- **Activity: Establish an Entity for Identification of New and Emerging Issues for Comparative Effectiveness**
  - Mechanisms:
    - Contracts: One new competitive cost-based reimbursement contract in the amount of $9.5 million (performance incentives, either positive or negative or both, shall be incorporated into the cost-based reimbursement contract to encourage contractors to increase efficiency and maximize performance)
    - Project Length: Two years funded with ARRA funds with three option years (possible funding with annual appropriations based on availability of funds)

**II. Evidence Synthesis: Total Expenditure $25 M (FY 09 - $25 M; FY 10 - $0 M)**

Evidence syntheses include the review and synthesis of current medical research to provide rigorous evaluation of what is known on the basis of existing research about the comparative effectiveness of alternative approaches to the given clinical problem.

Working with lists of priority topics developed within the Effective Health Care Program, topics generated through the increased horizon scanning and priority setting efforts, and other lists of priority topics such as those to be recommended by the Institute of Medicine through their project on Priority Setting for Comparative Effectiveness Research, AHRQ will use ARRA funds to increase support for comparative effectiveness reviews. The goal of this effort will be to increase the number of comparative effectiveness reviews conducted through AHRQ’s Evidence-based Practice Centers (EPC) Program, thereby increasing the information base of research synthesis available to support decisions in the clinical and other health care decision settings. The EPCs are 14 institutions that critically examine existing scientific evidence on a clinical topic and summarize what is known and not known from the current science base. Comparative effectiveness reviews range in cost from $500,000 to $2 million since there is wide variability in scope and applicability of evidence. Approximately 10 to 30 comparative effectiveness reviews are expected to be funded with ARRA funds, depending on the research to be pursued.

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The increase in ARRA funding for evidence synthesis will also allow AHRQ to strategically build upon the existing strengths of the EPC Program to include a focus on capacity-building to create a larger and stronger pool of expertise in systematic review and to advance the scientific methods of systematic review. To build capacity and expertise, EPCs may hire additional researchers and/or provide additional training. This will strengthen the research infrastructure to conduct systematic reviews and will allow the application of sophisticated techniques in systematic review such as individual patient level data analysis, increased use of transparent decision modeling, and sophisticated gap analysis. It will also allow for continued and enhanced investments in research methods for conducting systematic reviews to answer comparative effectiveness research questions. New methodological research may focus meta-analysis, decision analysis1, assessing and interpreting evidence, identifying clinically diverse populations in which treatment effectiveness may be different than the general population, methods for risk stratification2, and methods to evaluate medical tests.

Results of this methods research will be documents and tools that will serve as a resource for our EPCs as well as for other investigators interested in conducting comparative effectiveness reviews. Dissemination of methods guidance will require active engagement with stakeholders include researchers. This may be conducted through publication of monographs, active engagement with specific stakeholder groups, organization of meetings with presentation of methods guidance and discussion of implications for research community, and follow-up publication of stakeholder response.

The comparative effectiveness reviews will contribute to the identification of comparative effectiveness research needs and knowledge gaps. Identification of evidence gaps has been a component of evidence syntheses conducted through AHRQ’s EPC program – the expectation is that researchers steeped in the literature relevant to a research question gain an important perspective on areas where evidence is needed and what study designs are most appropriate. With ARRA funding, this component of evidence synthesis will be built upon as described in the “Evidence Gap Identification” section, below.

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1 Decision analysis: an approach to decision making under conditions of uncertainty that involves modeling of the sequences or pathways of multiple possible strategies (e.g., of diagnosis and treatment for a particular clinical problem) to determine which is optimal. It is based upon available estimates (drawn from the literature or from experts) of the probabilities that certain events and outcomes will occur and the values of the outcomes that would result from each strategy. (www.nlm.nih.gov/nichsr/hta101/ta101014.html)

2 Risk stratification: arranging patients according to the severity of their illness. Implicit in this definition is the ability to predict outcomes from a given intervention based on preexisting illness or the severity of intervention. Risk stratification is therefore defined as the ability to predict outcomes from a given intervention by arranging patients according to the severity of their illness. (http://cardiacsurgery.ctsnetbooks.org/cgi/content/full/2/2003/187?ck=nck#Risk_Stratification)
The amount of staff time that will be used to administer the activity will vary. Key factors that will impact the amount of FTE on this activity include the availability and expertise of staff and the phase of the project. An approximate FTE allocation to administer this activity is 2 FTE based on our current experience. Actual FTE utilization will not be available until all projects are solicited, reviewed, approved and completed.

