#### OMB 0990-0115

#### Request for Proposal Number AHRQ-2009-10001

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

Date Issued:

Date Questions Due:

Date of Webex Only Conference:

Date Notice of Intent Due:

Date Proposals Due:

August 15, 2008

August 29 2008

September 05, 2008

September 13, 2008

October 13, 2008

You are invited to submit a proposal to the Agency for Healthcare Research and Quality (AHRQ) for Request for Proposal (RFP) No. AHRQ-09-10001, entitled "Assessing the Evidence Base for Context-Sensitive Effectiveness and Safety of Patient Safety Practices: Developing Criteria". Your proposal must be developed and submitted in accordance with the requirements and instructions of this RFP.

The Government anticipates awarding one (1) contract from this solicitation with the contract estimated to have a maximum budget of \$1 Million. A Cost Plus Fixed Fee (CPFF) type of contract is contemplated for a 12 month period of performance. Please see Section L.10 Technical Proposal Instructions for further information. The North American Industry Classification System (NAICS) code that best describes the requirement is 541611. This procurement is advertised on a full and open competition basis.

#### Offerors shall submit the following:

- A. Technical Proposal (See Section L.10) (Original, 11 copies, 1 electronic copy)
- B. Past Performance Information (See Section L.11) (Original and 3 copies)
- C. Business Proposal (See Section L.12) (Original and 3 copies, 1 electronic copy)
- D. Small Disadvantaged Business Participation Plan ((See Section L.13) Original Only

Your **technical proposal** must be concisely written and should be **limited to 50 typewritten pages** (double-spaced, single sided), exclusive of cover page, table of contents, bibliography, personnel qualifications (i.e., resume, etc., see Section L.10 for additional details). Your **appendices are limited to 50 pages** (single sided) including all resumes, bibliographies, exhibits and attachments. This limitation is for administrative purposes only and exceeding the limitation shall not, of itself, be considered a basis for rejection of your proposal.

All offerors except small businesses are 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 listed as an attachment to this solicitation and is available at <a href="http://www.knownet.hhs.gov/smallbus/sb-subplan-hhs.pdf">http://www.knownet.hhs.gov/smallbus/sb-subplan-hhs.pdf</a>.

Your proposal must provide the full name of your organization, 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.

A Bidders Webex Conference will be held on **Friday**, **September 5**, **2008 from 1-2:30 PM EDT.** Instructions for participating in the conference are located in Section L.16.

If you intend to submit a proposal in response to this solicitation, please inform the Contract Specialist of your intent by completing the Proposal Intent Response Form (attached) and submit the form no later than September 13, 2008. Please fax it to 301-427-1740, Attention: Linda Simpson, Contract Specialist, or email to: Linda.Simpson@ahrq.hhs.gov.

Questions regarding this solicitation shall be received in this office **no later than August 29, 2008.** (See Section L.7). All questions shall be submitted electronically by e-mail to the Contract Specialist, at the following email address:

<u>Linda.Simpson@ahrq.hhs.gov</u>. The subject line should be marked "**Proposal Questions RFP Number AHRQ-09-10001**"

Answers to questions will be provided in the form of an Amendment to this solicitation and will be posted on AHRQ's web page: <a href="www.ahrq.gov">www.ahrq.gov</a> under "Funding Opportunities," "Contracts" and the Federal Business Opportunities web page: <a href="www.fedbizopps.gov">www.fedbizopps.gov</a>. It is your responsibility to monitor the web sites where the RFP will be posted to learn about any amendments to the solicitation. An amendment will not be posted until after the Bidders Webex Conference.

## <u>Discussions with any other individual outside the Division of Contracts</u> 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**, **EST**, **October 13**, **2008**. Your proposal must be mailed to the following address:

Agency for Healthcare Research and Quality Division of Contracts Management 540 Gaither Road, Room 4315 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. 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 <a href="http://www.ccr.gov">http://www.ccr.gov</a> or by calling 1-888-227-2423, or 269-961-5757.

Requests for any information concerning this RFP should be referred to the Contract Specialist at <u>Linda.Simpson@ahrq.hhs.gov</u>. Please note e-mail requests should state subject as **RFP Number AHRQ-09-10001**.

#### TABLE OF CONTENTS

PART I	TABLE OF CONTENTS	<u>Pages</u>
Section A	Solicitation	1-3
	Table of Contents	
Section B	Supplies or Services & Prices/Costs	5-7
Section C	Description/Specification/Work Statement	8-25
Section D	Packaging and Marking	26
Section E	Inspection and Acceptance	26
Section F	Period of Performance/Delivery Schedule	27-28
Section G	Contract Administration Data	29-32
Section H	Special Contract Requirements	33-39
PART II		
Section I	Contract Clauses	40-45
PART III		
Section J	List of Attachments	46
PART IV		
Section K	Representations and Instructions	47-53
Section L	Instructions, Conditions & Notices to Offerors	54-77
Section M	Evaluation Factors for Award	78-81

#### **Attachments**

- 1. Delivery Schedule and Requirements
- 2. Past Performance Questionnaire and Contractor Performance Form
- 3. Proposal Intent Response Sheet
- 4. Sample Subcontracting Plan

#### SECTION B-SUPPLIES OR SERVICES AND PRICES/COSTS

#### **B.1** BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The Agency for Healthcare Research and Quality (AHRQ) of the U.S. Department of Health and Human Services (DHHS), Division of Contracts Management (DCM) will award a contract to assist AHRQ in developing criteria for assessing the evidence base for the context-sensitive effectiveness and safety of patient safety practices.

See Section C for a complete description

#### **B.2. ESTIMATED COST**

Daga

- a. The estimated cost (exclusive of fees) for performance of the work under this contract, including direct and indirect costs is \$ (TO BE NEGOTIATED)
- b. The fixed fee for this contract is \$ (TO BE NEGOTIATED). The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer. Payment shall be subject to the withholding provisions of the Clause ALLOWABLE COST AND PAYMENT and FIXED FEE incorporated herein.
- c. The Government's maximum obligation, represented by the sum of the estimated cost plus the fixed fee is as follows:

(TO BE NEGOTIATED)

Dasc			
Period of Performance	Estimated Cost	Fixed Fee	Total Estimated Cost Plus Fixed Fee
TO BE DETERMINED			
TOTAL			

d. Total funds currently available for payment and allotted to this contract are \$(TO BE NEGOTIATED) of which \$ (TO BE NEGOTIATED) represents the estimated cost, and of which \$(TO BE NEGOTIATED) represents the fixed fee.

- e. It is estimated that the amount currently allotted will cover performance of the contract through (TO BE NEGOTIATED).
- f. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor. For further provisions on funding, see the LIMITATION OF COST/LIMITATION OF FUNDS and the ALLOWABLE COST AND PAYMENT (AND FIXED FEE) clauses incorporated herein.
- g. COST AND PAYMENT (AND FIXED FEE) clauses incorporated into this contract.

#### **B.3 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;
  - 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 \$1,000/day; and
- (11) Information Technology hardware or software.
- (12) Food and/or 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 – DESCRIPTION/SPECIFICATIONS/ WORK STATEMENT

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below:

#### BACKGROUND

#### AHRQ's Role in Evidence Review and Synthesesi

Under congressional authorizing legislation from Congress (The Healthcare Research and Quality Act of 1999<sup>1</sup>), AHRQ) was directed to identify "methods or systems to rate the strength of the scientific evidence underlying health care practice. recommendations in the research literature, and technology assessments." AHRQ continues to respond to this charge by taking a leadership role in building and using rigorous methods and criteria for conducting evidence reviews and syntheses.<sup>2</sup> Because of unrelenting demand, most AHRQ-supported methods-development activities have to date focused on the assessment of the evidence of the effectiveness of clinical interventions for treatment, diagnosis, and clinical preventive services. Systematic evidence reviews for clinical aspects of health care are increasingly well accepted by policymakers and healthcare providers. In clinical care they provide a rigorous method of compiling scientific evidence to answer questions regarding healthcare issues of treatment, diagnosis, and prevention. They can provide a way to set priorities for resource allocation. Systematic evidence reviews are the subject of study on their own, and guidance on conducting systematic evidence reviews, and how to use them for making recommendations, continues to be developed.

## The need for systematic reviews to identify effective and safe practices in patient safety—opportunities and challenges to date

In its landmark report To *Err is Human: Building a Safer Health System*,<sup>4</sup> the Institute of Medicine (IOM) drew attention to the need for additional work to develop and apply knowledge to make care safer for patients. The IOM report recommended that AHRQ should evaluate methods for identifying and preventing errors, and fund dissemination and communication activities to improve patient safety. IOM specifically noted the need to establish a national focus to create leadership, conduct research, and develop tools and protocols to enhance the knowledge base about safety. AHRQ has become not only the evidence-based medicine agency but also the lead agency within the federal government for patient safety.

As one of its first efforts in patient safety, AHRQ commissioned the evidence-based practice center (EPC) at UCSF–Stanford University to prepare an evidence report on patient safety practices (PSPs). The report was published in 2001<sup>5, 6;</sup> its methodology was controversial.<sup>7</sup> The EPC's search for evidence needed to include studies on safety practices employed in non-health care settings, such as aviation, nuclear power, and manufacturing, because these could be the building blocks of PSPs in health care. While recognizing that application of standard, clinically focused, evidence-based medicine methodology and review criteria would create a difficult standard for many PSP

evaluations to meet, it the EPC nevertheless used clinically-focused criteria in their review. As a consequence, practices shown to offer a clear opportunity for improving patient safety in the EPC review tended to be clinical rather than organizational. A lack of evidence also hampered promotion of certain practices, particularly those developed and used extensively outside of standard health care, as candidates for further research. In summary, relatively few of the PSPs being applied in the field were addressed in the report, and even fewer received an endorsement for good evidence of effectiveness or as highly beneficial candidates for future research.

The EPC report's focus on medical technology and clinical interventions rather than systems-related practices ignored the IOM Report's conclusion that systems approaches are the very practices that will most improve patient safety.

The concern over what constitutes evidence for patient safety was also raised at the Second National Summit on Patient Safety Research sponsored by the Quality Inter-Agency Coordination Task Force (QuIC) in November 2003. The QuIC panel on effective practices and tools was charged with addressing research needs regarding development and field testing of effective patient safety practices, taking into account the level of evidence needed to assess patient safety practices. The panel noted that for many PSPs, it is impractical or impossible to evaluate performance using randomized controlled trials (RCT), which traditionally have been used to assess interventions in clinical medicine. The panel concluded that other types of research designs should be considered in evaluating evidence of the effectiveness of patient safety practices. The panel recommended that standards be developed that define what an acceptable body of evidence is based on alternative research designs and analytic methods, and that AHRQ should support such an effort.

This debate regarding the nature and content of the evidence for patient safety continues to be voiced throughout the field. Several approaches to assessing evidence for purposes of SERs have built on the 2001 EPC report. For example, the 2003 National Quality Forum (NQF)'s first set of best practices, Safe *Practices for Better Healthcare* drew on information presented in the 2001 evidence report as well as on other sources (e.g., Leapfrog). In the 2006 edition of the NQF *Safe Practices for Better Healthcare*, the NQF committee preparing the report began to shift to a "preponderance of evidence" standard in addition to the more limited grading criteria used in the 2001 EPC report, in an effort to harmonize safety practice recommendations of the NQF, Leapfrog and The Joint Commission. Both the 2003 and 2006 NQF reports also identified areas for future research. Updating and maintenance of a set of "Safe Practices" is now a routine part of NQF's activities, and an evidence review for a 2008 update is under way.

