

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	Agency for Healthcare Research and Quality (AHRQ) NOTE: The policies, guidelines, terms, and conditions stated in this announcement may differ from those used by the NIH. Where this Funding Opportunity Announcement (FOA) provides specific written guidance that may differ from the general guidance provided in the grant application form, please follow the instructions given in this FOA. Also note that AHRQ may have different page limits than NIH for the application Research Strategy, which can be found within each individual FOA (see Section IV below). AHRQ Grants Policy and Information to applicants regarding Funding Opportunity Announcement procedures can be found at Funding Opportunity Announcement Guidance .
Components of Participating Organizations	Agency for Healthcare Research and Quality)
Funding Opportunity Title	Closing the Gap in Healthcare Disparities through Dissemination and Implementation of Patient Centered Outcomes Research (U18)
Activity Code	U18 Research Demonstration – Cooperative Agreement
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement OA) Number	RFA-HS-13-010
Companion Funding Opportunity	None
Number of Applications	See Section III. 3. Additional Information on Eligibility .
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.226
Funding Opportunity Purpose	The purpose of this funding opportunity announcement (FOA) is to identify strategies to engage stakeholders through shared decision making that can be used to effectively implement interventions specific to health care delivery systems, clinicians, and/or patients that focus on the reduction of racial/ethnic healthcare disparities in under-resourced settings. The effective strategies will incorporate the translation, dissemination, and implementation of patient-centered outcomes research (PCOR) findings for racial/ethnic minority populations. Successful applicants are required to demonstrate an ability to leverage the capacities of relevant and diverse stakeholders in their strategies to reduce healthcare disparities in under-resourced settings.

Key Dates

Posted Date	May 1, 2013
Open Date (Earliest Submission Date)	June 30, 2013

Letter of Intent Due Date(s)	June 14, 2013
Application Due Date (s)	July 31, 2013, by 5:00 PM local time of applicant organization.
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	Generally, four months after receipt date
Advisory Council Review	Not Applicable
Earliest Start Date	Generally, four months after peer review date.
Expiration Date	August 1, 2013
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the [SF424 \(R&R\) Application Guide](#), except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts](#)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Apply for Grant Electronically

A compatible version of [Adobe Reader](#) is required for download. For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at <http://www07.grants.gov/contactus/contactus.jsp>.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

This funding opportunity announcement (FOA) solicits U18 Research Demonstration Cooperative Agreement applications from institutions to establish and engage relationships with relevant and diverse stakeholders to identify effective strategies to reduce racial/ethnic healthcare disparities through shared decision making and through the translation, dissemination, and implementation of patient centered outcomes research (PCOR) findings. Under the U18 mechanism, AHRQ will have substantial programmatic involvement that is above and beyond the normal stewardship role for planning, directing, and executing the proposed project.

Background:

Health disparities are defined as significant gaps or preventable differences in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates in racial/ethnic minority populations as compared to the health status of the general population (Minority Health and Disparities Research and Education Act of 2000. Public Law 106-525, November 20, 2008.) The 2011 *National Healthcare Disparities Report* released in 2012 by the Agency for Healthcare Research and Quality (AHRQ) shows that access to health care has not been improving for most racial and ethnic groups in the years 2002 through 2008. Fifty percent of the measures that tracked disparities in health care access showed no improvement between the years 2002 and 2008, while 40 percent of those measures were getting worse.

According to a 2009 study by the Joint Center for Political and Economic studies, eliminating healthcare disparities for minorities would have reduced direct medical care expenditures by \$229.4 billion between 2003 and 2006. Many factors contribute to racial, ethnic, and socioeconomic healthcare disparities, including poverty, inadequate access to quality care, environmental threats, personal behaviors, and educational inequalities, among others.

This FOA focuses on reducing health disparities for minorities in under-resourced settings. Under-resourced settings are generally considered to be settings that provide care for people who have insurance with low reimbursement rates or those who have no insurance which leads to a relatively low level of resources to make the required capital and human resource investments.

Research Objectives:

This FOA supports a two-phase research proposal(s) to identify effective strategies to reduce healthcare disparities in racial and ethnic minority populations in under-resourced healthcare settings, with a particular focus on strategies for stakeholder engagement and shared decision making specific to health care delivery systems, clinicians, and patients. Applications must provide a timeline (in 12 month increments) that describes the work that will be completed as part of each phase.

Knowledge to be gained/Expected Outcome:

Successful applicants will conduct an evaluation of the process for engaging stakeholders, (health care delivery systems, clinicians, and/or patients) and an evaluation of the effective strategies to reduce racial/ethnic disparities in an under-resourced setting. Successful applicants are encouraged to develop a tool, such as a handbook, that will serve as a mechanism to communicate the work conducted by the applicant to stakeholders (health care delivery systems, clinicians, and/or patients) and to serve as a document that identifies effective strategies to reduce racial/ethnic disparities in an under-resourced setting. The tool developed to disseminate knowledge gained from the work conducted as part of this funding announcement will provide a documented and replicable process for engaging stakeholders (health care delivery systems, clinicians, and/or patients) through shared decision making. The specific information provided to clinicians will be applicable to a variety of clinicians (e.g., nurses, physicians, physician assistants, social workers, pharmacists). Finally, the tool should also include a detailed implementation and evaluation plan for the suggested strategies in which stakeholders in diverse settings representing diverse patient populations can replicate.

Section II. Award Information

Funding Instrument	Cooperative Agreement
Application Types Allowed	New The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	AHRQ intends to fund one to three awards, for a total of up to \$3 million for the three year duration of the initiative. The number of awards is contingent upon AHRQ appropriations and the submission of a sufficient number of meritorious applications.
Award Budget	The total costs (direct and indirect) for a project awarded under this FOA must not exceed \$500,000 annually. An application that exceeds this amount will not be reviewed.
Award Project Period	The project period for this award is three years.

These projects are authorized by 42 U.S.C. 299a, which provides that AHRQ shall conduct and support research, support demonstration projects, and disseminate information on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness, and value of health care services, and by 42 U.S.C. 299b-37.

All applications submitted and AHRQ grants made in response to this FOA are subject to AHRQ's grant regulations at 42 CFR Part 67, Subpart A, the HHS Grants Policy Statement (see <http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html> and <http://dhhs.gov/asfr/ogapa/grantinformation/hhsqps107.pdf>), and the terms and conditions set forth in the Notice of Award.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

You may submit an application(s) if your institution/organization is a (an):

- Public or non-profit private institution, such as a university, college, or a faith-based or community-based organization;
- For-profit private institution
- Unit of local or State government;
- Eligible agency of the Federal government.
- Indian/Native American Tribal Government (Federally recognized)
- Indian/Native American Tribal Government (Other than Federally recognized);
- Indian/Native American Tribally Designated Organization.

Because the purpose of this program is to improve healthcare in the United States, foreign institutions may participate in projects as members of consortia or as subcontractors only. Applications submitted by foreign institutions will not be reviewed. Organizations described in section 501(c) 4 of the Internal Revenue Code that engage in lobbying are not eligible.

AHRQ strongly encourages applications from or in partnership with Minority Academic Institutions including: Historically Black Colleges and Universities, Tribal Colleges and Universities, Hispanic-Serving Institutions, and Asian American and Pacific Islander Serving Institutions.

HHS grants policy requires that the grant recipient perform a substantive role in the conduct of the planned project or program activity and not merely serve as a conduit of funds to another party or parties. If consortium/contractual activities represent a significant portion of the overall project, the applicant must justify why the applicant organization, rather than the party(s) performing this portion of the overall project, should be the grantee and what substantive role the applicant organization will play. Justification can be provided in the Specific Aims or Research Strategy section of the PHS398 Research Plan Component sections of the SF424 (R&R) application. There is no budget allocation guideline for determining substantial involvement; determination of substantial involvement is based on a review of the primary project activities for which grant support is provided and the organization(s) that will be performing those activities.

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Required Registrations

Applicant organizations must complete the following registrations as described in the SF424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- [System for Award Management \(SAM\)](#)– must maintain an active entity registration (formerly CCR registration), to be renewed at least annually. Use the Sam.gov "Manage Entity" function to manage your entity registrations. See the Grants Registration User Guide at SAM.gov for additional information.

- Grants.gov
- eRA Commons

The Program Director/Principal Investigator (PD/PI) must also work with his/her institutional officials to register with the eRA Commons or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization.

All registrations must be completed by the application due date. Applicant organizations are strongly encouraged to start the registration process at least 6 weeks prior to the application due date.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for AHRQ support.

The PD/PI must commit **at least 10% effort annually** for the duration of the proposed project.

Only **one PD/PI** may be designated on the application.

