

### **REQUEST FOR PROPOSAL - Review of Guidance Documents for Selected Methods in Patient Centered Outcomes 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 provide patients and those who care for them with reliable, evidence-based information for the health care choices they face.

Patient-centered outcomes research (PCOR) helps people make informed health care decisions and allows their voice to be heard in assessing the value of health care options. This research answers patient-focused questions:

1. “Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”
2. “What are my options and what are the benefits and harms of those options?”
3. “What can I do to improve the outcomes that are most important to me?”
4. “How can the health care system improve my chances of achieving the outcomes I prefer?”

To answer these questions, PCOR:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people;
- Is inclusive of an individual's preferences, autonomy and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health-related quality of life;
- Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and
- Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, resources, and other stakeholder perspectives.

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The Methodology Committee of PCORI has been tasked with preparing a Methodology Report by May 2012 that outlines existing methodologies for conducting patient-centered outcomes research, proposes appropriate methodological standards, and identifies important methodological gaps that need to be addressed. This solicitation addresses one component, namely methodological standards for conducting patient-centered outcomes research.

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.

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 **December 2<sup>nd</sup>, 2011**.

### **Key Dates**

**Because the final 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 final paper by March 15<sup>th</sup>, 2012. There will be no extensions.**

<b>Date</b>	<b>Event</b>
October 31 <sup>th</sup> , 2011	Solicitation Issued
November 8 <sup>th</sup> , 2011	E-mail to <a href="mailto:RMWG@PCORI.org">RMWG@PCORI.org</a> noting your intent to respond to solicitation, including which methodology topic(s) your proposal(s) will address
December 2 <sup>nd</sup> , 2011	Proposals Due
December 16 <sup>th</sup> , 2011	Selection of Final Candidate(s)
December 19 <sup>th</sup> , 2011	Anticipated announcement of awardee(s)
December 30 <sup>th</sup> , 2011	Execution of Contract
January 3 <sup>rd</sup> , 2012	Anticipated Start Date
February 3, 2012	Interim Status Report Due
March 15 <sup>th</sup> , 2012	Final Contractors' Reports Due
May 15 <sup>th</sup> , 2012	Final MC Report Due

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June 15, 2012	Non-technical report Due
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### **TOTAL CONTRACT AMOUNT**

Up to \$1,000,000 in total funding will be awarded under this solicitation. Up to nine contracts will be awarded under this solicitation, with the expectation to award one contract per candidate topic listed in the statement of work, depending on the quality of proposals received. Single entities can bid on multiple topics. Applicants are expected to provide budgets commensurate with the work proposed in their application. The level of effort required to perform the work described in this solicitation varies widely across the different candidate topics listed. PCORI expects applicants to scale their budget accordingly. For example, work focused on adaptation of guidance already developed by established entities (e.g., IOM, FDA) should require substantially less effort than other less-developed topic areas. We expect to receive budgets approximately in the range of \$50,000 - \$110,000 in total costs for each contract, with the request justified based on the effort allocated by each person named on the contract. All proposals must include a detailed budget justification. 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.

Indirect costs are limited to 40% of the direct costs for salary and fringe for the recipient and all partners receiving PCORI funds.

PCORI will cap salary reimbursement for any individual at \$200,000 per year (included compensated absences such as vacation or sick leave) or the percentage of that amount based on the percentage of time allocated to the project) plus fringe benefits.

### **ELIGIBILITY**

This solicitation 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)

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### 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**

The work described in this solicitation from the PCORI Methodology Committee will inform the ongoing work of the Committee and specifically the Methodology Report due May 2012.

In addition to fulfilling the legislative mandate for the 2012 Methodology Report, we hope that these solicited papers will inform investigators requesting PCORI funding and assist grant reviewers in evaluating research proposals so as to ensure methodological rigor in patient-centered outcomes research.