In addition, to NQF's efforts to expand criteria for assessing evidence of the effectiveness of patient safety practices (PSPs), The Joint Commission's International Center for Patient Safety is developing processes for the identification, prioritization, development and dissemination of "Patient Safety Solutions." <sup>16</sup> The processes under development include identification of criteria for assessing individual study quality and for making recommendations based on the strength of evidence and many other factors identified by several levels of expert consensus review.

AHRQ contracted with the Research Triangle Institute (RTI)-University of North Carolina (UNC) EPC to produce an evidence report that describes systems to rate the

strength of evidence, including methods to evaluate both the quality of individual studies and overall bodies of evidence. While the evidence report and accompanying article do not specifically address the challenges of patient safety, they may provide a useful basis upon which to build efforts to develop standards of evidence for patient safety practices. The report assessed study designs other than RCTs, including discussion of their relative strengths and weaknesses. The greatest contribution of the report to patient safety may well be its evaluation of assessment schemes to rate the strength of a body of evidence. The ability to incorporate results from a variety of study designs into a determination of the overall body of evidence is particularly important for patient safety, which involves a diversity of practices that require different methodological approaches for evaluating their effects. The report did not, however, address how to assess evidence on context and processes of change, a critically important question in patient safety practice implementation research.

The definition of what constitutes an acceptable body of evidence for any practice requires a two-step review. First, judgments must be made regarding each study that has tested a particular practice, including both the appropriateness of the study design and the soundness of the study methodology. Second, for those studies that qualify for inclusion in the assessment of evidence, appropriate methods must be used to synthesize the collective results and draw conclusions regarding the effectiveness of the practice and the strength of the body of evidence.

In rating individual studies, hierarchies have been developed that rank research designs by level of quality. 10 In general, RCTs are ranked as the study design of highest quality because well-designed RCTs enable conclusions to be drawn regarding causality. RCTs are followed in the rankings by quasi-experimental studies. nonrandomized studies with control groups, studies without control groups, and expert opinion. However, even an RCT can fail to contribute to the evidence if it is poorly implemented. 18, 19 Many patient safety practices, by definition, cannot be tested by RCTs at the patient level of intervention and analysis. An excellent example is implementation of multiple changes across a clinic or an entire institution. Such systemwide changes should optimally affect all patients served in a setting, precluding randomization at the individual patient level. If multiple organizations are involved in a study, some could be randomly selected as experimental or control sites, but differences in the organizations' characteristics could remain as confounding factors because of our current limited understanding of the organizational factors related to safety and uptake of improvement strategies. Measurement of potentially important organizational factors (e.g., identified by theory and empirical literature) during implementation of a PSP could help build this knowledge base and contribute to future opportunities for randomization. More importantly, increased understanding of the context in which a PSP is implemented would help potential users to assess whether an effective and safe PSP in one setting would "work" in their settings.

Establishing more appropriate criteria for evidence reviews of patient safety practices can be expected to have three closely related effects. First, the criteria should broaden the scope of patient safety practices that can be assessed for effectiveness and safety based on scientific evidence. Second, the availability of the criteria will strengthen research studies that are assessing those practices. Third, if developed in a way that is usable to implementers of patient safety practices beyond researchers (e.g., individual clinicians, health policymakers, and patient advocates), criteria can be applied in situations where PSPs should be evaluated for individual and institutional learning without regard to publication in peer-reviewed journals. Therefore, it will be important to

publish clear guidance on the conditions under which alternative study designs and methods can or should be used, as well as on how each of those study designs and methods must be implemented to yield valid results.

#### PATIENT SAFETY PRACTICES (PSPs): DEFINITION FOR PURPOSES OF THIS RFP

For purposes of this RFP, we define patient safety practices as interventions, strategies, or approaches intended to prevent or mitigate unintended consequences of the delivery of health care and to improve the safety of health care for patients. PSPs may include clinical interventions; systems, organizational and behavioral interventions; and various combinations of these. The effectiveness of PSPs may be affected by the nature, number, and sequencing of components; where they are implemented; with whom, for what purposes; as well as by features of the external environment as noted above. The appendix to this attachment provides selected examples of current PSPs. For purposes of developing criteria for evidence review, it is important to note that the labels given to these PSPs often do not convey the full range of the PSP intervention or construct.

## SETTING THE STAGE FOR DEVELOPING CRITERIA: CALLS FOR EVIDENCE-BASED IMPLEMENTATION, EVIDENCE-BASED MANAGEMENT, AND A SYSTEMS APPROACH TO IMPROVEMENT IN HEALTH CARE

Since at least 1999, there have been calls for developing guidance relevant to "evidence-based implementation" of evidence-based medicine. <sup>20</sup> More recently, calls have been made for "evidence-based management" of health care systems for improved quality and safety. 14 15 16 17 These calls recognize that rules for gathering and synthesizing evidence can be developed and applied to the "how" as well as the "what" of health care delivery. Developing methods for non-clinical evidence reviews and syntheses is particularly relevant to assessing the evidence base for efforts to improve patient safety in health care. However, development of such methods faces several challenges. As noted above, few patient safety problems can be ameliorated by a clinical or even technical intervention alone.<sup>7 21 6, 22</sup> PSPs are likely to be organizational or behavioral in nature or, if clinical or technical, to be embedded within organizational, behavioral or policy approaches to patient safety improvement.<sup>23</sup> Detailed processes of implementation as well as organizational and policy contexts in which particular patient safety practices are implemented may be critically important to understanding the practices' success or failure. We clearly need to apply a broader range of research and evaluation designs and methods to assessment of the context-sensitive effectiveness and safety of PSPs. As Berwick recently noted:

"...[T]here is, or ought to be, a strong relationship between what is studied, and how it is studied. To study a linear, mechanical or natural, tightly coupled causal relationship most efficiently (for example, determining benefits of [beta] blockers for heart failure), a...design (such as an RCT) may be exactly correct. But with social changes – multicomponent interventions, some of which are interpersonal, ...in complex social systems – then other, richer but equally disciplined, ways to learn...are needed."9

## THE NEED FOR USER-FRIENDLY APPROACHES TO REVIEWING AND UNDERSTANDING EVALUATION AND RESEARCH

Activities in response to this RFP should also focus on making approaches to evaluation and review understandable and accessible to this wide range of stakeholders. The health care system has many stakeholders and few are pure researchers or experts in evaluation and evidence reviews and syntheses. In its clinical evidence syntheses, AHRQ continues to work to make the approaches and results user-friendly to all stakeholders in the health care system: patients, patient advocates, clinical providers, health plan administrators and decisionmakers, and policymakers at multiple levels. <sup>22</sup>

## THE CHALLENGE OF DEVELOPING EVIDENCE CRITERIA FOR REVIEWS OF PSPs' EFFECTIVENESS AND SAFETY

Most expert observers agree that evidence reviews and syntheses must address issues of construct validity, internal validity, and to some extent external validity both in the studies reviewed and for the synthesis itself. That is, it is important to be able to make generalizable causal inferences about well-defined and theoretically grounded interventions. These concepts are important to studies and reviews of PSPs, but the issues faced in each topic differ substantially between PSPs and clinical interventions.

Construct validity. According to Shadish and colleagues, "the naming of things is a key problem in all science, for names reflect category memberships that themselves have implications about relationships to other concepts, theories and uses.". Addressing the construct validity challenge in patient safety practices is the most fundamental component of developing evidence and criteria for its assessment. How should the "it" (PSP) that is being implemented be characterized? Is it, for example, only a CPOE, hospital discharge form, checklist or antibiotic-coated device? Or is the actual PSP a subset or combination of multiple different policy, structural, organizational, behavioral and process components? Although some of the PSPs listed in the Appendix may sound relatively straightforward, PSPs as they are implemented typically include many component parts and complex interactions among these parts<sup>25</sup> and thus are often difficult to characterize, in comparison to the "constructs" used in clinical research (e.g., drugs). Efforts to develop a common taxonomy of PSPs are still emerging, So PSPs may be defined differently in different studies and implementation efforts.

*Internal validity.* The question of internal validity is whether "the experimental [interventions] make a difference in this specific experimental instance" (Campbell and Stanley, 1963, cited by Shadish et al.<sup>24</sup>). In medicine and behavioral research focused on interventions with patients and analyses of patient (or other individual participant) results data, the randomized controlled trial became a shorthand, well-accepted means to infer high interval validity. When well done in certain well-defined circumstances, RCTs at the individual person (usually patient) level of intervention and analysis deal convincingly with the many potential threats to internal validity. The limitations of the standard RCT (at the patient level of analysis) for complex interventions at levels beyond the patient (e.g., policy, organizational, practice, community), at least in the U.S., and alternatives to these designs, are beginning to be well-characterized.<sup>7 9, 27</sup> However, other potentially applicable designs (e.g., cluster randomized trial, interrupted time series designs) can be difficult to do well...<sup>5, 28-34</sup>

Consideration of how a broader range of designs can ameliorate common threats to internal validity in evaluations of PSPs and be made acceptable for evidence reviews

and syntheses is a critical component of the tasks described in this RFP. <sup>35 36</sup> For example, a National Quality Forum (NQF) consensus standards-setting process had to rely in part on "experiential data" (e.g., widespread opinion, professional consensus) as evidence for the effectiveness of a set of PSPs that built on the AHRQ evidence review.<sup>37</sup> Currently, The Joint Commission's initial approach to endorsing "patient safety solutions" relies on a combination of using prospective, randomized, controlled trials as the highest level of evidence study quality and a number of other less well-defined factors (e.g., also strongly supported by expert opinion and "strong emerging evidence") to consider a "Grade A" recommendation.<sup>16</sup>

**External validity.** External validity is traditionally defined as "the validity of inferences about whether the cause-effect relationship holds over variation in persons, settings, [intervention] variables, and measurement variables."<sup>24</sup> Considerations of external validity are highly relevant to making inferences about how and why a particular PSP may have been successful (or not) in a particular circumstance, inferences that are crucial for future implementers of PSPs. In addition to the nature of the PSP itself and related implementation processes (whether included in the initial PSP construct or not), the local **context** may influence PSP outcomes. Context also may affect the potential for effective scaling of a promising PSP and dissemination or "spread" to other settings with other populations of patients and providers in different policy environments. Context refers to features of the setting for the PSP, such as market conditions, policy and legal requirements, ownership, size, structure, resources, patient characteristics, patterns of work flow, standard operating procedures, and culture.

Guidance on how to address questions of context in PSP and QI evaluations is beginning to emerge.<sup>38</sup>. However, external validity at the organizational or policy level is rarely addressed systematically in descriptions of PSPs, with the exception of studies based on retrospective secondary data. In addition to the general lack of perceived need in health care research about the applicability of interventions to additional patient populations, reasons may include the lack of validated measures of organizational context, leadership, teamwork, policy environments, and other factors. When validated measures exist, they may rely primarily on time-consuming survey methods for data collection. Thus, development of criteria for assessing context-relevant effectiveness and safety must include attention to the validity of measures of context.

**Putting it all together:** Importance of theory in development and evaluation of PSPs in context. The use of theory (or conceptual frameworks or logic models<sup>v</sup>) in assessing the evidence for context-sensitive effectiveness and safety of PSPs (and other quality improvement interventions) is essential. According to the Improved Clinical Effectiveness through Behavioral Research Group (ICEBeRG)<sup>39</sup>:

"The explicit use of theory ... has a number of advantages, such as providing: a generalisable framework within which to represent the dimensions that implementation studies address, a process by which to inform the development and delivery of interventions, a guide when evaluating, and a way to allow for an exploration of potential causal mechanisms. ... The explicit use of theory offers potential advantages in terms of facilitating a better understanding of the generalisability and replicability of implementation interventions."