2. Cost Sharing

This FOA does not require cost sharing.

While there is no cost sharing requirement included in this FOA, AHRQ welcomes applicant institutions, including any collaborating institutions, to devote resources to this effort. An indication of institutional support from the applicant and its collaborators indicates a greater potential of success and sustainability of the project. Examples of institutional support would include: donated equipment and space, institutional funded staff time and effort, or other resource investments. Applicant institutions should indicate institutional support by outlining the specific contributions to the project and providing assurances that their organization and any collaborators are committed to providing these funds and resources to the project. This information can be included at the end of the budget justification section of the application, but institutional support dollars are not to be shown/included in the detailed budget request.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

AHRQ will not accept any application that is essentially the same as one already reviewed within the past thirty-seven months, except for submission:

- To an RFA of an application that was submitted previously as an investigator-initiated application but not paid;
- Of an investigator-initiated application that was originally submitted to an RFA but not paid; or
- Of an application with a changed grant activity code.

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity using the "Apply for Grant Electronically" button in this FOA or following the directions provided at Grants.gov.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the [SF424 \(R&R\) Application Guide](#), except where instructed in this

funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit [Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications](#).

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows AHRQ staff to estimate the potential review workload and plan the review.

By the date listed in [Part 1. Overview Information](#), prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research
- Name(s), address(es), and telephone number(s) of the PD/PI
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent electronically to:

Jennifer E. Moore, Ph.D., R.N.

Email: Jennifer.Moore@ahrq.hhs.gov

Required and Optional Components

The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow all instructions in the SF424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.

Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits](#) must be followed.

PHS 398 Research Plan Component

All application instructions outlined in the SF424 (R&R) Application Guide **that are not otherwise specified within this Funding Opportunity Announcement** must be followed, incorporating "Just-in-Time" information concepts, and with the following additional requirements:

- Introduction is limited to 1 page.
- Specific Aims is limited to 1 page.
- Research Strategy, including tables, graphs, figures, diagrams, and charts is limited to **12 pages** and must address the following components:

The **first phase** of the research proposal will use evidence synthesis to determine the effective strategies to communicate, translate, disseminate, and implement patient-centered research findings that can be used to reduce racial/ethnic healthcare disparities in under-resourced settings through stakeholder engagement and shared decision making. It is recognized that the current research on effective strategies to reduce disparities for key clinical topics may not include strategies specific to racial/ethnic minorities in under-resourced settings. Therefore, it is possible that the evidence synthesis for this project may utilize literature that is not specific to the clinical topic identified but in which the information can be applied to this population and setting. Phase one must be completed by the end of year one of funding. Phase two funding for continuation of the project is dependent on the successful and timely completion of the objectives described in Phase I.

The **second phase** of the research proposal must engage diverse stakeholder representatives (derived from

racial/ethnic minority consumer and patient groups, organizations, clinicians, policy, health education, information technology, and diverse health system communities including under-resourced settings) in order to:

- 1) identify the most effective, evidence-based strategies that health care delivery systems, clinicians, and/or patients can utilize to improve racial/ethnic disparities in under-resourced settings through stakeholder engagement and shared decision making as identified in step one,
- 2) design an implementation and evaluation plan for these strategies that can be replicated by stakeholders in diverse settings representing diverse patient populations, and
- 3) provide a platform for continuing dialogue with AHRQ and other pertinent HHS agencies regarding ongoing solutions to improve the access and quality of healthcare for racial/ethnic minority populations.

Phase I establishes what, why, and how the PCOR findings can be used to inform strategies to reduce racial/ethnic disparities in under-resourced settings. The following two components must be addressed in Phase I:

Priority Setting

- 1) For Phase I, applicants must describe the process that will be used to identify priority areas specific to racial/ethnic disparities in under-resourced settings. As part of this process, AHRQ will be actively engaged and have a key role in assisting with identifying priorities. A rationale for the selected process must be provided in the application.
- 2) The priorities selected must include rationale for their inclusion.
- 3) The priorities selected must represent persistent and important racial/ethnic disparities (e.g., as identified by AHRQ's *National Healthcare Disparities Report*) in under-resourced settings.

Data and Evidence Reviews

- 1) The evidence synthesis will determine effective evidence-based strategies to communicate, translate, disseminate, and implement patient-centered research findings that can be used to reduce racial/ethnic healthcare disparities in under-resourced settings through stakeholder engagement and shared decision making.
- 2) The proposed methodology to conduct the evidence reviews must be provided with adequate justification in the application.
- 3) The data synthesis that will serve as the evidence to guide the strategies may be pulled from literature that does not necessarily represent under-resourced settings, but it must have the capacity to be applied, appropriately, to these settings.

