

**PART I - THE SCHEDULE
SECTION A - SOLICITATION FORM**

Request for Proposal
No. AHRQ-10-10006

Date Issued: **March 8, 2010**
Date Questions Due: **March 23, 2010 12:00 PM ET**
Date Notice of Intent Due: **April 12, 2010**
Date Proposals Due: **April 27, 2010 12:00 PM ET**

You are invited to submit a proposal to the Department of Health and Human Services, Agency for Healthcare Research and Quality (AHRQ) for Request for Proposal (RFP) No. AHRQ-10-10006, entitled "Developing Evidence to Inform Decisions about Effectiveness Research Network-2 (DEcIDE-2). Your proposal must be developed and submitted in accordance with the requirements and instructions of this RFP.

A multiple-award, task order-type contract (IDIQ) is contemplated for a period of three years.

The Government anticipates awarding 6 – 10 contracts from this one solicitation.

Offerors shall submit the following:

- A. Technical Proposal (See Section L.10) (Original and 12 copies)
- B. Past Performance Information (See Section L.11) (Original and 2 copies)
- C. Business Proposal (See Section L.13) (Original and 5 copies)

Your technical proposal must be concisely written and should be limited to **100 typewritten pages** (double-spaced), exclusive of personnel qualifications (i.e., resume, etc., see Section L.10 for additional details). This limitation is for administrative purposes only and exceeding the limitation shall not, of itself, be considered a basis for rejection of your proposal.

As part of the business proposal, offerors shall provide an original and five (5) copies of their cost/price proposal, only to the extent that it shall include:

1. Certified, unloaded, labor rates for individuals expected to work on a project of this size and nature (Class Levels I through IV, see Sections B.3 and L.10).
2. Certified documentation indicating that the offeror has a cost accounting system in place which allows for the collection, tracking and reporting of all costs under a cost reimbursement-type contract.
3. Certified documentation that the offeror has a current indirect cost rate agreement in place with a federal agency or that is in the process of obtaining or revising such an agreement. A copy of the indirect cost rate agreement or the proposed rate agreement must be provided.

Your proposal must provide the full name of your company, the address, including county, Tax Identification Number (TIN), DUN and Bradstreet No., and if different, the address to which payment should be mailed.

YOUR ATTENTION IS CALLED TO THE LATE PROPOSAL PROVISIONS PROVIDED IN SECTION L.3 OF THIS RFP. YOUR ATTENTION IS ALSO DIRECTED TO THE TECHNICAL PROPOSAL INSTRUCTIONS PROVIDED IN SECTION L.10 OF THE SOLICITATION.

If you intend to submit a proposal in response to this solicitation, please inform the Contracting Officer of your intent by completing the Proposal Intent Response Form (Attachment 3 to this solicitation) and send it to the Contracting Officer no later than **April 12, 2010**. You may send it to the address below or fax it to 301-427-1740, Attention: Mary Haines, Contracting Officer.

Questions regarding this solicitation shall be received in this office no later than **March 23, 2010, 12:PM PM ET** (See Section L.7). All questions shall be submitted electronically by e-mail to Mary Haines, Contracting Officer at the following email address: mary.haines@ahrq.hhs.gov Subject line shall read: "**Proposal Questions RFP No. AHRQ-10-10006.**"

Answers to questions will be provided in the form of an Amendment to this solicitation and will be posted on AHRQ's web page: www.ahrq.gov under "Funding Opportunities," "Contract Solicitations" and Federal Business Opportunities web page: www.fedbizopps.gov. It is your responsibility to monitor the web sites where the RFP will be posted to learn about any amendments to the solicitation.

Discussions with any other individual outside the Division of Contracts Management, may result in rejection of the potential offeror's proposal.

The proposal shall be signed by an authorized official to bind your organization and must be received in our Contracts Office no later than **12 noon**, local prevailing time, on **April 27, 2010**. Your proposal must be mailed to the following address:

Agency for Healthcare Research and Quality
Division of Contracts Management
540 Gaither Road
Rockville, Maryland 20850

Hand carried proposals may be dropped off at the above location. However, please allow ample time as proposals cannot be accepted until they have gone through security. We will not be held responsible for any delays that may be incurred getting your proposal through security. The Contractor is responsible for paid parking for proposal delivery

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to our Rockville, Maryland address. Packages delivered via this service will be held at a local post office for pick-up. The Government will not be responsible for picking up any mail at a local post office. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal."

The RFP does not commit the Government to pay any cost for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition.

In accordance with Federal Acquisition Circular (FAC) 2001-16, all contractors must be registered in the central contractor registration (CCR) database in order to conduct business with the government [See Section I - FAR clause 52.204-7 Central Contractor Registration (OCT 2003), Alternate 1 (Oct 2003)] . As stated in paragraph (h) of this clause, additional information can be obtained at <http://www.ccr.gov> or by calling 1-888-227-2423, or 269-961-5757.

Requests for any information concerning this RFP should be referred to Mary Haines, 301-427-1786 or e-mail: Mary.Haines@ahrq.hhs.gov. Please note e-mail requests should state subject as **RFP AHRQ 10-10006**.

Sincerely,

Mary Haines
Agency for Healthcare Research and Quality

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SECTION B-SUPPLIES OR SERVICES AND PRICES/COSTS

B.1 BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

“Developing Evidence to Inform Decisions about Effectiveness (DECiDE) Research Network (DECiDE-2”

See Section C for a complete description.

B.2 TASK ORDERS

This is a task order (IDIQ) contract for “Developing Evidence to Inform Decisions about Effectiveness (DECiDE) Research Network (DECiDE-2)”. Services will be acquired on an as-needed basis through issuance of task orders. See Section H.14 for Task Order Issuance Procedures. Typical task orders are expected to range between \$250,000.00 and \$1,000,000.00

B.3 PROPOSED LABOR RATES FOR TASK ORDERS

Note: The following labor rates are NOT loaded rates. (Ranges in rates may be provided)

Base Year 1

<u>LABOR CATEGORY</u>	<u>HOURLY RATE</u>
Class I	\$
Class II	\$
Class III	\$
Class IV	\$

Base Year 2

<u>LABOR CATEGORY</u>	<u>HOURLY RATE</u>
Class I	\$
Class II	\$
Class III	\$
Class IV	\$

Base Year 3

<u>LABOR CATEGORY</u>	<u>HOURLY RATE</u>
Class I	\$
Class II	\$
Class III	\$
Class IV	\$

B.4 PROVISIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable Unless Otherwise Provided Notwithstanding the clauses, ALLOWABLE COST AND PAYMENT, and FIXED FEE, incorporated into this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

- (1) Acquisition, by purchase or lease, of any interest in real property;
- (2) Rearrangement or alteration of facilities;
- (3) Purchase or lease of any item of general purpose-office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);
- (4) Accountable Government property (defined as both real and personal property with an acquisition cost of \$1,000 or more, with a life expectancy of more than two years) and "sensitive items" (defined and listed in the Contractor's Guide for Control of Government Property, 1990, regardless of acquisition value;
- (5) Travel to attend general scientific meetings;
- (6) Foreign Travel;
- (7) Any costs incurred prior to the contract's effective date;
- (8) Rental of meeting rooms not otherwise expressly paid for by

the contract;

- (9) Any formal subcontract arrangements not otherwise expressly provided for in the contract;
- (10) Consultant fees in excess of \$1000/day;
- (11) Information Technology hardware or software and
- (12) Food and Beverages.

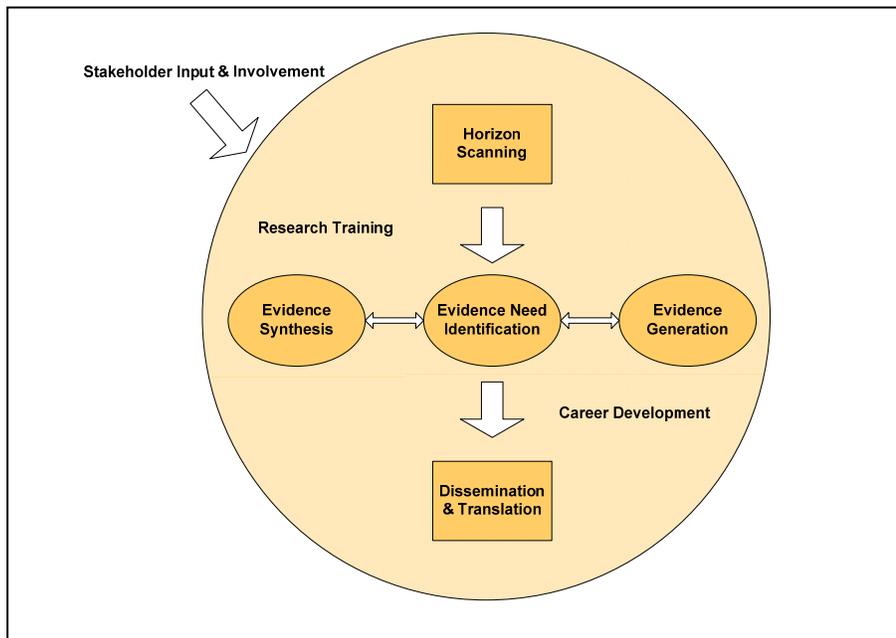
- b. This contract is subject to the provisions of Public Law (P.L.) 99-234 which amends the Office of Federal Procurement Policy Act to provide that contractor costs for travel, including lodging, other subsistence, and incidental expenses, shall be allowable only to the extent that they do not exceed the amount allowed for Federal employees. The Contractor, therefore, shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulations (FAR) 31.205-46.

SECTION C/ STATEMENT OF WORK

DESCRIPTION/SPECIFICATION/WORK STATEMENT

The Agency for Healthcare Research and Quality (AHRQ) is soliciting proposals for research centers to participate in the “Developing Evidence to Inform Decisions about Effectiveness” (DEcIDE) Research Network program. It is anticipated that between six and ten Task Order Contract awards will be made in response to this RFP to continue the collaborative research network that AHRQ established in 2005. The DEcIDE Network assists AHRQ and other Federal Agencies with patient-centered outcomes research, including studies on comparative clinical effectiveness as authorized by Section 1013 of the Medicare Modernization Act of 2003 (MMA) and subsequent legislation such as the American Recovery and Reinvestment Act (ARRA). Through this solicitation, new DEcIDE contracts (hereafter referred to as “DEcIDE-2”) will be awarded for 36 months. This is a full and open competition and not limited to existing DEcIDE research centers (hereafter referred to as “DEcIDE-1”). The DEcIDE-2 Research Network will continue to provide a variety of research services and scientific products to support the generation of new scientific evidence on patient-centered outcomes of healthcare items and services, with a focus on comparative clinical effectiveness research. Activities performed by the DEcIDE Research Network reflect the general principle that clinicians and patients should have the best available scientific evidence upon which to make individual decisions about health care items and services. Notably, a hallmark of the DEcIDE Research Network program is to provide high quality research that contributes to the evidence base and serves to inform healthcare decision-making. Hence, the DEcIDE Research Network program will continue its focus on original research that generates objective scientific evidence and new analytic tools for assisting patients, clinicians, purchasers, policy-makers, and others in making informed health care decisions. NOTE: None of the task orders awarded under the IDIQ contracts will be subject to ARRA funding and reporting requirements.

DEcIDE-2 research centers awarded under this contract will be expected to work closely and collaboratively with other AHRQ-supported investigators and programs involved with comparative effectiveness, under the auspices of AHRQ’s Effective Health Care (EHC) program. These programs include the Evidence-based Practice Centers (EPC’s), the John M. Eisenberg Center for Clinical Decisions and Communications Science (Eisenberg Center), EHC stakeholder and citizens’ forums, EHC horizon scanning systems, the Centers for Education and Research on Therapeutics (CERTs) program, investigator-initiated grant programs, training grant recipients, and most notably, all DEcIDE-1 and DEcIDE-2 research centers. In addition, investigators affiliated with the DEcIDE-2 program will be expected to work closely and collaboratively with AHRQ scientific staff on all projects. Figure 1 below presents a general diagram of AHRQ’s Effective Health Care program and its major components focused on evidence generation, evidence synthesis, and evidence translation for comparative effectiveness.



Independently and not as an agent of the Government, the Contractor shall be required to furnish all necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work. Services required by the Federal Government under this contract will be obtained on an as-needed basis through issuance of Task Orders (i.e., delivery orders). Following the award of the master Task Order Contracts, the Contracting Officer will issue competitive Requests for Task Order (RFTOs) to all DEcIDE-2 research centers as requirements arise. Refer to Section H.14 for Task order selection criteria and procedures.

Task Orders may address a variety of assignments, generally within a defined clinical topic area, involving original research, development of new scientific methods, interventional studies, stakeholder outreach, multi-center protocol development, data analysis, and collaborative studies employing prospective designs. Task orders will be responsive to priorities and requests from the Secretary of Health and Human Services (HHS), acting through the Director of AHRQ, as well as Congress, Federal agencies, and other stakeholder groups. Assignments may have tight and/or overlapping deadlines by which specific products or analyses will be required. Close adherence to deadlines and reporting requirements will be required. For most Task Orders, deliverables will be electronically published on AHRQ’s website with attribution by the report authors, the originating DEcIDE center(s), and AHRQ.

Awarded Task Orders may be of variable lengths in performance periods, depending on the complexity of the research topic(s), scope, and depth of activities required. Therefore, DEcIDE-2 research centers will be expected to meet a variety of due dates without routine need for extensions of time. In addition, research centers will also be expected to have excellent leadership, methodological expertise, analyzable health care databases, experienced project managers, and the organizational flexibility to satisfy a range of tasks that need to be performed concurrently and collaboratively within AHRQ’s Effective Health Care program.

As noted above, DEcIDE-2 research centers may be tasked to provide a range of related research projects related to comparative clinical effectiveness, safety, and patient-centered outcomes

research. The number of Task Orders to be awarded to a DEcIDE-2 research center will be determined by the Contracts Officer, in consultation with the Project Director of the DEcIDE Research Network.

The following paragraphs outline the major activities a DEcIDE-2 research center may perform.

1. Conduct multi-center prospective observational and interventional studies. Examples of the types of tasks include: a) studying the comparative effectiveness and safety of different therapeutic approaches including surgery, diagnostic tests, pharmaceuticals, and medical procedures; b) writing study protocols and complex data analysis plans for collaborative prospective studies; c) performing studies comparing the clinical effectiveness of treatment options in different patient subpopulations; d) identifying optimal medical management for varying levels of disease severity; e) carrying out evaluations of innovative healthcare services or medication therapy management; f) evaluating patient and prescriber decision-making tools; g) designing and implementation of prospective studies to examine health outcomes of diagnostic tests and treatments.

2. Analyze, link, and develop electronic health data for research. Examples of the types of tasks include: a) creation, linkage, and analysis of device, disease, or therapeutic registries; b) development of electronic surveillance systems to identify adverse medical reactions and sentinel events; and c) integration of clinically rich data into existing administrative data to enable studies of effectiveness through infrastructure building. All research will be performed with appropriate human subjects and privacy protections.

3. Perform retrospective analytical studies to inform and support research as well as research prioritization and decision-making. Examples of the types of tasks include: a) analyzing Medicare data collected as part of coverage with evidence development policy decisions under appropriate data use agreements; b) secondary database analyses to compare health outcomes (e.g., hospitalizations, deaths, patient costs, morbidity) according to a particular therapeutic approach like surgery; c) evaluations of the effects of insurance benefit and drug formulary structure on health outcomes; d) clinical economic and cost studies; e) epidemiologic studies to identify the benefits and harms of prescription medication, procedures, and medical device use; f) post-approval studies of the effectiveness of new medical products; and g) genetic studies to ascertain potential benefits of genetic tests in reducing adverse events or improving efficacy of therapeutic interventions.

4. Develop and apply new research methods, instruments, and methodologies. Examples of the types of tasks include: a) developing new ways to summarize the potential benefits and harms of therapies; b) developing analytic techniques to reduce bias and confounding in observational data; c) statistical research to advance the scientific use of disease registries, clinical repositories and health databases; d) advancing methods on clinical heterogeneity; e) research to develop computer algorithms for identifying inappropriate prescribing patterns; f) development of measurement and clinical monitoring instruments that can be implemented in ambulatory clinics, pharmacies, or long-term care facilities with minimal burden on patients and healthcare providers; g) developing guidance for the conduct of comparative effectiveness research; and h) simulations and modeling studies of clinical pathways, health outcomes, and the value of information.

5. Provide technical assistance to AHRQ and other assignments as requested. DEcIDE-2 centers will provide expertise and technical assistance to AHRQ on topics relevant to Section 1013 of MMA and subsequent legislative mandates for comparative effectiveness and safety research.

A. Background

The Agency for Healthcare Research and Quality (AHRQ) was established in 1989 as the Agency for Health Care Policy and Research. Its reauthorizing legislation (42 U.S.C. 299 et seq; "Healthcare Research and Quality Act of 1999") renamed the Agency as the Agency for Healthcare Research and Quality (AHRQ) and established it as the lead Federal agency for enhancing the quality, appropriateness, and effectiveness of health services and access to such services.

To achieve these goals, the Agency conducts and supports a broad base of scientific research and promotion of improvements in clinical and health system practices, including the prevention of diseases and other health conditions. AHRQ sponsors and conducts research that develops and presents evidence-based information on healthcare outcomes, quality, comparative effectiveness, patient safety, cost, use and access. As a result, AHRQ's mission is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. Included in AHRQ's mandate is support of generation, synthesis, and dissemination of scientific evidence, including effectiveness research and analytic methods. Table 1 below lists the six portfolio areas that AHRQ currently organizes its programmatic activities.

Table 1: AHRQ Research Portfolio's

Value
Health Information Technology
Comparative Effectiveness
Prevention/Care Management
Patient Safety
Innovations and Emerging Areas

AHRQ recognizes that a number of populations experience persistent disparities in health status, access to care, quality of care, and poor health outcomes. To address these disparities, AHRQ encourages research projects, including work performed by DEcIDE-2 research centers to include special populations such as low-income groups, racial and ethnic minority groups, women, children, the elderly, and individuals with disabilities, low-literacy, and rare health conditions. AHRQ-supported research helps health care decision makers - patients and clinicians, health system leaders, purchasers, and policymakers - make more informed decisions and improve the quality of health care.

In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) was enacted into law. This law brought the most dramatic and innovative changes to the Medicare program since it began in 1965. Section 1013 of MMA authorizes AHRQ to conduct research, demonstrations, and evaluations designed to improve the quality, effectiveness, and efficiency of Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). The essential goals of the Section 1013 mandate are to develop valid evidence, and make it easily accessible to decision makers, about the comparative effectiveness of different treatments and appropriate clinical approaches to difficult health problems. Achieving these key goals encompasses reviewing, synthesizing, and translating published and unpublished scientific evidence as well as identifying important issues for which existing scientific evidence is insufficient to inform decisions about health care. Through the DEcIDE Network, new scientific evidence is developed to address knowledge gaps that are essential to improving the quality, effectiveness, and efficiency of health care delivered

through Medicaid, Medicare, SCHIP, and other health care programs. Hence, the research and other activities performed by the DEcIDE-2 Network will focus on: a) understanding the outcomes, comparative clinical effectiveness, safety, and appropriateness of health care items and services (including prescription drugs); and b) developing strategies for improving the efficiency and effectiveness of the Medicare, Medicaid, SCHIP, and other health programs.

In consultation with relevant stakeholders, the Department of Health and Human Services (DHHS) undertook a priority setting process for identifying important topics to initially address the MMA Section 1013 legislation. Recommendations for research made by stakeholders were reviewed and prioritized by a steering committee composed of representatives from different components of DHHS. In 2005, the Department published an initial priority list of ten priority conditions under which research and related activities were undertaken under Section 1013. This list was updated in 2008 to fourteen conditions that are shown in Table 2. These priority conditions are the current focus of the Effective Health Care program, including the DEcIDE-2 Network. It is anticipated that this list of priority conditions will be reviewed regularly and updated according to programmatic needs, resources, and stakeholder input.

Table 2: 2008-current MMA Priority Conditions

Arthritis and nontraumatic joint disorders
Cancer
Cardiovascular disease, including stroke and hypertension
Dementia, including Alzheimer's Disease
Depression and other mental health disorders
Developmental delays, attention-deficit hyperactivity disorder, and autism
Diabetes mellitus
Functional limitations and disability
Infectious diseases including HIV/AIDS
Obesity
Peptic ulcer disease and dyspepsia
Pregnancy including preterm birth
Pulmonary disease/asthma
Substance abuse

Topics for research in the DEcIDE-2 Network will be informed by stakeholder input. DEcIDE-2 research centers will engage stakeholders to elicit topics for developing new research studies. Stakeholder groups broadly include patient, providers, and policymakers, such as prescription drug plans under Part D, state Medicaid Medical Directors, consumer organizations, and professional societies.

With the new funding resources made available through the ARRA in 2009, AHRQ expanded its research infrastructure for comparative effectiveness research, including strengthening the infrastructure of the DEcIDE Network. As part of ARRA, multi-center research consortia in the DEcIDE-1 Network were expanded with new research projects focused on national priorities and a new DEcIDE research methodology group was established. New research projects were incorporated into the existing DEcIDE-1 consortia (i.e., diabetes, cancer, cardiovascular disease, and analytics) and new consortia were formed for other priority conditions. By supporting multi-center research consortia and a dedicated methods group through ARRA funding, AHRQ plans to

continue the consortia model when appropriate for some DEcIDE-2 projects. These DEcIDE-2 projects will have a period of performance from six months to a maximum of three years. A general description of the current DEcIDE-1 consortia can be found in Appendix 1. Offerors are strongly encouraged to review this information prior to submitting a proposal.

While multicenter consortia are the model in which AHRQ plans to continue a substantial portion of its work in the DEcIDE-2 program, AHRQ may also award broad-based Task Orders or specific Task Orders to support other programmatic needs or stakeholder-nominated scientific work including development of research methods and analytic support.

B. Objectives

The overall aim of this Task Order contract is to maintain and strengthen a collaborative research program called the DEcIDE Research Network for conducting studies in support of MMA Section 1013 and subsequent statutory mandates for comparative effectiveness and safety research. The main purpose of the DEcIDE-2 Network will be to expeditiously develop valid scientific evidence and methodologies about the outcomes, comparative clinical effectiveness, safety, and appropriateness of health care items and services for improving the quality, effectiveness, and efficiency of healthcare delivered through the Medicare, Medicaid, SCHIP, and other health programs. The Network may be comprised of academic, clinic, private, and/or practice-based organizations each with their own unique area of emphasis and expertise/skills and will work in a coordinated and collaborative fashion to achieve these aims with other institutions in the Network and in close collaboration with AHRQ.

The overarching goal of comparative effectiveness research is to improve patient health outcomes by providing unbiased scientific evidence that informs the health care decisions of patients, their caregivers, clinicians, and policy makers. The Department of Health and Human Services (DHHS) currently uses the definition of comparative effectiveness research as set forth by the Federal Coordinating Council for Comparative Effectiveness Research:

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.

The primary objective of the DEcIDE-2 Network will be to support and conduct original research that examines the comparative clinical effectiveness of health care interventions including the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed. Services supporting this objective include the following activities:

- 1) conducting multi-center prospective observational or interventional studies that evaluate strategies for improving the effectiveness and efficiency of the Medicare, Medicaid, SCHIP and other health insurance programs, including ways in which medical therapies and diagnostic tests are provided, organized, managed, and delivered;

- 2) developing of valid scientific methods, measures, and instruments that can be rapidly applied to facilitate comparative effectiveness research, clinical care, or program evaluation;
- 3) establishing, maintaining, operating, and analyzing clinical registries that enroll participants based on characteristics such as demographics, disease status, drug exposure, or use of medical device(s);
- 4) evaluating distributed research networks, data standards, controlled terminologies, and ontologies that enable information system interoperability, comparative effectiveness research, safety studies, registry development and knowledge sharing while maintaining privacy;
- 5) conducting retrospective and prospective studies to assess various factors that may affect therapeutic effectiveness and patient health outcomes;
- 6) providing of technical assistance or consultative support to AHRQ on methods for conducting health outcomes research on the comparative effectiveness and safety of medications, diagnostics, surgery, health systems, and other healthcare interventions;
- 7) providing of technical assistance in establishing, maintaining, and mining clinical repositories and databases for comparative effectiveness and safety research;
- 8) evaluating of the feasibility of using administrative, claims, or other existing health data to a) improve oversight, b) support quality, safety, effectiveness, and efficiency initiatives, c) and estimate the impact on patients and populations of changes in clinical practices and insurance program policies;
- 9) conducting accelerated research that examines the a) outcomes, b) comparative clinical effectiveness, c) safety, and d) appropriateness of prescription medications and other therapies, using existing electronic health databases; and
- 10) implementing selected economic analysis including value of information or other quantitative methods for prioritizing the initiation of new research studies.

To better understand the context of this solicitation, it is recommended that offerors consult descriptions of the issues and definitions contained in the MMA Section 1013 legislation (see <http://www.medicare.gov/MedicareReform/108s1013.pdf>). This statute may also be found in 42 USC 299b-7. In addition, offerors are encouraged to review the literature including citations in the Bibliography section below as well as the Effective Health Care program website (see <http://effectivehealthcare.ahrq.gov>).

