REQUEST FOR PROPOSAL - Expert Stakeholder Interviews to Identify Evidence for Eliciting the Patient’s Perspective in Patient-Centered Outcomes Research (Interviews)

BACKGROUND AND INTRODUCTION

The Patient-Centered Outcomes Research Institute (PCORI) is an independent, non-profit research organization created by the Patient Protection and Affordable Care Act of 2010. The mission of PCORI is to help people make informed health care decisions – and improve health care delivery and outcomes – by producing and promoting high-integrity, evidence-based information derived from research guided by patients, caregivers and the broader health care community. Research commissioned by PCORI aims to be responsive to the values and interests of patients and provide patients and those who care for them with reliable, evidence-based information for the health care choices they face.

The Methodology Committee of the Patient-Centered Outcomes Research Institute (PCORI) has been tasked with preparing a Methodology Report by May 2012 that outlines existing methodologies for conducting patient-centered outcomes research (PCOR), proposes appropriate methodological standards, and identifies important methodological gaps that need to be addressed. This solicitation addresses one component, namely methods for eliciting the patient’s perspective.

There has been a large body of work that has determined effective methods for eliciting the patient’s perspective in a range of issues relevant to the mission and work of PCORI. In a companion solicitation we are requesting a comprehensive literature review to identify effective methods. Because there may be knowledge of effective methods for eliciting patient’ perspectives not be found in the literature, we are also interested in soliciting input of this topic from knowledgeable and experienced experts and individuals. In this solicitation we request that the applicant conduct key informant interviews with individuals from several stakeholder groups who are expert in eliciting the patients’ perspective stakeholder. The goal of the interviews is to ascertain what is known on the questions of interest listed below, synthesize the findings of these interviews, make recommendations for best practices as appropriate, and identify key knowledge gaps.

The applicant must systematically identify and interview members from each of the following stakeholder groups: patients; caregivers; advocates/community organizers; health care providers (including but not limited to physicians and nurses); payors (private and public); researchers, including those engaged in community participatory research; pharmaceutical and medical device industry representatives; government representatives/regulators (e.g., NIH, AHRQ, FDA, CMS); consumer advocacy organizations (inside and/or outside of health care); and industry/business (outside of health care). There may be overlap of individuals/organizations in these categories, and some the categories may be grouped. In the case of
patients and caregivers, the applicant must identify and interview representative members of the diverse spectrum of patients and caregivers. In the case of the other groups, the interviewees must have expertise and experience in methods that are effective in eliciting the patients’ perspectives. The final product will be a well-reasoned report with answers to the questions posed below. Because this report will be a crucial piece of the methodology report mandated by Congress to be completed by May 2012, only respond to this solicitation if you are certain that you and your organization can complete this work by the due date of March 1st, 2012. There will be no extensions. Full payment will be predicated on completing a high quality report, as judged by the PCORI Methodology Committee, by the due date.

This document provides background information on the solicitation, an outline of the final product (to guide your proposal and planned work, and an application form to complete and return by October 6th, 5pm EDT 2011.

**Key Dates**

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<th>Date</th>
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<tr>
<td>August 31st, 2011</td>
<td>Solicitation issued</td>
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<tr>
<td>September 15th, 2011</td>
<td>E-mail to <a href="mailto:PCWG@PCORI.org">PCWG@PCORI.org</a> noting your intent to respond to solicitation required</td>
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<tr>
<td>October 6th, 2011</td>
<td>Proposals Due</td>
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<td>October 13th, 2011</td>
<td>Selection of Final Candidate</td>
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<tr>
<td>March 1st, 2012</td>
<td>Final Report Due</td>
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**TOTAL CONTRACT AMOUNT**

Up to $300,000 in total funding will be awarded for this contract. It is anticipated that only one contract will be awarded. Cost will be considered - along with the quality of the proposal and specific plans to complete the required work and deliverables - in the selection process.

PCORI will pay indirect costs up to 40% of total direct costs; the total allowable dollar amount is inclusive of indirect costs. NIH salary caps apply.

