

# Cycle 3 2019: Improving Methods for Conducting Patient-Centered Outcomes Research (PCOR)

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Applicant Town Hall  
September 11, 2019

# Agenda

- Programmatic Overview
- Administrative Overview
- Merit Review Criteria
- Questions and Answers
  - [Submit questions via the question box in GoToWebinar](#)

# Today's Presenters



**Emily Evans, PhD MPH**  
Senior Program Officer,  
Clinical Effectiveness &  
Decision Science



**Michele Lee Clements, CRA**  
Contract Administrator



**Angela Hvitved, PhD, MA**  
Merit Review Officer

1.



# Programmatic Overview

# Programmatic Overview



## **Emily Evans, PhD MPH**

Senior Program Officer, Clinical Effectiveness & Decision Science

# Cycle 3 2019: Methods PFA Overview



- PCORI seeks to fund applications that make a significant *methodological* contribution to PCOR/CER
- The Cycle 3 2019 Methods PFA is available at: <https://www.pcori.org/funding-opportunities/announcement/improving-methods-cycle-3-2019>

## Available Funds & Project Duration:

- Up to \$750,000 in total direct costs per project
- Projects should be completed within 3 years

# Cycle 3 2019 PFA: Programmatic Priorities

## Resubmissions and New Applications

- Methods Related to Ethical and Human Subjects Protections (HSP) Issues in PCOR/CER
- Methods to Improve Study Design
- Methods to Support Data Research Networks
- Methods to Improve the Use of Natural Language Processing



*Research supported by the  
Methods PFA*

# General Guidance: Methods LOIs & Applications



- **Background and Significance**

- Identify, explain, and provide support for the specific anticipated *methodological* contributions to PCOR/CER.
  - Projects that simply apply best methods to a particular domain, seek to disseminate an approach, or develop infrastructure will not align with PCORI programmatic priorities.

- **Study Design or Approach**

- Provide a detailed description of the methodological work that is planned (e.g., theoretical development, simulation studies, data collection and analysis, empirical analyses, etc.).
- Applications must adhere to all relevant PCORI Methodology Standards.



# General Guidance: Methods LOIs & Applications

## *continued*

- **Evaluation**

- Describe and justify a plan for evaluation of the methods, including identification and examination of underlying assumptions.
- Applications must justify why the chosen data sources are optimal for the project (rather than just convenient to obtain).

- **Engagement (full application only)**

- Engagement plans should be tailored and justified with respect to the specific aims, methods, and targeted end-users.
  - *Note:* Engagement is not required for Methods proposals but lack of engagement should be justified.

# 2019 PCORI Methodology Standards

Research funded by PCORI must adhere to the PCORI Methodology Standards, which represent minimal requirements for the design, conduct, analysis, and reporting of patient-centered outcomes research.

The 65 standards can be grouped into 2 broad categories and 16 topic areas.

## ***Cross-Cutting Standards***

- Formulating Research Questions
- Patient Centeredness
- Data Integrity & Rigorous Analyses
- Preventing/Handling Missing Data
- Heterogeneity of Treatment Effects

## ***Design-Specific Standards***

- Data Registries
- Data Networks
- Causal Inference Methods\*
- Adaptive & Bayesian Trial Designs
- Studies of Medical Tests
- Systematic Reviews
- Research Designs Using Clusters
- Studies of Complex Interventions
- Qualitative Methods
- Mixed Methods Research
- Individual Participant-Level Data Meta-Analysis (IPD-MA)

*\*The first standard for Causal Inference Methods (CI-1) is considered cross-cutting and applicable to all PCOR/CER studies.*

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# Administrative Overview

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**Michele Lee Clements, CRA**  
Contract Administrator

# Using the PCORI Online System

- **PCORI Online** (<https://pcori.force.com/engagement>)
  - Please only use Chrome, Safari, and Firefox browsers to access the system



- **Reminders:**
  - Register and/or login to the PCORI system early
  - The PI and the AO cannot be the same individual
- **Resources**
  - [PCORI Online Training Slides](#)
  - [PCORI Online Application Cheat Sheet](#)

# Eligibility to Apply for Funding



- 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.
  - **Please see pp. 2-3 of the [Application Guidelines](#) for requirements for non-US institutions.**
- Individuals are **not** permitted to apply.