Phase II takes place in the second and third years of the project and focuses on the use of knowledge gained from phase one to engage diverse stakeholders to develop effective strategies to reduce racial/ethnic disparities through shared decision making in under-resourced settings, and developing an implementation and evaluation plan of the proposed strategies. Stakeholder engagement and an impact evaluation should be addressed in the application:

Stakeholder Engagement

- 1) Phase two requires the involvement and feedback from diverse stakeholders (e.g., organizations, community groups, health care delivery systems, clinicians, and/or patients) that represent ethnic/racial minorities, priority areas identified from phase one, and under-resourced settings. The clinicians identified must also represent diverse credentials (e.g., nurses, physicians, social workers, pharmacists).
- 2) The application should detail the methodology for stakeholder outreach and engagement, including justification.
- 3) Stakeholders should provide feedback on topics such as: (a) effectiveness of traditional, social media and Health Information Technology (HIT) methods for translation, dissemination, and implementation of PCOR findings and products targeting racial and ethnic minority populations in under-resourced settings; (b) the value of information, how the key stakeholders (health care delivery systems, clinicians, and/or patients) use information in decision making, and effective ways to measure the impact on these target audiences; and (c) setting priorities to assist users of HIT and implementers of traditional methods of dissemination to better promote incorporation of PCOR findings that can be used to reduce

healthcare disparities of racial/ethnic minorities in under-resourced settings.

4) Applicant should seek out consultation from experts related to key topics such as patient centered communication, knowledge transfer, health literacy, shared decision making, cultural and linguistic competency, cognitive theory, health disparities, under-resourced settings, and health information technology and social media.

5) The strategies identified can be innovative and extend beyond patient education as a primary strategy. Although education may be one strategy, strategies identified should address health care delivery systems, clinicians, and/or patients.

6) The process for engaging stakeholders, the strategies for reducing disparities in under-resourced settings through shared decision making, and the implementation and evaluation plan identified should be able to be replicable in diverse settings with diverse populations.

Impact Evaluation

1) Evaluation of the proposed strategies will involve quantitative and qualitative assessment of stakeholder engagement, as well as the effectiveness of translating, disseminating and implementing PCOR findings into the health care delivery systems serving racial/ethnic minority populations through shared decision making between clinicians and patients in under-resourced settings.

2) The evaluation plan must identify how other stakeholders in diverse settings that serve diverse populations would evaluate the implementation of the strategies identified in the handbook.

Research Strategy: Additional Requirements

The Research Strategy section should also address the following:

1) Explain how the proposed plan will engage key stakeholders (e.g., patients, communities, clinicians), employ novel and viable partnerships, approaches, or techniques to reduce racial/ethnic healthcare disparities; a timeline outlining anticipated completion of key objectives is encouraged.

2) Describe the composition, roles, responsibilities, and contribution of partners and stakeholders.

3) Describe the expertise of key personnel in relation to each phase of the proposed work that demonstrates an ability to successfully complete the project.

4) Describe previous experience establishing partnerships with relevant stakeholders

representing racial/ethnic minority populations and under-resourced settings.

5) Describe the dissemination plan, which may include a tool, and how the dissemination of information will be made available to the public.

Budget Component: Special Instructions for AHRQ applications

AHRQ is **not** using the Modular Grant Application and Award Process. Applicants for funding from AHRQ should ignore application instructions concerning the Modular Grant Application and Award Process, and prepare applications using instructions for the Research and Related Budget Components of the SF 424 (R&R). Applications submitted in the Modular format will not be reviewed.

Appendix

Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide with the following modification:

An appendix should be used to include a timeline describing the work that will be completed in Phase I and Phase II of the project. This material should supplement the discussion in the body of the research strategy. This appendix may not be greater than 2 pages in length.

3. Submission Dates and Times

[Part I. Overview Information](#) contains information about Key Dates. Applicants are encouraged to submit applications before the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via [Grants.gov](#), the online portal to find and apply for grants across all Federal agencies. Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons](#), NIH's electronic system for grants administration.

Applicants are responsible for viewing their application before the deadline in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review](#).

