Medication Assisted Treatment (MAT) Delivery for Pregnant Women with Substance Use Disorders Involving Prescription Opioids and/or Heroin

Cycle 2 2018 — Reissuance

Applicant Town Hall Webinar
Washington, DC
August 9, 2018 at 12:00pm ET

pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Agenda

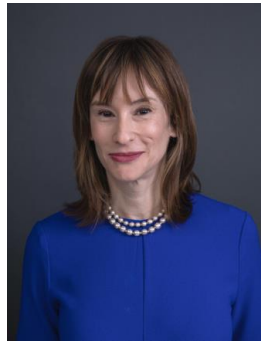
I. **Welcome and Introductions**
II. About PCORI
III. PFA Overview
IV. Patient and Stakeholder Engagement
V. Administrative Overview
VI. Merit Review
VII. Tips for Success and Resources
VIII. Q&A

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



Julie Kennedy Lesch
Engagement Officer
Public and Patient Engagement

Andrea Brandau
Program Officer
Healthcare Delivery and Disparities Research

Valerie Clark
Administrator
Contracts Management

Carolyn Mohan
Merit Review Officer
Merit Review

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About PCORI

Els Houtsmuller

Associate Director, Science

Healthcare Delivery and Disparities Research

PCORI

- An independent, non-profit [501-(c)(1)] 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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Targeted PFA Goal

The goal of this targeted PFA is to generate evidence regarding the **comparative effectiveness** of different **strategies** for providing **support** or **coordination of services** for components of **MAT** (induction and/or psychosocial services) to providers who offer **office-based opioid treatment** to **pregnant women**, in terms of maternal and neonatal outcomes.

PICOTS

Population: Pregnant women with OUD as defined by the DSM-5, and infants born to women with OUD.

- PCORI is particularly interested in proposals that focus on or include urban, low-income, and racial-ethnic minority populations.
- While Medicaid insurance covers close to 50% of US births, applications that include women with private insurance and uninsured women will also be considered responsive.

Interventions and Comparators: Provider support strategies that focus on provider barriers, including lack of expertise, time, support:

- Patient induction and stabilization: in the ED, hospital, opioid treatment program (OTP), at home vs in provider office
- Teleconsultations with an OTP
- Psychosocial services (e.g., on-site individual or group counseling, online services, referral)
- Service coordination by office staff or peer navigator
- Internet-based consultation or education systems

PICOTS
Continued

Outcomes

- Addiction specific outcomes (e.g. illicit drug use, relapse, treatment entry, treatment retention, post-partum treatment continuation, patient quality of life, anxiety/depression)
- Pregnancy and neonatal outcomes (e.g. preterm birth, pregnancy complications, birthweight, neonatal complications, Neonatal Abstinence Syndrome (NAS))
- Provider outcomes (e.g. satisfaction and stress)

Time

- Studies up to 4 years
- Repeated assessments to measure maternal and neonatal outcomes during pregnancy as well as at least 3-months post-partum

Setting

- Community-based settings; locations where pregnant and post-partum women with OUD typically receive care

Study Considerations

- Large randomized controlled trials (RCTs) or well justified observational studies; sufficient sample size
- Interested in heterogeneity of treatment (HTE) 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

Research Activities Not Supported

- This PFA will **NOT** support:
  - 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 $6 million for this PFA

The proposed budget for studies under this initiative may be **up to $4 million in direct costs**

The maximum **project period is 4 years** (three year studies are also encouraged)