**ELIGIBILITY**

This solicitation for a single contract is being issued as full and open. The following types of applicants are eligible to apply:
Higher Education Institutions:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Organizations) (Provided that the benefit to the US health care system and US efforts in the area of patient-centered research...
• Foreign (non-U.S.) components of U.S. Organizations (Provided that the benefit to the US health care system and US efforts in the area of patient-centered research

STATEMENT OF WORK

Introduction

Informed clinical decision-making requires input from a spectrum of individuals such as researchers who generate the evidence, clinicians who care for patients, and patients themselves. In this solicitation we focus on methods for eliciting the patient’s voice or perspective. PCORI is interested in all steps in the comparative effectiveness research (CER) process, beginning with identification of research questions that are most important to patients and including selection of population and settings, intervention comparators, outcomes and other aspects of study design. We are soliciting proposals from institutions and individuals with expertise and experience in: 1) eliciting the input of patients and/or surrogates (particularly those with a burden of chronic conditions and who represent patient populations that are often hard to reach); 2) knowledgeable in systematically identifying expertise among the key stakeholder groups on this topic; and 3) conducting qualitative interviews involving these stakeholder groups.

An overarching goal of Patient-Centered Outcomes Research (PCOR) is to help people make informed health care decisions and allow their voice to be heard in assessing the value of health care options. When considering the definition of PCOR, the PCOR Methodology committee decided PCOR should answers questions like, “Given my personal characteristics, conditions and preferences, What should I expect will happen to me? What are my options and what are the benefits and harms of those options? What can I do to improve the outcomes that are most important to me?”. A defining principle of PCOR is that it “allows the patient’s voice to be heard.”

The task is to translate this defining principle into the methodological underpinnings of PCOR. A Patient-Centeredness Workgroup of the Methodology Committee was established to determine what steps were needed to accomplish this task. The goal of this Workgroup is to keep the patient’s voice central to all aspects of PCOR. There was concern that patient’s voices were infrequently incorporated into the research questions posed and into the types of comparisons and outcomes being assessed, and in other aspects of health-related research.

Three domains that the Methodology Committee felt should be represented in all PCOR include: 1) assessment of benefits and harms to inform decision making, highlighting comparisons and outcomes that matter to people; 2) a focus on outcomes that people notice and care about; and 3) the incorporation of a wide variety of settings and diversity of participants. These domains are represented in current work being proposed by the Patient-Centeredness workgroup.
The work described in this initial solicitation from the PCORI Methodology committee will inform the ongoing work of PCORI.

We are soliciting applications from individuals and institutions that have done work in this area or that have the experience and expertise to complete this work effectively and on time. A preexisting familiarity with the topic and ability to respond to an aggressive timetable are essential. More than one institution or individual can co-apply to ensure the necessary expertise and ability to complete the work on time.

**Required components of the project**

The successful applicant will be expected to identify organization and individuals with expertise in eliciting patients’ and individuals’ perspectives and conduct qualitative interviews of these individuals, addressing the questions posed in the application. Because insights into eliciting the patient’s voice may come from settings other than health care, the applicant will be expected to interview non-healthcare (e.g., industry) organizations and individuals as well as health care sources. Interviewees should include both U.S. and international experts as appropriate.

Key informants from the following groups must be identified and interviewed: patients; caregivers; advocates/community organizers; health care providers (including but not limited to physicians and nurses); payors (private and public); researchers, including those engaged in community participatory research; pharmaceutical and medical device industry representatives; government representatives/regulators (e.g., NIH, AHRQ, FDA, CMS); consumer advocacy organizations (inside and/or outside of health care); and industry/business (outside of health care). There may be overlap of individuals/organizations in these categories, and some of the categories may be grouped. In the case of patients and caregivers, the applicant must identify and interview representative members of the diverse spectrum of patients and caregivers. In the case of the other groups, the interviewee must have expertise and experience in methods that are effective in eliciting the patients’ perspectives. The applicant will use the results of these interviews to answer the questions posed under **Components of the Report**. For each set of questions, report what approaches have been effective and why; and describe how these approaches can directly inform PCORI.

