Cycle 3 2016: Improving Methods for Conducting Patient-Centered Outcomes Research (PCOR)

LOI Town Hall
August 31, 2016
Agenda

- Programmatic Overview
- Administrative Overview
- Resources
- Questions and Answers

Submit questions via the chat function in Meeting Bridge.

Ask a question via phone (an operator will standby to take your questions).
PCORI CER Methods Program and Contracts Staff

CER Methods Program

• David Hickam, MD MPH, Program Director
• Lillian Agyei, MPH, Program Associate
• Emily Evans, PhD MPH, Program Officer
• Jason Gerson, PhD, Senior Program Officer
• Arletta Praszczalek, Senior Administrative Assistant
• Jamie Trotter, MPA, Program Associate

Contracts Management and Administration (CMA)

• Scott Yoo, JD, Supervisor, Contracts Operations
• Valerie Clark, LL.M, Associate, Contracts Operations
• Ashton Ferrara, Associate, Contracts Operations
• Mekia Winder, MPH MCHES, Administrator, Contracts Operations
Programmatic Overview

David Hickam, MD MPH
Program Director, CER Methods
Improving PCOR Methods

PCORI’s Mission
• PCORI was created to support research that provides high-integrity, evidence-based information to patients, clinicians, and the broader healthcare community.

Why Methods Matter
• Rigorous research methods are needed to produce relevant, trustworthy findings that can improve patients’ healthcare outcomes.

Methods for PCOR/CER
• Methods include the systematic processes, designs, and analytical approaches needed to ensure the sound scientific and ethical conduct of PCOR/CER.
Improving PCOR Methods: Program Goals

- **Identify Methods Gaps**
  - Identify methodological gaps relevant to the conduct of PCOR/CER

- **Fund Research**
  - Fund high impact studies which address gaps in methodological research

- **Disseminate Promising/Best Practices**
  - Disseminate and facilitate the adoption of new methods to improve the conduct of PCOR/CER
Cycle 3 2016: Methods PFA Overview

• The Methods Program seeks to fund applications that make a significant *methodological* contribution to PCOR/CER.
  • Proposals that simply apply methodological approaches to a particular domain or seek to disseminate an approach will not align with programmatic priorities.
  • Novelty and/or strong engagement cannot compensate for a lack of methodological contribution and scientific rigor.

• The Cycle 3 2016 Methods PFA is available at [pcori.org/funding/opportunities](pcori.org/funding/opportunities).

Available Funds & Project Duration:

• Up to $750,000 in total direct costs per project
• Projects should be completed within 3 years
Cycle 3 2016 PFA: Research Areas of Interest (RAIs)

Previously Invited Applications*

• Methods for Patient and Stakeholder Engagement
• Methods for Patient-Centered Outcomes and Methods for Patient-Reported Outcomes
• Methods to Improve Study Design
• Methods to Improve Validity and Efficiency of Analyses

Resubmissions and New Applications

• Research Related to Ethical and Human Subjects Protections (HSP) in PCOR/CER
• Methods to Support Data Research Networks

* Eligibility limited to applicants previously invited to submit a full application to Cycle 1 (Spring) 2015, Cycle 2 2015, Cycle 3 2015, and Cycle 1 2016.
Letter of Intent (LOI)

• **Background**
  • Describe the methodological gap the research is designed to address and how the proposed research will advance methods for PCOR/CER.

• **Objectives**
  • Describe the research objective(s) and list the specific aims that will address the identified methodological gap.

• **Methods**
  • Provide a detailed description of the methodological work that is planned and the specific ways in which it addresses the identified methodological gaps and the specific aims of the proposed project.
Letter of Intent (LOI)

- **Outcomes and Anticipated Impact**
  - Identify and explain the specific anticipated contributions and applications of the *methodological* advancement to PCOR/CER.

- **Engagement**
  - Briefly describe the plan for engaging patients and/or other stakeholders in the research.
LOI Review

LOIs are evaluated based on the following:

- Responsiveness to the Methods PFA
- Importance and relevance of the topics to PCORI priorities
- Clarity and credibility of applicants’ responses
- Sufficient detail and scientific rigor of the proposed methods
- Programmatic fit and balance

Note:

- Only applicants with LOIs deemed most responsive to this PFA will be invited to submit a full application.
- Eligibility to submit an LOI does not guarantee that a full application will be invited for this cycle.
Administrative Overview

Mekia Winder, MPH MCHES
Administrator, Contracts Operations
Eligibility to Submit a Proposal