5. Funding Restrictions

For efficient grant administration, AHRQ grant administration procedures will be used and conducted in accordance with the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement. The Grants Policy Statement can be found at <http://www.ahrq.gov/funding/grants/policies/hhspolicy.html>.

Pre-award costs are allowable. A grantee may, at its own risk and without AHRQ prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award if such costs are necessary to conduct the project and would be allowable under the grant, if awarded, without AHRQ prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain AHRQ approval before incurring the cost. AHRQ prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on AHRQ either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. AHRQ expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project.

6. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. [Section III. Eligibility Information](#) contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit [Applying Electronically](#).

Important reminders:

The PD/PI must include his/her eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to AHRQ.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

See [more tips](#) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH, and for responsiveness by AHRQ. Applications that are incomplete and/or nonresponsive will not be reviewed.

In order to expedite the review, applicants are requested to notify the AHRQ Referral Office by email Gerald.Calderone@ahrq.hhs.gov when the application has been submitted. Please include the FOA number and title, PD/PI name, and title of the application.

Institutional Review Board (IRB) approval of human subjects is not required prior to peer review of an application (see <http://grants.nih.gov/grants/guide/notice-files/NOT-HS-00-003.html>). However, initiation of IRB review, if necessary or applicable, is strongly encouraged to assure timely commencement of research.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within eight (8) weeks.

Priority Populations

AHRQ supports research, evaluations, and demonstration projects concerning the delivery of health care in inner-city and rural areas (including frontier areas), and health care for priority populations. Priority populations include low income groups; minority groups; women; children; the elderly; and individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care. 42 USC 299(c). Women and members of minority groups are included in all AHRQ-supported research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate, e.g. because of the lack of connection between the study and the health of women or particular minorities. Investigators should review the document entitled, "AHRQ Policy on the Inclusion of Priority Populations," which is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-HS-03-010.html>. Applicants under this FOA should consider and discuss including priority populations in the research design as specified in this Notice.

Plan for Sharing Research Data

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants who are planning to share data should describe briefly the expected schedule for data sharing; the format of the final dataset; the documentation to be provided; whether or not any analytic tools also will be provided; whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use); and the mode of data sharing (e.g., under its own auspices by mailing a disk or posting data on its institutional or personal website or through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement. References to data sharing may also be appropriate in other sections of the application.

The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

Data Confidentiality

The AHRQ confidentiality statute, 42 USC 299c-3(c), requires that information that is obtained in the course of AHRQ supported activities and that identifies individuals or establishments be used only for the purpose for which it was supplied. Information that is obtained in the course of AHRQ-supported activities and that identifies an individual may be published or released only with the consent of the individual who supplied the information or is described in it. There are civil monetary penalties for violation of the confidentiality provision of the AHRQ statute. 42 USC 299c-3(d). In the Human Subjects section of the application, applicants must describe procedures for ensuring the confidentiality of the identifying information to be collected. The description of the procedures should include a discussion of who will be permitted access to this information, both raw data and machine readable files, and how personal identifiers and other identifying or identifiable data will be restricted and safeguarded. Identifiable patient health information collected by grantees under this FOA will also be obtained and managed in accordance with the HIPAA Privacy Rule, 45 CFR Parts 160 and 164.

The grantee should ensure that computer systems containing confidential data have a level and scope of security that equals or exceeds that established by the HIPAA Security Rules if applicable (see HIPAA website in prior paragraph) and

that established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III - Security of Federal Automated Information Systems. The applicability and intended means of applying these confidentiality and security standards to subcontractors and vendors, if any, should be addressed in the application.

Sharing Research Resources: Rights in Data

Unless otherwise provided in grant awards, AHRQ grantees may copyright, or seek patents for, as appropriate, final and interim products and materials developed in whole or in part with AHRQ support, including, but not limited to, methodological tools, measures, software with documentation, literature searches, and analyses. Such copyrights and patents are subject to a royalty-free, non-exclusive, and irrevocable AHRQ license to reproduce, publish, use or disseminate for any purpose consistent with AHRQ's statutory responsibilities and to authorize others to do so for any purpose consistent with AHRQ's statutory responsibilities. In accordance with its legislative dissemination mandate, AHRQ purposes may include, subject to statutory confidentiality protections, making project materials, databases, results, and algorithms available for verification or replication by other researchers. In addition, subject to AHRQ budget constraints, final products may be made available to the health care community and the public by AHRQ or its agents if such distribution would significantly increase access to a product and thereby produce substantial or valuable public health benefits. Ordinarily, to accomplish distribution, AHRQ publicizes research findings but relies on grantees to publish research results in peer-reviewed journals and to market grant-supported products. AHRQ's Office of Communications and Knowledge Transfer (OCKT) wishes to be consulted in advance of publication in order to coordinate announcements of new AHRQ-supported research results with other AHRQ dissemination activities. Important legal rights and requirements applicable to AHRQ grantees are set out or referenced in AHRQ's grants regulation at 42 CFR Part 67, Subpart A (available in libraries and from the GPO's website at <http://www.gpoaccess.gov/cfr/index.html>) which incorporates additional applicable provisions on Rights in Data, including 45 CFR Part 74 and 37 CFR Part 401.