- **Activity: Enhancing the Current Evidence-based Practice Centers**
  - **Mechanisms:**
    - Contracts: Eight Request for Task Orders (RFTOs) competed among the EPC’s located in the United States ranging from $2 to $4 million each for a total of $25 million
    - Project Length: Three years with ARRA funds

**III. Evidence Gap Identification: Total Expenditure $25 M (FY 09 - $25 M; FY 10 - $0 M)**

With ARRA funds, AHRQ proposes to initiate an enhanced capacity for identifying and prioritizing evidence needs. A formal process will be developed that will involve stakeholders, including clinicians, funding agencies and researchers to consider the gaps identified in systematic reviews to shape future research agendas and to set priorities for a national investment in new research based on the findings. This process will involve bringing together the researchers that worked on the individual review, as well as stakeholders with interest in the topic, clinicians with expertise in the topic area, agencies with funds for potential future research, and researchers with expertise in the clinical area and study design to identify evidence needs and to develop new research based on the findings of the comparative effectiveness review. Funding will be used to develop this formal approach to ensure it is transparent, systematic, strategic and rigorous.

Stakeholders will be asked to review completed systematic reviews and what is known about a medical therapy, and to identify gaps where existing research is insufficient to address key questions. They will be asked to help identify which gaps should have the highest priority for new research to be completed. (Systematic reviews synthesize knowledge – what is known about a medical therapy – but also identify gaps, where existing research is insufficient to address key questions. Based on AHRQ’s significant experience in producing comparative effectiveness reviews, it has identified a critical need for new funding to systematically expand the use of these reviews in the identification and prioritization of research needs.)

This activity will build on and expand current AHRQ Effective Health Care Program efforts to involve stakeholders in the research (e.g. submitting suggestions for research

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* AHRQ scientific staff used its best judgment based on years of experience conducting related work to determine the funding amounts for each activity. In addition, the funding amounts are based on best government cost estimates for the type of work and tasks to be performed as well as the level of effort expected.
topics, commenting on draft key questions before research has begun, commenting on
draft comparative effectiveness reviews) by bringing together stakeholders, including
clinicians, funding agencies and researchers around a given topic to discuss and provide
input on potential future research to fill the gaps identified in the comparative
effectiveness review.

Funding will be used to invest in the initial development of this approach to assure that it
is systematic, transparent, strategic, and methodologically rigorous. This effort will be
designed to produce recommendations that consider the timing, cost, and feasibility of
research that would address key questions, in addition to the predicted value of the
information generated. Inputs to the process will include stakeholder nominations and
recommendations from sources such as the Federal Coordination Council for
Comparative Effectiveness Research or the Institute of Medicine’s project on Priority
Setting for Comparative Effectiveness Research, as well as AHRQ’s systematic review
process.

The amount of staff time that will be used to administer the activity will vary. Key
factors that will impact the amount of FTE on this activity include the availability and
expertise of staff and the phase of the project. An approximate FTE allocation to
administer this activity is 2 FTE based on our current experience. Actual FTE
utilization will not be available until all projects are solicited, reviewed, approved and
completed.

- **Activity: Produce Research Gap Reports**
  - **Mechanisms:**
    - Contracts: Eight RFTOs competed among the existing EPCs located in the United States ranging from $2 to $4 million each for a total of $25 million
    - Project Length: Three years with ARRA funds

**IV. Evidence Generation: Total Expenditure $173 M (FY 09 - $1 M; FY 10 - $172 M)**

This proposal is the largest investment in ARRA funds and is intended to establish a
coordinated national investment in practical/pragmatic comparative effectiveness
research that is focused on important research questions for the health care system and its
users with a concentration in under-represented populations.

