

REQUEST FOR PROPOSAL – Methods for Setting Priorities in Research

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 Outcome 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 set of methods relevant for PCOR, methods for research prioritization. The purpose of this RFA is not to identify research priorities for PCORI, but to solicit papers that can provide insights into how selected methods for identifying research priorities might be used by PCORI to inform the process of establishing research priorities. These methods can include: 1. Approaches for Topic Generation for Comparative Effectiveness Research (CER), 2. Use of Gap Analyses in Establishing Research Priorities, 3. Value of Information Analysis, and 4. Peer Review for Research Prioritization.

The interest in these methods by PCORI should be understood in the context of additional approaches for research prioritization by PCORI. Specifically, 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. This begins with identifying research questions that are important to patients, understanding how best to rank order those questions, determining the most credible sources of information to address those questions, assigning relative importance or ‘value’ to that information, interpreting the benefit of expert opinion in refining the answers to those questions and including selection of population and settings, intervention comparators, outcomes, and other aspects of study design. These critical methods will serve to shape future PCORI – initiated projects and allow a consistent and rigorous approach that will yield strong lines of evidence and thus potentially have a meaningful and beneficial impact on health care.

An overarching goal of patient-centered outcomes research 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 patient-centered outcomes research, the PCORI Methodology committee decided patient-centered outcomes research should answers questions like, “Given my personal characteristics, conditions and

Patient-Centered Outcomes Research Institute

Request for Proposal – White Papers

2011

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 patient-centered outcomes research is that it *"allows the patient's voice to be heard."*

The task is to translate these defining principles into the methodological underpinnings of PCORI. A Research Prioritization Workgroup of the Methodology Committee was established to determine what steps were needed to accomplish this task. One of the goals of the Methodology Committee 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 Patient-Centered Outcomes Research 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.

The work described in this 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.

STATEMENT OF WORK

In this request for applications, we seek background papers that explore one of several methodological areas relevant to research prioritization. We anticipate that these reviews will include a review of the literature that should be as systematic as possible, examples of innovative methods in this area, and gaps in knowledge that should be addressed in future research. A paper in a topic area may seek to review the entire area or to focus on some aspect of the area. The papers will be presented at a conference in early 2012 along with other authors and a reactor. The working paper should be of manuscript length (5,000 words or less), sources cited, and appendixes as needed. The author(s) or their designees must be available to present their paper at the conference expected to be held in the second half of January 2012.

Note: *More than one award may be made per topic area.*

The methodological areas relevant to research prioritization in which we are seeking papers are:

1. Approaches for Topic Generation for Comparative Effectiveness Research (CER)

Prioritization of research topics can only result in identification of the most important topics if a robust process exists to generate those topics as part of list of topics that would then be prioritized. We are interested in best practices in topic generation for PCOR (or in other areas of research) that can be used as models for PCORI. Models may be drawn from the United States or internationally and could be drawn from existing CER programs or other research areas where best practices in topic generation can be identified.

2. Use of Gap Analyses in Establishing Research Priorities

Gap analysis within systematic reviews can be used to identify questions that are not adequately addressed by existing knowledge. We are interested in best practices in Gap Analysis for PCOR (or in other areas of research) that can be used as models for PCORI. Models may be drawn from the United States or internationally and could be drawn from existing CER programs or other research areas where best practices in topic generation can be identified.

3. Value of Information Analysis

PCORI seeks papers that will address the potential use of value of information analysis by PCORI to inform research priorities. Three illustrative examples of the papers we might be interested in are the following:

Value of Information Analysis for Patient-Centered Research: This paper will examine the potential for value of information analysis to inform priorities for outcomes research that is specifically patient-centered. The emphasis should be on practical empirical methods that can be used to inform research priorities given the potential for individuals and groups to vary in how interventions affect outcomes. The paper should review the existing literature and may suggest gaps in and extensions to current knowledge. The paper should include specific recommendations for the use of value of information analysis by PCORI.

Lessons from the Application of Value of Information Analysis to Research Prioritization: This paper will examine experience with the application of value of information analysis to inform research priorities. The paper should discuss practical challenges in the application of these methods and how the results of these analyses have been used to inform decision making about research priorities. The paper should include specific recommendations for the use of value of information analysis by PCORI.

Value of Information Methods for Research Prioritization: This paper will examine state of the art value of information methods for research prioritization. Key methodological approaches should be reviewed with the goal of describing approaches that could be reliably applied to compare the potential value of alternative

Patient-Centered Outcomes Research Institute

Request for Proposal – White Papers

2011

research projects. The paper should include specific recommendations for the use of value of information analysis by PCORI.

4. Peer Review for Research Prioritization

PCORI seeks papers that will address the potential use peer review of research proposals to inform priorities for funding specific PCOR studies. Papers could address diverse topics, including the evidence-based design of the peer review process, techniques for evaluating the process, and alternative processes, including those used outside the United States. Papers should include specific recommendations for the use of peer review by PCORI for research prioritization.