In the evaluation world, "theory-based evaluation" is a relatively new approach, still subject to debate: According to Shadish and colleagues, "While advocates may have some differences with each other, basically they all contend that it is useful:

- "1) to explicate the theory of a[n intervention] by detailing the expected relationship among inputs, mediating processes, and short- and long-term outcomes.
- "2) to measure all the constructs specified in the theory; and
- "3) to analyze the data to assess the extent to which the postulated relationships actually occurred." <sup>24</sup>

Specification of conceptual frameworks, logic models, or theories, and criteria for assessing theoretical validity, are requirements of this RFP.

Conclusion: The interactions among PCP components and among the PCP and its context and implementation processes give rise to a set of evaluation questions that are illustrated in Box 1. Previous examinations of evidence for PSPs (and QIs) have struggled with these questions and the interactions among them, but we do not yet have a consensus set of criteria for: characterizing PSPs, measuring and understanding the contexts in which they are implemented, assessing the effects of implementation processes on uptake and outcomes, identifying the kinds of indicators best suited to assessing results (including potential harms), or providing guidance on appropriate evaluation research designs and analytic strategies. As has happened with the development of criteria for assessing evidence for the effectiveness of clinical evidence, development of criteria for assessing evidence of the effectiveness and safety of PSPs should strengthen: individual studies (to build the knowledge base); evidence reviews and syntheses (to share the knowledge base); the ability of potential implementers and designers of PSPs to develop theoretically sound approaches to improvement and to know whether those PSPs have been effectiveness and safe in their own settings; and the ability of policymakers to recommend PSPs that will be effective and safe in a broader range of settings.

Unlike the development of criteria and standards for other evidence reviews and syntheses, the development of criteria and standards must go beyond addressing criteria for internal validity but address criteria for construct and external validity and the potential tradeoffs among various types of validity.

#### STATEMENT OF WORK

In order to assist AHRQ to develop criteria for assessing the evidence base for the context-sensitive effectiveness and safety of patient safety practices (PSPs), the contractor shall work closely with the AHRQ project officer (PO) to:

1. Form an interdisciplinary panel of experts in patient safety practice, frontline healthcare delivery, clinical and health services research, behavioral and social sciences, research and evaluation design and methodology, systems engineering, management science, and other disciplines as necessary. The interdisciplinary panel of experts shall assist with all phases of the development of criteria, as described in the following sections. The composition of the interdisciplinary panel of experts shall be developed in consultation with the PO and shall be approved by the PO before appointments are made. Signed letters of agreement from potential experts who may

be included in the interdisciplinary panel must accompany the offeror's proposal. The interdisciplinary panel of experts shall be no larger than 15-20 individuals.

# 2. Identify a diverse and representative set of PSPs to be used as initial subjects for helping to iteratively develop criteria for rigorous and systematic assessment of the context-sensitive effectiveness and safety of PSPs. Candidate PSPs should be:

- in actual use,
- appear to be the most promising in terms of underlying logic models (theories) for achieving effectiveness, safety and generalizability.
   Aspects of the logical models must include:
  - a) Components of the intervention (see Background and History, Attachment A, and figure 1 with this SOW for examples);
    - b) Relationships among these components, 40 and
  - c) Ways that these linkages among the components are expected to produce the expected results for the PSP..
- address high-impact patient and diverse safety problems, and
- represent the contexts in which patient safety is an important concern (e.g., include settings with varying levels of resources, provider types, patient populations).

Note that even "promising" PSPs in widespread use may not have been evaluated optimally. The contractor shall not limit the development of criteria for evaluating the strength of evidence for PSPs to approaches used in available approaches to implementation and evaluation.

If possible, identify an overall conceptual framework for considering the different types of PSPs in a variety of contexts and for a variety of purposes (uptake, outcomes).

## 3. Identify research and evaluation models, methods, and designs that could be used to rigorously evaluate the PSPs identified as part of the task

Rigor means that potential future implementers of identified PSPs will be able to have a high level of confidence in the results as stated, including level of confidence in how well the PSP would work in their context.

Consideration should be given to whether the necessary level of confidence in results should be the same as that for clinical treatment studies. High priority threats to internal, external, and construct validity, if and how different methods and designs can overcome them (or be adapted to overcome them), must be addressed.

Candidate research and evaluation models, methods, and designs should come from clinical science, health services research, public health, the behavioral and social sciences, management science, and other fields as appropriate. 17, 24, 27, 33, 38, 41-57 Include designs that can assess the effectiveness of implementation in single sites (e.g., States, hospitals, health plans), as well as in multiple sites for which use of one or more comparison groups is possible. Contractor shall address the extent to which common

evaluation types (e.g., post-only studies with no comparison group; retrospective studies) can contribute to the evidence base, and address the extent to which large learning collaboratives for patient safety can be evaluated with rigor. Focus on intervention studies, but also address how non-intervention research may provide useful information.

In considering research designs and methods, identify or develop approaches that measure contexts and implementation processes in PSP interventions and suggest how collection of contextual and process data needed for assessing the generalizability of the PSP can be combined with designs that are strong on internal and construct validity.<sup>2, 58, 59</sup>

Pay close attention to assessing both the positive and negative impacts of PSPs,.. While few studies of PSPs have addressed potential or actual harms associated with implementation (e.g., different types of errors resulting from an intended sociotechnical "improvement"), studies that have focused on harms<sup>60</sup> and anecdotes of implementation experience have raised concerns. There is little guidance for how to systematically include consideration of harms in intervention evaluation and research and systematic reviews of such evaluations outside the clinical context.<sup>61</sup>

Pay close attention to identifying appropriate measures of aspects of the PSP, including the PSP itself, the context, unplanned implementation processes, and the results. For example, when assessing CPOEs, should outcome measures include reduction in prescribing errors, administration errors, timing discrepancies, all of these, or other. 62

- **4. Develop a set of criteria, including criteria for strength of evidence, to be used for assessing future studies and reports.** Criteria are necessary to guide both a) future assessments of evidence and safety relative to the effectiveness, implementation, and adoption of the identified types of PSPs, and b) systematic reviews of patient safety evidence. Criteria are needed to increase users' level of confidence in reviews of the context-sensitive effectiveness of PSPs and in individual studies. While no such criteria have been developed for reporting and synthesizing research evaluating PSPs specifically, numerous models for creating criteria and procedures for reporting and reviewing exist in related fields. <sup>17, 63-68</sup>
- **5. Identify specific needs for** future development of theories, constructs, and research/evaluation designs and methods to further strengthen evaluations of PSPs and criteria for systematic review.
- **6. Provide a final summary report** of the methods employed to develop the criteria, and recommendations for next steps.
- 7. The Contractor shall produce the required items to the Project Officer in accordance with the delivery schedule (See Attachment 1). Delivery times represent calendar time unless otherwise specified (See Section F).

#### Additional considerations:

**User-friendliness/plain language**. Throughout activities 1-6, explicit consideration must be given to how the approaches and results of the effort will be made understandable and user-friendly for a broad range of healthcare stakeholders, including patients, providers, health plan administrators, and policymakers. All reports to AHRQ must be clear and understandable to this broad range of stakeholders.

**Partnerships/team approach.** For the purposes of this contract offerors are strongly encouraged to partner with other organizations that have special expertise in assessing evidence based practices in health care such as the AHRQ Evidence Based Practice Centers, ACTION contractors with experience in implementing PSPs, as well as relevant organizations outside of healthcare.

**Authorities**. The PO will review all plans with an internal AHRQ advisory group and recommend changes to the contractor. The PO cannot make recommendations that would cause the project to change its scope or timeline without approval from the AHRQ CO.

#### **APPENDIX**

#### **SELECTED EXAMPLES OF PSPs**

#### **Selected Examples of Current PSPs.**

A broad range of PSPs have been recommended to address the broad range of patient safety problems in the United States and worldwide. Some PSPs are supported by evidence, some are now being subjected to evaluation, and others are not being evaluated in any systematic way.

For example, the broad range of PSPs currently under study with AHRQ funding include, but are not limited to activities labeled as follows: a national implementation program for team training call TeamSTEPPS<sup>69</sup>; regional health information exchanges in Colorado, Delaware, Indiana, and Tennessee; a statewide effort to eliminate hospital associated infections in ICU in Michigan; a multi-organization effort to create real-time electronic prescribing for elderly people in long-term care settings in Oregon; a work system intervention that employs bar coding technology for medication dispensing and administration in a pediatric hospital; error reduction programs based on results of root cause analyses of anatomic diagnostic errors; creation and testing of a tailored digital video disc (DVD) to improve medication management for low literate elderly patients; simulation training for cardiac catheterization<sup>23;</sup> a model for disclosure<sup>70</sup>; and a Patient Safety Improvement Corps.<sup>71</sup>

Examples of patient safety interventions recently reported in the medical and popular literature include use of smart infusion pumps in critically ill patients<sup>72</sup>; screening for infections at hospital intake followed by isolation of affected patients<sup>73</sup>; patient safety education and training programs<sup>74</sup>; and encouraging the addition of patient safety into medical and nursing school curricula.<sup>28</sup>

Other "solutions" and "safe practices" have been proposed for implementation, including: fall reduction programs; machine-readable patient identification systems to replace conventional wristbands; hand held electronic prescribing devices; strategies to inform patients of clinically significant abnormal or questionable lab results (e.g., computerized reminders in the primary care setting); use of computerized prescription order entry; training programs to reduce fatigue-related preventable adverse events; development of institutional incentives to implement recommended safe practices; development of strategies to involve consumers in implementation of safety practices; and implementation of antibiotic-impregnated catheters versus non-coated catheters, peri-operative oxygen supplementation to reduce infection rates. 34 75-79 37

## BOX: KEY QUESTIONS IN EVALUATING CONTEXT SENSITIVE EFFECTIVENESS OF PATIENT SAFETY PRACTICES

#### **EFFECTIVENESS**

- What is the logic model underlying the practice?
- What is the evidence for assumed links in the logic model?
- What assumptions are made about context?
- What is the evidence for an association between practice, context, and outcomes?

#### **IMPLEMENTATION**

- How do implementation processes affect the uptake and outcomes of a practice?
- What unintended consequences emerge during implementation of the practice?

#### ADOPTION AND SPREAD

- How readily can the practice be applied in contexts other than the ones in which it was developed?
- How easy is the practice for clinicians and other users (usability)? How useful is it for them?
- How readily can the practice be incorporated into current routines?