- Any private sector (non-profit or for-profit) research organization
- Any public sector research organization (university or college hospital or healthcare system, laboratory or manufacturer, unit of local, state, or federal government)
- Non-domestic components of organizations based in the US and foreign organizations may apply, as long as there is demonstrable benefit to the US healthcare system and US efforts in the area of patient-centered research can be clearly shown.
- Individuals are not permitted to apply.
Competitive LOI Process

This is a competitive LOI process:

• An LOI is required and must be submitted prior to completion of an application.
• The LOI is due on September 14, 2016, by 5:00 p.m. (ET).
• Only those LOIs deemed most responsive to this PFA will be invited to submit a full application.
• Applicants will be notified by October 21, 2016, whether or not to submit a full application.
• Please refer to the PFA, Application Guidelines, and PCORI Online User Manuals in the Funding Center here: http://www.pcori.org/Cycle-3-2016-methods/
LOI and Application

Changes to the following require PCORI’s approval:

- Principal Investigator
- Institution
- Research question(s)
- Specific Aims
- Study Design
- Comparators
Using the PCORI Online System

- Apply through PCORI Online ([https://pcori.fluxx.io](https://pcori.fluxx.io))
- Access the website using Chrome or Safari browsers only
- Create a new request and begin the LOI
- Designate the LOI with the following individuals:
  - PI, PI Designee, AO, and Financial Officer
- Enter information into all required fields in the system
- Convert the document to PDF file
- Upload the LOI in the system
Completing the LOI

- Refer to the PCORI Online User Manual: Submitting a Letter of Intent
  - Pre-Screen Questionnaire
  - PI and Contact Information
  - Project Information
  - Key Personnel
  - Template Upload
- Refer to the PFA-specific LOI Template to address the program’s areas of interest
  - Please make sure to address all required sections of the LOI template
  - Please refer to the specific PFA as each program has its own unique characteristics and requirements
Letters of Intent

- Download the **Letter of Intent Template specifically for the Cycle 3 2016 Methods PFA** from the [Funding Center](#) to begin your LOI.
- LOIs must not be more than three pages, excluding references. All references should be included in American Medical Association (AMA) citation style. LOIs that exceed three pages will not be reviewed.
- Do not upload additional documents as part of your LOI.
- Letters of endorsements or support are not accepted at this stage.
- You must upload your LOI as a PDF in PCORI Online.
Formatting

• Include the Principal Investigator’s (PI’s) full name on every page in the top left corner of the page header.

• Use at least half-inch margins and single spacing. (The header may fall within the top margin, but the body text should not begin closer than a half-inch from the edge of the page.)

• Use font size Calibri 11 for the main body of the text. Figures and captions may have size 8 font.

• Keep the numbering of the LOI questions within the LOI template.
### Submission and Key Dates

<table>
<thead>
<tr>
<th>What</th>
<th>When</th>
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<tbody>
<tr>
<td>LOI Town Hall</td>
<td>August 31, 2016 at 1:30 pm ET</td>
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<tr>
<td>LOI due in PCORI Online</td>
<td>September 14, 2016 by 5:00 PM ET</td>
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<tr>
<td>Applicants notified as to whether they have been selected to submit a full application</td>
<td>October 21, 2016</td>
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<td>Applicant Town Hall (if invited)</td>
<td>TBD</td>
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<tr>
<td>Application Deadline (by invitation only)</td>
<td>December 19, 2016 by 5:00 PM ET</td>
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<tr>
<td>Merit Review Dates</td>
<td>March 2017</td>
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<tr>
<td>Awards Announced</td>
<td>June 2017</td>
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<tr>
<td>Earliest Start Date</td>
<td>August 2017</td>
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Resources

Refer to the funding opportunities page in our Funding Center (http://www.pcori.org/funding/opportunities) for the following resources:

• PFA and Application Guidelines
• PCORI Online User Manuals
• Sample Engagement Plans
• PCORI Online: https://pcori.fluxx.io/
• Research Methodology: http://www.pcori.org/node/4020
Where can I find help?

Visit pcori.org/apply
- Application Guidelines
- FAQs
- PCORI Online User Manuals
- Sample Engagement Plans

Schedule a Call with a Program Officer
- Submit a request at pcori.org/content/research-inquiry
- Call 202-627-1884 (programmatic inquiries)
- E-mail sciencequestions@pcori.org

Contact our Helpdesk
- E-mail pfa@pcori.org
- Call 202-627-1885 (administrative and technical inquiries)
Q&A

Ask a question via the chat function in Meeting Bridge.

Ask a question via phone (an operator will be on standby to take your questions).

If we are unable to address your question during this time, e-mail the Helpdesk at pfa@pcori.org.
Thank You