The amount of staff time that will be used to administer each activity will vary. Key
factors that will impact the amount of FTE on each activity include the availability and
expertise of staff and the phase of the project. An approximate FTE allocation to
administer this activity is 5 FTE based on our current experience. Actual FTE

* AHRQ scientific staff used its best judgment based on years of experience conducting related work to determine the funding amounts for each activity. In addition, the funding amounts are based on best government cost estimates for the type of work and tasks to be performed as well as the level of effort expected.
utilization will not be available until all projects are solicited, reviewed, approved and completed.

- **Activity**: CHOICE Studies ($100 million)
  Request for Registries ($48 million)
  DEcIDE Consortium Support ($24 million)
  Unfunded Meritorious Applications ($1 million)

a) **CHOICE Studies ($100 million -- FY 09 - $0 M; FY 10 - $100 M):** The Clinical and Health Outcomes Initiative in Comparative Effectiveness (CHOICE) will represent the first coordinated national effort to establish a series of pragmatic clinical comparative effectiveness studies in the United States. These pragmatic studies will measure effectiveness – the benefit the treatment produces in routine clinical practice – and will include novel study designs focusing on real-world populations. Each CHOICE study will address at least one of the 14 priority health conditions. This initiative will concentrate on under-represented populations (children, elderly, racial and ethnic minorities and other under studied populations) and oversample or deliberately obtaining information on under-represented populations, to make sure that this effort achieves the goals of understanding treatment effects in under-represented populations.

- **Mechanisms:**
  - **Grants:** CHOICE: RFA (R01) up to ten awards up to $10 million each depending on the scope of the study for a total of $100 million
  - **Project Length:** CHOICE: Three years with ARRA funds with competitive option years (up to five years total, possible funding with annual appropriations based on availability of funds)

b) **Request for Registries ($48 million -- FY 09 - $0 M; FY 10 - $48 M):** Disease registries are databases that collect clinical data on patients with a specific disease or keep track of specific medical tests, devices, or surgical procedures (joint replacements, heart valve replacements, etc.). AHRQ will make up to five awards for the establishment or enhancement of national patient registries that can be used for researching the longitudinal effects of different interventions and collect data on under-represented populations. Clinical areas within the 14 priority conditions will be targeted. Ongoing and completed projects on patient registries for studying outcomes in real work practice settings funded by AHRQ will inform all future investments in registries by AHRQ. AHRQ will also continue to consult with other agencies across the Department of Health and Human Services on existing registries, registries in need of expansion, and areas where registries are needed but do not exist. It is expected that grantees will develop registries that are sustainable such that the registries will continue once AHRQ funding has ended.
• Mechanisms:
  
  o Grants: Request for Registries: RFA (R01) up to five awards up to $10 million each depending on the scope of the project for a total of $48 million
  
  o Project Length: Request for Registries: Four years with ARRA funds

c) DEcIDE Consortium Support ($24 million -- FY 09 - $0 M; FY 10 - $24 M): The DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) Network conducts accelerated practical studies about the outcomes, comparative clinical effectiveness, safety, and appropriateness of health care items and services. The network is comprised of research-based health organizations with access to electronic health information databases and the capacity to conduct rapid turnaround research. AHRQ will enhance its investments in establishing a learning health care system by funding the DEcIDE Network to expand multi-center research consortia, comprised of academic, clinic, and practice-based centers, to study diabetes, cancer, cardiovascular disease, and other priority conditions, and by funding distributed data network models utilizing clinically rich data from electronic health records. Consortia were developed in diabetes, cancer, and cardiovascular disease because they are among the priority conditions established by the Secretary, they are three leading causes of the burden of disease in the United States, and they represent areas with potential impact for reducing clinically significant variations in the prevention, diagnosis, treatment, or management of a disease or condition, or in the use of a procedure or technology.