NOTE: PCORI funding does **not** cover clinical healthcare costs

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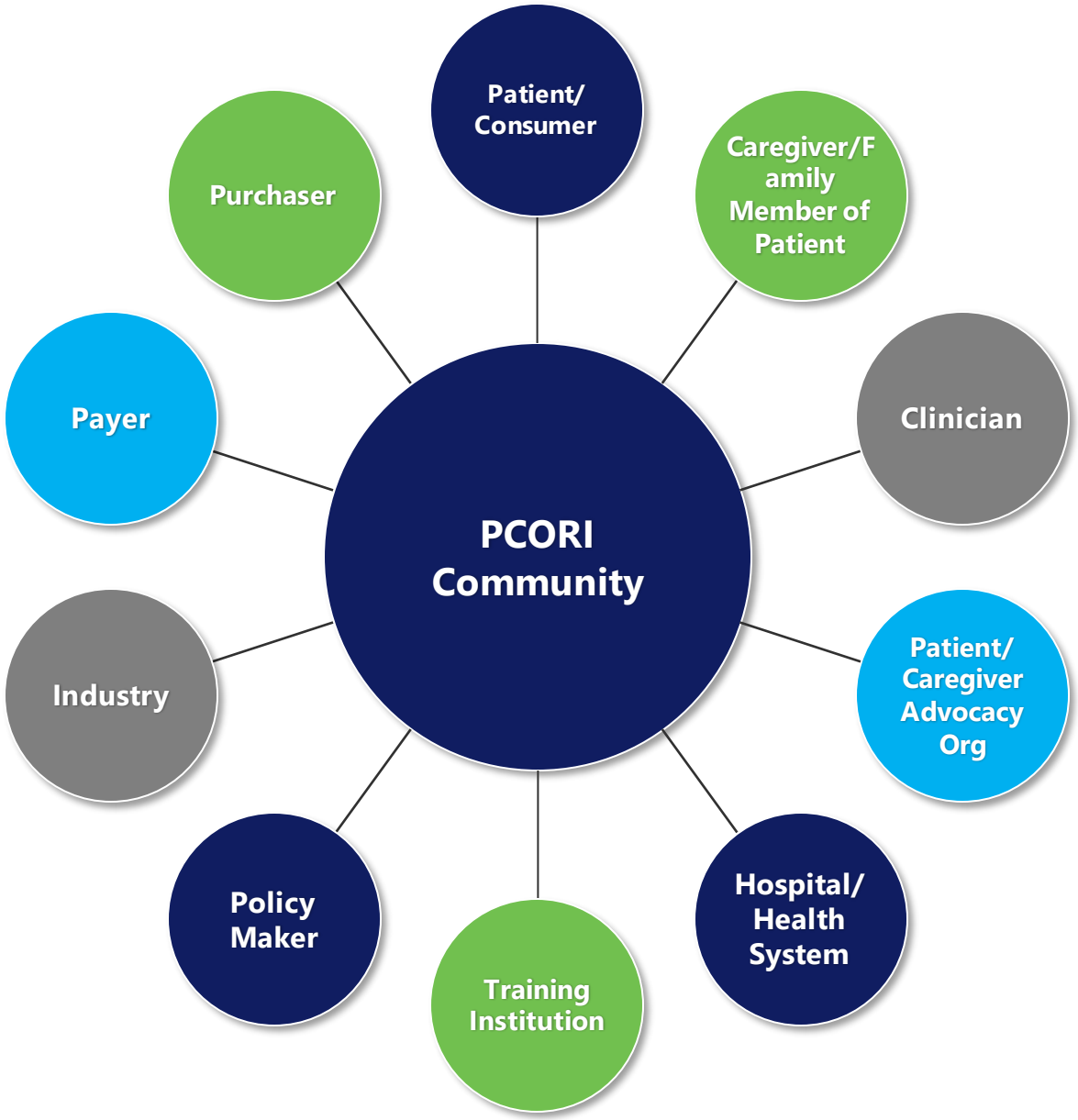
Patient and Stakeholder Engagement

Julie Kennedy Lesch
Engagement Officer
Public and Patient Engagement

Patients and Other Stakeholders



Patient-Centeredness

- Is the research focused on questions that affect outcomes of interest to patient and their caregivers?
    - Does the research question address choices that are important to — and faced frequently by — patients, their caregivers, or clinicians?
    - Is the study powered on outcomes that are important to patients?

- Are the interventions being compared in the study available to patients now?

Addressing Patient-Centeredness

- Provide evidence that the research question(s) and outcomes are important to patients (and/or their caregivers)
- Describe your strategy for measuring outcomes that are important to patients
- Remember that a study can be patient-centered even if the end-user is not the patient, as long as patients will benefit from its information
    - If the end-user is not the patient, be sure to carefully describe how your study is still patient-centered

Patient and Stakeholder Engagement

- Evidence that patients, caregivers, clinicians, and other stakeholders have been and will be engaged in:
  - Formulating the research questions
  - Defining the characteristics of study participants, comparators and outcomes
  - Selecting the important outcomes to be assessed
  - Monitoring study conduct and progress
  - Designing plans for dissemination of study results
- Clear statement of the roles and the decision-making authority of all patient and stakeholder research partners
- An organizational structure, including a Study Advisory Committee or similar entity, which will bring together national patient and stakeholder groups to further the goals of the study

Patient-Centeredness vs. Patient Engagement

- Patient-centeredness is about whether the project aims to answer questions or examine outcomes that matter to patients/caregivers
- Patient engagement is about having patients/caregivers as partners in research, as opposed to merely being recruited as study participants

Our Engagement Rubric
A Valuable Resource

Provides practical guidance to applicants, merit reviewers, awardees, and engagement/program officers on effective engagement in research

- **Planning the Study:** How patient and stakeholder partners will participate in study planning and design
- **Conducting the Study:** How patient and stakeholder partners will participate in the conduct of the study
- **Disseminating the Study Results:** How patient and stakeholder partners will be involved in plans to disseminate study findings and ensure that findings are communicated in understandable, usable ways
- **PCOR Engagement Principles:** Reciprocal relationships, co-learning, partnership, trust, transparency, honesty

http://www.pcori.org/sites/default/files/Engagement-Rubric.pdf

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, AV)
- Additional time and resource to incorporate partner feedback into various project process

Engagement Resources

- **PCORIs "Engagement Rubric:"** http://www.pcori.org/sites/default/files/Engagement-Rubric.pdf
- **Compensation Framework:** http://www.pcori.org/sites/default/files/PCORI-Compensation-Framework-for-Engaged-Research-Partners.pdf
- **Engagement Budgeting:** http://www.pcori.org/sites/default/files/PCORI-Budgeting-for-Engagement-Activities.pdf
- **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
- **PCORI in Practice Webinars:** https://www.pcori.org/engagement/engage-us/participate-pcori-events/pcori-practice

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Administrative Overview

Valerie Clark

Administrator

Contracts Management

LOI and Application

- Full applications have been 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

Research Plan Template

- **Research Strategy: Maximum 15 pages in length**
  - Provide all information requested, as outlined in the template:
    - Specific Aims
    - Background
    - Significance
    - Study Design or Approach
    - Study Population(s)

- **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

Research Plan Template
Continued

- **Dissemination & