Psychosocial Interventions with Office-based Opioid Treatment for Opioid Use Disorder

*Cycle 2 2018*

Town Hall Webinar
Washington, DC

*June 13, 2018 at 12:00pm ET*
Agenda

I. Welcome and Introductions
II. About PCORI
III. Topic Background and PFA Overview
IV. Patient and Stakeholder Engagement
V. LOI Process and Review
VI. Resources and Q&A

Submitting Questions:
Submit questions via the “Questions” function in the GoToWebinar control panel
Today’s Presenters

Els Houtsmuller
Associate Director
Healthcare Delivery and Disparities Research

Andrea Brandau
Program Officer
Healthcare Delivery and Disparities Research

Denese Neu
Engagement Officer

Perrinne Kelley
Administrator
Contracts Management

Jamie Trotter
Program Associate
Healthcare Delivery and Disparities Research
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About PCORI, Topic Background and PFA Overview

Els Houtsmuller
Associate Director, Science
Healthcare Delivery and Disparities Research
• An independent research institute authorized by Congress in 2010 and governed by a 21-member Board of Governors representing the entire healthcare community
Our Focus

Comparative Effectiveness Research

• Compares two or more interventions that are evidence-based or in widespread use
• Is performed in real-world populations and settings
• Patient-centered:
  — Engages patients and key stakeholders throughout the research process
  — Answers questions that matter to patients and other clinical decision makers
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Pathway for this Reissuance

Priority topic development

Stakeholder engagement

PCORI Board of Governors Approval (May, 2018)

tPFA released (June, 2018)
Prevalence of opioid use has increased dramatically; associated with serious social, health, economic, and legal consequences

Medication-Assisted Treatment (MAT; maintenance therapy with opiate agonist [methadone, buprenorphine] plus psychosocial services) is an evidence-based, clinically effective treatment

Buprenorphine is safer than methadone and can be offered in clinician’s office (Drug Addiction Treatment Act) by MDs PAs or NPs

Federal regulations require clinicians who prescribe MAT to provide or refer patients to psychosocial services

Systematic reviews and individual studies show mixed results on which psychosocial treatments are (most) effective

Most research conducted with methadone; research on psychosocial services with buprenorphine is limited
Targeted PFA Goal

The goal of this targeted PFA is to generate evidence regarding the comparative effectiveness of psychosocial interventions for patients with opioid use disorder (OUD) who receive office-based opioid treatment (OBOT)
**Population:** Patients who receive office-based opioid treatment with buprenorphine

**Interventions and Comparators:** Studies may compare different levels of intensity (e.g., different frequencies, group vs individual format, combinations of interventions), and different durations of efficacious interventions.

➢ Proposed studies should compare two or more approaches that include interventions that are documented to be efficacious or in common use, and that are well characterized to facilitate replication and dissemination efforts.
Outcomes

- Outcomes: treatment adherence/retention, patient function, illicit opioid use, other drug use, emergency department visits, overdose, provider satisfaction, and provider stress

Time

- Studies up to 4 years
- Periodic outcome assessments; at least one year of patient follow-up

Setting

- Community-based settings, places where office-based opioid treatment is offered
Study considerations

• Large RCTs or well justified observational studies; sufficient sample size
  – Interested in heterogeneity of treatment effects among subgroups (e.g., addiction severity, low income or disadvantage)
• Urban, low-income, and racial-ethnic minority populations
• Studies should propose interventions that are or can be made available to most patients
• Stepped-care and needs-based approaches rather than straightforward comparisons of interventions
This PFA will **NOT** support the following types of studies:

- Pilot studies
- Efficacy trials
- Cost-effectiveness analyses
- Direct comparisons of the costs of care between two or more alternative approaches
- Development of clinical prediction or prognostication tools
- Evaluation of new or existing decision-support tools
- Studies of the natural history of disease, instrument development, pharmacodynamics, and fundamental science of biological mechanisms
Budget Parameters

- PCORI has allocated a total of up to $25 million for this PFA
- The proposed budget for studies under this initiative may be up to $4 million in direct costs
  - At the LOI stage, the only necessary budget information is the total amount requested
- The maximum project period is 4 years (three year studies are also encouraged)
- Note that PCORI funding does not cover clinical healthcare costs
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Patient and Stakeholder Engagement

Denese Neu
Engagement Officer
Patients and Other Stakeholders

- Patient/Consumer
- Caregiver/Family Member of Patient
- Patient/Caregiver Advocacy Org
- Hospital/Health System
- Training Institution
- Hospital/Health System
- Policy Maker
- Industry
- Payer
- Purchaser

PCORI Community
Patient-Centeredness

- The outcomes (both benefits and harms) are important to patients.
- The interventions being proposed for comparison are presently available to patients.