The DEcIDE Network also conducts research in methods for comparative effectiveness. AHRQ will use ARRA investment to funds to continue support for the development of a research framework that organizes the major methods topics and prioritizes critical areas for new research on methods, including validation. New areas for research will include:
  
  - development and dissemination of methods for collecting, analyzing, understanding, and interpreting health data for studies of treatment effectiveness;
  - methods for analyzing data submitted as part of coverage with evidence development programs;
  - methods for prospective comparative effectiveness studies;
  - methods for studies conducted across distributed data networks;
  - methods for observational comparative effectiveness studies in selected thematic area like marginal structure models;
  - studies that aim at better understanding heterogeneity in treatment effects and the development and validation of clinically informative risk stratification and classification models in different clinical domains; and
additional research on the design, implementation, analysis, interpretation, and evaluation of the quality of a registry for understanding patient outcomes.

For DEcIDE research with a methodological emphasis, the goals will be to advance study designs and methods to fill specific knowledge gaps and to enhance the consistency, applicability, and generalizability of the comparative effectiveness studies.

- **Mechanisms:**
  - Contracts: **DEcIDE Consortium Support**: Five to Eight Request for Task Orders (RFTOs) competed among the existing DEcIDE Centers up to $5 million each for a total of $24 million
  - Project Length: **DEcIDE Consortium Support**: Two to three years with ARRA funds

d) **Unfunded Meritorious Applications ($1 million -- FY 09 - $1 M; FY 10 - $0 M):** AHRQ will use the ARRA investment to fund meritorious grant applications that were not funded in previous cycles due to limited funding. Research projects selected for funding may have either a clinical or methodological emphasis, but will focus tightly on the study and/or the use of comparative effectiveness research. Studies with a methodological emphasis may advance study designs and methods to fill specific knowledge gaps and to enhance the consistency, applicability, and generalizability of comparative effectiveness studies. Studies with a clinical emphasis may develop new scientific evidence that fills important knowledge gaps and generates critical insights on the clinical effectiveness and comparative clinical effectiveness of health care interventions.

- **Mechanisms:**
  - Grants: **Unfunded Meritorious Applications**: Multiple grant mechanism - $1 million
  - Project Length: **Unfunded Meritorious Applications**: Two to three years with ARRA funds

V. **Translation and Dissemination: Total Expenditure $34.5 M (FY 09 - $2.5 M; FY 10 - $32 M)**

AHRQ has a strong and long-term commitment to bridging the gap between research and practice by translating findings on the comparative effectiveness of interventions for

* AHRQ scientific staff used its best judgment based on years of experience conducting related work to determine the funding amounts for each activity. In addition, the funding amounts are based on best government cost estimates for the type of work and tasks to be performed as well as the level of effort expected.
different audiences including consumers, clinicians and policymakers, and disseminating these findings. This proposal will use ARRA funds to expand AHRQ’s translation and dissemination activities (and thereby strengthen the infrastructure supporting these activities), including the John M. Eisenberg Clinical Decisions and Communications Science Center whose workload will substantially increase. The Eisenberg Center contract modification will expand their scope of work to include additional translation and dissemination activities (e.g. additional summary guides and decision support tools, development of dissemination channels, etc.). Approximately 15 to 45 tools including summary guides for consumers, clinicians and policymakers are expected to be funded with ARRA funds, depending on the number of comparative effectiveness reviews produced and the scope of those reports.

The ARRA funds will primarily be used to support grantees in developing and implementing innovative approaches to integrating comparative effectiveness research findings into clinical practice and health care decision making. Investments will be in multiple geographically dispersed translation, implementation, and evaluation projects to be carried out by local organizations such as medical societies, state institutions of higher learning, patients, community advocacy organizations and others to promote education, dissemination and application of comparative effectiveness research.