C. Specific Requirements

Research conducted by the DEcIDE-2 Network will help address important questions about the best clinical options for the treatment and diagnosis of conditions where additional scientific evidence will help reduce the uncertainty that health care providers and patients face when making decisions about health care options. In addition, the DEcIDE-2 Network will advance research methods for strengthening the validity of comparative clinical effectiveness research. In order to qualify as a DEcIDE-2 research center, offerors are required to have a multidisciplinary core team of investigators that includes clinicians, pharmacists, statisticians and epidemiologists, and access to additional clinical specialists, information technologists, and other research experts. In addition, the

research center is required to have professional project management staff to facilitate adherence to project timelines, DEClDE program procedures, management, communication, and deliverable schedules.

Principal Investigator or Project Director. Each DEClDE-2 center will have one principal investigator or project director (PI/PD), who is assisted by a project manager. In addition, a deputy principal investigator may or may not be named by the offeror. The PI/PD shall be a senior scientist with experience in conducting comparative effectiveness and/or safety studies and a substantial record of scholarship in research. The PI/PD shall have an advanced degree such as an MD, PhD or MPH with a minimum of 8 years' experience in the development, implementation, and dissemination of research findings. In addition, the PI/PD will be expected to have strong administrative experience in successfully managing multiple research projects. The PI/PD will be expected to remain the PI/PD of the DEClDE contract for the entire 36 month period of performance for the contract.

Project Manager. Each center shall have an experienced project manager (PM) who will be responsible for project management across all Task Orders at the center. While the role of the project manager will be specified with each Task Order, responsibilities will generally include monthly status reporting, coordination of various tasks, managing, communication with AHRQ and stakeholders, arranging monthly conference calls, and assisting investigators with adhering to deliverable schedules and program policies.

Core Teams. The DEClDE-2 research centers are to be comprised of the PI/PD and a core staff of experienced professionals with advanced research training and expertise in conducting experimental and nonexperimental research. Team members shall be clinical researchers or epidemiologists trained from fields such as medicine, nursing, pharmacy, statistics, computer science, clinical trials, information science, health services research, behavioral research, public health, social sciences, and science writing and editing. In the event that the DEClDE-2 center's core staff does not include particular expertise needed to accomplish a Task Order, the center is to obtain such expertise through intra-institutional agreements (e.g., working with another department within a larger organization), consultants, and/or sub-contracts. Offerors, may not, however, subcontract a majority of the work to outside organizations. Offerors may also include professional organizations with the capacity to conduct research or partnerships with professional organizations. It is AHRQ's expectation that at least one topic-specific content expert will be included as key personnel for each Task Order that is issued by AHRQ.

Data Resources and Infrastructure Capacity. DEClDE-2 centers shall have access (or partners providing access) to electronic health information databases and the capacity to conduct retrospective and prospective research that meets the priorities and requests for evidence described in MMA Section 1013 and subsequent legislation. Examples of electronic health databases relevant to the DEClDE-2 Network include electronic medical record data, pharmacy records, public or private health insurance data, long-term care data, and special databases such as disease, medical procedure, or medical device registries.

Offerors will also need the capacity to develop therapeutic databases that can be analytically linked with other applicable healthcare data such as clinical, pharmacy, laboratory, diagnostic, medical device, survey, surveillance, genetic, and administrative claims information. All research performed by the DEClDE Research Network must comply with standards for privacy of individually identifiable health information and protect the rights of human subjects in research.

Clinical. Over the 36-month period of performance, AHRQ anticipates that scientific evidence will be developed across a range of diseases and health conditions. As discussed above, evidence developed will be initially in the topic areas identified in Table 2 above. Furthermore, clinical economic analyses, analyses of care delivery at micro-clinical systems level or organizational level, and development of patient and prescriber decision-making tools, may also be required. **In addition, it is anticipated that AHRQ will issue Task Orders to form specialized research consortia comprised of investigators from multiple DEcIDE centers.** These specialized consortia will conduct collaborative research on comparative effectiveness within a specific disease, health care condition, or other topic area (see below and Appendix 1).

Administrative. The DEcIDE-2 research centers will collaborate to develop multi-center research consortia that are to be comprised of core staff of experienced professionals. Topics selected for research studies will be narrowly focused and will generally require a rapid response by the DEcIDE network to scientific inquiries deemed to be of high priority. AHRQ and its affiliated resource centers will work with this Administrative Component of the DEcIDE-2 network to define the focus of topics for research, so that databases can be searched, analyses performed, and final scientific reports delivered to AHRQ within established and possibly tight and overlapping due dates set to meet Client/Partner needs (e.g., to make timely coverage decisions or develop timely clinical pathways). In the event that another Federal health agency requests on-going technical or scientific support from a DEcIDE research center, AHRQ will compete an RFTO for a multi-year task order for designated DEcIDE network support to that agency. Given that the centers must demonstrate ready and ongoing availability of the necessary clinical, epidemiological, pharmaceutical, pharmacogenetic, economic, and methodological expertise to successfully develop Consortia and undertake multiple Task Orders in any of topic areas relevant to the Medicare, Medicaid or the SCHIP programs offerors that are interested in being an overarching administrative center must describe their expertise in coordinating projects across multiple sites and areas of expertise and facilitating communication.

Expertise in Research Design, Statistics, and Epidemiology. DEcIDE-2 research centers will be expected to demonstrate methodological and analytic expertise in the assessment of a broad range of scientific data, such as data from randomized controlled trials, computerized health records, diagnostic studies, technology assessments, epidemiologic and social sciences research (including but not limited to economics, sociology, and behavioral research). Specifically, the offeror's processes and approach for:

- 1) Identifying specific types of study designs that would be appropriate to answer important questions related to a given topic with an emphasis on prospective evaluation;
- 2) Deriving measures of therapeutic use, prescription drug consumption, exposure, and utilization using electronic databases and epidemiologic techniques;
- 3) Accessing and using drug or medical device information resources and compendia, including electronic drug information databases, drug classification systems, and drug coding nomenclatures such as the National Drug Coding (NDC), the HCFA Common Procedure Coding System (HCPCS), the National Drug File by the VHA, and the RxNorm project by the National Library of Medicine;
- 4) Developing algorithms for identifying episodes of disease, episodes of care, and service utilization using standard coding systems such as the International Classification of Diseases (ICD-9-CM), clinical procedure coding (e.g, CPT codes) and professional services codes (e.g., Nursing Interventions Classification, PPAC-- Pharmacist Practice Activity Classification); and
- 5) Defining health and drug insurance eligibility windows to examine the effects of insurance coverage on health outcomes.

Expertise in Stakeholder Outreach. The Effective Health Care program is focused on providing unbiased evidence to addresses national research priorities identified by stakeholders. DEcIDE-2 centers will be asked to identify decisions under consideration by stakeholders for which available scientific evidence is insufficient to act upon with a high certainty of the outcome. To evaluate offeror's expertise with working with stakeholders, the information set out below must be included in each proposal. Specifically, offeror's processes for working with stakeholders to identify scientific questions within a given topic that are of the greatest importance for patients, practice or policy, including relevant health outcomes.

Organization or Institutional Experience. Offerors shall demonstrate corporate experience in conducting original research citing a minimum of 20 original projects over the past 10 years with evidence of publication in peer-reviewed health science journals. In addition, the applicant organization or institutions shall have demonstrated evidence of a minimum of 5 years' experience in health care research in one or more of the following fourteen conditions: arthritis and nontraumatic joint disorders; cancer; cardiovascular disease; dementia, including Alzheimer's Disease; depression and other mental health disorders; developmental delays, attention-deficit hyperactivity disorder, and autism; diabetes mellitus; functional limitations and disability; infectious diseases including HIV/AIDS; obesity; peptic ulcer disease and dyspepsia; pregnancy including preterm birth; pulmonary disease/asthma; and substance abuse. In addition, the organization should have the capacity to conduct research on other clinical, behavioral, and health system issues as new priorities are established at AHRQ.

In addition DEcIDE-2 research centers must be familiar with federal task order contract mechanisms and must be prepared to adhere to the requirements of the master contract. While this point seems obvious, past experience has shown some misunderstanding of the terms and conditions of the signed task order contract by the lead contractor organization or the subcontractors on a given task order. ***Task order contracts differ substantially from grants.*** For example: task orders must conform strictly to the scope of work for which the task order is awarded unless a modification is agreed to in advance by appropriate AHRQ staff; deliverables must be submitted on time and their quality must be approved by AHRQ staff; deliverables must be reviewed by AHRQ staff prior to publication or presentation; invoices for hours worked during the invoice period must be submitted regularly and must include all required details; payment is conditional on submission of invoices and task order officer approval of the quality of the work performed; work conducted past the end date of the task order period of performance will not be reimbursed; and OMB clearance is required for collection of certain types and amounts of data as specified by the Paperwork Reduction Act.

NOTE: While a qualified contractor does not have to have prior experience working for AHRQ, the contractor must show a significant presence working in health care research.

D. Tasks

Following designation of offerors as DEcIDE-2 research centers, and as resources permit, AHRQ plans to simultaneously compete among the DEcIDE-2 research centers a series of Requests For Task Order (RFTO) covering multi-year periods of performance.

Topics. The topics for DEcIDE-2 Task Orders will be generated from stakeholders and may vary from comparing treatment effectiveness within a drug class, to organization and delivery of health care services, to development of the scientific or evidence base for informing decisions. Deliverables from the DEcIDE-2 Network will be determined by the specific Task Order but at a minimum will include one or more final, written reports describing the background, research

methods, results, and conclusions of the research. Reports will be released in a manner determined by AHRQ and generally made available in multiple formats.

Range of Activities. Over the 3-year period of performance, AHRQ anticipates that scientific evidence will be developed across a range of diseases and health conditions. As discussed above, evidence developed will be in the priority conditions listed in Table 2 above. Furthermore, clinical economic analyses, analyses of care delivery at micro-clinical systems level or organizational level if appropriate, and development of patient and prescriber decision-making tools, may also be required. While DEcIDE-2 research centers may specialize in specific topic areas or disease conditions, the centers must also demonstrate ready and ongoing availability of the necessary clinical, epidemiological, pharmaceutical, pharmacogenetic, economic, and methodological expertise to successfully undertake multiple Task Orders in any of topic areas relevant to the Medicare, Medicaid, SCHIP, or other health programs. To that end, offerors are encouraged to describe their expertise.

Topics selected for research studies will be narrowly focused and will generally require a rapid response by the DEcIDE-2 Network to scientific inquiries deemed to be of high priority. AHRQ and its affiliated resource centers will work with the DEcIDE-2 Network to define the focus of topics for research, so that databases can be searched, analyses performed, and final scientific reports delivered to AHRQ within established and possibly tight and overlapping due dates set to meet Client/Partner needs (e.g., to make timely coverage decisions or develop timely clinical pathways).

In the event that another Federal health agency requests on-going technical or scientific support from a DEcIDE-2 research center, AHRQ will compete an RFTO for a multi-year task order for designated DEcIDE-2 Network support to that agency.

The required level of time commitment for senior clinical and methodological expertise will generally be consistent across the multi-year awards. However, time commitments and work products may vary to reflect discrete programmatic needs. DEcIDE-2 research centers that are awarded a multi-year task order will be required to maintain, throughout the period of performance, core staff whose dedicated time is at the required level specified in the particular multi-year task order. The multi-year task orders require stable “teams” with substantial time commitments to ensure rapid response and turnaround of assigned topics, as well as continuity of effort over an extended period of time.

Task Orders. Specific requirements tailored to meet particular program needs will be included in each of the RFTOs, including specific deliverables and schedules for the deliverables. A common requirement across all DEcIDE-2 task orders, whether multi-year or single topic, will be the DEcIDE-2 research center needs to demonstrate the capacity, capability and track record for delivering interim and final products to AHRQ by established and agreed upon due dates. Rapid turnaround, from assignment of DEcIDE-2 topics, completion of reports, to AHRQ’s publication of the reports, is a hallmark of the new DEcIDE-2 Program.

AHRQ may consider more than one award of a multi-year task order to a DEcIDE-2 research center, in response to programmatic needs, but only if a center has demonstrated the capacity and capability for adding additional clinical and methodological expertise (i.e., not reducing time commitments in place) plus a then-current performance record for meeting or exceeding due dates. DEcIDE-2 research centers may also receive single-topic Task Orders in addition to multi-year task order(s). Single-topic Task Orders may be competed or assigned, according to programmatic need.

Facilitating Communication. Each DEcIDE-2 center will be expected to help AHRQ maintain a system of monitoring and tracking outcomes and impact for its work. Centers will report outcomes

and impact at regular intervals to AHRQ for overall coordination of activities and for project management. In addition to regular emails, an annual face-to-face invitational meeting and periodic phone conferences, AHRQ will provide a secure website for submitting and sharing documents.

In addition, an annual workshop will be convened for AHRQ task order officers, the AHRQ Contracting Officer, the Program Officer and DEcIDE-2 Network administrative staff from each center to share insights on substantive accomplishments in the work in which they are involved and strategies they have developed to meet contractual requirements.

NOTES

1. Information about the Agency for Healthcare Research and Quality (AHRQ) programs is available at <http://www.ahrq.gov/>. Accessed January 1, 2010.
2. Information about the Effective Health Care program is available at <http://www.effectivehealthcare.ahrq.gov/>. Accessed January 1, 2010.
3. Information about the DEcIDE program is available at <http://www.effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-the-decide-network/>. Accessed January 1, 2010.
4. Information about the Evidence-based Practice Centers (EPC) program is available at <http://www.ahrq.gov/clinic/epc/>. Accessed January 1, 2010.
5. Information about the Centers for Education and Research on Therapeutics (CERTs) program is available at <http://certs.hhs.gov/about/certsovr.htm>. Accessed January 1, 2010.
6. Information about the Accelerating Change and Transformation in Organizations and Networks (ACTION) program is available at <http://www.ahrq.gov/research/action.htm>. Accessed January 1, 2010.
7. Information about the Primary Care Practice-based Research Networks (PBRNs) is available at <http://www.ahrq.gov/research/pbrn/pbrnfact.htm>. Accessed January 1, 2010.
8. Information about the Medical Expenditure Panel Survey (MEPS) is available at <http://www.meps.ahrq.gov/mepsweb/>. January 1, 2010.
9. Information about the Healthcare Cost & Utilization Project (HCUP) is available at <http://www.ahrq.gov/data/hcup/>. Accessed January 1, 2010.
10. Information about DEcIDE is available at: <http://effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-the-decide-network/>

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APPENDIX 1

A. Background – DEcIDE-1 Multi-Center Research Consortium

In 2007 AHRQ began to establish multi-center research consortia within the DEcIDE program focused on three selected clinical conditions: cardiovascular disease, cancer, and diabetes. By funding multi-center research consortia, AHRQ supports an infrastructure for stakeholders to work with researchers to develop scientific evidence on the comparative effectiveness and safety of interventions used in treating these important clinical conditions. In addition, by forming multi-center consortia the generalizability, reliability, and applicability of research findings is improved since the work spans across multiple DEcIDE centers, each with access to rich sources of data and scientific resources as well as the ability to work together to collect new data at different locations across the United States. Furthermore, the research consortia model affords AHRQ the opportunity to conduct multiple projects over time using an established infrastructure that allows for use of data and other resources from multiple centers, thereby increasing efficiency and fueling rapid cycle research. The DEcIDE consortia also leverage the vast amount of scientific expertise in multiple DEcIDE research centers, which further facilitates the development of pertinent and timely research questions and research agendas, refinement of study protocols, and identification of knowledge gaps and the ability to systematically address them.

B. Overall Objectives/Goals of the DEcIDE Consortia

A DEcIDE consortium may be established with the issuance of Task Orders by AHRQ. Although the RFTO will provide the specifics scope of work for new consortia, they are generally composed of investigators from two to three DEcIDE centers and conduct stakeholder-driven research on topics related to the comparative effectiveness for a particular priority condition. A DEcIDE consortium works closely with AHRQ to carry out a coordinated and collaborative research agenda that addresses stakeholder questions about the comparative effectiveness, safety, and clinical effectiveness of diagnostics and therapeutics for a broad range of topics. DEcIDE consortia function as an integral part of the DEcIDE program and are not established to be independent from the program or from AHRQ. The DEcIDE consortia also develops written scientific reports and assists the AHRQ Eisenberg Center in the development of dissemination materials based on studies that have been completed by the consortium.

Historically, DEcIDE consortia have used a multi-center model. In this model, one DEcIDE center serves as the lead or “Coordinating Center” for the consortium and other DEcIDE centers serve as “Affiliate Centers”. The Coordinating Center supports all functions of the consortium by establishing an Administrative Core and managing up to six committees that will work directly with the AHRQ Task Order Officer (TOO), an Executive Committee of Principal Investigators (PI’s) and others appointed by the TOO, the EHC Scientific Resource Center, the Eisenberg Center, and other DEcIDE centers. The standing committees of a DEcIDE consortium usually include the Data, Methods/Statistical, Clinical, and Stakeholder Committees. Each committee works collaboratively with the TOO, the Administrative Core, other committees, AHRQ, and other components of the EHC program.

Affiliate Centers support the consortium by leading at least one committee other than the Administrative Core which is reserved for the coordinating center. Affiliate Centers can range in size and scope but are expected to make substantial contributions to at least one research study each year either by contributing data, methodologic expertise, clinical input, research analysis, or stakeholder activities. Affiliate Centers may also propose new studies for review by the Executive Committee and by AHRQ and participate in approved studies conducted by other Affiliate Centers.

In all cases, the Affiliate Center agrees to work under the governance of the Executive Committee and ultimately the AHRQ program officials.

At AHRQ's direction, the Administrative Core shall work with the designated committees and other DEcIDE centers on collaborative activities. These activities will include joint research projects, working with the Eisenberg Center to develop educational products, and being involved in dissemination efforts. As such, all DEcIDE centers who participate in the consortia structure are prepared to work jointly and collaboratively with AHRQ, the Administrative Core, and within the committee structure.

The centers and committees work closely with each other although different individual DEcIDE centers may lead specific studies. For example, a particular assignment from AHRQ may benefit most from the methodologic leadership and/or expertise from the Coordinating Center, data from another DEcIDE center and clinical expertise from a third DEcIDE center. It is envisioned that no project will initially require more than three DEcIDE centers to complete a project. Some projects may be completed solely by the one center using shared resources from the consortium, while others will require two or three centers. Such collaborations, especially between DEcIDE centers with large data sets and data registries, have the potential to increase sample size.

In developing consortia within DEcIDE-1, AHRQ had the following objectives:

- To support innovative new research that is responsive to stakeholders, protocol-driven, based on established principles of good research practice, and includes analyses of both existing data as well as new data collection for research.
- To support studies that address research gaps identified in systemic reviews, particularly those completed by the EHC program.
- To support harmonization of DEcIDE studies within clinical areas like cancer and diabetes.
- To allow maximal flexibility in responding to findings of benefits and/or harms from diagnostic or therapeutic interventions that may occur with initial studies with follow-up research;
- To assist stakeholders, AHRQ, other HHS agencies, and the Federal government in prioritizing research to understand benefit and risks of diagnostic and therapeutic interventions that are of the greatest public health significance.

C. General Configuration of the DEcIDE-1 Consortium

The structure of a DEcIDE-1 consortium includes a primary Coordinating Center and one or more Affiliate Centers. The Coordinating Center houses the Administrative Core; several committees were also formed for the management of the project; Affiliate centers work collaboratively with the coordinating centers, other affiliated centers, and AHRQ. The Principal Investigator of the Coordinating Center co-chairs the Executive Committee (along with the AHRQ TOO as co-chair) of members appointed by AHRQ including the Principal Investigators from the Affiliated Centers in the consortium.

The functions of the Administrative Core and the committees are as follows:

1. Executive Committee

The PI of the Coordinating Center co-chairs the Executive Committee with the AHRQ TOO to jointly lead the research agenda and coordination of clinical effectiveness studies of drugs, devices, and diagnostics in a clinical area. Other Executive Committee members are appointed by AHRQ and are comprised of individuals from the Affiliated Centers, EHC program, federal government and other at large members. The DEClDE Program Director is an ex officio member of the Executive Committee. The Committee meets approximately once a month to oversee all aspects of the consortium including vetting of topics nominated for research through Stakeholders and other EHC forums.

The Committee concentrates its efforts on conducting a series of related studies that focus on expanding the knowledge base specified by EHC stakeholders, federal partners, and public nominations. The consortium also harmonizes ongoing and currently funded studies in the consortium identify the strengths and resources of other DEClDE centers, prioritize new studies, and commence with requisite work assignments under the direction of the AHRQ Task Order Officer and the DEClDE Program Director. With substantial stakeholder input, the Committee may propose studies or review studies proposed by the consortium centers; these reviews would then provide input to AHRQ in its deliberations on topic generation and development.

2. Administrative Core

The Administrative Committee is the central component of the Consortium. After a task order is awarded to establish the coordinating center, it establishes an Administrative Core and up to six committees. These committees are usually a Data Committee, a Methods/Statistical Committee, a Clinical Committee, and a Stakeholder Committee. A leader from the coordinating center or an Affiliate Center is appointed by AHRQ to lead each committee. All committees are open to representation from all centers.

The Administrative Core is lead by the Principal Investigator (PI), assisted by a Project Manager (PM) with at least five years of experience in project of similar scope. The PM operates under the direction of the PI to coordinate all functions of the Coordinating Center, the committees as well as the relationship with the Eisenberg Center, the Scientific Resource Center, and the Executive Committee. The PM coordinates with the AHRQ TOO and Methods/Statistical Committee to ensure any requisite Institutional Review Board (IRB) and Office of Management and Budget (OMB) clearances, as well as conflict of interest management. Also, the PM facilitates coordination and communication between the other existing DEClDE research centers and offers administrative support. The Administrative Committee also coordinates with other DEClDE centers in the network as needed for data, needed expertise, and/or other resources, and is able to coordinate other related studies that are already occurring in the DEClDE network.

The Administrative Core ensures that there is open and frequent communication, including establishing communication links from the advent of the consortium; this is of paramount importance to successfully sustain collaborative efforts. Monthly Consortium conference calls are arranged by the PM and include the AHRQ TOO, the DEClDE Program Director, and any other individuals requested by the TOO. The purpose of the calls shall be to assess the progress of work assignments and other projects, address and resolve any impending issues, and plan for future activities. The PM also assists in protocol development and the coordination of subsequent phases of the research agenda.

The Administrative Committee supports the Executive Committee, as well as the other DEcIDE centers and committees within the coordinating center. Consistent with AHRQ's philosophy, the Consortium is transparent in all of its programmatic activities and relationships with the aforementioned entities. AHRQ, the Executive Committee, and the Administrative Core works with all DEcIDE centers and committees to address the methodological and technical challenges of multi-center research, including governance, multiple IRB approvals, ownership of data, and privacy/HIPPA issues. Additionally, AHRQ and the Administrative Core established a common vocabulary and ensure that there are concrete and attainable goals and objectives in comparative research for the DEcIDE-1 centers, the Administrative and secondary research committees.

3. Data Committee

The Data Committee focuses on data development for multiple studies; support existing comparative effectiveness (CE) research databases; and maintains access to a limited number of public datasets. The Data Committee secures, manages and ensures the scientific integrity of the data used for research. This committee also ensures compliance with federal, state, and local privacy laws and any other legal or regulatory requirements. This committee is also expected to develop data for multiple studies suitable for the comparative and clinical effectiveness of therapeutic drugs and devices. This requires the creation and/or use of existing data resources/repositories such as laboratory values, pharmaceutical information, outpatient, and inpatient clinical data, administrative and possibly claims data. The Data Committee obtains and validates electronic and medical records, and makes every effort to overlay with existing databases and registries. The Data Committee also maintain access and expertise to a limited number of public data sets for research, epidemiologic, and the Data Committee responds rapidly to any requests by AHRQ for research, quick turnaround, and descriptive analysis, (e.g. number of outpatient visits for cancer in the last two years). Finally, the Data Committee has the capability to support the consortium on prospective data collection efforts should sufficient resources be available to conduct such a study.

4. Clinical Committee

The Clinical Committee evaluates and scientifically refines research questions received from the stakeholders to ensure clinical meaningfulness and relevance for purposes of developing work assignments. It is preferred that the committee be a multidisciplinary group of primary care physicians, medical specialists, radiologists, surgical oncologists, pharmacists, and nurses to provide such clinical expertise. The committee oversees the progress of the research and other projects and is readily available to answer any questions posed by the centers, stakeholders, or committees during the course of any work assignments. The Clinical Committee reviews study protocols, reports and manuscripts to ensure the clinical accuracy and relevancy.

5. Methods/Statistical Committee

The Methods/Statistical Committee oversees the methodologic and statistical integrity of the proposed observational studies, and explores avenues for expansion to prospective data collection. The committee is composed of consortium center members with representation from the Scientific Research Center. This committee works to advance and continually update research in comparative and clinical effectiveness. The committee accomplishes this by developing the following: algorithms for publicizing on AHRQ's Effective Health Care website, plans for prospective cohort studies particularly those including data registries,

simulations of existing data, new methods for controlling for confounding variables in research studies, plans for sharing and disseminating resources, findings and methods, identifying important outcomes and comparators in the treatment of cancer. It is critical that the Methods/Statistical Committee coordinates across the other DEcIDE centers and committees and work closely with the TOO, the SRC, and others at AHRQ. This committee, in conjunction with the PM also prepares requisite OMB clearance packets for new projects and provides a detailed example (template) of such a document for submission to OMB. Finally, the committee identifies important outcomes and comparators in diagnostics and treatment. The committee is encouraged, in collaboration with the other centers and committees, to provide commentary in scientific journals regarding such issues, and develop white papers for controversial topics, while maintaining transparency to the public.