NOTE: Grantees must agree to the "Cooperative Agreement Terms and Conditions of Award" in Section VI.2.A "Award Administration Information".

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [NOT-OD-10-115](#).

Section V. Application Review Information

1. Criteria

The mission of AHRQ is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. As part of this mission, applications submitted to AHRQ to support health services research are evaluated for scientific and technical merit through the AHRQ peer review system.

Applications that are complete and responsive to the FOA will be evaluated for scientific and technical merit by an appropriate peer review group convened in accordance with standard AHRQ peer review procedures that are described in 42 CFR Part 67, Subpart A. Incomplete and/or non-responsive applications or applications not following instructions given in this FOA will not be reviewed.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit will be discussed and assigned a priority score
- Receive a written critique

Administrative Criteria: Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH, and for responsiveness by AHRQ.

Merit Review Criteria: Merit Review Criteria, as described below, will be considered in the review process.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a

sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

If the proposed aims of the application are achieved, how will scientific knowledge or clinical practice regarding the reduction of disparities in racial and/or ethnic minorities in under-resourced settings be advanced? What will be the effect of this project on PCOR specific to disparities in racial and/or ethnic minorities in under-resourced settings that will drive the dissemination and implementation of knowledge?

Investigator(s)

Are the PD/PI, collaborators, and other researchers appropriately trained, experienced and well suited to carry out the work specific to PCOR, healthcare disparities in racial and ethnic minorities, and under-resourced settings? Is the work proposed appropriate to the experience level of the PD/PI and other researchers? Do the PD/PI and investigative team bring complementary and integrated expertise to the project? Is the leadership approach, governance and organizational structure appropriate for the project? Does the PD/PI demonstrate a realistic strategy to manage the project and the research team, which takes into consideration key personnel's organizational affiliation?

Innovation

Is the project original and innovative? For example: Does the project challenge current research or seek to shift clinical practice paradigms specific to PCOR, healthcare disparities in racial and/or ethnic minorities, shared decision making, and under-resourced settings while addressing an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches or methodologies, tools, or technologies for this area?

Approach

Are the PCOR conceptual framework, design, methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims and specific research requirements of the project? Does the applicant outline in 12 month increments the work planned and the key personnel assigned to each phase that will contribute to the success of the project? Does the applicant acknowledge potential problem areas in addressing healthcare disparity reduction in ethnic and/or racial minorities in under-resourced settings and consider alternative strategies? Are plans described for the successful and effective implementation and dissemination of strategies along with an evaluation plan that can be used in diverse settings with diverse populations presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

Environment

Do(es) the scientific environment(s) in which the work will be done contribute to the probability of success? Does the proposed project focused on PCOR and healthcare disparity reduction in racial and ethnic minorities in under-resourced settings benefit from unique features of the scientific environment(s), or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support? Does the budget appear to be reasonable to the potential contribution of the research?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt

under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

Degree of Responsiveness

Reviewers will assess how well the application addresses the purpose and objectives of this FOA. How responsive is the application to the special eligibility criteria, including the project requirements, noted in the FOA? [NOTE: Information may be added here]

Inclusion of Priority Populations

Adequacy of plans to address the needs of both genders, racial and ethnic minorities (and subgroups). Adequacy of attention to AHRQ priority populations (see above discussion on Priority Populations in section IV.6 "Other Submission Requirements").

Budget and Period of Support

The committee will evaluate whether the proposed budget is reasonable and whether the requested period of support is appropriate in relation to the proposed research. [

Privacy and Security Protections for Patients

Reviewers will assess the resources and processes to be used to address privacy and security issues in the development and implementation of the intervention.