In conducting this work, assume a broad PCOR research topic already exists and has been prioritized via a process which included the patient (or surrogate) perspective. We are interested in the subsequent steps of incorporating the patient (or surrogate) perspective into development of specific research questions within the broad topic. We are also interested in identifying methodological standards for incorporating the patient (or surrogate) perspective into study design components, including selection of population, interventions, comparators, outcomes, and setting/timing and others.
Statement of Objectives for Final Product

The product of the work described in this solicitation will be a report that addresses the specific questions posed below. The PCORI Methodology Committee is interested in what is already known about these topics that can be incorporated into subsequent PCORI research supported by PCORI and in what gaps exist that should be the topic of subsequent PCORI research. The final product will be a report that fills in the outline below. The sections of the report should describe the methods that have been effective at addressing the issues listed, describe the methods employed in synthesizing the applicants’ findings from the expert stakeholder interviews, and should summarize identified best practices, recommendations, and knowledge gaps.

Components of the Report

1. **Stakeholder interviews for ascertaining the data that address methods for engaging patients and other stakeholders**
   a. What practical methods are effective in engaging patients and their surrogates in 1) identifying and prioritizing research questions; 2) identifying outcomes that are meaningful to them; and 3) identifying comparators/interventions that are meaningful to them?
      i. What methods are effective in ensuring that the full spectrum of patients is represented, including hard to reach and under-represented patients?
   b. What methods are effective in ensuring that informants understand the pertinent clinical and research issues (e.g., framing risk-benefit tradeoffs) so that results can meaningfully inform decision making?
   c. What data are available that identify other factors and issues that are important to patients (or surrogates) that need to be considered?
   d. What practical methods are effective in determining whether other stakeholders (e.g., advocates, clinicians) accurately reflect the patients’ perspective in: 1) identifying and prioritizing research questions; 2) identifying outcomes meaningful to patients; and 3) identifying comparators/interventions that are meaningful to patients?
      i. Under what situations is it appropriate to engage these stakeholders as surrogates or representatives of patients?
      ii. What methods are effective in ensuring that responses elicited from stakeholders accurately represent the patient perspective?
      iii. What methods are effective in identifying and engaging these stakeholders?

2. **Methods for synthesizing findings and accounting for heterogeneity**
   a. What methods are effective in synthesizing the information elicited by engaging patients, their surrogates, and other stakeholders? Address strategies necessary to assure adequate representation
of the population of interest, incorporating diversity of perspectives, balancing quantitative and qualitative analyses, and creating typologies that capture the range of perspectives elicited.

**NOTE:** For items in 1 and 2, describe your approach to defining outcomes or metrics to define “effective.” That is, please describe what outcomes you propose to measure in determining that the method was effective.

3. **Recommendations and best practices**
   a. Synthesize the results of your work to provide a practical and stepwise roadmap for integrating the patient perspective into processes to 1) identify and prioritize research questions; 2) identify outcomes meaningful to patients; and 3) identify comparators/interventions meaningful to patient.
   b. Briefly describe the design pilot projects or other activities to implement the recommended methods and to evaluate whether these methods are effectively capturing the patient (or surrogate) perspective.

4. **Knowledge and evidence gaps**
   a. Describe the most important knowledge gaps/areas of needed research that you have identified in completing this work that you think should be the focus of methodological research by PCORI. Prioritize these gaps as appropriate.

**Project management requirements - Calls and written Status Reports**
   a. Throughout the contract period, awardees are required to attend bi-weekly Methodology Committee Patient-Centeredness Sub-committee calls to provide updates of progress. Written status reports will also be required every 8 weeks during the contract period, including: 1) an overview of the status of completion of deliverables including specifics of the literature search and landscape scans; 2) a description of progress addressing discrete Components of the Report (detailed above); 3) a description of challenges encountered, potential risks and associated mitigation strategies.
   b. The awardee will be required to attend and possibly present at a PCORI workshop in Washington, DC in 2012.