KEY DATES

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 sure that you and your organization can produce a complete draft paper by the due date of **January 10, 2012** and a final paper by March 15th, 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 includes a background on the solicitation, outline of the final product that should guide your application and eventual work, and the application for you to complete and return by **September 30th, 5pm EDT, 2011**. We expect to provide decisions about proposals by October 14th, 2011.

Date	Event
Sept. 9 th , 2011	Solicitation issued
Sept. 15 th , 2011	E-mail to RPWG@PCORI.org noting your intent to respond to solicitation required
Sept. 30 th , 2011	Proposals Due
Oct. 1 st – Oct. 13 th 2011	Selection of Final Candidate
Oct. 14 th , 2011	Anticipated announcement of awardees
Oct. 24 th , 2011	Execution of Contract
Oct. 25 th , 2011	Anticipated Start Date
Jan 10 th , 2012	Complete Draft of Paper for January Conference Due
Last 2 weeks, Jan 2012	Present Paper at January Conference
March 15 th , 2012	Final Report Due

TOTAL CONTRACT AMOUNT

Up to \$200,000 in total funding will be awarded under this solicitation. It is expected that **more than one contract per topic area** will be awarded. We expect that applicants will provide budgets in the range of \$5,000

Patient-Centered Outcomes Research Institute

Request for Proposal – White Papers

2011

to \$25,000 in direct costs for each manuscript, with the amount requested justified based on the effort allocated by each person named on the contract. NIH salary caps apply (http://grants.nih.gov/grants/policy/salcap_summary.htm). Fringe benefits are calculated at designated institutional rates. PCORI will pay indirect costs up to 40% of total direct costs; the total allowable dollar amount is inclusive of indirect costs. Applicants should request funds to cover domestic travel and hotel costs for a meeting of up to 2 days to cover the costs of presenting in the January 2012 meeting referred to above.

Note: A budget template is provided below in section *INSTRUCTIONS FOR COMPLETING THE PROPOSAL*.

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

Patient-Centered Outcomes Research Institute

Request for Proposal – White Papers

2011

- 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)

LIST OF DELIVERABLES

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 above in *STATEMENT OF WORK*. 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.

Project management requirements – Interim Status Report and Conference Attendance

- a. Awardees are required to provide one interim progress report 30 days after contract start date.
- b. The awardees will be required to attend and present at a conference to be held in Washington, DC in late January, 2012.

Additional reporting requirement

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

- a. 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 budget justification. 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 budget justification. For those proposals determined to be technically acceptable, budget justification, 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 for reviewing research relevant to the topic being studied, including how the applicant will identify sources from health care and non-health care settings.
- b. Evaluation of the approach the applicant will use for synthesizing the information identified through review and additional information or approaches the applicant may choose to use to address the topic being studied
- 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).

Patient-Centered Outcomes Research Institute

Request for Proposal – White Papers

2011

- 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 January 10th 2012. Interim report is due 30 days after contract start date.

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. This input will be considered during the review process.

Publication Policy -- The reports generated under this contract become the property of the 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.

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.

Patient-Centered Outcomes Research Institute

Request for Proposal – White Papers

2011

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. Proposals in excess of 3 pages will not be considered. Required font type and size is Times Roman 12 or Arial 12 font, single spaced (not including references). Number of pages may be allocated amongst sections 1-4 outlined in the *Overview of sections* 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 research required to produce the narrative review, 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. 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. Budget Appraisal

- a. Provide line item budget

Patient-Centered Outcomes Research Institute

Request for Proposal – White Papers

2011

The following is a budget template:

ROLE	ANNUAL SALARY	% EFFORT	FRINGE	TOTAL
Role #1: e.g. Principal Investigator				
Role #2: e.g. Consultant				
Role #3:				
Travel/Hotel				
Total Direct Costs				
Indirect Costs (calculated at ___% institutional rate to a maximum of 40%)				
TOTAL COSTS				

A brief budget justification should explain the need for each item of funding requested.

6. Contracting

- a. Inclusion of signed letter from respective contracting authority ensuring the contract can be executed by October 24th, 2011 with an anticipated project start date of October 25th, 2011.

7. Biosketches (NIH biosketch style) of key personnel

E-mail Notification of Intent to Bid

The required e-mail notification of intent to bid of should be e-mailed to **RPWG@PCORI.org**. Please include “Research Priorities White Papers” 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.

Patient-Centered Outcomes Research Institute

Request for Proposal – White Papers

2011

Submission

Proposals must be submitted in electronic format to arrive by **5pm EDT on September 30th, 2011** and two hard copies of the proposal must be received by 5pm EDT on October 1st, 2011. Both submissions must include the following information:

- a) Proposal that follows the *INSTRUCTIONS FOR COMPLETING THE PROPOSAL*
- b) 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 24th, 2011.

In your proposal, please clearly label each section as listed above.

The proposal should be e-mailed to **RPWG@PCORI.org** (Please include “Research Priorities White Papers” in the subject line) and two hard copies sent to:

Patient-Centered Outcomes Research Institute (PCORI)
c/o Gail Shearer
ATTN: PCORI Request for Proposal – White Papers (Research Priorities 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-RPWG-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.