#### References

- 1. U.S. Congress. Healthcare Research and Quality Act <a href="http://www.ahrq.gov/hrqa99a.htm">http://www.ahrq.gov/hrqa99a.htm</a>. Accessed Mar. 25, 2008.
- 2. Agency for Healthcare Research and Quality. Evidence-based Practice. <a href="http://www.ahrq.gov/clinic/epcix.htm">http://www.ahrq.gov/clinic/epcix.htm</a>. Accessed May 29, 2008.
- **3.** Agency for Healthcare Research and Quality. Effective Health Care. http://effectivehealthcare.ahrq.gov/. Accessed Nov. 5, 2007.
- **4.** Institute of Medicine. *To Err is Human: Building a Safer Health System.* Washington, DC: National Academy Press; 1999.
- Agency for Healthcare Research and Quality. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. *Evidence based practice* [July 2001; http://www.ahrq.gov/clinic/tp/ptsaftp.htm. Accessed Mar. 25, 2008.
- 6. Shojania K, Duncan B, McDonald K, Wachter R, Markowitz A. Making health care safer: a critical analysis of patient safety practices. *Evid Rep Technol Assess*. 2001;43(i-x):1-668.
- 7. Leape L, Berwick D, Bates D. What practices will most improve safety? Evidence-based medicine meets patient safety. *JAMA*. Jul. 24/31 2002;288(4):501-507.
- **8.** Quality Inter-agency Coordination Task Force (QUIC). Paper presented at Second National Summit on Patient Safety <a href="http://www.quic.gov/summit/index.htm">http://www.quic.gov/summit/index.htm</a>. Accessed Aug. 4, 2008.
- **9.** Berwick D. The science of improvement. *JAMA*. Mar. 12 2008;299(10):1182-1184.
- **10.** Auerbach A, Landefeld C, Shojania K. The tension between needing to improve care and knowing how to do it. *NEJM*. Aug. 9 2007;357(6):608-613.
- **11.** Pronovost P, Wachter R. Proposed standards for quality improvement research and publication: one step forward and two steps back. *Quality and Safety in Health Care*. 2006;15:152-1153.
- **12.** National Quality Forum. *Safe Practices for Better Healthcare: A Consensus Report-Executive Summary*. Washington, DC 2003.
- **13.** National Quality Forum. National Quality Forum Updates Endorsement of Safe Practices for Better Healthcare. Washington, DC author; 2006:2.
- **14.** National Quality Forum. Safe Practices for Better Healthcare. Washington, DC: Author; 2005:1.
- **15.** National Quality Forum. Safe Practices For Better Healthcare: 2008 Update *Safe practices for better healthcare* [2008. Available at: <a href="www.qualityforum.org">www.qualityforum.org</a>. Accessed May 29, 2008.
- **16.** The Joint Commission. Patient Safety Solutions--Development Process. *Patient Safety Solutions* [undated; 4 pager identifying "initial processes for the identification, prioritization, development and dissemination of Solutions". Available at: <a href="https://www.jcipatientsafety.org">www.jcipatientsafety.org</a>. Accessed May 22, 2008.
- 17. Lohr K. Emerging methods in comparative effectiveness and safety: Symposium overview and summary. *Medical Care*. Oct. 2007;45(10 Suppl 2):S5-S8.
- **18.** Localio A, Berlin J, Ten Have T, Kimmel S. Adjustments for center in multicenter studies: an overview. *Ann Int Med.* Jul. 17 2001;135(2):112-123.

- **19.** Grossman J. The randomized controlled trial: gold standard, or merely standard? *Perspectives in biology and medicine.* Autumn 2005;48(4):516-534.
- **20.** Grol RP, Bosch M, Hulscher M, Eccles M, Wensing M. Planning and studying improvement in patient care: The use of theoretical perspectives. *Milbank Q*. 2007;85(1):93-138.
- **21.** Shortell S, Singer S. Improving patient safety by taking systems seriously. *JAMA*. Jan. 30 2008;299(4):445-447.
- **22.** Shojania K, Duncan B, McDonald K, Wachter R. Safe but sound: Patient safety meets evidence-based medicine. *JAMA*. Jul 24/31 2002;288(4):508-513.
- **23.** Harrison M, Koppel R, Bar-Lev S. Unintended consequences of information technologies in health are--An interactive sociotechnical analysis. *JAMIA*. 2007;14:542-549.
- **24.** Shadish W, Cook T, Campbell D. *Experimental and quasi-experimental designs for generalized causal inference*. Boston: Houghton-Mifflin Co.; 2002.
- **25.** Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *NEJM*. Dec. 28 2006;355(26):2725-2732.
- World Health Organization. More than words: International Classification for Patient Safety (ICPS). <a href="http://www.who.int/patientsafety/taxonomy/en/">http://www.who.int/patientsafety/taxonomy/en/</a>. Accessed May 29, 2008.
- **27.** Mercer S, DeVinney B, Fine L, Green L, Dougherty D. Study designs for effectiveness and translation research: Identifying the tradeoffs. *Amer J Prev Med.* August 2007;33.
- 28. Ranji S, Steinman M, Shojania K, et al. *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies -- Volume 4: Antibiotic Prescribing Behavior*. Rockville, MD: AHRQ; January 2006. AHRQ Pub. No. 04(06)-0051-4.
- 29. Shojania K, McDonald K, Wachter R, Owens D. *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies--Volume 1--Series Overview and Methodology*. Rockville, MD: USDHHS Agency for Healthcare Research and Quality; August 2004. AHRQ Publication No 04-0051-1.
- **30.** Walsh J, McDonald K, Shojania K, et al. *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies--Volume 3: Hypertension Care.* Rockville, MD: AHRQ; January 2005. AHRQ Pub. No. 04-0051-3.
- **31.** Agency for Healthcare Research and Quality. *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies--Volume 5: Asthma Care.* Rockville, MD: AHRQ; January 2007. AHRQ Pub. No. 04(07)-0051-5.
- **32.** Agency for Healthcare Research and Quality. *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies--Volume 6: Prevention of healthcare-associated infections.* Rockville, MD: Agency for Healthcare Research and Quality; January 2007. AHRQ Pub. No. 04(07)-0051-6.
- 33. Shojania K, McDonald K, Wachter R, Owens D. *Closing the Quality Gap: Volume 1--Series Overview and Methodology* Rockville, MD: AHRQ; July 2004. AHRQ Publication No. 04-0051-1.
- 34. Shojania K, Ranji S, Shaw L, Charo L, et al. *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies -- Volume 2: Diabetes Mellitus Care*. Rockville, MD: AHRQ; September 2004. AHRQ Pub. No. 04-0051-2.
- **35.** Dougherty D, Conway P. The "3Ts" Roadmap to Transform U.S. Health Care: The How of High Quality Care. *JAMA*. 2008.

- **36.** Eslami S, Keizer N, Abu-Hanna A. The impact of computerized physician medication order entry in hospitalized patients-A systematic review. *International Journal of Medical Informatics*. Nov. 17 2007;epub ahead of print
- **37.** National Quality Forum. *Chapter 1--Background, Summary, and Set of Safe Practices.* Washington, DC: Author; Nov. 14 2006.
- **38.** Davidoff F, Batalden P. Toward stronger evidence on quality improvement: Draft publication guidelines. *Quality and Safety in Health Care*. October 2005;14:319-325.
- **39.** Improved Clinical Effectiveness through Behavioural Research Group (ICEBeRG). Designing theoretically-informed implementation interventions. *Implementation Science*. Feb. 23 2006;1(4):1-8.
- **40.** VanDeusen Lukas C, Holmes S, Cohen A, et al. Transformational change in health care systems: An organizational model. *Health Care Manage Rev.* Oct-Dec 2007;32(4):309-320.
- **41.** Zuckerman I, Lee E, Wutoh A, Xue Z, Stuart B. Application of regression-discontinuity analysis in pharmaceutical health services research. *Health Serv Res.* Apr 2006;41(2):550-563.
- **42.** Yasui Y, Feng Z, Diehr P, McLerran D, Beresford S, McCulloch C. Evaluation of community-intervention trials via generalized linear mixed models. *Biometrics*. Dec 2004;60(4):1043-1052.
- **43.** Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review a new method of systematic review designed for complex policy interventions. *J Health Serv Res Policy*. July 2005;10(Suppl 1):S1:21-S21-34.
- **44.** Murray D, Varnell S, Blitstein J. Design and analysis of group-randomized trials: a review of recent methodological developments. *Am J Public Health*. Mar 2004;94(3):423-432.
- **45.** Biglan A, Ary D, Wagenaar A. The value of interrupted time-series experiments for community intervention research. *Prev Sci.* 2000;1:31-49.
- **46.** Braslow J, Daun N, Weisz J, Starks S. Randomized encouragement trial: A pragmatic paradigm for clinical research. Abstract. Available at: <a href="http://www.hsrd.research.va.gov/about/national\_meeting/2004/abstracts/1018.htm">http://www.hsrd.research.va.gov/about/national\_meeting/2004/abstracts/1018.htm</a>. Accessed Aug. 1, 2006.
- 47. Bravata D, McDonald K, Shojania K, Sundaram V, Owens D. Challenges in systematic reviews: Synthesis of topics related to the delivery, organization, and financing of health care. *Annals of Internal Medicine*. June 21 2005;142(12 (Part 2)):1056-1065.
- **48.** Cable G. Enhancing causal interpretations of quality improvement interventions. *Qual Health Care*. Sep 2001;10(3):179-186.
- **49.** Shojania K, Grimshaw J. Evidence-based quality improvement: The state of the science. *Health Affairs*. Jan-Feb 2005;24(1):138-150.
- **50.** Greenhalgh T, Russell J, Swinglehurst. Narrative methods in quality improvement research. *Quality and Safety in Health Care Online*. 2005;14:443-449.
- **51.** Greenhalgh T, Robert G, MacFarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: Systematic review and recommendations. *Milbank Quarterly*. 2004;82(4):581-629.
- **52.** Green LW. Translation 2 research: The roadmap less traveled. *Am J Prev Med.* August 2007;33(in press).

- **53.** Hawkins N, Sanson-Fisher R, Shakesshaft A, D'Este C, Green L. The multiple baseline design for evaluating population-based research. *American Journal of Preventive Medicine*. Aug 2007;33(2):162-168.
- 54. Des Jarlais D, Lyles C, Crepaz N, and the TREND Group. Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND Statement. *American Journal of Public Health*. March 2004;94(3):361-366.
- de Keizer N, Ammenwerth E. The quality of evidence in health informatics: How did the quality of healthcare IT evaluation publications develop from 1982 to 2005? *Int J Med Inform.* epub ahead of print in medline. get info if used. 2007.
- **56.** Chin M, Walters A, Cook S, Huang E. Interventions to reduce racial and ethnic disparities in health care. *Medical Care Research and Review*. Oct. 2007;64(5 Suppl):7S-28S.
- 57. Gartlehner G, Hansen R, Nissman D, Lohr K, Carey T. A simple and valid tool distinguished efficacy from effectiveness studies. *J Clinical Epidemiology*. 2006;59:1040-1048.
- **58.** Agency for Healthcare Research and Quality. Outcomes and Effectiveness. http://www.ahrq.gov/clinic/outcomix.htm. Accessed nOV. 5, 2007.
- **59.** Atkins D, Briss P, Eccles M, et al. Systems for grading the quality of evidence and the strength of recommendations II: Pilot study of a new system. *BMC Health Services Research*. Mar 23 2005;5(25):1-35.
- **60.** Koppel R, Metlay J, Cohen A, et al. Role of computerized physician order entry systems in facilitating medical errors. *JAMA*. Mar. 9 2005;293(10):1197-1203.
- 61. Agency for Healthcare Research and Quality. Methods Reference Guide for Effectiveness and Comparative Effectiveness Reviews. Version 1.0:http://effectivehealthcare.ahrq.gov/. Accessed May 13, 2008.
- **62.** FitzHenry F, Peterson J, Arrieta M, Waitman L, Schildcrout J, Miller R. Medication administration discrepancies persist despite electronic ordering. *JAMIA*. Nov-Dec. 2007;14(6):756-764.
- West S, King V, Carey T, et al. Systems to rate the strength of scientific evidence. *Evidence Report/Technology Assessment* [Publication No. 02-E016:Report to AHRQ prepared under contract 290-297-0011. Available at: <a href="http://www.ahrq.gov/clinic/tp/strengthtp.htm">http://www.ahrq.gov/clinic/tp/strengthtp.htm</a>. Accessed Mar. 18, 2008.
- **64.** Equator Network. Equator Network: Enhancing the quality and transparency of health research. *Equator Network* [The EQUATOR Network is a new initiative that seeks to improve the quality of scientific publications by promoting transparent and accurate reporting of health research.
- . Available at: <a href="http://www.equator-network.org/?o=1001">http://www.equator-network.org/?o=1001</a>. Accessed Mar. 14, 2008.
- 65. The Campbell Collaboration Methods Group. Guidelines for authors and reviewers. <a href="http://www.campbellcollaboration.org/MG/guidelines.asp">http://www.campbellcollaboration.org/MG/guidelines.asp</a>. Accessed Mar. 18, 2008.
- Agency for Healthcare Research and Quality. Medical Care Supplement: The Comparative Effectiveness and Safety Emerging Methods Symposium. *Effective Health Care research reports*[http://effectivehealthcare.ahrq.gov/healthInfo.cfm?infotype=nr&ProcessID=32&DocID=74. Accessed Mar. 18, 2008.
- **67.** Pawson R. Evidence-based policy: In search of a method. *Evaluation*. 2002;8(2):157-181.