The amount of staff time that will be used to administer each activity will vary. Key factors that will impact the amount of FTE on each activity include the availability and expertise of staff and the phase of the project. An approximate FTE allocation to administer this activity is 2 FTE based on our current experience. Actual FTE utilization will not be available until all projects are solicited, reviewed, approved and completed.

- **Activity:** CE Dissemination and Translation Innovation Grants ($29.5 million)
  Eisenberg Center Modification ($5 million)

  - **Mechanisms:**
    - Grants: RFA (R18) up to 20-25 awards ranging from $1 to $2 million each for a total of $29.5 million
    - Contracts: Modification of Eisenberg Center Contract - $5 million
    - Project Length: Grants – two to three years with ARRA funds
      Eisenberg Center Modification – three years with ARRA funds
CROSS-CUTTING INVESTMENTS:

VI. Training and Career Development: Total Expenditure $20 M (FY 09 - $0 M; FY 10 - $20 M)

AHRQ proposes using ARRA funding for comparative effectiveness capacity building. AHRQ will provide institutional support to increase the intellectual and organizational capacity for larger scale programs in comparative effectiveness and allow fellowship training opportunities. Through grant mechanisms, funding will support the career development of clinicians and research doctorates focusing their research on the synthesis, generation and translation of new scientific evidence and analytic tools for comparative effectiveness research. In particular, the goal will be to enhance the research and methodological capacity for conducting and improving the quality of systematic review, retrospective studies, and clinical trials in comparative effectiveness research and the development of data sources and other aspects of the research infrastructure. Two grant mechanisms to be used are:

- **Mentored Clinical Scientist Development Program Award (K12)**, which provides support to an institution for the development of independent scientists. Most, but not all, K12 programs are focused on enhancing the careers of physician scientists.

- **Institutional Research Training Grants (T32)**, which are used by eligible institutions as the primary means of supporting predoctoral and postdoctoral research training to help ensure that a diverse and highly trained workforce is available to assume leadership roles related to the Nation’s biomedical, behavioral and clinical research agenda. The primary objective of the T32 program is to prepare qualified individuals for careers that have a significant impact on the health-related research needs of the Nation. This program supports predoctoral, postdoctoral and short term research training programs at domestic institutions of higher education with the T32 funding mechanism. Awards for T32 institutional NRSA research training grants may be for project periods up to five years in duration and are renewable. Because the nature and scope of the proposed research training will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration, and costs of the applications received.

The amount of staff time that will be used to administer the activity will vary. Key factors that will impact the amount of FTE on this activity include the availability and expertise of staff and the phase of the project. An approximate FTE allocation to administer this activity is 1 FTE based on our current experience. Actual FTE utilization will not be available until all projects are solicited, reviewed, approved and completed.
• **Activity:** Institutional Training Awards and Comparative Effectiveness Fellowship

  ○ Mechanisms:

  - Grants: K12, five-six awards - $15 million  
    T32, multiple - $5 million

  - Project Length: K12 – three years with ARRA funds  
    T32 – remaining 4 years of performance period with ARRA funds

VII. **Citizen Forum: Total Expenditure $10 M (FY 09 - $0 M; FY 10 - $10 M)**

AHRQ proposes using ARRA funds to establish and support a Citizen Forum on Effective Health Care to formally engage stakeholders in the entire Effective Health Care enterprise and to continue to open up and make the program inclusive and transparent. This initiative will build on the smaller initiative that has guided AHRQ’s Effective Health Care Program until now and will be an important component for a larger and more sustained national initiative in comparative effectiveness research, translation, and use.

