

**AHRQ Announces a Request For Applications and Funding Opportunity for Comparative Effectiveness Research Clinical Registries – Initial Focus on Orthopedic Devices, Drugs, and Procedures**

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On July 6, 2009, the Agency for Healthcare Research and Quality (“AHRQ”) announced its intention to provide, for the first time, funding for the development of “a prospective clinical registry of orthopedic devices, drugs and procedures.”<sup>1</sup> **Letters of Intent are due September 4, 2009. Applications must be received by September 23, 2009.** Although this clinical registry will focus on orthopedic devices, drugs, and procedures, AHRQ believes that this clinical registry will serve as a model for other medical device, drugs, and procedures registries and ultimately may promote the use of study results in clinical practice. AHRQ prefers this to be a national registry.

AHRQ’s Request For Applications (“RFA”) RFA-HS-10-008 is a grant Funding Opportunity Announcement (“FOA”) entitled *AHRQ Developing Prospective Practice-based Comparative Effectiveness Research Clinical Registries: Orthopedic Devices, Drugs and Procedures* (<http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-10-008.html>). The purpose of AHRQ’s FOA is to provide funding to assist AHRQ in developing a prospective practice-based comparative effectiveness research clinical registry of orthopedic devices, drugs, and procedures to provide for a national clinical and outcomes data resource.<sup>2</sup> AHRQ envisions the orthopedic clinical registry as a sustainable data infrastructure that will aid in conducting comparative effectiveness and safety research. Ultimately, AHRQ would like to enhance and develop evidence relating to the short-term and long-term benefits, as well as the harms associated with, the treatments of orthopedic conditions through the development of the clinical registry across a broad network of providers. AHRQ is seeking applications responsive to the grant FOA from interested parties.

## Background

AHRQ is a federal agency within the U.S. Department of Health and Human Services (“DHHS”). It was established by the Omnibus Budget Reconciliation Act of 1989. At that time, AHRQ’s purpose was “to enhance the quality, appropriateness, and effectiveness of health care services, and access to such services, through the establishment of a broad base of scientific research . . . .”<sup>3</sup> AHRQ’s purpose was broadened by Section 1013 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (“**MMA**”) which authorized AHRQ to develop a comparative effectiveness research program.<sup>4</sup>

Currently, AHRQ’s mission is to improve the quality, safety, efficiency, effectiveness, and cost effectiveness of health care for all Americans by developing and working with health care systems: (1) to reduce the risk of patient harm from health care services, using evidence-based research and technology; (2) to achieve broad access to effective services, while promoting efficient use of resources; and (3) to improve health care outcomes by encouraging providers, consumers, and patients to use evidence-based information to make informed treatment decisions.

AHRQ’s comparative effectiveness research to date has been funded through AHRQ’s “Effective Health Care Program.” In this FOA, AHRQ is providing additional support to develop the necessary infrastructure for an orthopedic clinical registry that will allow for multiple collaborative, prospective multi-center studies.

## Who is eligible to apply for the RFA grant?

Domestic institutions and organizations are eligible to apply for grant funding under this FOA. Eligible institutions include local or State governments and Federal agencies, as well as public or non-profit private institutions (e.g., universities, colleges, and faith- or community-based organizations). For profit organizations and foreign institutions “may participate as members of consortia or as subcontractors only.”<sup>5</sup> Institutions and organizations may consider any individual for the position of Program Director (“PD”) or Principal Investigator (“PI”), provided that the applicant has the requisite “skills, knowledge, and resources” to conduct the proposed research as the PD or PI.<sup>6</sup> However, “a minimum time commitment of 40% annual effort is expected” of the principal investigator and a minimum time commitment of “25% annual effort is expected from the Lead Co-Investigator at each Clinical Center.”<sup>7</sup>

## What are the required activities?

Applicants for the AHRQ FOA are expected to develop the necessary infrastructure to allow for collection of comparative effectiveness research data with a concentration on hip and knee replacements. Overall, the applicant is expected to “form the core of the registry.”<sup>8</sup> The core of the registry consists of the creation of a Research and Data Coordinating Center and the inclusion of at least five (5) Clinical Centers at institutions that perform large volumes of hip and knee replacements. The applicant also must include a minimum of three (3) research studies utilizing the orthopedic registry.

**What is the stated purpose of the orthopedic clinical registry?**

The purpose of AHRQ's orthopedic clinical registry is to develop "a sustainable data infrastructure and to conduct rigorous clinical and scientific research", primarily focusing on comparative effectiveness and safety related to hip and knee replacements.<sup>9</sup> The orthopedic clinical registry will be used to establish scientific support for the short-term and long-term advantages and risks associated with implantable orthopedic devices, drugs, and procedures. AHRQ's comparative effectiveness program will focus "on evidence of the relative benefits and risks of alternative interventions" and "not make treatment or coverage recommendations."<sup>10</sup>

**What is the budget for this funding award?**

AHRQ will award one grant for "the development of the prospective clinical registry of orthopedic devices, drugs, and procedures."<sup>11</sup> AHRQ will commit up to \$3 million dollars per fiscal year towards the applicant's costs in developing and maintaining the clinical registry, including the Research and Data Coordinating Center. The AHRQ grant may be renewed up to three additional times, for a total amount of up to \$12 million dollars over a four-year period.<sup>12</sup> Overall, the total value of the AHRQ grant will depend upon the "quality, duration, and proposed research projects of the applications received."<sup>13</sup> However, applications that have budgets in excess of \$12 million dollars or exceed four (4) years in length will not be reviewed by AHRQ.