- **68.** Mistiaen P, Francke A, Poot E. Interventions aimed at reducing problems in adult patients discharged from hospital to home: a systematic meta-review. *BMC Health Services Research*. Apr 2007;2007(7):47-.
- 69. Clancy C, Tornberg D. TeamSTEPPS: Integrating teamwork principles into healthcare practice. http://www.psqh.com/novdec06/ahrq.html. Accessed Nov. 15, 2007.
- **70.** Agency for Healthcare Research and Quality. Grants On Line Database. www.gold.ahrq.gov. Accessed Mar. 28, 2008.
- **71.** Agency for Healthcare Research and Quality. Patient Safety Improvement Corps: An AHRQ/VA Partnership. <a href="http://www.ahrq.gov/about/psimpcorps.htm">http://www.ahrq.gov/about/psimpcorps.htm</a>. Accessed May 28, 2008.
- **72.** Rothschild J, Keohane C, Cook E, et al. A controlled trial of smart infusion pumps to improve medication safety in critically ill patients. *Critical Care Medicine*. Mar 2005;33(3):533-540.
- **73.** Robicsek A, Beaumont J, Paule S, et al. Universal surveillance for methicillin-resistant staphylococcus aureus in 3 affiliated hospitals. *Annals of Internal Medicine*. Mar. 18 2008;148(6):409-418.
- 74. Tennessee Department of Health. Tennessee Improving Patient Safety. <a href="http://health.state.tn.us/IPS/index.htm">http://health.state.tn.us/IPS/index.htm</a>. Accessed Mar. 28, 2008.
- 75. The Joint Commission. 2008 National Patient Safety Goals National Patient Safety Goals [2008; <a href="http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/">http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/</a>. Accessed Mar. 28, 2008.
- 76. The Joint Commission International and World Health Organization Collaborating Centre for Patient Safety Solutions. Patient safety solutions. *Patient safety solutions* [2007; http://www.jcipatientsafety.org/24725/. Accessed Mar. 31, 2008.
- 77. The Joint Commission. Patient Safety Practices. 2008; An online resource for improving patient safety Available at: <a href="http://www.jointcommission.org/PatientSafety/PSP/">http://www.jointcommission.org/PatientSafety/PSP/</a>. Accessed Mar. 31, 2008.
- **78.** Joint Commission International Center for Patient Safety. High 5s Project. <a href="http://www.jcipatientsafety.org/24433/">http://www.jcipatientsafety.org/24433/</a>. Accessed Mar. 31, 2008.
- **79.** World Health Organization. Action on Patient Safety High 5s. *Patient safety* [http://www.who.int/patientsafety/solutions/high5s/en/index.html. Accessed Mar. 31, 2008.

#### **ENDNOTES**

- <sup>1</sup> **Evidence Synthesis:** A type of evidence summary. Evidence synthesis is the term used by the Agency for Healthcare Research and Quality (AHRQ) and is synonymous with the term, systematic review (see below). **Evidence Summary**: An inclusive term for systematic review, evidence synthesis, and integrative review. It refers to a systematic, scientifically rigorous approach to summarizing knowledge across a number of research studies, so that the variations in studies and contradictory study results can be understood within a single conclusion; it provides a "state of the science" conclusion. http://www.acestar.uthscsa.edu/Learn\_terminology.htm.
- <sup>1</sup> Research methods such as a double blinding and randomization of patients are not possible or appropriate for many patient safety practices because they are organizational/social in nature.
- <sup>1</sup> Scholars in other related fields may use different terms and recognize additional considerations. The use of these terms is not meant to imply that these terms must be used throughout the effort required by the RFP, but the concepts must be addressed.
- <sup>1</sup> For example, the Oregon project noted above required multiple steps to reach the goal of sharable e-prescribing. These steps included relationship-building, making data systems interoperable, and resolving HIPAA issues. Implementation of a strong, centralized IT system in a community hospital in Wisconsin was preceded by changes in the physical design of the facility, which itself was preceded by a leadership initiative in the community creating "synergy." An effort to implement "smart" infusion pumps was reported to be stymied by technical and nursing behavioral factors

  (http://healthit.ahrg.gov/portal/server.pt?open=512&obiID=650&PageID=0&parentname=ObiMgr&parentid
- (http://healthit.ahrq.gov/portal/server.pt?open=512&objlD=650&PageID=0&parentname=ObjMgr&parentid=106&mode=2&dummy=). The National Quality Forum's current set of safe practices includes many additional specifications that together comprise a single safety practice. For example, the recommended practice "Create and sustain a healthcare culture of safety" includes creating awareness structures and systems (e.g., for identification of risks and hazards), accountability structures and systems (e.g., external reporting), assessment of budgets and other resources, action structures and systems (e.g., performance improvement programs), and more. Multiple steps are recommended to achieve an additional standard: implement critical components of a well designed nursing workforce.
- <sup>1</sup> In some fields, the use of "theory" (and the related term "hypothesis") per se is unacceptable, but most agree that identification of a logic model or conceptual framework is essential to increasing understanding of relationships among inputs and outputs for scientists and those on the front lines of implementation. Much has been written about differences among the concepts of theory, conceptual frameworks, and logic models. For purposes of this RFP, we accept these concepts are broadly similar and as labels for approaches to PSP development and evaluation that achieve the goals set out by the ICEBeRG group and others.
- <sup>1</sup> Internal validity is the extent to which observed covariation should be interpreted as a causal relationship. External validity is the extent to which causal relationships can be generalized to different measures, persons, settings, and times. Construct validity is the extent to which operational variables adequately represent theoretical constructs. (Steckler and McLeroy, 2008, citing Campbell and Stanley, 1966).

#### SECTION D - PACKAGING AND MARKING

The Contractor shall mark each delivery/deliverable with the Contractor's name, Contract Number, and quantity. It is very important that the contractor indicate if this is a partial, full, or final shipment. As appropriate, note on the face page of each deliverable or on the binding, (1) 'one volume only' or (2) 'volume 1 of 2, volume 2 of 2' etc.

#### **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. The full text of a clause may be accessed electronically at this address: <a href="http://www.arnet.gov/far/">http://www.arnet.gov/far/</a>.

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. The full text of a clause may be accessed electronically at this address: <a href="http://www.arnet.gov/far/">http://www.arnet.gov/far/</a>.

## 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 (TO BE NEGOTIATED) and run through (TO BE NEGOTIATED).

#### F.3 DELIVERY SCHEDULE

The Contract Specialist shall receive one copy of each progress report and final report/final deliverable. In addition, one electronic and one hard copy of final reports and all other deliverables shall be submitted to the Project Officer.

Agency for Healthcare Research and Quality ATTN: Linda L. Simpson, Contract Specialist Contracts Management / OPART 540 Gaither Road Rockville, Maryland 20850 Linda.Simpson@ahrq.hhs.gov

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

Items specified for delivery are subject to the review of the Project Officer (PO) before final acceptance. The contractor shall be required to make revisions as deemed necessary by the PO to ensure a report of high quality. The contractor shall submit items to the specified recipient at the email address specified earlier, in the format and within the time frames indicated. Due dates which fall on a weekend or holiday are due on the next business day.

#### F.4 Schedule of Deliverables and Reporting Requirements

The items specified for delivery are subject to the review and approval of the Project Officer before final acceptance. The Contractor shall be required to make revisions deemed by the Project.

See Attachment 1 for complete list of Deliverables.

#### **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:

NAME <u>TITLE</u>

#### (TO BE COMPLETED AT TIME OF 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 PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

#### (TO BE COMPLETED AT TIME OF AWARD)

The Project Officer(s) 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 Government may unilaterally change its Project Officer designation.

#### G.3 CONTRACTING OFFICER

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 designation.

#### **G.4 CONTRACT SPECIALIST**

The Contracting Officer has designated Linda Simpson, Contract Specialist, as the point of contact for all contractual matters associated with this contract.

#### G.5 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.6 INFORMATION ON VOUCHERS**

- (1) The Contractor is required to include the following minimum information on vouchers:
  - (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.
- (2) The Contractor shall furnish the following <u>minimum</u> information in support of costs submitted:
  - (a) <u>Direct Labor</u> 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) <u>Fringe Costs</u> 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) <u>Consultants</u> include the name, number of days or hours worked, a total amount per consultant and a total amount for this category;

- (e) <u>Travel</u> 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) <u>Subcontractors</u> 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) <u>Data Processing</u> 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) <u>Equipment Cost</u> itemize and identify separately from material costs including reference to approval in all cases;
- (j) <u>G&A</u> show rate, base and total as well as verification/allowability of rate changes (when applicable);
- (k) Fee show rate, base and total and;
- (I) <u>Current amount billed</u> 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.7 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.8 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. 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.

The purpose of such consultation is to assure that:

- (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.
- (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) CONTRACT#. 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

Award of any subcontract is subject to the prior written approval of the Contracting Officer upon review of the supporting documentation. Failure to obtain prior written approval of the Contracting Officer may result in disallowance of use of Federal funds to cover services under the subcontract. 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, and H.7. These requirements are to be included without substantive alteration, and no clause may be included to diminish these requirements. If approved, 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:

- 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 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.7 SALARY CAP GUIDE NOTICE

Pursuant to the applicable HHS appropriations acts 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
108–447, Div F, Title II, General Provisions, Section 204	10/01/05— 12/31/05	\$180,100
109–149, General Provisions, Section 204	01/01/06—until revised	\$183,500

Executive Level salaries for the current and prior periods can be found at the following Web site: <a href="http://www.opm.gov/oca/05tables/html/ex.asp">http://www.opm.gov/oca/05tables/html/ex.asp</a>. Click on "Salaries and Wages" and then scroll to the bottom of the page to select the desired period.

#### 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.

SF-85 Questionnaire for Non-Sensitive Positions

**HHS Credit Release** 

OF-306 Declaration for Federal Employment Current resume

Note: Forms are available at: <a href="http://www.gsa.gov/Portal/formslibrary.isp">http://www.gsa.gov/Portal/formslibrary.isp</a>

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) and will be arranged by AHRQ.