In this request for applications, we seek background papers that propose and justify minimum methodologic standards in each of the research methodology domains listed below. We anticipate that these reviews will include 1) a review that should be as systematic as possible of any currently existing methodology guidance statements and relevant literature, 2) a succinct summary of minimum standards for the conduct of research using the designated methodology, with illustrative examples of publications that demonstrate adherence to these standards, and 3) an explanation for how or which proposed guidelines will help further the goals of research sponsored by PCORI (as described in the Background and Introduction of this solicitation), with particular attention to patient-centeredness. These background papers should explain the rationale behind the proposed standards, providing theoretical or empirical justification, appropriately referenced. The standards, examples and rationale for each recommended standard should follow the format of a CONSORT Explanation and Elaboration document (Moher et al., BMJ, 2010)<sup>1</sup>. While the focus here is on minimum standards, the current state of the art in the area as well as important gaps in knowledge should also be summarized briefly. The background paper should be of manuscript length (approximately 5,000 words or less), sources cited, and appendices as needed. The final product must be submitted by **March 15<sup>th</sup>, 2012. No extensions will be granted.**

### Brief Description of Candidate Topics

#### Cross Cutting Topics

1. Standards in Addressing Heterogeneity of Treatment Effectiveness in Observational and Experimental Patient Centered Outcomes Research. The PCORI enabling legislation requires research to be designed in order to take into account the potential for differences in the effectiveness of health care treatments and services among various subpopulations or care settings. The contractor should critically review published guidelines and the primary literature on:

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<sup>1</sup> Moher D, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2010 Mar 23;340:c869.

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- a. Study design features that facilitate the assessment of heterogeneity of treatment effectiveness.
  - b. Analytic methods to assess heterogeneity of treatment effectiveness.
2. Standards in the Prevention and Handling of Missing Data in Observational and Experimental Patient Centered Outcomes Research. Missing data is a problem that is frequently encountered in PCOR, either because existing data sources are incomplete, or prospective studies do not gather all protocol-specified data. PCORI seeks a contractor to propose methodologic standards based on an a critical review and adaptation of published guidelines or primary literature on:
  - a. Approaches to study design and conduct to minimize the occurrence of missing data, or that facilitate appropriate analysis when missingness cannot be prevented.
  - b. The analysis of datasets with missing data.

### **Patient-Reported Outcomes (PROS) Topics**

3. Standards in the Design and Selection of Patient-Reported Outcomes Measures (PROMs) for Use in Patient Centered Outcomes Research. PCORI seeks a contractor to propose minimum standards for the development and use of tools to assess patient reported outcomes. The contractor should review standards in qualitative and quantitative methods used to develop and select measures of the patient experience in experimental and observational clinical comparative effectiveness research. The review team should examine the primary literature and guidance statements for recommended minimum standards, as well as the properties to be sought or assessed in PROMs that are proposed for use. It is expected that such properties will include but not be limited to content validity; construct validity; reliability; sensitivity/responsiveness to change; how clinically meaningful change is determined, and feasibility in non-English speaking and/or low literacy populations. Examples of PROMs that adhere to the standards should be discussed. Contractors should include the potential methodological and logistical challenges of applying such standards in "real-world" or non-experimental settings.

### **Design-Specific Topics**

#### **Experimental**

4. Standards in the Design, Conduct, and Evaluation of Cluster Randomized Trials. Randomization of units that include more than one individual are increasingly being utilized in PCOR. These require special considerations in design, conduct, and analysis, including ethical considerations that differ from traditional trials that randomize individuals. PCORI seeks a contractor to propose methodologic standards based on a critical review and adaptation of published guidelines or primary literature on:

- a. Approaches to study design and conduct of cluster randomized trials.
  - b. The analysis of cluster randomized trials.
  - c. Ethical requirements of cluster randomized trials.
5. Standards in the Design, Conduct, and Evaluation of Adaptive Randomized Clinical Trials. Clinical trials whose design adapts to accumulating data either within a trial or external to that trial have been proposed as a means to more efficiently generate high quality evidence on comparative treatment effectiveness. Adaptive trials can be designed using either a frequentist or a Bayesian approach to analysis. PCORI seeks a contractor to propose methodologic standards based on a critical review and adaptation of published guidelines or primary literature on:
- a. Methods for the design and conduct of adaptive randomized clinical trials.
  - b. Methods for the analysis of adaptive randomized clinical trials.
6. Standards in the Design, Conduct, and Evaluation of Research Evaluating Diagnostic Testing Strategies for Patient Centered Outcomes Research. Medical tests designed either to assess the presence of disease or to monitor the course of disease are an important part of PCOR. Diagnostic tests add to what we know from the patient history and physical examination, and their aim is to affect clinical decisions in a manner that ultimately improves prognosis. These tests include but are not limited to blood and serological tests, biomarkers, imaging, and predictive multivariable algorithms. There exists a substantial literature on the typology, design, conduct, analysis and reporting of such studies. PCORI seeks a contractor to propose methodologic standards based on a critical review and adaptation of published guidelines or primary literature on:
- a. Methods for the design and conduct of diagnostic test studies.
  - b. Methods for the analysis of diagnostic test studies.

