REQUEST FOR PROPOSAL - Review and Synthesis of Evidence for Eliciting the Patient’s Perspective in Patient-Centered Outcomes Research (Literature Review)

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 to 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.

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. A defining principle of PCOR is ensuring that the patient’s voice and perspective drive every step of the research process, including prioritizing the research questions, designing and conducting the research, and implementing the results in practice. An initial step in this process is reviewing and synthesizing what is known about eliciting the patient’s voice and perspective and what important gaps need to be rapidly addressed to fulfill PCORI’s mission. For purposes of this solicitation we consider the patient, family, and other surrogates as relevant to eliciting the patient’s perspective.

In this solicitation, we request a comprehensive literature review, environmental scan, and a synthesis of findings with recommendations for best practices as appropriate, as well as identification of key knowledge gaps. The final product will be a well referenced and 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**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 31st, 2011</td>
<td>Solicitation issued</td>
</tr>
<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>
</tr>
<tr>
<td>October 6th, 2011</td>
<td>Proposals Due</td>
</tr>
<tr>
<td>October 13th, 2011</td>
<td>Selection of Final Candidate</td>
</tr>
<tr>
<td>October 14th, 2011</td>
<td>Anticipated announcement of awardee</td>
</tr>
<tr>
<td>October 31st, 2011</td>
<td>Execution of Contract</td>
</tr>
<tr>
<td>November 1st, 2011</td>
<td>Anticipated Start Date</td>
</tr>
<tr>
<td>March 1st, 2012</td>
<td>Final Report Due</td>
</tr>
</tbody>
</table>

**TOTAL CONTRACT AMOUNT**

Up to $215,000 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

PCORI is interested in identifying methods for integrating the patient perspective into the formulation of all steps in the patient-centered outcomes research (PCOR) 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.

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 PCORI 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 the Workgroup is to keep the patient’s voice central to all aspects of PCORI. There is concern that patient’s voices are infrequently incorporated into the research questions posed, 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 the 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

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. The successful applicant will be expected to conduct a structured and comprehensive review of the literature and environmental scan on the topic. Because much of the relevant information may be in sources other than peer reviewed publications, the applicant must also conduct an environmental scan of other relevant sources. Furthermore, because insights into eliciting the patient’s voice may come from settings other than health care, the applicant will be expected to review processes employed to engage people in non-health care as well as health care activities. The literature review and environmental scan should include both U.S. and international sources. The applicant will use the results of these literature review and environmental scan to answer the questions posed under Statement of Objectives for Final Product. For each set of questions, the applicant will report what approaches have been effective and why, and describe how these approaches can directly inform PCORI’s work.

In conducting this work, assume a broad PCOR topic already exists and has been prioritized via a process which included the patient 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, 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 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 literature review and environmental scan, and should summarize identified best practices, recommendations, and knowledge gaps.

Components of the Report

1) **Acquiring 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 determining categories of informants whose perspectives are salient?
ii. What methods are effective in identifying individuals who are representative of these categories?
iii. What qualitative and quantitative methods are effective in engaging and eliciting the perspectives of these individuals?
iv. What methods are effective in ensuring that the full spectrum of patients is represented, including hard to reach and under-represented patients?
v. What methods are effective in ensuring that informants understand and respond to pertinent clinical and research issues (e.g., framing risk-benefit tradeoffs)?
vi. What data are available that identify other factors and issues that are important to patients (or surrogates) that need to be considered?

b. 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.
   b. Describe how existing systematic and other reviews of relevant methods will be analyzed, synthesized, and included in the report.

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 (or surrogate) perspective into processes to 1) identify and prioritize research
questions; 2) identify outcomes meaningful to patients; 3) identify comparators/interventions meaningful to patients; 4) other results, if appropriate.

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

b. 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 environmental 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.

c. 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:

d. 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 on the approach the applicant proposes to conduct the literature review and environmental scan, including how the applicant will identify sources from health care and non-health care settings, to ensure a comprehensive overview of the available evidence.

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

   c. Evaluation of the process by which the applicant will translate the results of the data synthesis into best practices and knowledge gaps.

   d. Evaluation of the outline of the final report.

2. Past Performance (include a list of publications and products as appropriate) (25 points)

   a. Proposals will be evaluated based on the applicant’s and co-applicants’ past experience in conducting work in the content area (including health care and non-health settings).

   b. Evaluation criteria will 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 1st 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.

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 a proposal, comprised of the sections described below. Proposal 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**
   - a. Description of approach to conduct the literature review and environmental scan, including method used to identify sources from health care and non-health care settings, to ensure a comprehensive overview of the available evidence.
   - b. Description of approach for synthesizing the data discovered in the review and scan in order to complete the components of the final report as outlined.
   - c. 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 of should be e-mailed to PCWG@PCORI.org. Please include “Literature Review” 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) 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 “Literature Review” 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 – Literature Review (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-001] 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.