#### H.9 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 <a href="http://www.access-board.gov">http://www.access-board.gov</a>. 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 <a href="http://www.acquisition.gov">http://www.acquisition.gov</a>. The FAR rule implementing Section 508 can be found at <a href="http://www.section508.gov">http://www.section508.gov</a>. 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

# 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: <a href="http://www.arnet.gov/far/">http://www.arnet.gov/far/</a>

## 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)
52.203-14	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)
52.204-4	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 (JUN 1999)

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)
52.215-18	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)
52.217-8	Option to Extend Services (NOV 1999)
52.219-8	Utilization of Small Business Concerns (MAY 2004)
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	Notification of Employee Rights Concerning Payment of Union Dues or Fees (DEC 2004)
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 (JUNE 2003)
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-
52.227-3	Right Infringement (DEC 2007) Patent Indemnity (APRIL 1984)
52.227-17	Rights in Data – Special Works (DEC 2007)
52.228-7	Insurance-Liability to Third Persons (MAR 1996)
52.232-9	Limitation on Withholding of Payments (APRIL 1984)
52.232-17	Interest (JUNE 1996)
52.232-20	Limitation of Cost (APR 1984)
52.232-23	Assignment of Claims (JAN 1986)
52.232-25	Prompt Payment (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)
52.242-1	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) Alternate h
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)
352.270-5	Key Personnel (JAN 2006)
352.270-6	Publication and Publicity (JAN 2006)
352.270-7	Paperwork Reduction Act (JAN 2006)

#### CLAUSES APPLICABLE FOR A COST-PLUS-A-FIXED-FEE CONTRACT

Use the following FAR Clauses if applicable:

If supplies are to be furnished, the following clause is applicable:

52.215-14	Integrity of Unit Prices (OCT 1997)(when contracting with full and open competition)
-or-	
52.215-14	Integrity of Unit Prices (OCT 1997) Alternate I (OCT 1997) (when contracting without full and open competition)
52.215-17	Wavier of Facilities Capital Cost of Money (OCT 1997)
52.216-18	Ordering (OCT 1995)
52.216-19	Ordering Limitations (OCT 1995)
52.216-20	Definite Quantity (OCT 1995)
52.216-21	Requirements (OCT 1995)
52.216-22	Indefinite Quantity (OCT 1995)
52.217-2	Cancellation Under Multiyear Contracts (OCT 1997)
52.217-9	Option to Extend the Term of the Contract (MAR 2000)
52.219-3	Notice of Total HUBZone Set-Aside (JAN 1999)
52.219-4	Notice of Price Evaluation Preference for HUBZone Small Business Concerns (JUL 2005)
52.219-6	Notice of Total Small Business Set-Aside (JUNE 2003)
52.219-9	Small Business Subcontracting Plan (APR 2008) (Applicable to contracts over \$550,000)
52.219-10	Incentive Subcontracting Program (OCT 2001)
52.219-14	Limitation on Subcontracting(DEC 1996) (Applicable to 8(a) awards or if any portion is set aside for small businesses)
52.219-16	Liquidated Damages - Subcontracting Plan (JAN 1999)
52.219-18	Notification of Competition Limited to Eligible 8(a) Concerns (JUNE 2003)
52.219-23	Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (SEP 2005)  ***(Use 52.219-22(Section K) with the above Clause)***
52.219-25	Small Disadvantaged Business Participation Program - Disadvantaged Status and Reporting (APR 2008)
52.222-41	Service Contract Act of 1965 (NOV 2007)

## (NOTE: If 52.222-41 is used, Section I must contain clause 52.222-42 Statement of Equivalent Rates for Federal Hires-MAY 1989)

52.223-3	Hazardous Material Identification and Material Safety Data (JAN 1997) Alternate I (JUL 1995)	
52.224-1	Privacy Act Notification (APRIL 1984)	
52.224-2	Privacy Act (APRIL 1984)	
52.230-2	Cost Accounting Standards (APR 1998)	
52.230-3	Disclosure and Consistency of Cost Accounting Practices (APR 1998)	
52.230-6	Administration of Cost Accounting Standards (MAR 2008)	
52.230-7	Proposal Disclosure – Cost Accounting Practice Changes (APR 2005)	
52.232-18	Availability of Funds (APRIL 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.)	
52.232-33	Payment by Electronic Funds Transfer Central Contractor Registration (Oct 2003)	
52.239-1	Privacy or Security Safeguards (AUG 1996)	
Use the following HHSAR Clauses if applicable:		
352.224-70	Confidentiality of Information (JAN 2006)	
352.270-1	Accessibility of Meetings, Conferences, and Seminars to Persons With Disabilities (DEC 2006)	
352.270-2	Indian Preference (DEC 2006)	
352.270-3 Use the following HHSAR CI	Indian Preference Program (DEC 2006) auses if applicable:	
352.223-70	Safety and Health (JAN 2006)	
352.270-8	Protection of Human Subjects (JAN 2001)352.270-9	
352.270-9	Care of Laboratory Animals (JAN 2006)	

# PART III- LIST OF DOCUMENTS, EXHIBITS AND ATTACHMENTS SECTION J - LIST OF ATTACHMENTS

Attachment		<u>Pages</u>
1.	Delivery Schedule and Requirements	3
2.	Past Performance Questionnaire and Contractor Performance Form	5
2.	Proposal Intent Form	1
3.	Sample Subcontracting Plan	11

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

#### 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 (JAN 2006)
K.3.	FAR 52.222-21	Prohibition of Segregated Facilities (FEB 1999)
K.4.	FAR 52.230-1	Cost Accounting Standards Notices and Certification (JUNE 2000)
K.5.	FAR 15.406-2	Certificate of Current Cost and Pricing Data
K.6.	P.L. 103-227	Certification Regarding Environmental Tobacco Smoke

#### K.1 REPRESENTATIONS AND INSTRUCTIONS HHSAR 315.204-5

- (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 (JAN 2006) (FAR 52.204-8)

- (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 (b) 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 (b) applies
  - [ ] (ii) Paragraph (b) does not apply and the offeror has completed the individual representations and certification in the solicitation.
- (c) The offeror has completed the annual representations and certifications electronically via the Online Representations and Certifications Application (ORCA) website at <a href="http://orca/bpn.gov">http://orca/bpn.gov</a>. 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
i Air Clause#	TILLE	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. PROHIBITION OF SEGREGATED FACILITIES (FEB 1999) (FAR 52.222-21)

"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.4. 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	e 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.5. CERTIFICATE OF CURRENT COST OR PRICING DATA (FAR 15.406-2)

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
NAMESignature
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.6. 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		

#### 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. The full text of a clause may be assessed electronically at this address: <a href="http://www.arnet.gov/far/">http://www.arnet.gov/far/</a>.

#### 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 iInternet at <a href="http://www.dnb.com">http://www.dnb.com</a>; 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 that 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) Submissions, 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 representative's identity is made known and the representative 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 submitted 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) Offers 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 after conducting discussions with offerors whose proposals have been determined to be within the competitive range. 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. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.
- (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 offerors 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 plus fixed fee contract resulting from this solicitation.

It is anticipated that one (1) contract award will be made from this solicitation.

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

The Government may elect to award a single contract or to award multiple 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 Project Officer.

All questions regarding this solicitation shall be in writing and received by the Contract Specialist no later than **12:00 noon EDT August 29, 2008.** All questions should be e-mailed to Linda Simpson at Linda.Simpson@ahrq.hhs.gov.

#### L.8 REFERENCE MATERIALS (IRESERVED)

#### L.9 GENERAL INSTRUCTIONS

#### Introduction

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals.

- a. <u>Contract Type and General Provisions</u>: It is contemplated that a cost 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. <u>Authorized Official and Submission of Proposal</u>: 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.
- c. <u>Separation of Technical, Past Performance Information, and Business</u>

  <u>Proposal</u>: The proposal shall be in 4 separate parts. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:
  - I. <u>TECHNICAL PROPOSAL</u>: See Technical Proposal Instructions for recommended format (L.10). Please mark as original or copy.
  - II. <u>PAST PERFORMANCE INFORMATION</u>: See Past Performance Information Instructions for format (L.11)
  - III. <u>BUSINESS PROPOSAL</u>: See Business Proposal Instructions for recommended format (L.12).
  - IV. <u>SMALL DISADVANTAGED BUSINESS PARTICIPATION PLAN</u> Information Instructions for format (L.13).

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.

- d. <u>Evaluation of Proposals</u>: The Government will evaluate technical proposals in accordance with the criteria set forth in Section M, Evaluation/Award Criteria.
- e. <u>Rejection of Proposals</u>: 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. <u>Unnecessarily Elaborate Proposals</u>: 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 Government Accountability Office (GAO) 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 an original and eleven (11) copies. The technical proposal described below shall be limited to 50 not including cover page, introduction, table of contents, resumes or bibliographies, with no less than a 11 point pitch, with page numbers, with the majority of the text double-spaced (lists of deliverables, person loading charts, and similar materials need not be double-spaced, so long as they are legible) and with margins that are a minimum of 1 inch. Resumes or CVs are only required for key personnel (i.e. the proposed Project Director and senior personnel that play a major role in the management and execution of the project activities). Brief biographic sketches of other personnel may be provided. 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.

#### a. <u>Technical Proposal Format</u>

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) <u>Cover Page</u>: The name of the proposing organization, author(s) of the technical proposal, the RFP number and the title of the RFP should appear on the cover. One (1) manually signed original copy of the proposal and the number of copies specified in the RFP cover letter are required.
- (2) <u>Table of Contents</u>: Provide sufficient detail so that all important elements of the proposal can be located readily.
- (3) <u>Introduction</u>: This should be a one or two page summary outlining the proposed work, your interest in submitting a proposal, and the relevance of this effort in relation to your overall operation.
- (4) <u>Technical Discussion</u>: The offeror shall prepare a technical discussion with the following sections that correspond to the evaluation criteria. The offeror shall further state that no deviations or exceptions to the SOW are taken.
  - A. Understanding the Purpose and Objectives
  - B. Technical Approach
  - C. Qualifications of Proposed Staff, Including Consultants
  - D. Organizational/Corporate Experience
  - E. Management Plan
  - F Facilities and Equipment
  - G. Past Performance Information (See Section L.11)

A draft but specific approach for identifying the diverse, representative, and promising set of PSPs to be used as exemplars for helping to identify criteria for reviews of evidence of context-sensitive effectiveness and safety must be included in the response to this RFP.

Responses to the RFP should specify how offerors plan to go about creating criteria for assessing evidence (including the strength of evidence), and to identify specific gaps where criteria cannot yet be created.

#### b. <u>Technical Proposal Requirements</u>

Technical proposals submitted in response to this RFP shall address each of the items described below, and shall be organized in the manner described above. Proposals shall be prepared in double-spaced format, with numbered pages. Suggested page lengths are indicated for each section. These section page lengths are not mandatory, however the total length of the technical proposal (not including cover page, table of contents, resumes or bibliographies) may not exceed 50 pages.

#### A. Understanding the Purpose and Objectives (1-2 pages)

Briefly (1-2 pages), but in sufficient detail to demonstrate a thorough understanding of the objectives, the offeror shall provide a description of the scope, purpose, products, and events called for under this contract.