# LOI and Application

- Only LOIs deemed most responsive to this PFA will be invited to submit a full application.
- Full applications are invited based on the information provided in the LOI
- Changes to the following require PCORI's approval:
  - Principal Investigator
  - Institution
  - Research question(s)
  - Specific Aims
  - Study Design
  - Comparators

# Full Application: Tips for Success



- **Programmatic**

- Adhere to the Application Guidelines for the appropriate PFA and funding cycle
- Have a copy of your approved LOI readily accessible
- Start and submit application early

- **Administrative**

- Ensure that all team members can see the application in the system (check during the LOI stage)
- Inform your AO of your intent to submit
- Submit the completed application on/before the due date by **5:00 PM ET**



# Application Components: Research Plan (1/2)



- **Research Strategy (12 pages)**
  - Provide all information requested, as outlined in the template:
    - Objectives
    - Background
    - Significance
    - Study Design or Approach
    - Engagement Plan (*should not exceed 1 page of the 12-page Research Strategy*)
- **Research Team & Environment (2 pages)**
  - Describe the research team's capabilities to accomplish the goals of the proposed research project and the appropriateness of the research environment to conduct the study.

# Application Components: Research Plan (2/2)



- **Dissemination & Implementation Potential (1 page)**
  - Discuss plans for making results available to participants (as applicable) and addressing limitations & barriers to usability of findings
  - *Note:* PCORI does **not** support awardees budgeting efforts or resources for the conduct of dissemination and implementation work at this juncture.
- **Consortium Contractual Arrangements (5 pages)**
- **References (10 pages)**
- **Appendices (10 pages) – optional**
  - Applicants can include additional materials that they believe are useful, but reviewers are not required to review the appendix materials in evaluating the application.
- **Methodology Standards Checklist**
  - Excel file that has a dedicated upload field in PCORI online; do not upload uploaded with the Research Plan Template. Applicants must complete Column D, and completed subsequent columns, as appropriate.

# Additional Application Components

- **Milestones/Deliverables Template**
  - Significant events, deliverables, tasks, and/or outcomes that occur over the course of the project that mark progress toward the project's overall aims
- **People & Places Template**
  - Professional/Patient/Stakeholder Biosketch (5 pages per individual)
  - Project/Performance Site(s) and Resources (15 pages)
- **Leadership Plan Template (5 pages)** – *Dual PI applications only*
- **Letters of Support**
  - Letters of support should be addressed to the PI to demonstrate the commitment of key personnel and supporting organizations to the proposed project
- **Resubmission letter (1 page)** – *if applicable*

# Application Components: Budget & Budget Justification



- **In PCORI Online, for the Budget tab complete the following sections:**
  - Detailed Research Project Budget for Each Year of the Research Project Period
  - Detailed Peer-Review Budget for Peer-Review-Related Costs
  - Budget Summary for Entire Project
- **In the Templates and Uploads tab:**
  - Upload the **Budget Justification Template** for the **prime applicant** and **each subcontracted organization** for the entire Research Project Budget and Peer-Review Budget for all research and peer-review-related costs

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# Merit Review Overview

# Merit Review Overview



**Angela Hvitved, PhD, MA**

Merit Review Officer

# What happens to your application after you submit it?

## **Administrative Screening**

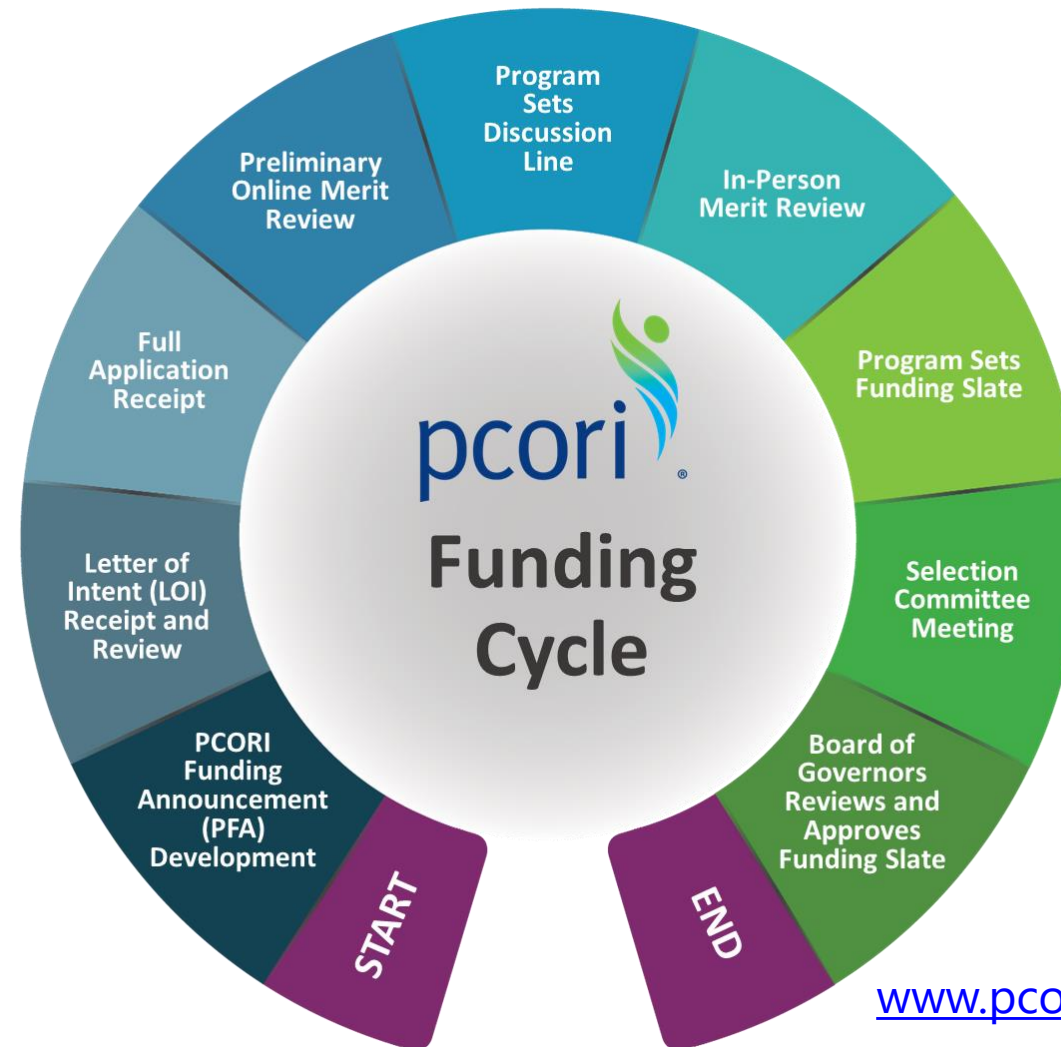
Applicants must follow the administrative requirements stated in PCORI's Application Guidelines.