AHRQ requests ARRA funding to expand and standardize public involvement in its Effective Healthcare Program by establishing a Citizens Forum. The goal of this request is to ensure consistent and comprehensive public involvement in all aspects of AHRQ’s expanded program in Comparative Effectiveness Research. The Citizens Forum on Effective Healthcare will formally engage stakeholders at the critical stages of identifying research needs, study design, interpretation of results, development of products, and research dissemination through a variety of mechanisms that are both inclusive and transparent. Funds will be used to develop formal processes for input, convene citizen panels in accordance with the processes that are developed, and convene a Workgroup on Comparative Effectiveness to provide formal advice and guidance to the Program. Funds will also support programs in citizen awareness addressing the use of comparative effectiveness evidence in health care decision-making. These programs, developed under the guidance of the Citizens Forum, may include town hall meetings, web-based information exchange, and community-based grassroots awareness efforts.

The amount of staff time that will be used to administer the activity will vary. Key factors that will impact the amount of FTE on this activity include the availability and expertise of staff and the phase of the project. An approximate FTE allocation to administer this activity is 2 FTE based on our current experience. Actual FTE

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* AHRQ scientific staff used its best judgment based on years of experience conducting related work to determine the funding amounts for each activity. In addition, the funding amounts are based on best government cost estimates for the type of work and tasks to be performed as well as the level of effort expected.
utilization will not be available until all projects are solicited, reviewed, approved and completed.

- **Activity: Citizen Forum on Effective Health Care**
  - **Mechanisms:**
    - Contract: New competitive, cost-based reimbursement contract - $10 million
    - Project Length: Five years with ARRA funds

3. **FTE - $3 million (FY 09 - $0.5 M; FY 10 - $2.5 M)**

AHRQ Personnel: We expect the amount of staff time used to administer the programs proposed above to be approximately 15 temporary FTE not to exceed a two-year period. AHRQ will administer the proposed activities in subsequent years using non-ARRA FTEs. The additional FTEs provided with ARRA funds are essential in the initial development phase where funding opportunities need to be written and reviewed, risk and monitoring plans needed to be developed and reporting requirements needed to be fully developed and operationalized.

4. **Means of execution**

To achieve the goals of comparative effectiveness research, AHRQ will use a variety of funding mechanisms including grants, contracts, and inter-agency agreements.

Expansion of extramural grant funds for research and infrastructure for additional research capacities through RFAs for comparative effectiveness and supporting methodological research is anticipated.

Means of execution will also include support for additional activities to be conducted within current AHRQ program such as the DEcIDE (Developing Evidence to Inform Decision about Effectiveness) Research Network³, the Evidence-based Practice Centers (EPC) Program⁴, and the Eisenberg Center⁵. All activities will be coordinated with other AHRQ research networks as well as other research networks and program across the Department of Health and Human Services.

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³ DEcIDE Research Network generates new scientific evidence and analytic tools in an accelerated and practical format.
⁴ Evidence-based Practice Centers perform comprehensive reviews of existing evidence.
⁵ John M. Eisenberg Clinical Decisions and Communications Science Center compiles the research results into a variety of useful formats
5. **Intended award recipients**

AHRQ anticipates that award recipients will include a combination of researchers, academic institutions, states, community-based organizations, national organizations, and federal agencies.

6. **Fiscal year of expenditure**

In FY 2009, approximately $54 million of the total funds available (18%) will be obligated. In FY 2010, approximately $246 million (82%) will be obligated.

7. **Timing of milestones**

AHRQ is developing a schedule with milestones and planned delivery dates for major phases of the program’s activities. AHRQ anticipates making the initial CER awards no later than September 2009.

<table>
<thead>
<tr>
<th>July 2009</th>
<th>Begin publishing Recovery Act specific requests for task order contracts.</th>
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<tr>
<td>August 2009</td>
<td>Review proposals.</td>
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<tr>
<td>September 2009</td>
<td>Award FY 2009 task order contracts; award FY 2009 contract modification; award meritorious grant applications that were not funded in prior cycles.</td>
</tr>
<tr>
<td>Ongoing after September 2010</td>
<td>Begin publishing Recovery Act specific requests for contracts and funding announcements, conducting reviews and making awards for FY 2010 contracts and grants.</td>
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8. **Congressionally-required spend plan**

The FY2009 congressionally-required spend plan is required for submission to Congress by July 30, 2009.