6. Stakeholder Committee

The Stakeholder Committee assists with developing, prioritizing, and refining the research agenda for comparative and clinical effectiveness in a consortium. To accomplish this, the committee works with CMS, Medicaid, AHRQ, NIH, FDA, SRC, the Eisenberg Center, EHC stakeholders, representatives from priority populations, and others for input into the research agenda. The Stakeholder Committee provides input to the consortium on critical research information gaps in comparative effectiveness, provide input on implementation issues for DEcIDE reports, publications, and findings, define products that will be most useful to the public and provide feedback on how the program can have more of an impact on users. The Stakeholder Committee convenes at least once a year or more as needed.

SECTION D - PACKAGING AND MARKING

Not Applicable

SECTION E - INSPECTION AND ACCEPTANCE

E.1 INSPECTION AND ACCEPTANCE

- a. The contracting officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION the Government Project Officer is the authorized technical representative of the contracting officer.
- c. Inspection and acceptance will be performed at:

Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, Maryland 20850

E.2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause No.	Title and Date
52.246-5	Inspection of Services-Cost Reimbursement (April 1984)

SECTION F - PERIOD OF PERFORMANCE AND DELIVERY SCHEDULE

F.1 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates the following clause by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

FAR Clause No.	Title and Date
52.242-15	Stop Work Order (AUG 1989) Alternate I (APRIL 1984)

F.2 PERIOD OF PERFORMANCE

The Government anticipates the period of performance shall begin on or about July 19, 2010 through July 18, 2013. (ordering period)

F.3 DELIVERABLE SCHEDULE

The items specified for delivery below are subject to the review and approval of the Government Task Order Officer before final acceptance. Items # 1 and 2 shall be provided to the Task Order Officer as electronic and hard copy. The Contractor shall be required to make revisions deemed necessary by the Task Order Officer.

The Contractor shall produce the following scheduled reports/deliverables in the amount, and within the time frame indicated. Complete delivery instructions will be provided with each Task Order awarded.

The Contractor shall submit the following items in accordance with the stated delivery schedule:

<u>Item</u>	<u>Description</u>	<u>Quantity/Delivery Date</u>
1	Administrative, progress, and financial reports	As specified in each task order
2	All other deliverables identified in each task order	As specified in each task order
3	Subcontracting Report for Individual Contracts through eSRS	April 30 (annually) October 30 (annually) to the Contracting Officer
4	Summary Subcontractor Report through eSRS	October 30 (annually) to the Office of Small and Disadvantaged Business Utilization (DHHS))

5	Small Disadvantaged Business Participation Report	1 copy at contract completion
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In addition, one electronic and one hard copy of final reports and all other deliverables shall be submitted to Project Officer at the address below:

The Contracting Officer shall receive one copy of each progress report and final report/ final deliverable.

Agency for Healthcare Research and Quality
ATTN: Mary Haines, Contracting Officer
Contracts Management / OPART
540 Gaither Road
Rockville, Maryland 20850

Agency for Healthcare Research and Quality
ATTN: Scott Smith, PhD
Center for Outcomes and Evidence
COE
540 Gaither Road
Rockville, Maryland 20850

SECTION G - CONTRACT ADMINISTRATION DATA

G.1 KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in Section I of this contract, the following individual(s) is/are considered to be essential to the work being performed hereunder:

<u>NAME</u>	<u>TITLE</u>
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(TO BE COMPLETED AT TIME OF CONTRACT AWARD)

The clause cited above contains a requirement for review and approval by the Contracting Officer of written requests for a change of Key Personnel reasonably in advance of diverting any of these individuals from this contract. Receipt of written requests at least 30 days prior to a proposed change is considered reasonable.

G.2 CONTRACTING OFFICER'S TECHNICAL REPRESENTATIVE & TASK ORDER OFFICER

The following Contracting Officer's Technical Representative (s) and Task Order Officer(s) will represent the Government for the purpose of this contract:

**(TO BE COMPLETED AT TIME OF CONTRACT AWARD)
(TASK ORDER OFFICER DESIGNATION PER TASK ORDER)**

The Contracting Officer's Technical Representative and Task Order Officer is/are responsible for: (1) monitoring the contractor's technical progress, including the surveillance and assessment of performance and recommending to the contracting officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as an agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the contractor of any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Contracting Officer's Technical Representative or Task Order Officer designation

G.3 INVOICE SUBMISSION

a. INVOICE SUBMISSION

Billing Instructions are attached and made part of this contract. Instructions and the following directions for the submission of invoices must be followed to meet the requirements of a

"proper" payment request pursuant to FAR 32.9, and must be in accordance with the General Provisions clause 52.232-25 Prompt Payment (OCT 2003).

Invoices/financing requests shall be submitted in an original and three copies to:

Contracting Officer
Agency for Healthcare Research and Quality
Division of Contracts Management
540 Gaither Road
Rockville, Maryland 20850

G.4 INFORMATION ON INVOICES

G.4 INFORMATION ON INVOICES

(1) The Contractor is **REQUIRED** to include the following minimum information on invoices:

- (a) Contractor's name and invoice date;
- (b) Contract Number;
- (c) Description and price of services actually rendered;
- (d) Other substantiating documentation or information as required by the contract;
- (e) Name (where practicable), title, phone number, and complete mailing address or responsible official to whom payment is to be sent; and
- (f) The Internal Revenue Service Taxpayer Identification Number.
- (g) Task Order Number

(2) The Contractor shall furnish the following minimum information in support of costs submitted:

- (a) Direct Labor – include all persons, listing the person's name, title, number of hours or days worked, hourly rate (unburdened), the total cost per person and a total amount of this category.
- (b) Fringe Costs - show rate, base and total amount as well as verification/allowability or rate changes (when applicable);
- (c) Overhead or Indirect Costs - show rate, base and total amount as well as verification/allowability or rate changes (when applicable);
- (d) Consultants - include the name, number of days or hours worked, a total amount per consultant and a total amount for this category;
- (e) Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation, shown separately, and per diem costs. Other travel costs shall also be listed. A total amount for this category shall be provided;
- (f) Subcontractors - include for each subcontractor, the same data that is being provided for the prime contractor. A total number for this category shall be provided.

- (g) Data Processing - include all non-labor costs, i.e., computer time, equipment purchase, lease or rental, data tapes, etc. A total amount for this category shall be provided.
 - (h) Other - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, equipment rental, duplication, etc.
 - (i) Equipment Cost - itemize and identify separately from material costs including reference to approval in all cases;
 - (j) G&A - show rate, base and total as well as verification/allowability of rate changes (when applicable);
 - (k) Fee - show rate, base and total and;
 - (l) Current amount billed by individual cost element and total dollar amount and cumulative amount billed by individual cost element and total dollar amount.
- (3) Payment shall be made by:

PSC Finance
Parklawn Building, Room 16-23
5600 Fishers Lane
Rockville, Maryland 20857
Telephone Number (301) 443-6766

G.5 INDIRECT COST RATES and FEE

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7(d)(2), Allowable Cost and Payment, incorporated by reference in this contract, in Part II, Section I, the primary contact point responsible for negotiating provisional and/or final indirect cost rates is the cognizant contracting official as set forth in FAR Subpart 42.7 - Indirect Cost Rates.

Reimbursement will be limited to the rates and time periods covered by the negotiated agreements. The rates, if negotiated, are hereby incorporated without further action of the contracting officer.

G.6 ELECTRONIC FUNDS TRANSFER

Pursuant to FAR 52.232-33, Payment by Electronic Funds Transfer - Central Contractor Registration (OCT 2003), the Contractor shall designate a financial institution for receipt of electronic funds transfer payments. This designation shall be submitted, in writing, to the finance office designated in the contract.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

H.1 RELEASE AND USE AND COPYRIGHT OF DATA FIRST PRODUCED FROM WORK PERFORMED UNDER THIS CONTRACT

(a) *Release and Use – Data first produced in the performance of the Contract.* As permitted in FAR 52.227-17, the provisions of this Section H.1 shall apply to any release or use of data first produced in the performance of the Contract and any analysis, tools, methodologies, or recorded product based on such data.

(b) *Release and Use – Requirements related to confidentiality and quality.* To ensure public trust in the confidentiality protections afforded participants in Agency for Healthcare Research and Quality (AHRQ)-supported research, AHRQ requires and monitors compliance by its contractors with section 934(c) of the Public Health Service Act (PHS Act) (42 U.S.C. 299c-3(c)), which states in part that

No information, if the establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under this title, may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented...to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented...to its publication or release in other form.

In addition to this requirement, section 933(b)(1) of the PHS Act (42 U.S.C. 299c-2(b)(1)) requires AHRQ to assure that statistics and analyses developed with Agency support are of high quality, comprehensive, timely, and adequately analyzed. Accordingly --

(1) prior to the release or use of data based upon work performed under this Contract, the Contractor agrees to consult with the Project and Contract Officers regarding the proposed release or use. AHRQ will, within 6 months of the receipt of any proposed publication, presentation, or any other disclosure of materials derived from information collected or produced for this contract, use best effort to review the proposed report, presentation, or other text to assure:

- (A) Identifiable information is being used exclusively for the purpose(s) for which it was supplied or appropriate consents have been obtained;
- (B) The confidentiality promised to individuals and establishments supplying identifiable information or described in it is not violated; and
- (C) The quality of statistical and analytical work meets the statutory standards cited above.

The Contractor will in good faith consider, discuss, and respond to any comments or suggested modifications that are provided by AHRQ within two months of receiving the proposed release or use.

(2) The Contractor must satisfy conditions (1) (A) and (1) (B). At the conclusion of any consultation required by paragraph (b) (1) above, if AHRQ and the Contractor cannot agree that a proposed use or release satisfies condition (1) (C) above:

- (A) the research professional at the Contractor responsible for the quality of the Contract work will, in advance of any release or use of such data, certify in a letter to the Contracting Officer what differences of opinion cannot be resolved regarding the statutory standards referenced in condition (1) (C) and the basis for Contractor assertions that these standards have been met; and
- (B) The Contractor must print prominently on the release or other product, or on any portion that is released, or state prior to any oral presentation or release of such material, the following disclaimer:

THIS PRESENTATION/ PUBLICATION/OR OTHER PRODUCT IS DERIVED FROM WORK SUPPORTED UNDER A CONTRACT WITH THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ) (#). HOWEVER, THIS PRESENTATION/ PUBLICATION/OR OTHER PRODUCT HAS NOT BEEN APPROVED BY THE AGENCY.

(3) If the AHRQ COTR does not provide written conditions or approvals by the end of the six month period following submission of a request to publish a report or to make a presentation or other disclosure of material derived from work performed for AHRQ-funded research, the Contractor may publish, present, or otherwise disclose this material subject to the restrictions of Section 903(c). However, the Contractor must print prominently on the report or any portion of it which is released, or state prior to any oral or other disclosure of the material derived from work performed under this contract, the following disclaimer:

THIS PRESENTATION/ PUBLICATION/OR OTHER PRODUCT IS DERIVED FROM WORK SUPPORTED UNDER A CONTRACT WITH THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ) (#). HOWEVER, THIS PRESENTATION/ PUBLICATION/OR OTHER PRODUCT HAS NOT BEEN APPROVED BY THE AGENCY.

(c) *Required Statement Regarding Protected Information.* On all written material or other recorded products, or preceding any presentation or other oral disclosure, release or use of material based on identifiable information obtained in the course of work performed under this contract, the Contractor shall make the following statement:

IDENTIFIABLE INFORMATION ON WHICH THIS REPORT, PRESENTATION, OR OTHER FORM OF DISCLOSURE IS BASED IS PROTECTED BY FEDERAL LAW, SECTION 934(c) OF THE PUBLIC HEALTH SERVICE ACT, 42 U.S.C. 299c-3(c). NO IDENTIFIABLE INFORMATION ABOUT ANY INDIVIDUALS OR ENTITIES SUPPLYING THE INFORMATION OR DESCRIBED IN IT MAY BE KNOWINGLY USED EXCEPT IN ACCORDANCE WITH THEIR PRIOR CONSENT. ANY CONFIDENTIAL IDENTIFIABLE INFORMATION IN THIS REPORT OR PRESENTATION THAT IS KNOWINGLY DISCLOSED IS DISCLOSED SOLELY FOR THE PURPOSE FOR WHICH IT WAS PROVIDED.

(d) *Copyright – Data first produced in the performance of the Contract.* Subject to the terms of this Section regarding release and use of data, AHRQ, through its Contracting Officer, will grant

permission under FAR 52.227-17(c) (1) (i) to the Contractor to establish claim to copyright subsisting in scientific and technical articles based on or containing data first produced in the performance of this contract that are submitted for publication in academic, technical or professional journals, symposia proceedings or similar works. When claim to copyright is made, the Contractor shall affix the applicable copyright notice of 17 U.S.C. 401 or 402 and acknowledgment of Government sponsorship (including contract number) to the data when such data are delivered to the Government, as well as when the data are published or deposited for registration as a published work in the U.S. Copyright Office. In such circumstances, the Contractor hereby agrees to grant to AHRQ, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license for all such data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of AHRQ. A description of this license will be incorporated into the copyright notices required above.

(e) *Subcontracts.* Whenever data, analyses, or other recorded products are to be developed by a subcontractor under this Contract, the Contractor must include the terms of H.1 in the subcontract, without substantive alteration, with a provision that the subcontractor may not further assign to another party any of its obligations to the Contractor. No clause may be included to diminish the Government's stated requirements or rights regarding release or use of products or materials based on data derived from work performed under this contract.

H.2 LACK OF COMPLIANCE WITH REQUIREMENTS FOR RELEASE OR USE

Failure to submit materials for statutorily mandated confidentiality and statistical and analytic quality reviews as required by Section H.1 of this contract will be viewed as a material violation and breach of the terms of this contract, as the requirements of this provision are necessary for AHRQ to carry out its statutory obligations and responsibilities. Records of the Contractor's performance, including the Contractor's performance pertaining to this Contract, will be maintained in AHRQ's Contracts Management Office and will be considered as an element of past performance which is part of all subsequent competitive contract proposal reviews.

H.3 SUBCONTRACTS

The contractor must include in any subcontracts executed or used to provide the support specified in this contract the terms of requirements H.1, H.2, H.4, H.5, H.6, H.7, H.10, H.11 and H.13. These requirements are to be included without substantive alteration, and no clause may be included to diminish these requirements.

Award of any subcontract is subject to the written approval of the Contracting Officer upon review of the supporting documentation as required by FAR Clause 52.215-12, Subcontractor Cost or Pricing Data, of the General Clauses incorporated into this contract. A copy of the signed subcontract shall be provided to the Contracting Officer.

H.4 LATE PAYMENTS TO THE GOVERNMENT

Late payment of debts owed the Government by the Contractor, arising from whatever cause, under this contract/order shall bear interest at a rate or rates to be established in accordance with the Treasury Fiscal Requirements Manual. For purposes of this provision, late payments are defined as payments received by the Government more than 30 days after the Contractor has been notified in writing by the Contracting Officer of:

- a. The basis of indebtedness.

- b. The amount due.
- c. The fact that interest will be applied if payment is not received within 30 days from the date of mailing of the notice.
- d. The approximate interest rate that will be charged.

H.5 PRIVACY ACT

The Privacy Act clauses cited in Section I (FAR 52.224-1 and 52.224-2) are applicable to the consultant records kept by the Contractor for the Agency for Healthcare Research and Quality.

You are hereby notified that the Contractor and its employees are subject to criminal penalties for violations of the Act (5 U.S.C. 552a(i)) to the same extent as employees of the Department. The Contractor shall assure that each Contractor employee is aware that he/she can be subjected to criminal penalties for violations of the Act. Disposition instructions: Records are to be destroyed after contract closeout is completed and final payment is made and in accordance with IRS regulations.

H.6 SALARY RATE LIMITATION

Pursuant to the applicable Public Law cited in the table below, the Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the salary level in effect on the date the expense is incurred as shown in the table below.

For purposes of the salary limitation, the terms direct salary, salary, and institutional base salary have the same meaning and are collectively referred to as direct salary in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care, or other activities. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

The salary rate limitation also applies to individuals performing under subcontracts. However, it does not apply to fees paid to consultants. If this is a multiple-year contract, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish contract funding.

Public law	Period Covered	Salary Limitation (based on Executive Level I)
Consolidated Appropriations Act, 2010 Public Law 111-117	1/1/10 – Until revised	\$199,700

H.7 PRO-CHILDREN ACT of 1994

The Pro-Children Act of 1994, P.L. 103-227, imposes restrictions on smoking where certain federally funded children's services are provided. P.L. 103-227 states in pertinent part:

"PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. In addition, P.L. 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children."

H.8 PERSONNEL SECURITY REQUIREMENTS

BACKGROUND

The Office of Assistant Secretary for Management and Budget, Department of Health and Human Services (DHHS), requires that all DHHS employees and contractor employees (including subcontractors) who will be working in a DHHS-owned or leased space and/or who will have access to DHHS equipment, and non-public privileged, proprietary, or trade secret information, undergo a background investigation.

GENERAL

Notwithstanding other submission requirements stated elsewhere in this contract, the contractor shall appoint and identify a Contractor Security Representative and submit the following information for each employee to the Contracting Officer within thirty (30) calendar days after contract award.

DHHS ID Badge Request (HHS-745)

E-QIP Initiation Request Form

Within thirty (30) days after contract award each employee will be required to have electronic fingerprinting performed — Fingerprinting services are available by appointment only through the Program Support Staff (PSC). Upon receipt of the ID Badge Request Form and E-QIP Initiation Form, a security specialist from PSC will e-mail the contractor with instructions on completing the on-line background investigation questionnaire and making arrangements for the contractor to complete the electronic fingerprints at the Parklawn Building.

H.9 PROTEST

No protest under FAR Subpart 33.1 is authorized in connection with the issuance or proposed issuance of a Task Order under this contract except on grounds that the order increases the scope, period, or maximum value of the contract.

H.10 SECTION 508 COMPLIANCE

This language is applicable to Statements of Work (SOW) or Performance Work Statements (PWS) generated by the Department of Health and Human Services (HHS) that require a contractor or consultant to (1) produce content in any format that could be placed on a Department-owned or Department-funded Web site; or (2) write, create or produce any communications materials intended for public or internal use; to include reports, documents, charts, posters, presentations (such as Microsoft PowerPoint) or video material that could be placed on a Department-owned or Department-funded Web site.

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) requires Federal agencies to purchase electronic and information technologies (EIT) that meet specific accessibility standards. This law helps to ensure that federal employees with disabilities have access to, and use of, the information and data they need to do their jobs. Furthermore, this law ensures that members of the public with disabilities have the ability to access government information and services.

There are three regulations addressing the requirements detailed in Section 508. The Section 508 technical and functional standards are codified at 36 CFR Part 1194 and may be accessed through the Access Board's Web site at <http://www.access-board.gov>. The second regulation issued to implement Section 508 is the Federal Acquisition Regulation (FAR). FAR Part 39.2 requires that agency acquisitions of Electronic and Information Technology (EIT) comply with the Access Board's standards. The entire FAR is found at Chapter 1 of the Code of Federal Register (CFR) Title 48, located at <http://www.acquisition.gov>. The FAR rule implementing Section 508 can be found at <http://www.section508.gov>. The third applicable regulation is the HHS Acquisition Regulation (HHSAR).

Regardless of format, all Web content or communications materials produced for publication on or delivery via HHS Web sites - including text, audio or video - must conform to applicable Section 508 standards to allow federal employees and members of the public with disabilities to access information that is comparable to information provided to persons without disabilities. All contractors (including subcontractors 1) or consultants responsible for preparing or posting content intended for use on an HHS-funded or HHS-managed Web site must comply with applicable Section 508 accessibility standards, and where applicable, those set forth in the referenced policy or standards documents below. Remediation of any materials that do not comply with the applicable provisions of 36 CFR Part 1194 as set forth in the SOW or PWS, shall be the responsibility of the contractor or consultant retained to produce the Web-suitable content or communications material.

1 - Prime contractors may enter into subcontracts in the performance of a Federal contract, but the prime remains obligated to deliver what is called for under the contract.

References:

HHS Policy for Section 508 Electronic and Information Technology (E&IT) (January 2005):

http://www.hhs.gov/od/Final_Section_508_Policy.html

HHS Section 508 Web site: <http://508.hhs.gov/>

HHS ASPA Web Communications Division Web site:

<http://www.hhs.gov/web/policies/index.html>

US General Services Administration (GSA) Section 508 Web site:

<http://www.section508.gov/index.cfm>

H.11 SECURITY AND PRIVACY REQUIREMENTS

- 1. Adherence to security and privacy policy.** The Contractor shall comply with all Federal and Department of Health and Human Services (HHS) security and privacy guidelines in effect at the time of the award of this contract. A list of applicable United States (U.S.) laws, Office of Management and Budget (OMB) requirements, HHS policies, standards and guidance, and Federal Government Computer Security guidelines can be located on the [Secure One HHS website](#). The Contractor shall perform periodic reviews to ensure compliance with all information security and privacy requirements. The Contractor shall make all system information and documentation produced in support of the Contract available to the agency and agency auditors upon request.

2. **Perimeter defense and notification.** The Contractor shall ensure that the system and the information it contains are secured using appropriate perimeter defense technologies and that these technologies are monitored for anomalous traffic behavior. The Contractor shall immediately report any unauthorized system access to the agency COTR and/or System Owner.
3. **Protection of sensitive information.** The Contractor shall ensure that sensitive information is protected by information security and privacy controls commensurate with the risk associated with the potential loss or compromise of this information. For purposes of this contract, information is sensitive if *the loss of confidentiality or integrity could be expected to have a **serious, severe or catastrophic** adverse effect on organizational operations, organizational assets, or individuals.*¹ Further, the loss of sensitive information confidentiality or integrity could: (i) *cause a significant or severe degradation in mission capability to an extent and duration that the organization is unable to perform its primary functions or the effectiveness of the functions is significantly reduced;* (ii) *result in significant or major damage to organizational assets;* (iii) *result in significant or major financial loss;* or (iv) *result in significant, severe or catastrophic harm to individuals.*

Personally identifiable information (PII) is a subset of sensitive information and is defined as data which can potentially be used to identify, locate, or contact an individual, or potentially reveal the activities, characteristics, or other details about a person.² PII shall receive a level of protection commensurate with the risk associated with the loss or compromise of sensitive information.

4. **Sensitive information on public systems.** The Contractor shall ensure that sensitive information is not stored, processed or transmitted on a publicly-available system (via the Internet) without the appropriate controls in place and specific authorization from the AHRQ Chief Information Officer (CIO).
5. **Privacy requirements.** The Contractor shall conduct and maintain a Privacy Impact Assessment (PIA) as defined by Section 208 of the E-Government Act of 2002 and Federal Acquisition Regulation (FAR) Clause 52-239-1, and required by HHS policy. The PIA shall be completed in accordance with [HHS PIA guidance](#). Periodic reviews shall be conducted to determine if a major change to the system has occurred, and if a PIA update is subsequently required. If it is determined that an update is necessary, the Contractor shall make the necessary changes to the PIA.

The Contractor shall abide by all requirements of the Privacy Act of 1974 and FAR Clause 52-239-1. Pursuant to those requirements, the Contractor shall create and publish a System of Records Notice (SORN) in the Federal Register when required and shall publish an updated SORN following a major change to the system, as directed by OMB Memorandum (M) 03-22, *OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002*, or subsequent replacement guidance.

6. **System accreditation.** The Contractor shall certify and accredit all systems in conformance with the standards set forth by the Federal Information Security Management Act (FISMA) and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-37, *Guide for the Security Certification and Accreditation of Federal Information Systems*, prior to the

¹ Federal Information Processing Standard (FIPS) 1999, *Standards for Security Categorization of Federal Information and Information Systems*, February 2004.

² HHS Rules of Behavior, February 12, 2008.

system becoming operational. This activity shall be performed in conjunction with the initial development of the system, updated when a major change occurs to the system, and renewed no less than every three years. All system certification and accreditation (C&A) packages shall be compliant with all Public Law (PL)-107-347, OMB mandates, FIPS, and additional applicable NIST guidance. This guidance includes, but is not limited to FIPS 199, FIPS 200, NIST SP 800-18, NIST SP 800-30, NIST SP 800-37, NIST SP 800-53, NIST SP 800-53A, and NIST SP 800-60. All NIST and FIPS documentation can be found at the [NIST website](#).

HHS has created a C&A checklist to facilitate compliance with the OMB-mandated C&A process. The HHS C&A Checklist will be provided upon contract initiation. Prior to becoming operational, all systems must receive a signed Authorization to Operate (ATO) issued by the agency Designated Authorization Authority (DAA). No system will be permitted into the production environment without a valid, signed ATO.

- 7. Annual requirements.** The Contractor shall be responsible for meeting ongoing information security and privacy system requirements. These include, but are not limited to, performing annual system testing, completing an annual system self-assessment, and supporting quarterly and annual AHRQ FISMA reporting. Additionally, AHRQ reserves the right to test or review the system security and privacy controls at any time.
- 8. Security and privacy training.** All Contractors shall receive general awareness training and role-based training, commensurate with the responsibilities required to perform the work articulated in the terms and conditions of the Contract.