#### B. Technical Approach (10-15 pages)

The offeror shall describe in detail the methodologies they will use to develop, design, implement, staff, and manage the statement of work for this project. Within the content

of the narrative, the offeror shall address technical issues related to completing the tasks, indicating areas of anticipated difficulties and proposed solutions. The successful offeror should demonstrate their creativity, sense of innovation, and flexibility in completing each task.

The offeror should describe the approach with respect to the requirements of this acquisition, including:

- Rationale for the interdisciplinary panel of experts nominated as part of the proposal. Identify specifically how each proposed expert will contribute to the following project needs:
  - breadth and depth of knowledge about a broad range of research and evaluation designs, including those designed for a balance of internal, construct, and external validity.
  - breadth and depth of knowledge about the field of patient safety, with a particular emphasis on approaches to improving patient safety at multiple system levels.
  - breadth and depth of knowledge in the theoretical and practical foundations of implementing improvements from a variety of perspectives, including engineering, management science, organizational theory, other social science, behavioral sciences, and fields outside of health care where theory and experience can be expected to be helpful to designing effective and safe patient safety practices.
  - Breadth and depth of knowledge of the organization and financing of health care delivery in the United States, including variations by population, setting, and service.
  - Breadth and depth of understanding of disparities in health care that relate to patient safety, including observed disparities in medical errors.
  - Breadth and depth of knowledge about traditional and innovative approaches to systematic literature reviews, meta-analysis, and metaanalytic reviews, and narrative approaches to literature synthesis.
  - Creativity and innovation.
  - o Identify how the panel of experts will work together and work with the offeror's team and management.

#### Task 2:

- Plan for identifying patient safety practices to be used as initial subjects (cases) for helping to iteratively develop criteria for rigorous and systematic assessment of the context-sensitive effectiveness and safety of patient safety practices. As noted in the SOW, the proposal should address how the plan will include PSPs in actual use, published articles on PSPs, promising PSPs and a balance of PSPS across settings and populations.
- o Plan for developing a conceptual framework of PSPs.

#### Task 3:

 Plan for identifying a range of research and evaluation models, methods, and designs that could be used to develop criteria for rigorously evaluating reports of PSPs. What methodological literatures will be used and why? How will rigor be defined in the context of PSPs? How will criteria for identifying and analyzing context and change processes be developed and how will criteria for external validity be combined with internal validity in specific studies and in reviews? How will safety (adverse events) of PSPs be categorized and used in reviews?

#### Task 4:

- Plan or template for turning the knowledge from Tasks 2 and 3 into a set of criteria applicable to future studies and evidence syntheses of PSPs.
- Task 5: Recommendations for future work.
- Task 6: Provide a final summary report. Specify how this report will be written in plain enough language for understanding by implementers of PSPs as well as researchers.

## C. Qualifications of Proposed Staff, Including Subcontractors and Consultants (5-10 pages)

The offeror is expected to be specific in describing the proposed personnel and their relevant qualifications and experience, including their background and experience as they relate to the requirements of this acquisition. Highly qualified staff is considered critical to the successful completion of the tasks under this contract. The offeror should specifically describe the Project Director as it relates to the requirements of this acquisition as evidenced by educational attainment, employment history, experience and specific professional, scientific or technical accomplishments, including the minimum experience requirements below. The Project Director should be a highly qualified senior staff member who is available on a day-to-day basis to direct and monitor the project contract and the associated technical tasks.

The offeror shall provide the resumes of all key personnel, senior staff, and technical task leaders describing their qualifications as they relate to the requirements of this solicitation (in an appendix to the technical proposal).

#### Minimum qualifications of staff include:

- A minimum of 5 years' experience assessing evidence in health care delivery research (one or more high-level staff).
- Experience in assessing the role of clinical factors along with contextual factors and implementation processes in patient safety improvement implementation research and evaluation (one or more high level staff)
- Project leader must have an advanced degree such as a Ph.D. in social sciences and knowledge of the healthcare delivery system and patient safety issues, or an MD with experience in organizational, engineering, management science or similar fields and knowledge of the health care delivery system and patient safety issues, and 3 years of experience managing projects of this scope..
- Demonstrated project staff experience in translating complex research and evaluation concepts into language accessible to potential implementers of patient safety improvement practices.

#### D. Organizational/Corporate Experience (5-10 pages)

The offeror must have demonstrated several years of experience as an organization in successfully conducting and managing projects of the type specified in this RFP, within the required time and budgetary constraints. It is essential that the offeror demonstrate the capability to organize and manage resources and personnel effectively, and to successfully undertake and complete technical and non-technical tasks at the highest level of professional and scientific quality. The offeror must also have demonstrated experience and success in maintaining confidentiality in their organizational systems, procedures, and personnel. The Offeror's descriptions shall delineate how these organizational experiences and processes are relevant to fulfilling the requirements of this proposed contract.

Organizations should demonstrate their ability to attract a high-level trans-disciplinary and diverse set of technical experts and maintain their involvement in the development of criteria.

Offerors should list and summarize any contracts (state or federal), grants (state, federal, or private foundation), or self-funded projects recently completed (within the last 3 years), or that are currently in process, and describe the relevance to the tasks and associated activities that may be performed under this contract. Starting with the most current projects and working backward, this summary should contain: (a) a brief description of each project highlighting specific relevance to the RFP; (b) total level of effort required (e.g. FTEs) or annual dollar amount of the project; (c) length of project (include date began and completion date) (d) supporting organization (provide name, title, address and telephone number of program contact person or individual in authority who has direct knowledge of the offeror's performance); (e) project director and key staff involved; (f) role of offeror including whether functioned as prime or sub-contractor: (g) lists of examples of relevant products or other deliverables generated. The list of projects and associated information may be presented as a table, and if so, may be single spaced.

#### E. Management Plan (3-5 pages)

Offeror shall demonstrate their ability to achieve the delivery of performance requirements through the proposed use of organizational/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.

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 any subcontractors and consultants proposed for this contract. The plan shall indicate in detail how organizational roles and responsibilities will be divided, decisions made, work monitored, and quality and timeliness of products assured.

The management plan shall include a person loading chart (number of days for each staff member, consultant and sub-Contractor) by task. The following four (4) tasks shall be used in the person loading chart (offerors may also provide breakouts for sub-tasks within these four tasks, but sub-task breakouts are not required)

- Task 1- Collaborate with Panel of Experts and Other Stakeholders as Needed
- Task 2- Implementation Pan
- Task 3- Final report
- Task 4- Project management

The plan should at a minimum also address the following:

- a) personnel selection and assignment for key personnel, senior staff, and technical task leaders (why you chose an individual person for an individual job);
- monitoring and control of services provided: technical quality, responsiveness, cost control, and effective and efficient resource utilization, compliance with technical requirement and contract provisions;
- c) managerial problems offeror expects to encounter and methods proposed to solve these problems;
- d) project management tools (including software); and
- e) an organizational chart indicating clear lines of authority, delineating staff responsibilities;
- f) if the offeror proposes to use consultants or subcontractors to carry out work under this contract, Letters of Commitment from personnel other than current direct employees should be provided in an appendix.

#### F. Facilities and Equipment (2-5 pages)

The offeror shall describe the suitability, quality and cost-efficiency of their facilities and equipment (including computers, library/information resources facilities, telecommunications capabilities, travel and other logistics) available for the performance of all requirements of this acquisition.

#### L.11 PAST PERFORMANCE INFORMATION

Offerors shall submit the following information (original and 3 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, grants, or self-funded projects completed (most relevant or most related) during the past three years and all contracts and subcontracts currently in process in which the offeror is a contractor, grantee, or participant in a self-funded project. Reference contracts, subcontracts, grants, and self-funded projects completed during the past three years and include recently completed and ongoing work directly related to the requirements of this acquisition. 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, subcontract, grant, or self-funded project:
  - a. Name of activity
  - b. Contract number (if relevant)
  - c. Contract type (if relevant)
  - d. Total contract/grant/project value
  - e. Work performed
  - f. Reference (Contracting Officer and telephone number)
  - g. Program Manager and telephone number
  - h. Administrative Contracting Officer (if relevant), if different from item f, and telephone number
  - i. List of major subcontracts (if relevant)
- (2) The offeror may provide information on problems encountered on the projects identified in (1) above and corrective actions taken to resolve those problems. Offerors should not provide general information on their performance on the identified projects. 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 organization (one division or the entire organization) 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 projects 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.

69

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

Agency for Healthcare Research and Quality Division of Contracts Management Attn: Linda L. Simpson, Contract Specialist 540 Gaither Road, Suite 4315 Rockville, Maryland 20850

FAX: 301-427-1740

Evaluation forms must be received by the date and time (October 13, 2008 by 12:00 noon)I 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 Contract Specialist in a timely manner.

#### L.12 BUSINESS PROPOSAL

The offeror shall submit as part of the proposal a <u>separate</u> enclosure titled "Business Proposal." The Business Proposal shall include the Cost/Price Proposal, the Small Business Subcontracting Plan, and Other Administrative Data in accordance with the following:

#### A. Cost/Price Proposal

A cost proposal shall be submitted in accordance with FAR 15, in a format similar to the attachment. The offeror's own format may be utilized, but all required information in the attachment shall be provided.

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price.

As appropriate, cost breakdowns shall be provided for the following cost elements.

#### (a) Direct Labor

The estimated cost for all personnel who will be assigned for direct work on this project shall be included. Give the name, title, percent of effort or time, salary and fringe benefits for each employee.

Salary increases that are anticipated during performance of a resultant contract should be proposed as a cost. If escalation is included, state the degree (percent) and methodology, e.g., annual flat rate applied to a base rate as of a specific date or a mid-pointed rate for the period of performance. State whether any additional direct labor (new hires) will be required during the performance period of this procurement. If so, state the number required and anticipated date of hire. Also, specify the month and day on which your fiscal year commences.

#### (b) Supplies and Equipment

Include description, unit price, quantity, total price, justification for purchasing or leasing items and the basis for pricing (vendor quotes, invoices prices, etc.).

#### (c) Travel

The amount proposed for travel shall be supported with a breakdown which includes purposes, destination, duration, and estimated cost (transportation and per diem) for each proposed trip. If travel costs are proposed on the basis of your organization's established travel policy, a copy of the policy must be provided.

#### (d) <u>Consultants</u>

This element should include name(s) of consultant, number of days, and daily rate. The method of obtaining each consultant, either sole source or competitive, and the degree of competition or the rationale for sole source shall be explained.

#### (e) Subcontractors

Subcontractor costs shall be broken down and supported by cost and pricing data adequate to establish the reasonableness of the proposed amount. Support documentation should include degree of subcontract competition and basis for selecting source.

#### (f) Other Direct Costs

Any proposed other direct costs shall be supported with breakdown outlining the separate costs proposed and details supporting the formulation of the costs proposed. A signed agreement between the offeror and any personnel other than direct employees that includes dates of employment, salary, and specific tasks to be performed should be included.

#### (a) Indirect Costs

Indicate how you have computed and applied indirect costs, and provide a basis for evaluating the reasonableness of the proposed rates.

#### B. Small Business Subcontracting Plan:

All offerors except small businesses are 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 the AHRQ model subcontracting plan is provided as an attachment to this solicitation. 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 with the initial proposal, the offeror will be considered nonresponsive and their proposal will be returned without further consideration.

# 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:

- No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer. The plan will be incorporated in to 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 30% for Small Businesses, which shall include at least 11% (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 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.