- Applications may be administratively withdrawn for the following reasons:
  - Exceeding budget or time limitations
  - Not using PCORI's required templates
  - Submitting incomplete sections or applications

## **Programmatic Screening**

- Applications may be programmatically withdrawn for the following reasons:
  - Deviation from the approved LOI
  - Inclusion of cost-effectiveness analysis (CEA)
  - Inclusion of development and dissemination of clinical practice guidelines (CPG)
  - Not responsive to the program-specific PFA

# Merit Review Process



[www.pcori.org/content/merit-review-process](http://www.pcori.org/content/merit-review-process)



# Application Review

## Applications are reviewed against six criteria:

1. Study identifies critical methodological gap(s) in PCOR/CER
2. Potential for the study to improve PCOR/CER methods
3. Scientific merit
4. Investigator(s) and environment
5. Patient-centeredness
6. Patient and stakeholder engagement

- **Each application is reviewed by:**
  - **three scientists**
  - **one patient**
  - **one stakeholder**
- **PCORI's Board of Governors makes funding decisions based on merit review and staff recommendations.**

# Submission and Key Dates

What	When
LOI Deadline	October 1, 2019 by 5 PM ET
Application Deadline	January 14, 2020 by 5 PM ET
Merit Review	April 2020
Awards Announced	July 2020
Earliest Start Date	November 2020

Refer to the **funding opportunities** page in our **Funding Center** for the following resources:

<http://www.pcori.org/funding/opportunities>

- PFA and Application Guidelines
- General Applicant FAQs: <https://help.pcori.org/Applicant-Resources>
- PCORI Methodology Standards: <https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards>
- PCORI Online: <https://pcori.force.com/engagement/>
- PCORI Online User Manuals: <https://www.pcori.org/sites/default/files/PCORI-Online-User-Access-Cheat-Sheet.pdf>

# Where can I find help?

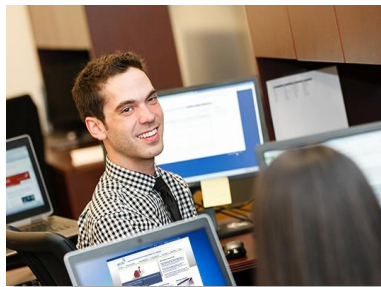


- Visit [pcori.org/apply](https://pcori.org/apply)
  - Application Guidelines
  - FAQs
  - PCORI Online User Manuals



- Discuss an LOI/proposal with a Program Officer
  - E-mail [sciencequestions@pcori.org](mailto:sciencequestions@pcori.org)
  - Call 202-627-1884 (programmatic inquiries)

**\*\*\*All requests re: LOIs should be made no later Tuesday, September 26\*\*\***



- Contact our Helpdesk
  - E-mail [pfa@pcori.org](mailto:pfa@pcori.org)
  - Call 202-627-1885 (administrative and technical inquiries)



**Ask question via the question box in GoToWebinar**

*\*\*\* If we are unable to address your question during this time, e-mail the Helpdesk at [pfa@pcori.org](mailto:pfa@pcori.org) \*\*\**

**Thank You!**