The Contractor shall be responsible for ensuring each contractor employee has completed the AHRQ Security Awareness Training as required by the agency prior to performing any contract work or accessing any system, and on an annual basis thereafter, throughout the period of performance of the contract. The Contractor shall maintain a list of all individuals who have completed this training and shall submit this list to the COTR upon request. As a part of this training, the Contractor shall ensure that all staff read, agree to, and sign the [HHS Rules of Behavior](#).

The Contractor shall ensure that all contractors with significant security responsibilities, as defined by HHS, receive commensurate role-based training. As stated in the Secure One HHS Memorandum, *Role-Based Training (RBT) of Personnel with Significant Security Responsibilities*, significant security responsibilities are defined as the responsibilities associated with a given role or position, which, upon execution, could have the potential to adversely impact the security posture of one or more HHS systems.³ The Contractor shall maintain a list of all individuals that possess significant security responsibilities and the subsequent role-based training courses completed, and shall submit this list to the COTR upon request.

- 9. Electronic communication.** All Contractor staff that have access to and use of HHS electronic mail (e-mail) must identify themselves as contractors on all outgoing e-mail messages, including those sent in reply or forwarded to another user. The Contractor shall ensure all contractor staff embed an e-mail signature ("AutoSignature") or an electronic business card ("V-card") within each electronic correspondence to automatically display "Contractor" in the signature.

³ HHS Memorandum, *Role-Based Training (RBT) of Personnel with Significant Security Responsibilities*, October 3, 2007.

10. Clearances. The Contractor shall ensure all staff has the required level of security clearance commensurate with the sensitivity of the information being stored, processed, transmitted or otherwise handled by the System or required to perform the work stipulated by the contract. At the minimum, all Contractor staff shall be subjected to a Public Trust background check and be granted a Public Trust clearance before access to the System or other HHS resources is granted.

11. Non-Disclosure. The Contractor shall not release, publish, or disclose agency information to unauthorized personnel, and shall protect such information in accordance with the provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of sensitive information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- PL 96-511 (Paperwork Reduction Act)

The Contractor shall ensure that each contractor employee who may have access to agency information under this contract shall complete and sign the Commitment to Protect Non-Public Information - Contractor Agreement (Non-Disclosure Agreement). A copy of each signed and witnessed Non-Disclosure Agreement shall be submitted to the COTR prior to performing any work under the contract.

12. Mobile device encryption. The Contractor shall: (a) encrypt all laptop computers, mobile devices and portable media which store or process, or may store or process, sensitive information using FIPS 140-2 compliant encryption technology; (b) verify that encryption products have been validated under the [Cryptographic Module Validation Program](#) to confirm compliance with FIPS 140-2; (c) establish key recovery mechanisms to ensure the ability to decrypt and recover sensitive information by authorized personnel; and (d) generate and manage encryption keys securely to prevent unauthorized decryption of information. For more information, reference the [HHS Encryption Standard for Mobile Devices and Portable Media](#).

13. Desktop Encryption. The Contractor shall: (a) encrypt all desktop computers which store or process, or may store or process, sensitive information using FIPS 140-2 compliant encryption technology; (b) verify that encryption products have been validated under the [Cryptographic Module Validation Program](#) to confirm compliance with FIPS 140-2; (c) establish key recovery mechanisms to ensure the ability to decrypt and recover sensitive information by authorized personnel; and (d) generate and manage encryption keys securely to prevent unauthorized decryption of information. In the case that appropriate compensating controls are implemented to protect sensitive desktop computers, the requirement for encryption may be waived with approval from the AHRQ Chief Information Security Officer (CISO). For more information, reference the [HHS Encryption Standard for Mobile Devices and Portable Media](#).

14. Minimum security configurations. The Contractor shall certify applications are fully functional, operate as intended, and comply with the HHS Minimum Security Configurations for Operating Systems (currently HHS has minimum configuration standards for Windows 2000 Server, Windows 2000 Professional, Windows 2003 Server, Windows NT, Windows XP, Solaris, HP-UX, Redhat Linux, Oracle, and Cisco IOS). These standard security configurations shall be provided to the Contractor at the time of contract initiation and upon completion of the required Non-Disclosure Agreements. Additionally, the Contractor shall adhere to these configurations when developing the system. As standard configurations may change frequently, the Contractor must ensure applications remain compliant with the most recent set of security configurations.

Additionally, for desktops and laptops within the system boundary, the Contractor shall comply with the configurations defined in the HHS Federal Desktop Core Configuration (FDCC) standards, which were designed to meet the requirements mandated by OMB. The FDCC standards will be provided upon contract initiation. The installation, operation, maintenance, update, and/or patching of software shall not alter the approved HHS Minimum Security Configurations or the HHS FDCC standards. Applications designed for normal end users shall run in the standard user context without elevated system administration privileges. Exceptions to the HHS requirements must be documented, accompanied by compensating controls, and approved by the HHS CISO and the AHRQ CISO in advance of implementation.

- 15. Maintenance.** The Contractor shall ensure that the system, once operational, is properly maintained and monitored, to include immediate response to critical security patches, routine maintenance windows to allow for system updates, and compliance with a defined configuration management process. All patches and system updates shall be properly tested in a development environment before being implemented in the production environment.

References

1. [Policy for Department-wide Information Security](#)
2. [HHS IRM Information Security Program Policy](#)
3. [HHS Personnel Security/Suitability Handbook](#)
4. [NIST SP 800-18, Rev. 1, Guide for Developing Security Plans for Information Technology Systems](#)
5. [NIST SP 800-37, Guide for Security Certification and Accreditation of Federal Information Systems](#)
6. [NIST SP 800-53, Recommended Security Controls for a Federal Information System](#)
7. [NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I](#)
8. [NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume II](#)
9. [NIST SP 800-64, Security Considerations in the Information System Development Life Cycle](#)
10. [FIPS 199, Standards for Security Categorization of Federal Information and Information Systems](#)
11. [Federal Information Processing Standards, Minimum Security, Requirements for a Federal Information System](#)
12. [Cryptographic Module Validation Program](#)

H.12 RESERVED

H.13 AHRQ APPLICATION AND SYSTEM DEVELOPMENT REQUIREMENTS

AHRQ has implemented a Distributed Systems Engineering Lab (DSEL) to support all internal development efforts and provide the facility for housing the software and documentation for all AHRQ sponsored systems and applications, regardless of where the system or application is hosted.

AHRQ uses a System Development Lifecycle (SDLC) framework which is consistent with the HHS Enterprise Lifecycle Framework (EPLC). This framework is the basis for implementation of the DSEL, conduct of development projects and the Rational Unified Process (RUP)/Capability Maturity Model (CMM) based processes that support its implementation. The SDLC framework provides a disciplined approach which employs the following traditional project phases:

- Concept

- Initiation
- Planning
- Requirements Analysis
- Design
- Development
- Testing
- Implementation / Deployment
- Operations and Maintenance
- Retirement

The AHRQ SDLC framework is closely aligned with the disciplines defined in the Rational Unified Process (RUP). The IBM Rational Suite of tools has been adopted by the Agency to provide a standard IT development environment for AHRQ sponsored systems and application development projects. The AHRQ SDLC framework has been enhanced through the use of tailored processes and artifacts based on the RUP methodology. The documentation deliverables required for all Information Technology (IT) projects are based on specific RUP artifacts identified by ARHQ. The Rational ClearCase libraries housed within the DSEL provide the repository for housing software and documentation artifacts related to all AHRQ sponsored systems and applications, regardless of where the system or application is hosted.

Contractors are not required to follow the RUP development methodology or use the Rational Suite of tools; however, the Contractor's SDLC must be capable of producing AHRQ required system deliverables containing the required content as described further in the following section. It is required that the Contractor use the lifecycle phases defined in the AHRQ SDLC framework and obtain COTR approval before moving from one phase to another. The contractor must also conform to AHRQ Configuration Management (CM) and change control standards which require appropriate controls for managing software and documentation baselines, changes to software artifacts using an appropriate IDE or version management tool, document change requests and obtaining approval through a formal change control process that requires and possible AHRQ IT approval prior to implementation.

The following table describes the documentation deliverables required for all IT projects and the content required for each deliverable.

Table 1.1 – Documentation Deliverables

Deliverable	AHRQ Life Cycle Phase	Formats
Project Initiation Document	Project Initiation	MS Word
Project Work Plan	Project Planning	MS Project
System Requirements Document (SRD)	Requirements and Analysis	Rational Requisite Pro, MS Word
Requirements Traceability Matrix	Requirements and Analysis	Rational Requisite Pro, MS Word
System Design Document (SDD)	Software Design	Rational Software Modeler, MS Word,

Deliverable	AHRQ Life Cycle Phase	Formats
		Rational Software Architect
Test Plan	Testing	MS Word
Test Scripts	Testing	MS Word, Rational Test Manager
User Acceptance Testing Report	Implementation	MS Word
User Guide	Deployment	MS Word
Operations Manual	Deployment	MS Word
Version Description Document	Deployment	MS Word

System Documentation

The Contractor will provide to the Agency system documentation of all proposed hardware, software, security, backup/recovery, and other information technology infrastructure and components and solutions needed to support this project. The documentation is to be delivered to the COTR for review and approval for each release. This documentation will be provided according to the content standards specified by AHRQ and will be maintained in the Agency’s Rational ClearCase Repository as a unique project library created and maintained by the AHRQ CM Manager. All documentation will be baselined with each system release. In addition, the source code for each production release will be delivered and stored in the same project library as the documentation artifacts. The contractor will be required to update these baselined artifacts for each production release of the system. Sample documents and templates for the required documentation artifacts are available as guidance. The following documents as mentioned in Table 1.1, “Documentation Deliverables”, are required by AHRQ.

Project Initiation Document

The Project Initiation Document (PID) is intended to be a statement of purpose and scope for initiating a given project and a guide to manage expectations in both process and deliverables throughout the System Development Lifecycle (SDLC). The PID defines the business case for the project by defining the purpose, the milestones, resources, objectives, costs, risks including mitigation strategies, and the artifacts and IT technologies (architecture) utilized and produced for, and during, the project. The PID serves as the formal funding commitment document approved by the COTR and Stakeholders. Additionally, the PID must be approved by AHRQ IT management, and in some cases, the AHRQ Information Technology Review Board (ITRB) for technical viability, adherence to Agency Enterprise Architecture (EA); technical standards and formal Project Management requirements as derived from Departmental standards and accepted Project Management Institute (PMI) Project Management Body of Knowledge (PMBOK) standards. In the case of external development contracts, the PID is satisfied by the formal proposal submitted by the vendor and accepted by AHRQ.

Project Work Plan

The System Project Plan or Project Work Plan (PWP) provides a method to assign and track the project resources, hours and specific deliverables. This plan provides the detailed Work Breakdown Structure (WBS) and resource loading that can be used to identify project costs and is intended for the project manager to track the schedule and cost of a project, including development of Earned Value Management (EVM) measures. The PWP is delineated by the phases of the project which include Project Initiation, Generation of the PWP Schedule, Requirements Gathering, System Design, System Development, System Testing including User Acceptance, System Deployment and System Support and production of project deliverables which require COTR or Stakeholder acceptance and signoff to continue project tasks identified in the PWP.

System Requirements Document

The System Requirements Document (SRD) contains the system requirements, use cases and supplementary specifications that provide the basis for design and development of the system. The following information is provided for each requirement identified in the document:

- Requirement ID, Name and Title
- Requirement Description
- Software Release Version
- Use Case Model
- Use Case Specifications
- Supplementary Specifications

A text-based Functional Requirements Document may be provided instead of a Use Case Model, Use Case Specifications, and Supplementary Specifications.

Requirements Traceability Matrix

The Requirements Traceability Matrix (RTM) associates requirements with the work products that satisfy them. This matrix is created at the beginning of a project's lifecycle to trace the requirements from identification through testing. The project elements are traced as they relate to other project elements, especially those related to requirements.

The purpose of establishing traceability is to help understand the sources of requirements, manage the scope of the project, manage changes to requirements; assess the project impact of a change in a requirement; and verify that all requirements of the system are fulfilled by the implementation.

The following values are required for the traceability matrix:

- Requirement ID and Title;
- The version of the system in which the requirement will be implemented;
- The Use Case to which the requirement can be traced;
- The version of the design document in which the requirement is implemented;
- The ID of the test script in which the requirement is tested;
- The version number of the source code in which the requirement is implemented.

The figure below shows a sample of the data traced through a project's life cycle.

Requirements:	Version	Trace To UC	Trace to Design	Trace to Test	Trace to Source	CR	Status
▶ FEAT8: The system shall display the Principal... The system shall capture and display the Principal Investigator's name on the Quarterly Report.	2.00.00	UC7, UC13				Prod00000098,Prod000000	Incorporated
FEAT9: The system shall display Principal... The system shall capture and display the Principal Investigator's Address.	2.00.00	UC7, UC13				Prod00000098,Prod000000	Incorporated
FEAT10: The system shall display Principal... The system shall display and capture the Principal Investigator's telephone number.	2.00.00	UC7, UC13				Prod000000262	Incorporated
FEAT11: The system shall display Principal... The system shall capture and display the E-mail address of the Principal Investigator.	2.00.00	UC7, UC13				Prod000000262	Incorporated
FEAT12: The system shall display the Principal... The system shall capture and display the main fax number for the Principal Investigator.	2.00.00	UC7, UC13				Prod000000262	Incorporated
▣ FEAT13: the system shall display and Track... The system shall capture and track milestones for a given project/grant. HIT uses the word Milestone while PS uses...	2.00.00	UC11, UC13				Prod000000268	Proposed
FEAT13.1: The system shall display and track... The system shall capture and track overall progress of project milestones and shall display these in the report.	2.00.00	UC11				Prod000000268	Proposed
FEAT13.2: The system shall display and track... The system shall capture and display milestone barriers.	2.00.00	UC11				Prod000000272	Proposed

System Design Document

The System Design Document (SDD) details the design and implementation of all custom software features of the system. The design descriptions must include use cases that detail the interaction which occurs between a user and the system.

The document describes the general nature of the system, and describes the architecturally significant parts of the design model, such as its decomposition into subsystems and packages. For each significant package, a section of the document should detail its decomposition into classes and class utilities. Architecturally significant classes should be introduced and a description of their responsibilities should accompany the introduction. Any significant relationships, operations, and attributes should be detailed in this document.

The document should be organized by use case, so that it provides traceability back to the initial requirements. The document must also contain a description of the database model and data elements used to support the application. This data can be referenced to an appropriately maintained Entity Relationship Diagram (ERD) and data definitions which conform to CM standards and are appropriately maintained in the Rational CM Libraries.

Test Plan

The purpose of the Test Plan is to define the approach for testing a particular application or system. The Test Plan is a high level description of the testing process which will be performed. The Test Plan outlines the types of testing to be performed, the requirements to be tested, the test environment, testing tools, pass/fail criteria and a risk assessment. At a minimum the document should contain the following:

A. Test Description

- A general overview of the plan for testing the entire system.
- Test objectives for all testing levels (e.g. module, unit).
- Scope and guiding principles for the testing effort.
- A policy for resolving conflicts that arise during the testing process.

B. Acceptance Criteria

- The criteria agreed upon with the customer for acceptance of the software.

C. Approach

- How each major group of software features will be adequately tested.
- Major testing activities, techniques, and testing tools.
- Test Environment – Hardware, Network, Software and Test Database

D. Tasks

- The individual tasks that must be performed.
- The individual or organization responsible for each task.

E. Schedule, Resources & Milestones

Test Scripts

The Test Scripts define testing scenarios completed for an application. Each scenario details the steps to be performed, expected results and pass/fail criteria. At a minimum the document should contain the following:

- Test Script Identifier
- Test Description
- Test Objective
- Test Environment/Setup including any required data such as Login credentials, etc.
- Mapping to specific requirements and design elements contained in the SRD and SDD
- Step sequences and actions
- Expected Results
- Pass/Fail Criteria
- Actual Results
- Comments

User Acceptance Test Report

The User Acceptance Testing (UAT) Report should include a summary of the testing environment (hardware, software, tools, participant list, etc.) and procedures used to demonstrate and obtain stakeholder approval of the application or system prior to production deployment. The UAT Report should contain a mapping to the SRD and SDD items included in the release as well as an exception list or identified change requests that were generated as the result of testing.

User Guide

The User Guide is completed prior to production. The User Guide is a “How To” manual which navigates the user in detail through the use of the application. This document usually contains system screen shots and provides step by step instructions for completing tasks and activities. It is written on a business level with the needs of the user in mind. At a minimum the document should contain the following content.

- Introduction
- Summary of the application
- Glossary (Definitions/Acronyms)

- Procedures (Step-by Step instructions on how to use the system)
- Troubleshooting tips

Operations Manual

The Operations Manual provides guidance and defines procedures related to the operational implementation of the system. At a minimum, the document should contain the following:

- System Overview
- Statement of acceptable use of the system and information
- Hardware and software descriptions
- Interfaces with other Systems and Databases
- Access and authentication requirements
- System Configuration and Administration Procedures
- Security procedures including virus protection
- Incident Reporting and Handling
- System Startup and Recovery Procedures
- Change Management Procedures

Version Description Document

The Version Description Document (VDD) identifies and describes the general release information, and inventory of software released (Bill of Materials), for a specific application, including prototype iterations. The document should include the following sections listed below:

- Introduction - Describes the objective of the document, defines the release identification and provides contact information.
- General Release Information - Provide information about the specific release, including any interfaces and dependencies
- Installation Instructions - Describes the steps required to install the software.
- Version Description - Provides an inventory of List Objects and Module Types such as: class files, SQL Scripts, HTML files, DTD and XML files.
- Recovery Instructions - Describe the steps required to reconstruct the release from the product baselines, established in the configuration management library.

Web Product and Web Site Development Guidelines

The following list highlights basic issues that need to be addressed when developing Web tools or sites under contract that will be **publicly available** when launched to ensure deliverables are on target, in compliance with legal and policy requirements, and do not require expensive rework to meet Federal and Department of Health and Human Services requirements for information resources.

Guidelines for Web-Based Products

Retrofitting Web-based products after the fact is highly undesirable because it adds time and costs to the process of making these products publicly available. All products that are developed with the intent of being posted on the AHRQ Web site should meet the following minimum requirements:

Titles of Products

Coordinate with your COTR on the titles of your products. They need to be concise and relevant to the purpose of the project, but cannot include the name of the contractor or grantee as the performing organization as part of the title. Report titles should be no more than 10-words maximum and Web-based tools should be no more than 5-words maximum (make every word count—eliminate initial articles such as “The” or “A”). Titles need to be distinct enough to differentiate among similar sounding products.

Quality Control/Editorial Review

This involves checking for spelling and grammar mistakes, formatting issues, general consistency, and style. This should be done by the AHRQ grantee or contractor prior to submission of the final product for posting on the AHRQ Web site. Federal resources follow the GPO Style Manual which is available electronically at:

<http://www.gpoaccess.gov/stylemanual/browse.html>

Accessibility

As an agency of the Federal Government, AHRQ must ensure that anything that is posted on our Web site is in compliance with requirements for information resources under Section 508 of the Rehabilitation Act. Also, federally funded resources need to be generally available to users in multiple formats to ensure that we are not forcing a particular platform, operational system, or proprietary software package on users.

Intellectual Property Rights

Before we can post a product on the AHRQ Web site, we must have a written explanation of the following four questions:

- Who retains the copyright?
- Who has licenses for what purposes and uses?
- What are the constraints imposed?
- Who grants permission for further use or adoption?

Usability

Web resources should include usability testing, evaluation, and modification as an integral and recurring part of the development effort to ensure they are effective for the electronic business processes they are designed to facilitate. A set of Research-Based Web Design and Usability Guidelines that should be consulted are available at: <http://www.usability.gov/guidelines/index.html>

Beta testing prior to release is desirable, evaluating the product against usability heuristics. As feedback is received and products are updated, the revisions will need to be designated by version number and date of release.

Privacy Act Protections

Web resources are subject to the Privacy Act and this can impact both the development of Web-based tools and the users of those tools. Persistent cookies should not be programmed into the functionality of a Web-based tool, although session cookies are allowed. Registration for use cannot

be requested if this would involve collection of individual identifiers from the users. Although exemptions to both rules can be sought, this involves a strong justification and several levels of review for approval through the U.S. Department of Health and Human Services (HHS).

Guidelines for Web Sites

Web sites being supported through contracts are considered Federal information resources and as such are required to be in compliance with laws, policies, and directives that affect such resources.

This includes content management and information categorization, including standard metadata, under the E-Gov Act requirements and Office of Management and Budget issuances to Federal agencies on IT resources.

For recommendations and guidance on requirements and best practices, go to:

http://www.firstgov.gov/webcontent/reqs_bestpractices/best_practices.shtml

Clearance

Web resources require clearance by HHS--including justification against a set of criteria. Publications cleared for printing are cleared for Web uploading at the same time. Web resources must comply with the numerous laws and directives that affect federally funded electronic information resources. Web content loaded on a site by contractors must be appropriate and follow all laws and directives. AHRQ Offices and Centers must coordinate initial review through AHRQ's Office of Communications and Knowledge Transfer (OCKT) before launch, and OCKT will coordinate departmental clearance.

Domain Names

All domain names for any Web resource funded in whole or in part by Federal funds must be registered as .gov through HHS with the General Services Administration (GSA). Although other domains, such as .org, .net, .edu, .com may also be reserved by the Agency, the .gov domain must be registered and that domain name will need to be indexed by FirstGov, the GSA portal to government-funded resources. The FirstGov link is then required on the home page of the site. Coordinate with OCKT on domain name requests.

Editorial Review

All content for upload needs to be reviewed to ensure consistency and compliance with best practices and established style and conventions. As a minimum, the copy needs to be production edited to ensure there are no typos and the GPO Style Manual is followed for punctuation, spelling, use of numerals, abbreviations, etc. Do not use unexplained acronyms; they need to be spelled out on first reference in any document or file. There should not be anything marked DRAFT on a public site. Once the materials are uploaded, they are published and considered in the "public domain." Do not use placeholders for content that does not exist. Government funded sites should not have anything designated "under construction." A process needs to be established for regular review of content and updating. Additional materials need to undergo editorial review and be approved before uploading. The GPO Style Guide is available electronically as a reference at: <http://www.gpoaccess.gov/stylemanual/browse.html>

Accessibility

Under the Rehabilitation Act, Federal agencies have an obligation to provide equal access for the disabled to their information and services. Requirements are specified in section 504 for individual accommodation and more recently in section 508 for electronic and information technology, which includes Web sites and multimedia products. Equivalent alternatives are required for auditory and visual information, such as providing alternative descriptive text for images for the blind and providing captions for audio-video files for the deaf. Written transcripts are required for all streaming audio. PDF files can be offered in conjunction with accessible files, such as HTML versions, but avoid uploading PDF-only versions of documents unless they are fully accessible PDF formats. OCKT has software used to evaluate Web sites and can provide a report on any accessibility violations that would need to be addressed before launch. Specific requirements are available at: <http://www.section508.gov>

Privacy

A privacy policy notice must be prominently displayed, and the Web site host has to follow it. A machine-readable format (P3P) of the privacy policy notice must also be uploaded to the site. A Privacy Impact Assessment is conducted to determine what kind of personal information is contained within a system, what is done with that information, and how that information is protected. Sites are periodically audited to ensure that they observe their stated privacy policy. A Privacy Act System notice may need to be prepared and published for users to register on a site if the registrations represent a group of records, under the control of the Agency (or a contractor), that can be retrieved by personal identifier. This notice must go through several levels of review--including the Office of General Counsel--and be published in the *Federal Register*. Persistent cookies cannot be used on Federal sites unless the Secretary of HHS grants an exemption, and this involves a strong justification and review process.

Web Site Mailbox

Every Web site must provide full contact information for the sponsor and have a Contact Us link for submission of comments or questions as a customer feedback mechanism. Web site e-mail is subject to the same privacy and records management issues that affect the overall Web site as well as departmental standards for handling inquiries and customer feedback. Each Web site must provide relevant Frequently Asked Questions that are included in the customer relationship management system used to handle AHRQ Web site inquiries.

Records Management

All content on the site and e-mail generated by the site must be archived electronically and handled according to records retention schedules and disposition authorities as established with the National Archives and Record Administration. This requirement also affects Web site log files and statistical reporting on Web site usage. For guidance on requirements, go to:

<http://www.archives.gov/records-mgmt/policy/managing-web-records-index.html>

Information Collection Budget

If a Web site is used to collect information from users, such as for surveys, evaluations, or beta testing feedback, then the Office of Management and Budget must first approve the burden hours for such an effort for this collection. A notice must be posted on the Web site at the point of collection with the OMB approval number and a statement on the process of collection.

Intellectual Property

Copyright and trademark protections need to be observed on Web sites. Permissions for use must be granted for any copyrighted information included and registered trademarks need to be reflected in copy. Any copyright or trademark constraints related to materials uploaded to a site must be specified for users. Public domain does not extend outside the borders of the United States. Therefore, foreign countries must request specific permission for use. Given the global nature of the Internet, citation as to source is a critical issue.

Linking

External links constitute an implied endorsement and create a business advantage for the linked sites. OMB requires Agencies to do a risk assessment of external links, and potential links need to be assessed against the HHS and AHRQ linking policies and criteria. If a site deviates from these policies, then the specific review and selection criteria must be justified and posted on the Web site for full disclosure. Outside Web resources may link to Agency resources providing that the link is not displayed in any way that would imply an endorsement by the Agency of a specific commercial product or service.