Patient and Stakeholder Engagement

- The proposed study builds an interdisciplinary study team that includes appropriate patient and stakeholder representation.
- Engagement activities will support a variety of study needs.
Evidence of Appropriate Engagement of Relevant Patients and Other Stakeholders

- Applicants are expected to consult with patients and other stakeholders on their decisional dilemma and evidence needs or to reference previously documented decisional dilemmas in preparation for the submission of LOIs.

- Identify the patients and stakeholders you consulted in determining that the proposed study addresses their evidentiary needs for decision-making and indicate your commitment to continuing to engage them actively in the conduct of the study.
The Engagement Rubric

The rubric is intended to provide guidance to applicants, merit reviewers, awardees, and engagement/program officers (for creating milestones and monitoring projects) regarding engagement in the conduct of research. It is divided into three segments:

Planning the Study

Conducting the Study

Disseminating the Study Results
Budgeting

- Financial compensation of partners
- Expenses of partners (transportation, childcare, caregiver)
- Budgeting for program staff dedicated to engagement tasks
- Costs of engagement meetings and events (travel, food, audio visual)
- Additional time and resource to incorporate partner feedback into various project process
Engagement Resources

- PCORI’s “Engagement Rubric:”
- Sample Engagement Plans:
- Compensation Framework:
- Engagement in Research Webpage: http://www.pcori.org/funding-opportunities/what-we-mean-engagement
- PCORI’s Methodology Standards PC-1 to PC-4:
  https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards
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Letter of Intent (LOI): Submission Process

Perrinne Kelley
Administrator
Contracts Management
LOI Purpose and Process

• The purpose of the LOI is for PCORI to identify ideas and proposals that are programmatically responsive and to provide feedback to applicants
• The LOI is due online by June 28, 2018 by 5:00 PM (ET)
• Applicants are required to submit an LOI and only those deemed most responsive to this PFA will be invited to submit a full application
• Applicants will be notified by July 23, 2018 whether or not they have been invited to submit a full application.
Application Requirements: Who Can Apply?

- Any private sector research organization
  - Non-Profit Organizations
  - For-Profit Organizations

- Any public sector research organization
  - Local, State, or Federal Government
  - Hospitals or Healthcare Systems
  - Universities or Colleges
  - Laboratories

- Foreign organizations
- Nondomestic components of organizations based in the US

NOTE: PI must be an employee of the prime applicant institution. Individuals are not eligible to submit research applications to PCORI.
LOI Outline of Sections in the Template

• Specific Aims
• Background
• Significance
• Study Design
• Engagement Approach
• Study Population and Setting

• Interventions
• Outcomes
• Analytic Plan
• Sample Size and Power
• Prior Relevant Experience
• Duration and Total Direct Costs
LOI Technicalities

- Download the **Letter of Intent Template specifically for the Cycle 2 2018 Psychosocial Interventions with Office-based Opioid Treatment for Opioid Use Disorder** from the Funding Center to begin your LOI
- LOIs are limited to 3 pages excluding references. LOIs that exceed the page limit will not be reviewed
- Please answer all questions, including the question on brief justification for the cost (e.g., “Will not exceed $4 million” is not a sufficient answer)
- Additional documents should not be included as part of your LOI, including letters of support
- The LOI should be uploaded as a PDF in the PCORI Online system
Using the PCORI Online System

- Submit your LOI through PCORI Online (https://pcori.force.com/engagement)
- Create a new request and begin the LOI as soon as possible
- Please note that the PI and AO cannot be the same individual
- Enter information into all required fields in the system
- **PCORI Online Training Resources**
Letter of Intent Review Process

Andrea Brandau
Program Officer
Healthcare Delivery and Disparities Research
LOI Review

- LOIs will be reviewed administratively to ensure each meets the requirements stated (e.g., limits for pages, budget, duration) prior to being referred for programmatic review.