### **Observational**

7. Standards for Causal Inference Methods in Analyses of Data from Observational and Experimental Studies in Patient Centered Outcomes Research. A suite of methods aimed at properly estimating causal effects from data affected by confounding or deviations from randomization has been increasingly used in PCOR. PCORI seeks an investigative team to review published standards and primary methodologic papers to recommend standards for the use of causal inference methods in the analysis of observational data and clinical trials. Techniques to review include but are not limited to:
- a. Propensity scores
  - b. Instrumental variable analyses
  - c. Principal stratification analysis

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- d. Structural equation modeling
  - e. Role of Intention to treat analytic approach.
  - f. Design features that can facilitate the use and improve the efficacy of application of causal inference methods
8. Standards in the Conduct of Registry Studies for Patient Centered Outcomes Research. Studies whose main source of data is derived from registries of disease cases or patients who have received a particular treatment (e.g. implantable cardiac defibrillators) have been proposed for a wide range of purposes related to PCOR. The contractor should review and critically examine published guidelines and the primary literature to recommend standards for:
- a. Design and conduct of disease or treatment registries.
  - b. Design and analysis of studies using primarily or exclusively registry data.

### Research Infrastructure

9. Standards in the Use of Collaborative Data Networks or Distributed Data Networks in Patient Centered Outcomes Research. PCORI seeks an investigative team to review and assess best practices in the design, implementation, and use of collaborative data networks and recommend standards for:
- a. Technical design, including the design process itself.
  - b. Structural components
  - c. Organizational structure

### Statement of Objectives for Final Product

The product of the work described in this solicitation is a set of minimum methodology standards that will inform investigators, grant reviewers, and/or decision makers and an accompanying background paper that 1) describes the rationale for these choices 2) gives examples of successful use of these standards, 3) identifies gaps where future work is needed, and 4) explains the connection between the minimum standards and patient-centered outcomes research. We are most interested in standards that are pertinent to patient centered outcomes research, including comparative effectiveness research.

### Components of the Report

#### 1. Methods

- a. Search Strategy

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- i. For subtopics where recent major guidelines exist (e.g. FDA guidance statements), authors do not need to review the primary methodology literature for guidance statements.
  - ii. For areas not addressed or incompletely addressed by recent guidance statements, contractors should review the primary literature.
- b. Description of Inclusion/Exclusion Criteria
  - i. Pertinent guidelines from organizations and groups outside of the U.S. should be included.
  - ii. Where pertinent draft guidelines exist, effort should be made to obtain a copy of the draft guidelines and include it in the search.
  - iii. Guidance statements that focus on state of the art methods should be included in the review and discussed in the background document.
  - iv. Guidance documents that do not apply to patient centered outcomes research or comparative effectiveness may be excluded.
  - v. If multiple versions of the same guideline exist, it is acceptable to include the most recently published guideline.
- c. Abstraction
  - i. Documents do not need to be dual abstracted but abstractions should be checked by a second author to verify accuracy.
- d. Synthesis
  - i. Describe the process of and criteria for selecting guidelines included in the recommended guidelines

## 2. Results

- a. Description of Results of Search
- b. Main Findings
  - i. Box 1. Recommended Guidelines for the topic addressed
    - 1. Reference source documents for each recommendation
    - 2. Focus on recommendations for minimum standards that apply to patient centered outcomes research (see definition at beginning of RFP), including comparative effectiveness
  - ii. Briefly describe the rationale for choosing the recommended guidelines and the evidence behind the recommended guidelines.
- c. Examples of Research that Demonstrates Selected Minimum Standards
  - i. Identify and briefly describe 3-5 publications that have successfully adhered to recommended standards in the Main Findings.
- d. Rationale for Main Findings
  - i. Provide detailed explanation for including the recommended guidelines