Electronic FOIA

The Agency is required by law to have an electronic FOIA reading room and to provide materials that can be requested under the Freedom of Information Act in electronic form, if so requested. HHS requires that any Web resource funded by the Agency provide a link to the AHRQ Freedom of Information Act page on the main AHRQ Web site.

Usability

Web resources should include usability testing, evaluation, and modification as an integral and recurring part of the development effort to ensure they are effective for the electronic business processes they are supposed to facilitate. Go to <http://www.usability.gov> as a reference for best practices in initial development or redesign of Web resources.

Web Sponsor Identity

AHRQ has uniform principles to identify AHRQ as the primary sponsor of AHRQ-related Web sites. These principles reflect HHS best practices for a consistent look and feel of Web resources, reinforce credibility, and support HHS and Agency branding efforts. The four specific principles that should be consistent across all AHRQ-funded Web sites are:

- **Web site URL name:** The name of a Web site should always contain AHRQ in the URL. A Web resource should either be a folder on the main AHRQ Web site (www.ahrq.gov/chiri) or a third-level domain of the Web site (www.webmm.ahrq.gov).
- **Title of Web site project:** AHRQ's name should be part of the formal title and appear at the beginning of the Web site's project name when referenced in print or promotional materials. For example: AHRQ's Web Morbidity and Mortality online journal.
- **HHS and AHRQ logos:** The HHS and AHRQ logos should be featured prominently on the Web site and in materials that are used to market that Web site.
- **Web site home page format:** The Web site home page should have common design and navigation elements with the HHS Portal and the AHRQ Web site so that all Web sites look as though they belong to the Department and AHRQ Web family. All AHRQ domain sites

must include a standard banner and footer that are branded for Web resources. Technical specifications and templates for developers to consult when designing Web resources are provided by the AHRQ Web Manager.

H. 14 TASK ORDER SELECTION CRITERIA AND PROCEDURES

All work required under this contract will be authorized through the issuance of task orders (TOs) signed by the Contracting Officer and accepted by the Contractor. TOs may be issued at any time within the contract period.

TOs may often vary in terms of content, cost and duration. Task orders will normally be cost-reimbursement. However, Task Orders may be negotiated using any pricing basis under FAR 16, including firm fixed price or performance-based cost plus award fee basis. It is anticipated that all contractors in the DEcIDE-2 domain will be given the opportunity to compete for each Task Order.

Each Contractor will be guaranteed a minimum of one task order during the 3-year base contract. The minimum dollar amount guaranteed per Contractor is \$25,000. The purpose of this task order is to provide for general management and administrative work that is not directly attributable to a particular task order topic. Services requested under this task order will be obtained on an as-needed basis through issuance of specific work assignments, as directed by the Task Order Officer (TOO).

- 1) Travel to AHRQ or other locations for meetings concerning ACTION II as directed by the TOO. These funds are not to be used for meetings relating to a specific task order, but rather for the purpose of the overall initiative.
- 2) Miscellaneous work associated with the general management and administration of this task order and other assignments as determined by the TOO.
- 3) Participation in workgroups on methods

It is expected that TOs will average between \$250,000 and \$1,000,000 and last between eighteen (18) to twenty-four (24) months. There may be circumstances where the amount and duration of task orders exceed these average amounts.

Task Order Officer (TOO) will be designated for each TO issued under this contract. The TOO will function as principle technical liaison between the Contracting Officer and the Contractor's Project Manager.

The minimum total amount to be awarded over the three year period is \$25,000. The maximum total amount to be awarded over the three year period is estimated at \$4,000,000. Typical task orders are expected to range between \$250,000 and \$1,000,000.

Procedures for Issuance of TOs

1. Each awardee will be provided a fair opportunity to be considered for each TO. Factors such as technical merit, past performance, quality of deliverables, cost control, price, cost, or other factors that the Contracting Officer believes are relevant to the placement of orders will be considered.
2. When a TO is to be awarded, the Government will solicit proposals from awardees based on those factors mentioned above. The TO Statement of Work will be sent to

those selected awardees and a cost proposal and a brief discussion of technical approach shall be submitted within the stated number of calendar days. In unusual circumstances, contractors may be requested to reply within a shorter amount of time. Oral proposals and streamlined procedures may be used in selecting the TO awardee.

3. The determination of award of the TO will be based on cost, technical merit, and any other relevant factors.
4. Awardees need not be given an opportunity to be considered for a particular TO if the Contracting Officer determines that:
 - A. The Agency need for such supplies or services is of such urgency that providing such opportunity would result in unacceptable delays;
 - B. Only one such contractor is capable of providing such supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized;
 - C. The order should be issued on a sole-source in the interest of economy and efficiency as a logical follow-on to an order already issued under the contract, provided that all awardees were given a fair opportunity to be considered for the original order;
 - D. It is necessary to place an order to satisfy a minimum guarantee; or
 - E. When the dollar value of the order is less than \$3,000.
5. Each TO will be subject to review and negotiation and will not be effective until signed by both parties.

Required content of TO proposals will usually include, but not necessarily be limited to, the following:

--offeror's understanding of TO objectives;

--proposed approach to solving the problem in terms of major steps or subtasks of the proposed study program;

--types of final products anticipated;

--proposed staff by name and percentage of time each individual will be assigned to the work; and

--management plan for conducting the TO.

6. Each TO will be negotiated based on the fixed maximum labor rates set forth in Section B - Supplies or Services and on other cost/fee issues.
7. Upon negotiation and agreement on the proposal submitted, the Contracting Officer shall issue for the signature of the Contractor a formal TO. The Contractor shall not

proceed with performance until the Contracting Officer has signed the TO and provided written approval to proceed.

8. The Contractor's performance of the TO is subject to the terms and conditions in the contract, and the TO may be modified by the Contracting Officer and **ONLY** the Contracting Officer.
9. Protests **ARE NOT** authorized in connection with the issuance or proposed issuance of a TO except for a protest on the ground that the order increases the scope, period, or maximum value of the contract under which the order is issued.
10. The Contractor is not required to compete for a particular TO if it chooses not to do so, i.e., the Contractor may elect not to submit a proposal on a particular TO. Such election will not preclude the Contractor from an opportunity to submit proposals on future TOs.
11. Requests for Task Orders will be issued by the Contracting Officer primarily electronically through e-mail or internet but they can also be issued by facsimile or mail. Contractors are required to have internet or external electronic mail capabilities. When a RFTO is issued, the Contractor shall provide a proposal containing both technical and cost/price information for performing the required services. Specific directions will be provided for the number of copies of each proposal. The Contractor shall also submit two CD's of the task order proposal, specifically identified. Some RFTOs will contain quick turn-around due dates.
12. **Offerors shall provide appropriate staff for work on task orders, including personnel in the following labor classes:**

Class I

Senior management personnel, holding an advanced clinical, technical or professional degree, at the M.D., Ph.D., or Masters level, with a minimum of 10 years experience in analyzing biomedical, social sciences, behavioral, medical effectiveness, epidemiological or outcomes data, or similar scientific literature, research findings and data, preferably with significant experience related to development of clinical practice guidelines, medical review criteria, quality measures or indicators, or patient safety and other performance measures; biomedical or social sciences literature reviews and syntheses; meta-analysis; cost-effectiveness analysis; and/or experience in working with professional societies and healthcare delivery systems, such as hospitals and health plans. Class I personnel shall also have corporate level management experience that reflects an ability to command organizational resources and direct staff within the broader organization.

Class II

Associate management or clinical/professional/technical personnel, holding an advanced degree, at the M.D., Ph.D., or Master level, with a minimum of 5 years experience in analyzing biomedical, social sciences, medical effectiveness, epidemiological data, or similar scientific literature, research

findings and data.

Class III

Intermediate clinical/technical personnel, holding a BS or BA degree and at least 3 years experience in technical activities of which 2 years experience are directly related to analysis of biomedical, social sciences, and related scientific literature and other data. The individual is capable of carrying out independent assignments with minimum supervision or acting as leader of small projects. Class III personnel includes specialists in science writing and editing, as well as computer programming.

Class IV

Data support, literature search and retrieval, report drafting, etc. at a research assistant level.

PART II - CONTRACT CLAUSES

**(12/09-DCM)
(FAC 2005-38)**

**SECTION I
CONTRACT CLAUSES
GENERAL CLAUSES FOR A COST-PLUS-A-FIXED-FEE CONTRACT**

CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.arnet.gov/far/>

I. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

FAR Clause No.	Title and Date
52.203-3	Gratuities (APR 1984)
52.203-5	Covenant Against Contingent Fee (APR 1984)
52.203-6	Restrictions on Subcontractor Sales to the Government (SEPT 2006)
52.203-7	Anti-Kickback Procedures (JUL 1995)
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (JAN 1997)
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (JAN 1997)
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (SEP 2007)
52.203-13	Contractor Code of Business Ethics and Conduct (DEC 2008)
52.203-14	Display of Hotline Poster(s) (DEC 2007) (Department of Health and Human Services Poster at: http://www.oig.hhs.gov/hotline/OIG_Hotline_Poster.pdf)
52.203-15	Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009 (MAR 2009)
52.204-4	Printing or Copying Double-Sided on Recycled Paper (AUG 2000)
52.204-7	Central Contractor Registration (APR 2008)
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (SEPT 2006)

52.215-2	Audit and Records - Negotiation (MAR 2009)
52.215-8	Order of Precedence-Uniform Contract Format (Oct 1997)
52.215-10	Price Reduction for Defective Cost or Pricing Data (OCT 1997) (applicable to contract actions over \$550,000)
52.215-12	Subcontractor Cost or Pricing Data (OCT 1997) (applicable to contract actions over \$550,000)
52.215-15	Pension Adjustments and Asset Reversions (OCT 2004)
52.215-17	Wavier of Facilities Capital Cost of Money (OCT 1997)
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other Than Pensions (JUL 2005)
52.215-19	Notification of Ownership Changes (OCT 1997)
52.216-7	Allowable Cost and Payment (DEC 2002)
52.216-8	Fixed Fee (MAR 1997)
52.216-18	Ordering (OCT 1995) in full text below
52.216-19	Ordering Limitations (OCT 1995)
52.216-22	Indefinite Quantity (OCT 1995)
52.217-8	Option to Extend Services (NOV 1999)
52.219-8	Utilization of Small Business Concerns (MAY 2004)
52.219-9	Small Business Subcontracting Plan (APR 2008)
52.219-16	Liquidated Damages - Subcontracting Plan (JAN 1999)
52.219-28	Post-Award Small Business Program Representation (JUNE 2007)
52.222-2	Payment for Overtime Premiums (JUL 1990). The amount in paragraph (a) is "zero" unless different amount is separately stated elsewhere in contract.
52.222-3	Convict Labor (JUNE 2003)
52.222-26	Equal Opportunity (APR 2002)
52.222-35	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans. (SEPT 2006)

52.222-36	Affirmative Action for Workers With Disabilities (JUNE 1998)
52.222-37	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans. (SEPT 2006)
52.222-39	Reserved
52.222-50	Combating Trafficking in Persons (FEB 2009)
52.222-54	Employment Eligibility Verification (FEB 2009)
52.223-6	Drug Free Workplace (MAY 2001)
52.223-14	Toxic Chemical Release Reporting (AUG 2003)
52.224-1	Privacy Act Notification (APR 1984)
52.224-2	Privacy Act (APR 1984)
52.225-1	Buy American Act - Supplies (FEB 2009)
52.225-13	Restrictions on Certain Foreign Purchases (JUNE 2008)
52.227-1	Authorization and Consent (DEC 2007)
52.227-2	Notice and Assistance Regarding Patent and Copy- Right Infringement (DEC 2007)
52.227-3	Patent Indemnity (APRIL 1984)
52.227-17	Rights in Data – Special Works (DEC 2007)
52.228-7	Insurance-Liability to Third Persons (MAR 1996)
52.230-2	Cost Accounting Standards (OCT 2008)
52.230-3	Disclosure and Consistency of Cost Accounting Practices (OCT 2008)
52.230-6	Administration of Cost Accounting Standards (MAR 2008)
52.230-7	Proposal Disclosure – Cost Accounting Practice Changes (APR 2005)
52.232-9	Limitation on Withholding of Payments (APRIL 1984)
52.232-17	Interest (OCT 2008)
52.232-18	Availability of Funds (APRIL 1984)
52.232-20	Limitation of Cost (APR 1984)

52.232-22	Limitation of Funds (APR 1984) (This clause supersedes the Limitation of Cost clause found in the General Clauses of this contract.)
52.232-23	Assignment of Claims (JAN 1986)
52.232-25	Prompt Payment (OCT 2008)
52.232-33	Payment by Electronic Funds Transfer Central Contractor Registration (Oct 2003)
52.233-1	Disputes (JULY 2002)
52.233-3	Protest After Award (AUG 1996) Alternate I (JUNE 1985)
52.233-4	Applicable Law for Breach of Contract Claim (OCT 2004)
52.237-10	Identification of Uncompensated Overtime (Oct 1997)
52.239-1	Privacy or Security Safeguards (AUG 1996)
52.242-1	Notice of Intent to Disallow Costs (APRIL 1984)
52.242-3	Penalties for Unallowable Costs (MAY 2001)
52.242-4	Certification of Final Indirect Costs (Jan 1997)
52.242-13	Bankruptcy (JULY 1995)
52.243-2	Changes - Cost Reimbursement (AUG 1987) - Alternate II (APRIL 1984)
52.244-2	Subcontracts (JUNE 2007)
52.244-5	Competition in Subcontracting (DEC 1996)
52.245-5	Government Property (Cost Reimbursement, Time-and-Material, or Labor-Hour Contract (MAY 2004)
52.246-5	Inspection of Services-Cost Reimbursement (APRIL 1984)
52.246-23	Limitation of Liability-(FEB 1997)
52.248-1	Value Engineering (FEB 2000)
52.249-6	Termination (Cost-Reimbursement) (MAY 2004)
52.249-14	Excusable Delays (APRIL 1984)
52.251-1	Government Supply Sources (APRIL 1984)

52.253-1

Computer Generated Forms (JAN 1991)

II. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION
REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR

Clause No.	Title and Date
352.202-1	Definitions (JAN 2006)
352.223-70	Alternate h Safety and Health (JAN 2006)
352.224-70	Confidentiality of Information (JAN 2006)
352.228-7	Insurance - Liability to Third Persons (DEC 2006)
352.232-9	Withholding of Contract Payments (JAN 2006)
352.233-70	Litigation and Claims (JAN 2006)
352.242-71	Final Decisions on Audit Findings (APRIL 1984)
352.270-1	Accessibility of Meetings, Conferences, and Seminars to Persons With Disabilities (DEC 2006)
352.270-5	Key Personnel (JAN 2006)
352.270-6	Publication and Publicity (JAN 2006)
352.270-7	Paperwork Reduction Act (JAN 2006)

The following clauses are applicable to this contract and are provided in full text:

ORDERING (OCT 1995) (FAR 52.216-18)

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from the contract award date through the contract expiration date.

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of clause)

ORDER LIMITATIONS (OCT 1995) (FAR 52.216-19)

(a) *Minimum order.* When the Government requires supplies or services covered by this contract in an amount of less than \$10,000, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) *Maximum order.* The Contractor is not obligated to honor—

(1) Any order for a single item in excess of \$1,500,000;

(2) Any order for a combination of items in excess of \$ 1,725,000; or

(3) A series of orders from the same ordering office within 30 days that together call for quantities exceeding the limitation in paragraph (b)(1) or (2) of this section.

(c) If this is a requirements contract (*i.e.*, includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) of this section.

(d) Notwithstanding paragraphs (b) and (c) of this section, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within 5 days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source. (End of clause)

PART III- LIST OF DOCUMENTS, EXHIBITS AND ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

<u>Attachment</u>	<u># of Pages</u>
1. Past Performance Questionnaire and Contractor Performance Form	5
2. SF LLL-A, Disclosure of Lobbying Activities	3
3. Proposal Intent Form	1
4. Small Business Subcontracting Plan	8

Appendix

1. Background-DEcIDE Multi-Center Research Consortium	at end of SOW
2. AHRQ PORTFOLIOS	127-128
3. Sample Format for Task Order Proposal	130-131

NOTE: ALL ATTACHMENTS ARE LOCATED AT THE END OF THIS REQUEST FOR PROPOSAL.

PART IV. REPRESENTATIONS AND INSTRUCTIONS

SECTION K

(FAC 2005-30)

PART IV. REPRESENTATIONS AND INSTRUCTIONS

SECTION K

REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

K.1	HHSAR 315.204-5	Representations and Instructions
K.2.	FAR 52.204-8	Annual Representations and Certifications (FEB 2009)
K.3	FAR 52.209-5	Certification Regarding Responsibility Matters (DEC 2008)
K.4.	FAR 52.222-21	Prohibition of Segregated Facilities (FEB 1999)
K.5.	FAR 52.230-1	Cost Accounting Standards Notices and Certification (JUNE 2000)
K.6.	FAR 15.406-2	Certificate of Current Cost and Pricing Data
K.7.	P.L. 103-227	Certification Regarding Environmental Tobacco Smoke
K.8.	HHSAR 352.204	Certification of Filing and Payment of Federal Taxes.

K.I REPRESENTATIONS AND INSTRUCTIONS

(a) Section K, Representations, certifications, and other statements of offerors.

(1) This section shall begin with the following and continue with the applicable representations and certifications:

TO BE COMPLETED BY THE OFFEROR: (The Representations and Certifications must be executed by an individual authorized to bind the Offeror.) The Offeror makes the following Representations and Certifications as part of its proposal. (Check or complete all appropriate boxes or blanks on the following pages.)

(Name of Offeror)

(RFP No.)

(Signature of Authorized Individual) (Date)

(Typed Name of Authorized Individual)

NOTE: The penalty for making false statements in offers is prescribed in 18 U.S.C. 1001.

K.2. ANNUAL REPRESENTATIONS AND CERTIFICATIONS (FEB 2009) (FAR 52.204-8)

ANNUAL REPRESENTATIONS AND CERTIFICATIONS (FEB 2009)

(a)(1) The North American Industry Classification System (NAICS) code for this acquisition is _____ [*insert NAICS code*].

(2) The small business size standard is _____ [*insert size standard*].

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b)(1) If the clause at [52.204-7](#), Central Contractor Registration, is included in this solicitation, paragraph (c) of this provision applies.

(2) If the clause at [52.204-7](#) is not included in this solicitation, and the offeror is currently registered in CCR, and has completed the ORCA electronically, the offeror may choose to use paragraph (c) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The offeror shall indicate which option applies by checking one of the following boxes:

(i) Paragraph (c) applies.

(ii) Paragraph (c) does not apply and the offeror has completed the individual representations and certifications in the solicitation.

(c) The offeror has completed the annual representations and certifications electronically via the Online Representations and Certifications Application (ORCA) website at <http://orca.bpn.gov>. After reviewing the ORCA database information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR [4.1201](#)); except for the changes identified below [*offeror to insert changes, identifying change by clause number, title, date*]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR CLAUSE #	TITLE	DATE	CHANGE
_____	_____	_____	_____

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on ORCA.

(End of provision)

K. 3 Certification Regarding Responsibility Matters (Dec 2008)

(a)(1) The Offeror certifies, to the best of its knowledge and belief, that—

(i) The Offeror and/or any of its Principals—

(A) Are ___ are not ___ presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have ___ have not ___, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, state, or local) contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property;

(C) Are ___ are not ___ presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in paragraph (a)(1)(i)(B) of this provision;

(D) Have ___, have not ___, within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds \$3,000 for which the liability remains unsatisfied.

(1) Federal taxes are considered delinquent if both of the following criteria apply:

(i) The tax liability is finally determined. The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(ii) The taxpayer is delinquent in making payment. A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(2) Examples.

(i) The taxpayer has received a statutory notice of deficiency, under I.R.C. § 6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(ii) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. § 6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability.

Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(iii) The taxpayer has entered into an installment agreement pursuant to I.R.C. § 6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(iv) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. 362 (the Bankruptcy Code).

(ii) The Offeror has ___ has not ___, within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) "Principal," for the purposes of this certification, means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a subsidiary, division, or business segment; and similar positions).

This Certification Concerns a Matter Within the Jurisdiction of an Agency of the United States and the Making of a False, Fictitious, or Fraudulent Certification May Render the Maker Subject to Prosecution Under Section 1001, Title 18, United States Code.

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

(End of provision)

K.4. PROHIBITION OF SEGREGATED FACILITIES (FEB 1999) (FAR 52.222-21)

(a) "Segregated facilities," as used in this clause, means any waiting rooms, work areas, rest rooms and wash rooms, restaurants and other eating areas, time clocks, locker rooms and other storage or dressing areas, parking lots, drinking fountains, recreation or entertainment areas, transportation, and housing facilities provided for employees, that are segregated by

explicit directive or are in fact segregated on the basis of race, color, religion, or national origin because of written or oral policies or employee custom. The term does not include separate or single-user rest rooms or necessary dressing or sleeping areas provided to assure privacy between the sexes.

- (b) The Contractor agrees that it does not and will not maintain or provide for its employees any segregated facilities at any of its establishments, and that it does not and will not permit its employees to perform their services at any location under its control where segregated facilities are maintained. The Contractor agrees that a breach of this clause is a violation of the Equal Opportunity clause in this contract.
- (c) The Contractor shall include this clause in every subcontract and purchase order that is subject to the Equal Opportunity clause of this contract.
(End of Clause)

K.5. COST ACCOUNTING STANDARDS NOTICES AND
CERTIFICATION
(FAR 52.230-1) (JUNE 2000)

NOTE: This notice does not apply to small businesses or foreign governments. This notice is in three parts, identified by Roman numerals I through III.

Offerors shall examine each part and provide the requested information in order to determine Cost Accounting Standards (CAS) requirements applicable to any resultant contract.

If the offeror is an educational institution, Part II does not apply unless the contemplated contract will be subject to full or modified CAS-coverage pursuant to 48CFR 9903.201-2(c)(5) or 9903.201-2(c)(6), respectively.

I. Disclosure Statement - Cost Accounting Practices and Certification

(a) Any contract in excess of \$500,000 resulting from this solicitation, will be subject to the requirements of the Cost Accounting Standards Board (48 CFR, Chapter 99), except for those contracts which are exempt as specified in 48 CFR 9903.201-1.

(b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR Chapter 99 must, as a condition of contracting, submit a Disclosure Statement as required by 48 CFR 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph (c) of Part I of this provision. Caution: In the absence of specific regulations or agreement, a practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed-to practice for pricing proposals or accumulating and reporting contract performance cost data.

(c) Check the appropriate box below:

- (1) Certificate of Concurrent Submission of Disclosure Statement.
The offeror hereby certifies that, as a part of the offer, copies of the Disclosure Statement have been submitted as follows: (i) original and one copy to the cognizant Administrative Contracting Officer (ACO) or cognizant Federal agency official authorized to act in that capacity, as applicable, and (ii) one copy to the cognizant Federal auditor.

(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable. Forms may be obtained from the cognizant ACO or Federal official and/or from the loose-leaf version of the Federal Acquisition Regulation.)

Date of Disclosure Statement: _____

Name and Address of Cognizant

ACO or Federal official where filed:

The offeror further certifies that practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement.

- (2) Certificate of Previously Submitted Disclosure Statement.

The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement: _____

Name and Address of Cognizant

ACO or Federal official where filed:

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable Disclosure Statement.

- (3) Certificate of Monetary Exemption.

The offeror hereby certifies that the offeror together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and subcontracts subject to CAS totaling more than \$25 million in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

- (4) Certificate of Interim Exemption.

The offeror hereby certifies that (i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted and (ii) in accordance with 48 CFR, Subpart 9903.202-1, the offeror is not yet required to

submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a review certificate to the Contracting Officer, in the form specified under subparagraph (c)(1) or (c)(2) of Part I of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

Caution: Offerors currently required to disclose because they were awarded a CAS-covered prime contract or subcontract of \$25 million or more in the current cost accounting period may not claim this exemption (4). Further, the exemption applies only in connection with proposals submitted before expiration of the 90-day period following the cost accounting period in which the monetary exemption was exceeded.

II. Cost Accounting Standards - Eligibility for Modified Contract Coverage

If the offeror is eligible to use the modified provisions of 48 CFR, Subpart 9903.201-2(b) and elects to do so, the offeror shall indicate by checking the box below. Checking the box below shall mean that the resultant contract is subject to the Disclosure and Consistency of Cost Accounting Practices clause in lieu of the Cost Accounting Standards clause.

- The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR, Subpart 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received less than \$25 million in awards of CAS-covered prime contracts and subcontracts or the offeror did not receive a single CAS-covered award exceeding \$1 million. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

Caution: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of \$25 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or subcontract of \$25 million or more.

III. Additional Cost Accounting Standards Applicable to Existing Contracts

The offeror shall indicate below whether award of the contemplated contract would, in accordance with subparagraph (a)(3) of the Cost Accounting Standards clause, require a change in established cost accounting practices affecting existing contracts and subcontracts.

Yes No

(End of Provision)

ALTERNATE I (APR 1996)

- (5) Certificate of Disclosure Statement Due Date by Educational Institution.

If the offeror is an educational institution that, under the transition provisions of 48 CFR 9903.202-1(f), is or will be required to submit a Disclosure Statement after receipt of this award, the offeror hereby certifies that (check one and complete):

(a) A Disclosure Statement filing Due Date of _____ has been established with the cognizant Federal agency.

(b) The Disclosure Statement will be submitted within the six month period ending months after receipt of this award.