9. **Designation of funding by organizational structure**

AHRQ will have the primary responsibility for providing funds control and for carrying out the activities described above.

10. **Accountability measures**
AHRQ will use current internal controls in accordance with the both the Federal Managers’ Financial Integrity Act (FMFIA) and Appendix A of OMB Circular A-123 to protect these funds from misappropriation, mismanagement, waste, and abuse. In addition, during the A-123 review AHRQ will provide additional testing of key controls (if necessary) to ensure ARRA funds are included in AHRQ’s testing sample. Finally, AHRQ is in the process of drafting a comprehensive Risk Management Plan to identify, prioritize, and mitigate Agency/program specific-risks. AHRQ consulted with the Office of the Inspector General (OIG) regarding our spend plan. The OIG suggested that AHRQ provide additional discussion of the oversight of recipients, especially new or high risk recipients. We have included this discussion below.

Historically, most of AHRQ’s grant awards are made to institutions that have had prior Federal funding and have demonstrated their ability to administer Federal funds. In accordance with HHS policy, for recipients that have not received prior Federal funding, non-profit status will be confirmed and a cursory assessment of the organization’s financial status will be made by AHRQ staff. Subsequent to funding, AHRQ will request that the OIG perform an audit to assess the recipients’ ability to properly expend and monitor grant funds where there are concerns. AHRQ anticipates that a large majority of large grants will be awarded to institutions that have had prior Federal funding and have demonstrated their ability to administer Federal funds.

Contract awards are made to organizations that must demonstrate that they have an adequate accounting system that has been approved by a Federal agency. This accounting system must allow the organization to track Federal obligations, expenses, and reimbursements for each project funded. The adequacy of the accounting system is verified prior to award. AHRQ also provides a two level review of each invoice received to ensure that the expenses are both allowable and allocable.

In terms of program review, AHRQ will use ARRA funds for comparative effectiveness to conduct and support research that will result in current, unbiased, evidence on health care interventions that will aid patients, health care providers, and policymakers in decision making. AHRQ will hold itself accountable to effectively spending the funds by continuing to measure the following:

- Amount of evidence available to clinicians, policymakers and patients to make health care decisions;
- Number of organizations disseminating evidence to their constituents;
- Amount of evidence used as a foundation for population-based policies, performance measures, and other strategies to improve decision making related to the effectiveness and appropriateness of health care interventions, technologies and services;

One potential risk for ineffective spending is funding projects that do no meet the needs of stakeholders. To minimize this risk, AHRQ will continue to increase the transparency and explicit process for comparative effectiveness research and will continue to engage stakeholders throughout the research process. Currently, there are many ways for stakeholders to get involved in AHRQ’s comparative effectiveness research, including:
• Submitting suggestions for research topics.
• Commenting on draft key questions before research has begun.
• Commenting on draft Research Reviews and Comparative Effectiveness Reviews.
• Providing expert input / scientific information to inform a report.
• Participating in a listening session. These sessions allow participants to provide focused comments on issues important to the EHC Program, such as research topics, program structure, and scientific methods.

Another potential risk for ineffective spending or waste is through non-performance of funded projects. To minimize this risk, AHRQ will carefully review and select projects for funding. The following criteria may be reviewed for each proposed project: understanding of the purpose and objectives of AHRQ’s comparative effectiveness research programs, technical approach, management plan, organizational experience, key personnel, stakeholder engagement, and facilities and database characteristics. AHRQ will also continue to standardize training required for program officials at the Agency working on contracts and grants. This will ensure effective oversight and management of contracts and grants and will decrease the risk of non-performance.
APPENDIX A

AHRQ’s Current Approach to Topic Selection for Comparative Effectiveness Research

The Agency for Healthcare Research and Quality (AHRQ) firmly believes that involving all stakeholders in the research enterprise from the beginning improves the end product and facilitates the diffusion and implementation of the findings by getting early buy in from users. Involving all stakeholders also helps to ensure that the research reflects the various needs of all diverse users.