- ii. Describe whether the guidelines are based on theoretical grounds, empiric evaluation, or other reasons, referencing the evidence behind the guidelines.
  - iii. Explain each recommendation, using the CONSORT Explanation and Elaboration<sup>2</sup> as a model
  - iv. Table 1. Description of Guidance Documents Included in Main Findings. See Appendix to the RFP for an example table.
- e. State of the Art Methods not included in the Main Findings
  - i. Summary and discussion of state of the art method guidance not included in the Main Findings
  - ii. Table 2. Description of any guidance documents not included in main findings (See Appendix for an example table)
- f. Challenges Encountered and Gaps
  - i. Identify areas where no guidance documents exist (or guidance documents are incomplete) but sufficient methodologic literature exists for substantial future development of new standards.
  - ii. Identify true methodology gaps where additional methodologic research or application is needed to develop and/or empirically test standards.
- g. Next Steps
  - i. Summarize next steps necessary in this methodology area based on assessment of methodology gaps.

### 3. Tables and Figures

- a. Figure 1. Study Flow Diagram
- b. Box 1. Recommended Guidelines
- c. Table 1. Description of Guidance Documents Included in Main Findings (See Appendix for example table)
- d. Table 2. Description of Guidance Documents Not Included in Main Findings (See Appendix for example table)
- e. Table 3. Selected Additional Characteristics of Guidance Statements (See Appendix for example table)

### 4. Appendix

- a. Abstraction tool
- b. Additional appendices as needed

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<sup>2</sup> See Moher D, *et al.*

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### **Project Management Requirements - Calls and Written Status Reports**

- a. Throughout the contract period, awarded contractors are required to be in contact with a designated representative of the Methodology Committee Research Methods Working Group no less than bi-weekly.
- b. Awardees are required to deliver one interim status report 30 days after the contract start date that summarizes the status of the literature search and identification of guidelines and provides a description of challenges encountered.
- c. The awardee may be asked to attend and possibly present at a PCORI Methodology Committee meeting in late March or early April 2012.

### **Additional Reporting Requirement**

A final, non-technical report is due by June 15, 2012. 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**

The successful applicant will have pre-existing expertise in the methodology and a team that can complete the work in a timely fashion.

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 (45 points)**

Proposals will be evaluated based on the understanding of the project goals and descriptions of the methodology subtopics the applicant anticipates including in their review.

- a. Congruence with the RFP project goals
  - b. Descriptions of the methodology subtopics the applicant anticipates including in their review
  - c. Search strategy to identify standards, including results of preliminary search.
  - d. Method and criteria to select recommended standards
  - e. Comprehensiveness of the outline for 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 (20 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 of work in the prescribed time frame, with the scope of work defined as that comprised by all applications from the same organization.
- 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 15<sup>st</sup> 2012.

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

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### **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 5 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. Identification and description of methodology subtopics pertinent to the particular methodology topic.
- b. Basic strategy for identifying relevant documents.
- c. Identification of guidance documents in the methodology field already known to team.

- d. Methods for selection of patient centered outcomes research standards.
- e. Approach to selection of minimum recommended standards.
- f. 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.
- c. If applying for more than one topic, description of how the applicant would staff the work if all proposals were accepted.

### **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.
- b. If applying for more than one topic, description of how the applicant would assure timely completion of the work if all proposals were successful.

### **5. Contracting**

- a. Inclusion of signed letter from respective contracting authority ensuring the contract can be executed by December 30<sup>th</sup>, 2011 with an anticipated project start date of January 3<sup>rd</sup>, 2012.

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

### Applying for Multiple Topics

Individuals/Groups may apply to review more than one of the methodology topics listed, up to a maximum of five, if they have the necessary methodology expertise and personnel to complete the tasks with adequate quality by the deadline. Applicants should submit one application per topic listed in this solicitation, but indicate on each one which other topics have been applied for. Applicants should not apply for more contracts than they can fulfill if all of their proposals were successful. As noted below, this justification must be included in each application.