Name and Address of cognizant ACO or Federal Official where Disclosure Statement is to be filed:

(END OF ALTERNATE I)

K.6. CERTIFICATE OF CURRENT COST OR PRICING DATA
(FAR 15.406-2)

CERTIFICATE OF CURRENT COST OR PRICING DATA

When cost or pricing data are required, the contracting officer shall require the contractor to execute a Certificate of Current Cost or Pricing Data using the format in this paragraph, and shall include the executed certificate in the contract file.

This is to certify that, to the best of my knowledge and belief, the cost or pricing data (as defined in Section 15.401 of the Federal Acquisition Regulation(FAR) and required under FAR subsection 15.403-4) submitted, either actually or by specific identification, in writing, to the contracting officer or the contracting officer's representative in support of _____* are accurate, complete, and current as of _____**.

This certification includes the cost or pricing data supporting any advance agreements and forward pricing rate agreements between the offeror and the Government that are part of the proposal.

FIRM

NAME _____ Signature

TITLE

DATE OF EXECUTION***

* Identify the proposal, request for price adjustment, or other submission involved, giving the appropriate identifying number (e.g., Request for Proposal number).

** Insert the day, month, and year when price negotiations were concluded and price agreement was reached or, if applicable, an earlier date agreed upon between the parties that is as close as practicable to the date of agreement on price.

*** Insert the day, month, and year of signing, which should be as close as practicable to the date when the price negotiations were concluded and the contract price agreed to.

End of Certificate

K.7. ENVIRONMENTAL TOBACCO SMOKE

The Public Health Service strongly encourages all grant and contract recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE

Public Law 103-227, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law also applies to children's services that are provided in indoor facilities that are constructed, operated, or maintained with such federal funds. The law does not apply to children's services provided in private residences; portions of facilities used for inpatient drug or alcohol treatment; service providers whose sole source of applicable Federal funds is Medicare or Medicaid; or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to \$1000 for each violation and/or the imposition of an administrative compliance order on the responsible entity.

By signing this certification, the offeror/contractor certifies that the submitted organization will comply with the requirements of the Act and will not allow smoking within any portion of any indoor facility used for the provision of services for children as defined by the Act.

The submitting organization agrees that it will require that the language of this certification be included in any subawards which contain provisions for children's services and that all subrecipients shall certify accordingly.

Organization: _____

Signature _____ Title _____

Date _____

K.8 Certification of Filing and Payment of Federal Taxes

As prescribed in 304.1202, "Solicitation Provision," insert the following provision. If the solicitation is a Request for Quotations, the term "Quoter" may be substituted for "Offeror."

Certification of Filing and Payment of Federal Taxes (March 2008)

(a) The offeror certifies that, to the best of its knowledge and belief:

- 1) It has filed all Federal tax returns required during the three years preceding this certification;
- 2) It has not been convicted of a criminal offense under the Internal Revenue Code of 1986; and
- 3) It has not been notified of any unpaid Federal tax assessment for which the liability remains unsatisfied, unless the assessment is the subject of an installment agreement or offer in compromise that has been approved by the Internal Revenue Service and is not in default, or the assessment is the subject of a non-frivolous administrative or judicial proceeding.

(b) The signature of the offer is considered to be a certification by the offeror under this provision.

Name of Offeror

Signature of authorized individual

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

L.1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (FEB 1998) (FAR 52.252-1)

This solicitation incorporates the following solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the contracting officer will make the full text available. Also, the full text of a clause may be assessed electronically at this address: <http://www.arnet.gov/far/>

- a. Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Solicitation Provisions
 - (1) 52.215-16 Facilities Capital Cost of Money (OCT 1997)
 - (2) 52.215-20 Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data (OCT 1997)

L.2 DATA UNIVERSAL NUMBERING (DUNS) (OCT 2003) (FAR 52.204-6)

- (a) The offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation "DUNS" or "DUNS+4" followed by the DUNS number or "DUNS+4" that identifies the offeror's name and address exactly as stated in the offer. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. The DUNS+4 is the DUNS number plus a 4-character suffix that may be assigned at the discretion of the offeror to establish additional CCR records for identifying alternative Electronic Funds Transfer (EFT) accounts (see Subpart 32.11) for the same parent concern.
- (b) If the offeror does not have a DUNS number, it should contact Dun and Bradstreet directly to obtain one.
 - (1) An offeror may obtain a DUNS number—
 - (i) If located within the United States, by calling Dun and Bradstreet at 1-866-705-5711 or via the Internet at <http://www.dnb.com>; or
 - (ii) If located outside the United States, by contacting the local Dun and Bradstreet office.
 - (2) The offeror should be prepared to provide the following information:
 - (i) Company legal business name.
 - (ii) Tradestyle, doing business, or other name by which your entity is commonly recognized.
 - (iii) Company physical street address, city, state and Zip Code.
 - (iv) Company mailing address, city, state and Zip Code (if separate from physical).
 - (v) Company telephone number.
 - (vi) Date the company was started.
 - (vii) Number of employees at your location.
 - (viii) Chief executive officer/ key manager.
 - (ix) Line of business (industry)

(X) Company Headquarters name and address (reporting relationship within your entity).

(End of provision)

**L.3 INSTRUCTIONS TO OFFERORS - COMPETITIVE ACQUISITION (MAY 2001)
ALTERNATE I (JAN 2004)(FAR 52.215-1)**

(a) *Definitions.* As used in this provision --

“Discussions” are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer’s discretion, result in the offeror being allowed to revise its proposal.”

“In writing,” “writing,” or “written” means any worded or numbered expression which can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

“Proposal modification” is a change made to a proposal before the solicitation’s closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

“Proposal revision” is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

“Time,” if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.*

(1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages

(i) addressed to the office specified in the solicitation, and

(ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show --

- (i) The solicitation number;
 - (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
 - (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
 - (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
 - (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.
- (3) *Submission, modification, revision, and withdrawal of proposals.*
- (i) Offerors are responsible for submitting proposals, and any modification, or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.
 - (ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and --
 - (1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
 - (2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
 - (3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.
 - (iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal

wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

- (iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
 - (v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.
 - (4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.
 - (5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.
 - (6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.
 - (7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.
 - (8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.
- (d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).
- (e) *Restriction on disclosure and use of data.* Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall --
- (1) Mark the title page with the following legend:

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed -- in whole or in part -- for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of -- or in connection with -- the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [*insert numbers or other identification of sheets*]; and

- (2) Mark each sheet of data it wishes to restrict with the following legend:

Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

(f) *Contract award.*

- (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.
- (2) The Government may reject any or all proposals if such action is in the Government's interest.
- (3) The Government may waive informalities and minor irregularities in proposals received.
- (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.
- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced

pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:
 - (i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
 - (ii) The overall evaluated cost or price and technical rating of the successful and the debriefed offeror and past performance information on the debriefed offeror.
 - (iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection.
 - (iv) A summary of the rationale for award.
 - (v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
 - (vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of provision)

L.4 TYPE OF CONTRACT (APRIL 1984)(FAR 52.216-1)

The Government contemplates award of a cost reimbursement, completion type, task order (IDIQ) contract resulting from this solicitation.

It is anticipated that six to ten (6 – 10) Contract awards will be made from this solicitation and that the awards are estimated to be made in July 2010.

L.5 SINGLE OR MULTIPLE AWARDS (OCT 1995)(FAR 52.216-27)

The Government may elect to award a single delivery order contract or task order contract or to award multiple delivery order contracts or task order contracts for the same or similar supplies or services to two or more sources under this solicitation.

L.6 SERVICE OF PROTEST (AUG 1996)(FAR 52.233-2)

- (a) Protests, as defined in Section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO) shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Director, Division of Contracts Management
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, Maryland 20850

- (b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

L.7 POINT OF CONTACT FOR TECHNICAL INQUIRIES

The technical contact for additional information and answering inquiries is the Contracting Officer. All questions regarding this solicitation shall be in writing and received by the Contracting Officer no later than 12:00 noon ET on March 23, 2010. All questions shall be e-mailed to Mary Haines at Mary.Haines@ahrq.hhs.gov. All questions should include the subject line DEcIDE-2 Questions and sent with High Importance.

L.8 REFERENCE MATERIALS

Offers are directed to information about DEcIDE at <http://effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-the-decide-network/>

L.9 GENERAL INSTRUCTIONS

Introduction

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions:

- a. Contract Type and General Provisions: It is contemplated that a task order type contract will be awarded. In addition to the special provisions of this request for proposal (RFP), any resultant contract shall include the general clauses applicable to the selected offeror's organization and type of contract awarded. Any additional clauses required by Public Law, Executive Order, or

procurement regulations, in effect at the time of execution of the proposed contract, will be included.

- b. Authorized Official and Submission of Proposal: The proposal shall be signed by an official authorized to bind your (the offeror's) organization. Your proposal shall be submitted in the number of copies, to the address, and marked as indicated in the cover letter of this solicitation. Proposals will be typewritten, reproduced on letter sized paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:
- I. TECHNICAL PROPOSAL: See Technical Proposal Instructions for recommended format (L.10). Please mark as original or copy.
 - II. PAST PERFORMANCE INFORMATION: See Past Performance Information Instructions for format (L.11)
 - III. SMALL DISADVANTAGED BUSINESS PARTICIPATION PLAN: See Small Disadvantaged Business Plan Instructions for format (L.12)
 - IV. BUSINESS PROPOSAL: See Business Proposal Instructions for recommended format, including Small and Small Disadvantaged Business Plan (L.13).
- c. Separation of Technical, Past Performance Information, and Business Proposal: The proposal shall be in 3 parts:
- (1) Technical Proposal; (2) Past Performance Information; and (3) Business Proposal. Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. **The technical proposal shall not contain reference to cost**; however resources information, such as data concerning labor hours and categories, materials, subcontracts, etc., shall be contained in the technical proposal so that your understanding of the Statement of Work (SOW) may be evaluated. It must disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.
- d. Evaluation of Proposals: The Government will evaluate technical proposals in accordance with the criteria set forth in Section M, Evaluation/Award Criteria.
- e. Rejection of Proposals: The Government reserves the right to reject any or all proposals received. It is understood that your proposal will become part of the official contract file.
- f. Unnecessarily Elaborate Proposals: Unnecessarily elaborate brochures or other presentations beyond those sufficient to present a complete and effective proposal are not desired and may be construed as an indication of the offeror's lack of cost consciousness. Elaborate art work, expensive visual and other presentation aids are neither necessary nor wanted.

- g. Privacy Act: The Privacy Act of 1974 (Public Law (P.L.) 93-579) requires that a Federal agency advise each individual whom it asks to supply information: 1) the authority which authorized the solicitation; 2) whether disclosure is voluntary or mandatory; (3) the principal purpose or purposes for which the information is intended to be used; (4) the uses outside the agency which may be made of the information; and 4) the effects on the individual, if any, of not providing all or any part of the requested information.

Therefore:

- (1) The Government is requesting the information called for in this RFP pursuant to the authority provided by Section 301(g) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.
- (2) Provisions of the information requested are entirely voluntary.
- (3) The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.
- (4) Failure to provide any or all of the requested information may result in a less than adequate review.
- (5) The information provided by you may be routinely disclosed for the following purposes:
 - to the cognizant audit agency and the General Accounting Officer for auditing;
 - to the Department of Justice as required for litigation;
 - to respond to Congressional inquiries; and
 - to qualified experts, not within the definition of Department employees for opinions as a part of the review process.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of AHRQ contracting programs. Authority for requesting this information is provided by Section 305 and Title IV of the Public Health Service Act, as amended.

- h. The RFP does not commit the Government to pay any cost for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with this or any acquisition action.

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

L.10 TECHNICAL PROPOSAL INSTRUCTIONS

The technical proposal shall contain 12 printed copies and two CDs (of the proposal) enclosed with the printed copies. The technical proposal shall provide specific information addressing the elements in the Statement of Work and those specified below. The technical proposal shall not exceed 100 pages not including biographic sketches, with no less than a 11 point font, double-spaced (tables, organizational charts, and similar materials need not be double-spaced, so long as they are legible). Brief biographic sketches or CVs (less than ten pages in length) providing the relevant qualifications necessary for this effort are only required for key personnel. The technical proposal shall not contain reference to cost; however resources information, such as data concerning labor hours and categories, labor mix, materials, subcontracts, etc., shall be contained in the technical proposal so that the offeror's understanding of the Statement of Work (SOW) may be evaluated. The proposal must disclose the offeror's technical approach in as much detail as possible, including, but not limited to, the requirements of these instructions. Lengthy proposals and voluminous appendices are neither needed nor desired as they are difficult to read and evaluate and may indicate the offeror's inability to concisely state their proposal. Proposals should be well-organized and formatted with subheadings and sufficient white space so each page is easily read. Use of tables and figures to summarize key information is encouraged.

Recommended Technical Proposal Format

The offeror's proposal should present sufficient information to reflect a thorough understanding of the work requirements and a detailed plan for achieving the objectives of the scope of work. Technical proposals shall not merely paraphrase the requirements of the Agency's Scope of Work or parts thereof, or use of phrases such as "will comply" or "standard techniques will be employed." The technical proposal must include a detailed description of the techniques and procedures to be used in achieving the proposed end results in compliance with the requirements of the Agency's Scope of Work.

1. Cover Page

The name of the proposing organization, list of proposed subcontractors, author(s) of the technical proposal, the RFP number and the title of the RFP should appear on the cover. The cover page must also include the DUNS and TIN as well as a point of contact and contact information including email address. One (1) manually signed original of the proposal and the number of copies specified in the RFP cover letter are required.

2. Executive Summary

Provide a one to five page summary of the technical proposal including approach, management plan, key personnel, and facilities.

3. Table of Contents

Provide sufficient detail so that all important elements of the proposal can be located readily.

4. Introduction

This should be a short opening that outlines the proposed work, the offeror's interest in submitting a proposal, and the importance of this effort in relation to the offeror's overall operation. Summarize unique strengths of the proposal for conducting comparative effectiveness research in collaboration with the Agency.

5. Technical Discussion

Technical proposals submitted in response to this RFP shall address each of the items described below, and shall be organized in the same manner and within the page limitations specified. Proposals shall be prepared in double-spaced format, with numbered pages. At a minimum, the following information shall be contained in the proposal:

a.) **Understanding the Purpose and Objectives of the DEcIDE Research Network and Comparative Effectiveness Research at AHRQ**

1. Briefly, but in sufficient detail to give an appropriate response to this evaluation criterion, the offeror shall provide a background discussion on comparative effectiveness research, comparative effectiveness reviews (i.e., systematic reviews and technology assessments), and communication of comparative effectiveness research findings to diverse stakeholders. The offeror shall discuss the appropriate uses and limitations of comparative effectiveness research for improving patient outcomes and for informing the decisions of patients, providers, and policy makers about the benefits and harms of health care interventions used in clinical practice.
2. The offeror shall describe the mission and objectives of the DEcIDE-2 Network, including how the Network will fulfill Section 1013 of the Medicare Modernization Act and subsequent legislative mandates to conduct comparative effectiveness research. Additionally, the offeror shall demonstrate a general, but thorough, understanding of the objectives, organization, and operation of AHRQ's Effective Health Care program including key components such as the Evidence-based Practice Centers, the DEcIDE-1 research centers and DEcIDE-1 consortia, and the Eisenberg Center. Offerors may provide a conceptual framework to explain how the proposed DEcIDE-2 research center can operate in collaboration with AHRQ scientists to generate new scientific evidence that fills evidence gaps identified in systematic literature reviews and topics nominated by stakeholders as important priorities.
3. The offeror shall show experience and understanding of the Medicare, Medicaid, SCHIP, and other public health programs both currently as well as projections for the future.

b.) Technical Approach

The offerors shall submit a narrative that clearly addresses how he or she plans to develop, design, and implement the Statement of Work. Within the content of the narrative, the offeror shall address technical issues related to conducting comparative effectiveness and patient-centered outcomes research, particularly within a collaborative research network. Technical issues to address include:

1. Design and implementation of clinical and epidemiologic studies, particularly studies of the comparative effectiveness of different therapeutic approaches including surgery, diagnostic tests, pharmaceuticals, and medical procedures. **The offeror shall describe up to four comparative effectiveness studies that could be immediately initiated and completed by the proposed center within 24 to 36 months.** These studies should be succinctly described according to key research questions, methods including data and analysis, and relevancy of the study findings to the actions or decisions of at least one stakeholder group.
2. Conduct of multi-center, collaborative prospective observational or interventional studies that evaluate strategies for improving the effectiveness and efficiency of the Medicare, Medicaid, SCHIP, other insurance, and public health programs, including ways in which medical therapies and diagnostic tests are provided, organized, managed, and delivered under such programs. **The offeror shall describe specific functions or resources their proposed DEcIDE-2 center can offer to support collaborative prospective studies in the DEcIDE Network.**
3. Conduct of multi-center collaborative retrospective and prospective studies to assess various factors that may affect therapeutic effectiveness and patient health outcomes. **Specifically, offerors shall address their capacity to participate or lead one or more consortia of DEcIDE-2 investigators to conduct research in one or more of the EHC priority conditions.**
4. Development of valid methods, measures, study protocols, and measurement instruments that can be publicly disseminated on behalf of the DEcIDE program to scientists and other experts to facilitate comparative effectiveness research, clinical care, or program evaluation. **The offeror shall propose up to two research methods projects that the proposed DEcIDE-2 center could immediately initiate and complete within 24 to 36 months.**
5. Provision of technical assistance to AHRQ staff including analysis of existing databases for decisional support.

c.) Management Plan

The offeror shall demonstrate the ability to achieve the delivery of performance requirements through the proposed use of corporate management and other personnel resources as well as demonstrate that the offeror's organizational structure and capabilities will meet the project's milestones in a timely and expeditious manner.

1. Offerors shall show understanding of the requirements in the Statement of

Work from a managerial perspective. In doing so, offerors shall describe the overall plan for organizing, staffing, and managing the tasks required by this task order contract. The plan shall indicate how organizational roles and responsibilities will be divided, decisions made, work monitored, and quality and timeliness of products assured. It is suggested that flow diagrams be included to explain how tasks will be managed. In addition, submission of organizational diagram(s) is recommended. The narrative should at a minimum address the following topics:

- a) labor skill mix determination (why you chose the skill mix for this project);
 - b) personnel selection and assignment (why you chose an individual person for an individual job);
 - c) core personnel for the DEcIDE-2 center;
 - d) managerial problems offeror expects to encounter and methods you propose to solve these problems;
 - f) project management tools (including software); and
 - g) the ability and flexibility to respond rapidly to changes in budget, priorities, and schedule.
2. The offeror shall explain how this management plan demonstrates the offeror's capability to start projects quickly, function in one or more DEcIDE consortia, ensure that qualified personnel are available for individual task orders, conduct more than one task order concurrently, complete complex tasks within narrow time frames, and assure the quality of the products.
 3. The offeror shall describe planned subcontracting and consulting relationships, and other special organizational relationships. In addition, Letters of Intent from proposed consultants should be provided. If the offeror proposes to use consultants or subcontractors to carry out work under this task order contract, the management plan shall specify how the contractor, consultants, and/or subcontractors will work together, how tasks will be divided, how decisions will be made and communicated, how activities will be coordinated, and how the relationships will be managed to assure quality, timeliness, and productivity. In addition, the offeror shall describe how subcontractors, consultants, and non-core staff will be educated on the DEcIDE-2 program policies and procedures to assure adherence in carrying out the work of a particular task order.
 4. The offeror shall demonstrate familiarity with federal task order contracts and describe mechanisms to adhere to the requirements of the master contract, particularly conformance to the scope of work for which the task order was awarded, on time submission of deliverables, quality assurance, AHRQ staff review prior to publication or presentation of deliverables, and knowledge of OMB clearance procedures as required by the Paperwork Reduction Act.

d.) Organizational or Corporate Experience

1. The offeror must have demonstrated experience as an organization in successfully conducting and managing large scale and complex research, evaluation, and/or development projects in the health care field. It is essential that the offeror demonstrate the capability to organize and manage resources and personnel effectively, and to successfully undertake and complete highly technical and, potentially, controversial projects within stipulated performance periods and in a way that avoids bias.
2. The offeror shall describe its relevant organizational qualifications and experience, especially those that relate to review and analysis of prescription drug and therapeutic data, conducting therapeutic effectiveness or health outcomes research, including conducting epidemiology studies, analysis of secondary databases, creating disease registries, building clinical repositories, conducting decision analyses, and economic analyses, and writing and editing technical or scientific reports. In addition, the offeror shall show corporate experience in conducting original research citing a minimum of 20 original projects over the past 10 years with evidence of publication in peer-reviewed health science journals.
3. Offeror's descriptions shall delineate how these organizational experiences and processes are relevant to fulfilling the requirements of this proposed contract. In addition, the offeror shall submit, three examples of similar work that it has performed in the past five (5) years.
4. Offeror shall demonstrate extent and relevance of prior experience in successfully working with stakeholder groups, such as professional societies, patients, hospitals, health plans, payers, etc., in producing products which are responsive to user needs.
5. The offeror shall provide evidence of a minimum of 5 years' experience in health care research in one or more of the following fourteen conditions: arthritis and nontraumatic joint disorders; cancer; cardiovascular disease; dementia, including Alzheimer's Disease; depression and other mental health disorders; developmental delays, attention-deficit hyperactivity disorder, and autism; diabetes mellitus; functional limitations and disability; infectious diseases including HIV/AIDS; obesity; peptic ulcer disease and dyspepsia; pregnancy including preterm birth; pulmonary disease/asthma; and substance abuse.

e.) Key Personnel

The Technical Proposal shall include a Staffing Plan for the conduct of the Statement of Work, including role descriptions and level of effort of key scientific, technical and administrative personnel and, plans for back-up scientific, technical and administrative staffing.

The offeror is expected to be specific in describing the proposed staff. Highly qualified staff

are considered critical to the successful completion of short-term and long-term, high priority projects envisioned under this task order contract. The offeror shall submit NIH biosketches or CV's for personnel who may be utilized during this contract period. Identified individuals should be readily available for assignment to requirements which may arise.

Proposed staff, including consultants and subcontractors, shall reflect diverse experience and skills. Staff shall have advanced research training and expertise in conducting experimental and/or nonexperimental research. In addition to clinical training and experience, relevant areas of staff expertise include, among others, epidemiology, biostatistics, pharmaceutical research, social sciences, behavioral research, decision analysis, cost and cost-effectiveness analysis, economic analysis, health services research, health policy analysis, organization and financing analysis, technical or scientific writing and editing, and systematic searches of literature and other data resources.

1. Project Director/Principal Investigator. The offeror's proposed Director shall be identified. This individual shall possess strong corporate level management experience. The Director is responsible for the overall management of this task order contract, including coordination and cooperation with Federal Government staff and policy officials, direction and oversight of all studies awarded under the task order contract, and assuring quality and timeliness of work performed. He or she shall have an advanced degree such as an MD, PhD or MPH with a minimum of 8 years' experience in the development, implementation, and dissemination of research findings.
2. Key/Core Scientific and Technical Personnel: Describe the experience and qualifications, as well as the percentage of the total time each will be committed to the project. Identify the composition of the task or work group, its general qualifications and recent experience with similar efforts. As a minimum, this effort will require different staff/areas of expertise at different times over the course of the contract.

Please provide documentation to describe:

- a. Key Scientific and Technical Personnel (limit CVs to 2-3 pages for non-scientific personnel) including doctoral level statistical analysts and epidemiologists, and one or more competent scientific writers, and data programmers;
 - b. Qualifications and relevant training as supported by academic degree(s) and demonstration of previous experience doing similar complex projects;
 - c. References to all publications;
 - d. Availability for the proposed project.
 - e. Summary of related activities.
2. Other Personnel: Offerors should discuss the related experience and the role of other personnel as well as the ability to access and secure ad hoc clinical and scientific expertise as needed to address new scientific agendas in

upcoming years. Other personnel may include non-key scientific, technical, and administrative personnel.

The offeror shall identify proposed one or more Project Managers. Project Managers are responsible for the day-to-day management of individual task orders. These individuals must be highly qualified, with significant leadership and communication skills, and demonstrated experience and competence in managing complex projects with similar or differing requirements. In most cases it is expected that Project Managers will have training and experience in critical evaluation of biomedical, social sciences, behavioral, and/or health services research (e.g., epidemiology, biostatistics). In addition, it is highly desirable that the Project Manager have at least some general clinical training and experience.

3. Offerors shall describe their access to general and specialized clinical, behavioral, social sciences, economic and management expertise. Contractors are not required to have all types of expertise available on a full-time basis with the DEClDE's centers. To ensure adequate management of tasks required under typical task orders, however, contractors should demonstrate that there will be personnel with general clinical training and experience, with basic knowledge of biostatistics and epidemiology, pharmaceutical research, and with scientific writing and editing expertise, available within the DEClDE's centers and who will be involved in each task order.
4. In concurrence with the narrative, provide an organizational chart for the staffing plan.

Offerors shall provide appropriate staff for work on task orders, including personnel in the following labor classes:

Class I

Senior management personnel, holding an advanced clinical, technical or professional degree, at the M.D., Ph.D., or Masters level, with a minimum of 10 years experience in analyzing biomedical, social sciences, behavioral, medical effectiveness, epidemiological or outcomes data, or similar scientific literature, research findings and data, preferably with significant experience related to development of clinical practice guidelines, medical review criteria, quality measures or indicators, or patient safety and other performance measures; biomedical or social sciences literature reviews and syntheses; meta-analysis; cost-effectiveness analysis; and/or experience in working with professional societies and healthcare delivery systems, such as hospitals and health plans. Class I personnel shall also have corporate level management experience that reflects an ability to command organizational resources and direct staff within the broader organization.