**Additional reporting requirement**

A final report is due 90 days following the end of the funding period. This report must include:

   b. A non-technical summary of study findings, written in language understandable to patients and providers that includes the following:
i. A summary of the study methods, key findings, and interpretations of the relevance of findings to patients and clinicians.

ii. If applicable - specific discussion of any possible differences in study findings or conclusions among patient subgroups defined by age, gender, race/ethnicity, socio-economic, clinical, or genetic makeup (if studied).

**EVALUATION CRITERIA**

Selection of an offer for contract award will be based on an evaluation of proposals against two factors. The factors are: technical merit and price. Proposals shall first be evaluated from a technical standpoint based on the technical proposal and the technical evaluation criteria defined below without regard to proposed price. For those proposals determined to be technically acceptable, Price, which is not a numerically weighted factor, will be evaluated.

1. **Approach (40 points)**
   
a. Proposals will be evaluated based on the understanding of the project goals and of the approach applicants will use to conduct the interviews, including methods used
   
i. to systematically identify individuals with expertise in eliciting patients’ perspectives within each category of stakeholders to ensure a comprehensive sampling (the stakeholder groups that must be included in the interviews are listed in Section *Required components of the project*);
   
ii. to determine that necessary number of interviews have been completed and that theme saturation has been reached within each category of stakeholder.

b. Evaluation of the of approach for synthesizing the information developed through the review and scan in order to complete the components of final report as outlined.

c. Evaluation of the outline of the final report.

2. **References and Past Performance (include a list of publications and products as appropriate) (25 points)**
   
a. Proposals will be evaluated based on the applicants’ and co-applicants’ past experience in conducting work in the content area (including health care and non-health settings).

b. Evaluation criteria include an assessment of the applicants’ past experience of completing similar scopes of work within a similar time frame.
3. **Staff Capabilities (25 points)**

   a. Proposals will be evaluated on the qualifications and experiences of key staff who will be working on this project and associated project role(s) and responsibilities.

   b. Evaluation criteria will include an assessment of the staff to complete the scope work in the prescribed time frame.

4. **Timeline including an outline of major milestones to inform the milestone reports (10 points)**

   a. Proposals will be evaluated on the production of a timeline outlining completion dates of interim deliverables to assure completion of the project by the non-negotiable deadline of March 1\(^{st}\) 2012.

*Note: Given comparable quality of proposals and completeness of research plans, we will give preference to the proposal with the lowest total costs.*

**ABOUT PCORI POLICIES**

*Conflict of Interest* – PCORI requires disclosure of any potential conflicts of interest (see attached form) as part of the application.

*Use of research findings* – PCORI considers the sharing of unique research resources developed through PCORI-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with PCORI funds and the associated research findings published or provided to PCORI, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. If the final data/resources are not amenable to sharing, this must be explained in the application.

*Use of contracted work* – The reports generated under this contract become the property of PCORI. PCORI retains the rights to publish these materials in whole or in part. Contracted authors are free to publish other paper(s) derived from work conducted under this contract, with or without participation of PCORI representatives, but they cannot publish the Report or parts of the Report. The contracted authors must acknowledge PCORI funding in any such publication. The contracted author must also state explicitly that the work does not necessarily represent the views of PCORI unless the publication includes PCORI representatives as co-authors and has been reviewed and approved by PCORI.
INSTRUCTIONS FOR COMPLETING THE PROPOSAL

A contractor to complete this work will be selected by PCORI based on submission of an Application, comprised of the sections described below. Application Sections 1-4 should be 12 pages or less, Times Roman 12 or Arial 11 font, single spaced (not including references). Number of pages may be allocated amongst the 1-4 as necessary to best convey your capability of completing the proposed work thoroughly, well, and on time.