Resubmissions

Not Applicable

Renewals

Not Applicable

Additional Review Considerations

Not Applicable

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group in accordance with AHRQ review policy and procedures, using the stated [review criteria](#). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Applications will compete for available funds with all other recommended applications submitted in response to this FOA. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by peer review.
- Availability of funds.
- Responsiveness to goals and objectives of the FOA.
- Relevance and fit within AHRQ portfolio priorities, as well as overall programmatic balance.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons](#).

Generally, applicants should anticipate eight months between the application submission date and the earliest possible start date.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, AHRQ will request "Just-In-Time" information from the applicant. Just-In-Time information generally consists of information on other support, any additional information necessary to address administrative and budgetary issues, and certification of IRB approval of the project's proposed use of human subjects. For details regarding IRB approval, applicants may refer to the "AHRQ Revised Policy for Institutional Review Board (IRB) Review of Human Subjects Protocols in Grant Applications" (<http://grants.nih.gov/grants/guide/notice-files/not-hs-00-003.html>).

Once all administrative and programmatic issues have been resolved, a formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the AHRQ grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in [Section IV.5. Funding Restrictions](#).

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NOA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See also [Section IV.5.](#), "Funding Restrictions."

Any application awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements as noted on the AHRQ web site at <http://www.ahrq.gov/fund/postawrd.htm#terms>.

2. Administrative and National Policy Requirements

All AHRQ grant and cooperative agreement awards are subject to AHRQ's grants regulations at 42 CFR Part 67, Subpart A, the HHS Grants Policy Statement (see <http://www.ahrq.gov/funding/grants/policies/hhspolicy.html>), and the terms and conditions set forth in the Notice of Award.

As necessary, additional Terms and Conditions will be incorporated into the NoA.

Activities conducted under this award that involve the collection of information e.g., conducting surveys or requesting responses to uniform questions from nine or more persons, establishments or other entities, are currently required by HHS to be cleared by OMB under the Paperwork Reduction Act (PRA) (44 USC 3501-3521). Submissions for clearance under PRA are through AHRQ and HHS. Therefore, affected grantees should include the time in their proposed timelines to develop materials and receive necessary clearances. It typically takes at least six months from date of initial submission to AHRQ to receive clearances, and sometimes much longer if submissions are incomplete or the justification for the proposed data collection plans are questioned during the clearance process. Information collection that requires PRA clearance may not begin until grantees receive written notification via e-mail from AHRQ that clearance has been obtained. Detailed information on the PRA can be found at <http://www.hhs.gov/ocio/policy/collection/>.

Cooperative Agreement Terms and Conditions of Award

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to otherwise applicable OMB administrative guidelines: DHHS grant administration regulations at 45 CFR Parts 74 or 92 (Part 92 is applicable for State and local Governments), and other DHHS, PHS, and AHRQ grant administration policy statements.

The administrative and funding instrument used for this program is the cooperative agreement. A cooperative agreement is an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial AHRQ programmatic involvement with the grantee is anticipated during the performance of the activities. Under the cooperative agreement, the AHRQ purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the PD/PI for the project as a whole, although specific tasks and activities may be shared between a grantee and AHRQ as described in this subsection of the FOA. Cooperative activities are intended to strengthen the individual grantee activities through the facilitation of data sharing, data access and communications.

All cooperative activities that include significant government involvement will require prior approval by the AHRQ Program Official.

Program Director/Principal Investigator (PD/PI) Rights and Responsibilities

The PD/PI will have the primary responsibility for providing leadership for the project as a whole including all elements as described in phase I and II in the research plan component. The PD/PI will also be responsible for communication with AHRQ program staff on scientific and operational matters.

AHRQ Responsibilities

AHRQ program staff will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. This includes the following items:

- Ensuring that patients, families, and community input is integrated throughout the process.
- Ensuring diversity in the selection of stakeholders that are involved in the project.
- Conducting regular conference calls with project staff to review workflow, products, and timelines.
- Being actively engaged and having a key role in assisting with the identification of priorities.
- Participating in team meetings and/or stakeholder calls as negotiated with PD/PI.
- Evaluating the successful completion of each phase.
- Reviewing all documents specified herein.
- Providing conceptual, consultative, and technical assistance throughout the process.
- Ensuring that the timeline is reasonable, measurable, and achieved.