Class II

Associate management or clinical/professional/technical personnel, holding as

advanced degree, at the M.D., Ph.D., or Master level, with a minimum of 5 years experience in analyzing biomedical, social sciences, medical effectiveness, epidemiological data, or similar scientific literature, research findings and data.

Class III

Intermediate clinical/technical personnel, holding a BS or BA degree and at least 3 years experience in technical activities of which 2 years experience are directly related to analysis of biomedical, social sciences, and related scientific literature and other data. The individual is capable of carrying out independent assignments with minimum supervision or acting as leader of small projects. Class III personnel includes specialists in science writing and editing, as well as computer programming.

Class IV

Data support, literature search and retrieval, report drafting, etc. at a research assistant level.

f.) Existing Facilities and Database Characteristics

The Technical Proposal shall document availability and adequacy of facilities, equipment, space and other resources necessary to carry out the Statement of Work. In responding to this RFP, offerors should submit a detailed description of their capabilities discussing available information in greater depth, specifically as they relate to comparative effectiveness studies.

Using a table format, please list and briefly explain 1) current database holdings at your center and the databases and separately 2) databases that you may be able access if funded through a task order. Please also describe the timeliness, ownership, signed usage agreements, restrictions on use, population size, updates, and core investigator experience analyzing key database(s). In addition, note whether clinical, health outcome, laboratory, and drug use information contained in the database for which AHRQ could issue a task order.

Specifically please provide the following:

Current access	How does your proposed DEcIDE center access the database? Could studies be initiated immediately using the database?
Timeliness	Approximately what period of time does the data cover?
Ownership	Who owns the database? If the database is not owned by the proposed DEcIDE center, what is the average length of time to acquire the data?
Signed usage agreements	What general Data Use Agreements or Memo of Understanding does your DEcIDE hold with the database owners?
Restrictions on use	Explain any restrictions on using the data.

Population size	Approximately how many individuals or events are represented in the database?
Updates	How often are files updated? Will the database continue to be updated in future years?
Investigator experience	What experience does the core investigators have with analyzing the database? Cite key publications if available.
Clinical variables	Is medical procedure coding and diagnostic information contained in the database?
Health outcome variables	Are health outcomes available? Is it possible to link the database to health outcome information like the National Death Index?

L.11 PAST PERFORMANCE INFORMATION

Offerors shall submit the following information (original and 5 copies) as part of their proposal for both the offeror and proposed major subcontractors:

(1) A list of the last five (5) contracts and subcontracts completed during the past three years and all contracts and subcontracts currently in process. Contracts listed may include those entered into by the Federal Government, agencies of State and local governments and commercial customers. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required for all key personnel. Include the following information for each contract and subcontract:

- a: Name of contracting activity
- b: Contract number
- c: Contract type
- d: Total contract value
- e: Contract work
- f: Contracting Officer and telephone number
- g: Program Manager and telephone number
- h: Administrative Contracting Officer, if different from item f, and telephone number
- i: List of major subcontracts

(2) The offeror may provide information on problems encountered on the contracts and subcontracts identified in (1) above and corrective actions taken to resolve those problems. Offerors should not provide general information on their performance on the identified contracts. General performance information will be obtained from the references.

(3) The offeror may describe any quality awards or certifications that may indicate the offeror possesses a high-quality process for developing and producing the product or service required. Identify what segment of the company (one division or the entire company) that received the award or certification. Describe when the award or certification was bestowed. If the award or certification is over three years old, present evidence that the qualifications still apply.

(4) Each offeror will be evaluated on his/her performance under existing and prior contracts for similar products or services. Performance information will be used for both responsibility determinations and as an evaluation factor against which offeror's relative rankings will be compared to assure best value to the Government. The Government will focus on information that demonstrates quality of performance relative to the size and complexity of the procurement under consideration. References other than those identified by the offeror may be contacted by the Government with the information received used in the evaluation of the offeror's past performance.

The attached Past Performance Questionnaire and Contractor Performance Form (Attachment 1) shall be completed by those contracting organizations listed in (1) above. The evaluation forms shall be completed and forwarded directly to the following:

Mary Haines
Agency for Healthcare Research and Quality
Division of Contracts Management
540 Gaither Road
Rockville, Maryland 20850
FAX: 301-427-1740

Evaluation forms must be received by **12:00 noon Local Time, April 27, 2010** in order to be included in the review process. It is the responsibility of the offeror to ensure that these documents are forwarded to the Contracting Officer.

L.12 SMALL DISADVANTAGED BUSINESS PARTICIPATION PLAN

In accordance with FAR Part 15.304(c)4, the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract shall be evaluated in unrestricted acquisitions expected to exceed a total estimated cost of \$500,000 (\$1,000,000 for construction) subject to certain limitations (see FAR 19.201 and 19.1202).

A. All offerors, regardless of size, shall submit the following information in an original and 2 copies.

A plan on the extent of participation of Small Disadvantaged Business concerns in performance of the contract. Participation in performance of the contract includes the work expected to be performed by SDB concern(s). This can include SDB (as prime contractor), joint ventures, teaming arrangements, and subcontracts. Include the following information in SDB participation plans:

1. The extent of an offeror's commitment to use SDB concerns. Commitment should be as specific as possible, i.e., are subcontract arrangements already in place, letters of commitment, etc. Enforceable commitments will be weighted more heavily than non-enforceable ones.

2. Specifically identify the SDB concerns with point of contact and phone number.
 3. The complexity and variety of the work SDB concerns are to perform.
 4. Realism for the use of SDB in the proposal.
 5. Past performance of the Offeror in complying with subcontracting plans for SDB concerns.
 6. Targets expressed as dollars and percentage of total contract value for each participating SDB; which will be incorporated into and become part of any resulting contract.
 7. The extent of participation of SDB concerns in terms of the total acquisition.
- B. SDB participation information will be used for both responsibility determinations and as an evaluation factor against which offeror's relative rankings will be compared to assure the best value to the Government. The Government will focus on information that demonstrates realistic commitments to use SDB concerns relative to the size and complexity of the acquisition under consideration. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's commitment to SDB participation.

(End of Information provided on Small Disadvantaged Business Participation Plan)

L.13 BUSINESS PROPOSAL INSTRUCTIONS

The offeror shall submit as part of the proposal a separate enclosure titled "Business Proposal" for each proposal being submitted. The Business Proposal shall include the Cost/Price Proposal and Other Administrative Data in accordance with the following:

A. Cost/Price Proposal

A cost proposal, in the amount of an original and five (5) hard copies, plus two electronic copies on CD, shall be provided only to the extent that it shall include:

1. Certified, unloaded, labor rates for individuals expected to work on a project of this size and nature. See the **Technical Proposal Instructions (L.10)** which provides a list of the specific labor categories. Labor rates or ranges of rates shall be indicated for each labor category as part of **B3 Proposed Labor Rates for Task Orders**.
2. A statement certifying that the offeror has a cost accounting system in place which allows for the collection, tracking and reporting of all costs under a cost reimbursement-type contract.

3. Certified documentation that the offeror has a current indirect cost rate agreement in place with a federal agency or that is in the process of obtaining or revising such an agreement. A copy of the indirect cost rate agreement or the proposed rate agreement shall be provided.
4. **Complete Appendix 3 Project Sample Format for Task Order Proposal** – Fill in the rate structure and associated indirects and fee if applicable and total cost for a sample task order proposal. The Appendix is at the end of the RFP.

B. Small Business Subcontracting Plan:

All offerors except small businesses will be required to submit a subcontracting plan in accordance with the Small Business Subcontracting Plan, FAR 52.219-9, incorporated in this solicitation. A copy of a model subcontracting plan is available at <http://www.hhs.gov/osdbu/read/SampleSubcontractingPlan.doc>. The use of the model plan is HIGHLY RECOMMENDED. If the model plan is not used, all elements outlined must be addressed in the offeror's format. If the offeror is not a small business and fails to submit a subcontracting plan when requested, the offeror will be considered nonresponsive and their proposal will be returned without further consideration.

For this specific Indefinite-Delivery Indefinite Quantity (IDIQ), HHS/ AHRQ suggests the offeror consider the total estimated value of the requirement, which is \$4,000,000. The Individual Small Business Subcontracting Plan's percentage goals will be applicable to each Task Order (TO) that is completed by a non-small business concern. An Individual Plan (IP) is applicable for the full term of the initial contract. If the contract is modified, the IP shall be modified.

This provision does not apply to small business concerns. This provision does apply to all other offerors, including large business concerns, colleges, universities and non-profit organizations.

The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

The offeror understands that:

- a. No Contract above the threshold will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer. The plan will be incorporated into the Contract.
- b. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for small business concerns and small business concerns owned and controlled by socially and economically disadvantaged persons to participate in the performance of the Contract.

- c. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
- d. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
- e. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to small business concerns and small business concerns owned and controlled by socially and economically disadvantaged individuals, and women-owned small business concerns, and that each such aspect of the offeror's plan will be judged independent of the other.
- f. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- g. For this particular acquisition, the AHRQ recommended goal (as a percentage of total contract value for the base period) is 11% for Small Businesses, which shall include at least 5% (as a percentage of total planned subcontract dollars for the base period) for Small Disadvantaged Businesses, at least 5% (as a percentage of total planned subcontract dollars for the base period) for Women-Owned Small Businesses, and at least 3% (as a percentage of total planned subcontract dollars for the base period) for HUBZone Small Businesses and at least 3% (as a percentage of total planned subcontract dollars for the base period) for Veteran-Owned Small Businesses. These goals represent AHRQ's expectations of the minimum level for subcontracting with small business at the prime contract level. Any goal stated less than the AHRQ recommended goal shall be justified and is subject to negotiation.

(End of information on Small Business Subcontracting Plan requirements)

C. Other Administrative Data

(1) Terms and Conditions: The proposal shall stipulate that it is predicated upon the terms and conditions of the RFP. In addition, it shall contain a statement to the effect that it is firm for a period of at least 120 days from the date of receipt thereof by the Government.

Minimum Bid Acceptance Period (April 1984)

- (a) "Acceptance period," as used in this provision, means the number of calendar days available to the Government for

awarding a contract from the date specified in this solicitation for receipt of bids.

- (b) This provision supersedes any language pertaining to the acceptance period that may appear elsewhere in this solicitation.
 - (c) The Government requires a minimum acceptance period of 120 days.
 - (d) A bid allowing less than the Government's minimum acceptance period may be rejected.
 - (e) The bidder agrees to execute all that it has undertaken to do, in compliance with its bid, if that bid is accepted in writing within (i) the acceptance period stated in paragraph (3) above, or (ii) any longer acceptance period stated in paragraph (4) above.
- (2) Authority to Conduct Negotiations: The proposal shall list the names and telephone numbers of persons authorized to conduct negotiations and to execute contracts.
- (3) Property:
- (a) It is HHS policy that contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the contracting officer. If additional equipment must be acquired, you shall include the description, estimated cost of each item and whether you will furnish such items with your own funds.
 - (b) You shall identify Government-owned property in your possession, and/or property acquired from Federal funds to which you have title, that is proposed to be used in the performance of the prospective contract.
 - (c) The management and control of any Government property shall be in accordance with HHS Publication (OS) 74-115 entitled, Contractor's Guide for Control of Government Property" 1990, a copy of which will be provided upon request.
- (4) Royalties: You shall furnish information concerning royalties which are anticipated to be paid in connection with the performance of work under the proposed contract.
- (5) Commitments: You shall list other commitments with the Government relating to the specified work or services and indicate whether these commitments will or will not interfere with the completion of work and/or services contemplated under this proposal.

- (6) Financial Capacity: You shall provide sufficient data to indicate that you have the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source. (Financial data such as balance sheets, profit and loss statements, cash forecasts, and financial histories of your organization's affiliated concerns should be utilized.)
- (7) Performance Capability: You shall provide acceptable evidence of your "ability to obtain" equipment, facilities, and personnel necessary to perform the requirements of this Contract. If these are not represented in your current operations, they should normally be supported by commitment or explicit arrangement, which is in existence at the time the contract is to be awarded, for the rental, purchase, or other acquisition of such resources, equipment, facilities, or personnel. In addition, you shall indicate your ability to comply with the required or proposed delivery or performance schedule taking into consideration all existing business commitments, commercial as well as Government.
- (8) Representations and Certifications: Section K, "Representations and Certifications and Other Statements of Offerors" shall be completed and signed by an official authorized to bind your organization. **This section shall be made a part of the original business proposal.**

L.14 SELECTION OF OFFERORS

- a. The acceptability of the technical portion of each contract proposal will be evaluated by the technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal will be subjected to a cost review, management analysis, etc.
- c. Past performance, Small Business Subcontracting Plan and the Small Disadvantaged Business Participation Plan of the technically acceptable offerors will be evaluated by AHRQ staff. A competitive range may be determined. Oral or written discussions will be conducted with all offerors in the competitive range, if necessary. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, Small Disadvantaged Business Participation Plan and contractual terms and conditions. Final Proposal Revisions will be requested with the reservation of the right to conduct limited negotiations after submission of the Final Proposal Revisions.
- d. A final analysis will be performed taking into consideration the results of the technical evaluation, cost analysis, past performance, and ability to complete the work within the Government's required schedule. The Government intends to make an award to the best value of the Government, technical merit, cost, past performance, and other factors considered.

- e. The Government reserves the right to make a single award, multiple awards, or no award at all to the RFP.

L.15 PROPOSAL INTENT

It is requested that if an offeror intends to submit a proposal to this solicitation that the attached Proposal Intent Form (Attachment 3) be completed and returned to the address indicated by **APRIL 12, 2010**. The submission of the intent form is not binding on an offeror to submit a proposal, nor does the failure to submit the form prohibit an offeror from submitting a proposal. The purpose is to provide us with an estimated number of proposals to assist us in our planning and logistics for proposal reviews. We have added a request to include your contact information to a bidders list. The bidders list will be provided to interested offerors for subcontracting opportunities. In order for AHRQ to include your contact information on the bidders list, you must return the Proposal Intent Form and check the box that grants permission to add your name no later than the date listed above.

SECTION M - EVALUATION FACTORS FOR AWARD

TECHNICAL EVALUATION CRITERIA

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors and award will be made to that responsible offeror whose proposal is offers the best value to the Government. The four factors are: (1)scientific technical merit, (2)cost, (3)past performance and (4) Small Disadvantaged Business Participation Plan. The scientific technical merit of the proposals will receive paramount consideration in the selection of the Contractor(s) for this acquisition. Offerors that submit technically acceptable proposals will be evaluated for past performance and SDB Participation.

All evaluation factors, other than cost or price, when combined are significantly more important than cost or price. However, cost/price may become a critical factor in source selection. In any event, the Government intends to make an award to that offeror whose proposal provides the best overall value to the Government. The Government reserves the right to make a single award, multiple awards, or no award at all.

**THE GOVERNMENT RESERVES THE RIGHT TO
MAKE AN AWARD WITHOUT DISCUSSION**

The Government reserves the right to make an award to the best advantage of the Government. The evaluation factors and assigned weights which will be used in the overall review of the offeror's proposal are outlined below. The technical proposal shall consist of the responses to evaluation criteria A through F (including subcriteria). The offeror should show that the objectives stated in the proposal are understood and offer a logical program for their achievement. The following criteria will be used to evaluate proposals and will be weighted as indicated in establishing a numerical rating for all proposals submitted. Factors facilitating the evaluation of each criteria below are referenced in the corresponding criteria found in Section L of this solicitation:

OFFERORS PLEASE NOTE: Evaluation Criteria A through F, for a total of 100 points, will be evaluated by a peer review technical committee that will also recommend technical acceptability or unacceptability of the proposal. Program staff and contracting personnel will review and evaluate Criteria G for a total of 20 points and F for a total of 5 points. The total possible points for Evaluation Criteria A though G are 125 points.

**DEcIDE-2 Research Network
Technical Evaluation Criteria & Mandatory Criteria**

Evaluation Criteria Weight

- A. Understanding the Purpose and Objectives of the DEcIDE-2 Network and Comparative Effectiveness Research at AHRQ 10 points**
The proposal shall be evaluated on the completeness of the proposal and the offeror's demonstrated understanding of the problems of the contract in its response to the objectives and tasks and solution approach thereto.

1. Explanation of comparative effectiveness research, comparative effectiveness reviews (i.e., systematic reviews and technology assessments), and communication of comparative effectiveness research findings to diverse stakeholders, including appropriate uses and limitations of comparative effectiveness research for improving patient outcomes and for informing health care decisions.
2. Understanding of the mission and objectives of the DEcIDE-2 Network, including how the Network will continue to implement Section 1013 of the Medicare Modernization Act and subsequent legislation to conduct comparative effectiveness research and patient-centered outcomes studies. Additionally, the offeror's understanding of the mission and objectives of the AHRQ Effective Health Care program and its key components such as the Evidence-based Practice Centers (EPC's), the DEcIDE-1 research centers, and the Eisenberg Center.
3. Experience and understanding of the Medicare, Medicaid, SCHIP, and other public health insurance programs.

B. Technical Approach..... 30 points

Demonstrated understanding of the scope and objectives of the contract as evidenced by the soundness and practicality of the technical approach.

Executing the requirements specified in the Statement of Work, with adequate explanation, substantiation and justification for the proposed methods for meeting the projected needs, including all of the following that are applicable to the proposal (not all necessarily apply):

1. Designing and implementing clinical and epidemiologic studies, particularly for comparative effectiveness studies of different therapeutic approaches including surgery, diagnostic tests, pharmaceuticals, and medical procedures.
2. Conducting multi-center, prospective observational or interventional studies that evaluate strategies for improving the effectiveness and efficiency of the Medicare, Medicaid, SCHIP, other insurance, and public health programs, including ways in which medical therapies and diagnostic tests are provided, organized, managed, and delivered under such programs.
3. Conduct of multi-center collaborative retrospective and prospective studies to assess various factors that may affect therapeutic effectiveness and patient health outcomes, including the capacity to participate or lead one or more consortia of DEcIDE investigators to conduct research in one or more of the EHC priority conditions.
4. Developing valid methods, measures, and instruments that can be rapidly applied by researchers and other analysts to facilitate comparative effectiveness research, clinical care, or program evaluation.
5. Provision of technical assistance to federal staff and working collaboratively with academic and non-academic researchers.
6. Provision of unique contribution(s) to support a clinical research network (e.g., methodologic support, unique data set expertise, patient or clinical center recruitment expertise).

C. Management Plan..... 10 points

Demonstrated ability to achieve the delivery of performance requirements through the proposed use of appropriate management techniques and the ability to complete projects within a timely period shall be evaluated.

1. Demonstrated effective procedures for managing multiple tasks, including: ensuring availability of qualified personnel; plans for organizing, managing, and coordinating the respective roles and responsibilities of personnel; quality control processes; procedures to assure timely start-up and completion of work; plans for identifying and procuring appropriate senior subcontracting and consultant personnel with experience and expertise required for individual tasks; and plans to involve, where appropriate, qualified personnel from postgraduate training programs, to acquire

experience in conducting research by participation in work envisioned under this RFP.

2. Demonstrated appropriate and efficient use of staff and other resources to accomplish required tasks, including clarity and appropriateness of lines of communication and authority for coordination and management of the project.
3. Demonstrated ability to coordinate multiple simultaneous studies of varying complexities and availability of varied scientific resources to ensure timely completion of projects.
4. Project management plans and local resources.
5. The offeror shall demonstrate familiarity with federal task order contracts and describe mechanisms to adhere to the requirements of the master contract, particularly conformance to the scope of work for which the task order, on time submission of deliverables, quality assurance, AHRQ staff review prior to publication or presentation of deliverables, and knowledge of OMB clearance procedures.

D. Organizational Experience 20 points

1. Extent and relevance of prior experience in conducting therapeutic effectiveness or health outcomes research, including conducting epidemiology studies, analysis of secondary databases, creating disease registries, building clinical repositories, conducting decision analyses, and economic analyses, and writing and editing technical or scientific reports.
2. Extent and relevance of prior experience in conducting comparative effectiveness and health outcomes research, particularly studies of prescription drugs and other therapies.
3. Extent and relevance of prior experience in successfully completing projects of a similar nature and scale as those envisioned under this RFP, within the required time and budgetary constraints.
4. Extent and relevance of prior experience in successfully working with patients and clinical organizations, such as professional societies, pharmacies, hospitals, health plans, payers, etc., in producing products which are responsive to user needs.
5. The offeror shall provide evidence of a minimum of 5 years' experience in health care research in one or more of the following fourteen conditions: arthritis and nontraumatic joint disorders; cancer; cardiovascular disease; dementia, including Alzheimer's Disease; depression and other mental health disorders; developmental delays, attention-deficit hyperactivity disorder, and autism; diabetes mellitus; functional limitations and disability; infectious diseases including HIV/AIDS; obesity; peptic ulcer disease and dyspepsia; pregnancy including preterm birth; pulmonary disease/asthma; and substance abuse.
6. Extent and relevance of prior experience in completing clinical trial studies and/or prospective epidemiology studies.

E. Key Personnel 10 points

The background, skills, professional experience and education of key personnel shall be evaluated.

1. Demonstrated availability of scientific staff with breadth and depth of methodological, technical, and clinical expertise required to support the work of the DEcIDE-2 program as described in the RFP.
2. A Principal Investigator/Project Director with an advanced degree such as an MD, PhD or MPH with a minimum of 8 years' experience in the development, implementation, and dissemination of research findings.
3. Principal Investigator/Co-Investigators including:

- a. Documented availability, training, qualifications, expertise, relevant experience, education, and leadership/management skills of the Principal Investigator and the co-investigators to successfully plan and manage the contract;
 - b. Expertise in the design of health outcomes or epidemiologic studies involving prescription medications and other therapies;
 - c. Expertise in the implementation of research ; and
 - d. Managerial ability to achieve delivery or performance requirements, drawing upon the resources of the primary contractor, and subcontractors/consultants as necessary.
4. Other Personnel
- a. Documented availability, training, qualifications, expertise, relevant experience, education and competence of the scientific, clinical, technical and administrative staff and any other proposed personnel [including proposed subcontractors and consultants], to perform the requirements of the Statement of Work; and
 - b. Expertise in the successful development and implementation of computerized databases and data management systems.

F. Facilities and Database Characteristics 20 points

1. Proposals will be evaluated on the availability of adequate databases and data characteristics, including as applicable:
 - a. *Population size/characteristics/representativeness* such as the number of individual participants or covered lives; geographic diversity of participants; demographic distribution of participants; representation of special populations of interest to the AHRQ, including children and the elderly; turnover rate for participation in health plans, if applicable; description of coverage or inclusion policies of pharmaceutical products under health care plans providing data, if applicable; and enrollment data, if applicable.
 - b. *Data availability and completeness* such as the total number of years of data available; the amount of analytic data available online or rapidly accessible; and the lag time between date of service and online availability.
 - c. Facilities to support contribution to research network. Should the proposal be focused on a unique contribution to support the research network, does the offeror have sufficient data and capacity, research facilities, or other capacity as necessary to support an expanding rapid-turnaround research program with capacity to perform multiple independent projects.
2. Proposals will be evaluated on the availability of adequate facilities, space, and equipment (personal computers, laptop computers, word-processing, telecommunications and conferencing capabilities) for accomplishing the project goals and objectives. In addition to computer hardware, the contractor must provide necessary computer software capability.

G. Past Performance..... 20 points

(TO BE RATED ONLY AFTER A DETERMINATION OF TECHNICAL ACCEPTABILITY OF THE OFFEROR'S PROPOSAL, BASED ON THE ABOVE TECHNICAL EVALUATION CRITERIA)

The offeror's past performance will be evaluated after completion of the technical evaluation. Only those offerors determined to be technically acceptable will be evaluated. Each offeror will be evaluated on its performance under existing and prior contracts for similar products or

services. Performance information will be used for both responsibility determinations and as an evaluation factor against which offeror's relative rankings will be compared. The Government reserves the right to evaluate relevant past performance information not specifically provided by the offeror.

The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by the offeror's record of past performance.

If the offeror or the proposed employees for the offeror, do not have a past performance history relative to this acquisition, or past performance not relative to this acquisition, the offeror will not be evaluated favorably or unfavorably on this factor. A neutral rating will be determined.

In evaluating past performance the Government, will consider the offeror's effectiveness in quality of products or services; timeliness of performance; cost control; business practices; customer satisfaction, and key personnel past performance.

NOTICE: Past Performance questionnaires are to be provided to the contracting office NO LATER than the closing date and time of this solicitation. It is the offeror's responsibility to ensure that these documents are forwarded to the contracting office.

H. Small Disadvantaged Business Participation Plan..... 5 points

The evaluation will be based on information obtained from the plan provided by the offeror, the realism of the proposal, other relevant information obtained from named SDB concerns, and any information supplied by the offeror concerning problems encountered in SDB participation.

Evaluation of the SDB Participation Plan will be a subjective assessment based on a consideration of all relevant facts and circumstances. It will not be based on absolute standards of acceptable performance. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform as the prime contractor.

The assessment of the offeror's SDB Participation Plan will be used as a means of evaluating the relative capability and commitment of the offeror and the other competitors. Thus, an offeror with an exceptional record of participation with SDB concerns may receive more points and a more favorable evaluation than another whose record is acceptable, even though both may have acceptable technical proposals.