Overview of sections:

1. **Approach**

   b. Description of approach to conduct the interviews, including:

      iii. Method used to systematically identify individuals with expertise in eliciting patients’ perspectives within each category of stakeholders to ensure a comprehensive sampling (the stakeholder groups that must be included in the interviews are listed in Section Required components of the project);

      iv. Method used to determine that necessary number of interviews have been completed and that theme saturation has been reached within each category of stakeholder.

   c. Description of approach for synthesizing the data discovered in the review and scan in order to complete the components of final report as outlined.

   d. Outline of the final report.

2. **References and Past Performance (include a list of publications and products as appropriate)**

   a. Description of relevant past experience and qualifications of applicant.

   b. List of applicant’s prior work directly relevant to the specific project scope outlined above.

3. **Staffing (please identify key staff)**

   a. Description of relevant past experience and qualifications of key staff working on project as well as a description of associated roles and responsibilities.

   b. Description of how staffing approach will ensure timely completion of scope of work.
4. **Timeline including major milestones**
   
a. Present a detailed timeline of interim deliverables that assure completion by the nonnegotiable deadline and will inform the status reports.

5. **Contracting**
   
a. Inclusion of signed letter from respective contracting authority ensuring the contract can be executed by October 31st, 2011 with an anticipated project start date of November 1st, 2011.

6. **Biosketches/Curriculum Vitae of key personnel (4 page limit is preferred; may be NIH biosketch or other style)**

**E-mail Notification of Intent to Bid**

The required e-mail notification of intent to bid should be e-mailed to PCWG@PCORI.org. Please include “Interviews” in the subject line and provide your name or name of organization and contact address as well as a short note describing your intent to respond to this solicitation in the body of the e-mail.

**Submission**

Proposals must be submitted in electronic format to arrive by 5pm EDT on October 6th, 2011 and two hard copies of the proposal must be received by 5pm EDT on October 7th, 2011. Both submissions must include the following information:

   a) Proposal that follows the INSTRUCTIONS FOR COMPLETING THE PROPOSAL
   b) Summary of Investigator Qualifications (CVs or biosketches) of Personnel
   c) Proposed budget with detailed justification i.e. line item budget
   d) Three examples of relevant written work related to the topic of this solicitation and/or CER/PCOR in general. See Past Performance section.
   e) Completed Conflict of Interest Disclosure Form (please see last page of RFP for form)
   f) Signed letter from contracting authority stipulating that the contract will be executed by October 31st, 2011.

In your proposal, please clearly label each section as listed above.
The proposal should be e-mailed to PCWG@PCORI.org (Please include “Interviews” in the subject line) and two hard copies sent by US Postal Service to:

Patient-Centered Outcomes Research Institute (PCORI)
c/o Gail Shearer
ATTN: PCORI Request for Proposal – Interviews (Patient-Centeredness WG)
1701 Pennsylvania Ave., NW, #300
Washington, DC 20006

Accepted proposals will be notified by phone and announced via www.pcori.org by October 14th, 2011.

Proposals that do not directly address all of the areas of interest specified in this RFP [PCORI-SOL-PCWG-002] will not receive further consideration.
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE
Conflict of Interest Disclosure Statement

1. Name: ____________________________________________________________

2. Date Submitted: _________________________________________________

3. List the nature of any conflict of interest:

____________________________________________________________________
____________________________________________________________________
____________________________________________________________________
____________________________________________________________________

The undersigned hereby affirms that he/she has disclosed any conflicts of interest that may have the potential to bias or has the appearance of biasing their obligations under the Services Agreement.

Signed: ____________________________________________________________

Print Name: _________________________________________________________

Title: _______________________________________________________________

Date: ________________________________________________________________

Definition:

“Conflict of interest”. The term “conflict of interest” means an association, including a financial, business, or personal association, that has the potential to bias or has the appearance of biasing an individual in matters related to the Patient-Centered Outcomes Research Institute (PCORI) or the conduct of PCORI activities.