Additionally, AHRQ program staff will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

Collaborative Responsibilities

When appropriate and feasible, AHRQ expects awardees to work with each other to identify collaborative opportunities that can contribute to the overall success of their projects. These collaborative relationships may be facilitated by AHRQ program officials or contractors; instigated by the awardees through self-identified opportunities, or developed via other mechanisms during the life of the project. It is expected that the projects will be conducted in a dynamic environment with AHRQ reviewing the results on an ongoing basis.

3. Reporting

When multiple years are involved, grantees will be required to submit the [Non-Competing Grant Progress Report \(PHS 2590\)](#) annually.

The annual progress reports must include Sections 2.2.6 A through F as described in the general PHS form 2590 instructions. For details regarding progress report submission, refer to <http://www.ahrq.gov/fund/noncomp.htm>. If instructions on the AHRQ website are different from the PHS form 2590 instructions, follow the instructions on the AHRQ website.

The Progress Report is to include descriptive and evaluative comments on both completed activities and plans for the remainder of that year and for the upcoming year, including any changes foreseen in the future. At a minimum, the reports

will include descriptive comments on: progress to date measured against project aims; methodological changes implemented; key preliminary findings; significant problems and resolutions; inclusion of priority populations; and project related publications, presentations, and dissemination activities. AHRQ does not currently limit the length of the progress report to 2 pages. AHRQ will provide the due date for submitting annual progress reports. In addition to the annual progress report, recipients may be required to submit quarterly progress reports to AHRQ. Detailed instructions on reporting requirements will be provided with the grant award.

Expenditure data is to be reported on the Federal Financial Report (FFR; SF 425). AHRQ requires annual financial expenditure reports for ALL grant programs as described in the HHS Grants Policy Statement (see <http://www.ahrq.gov/funding/grants/policies/hhspolicy.html>). AHRQ implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends. Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 4/30/2013, the annual FFR is due 9/30/2013 (90 days after the end of the calendar quarter of 6/30/2013).

A final Progress Report, final Federal Financial Report, and Final Invention Statement are required when an award ends. All final reports are due within 90 days of the project period end date. For further details regarding grant closeout requirements, refer to <http://www.ahrq.gov/fund/closeout.htm>.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

[Grants.gov Customer Support](#) (Questions regarding Grants.gov registration and submission, downloading or navigating forms)

Contact Center Phone: 800-518-4726

Email: support@grants.gov

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)

Telephone 301-435-0714

TTY 301-451-5936

Email: GrantsInfo@nih.gov

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues)

Phone: 301-402-7469 or 866-504-9552 (Toll Free)

TTY: 301-451-5939

Email: commons@od.nih.gov

Scientific/Research Contact(s)

Direct your questions about general FOA issues, including information on the inclusion of priority populations to:

Jennifer E. Moore, Ph.D., R.N.

Agency for Healthcare Research and Quality

Office of Extramural Research, Education, and Priority Populations

Telephone: (301) 427-1394

Fax: (301) 427-1562

E-mail address: Jennifer.Moore@ahrq.hhs.gov

Peer Review Contact(s)

Direct your questions about peer review issues of grant application made in response to this FOA:

Ying Tian, M.D., Ph.D.

Agency for Healthcare Research and Quality (AHRQ)
 Office of Extramural Research, Education, and Priority Populations
 Division of Scientific Review
 Telephone: (301) 427-1530
 Fax: (301) 427-1562
 E-mail address: Ying.Tian@ahrq.hhs.gov

Financial/Grants Management Contact(s)

Direct your questions regarding fiscal matters to:

Nicole Williams
 Office of Performance Accountability, Resources and Technology
 Grants Management
 Agency for Healthcare Research and Quality
 Telephone: (301) 427-1015
 Fax: (301) 427-1462
 E-mail address: Nicole.Williams@ahrq.hhs.gov

Section VIII. Other Information

Recently issued AHRQ policy notices may affect your application submission. A full list of policy notices published by AHRQ is provided in the [NIH Guide for Grants and Contracts](#). Notices can also be found at [AHRQ Grants Policy Notices](#). All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations

This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authority of 42 USC 299 et seq. and, 42 CFR Part 67 and in accordance with 45 CFR Parts 74 or 92 and other referenced applicable statutes and regulations. All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement. The HHS Grants Policy Statement can be found at <http://www.ahrq.gov/funding/grants/policies/hhspolicy.html>.

[Weekly TOC for this Announcement](#)
[NIH Funding Opportunities and Notices](#)

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