AHRQ’s approach to involving stakeholders in comparative effectiveness research includes requesting topic nominations and interacting with stakeholder groups to elicit topic nominations. AHRQ encourages research suggestions from all sources and all topic nominations are posted online on the Effective Health Care Program Web site, http://effectivehealthcare.ahrq.gov.

Once an interested person or group suggests a topic for research, AHRQ determines whether enough information is included in the topic nomination. The minimum amount of information needed to define a topic as a nomination includes the population of interest, interventions of interest, comparators of interest, outcomes of interest, and the policy and/or clinical context. If more information is needed, AHRQ will request additional information from the nominator if the nominator’s contact information is clearly identified. Once a topic is determined to have enough information, AHRQ evaluates how the topic nomination meets specific selection criteria.

Factors considered in the selection of topic nominations for AHRQ comparative effectiveness research and reports include:

- Burden of disease, including severity, incidence and/or prevalence, or relevance of organizational/financial suggestions of research to the general population and/or AHRQ's priority populations, which include:
  - Low-income groups
  - Minority groups
  - Women
- Children
- The elderly
- Individuals with special health care needs, such as those with disabilities, those who need chronic care or end-of-life care, or those who live in inner-city and rural areas.

- Controversy or uncertainty about the topic and availability of scientific data to support the systematic review and analysis.
- Total costs associated with a condition, procedure, treatment, or technology, or organization/financial topic, whether due to the number of people needing care, the unit cost of care, or indirect costs.
- Potential impact for reducing clinically significant variations in the prevention, diagnosis, treatment, or management of a disease or condition, or in the use of a procedure or technology.
- Potential impact for informing and for improving patient and/or professional decision-making, improving health outcomes, and/or reducing costs.
- Relevance to the needs of the Medicare, Medicaid, and other Federal health care programs.

AHRQ provides justifications to nominators when topic suggestions are accepted or denied. These justifications will soon be available on the Effective Health Care Web site.

Accepted suggestions are refined and forwarded to research teams to conduct either a research review (a synthesis of existing evidence such as a Effectiveness Review, Comparative Effectiveness Review or Technical Brief) or new research. New research is conducted if evidence does not support a full research review. A diagram showing the lifecycle of a topic nomination for research up to this stage is shown below.

If a research review is initiated, a set of key questions is posted for public comment. Key questions guide the review process and facilitate the extraction of relevant information. If new research is initiated, an abstract is posted online.
Upon completion of a research review, a draft report is produced. The draft report is available online for public comment for approximately 4 weeks. Comments are considered for incorporation into the final report.

Both final research reviews and new research final reports are published on the Effective Health Care Program Web site. Research review executive summaries are also posted online. Some report findings are also published in professional journal articles.

Research reviews are condensed and converted into plain language summary guides. Guides are tailored to different audiences – patients, clinicians and/or policymakers. Guides are developed and revised based on audience feedback and external review.
Lifecycle of a Topic Nomination for Research

**TOPIC IDENTIFICATION**

**TOPIC SOLICITATION**
EHC Program requests topic nominations

**TOPIC GENERATION**
EHC Program interacts with stakeholder groups to elicit topic nominations

**TOPIC NOMINATION**
Interested person or group suggests a topic for research

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**TOPIC NOMINATION DEVELOPMENT AND SELECTION**

**TOPIC SELECTION**
EHC Program evaluates how the topic nomination meets specific program selection criteria

Enough information in topic nomination → Topic is appropriate for Effectiveness Review or Comparative Effectiveness Review

Topic is appropriate for Technical Brief

Topic is not appropriate for Research Review

Not enough information in topic nomination → Topic Nomination Development

EHC Program requests additional information from nominator

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**TOPIC REFINEMENT FOR RESEARCH REVIEW**

EHC Program refines topic for Effectiveness Review or Comparative Effectiveness Review

EHC Program develops topic as a Technical Brief

EHC Program considers topic for New Research

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