- Programmatic review will consider responsiveness to this specific targeted PFA, especially the clinical dilemma being addressed, along the parameters (e.g., PICOTs) described in the PFA.
What PCORI will look for when reviewing LOIs

An important documented decisional dilemma

• Credible reviews calling out a research gap, such as systematic reviews
• CER question stated clearly in your Specific Aims
• Proposed comparators should be viable (realistic) and consistent with the decisional dilemma
What PCORI will look for when reviewing LOIs (cont.)

A well-thought out, appropriate, defensible research strategy

- Adequate study power/appropriate sample size
- Realistic assumptions
- Appropriate study design
- Realistic recruitment strategy, if applicable
Essential characteristics of studies

• Address the priority research question
• Include representative patient populations
• Compare the effectiveness of two or more approaches that include interventions that are documented to be efficacious or in common use, and that are well characterized to facilitate replication and dissemination efforts
• Conduct the study in typical clinical care and community settings
• Have a sufficiently large study population to enable precise estimates of effect sizes and to support evaluation of potential differences in intervention effectiveness in patient subgroups
Notes about “usual care”

• “Usual care” as a comparator must be:
  – justified (e.g., usual care is guideline-based)
  – clearly described
  – measurable
  – and include description of how appropriate inferences will be made.
# Key Dates

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Online System Opens:</td>
<td>June 1, 2018</td>
</tr>
<tr>
<td>Pre-LOI Applicant Town Hall:</td>
<td>June 13, 2018 (Today)</td>
</tr>
<tr>
<td>LOI Deadline:</td>
<td>June 28, 2018</td>
</tr>
<tr>
<td>LOI Decisions Announced:</td>
<td>July 23, 2018</td>
</tr>
<tr>
<td>Application Deadline:</td>
<td>September 25, 2018</td>
</tr>
<tr>
<td>Post-LOI Applicant Town Hall:</td>
<td>August 8, 2018</td>
</tr>
<tr>
<td>Merit Review Dates</td>
<td>December 2018</td>
</tr>
<tr>
<td>Awards Announced:</td>
<td>April 2019</td>
</tr>
<tr>
<td>Earliest Project Start Date:</td>
<td>June 2019</td>
</tr>
</tbody>
</table>
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Resources and Q&A

Jamie Trotter
Program Associate
Healthcare Delivery and Disparities Research
Tips for Success – Programmatic

- Propose a comparative effectiveness study
- Clearly describe comparators for the study
- Document evidence of efficacy/effectiveness for interventions and comparator(s) and/or demonstrate that they are in widespread use
- Clearly describe sustainability and scalability of interventions for successful trials
- Consider how your project applies to PCORI’s unique merit review criteria around Patient-centeredness and Patient and Stakeholder Engagement
  - What we mean by engagement: [http://www.pcori.org/funding-opportunities/what-we-mean-engagement](http://www.pcori.org/funding-opportunities/what-we-mean-engagement)
- Submit a Letter of Intent (LOI)
  - You must be invited, on the basis of the LOI, to submit an application
Tips for Success – Administrative

- Adhere to the PFA and Application Guidelines for the funding cycle you are applying to (Cycle 2, 2018)
- Talk to a Program Officer if you have questions
- Start and submit early
- Download PCORI’s Pre-Award Applicant User Guide
- Ensure that all team members can see the application in the system
- Inform your AO of your intent to submit
- Submit the completed application before September 25, 2018 5:00 PM ET
Applicant Resources

• **OBOT Pre-announcement:** [https://www.pcori.org/funding-opportunities/announcement/psychosocial-interventions-cycle-2-2018](https://www.pcori.org/funding-opportunities/announcement/psychosocial-interventions-cycle-2-2018)


• **April 30th, Board of Governors Meeting Slides:** [https://www.pcori.org/sites/default/files/PCORI-Board-Meeting-Presentation-Slides-043018.pdf#page=90](https://www.pcori.org/sites/default/files/PCORI-Board-Meeting-Presentation-Slides-043018.pdf#page=90)

• **Methodology Standards:** [https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards](https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards)

• **Engagement Rubric:** [https://www.pcori.org/sites/default/files/Engagement-Rubric.pdf](https://www.pcori.org/sites/default/files/Engagement-Rubric.pdf)
Applicant Resources: 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)
Ask a question via the “Questions” function in GoToWebinar control panel

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

Els Houtsmuller  
Associate Director, Healthcare Delivery and Disparities Research

Denese Neu  
Engagement Officer, Public and Patient Engagement

Perrinne Kelley  
Administrator, Contracts Management

Andrea Brandau  
Program Officer, Healthcare Delivery and Disparities Research