SDB participation will be scored with offerors receiving points from 0 to 5, with 5 being the most favorable.

TOTAL AVAILABLE POINTS 125

ATTACHMENT 1

PAST PERFORMANCE QUESTIONNAIRE

PART ONE: INSTRUCTIONS

The offeror listed below has submitted a proposal in response to the Agency for Healthcare Research and Quality (AHRQ) Solicitation No. AHRQ-10-10005, entitled "Accelerating Change and Transformation in Organizations and Networks II (ACTION II)." Past performance is an important part of the evaluation criteria for this acquisition, so input from previous customers of the offeror is important. This office would greatly appreciate you taking the time to complete this form. **This information is to be provided to Mary Haines, the AHRQ Contracting Officer and is NOT to be disclosed to the offeror either verbally or in writing.** Please provide an honest assessment and return to AHRQ to the address shown below, no later than **April 27, 2010**, 12:00 pm EST. If you have any questions, please contact Ms.Mary Haines at 301-427-1786.

Ms. Mary Haines
Agency for Healthcare Research and Quality
Division of Contracts Management
540 Gaither Road
Rockville, Maryland 20850

FAX: (301) 427-1740

NAME OF OFFEROR: _____

ADDRESS: _____

Identifying information of Evaluator, please print

Contractor Performance Form

1. Name of Contractor: _____
2. Address: _____

3. Contract/Grant Number: _____
4. Contract/Grant Value (Base Plus Options): _____
5. Contract/Grant Award Date: _____
6. Contract/Grant Completion Date: _____
7. Type of Contract/Grant: (Check all that apply) ()FP ()FPI ()FP-EPA
() Award Fee () CPFF-Completion () CPFF-Term () CPIF () CPAF
() IO/IQ () BOA () Requirements () Labor-Hour ()T&M () SBSA
()8(a) ()SBIR () Sealed Bid()Negotiated()Competitive ()Non-Competitive
8. Description of Requirement:

CONTRACTOR’S PERFORMANCE RATING

Ratings: Summarize contractor performance and circle in the column on the right the number which corresponds to the performance rating for each rating category. Please see reverse page for explanation of rating scale.

Quality of Product or Service	Comments	0 1 2 3 4 5
Cost Control	Comments	0 1 2 3 4 5
Timeliness of Performance	Comments	0 1 2 3 4 5
Business Relations	Comments	0 1 2 3 4 5

Customer Satisfaction - Is/was the Contractor committed to customer satisfaction? Yes No ;

Would you use this Contractor again? Yes No

Reason:

NAME OF EVALUATOR: _____

TITLE OF EVALUATOR: _____

SIGNATURE OF EVALUATOR: _____

DATE: _____

MAILING ADDRESS:

PHONE #: _____

PLEASE PRINT

Rating Guidelines: Summarize contractor performance in each of the rating areas. Assign each area a rating 0(Unsatisfactory), 1(Poor), 2(Fair), 3(Good), 4(Excellent) 5(Outstanding). Use the following instructions as guidance in making these evaluations.

	Quality	Cost Control	Timeliness of Performance	Business Relation
	<ul style="list-style-type: none"> -Compliance with contract requirements -Accuracy of reports -Technical excellence 	<ul style="list-style-type: none"> -Within budget(over/under target costs) -Current, accurate, and complete billings -Relationship of negotiated costs to actual -Cost efficiencies -Change orders issue 	<ul style="list-style-type: none"> -Met interim milestones -Reliable -Responsive to technical direction -Completed on time, including wrap-up and contract adm -No liquidated damages assessed 	<ul style="list-style-type: none"> -Effective management -Businesslike correspondence -Responsive to contract requirements -Prompt notification of problems - Reasonable/cooperative -Flexible -Pro-active -Effective small/small disadvantaged business sub-contracting program
0-unsatisfactory	Nonconformances are jeopardizing the achievement of contract requirements, despite use of Agency resources	Ability to manage cost issues is jeopardizing performance of contract requirements, despite use of Agency resources	Delays are jeopardizing the achievement of contract requirements, despite use of Agency's resources	Response to inquiries, technical/service/administrative issues is not effective
1-Poor	Overall compliance requires major Agency resources to ensure achievement of contract requirements	Ability to manage cost issues requires major Agency resources to ensure achievement of contract requirements	Delays require major Agency resources to ensure achievement of contract requirements	Response to inquiries, technical/service/administrative issues is marginally effective

2-Fair	Overall compliance requires minor Agency resources to ensure achievement of contract requirements	Ability to manage cost issues requires minor Agency resources to ensure achievement of contract requirements	Delays require minor Agency resources to ensure achievement of contract requirements	Response to inquiries, technical/service/administrative issues is somewhat effective
3-Good	Overall compliance does not impact achievement of contract requirements	Management of cost issues does not impact achievement of contract requirements	Delays do not impact achievement of contract requirements	Response to inquiries, technical/service/administrative issues is usually effective
4-Excellent	There are no quality problems	There are no cost management issues	There are no delays	Response to inquiries, technical/service/administrative issues is effective

5-Outstanding. The Contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where Contractor performance clearly exceeds the performance levels described as "Excellent."

15. Continuation Sheet(s) SF- Yes No
LLL-A attached:

<p>16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each failure.</p>	<p>Signature: _____ _____ Print Name: _____ _____ Title: _____ _____ Telephone No.: _____ Date: _____ _____</p>
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<p>Federal Use Only</p>	<p>Authorized for Local Reproduction Standard Form--LLL</p>
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**DISCLOSURE OF LOBBYING ACTIVITIES
CONTINUATION SHEET**

Approved by OMB
0348-0046

Reporting Entity: _____ Page _____
of _____

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee of prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.
2. Identify the status of the covered Federal action.
3. Identify the appropriate classification of this report. If this is a follow-up report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.
4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.
5. If the organization filing the report in item 4 checks "Subawardee," then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.
6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.
7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.
8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number, Invitation for Bid (IFB) number, grant announcement number, the contract, grant, or loan award number, the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."
9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.
(b) Enter the full names of the individual(s) performing services, and include full address if different from 10(a); Enter Last Name, First Name, and Middle Initial (MI).
11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material charge report, enter the cumulative amount of payment made or planned to be made.
12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.
13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.
14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.
15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.
16. The certifying official shall sign and date the form, print his/her name, title and telephone number.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.

PROPOSAL INTENT RESPONSE SHEET

RFP No. AHRQ-10-10006

Developing Evidence to Inform Decisions about Effectiveness Research Network-2 (DEcIDE-2)

Please review the attached request for proposal. Furnish the information requested below and return this page by April 12, 2010. Your expression of intent is not binding but will greatly assist us in planning for the proposal evaluation.

INTEND TO SUBMIT A PROPOSAL

DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

I GRANT PERMISSION TO THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, CONTRACTS OFFICE TO ADD THE CONTACT INFORMATION BELOW TO A BIDDERS LIST TO PROVIDE TO OTHER INTERESTED OFFERORS FOR SUBCONTRACTING OPPORTUNITIES. (*MUST INCLUDE AUTHORIZED SIGNATURE)

PLEASE PRINT

COMPANY/INSTITUTION NAME:

*AUTHORIZED SIGNATURE:

TYPED NAME AND TITLE:

DATE:

PLEASE DO NOT RELEASE THE CONTACT INFORMATION.

Please return to:

Mary Haines
Agency for Healthcare Research and Quality
Contracts Management
540 Gaither Road
Rockville, Maryland 20850
Fax 301-427-1740

Attachment 4

SMALL BUSINESS SUBCONTRACTING PLAN
(FOR INFORMATION PURPOSES ONLY)

DATE OF PLAN: _____

CONTRACTOR _____

ADDRESS: _____

DUNN & BRADSTREET NUMBER: _____

SOLICITATION OR CONTRACT NUMBER: _____

ITEM/SERVICE (Description): _____

TOTAL CONTRACT AMOUNT: \$ _____

\$ _____	\$ _____	\$ _____
Option #2 (if applicable)	Total contract or Base-Year, if options	Option #1 (if applicable)
	Option #3 (if applicable)	Option #4 (if applicable)

TOTAL MODIFICATION AMOUNT, IF APPLICABLE \$ _____

TOTAL TASK ORDER AMOUNT, IF APPLICABLE \$ _____

PERIOD OF CONTRACT PERFORMANCE (Month, Day & Year): _____

The following outline meets the minimum requirements of section 8(d) of the Small Business Act, as amended, and implemented by Federal Acquisition Regulations (FAR) Subpart 19.7. While this outline has been designed to be consistent with statutory and regulatory requirements, other formats of a subcontracting plan may be acceptable. It is not intended to replace any existing corporate plan that is more extensive. Failure to include the essential information of FAR Subpart 19.7 may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for performance of the contract or subcontract. **If assistance is needed to locate small business sources, contact the Office of Small and Disadvantage Business Utilization (OSDBU) at (202) 690-7300 or the OPDIV Small Business Specialist at _____.** Sources may also be obtained from SBA's PRONET website. Please note that the Department of Health and Human Services (HHS) has subcontracting goals of 30% for small business (SB), 11% for small disadvantaged business (SDB), 3% for HubZone businesses (HUBZone), 5% for women-owned business (WOSB), 3% for veteran-owned business (VOSB), and service disabled veteran-owned small business (SDVOSB) concerns for fiscal year _____. For this procurement, HHS expects all proposed subcontracting plans to contain the following goals, at a minimum, _____% for small business, _____% small disadvantaged business, _____% for HubZone businesses, _____% for woman owned businesses, and _____% for veteran-owned businesses. These percentages shall be expressed as percentages of the total estimated subcontracting dollars. **The offeror is required to include an explanation for a category that has zero as a goal.**

NOTE TO CONTRACTORS: Please provide your CCS number with your Dun & Bradstreet number.

1. Type of Plan (check one)

_____ **Individual plan** (all elements developed specifically for this contract and applicable for the full term of this contract).

_____ **Master plan** (goals developed for this contract) all other elements standardized and approved by a lead agency Federal Official; must be renewed every three years and contractor must provide copy of lead agency approval.

_____ **Commercial products/service plan** This plan is used when the contractor sells products and services customarily used for non-government purposes. Plan/goals are negotiated with the initial agency on a company-wide basis rather than for individual contracts. The plan is effective only during the year approved. The contractor must provide a copy of the initial agency approval, and must submit an annual SF 295 to HHS with a breakout of subcontracting prorated for HHS (with a OPDIV breakdown, if possible.)

2. Goals

State separate dollar and percentage goals for Small Business (SB), Small Disadvantaged Business (SDB), Woman-owned Small Business (WOSB), Historically Underutilized Business Zone (HUBZone) Small Business, Veteran-owned (VOSB), Service-Disabled Veteran-owned Small Business (SDVOSB) and "Other than small business" (Other) as subcontractors, for the base year and each option year, as specified in FAR 19.704 (break out and append option year goals, if the contract contains option years) or project annual subcontracting base and goals under commercial plans.

- a. Total estimated dollar value of ALL planned subcontracting, i.e., with ALL types of concerns under this contract is \$ _____ (b + h = a) (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option
\$ _____ \$ _____ \$ _____ \$ _____

- b. Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES (including SDB, WOSB, HUBZone, SDVOSB and VOSB): (% of "a") \$ _____ and _____% (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option
\$ _____ \$ _____ \$ _____ \$ _____

- c. Total estimated dollar value and percent of planned subcontracting with SMALL DISADVANTAGED BUSINESSES: (% of "a") \$ _____ and _____% (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option
\$ _____ \$ _____ \$ _____ \$ _____

- d. Total estimated dollar value and percent of planned subcontracting with WOMAN-OWNED SMALL BUSINESSES: (% of "a") \$ _____ and _____% (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option
\$ _____ \$ _____ \$ _____ \$ _____

- e. Total estimated dollar and percent of planned subcontracting with HUBZone SMALL BUSINESSES: (% of "a") \$ _____ and _____% (Base Year)

- i. Provide a description of the method used to develop the subcontracting goals for SB, SDB, WOSB, HUBZone, and VOSB concerns. Address efforts made to ensure that maximum practicable subcontracting opportunities have been made available for those concerns and explain the method used to identify potential sources for solicitation purposes. Explain the method and state the quantitative basis (in dollars) used to establish the percentage goals. Also, explain how the areas to be subcontracted to SB, SDB, WOSB, HUBZone, and VOSB concerns were determined, how the capabilities of these concerns were considered contract opportunities and how such data comports with the cost proposal. Identify any source lists or other resources used in the determination process. (Attach additional sheets, if necessary.)

- j. Indirect costs have ____ have not ____ been included in the dollar and percentage subcontracting goals above (check one).

- k. If indirect costs have been included, explain the method used to determine the proportionate share of such costs to be allocated as subcontracts to SB, SDB, WOSB, HUBZone, SDVOSB and VOSB concerns.

3. Program Administrator:

NAME/TITLE:
 ADDRESS:
 TELEPHONE/E-MAIL:

Duties: Does the individual named above have general overall responsibility for the company’s subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans and perform the following duties? (If NO is checked, please indicate who in the company performs those duties, or indicate why the duties are not performed in your company.)

Developing and promoting company-wide policy initiatives that demonstrate the company’s support for awarding contracts and subcontracts to SB, SDB, WOSB, HUBZone, SDVOSB and VOSB concerns; and for assuring that these concerns are included on the source lists for solicitations for products and services they are capable of providing. ____ yes ____ no

Developing and maintaining bidder source lists of SB, SDB, WOSB, HUBZone, SDVOSB and VOSB concerns from all possible sources; ____ yes ____ no

- a. Ensuring periodic rotation of potential subcontractors on bidder’s lists; ____ yes ____ no

- b. Assuring that SB, SDB, WOSB, HUBZONE, SDVOSB and VOSB businesses are included on the bidders' list for every subcontract solicitation for products and services that they are capable of providing.
_____ yes _____ no
- c. Ensuring that requests for proposals (RFPs) are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone, SDVOSB and VOSB concerns. _____ yes _____ no
- d. Reviewing subcontract solicitations to remove statements, clauses, etc., which might tend to restrict or prohibit small, HubZone small, small disadvantaged, and women-owned small business participation.
_____ yes _____ no
- e. Accessing various sources for the identification of SB, SDB, WOSB, HUBZone, SDVOSB and VOSB concerns to include the SBA's PRO-Net and SUB-Net Systems, (<http://www.sba.gov>), the National Minority Purchasing Council Vendor Information Service, the Office of Minority Business Data Center in the Department of Commerce, local small business and minority associations, contact with local chambers of commerce and Federal agencies' Small Business Offices; _____ yes _____ no
- f. Establishing and maintaining contract and subcontract award records; _____ yes _____ no
- g. Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc;
- h. Ensuring that SB, SDB, WOSB, HUBZone, and VOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company;
- i. Conducting or arranging for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended;
- j. Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals;
- k. Preparing, and submitting timely, required subcontract reports;
- l. Conducting or arranging training for purchasing personnel regarding the intent and impact of 8(d) of the Small Business Act on purchasing procedures.
- m. Coordinating the company's activities during the conduct of compliance reviews by Federal agencies; and
- n. Other duties: _____

4. Equitable Opportunity

Describe efforts the offeror will Describe efforts Describe efforts the offeror will make to ensure that SB, SDB, WOSB, HUBZone, and VOSB concerns will have an equitable opportunity to compete for subcontracts. These efforts include, but are not limited to, the following activities:

- a. Outreach efforts to obtain sources:
 - 1. Contacting minority and small business trade associations; 2) contacting business development organizations and local chambers of commerce; 3) attending SB, SDB, WOSB, HUBZone, and VOSB

procurement conferences and trade fairs; 4) requesting sources from the Small Business Administrations (SBA) PRO-Net and SUB-Net Systems, (<http://www.sba.gov/>) and other SBA and Federal agency resources. Contractors may also conduct market surveys to identify new sources, to include, accessing the NIH e-Portals in Commerce, (e-PIC), (<http://epic.od.nih.gov/>). The NIH e-Portals in Commerce is not a mandatory source and may be used at the offeror's discretion.

b. Internal efforts to guide and encourage purchasing personnel:

1. Conducting workshops, seminars, and training programs;
2. Establishing, maintaining, and utilizing SB, SDB, WOSB, HUBZone, and VOSB source lists, guides, and other data for soliciting subcontractors; and
3. Monitoring activities to evaluate compliance with the subcontracting plan.

Additional efforts:

5. Flow Down Clause

The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns," in all acquisitions exceeding the simplified acquisition threshold that offers further subcontracting opportunities. All subcontractors, except small business concerns, that receive subcontracts in excess of \$500,000 (\$1,000,000 for construction) must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." (Flow down is not applicable for commercial items/services as described in 52.212-5(e) and 52.244-6(c).)

6. Reporting and Cooperation

The contractor gives assurance of (1) cooperation in any studies or surveys that may be required; (2) submission of periodic reports which show compliance with the subcontracting plan; (3) submission of Standard Form (SF) 294, "Subcontracting Report for Individual Contracts," and attendant Optional Form 312, SDB Participation Report, if applicable, (required only for contracts containing the clause 52.219-25) and SF 295, "Summary Subcontract Report," in accordance with the instructions on the forms; and (4) ensuring that subcontractors agree to submit Standard Forms 294 and 295.

Reporting Period	Report Due	Due Date
Oct 1 - Mar 31	SF 294	4/30
Apr 1 - Sept 30	SF 294	10/30

Oct 1 - Sept 30	SF 295	10/30
Contract Completion	OF 312	30 days after completion

Special instructions for commercial plan: SF 295 Report is due on 10/30 each year for the previous fiscal year ending 9/30.

- a. Submit SF 294 to cognizant Awarding Contracting Officer.
- b. Submit Optional Form 312, (OF-312), if applicable, to cognizant Awarding Contracting Officer.
- c. Submit SF 295 to cognizant Awarding Contracting Officer and to the:

Office of Small and Disadvantaged Business Utilization
Department of Health and Human Services
200 Independence Avenue, SW
Humphrey H. Building, Room 517-D
Washington, D.C. 20201

- d. Submit “information” copy of the SF 295 and the SF 294 upon request to the SBA Commercial Market Representative (CMR); visit the SBA at <http://www.sba.gov/gc> and click on assistance directory to locate your nearest CMR.

7. Record keeping

FAR 19.704(a) (11) requires a list of the types of records your company will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. The following is a recitation of the types of records the contractor will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. These records will include, but not be limited to, the following:

- a. SB, SDB, WOSB, HUBZone, and VOSB source lists, guides and other data identifying such vendors;
- b. Organizations contacted in an attempt to locate SB, SDB, WOSB, HUBZone, and VOSB sources;
- c. On a contract-by-contract basis, records on all subcontract solicitations over \$100,000, which indicate for each solicitation (1) whether SB, SDB, WOSB, HUBZone, and/or VOSB concerns were solicited, if not, why not and the reasons solicited concerns did not receive subcontract awards.
- d. Records to support other outreach efforts, e.g., contacts with minority and small business trade associations, attendance at small and minority business procurement conferences and trade fairs;
- e. Records to support internal guidance and encouragement provided to buyers through (1) workshops, seminars, training programs, incentive awards; and (2) monitoring performance to evaluate compliance with the program and requirements; and
- f. On a contract-by-contract basis, records to support subcontract award data including the name, address, and business type and size of each subcontractor. (This item is not required on a *contract – by – contract basis* for company or division-wide commercial plans.)

g. Other records to support your compliance with the subcontracting plan: (Please describe)

8. Timely Payments to Subcontractors

FAR 19.702 requires your company to establish and use procedures to ensure the timely payment of amounts due pursuant to the terms of your subcontracts with small business concerns, HubZone small business concerns, small disadvantaged small business concerns, veteran-owned small business concerns and women-owned small business concerns.

Your company has established and uses such procedures: _____ yes _____ no

9. Description of Good Faith Effort

Maximum practicable utilization of small, HubZone small, small disadvantaged, veteran-owned, and women-owned small business concerns as subcontractors in Government contracts is a matter of national interest with both social and economic benefits. **When a contractor fails to make a good faith effort to comply with a subcontracting plan, these objectives are not achieved, and 15 U.S.C. 637(d) (4) (F) directs that liquidated damages shall be paid by the contractor.** In order to demonstrate your compliance with a good faith effort to achieve the small, HubZone, small disadvantaged, veteran-owned and women-owned small business subcontracting goals, outline the steps your company plans to take. These steps will be negotiated with the contracting officer prior to approval of the plan.

SIGNATURE PAGE

Signatures Required:

This subcontracting plan was submitted by:

Signature: _____
Typed Name: _____
Title: _____
Date: _____

This plan was reviewed by:

Signature: _____
Typed Name: _____
Title: Contracting Officer
Date: _____

This plan was reviewed by:

Signature: _____
Typed Name: _____
Title: Small Business Specialist
Date: _____

This plan was reviewed by:

Signature: _____
Typed Name: _____
Title: SBA Procurement Center Representative
Date: _____

And Is Accepted By:

OPDIV: _____
Typed Name: _____
Title: _____
Date: _____

APPENDIX 2

AHRQ PORTFOLIOS

The AHRQ portfolios are used to organize and prioritize research supported by the Agency. These portfolios have become the organizing framework for how Agency research is funded and how the products and findings of the research are disseminated. Each portfolio has a portfolio team and team lead. AHRQ's Office of Communication and Knowledge transfer (OCKT) has organized its communication and dissemination activities by assigning strategic planners to work with each portfolio team. Where appropriate, AHRQ Task Order Officers will coordinate AHRQ portfolio teams and OCKT's strategic planners to disseminate and market ACTION II research products and findings resulting from ACTION II task orders.

Description of AHRQ Portfolios

Comparative Effectiveness

The mission of the comparative effectiveness portfolio is to provide health care decision makers—including patients, clinicians, purchasers, and policymakers—with up-to-date, evidence-based information about their treatment options to make informed health care decisions.

Health Information Technology

This portfolio aims to identify challenges to health information technology (IT) adoption and use, solutions and best practices for making health IT work, and tools that will help hospitals and clinicians successfully incorporate new health IT. Research supported by the portfolio aims to develop evidence and inform policy and practice on how health IT can improve the quality of American health care. Further portfolio goals include making the best evidence and consumer health information available electronically when and where it is needed, and developing secure and private electronic health records.

Innovations/Emerging Issues

At this time, the Innovations and Emerging Issues Portfolio is being established and is expected to evolve in the coming months. The portfolio aims to identify and support research that has the potential to lead to significant advances in health care. Research and activities will reflect ideas substantially different from those already being pursued by AHRQ, and will constitute transformative research to solve pressing health care problems

Patient Safety

This portfolio aims to identify risks and hazards that lead to medical errors and find ways to prevent patient injury associated with delivery of health care. Important goals include: providing information on the scope and impact of medical errors, identifying the root causes of threats to patient safety, and examining effective ways to make system-level changes to help prevent errors. Disseminating and translating research findings and methods to reduce errors are also important. Additionally, the portfolio aims to develop an environment or culture within health care settings that encourages health professionals to share and report information about medical errors and ways to prevent them.

Prevention and Care Management

The mission of the prevention and care management portfolio is to improve the quality, safety, efficiency, and effectiveness of the delivery of evidence-based preventive services and chronic care management in ambulatory care settings. Portfolio goals include: 1) supporting clinical decision making for preventive services through the generation of new knowledge, synthesis of evidence, and dissemination and implementation of evidence-based recommendations, and 2) developing the evidence base for and implementation of activities to improve primary care and clinical outcomes through health care redesign, clinical-community linkages, self management support, integration of health information technology, and care coordination.

Value

The goal of the value portfolio is to help assure that consumers and patients are served by health care organizations that reduce unnecessary costs (waste) while maintaining or improving quality. This is done by developing measures, data, evidence, tools, and strategies that health care organizations, systems, insurers, purchasers, and policymakers use to reduce unnecessary costs while maintaining or improving quality. Strategies include process redesign, leadership and management strategies, organizational and community-wide quality improvement initiatives, legal and regulatory changes, consumer choice, public reporting, incentives, and payment changes. Also, the portfolio conducts and supports methodological work and modeling to improve data and research, and to facilitate its use for policy and management.

Appendix 3

Sample format for
Task Order proposal

Direct Labor:

<u>No.</u>	<u>Classification</u>	<u>Hours</u>	<u>Rate</u>	<u>Cost</u>
_____	Class I	100		0
_____	Class II	100		0
_____	Class III	100		0
_____	Class IV	100		0
_____				0

Total Direct Labor

Fringe Benefits: XX% x Total Direct Labor _____ 0

Total Labor & Fringe _____ 0

Overhead:

Place rate
on the line
below:

_____ _____ 0

Consultants

No. of days x Daily Rate for each Expertise Required _____ 0

Travel:

Transportation (air, ground, local)
Per Diem (No. of days x rate) _____
Total Travel _____

Other Direct Costs:

Supplies
Postage
Telephone
Materials
Computer
Subcontracts (total here by sub; attach pgs for detail at same level as prime)
Other Appropriate Costs

Total Other Direct Cost		<u>0</u>
SUBTOTAL		0
G&A Expense - (if applicable) % of subtotal		<u>0</u>
Total Cost		0
Fixed Fee (apply up to 10% for R&D; up to 7% for all other work)	<u>Rate</u>	
Rate: place rate in column under rate	0.00%	0
TOTAL ESTIMATED COST AND FEE		<u><u>0</u></u>