#### C. Other Administrative Data

(1) <u>Terms and Conditions</u>: 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) <u>Authority to Conduct Negotiations</u>: 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, <u>Contractor's Guide for Control of Government Property</u>" 1990, a copy of which will be provided upon request.
- (4) <u>Royalties</u>: You shall furnish information concerning royalties which are anticipated to be paid in connection with the performance of work under the proposed contract.
- (5) <u>Commitments</u>: 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) <u>Financial Capacity</u>: 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 project. 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.13 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 (an original only is required).

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:

- 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.

#### 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, and the Small Disadvantaged Business Participation Plan of the technically acceptable offerors will be evaluated by AHRQ staff. A competitive range will 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 best-buy 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 reserves the right to make an award to the best advantage 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 September 13, 2008. 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.

#### L.16 Webex Conference Participation Instructions

You are invited to participate in the following online teleconference session:

Topic: Assessing the Evidence Base for Context-Sensitive Effectiveness and Safety of

Patient Safety Practices: Developing Criteria - Bidding Conference

**HOST: Project Officer** 

Technical Facilitator: Scott Rowe Date: Friday, September 5, 2008

Time: 1:00 PM Eastern Daylight Time (EDT)

Session Number: 711 495 558 Session Password: **knowledge** 

-----

To join the session via the WebEx computer teleconferencing software:

------

- 1. Go to <a href="https://hhs-ahrq.webex.com/hhs-ahrq/k2/j.php?ED=108248837&UID=1034979527">https://hhs-ahrq.webex.com/hhs-ahrq/k2/j.php?ED=108248837&UID=1034979527</a>
- 2. Enter your name and email address.
- 3. Enter the session password: knowledge
- 4. Click "Join Now".
- 5. Follow the instructions that appear on your screen.

Note: You can view more information about the session at <a href="https://hhs-ahrq.webex.com/hhs-ahrq/k2/i.php?ED=108248837&UID=1034979527">https://hhs-ahrq.webex.com/hhs-ahrq/k2/i.php?ED=108248837&UID=1034979527</a>.

\_\_\_\_\_

To join the session via telephone:

.

(877) 428-3953

Participant code: 804985 Leader code: 249905

------

For technical assistance related to this specific teleconference session

-----

You can contact Scott Rowe prior to the start of the session at: <a href="mailto:scott.rowe@ahrq.hhs.gov">scott.rowe@ahrq.hhs.gov</a>

1-301-427-1885

To add this meeting to your calendar program (for example Microsoft Outlook), click this link:

https://hhs-ahrq.webex.com/hhs-

 $\frac{ahrq/k2/j.php?AT=down\&ED=108248837\&EF=MA\&UUID=1034979527\&SHA2=0X/8itltNro0/xwr9vmZHmmywwUorgSkMGXtGtCJ2NQ=$ 

## **SECTION M - EVALUATION FACTORS FOR AWARD**

## **EVALUATION FACTORS FOR AWARD**

- 1. Award will be made to that responsible offeror whose proposal is most advantageous to the Government, cost and the below factors considered. Paramount consideration shall be given to technical quality rather than cost. It is pointed out, however, that should technical quality between offerors be considered approximately the same, then cost may become the determining factor in award selection.
- 2. The technical proposal will be evaluated in terms of its responses to the evaluation factors. The evaluation factors and assigned weights which will be used in the technical review of the proposal submitted are outlined below.

EVALUATION CRITERIA	WEIGHT
A. Understanding the purpose and objectives	20
B. Technical approach	50
C. Qualifications of Proposed Staff, including Consultants	10
D. Organizational/Corporate Experience	10
E. Management Plan	10
F. Facilities and Equipment	10
G. Past Performance	15
H. Small Disadvantaged Business Participation Plan	5

#### **EVALUATION CRITERIA**

1. Award will be made to that responsible offeror whose proposal is most advantageous to the Government, cost and the below factors considered. Paramount consideration shall be given to technical quality rather than cost. It is pointed out, however, that should technical quality between offerors be considered approximately the same, then cost may become the determining factor in award selection.

# THE GOVERNMENT RESERVES THE RIGHT TO MAKE AN AWARD WITHOUT DISCUSSION.

2. The technical proposal will be evaluated in terms of its responses to the evaluation factors. The evaluation factors and assigned weights which will be used in the technical review of the proposal submitted are outlined below. Factors facilitating the evaluation of each criterion below are described in Attachment 1 of the solicitation:

<u>Evaluation Criteria</u> <u>Weight</u>

## A. <u>Understanding the Purpose and Objectives</u>

20

The proposal shall be evaluated on the completeness of the proposal and the offeror's demonstrated understanding of the problems of the project in its response to the objectives and tasks and solution approach thereto.

#### B. Technical Approach

50

The proposal shall be evaluated on the completeness, reasonableness, clarity, and feasibility of the approach to satisfy the Technical Proposal requirements.

#### C. Qualifications of Proposed Staff, including Consultants

10

The background and experience of individuals proposed as they relate to the requirements of this acquisition (see Section L.10)

## D. Organizational/Corporate Experience

<u>10</u>

The offeror will be evaluated on its demonstrated ability to achieve the delivery of performance requirements through the proposed use of corporate management and other personnel resources. Evaluation will consider the offeror's proposed organizational structure and demonstrated capabilities to meet the projects milestones within the timeframe of the proposed contract and within the negotiated fixed price.

The offeror will be evaluated on it's demonstrated understanding of the requirements of the Statement of Work from a managerial perspective, as detailed below:

- a) labor skill mix determination
- b) personnel selection and assignment
- c) timelines and capacity for scheduling and executing the tasks of the SOW within the timeframe of the proposed contract and within the negotiated fixed price.

## E. Management Plan

10

## F. Facilities and Equipment

<u>10</u>

Proposals will be evaluated on relevant projects, provided as examples, with specific narrative of how they apply to the above criteria.

#### G. Past Performance

<u>15</u>

(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.

## H. Small Disadvantaged Business Participation Plan

<u>5</u>

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 DOINTS	S	120
IUIAL	AVAILABLE FUINTS	,	130

# 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-09-10001, entitled "Assessing the Evidence Base for Context-Sensitive Effectiveness and Safety of Patient Safety Practices: Developing Criteria." Past performance is an important part of the evaluation criteria for this acquisition therefore, 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 Linda Simpson, the AHRQ Contract Specialist, and is NOT to be disclosed to the offeror either verbally or in writing. Please provide an honest assessment and return (via fax) to AHRQ at the address shown below, no later than October 13, 2008, 12 noon EST

Agency for Healthcare Research and Quality Division of Contracts Management Attn: Linda Simpson, Contract Specialist 540 Gaither Road, Suite 4315 Rockville, Maryland 20850

FAX: (301) 427-1740

If you have any questions, please contact the Contract Specialist via e-mail at Linda.Simpson@ahrq.hhs.gov.

NAME OF OFFEROR:	·
ADDRESS:	

# **ERFORMANCE RATING**

Ratings: Summarize performance and circle in the column on the right the number which corresponds to the performance rating for each rating category. An explanation of rating scale is provided with this attachment.

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 organization committed to customer satisfaction? _Yes No ;
Would you use this organization again? _YesNo
Reason:

NAME OF EVALUATOR:(Please Print)
TITLE OF EVALUATOR:
SIGNATURE OF EVALUATOR:
DATE:
MAILING ADDRESS: Include name of organization/ federal agency
PHONE #:
E-MAIL :

**Rating Guidelines:** Summarize 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
	-Compliance with project requirements -Accuracy of reports -Technical excellence	-Within budget(over/ under target costs) -Current, accurate, and complete billings -Relationship of negotiated costs to actual -Cost efficiencies -Change orders issue	-Met interim milestones -Reliable -Responsive to technical direction -Completed on time, including wrap- up and project adm -No liquidated damages assessed	-Effective management -Businesslike correspondence -Responsive to project requirements -Prompt notification of problems - Reasonable/cooperati ve -Flexible -Pro-active -Effective small/small disadvantaged business sub- contracting program
0-unsatisfactory	Nonconformances are jeopardizing the achievement of project requirements, despite use of Agency resources	Ability to manage cost issues is jeopardizing performance of project requirements, despite use of Agency resources	Delays are jeopardizing the achievement of project requirements, despite use of Agency's resources	Response to inquiries, technical/service/admi nistrative issues is not effective
1-Poor	Overall compliance requires major Agency resources to ensure achievement of project requirements	Ability to manage cost issues requires major Agency resources to ensure achievement of project requirements	Delays require major Agency resources to ensure achievement of project requirements	Response to inquiries, technical/service/admi nistrative issues is marginally effective

2-Fair	Overall compliance requires minor Agency resources to ensure achievement of project requirements	Ability to manage cost issues requires minor Agency resources to ensure achievement of project requirements	Delays require minor Agency resources to ensure achievement of project requirements	Response to inquiries, technical/service/admi nistrative issues is somewhat effective
3-Good	Overall compliance does not impact achievement of project requirements	Management of cost issues does not impact achievement of project requirements	Delays do not impact achievement of project requirements	Response to inquiries, technical/service/admi nistrative 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/admi nistrative issues is effective

5-Outstanding. The organization 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 organization performance clearly exceeds the performance levels described as "Excellent."

# **Contractor Performance Form**

1.	Name of Organization:
2.	Address:
3.	Contract/Grant Number (if relevant):
4.	Contract/Grant Value (Base Plus Options) (if relevant):
5.	Contract/Grant Award or Project Beginning Date:
6.	Contract/Grant/Project Completion Date:
7.	Type of Contract/Grant/Project: (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 ( ) Other
8.	Description of Requirement:

# PROPOSAL INTENT RESPONSE SHEET

# RFP No. AHRQ-09-10001

Please review the attached request for proposal. Furnish the information requested below and return this page by August 15, 2008. 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:
QUALITY, CONTRACTS O BIDDERS LIST TO PROVI	ON TO THE AGENCY FOR HEALTHCARE RESEARCH AND OFFICE TO ADD THE CONTACT INFORMAION BELOW TO A DE TO OTHER INTERESTED OFFERORS FOR NG OPPORTUNITIES. (*MUST INCLUDE AUTHORIZED
COMPANY/INSTITU	TION NAME & ADDRESS:
*AUTHORIZED SIGN	NATURE:
TYPED/PRINT NAME	AND TITLE:
[ ] PLEASE <u>DO NOT</u> REL	EASE THE CONTACT INFORMATION.
Please return to:	Agency for Healthcare Research and Quality Division of Contracts Management Attn: Linda Simpson, Contract Specialist 540 Gaither Road, Suite 4315

Fax; 301-427-1740

Rockville, Maryland 20850

Office of the Secretary Washington, D.C. 20201

#### ATTACHMENT 4

# OFFICE OF SMALL AND DISADVANTAGED BUSINESS UTILIZATION SMALL BUSINESS SUBCONTRACTING PLAN

HHS Operating Division (OPDIV):					
DATE OF PLAN:					
CONTRAC	CTOR:				
DUNN &	BRADSTREET NUMBER:				
SOLICITA	TION OR CONTRACT NU	MBER;			
ITEM/SE	RVICE (Description):				
	•				
		<del>.</del>			
NEW/IN	TIAL CONTRACT				
PERIOD Q	F CONTRACT PERFORMANCE	E (Month, Day & Year):			
Base	\$	Performance Period/Quantity _			
Option 1:	\$	Performance Period/Quantity			
Option 3:	\$	Performance Period/Quantity _ Performance Period/Quantity _	· · · · · · · · · · · · · · · · · · ·		
Option 4:	\$	Performance Period/Quantity _			
	\$	Total Contract Cost			