### E-mail Notification of Intent to Bid

The invited e-mail notification of intent to bid should be e-mailed to [RMWG@PCORI.org](mailto:RMWG@PCORI.org). Please include “Landscape” 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 and identifying the topic area(s) your proposal(s) will address. Although this e-mail notification of intent is not required, it is valuable in helping PCORI plan for the review process. We therefore ask applicants to e-mail their intent to bid by **November 8, 2011**.

### E-mail inquiries

Any questions about the proposal, selection or contracting process should be emailed to [RMWG@PCORI.org](mailto:RMWG@PCORI.org) with the subject line “Landscape inquiry.” Answers to questions of general interest or potential relevance to other applicants will be posted on the PCORI website.

### Submission

Proposals must be submitted electronically, and two hard copies received, by **5pm EDT on December 2<sup>nd</sup>, 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 December 30<sup>th</sup>, 2011.

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

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The proposal should be e-mailed to [RMWG@PCORI.org](mailto:RMWG@PCORI.org) (Please include “Landscape” 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 – Landscape (Research Methods WG)  
1701 Pennsylvania Ave., NW, #300  
Washington, DC 20006

Accepted proposals will be notified by phone and announced via [www.pcori.org](http://www.pcori.org) by **December 19<sup>th</sup>, 2011**.

Proposals that do not directly address all of the components specified in this RFP [PCORI-SOL-RMWG-001] for the selected topic will not receive further consideration.

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## PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE Conflict of Interest Disclosure Statement

1. Name: \_\_\_\_\_

2. Date Submitted: \_\_\_\_\_

3. List the nature of any conflict of interest:

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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.

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## **APPENDICES**

### **Appendix I. Sources of Guidance Statements**

1. Official Guidance. (e.g. IOM, FDA, CADTH, IQWiG, EMA)
2. Expert Groups. (e.g. Cochrane, USPSTF, AHRQ, Professional Organizations)
3. Primary Methodology Literature

### **Appendix II. Templates for Tables Described in this Solicitation**

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Template for Tables 1 and 2. Description of Guidance Statements*							
Guideline	Organization or Authors	Year	Program	Country or Region	Guideline subjected to independent external review?	Research Design	Description
The Prevention and Treatment of Missing Data in Clinical Trials Panel of Handling Missing Data in Clinical Trials	National Research Council	2010	Committee on National Statistics	USA	Yes	Phase III confirmatory clinical trials	Document provides 18 recommendations to address missing data in clinical trials through careful trial design, conduct, and analysis; document created at request of FDA for a future FDA guidance report on missing data

\*Table 1 describes the guidance statements included in the recommended minimum guidelines. Table 2 describes the guidance statements discussed in the background paper but not included in the recommended minimum guidelines.

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Template for Table 3. Selected Characteristics of Documents Included in Recommended Guidelines <sup>3</sup>													
Guideline	The purpose of the work is to define methodological standards for PCOR	The applications of the standards to PCOR is clear	The standards were developed by a professional group	Patient's views and preferences were sought	Stakeholders were involved in the development of Standards	A systematic process was used to generate recommendations	Details of the systematic process used to generate recommendations are provided	There is an explicit link between the rationale for and the recommended standards (evidence)	The standards underwent independent external review (See note)	The recommendation are specific and unambiguous	Key recommendations are clear	The standards are editorially independent from the funding body	Conflicts of interest have been recorded
NAD/NRC Panel on Missing Data	Yes	Yes	Yes	No	Limited (Mostly experts involved)	Not Specified	No	Yes (Document Cites relevant methodology papers)	Yes	Yes	Yes	Yes	Yes (None reported)

Note: Independent external review process by a group of experts. A publication in a peer-reviewed journal would not be considered having undergone a formal, independent external review.

<sup>3</sup> Modified from the AGREE Criteria: Cluzeau F, Burgers J, Brouwers M, Grol R, Mäkelä M, Littlejohns P, *et al.* Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: The AGREE project. *Qual Safety Health Care.* 2003; 12 (1): 18-23.

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