**How does this initiative relate to the comparative effectiveness provisions of the American Recover and Reinvestment Act of 2009 (ARRA)?**

The MMA established AHRQ's comparative effectiveness research program. AHRQ's FOA implements the agency's purposes under MMA, but does not relate directly to ARRA. ARRA allocated a total of \$1.1 billion in funding for comparative effectiveness research of drugs, devices, and medical procedures to three Federal Agencies.<sup>14</sup> These funds were specifically appropriated to advance the development and diffusion of treatments and health care strategies through research that evaluates clinical outcomes, effectiveness, and appropriateness of products, services, and procedures used to prevent, diagnose, or treat disease and other health conditions. The ARRA further stipulated that the available funds should promote the creation and use of clinical registries and electronic data networks for generating outcomes data. Of the \$1.1 billion, AHRQ was allocated \$300 million to carry out the comparative effectiveness research program established under the MMA.

**What is the status of the ARRA comparative effectiveness research activities?**

On June 30, 2009, the Federal Coordinating Council for Comparative Effectiveness Research, established under the ARRA, issued a report to the President and Congress describing the recommended use of the funds appropriated under the ARRA.<sup>15</sup> The report specified that the primary focus of investment in the near term should be on the development of a data infrastructure. Such an effort would enable the linking of existing electronic data networks and patient registries, promote partnerships with the private

sector, and advance the discovery of answers to numerous comparative effectiveness research questions. The Federal Coordinating Council also recommended funding efforts that facilitate the dissemination and translation of comparative effectiveness research results and identify priority patient populations (e.g., racial and ethnic minorities, persons with disabilities, persons with multiple chronic conditions, the elderly, and children) and therapies.

On August 7, 2009, AHRQ issued a “Notice of Intent to Publish” in order to let the public know about the grant and contract solicitations for comparative effectiveness research projects with the \$300 million in funds from the ARRA. AHRQ anticipates grant and contract solicitations to be published beginning in the Fall 2009 with awards starting in the Spring 2010.

AHRQ’s comparative effectiveness research projects that will be funded under ARRA will focus initially on 14 priority conditions that the Secretary of the Department of Health and Human Services established under Section 1013 of the MMA, which can be found at <http://effectivehealthcare.ahrq.gov/aboutUs.cfm?abouttype=program#Conditions>.

Grants for comparative effectiveness research funded under ARRA include the following amounts and areas:

- \$148 million evidence generation, including prospective studies and patient registries.
- \$29.5 million to support innovative translation and dissemination grants.
- \$20 million to support training and career development.

Contracts for comparative effectiveness research funded under ARRA include the following amounts and topics:

- \$9.5 million to establish an infrastructure to identify new issues for comparative effectiveness review investments.
- \$10 million to establish a citizen’s forum to formally engage all stakeholders and to expand and standardize public involvement in the entire effective health care enterprise.

Additionally, AHRQ anticipates supporting other grants (\$1 million) and enhancing existing contracts for evidence synthesis (\$50 million), evidence generation (\$24 million), translation and dissemination (\$5 million), and salary benefits for ARRA-related full-time equivalent positions (\$3 million).

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<sup>1</sup> Request for Applications, Dep't Health & Human Servs., *AHRQ Developing Prospective Practice-based Comparative Effectiveness Research Clinical Registries: Orthopedic Devices, Drugs, and Procedures* pt. I (July 6, 2009), <http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-10-008.html>.

<sup>2</sup> *Id.*

<sup>3</sup> Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6103, 103 stat. 2106 (1989).

<sup>4</sup> 42 U.S.C. § 299b-7.

<sup>5</sup> Request for Applications, *supra* note 1, pt. III. Congress authorized AHRQ to “make grants to, and enter into cooperative agreements with, public and nonprofit private entities and individuals . . . .” Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6103, 103 stat. 2106 (1989). Under 42 C.F.R. § 67.12, “any public or nonprofit private entity or any individual is eligible to apply for a grant” relating to research for health services, evaluation, demonstration, and dissemination projects.

<sup>6</sup> Request for Applications, Dep't Health & Human Servs., *AHRQ Developing Prospective Practice-based Comparative Effectiveness Research Clinical Registries: Orthopedic Devices, Drugs, and Procedures* pt. I (July 6, 2009), <http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-10-008.html>.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.* pt. I.

<sup>9</sup> *Id.*

<sup>10</sup> Request for Applications, Dep't Health & Human Servs., *AHRQ Developing Prospective Practice-based Comparative Effectiveness Research Clinical Registries: Orthopedic Devices, Drugs, and Procedures* pt. I (July 6, 2009), <http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-10-008.html>.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, tit. VIII.

<sup>15</sup> Fed. Coordinating Council for Comparative Effectiveness Research, Dep't Health & Human Servs., *Report to the President and the Congress* (2009), available at <http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf>.

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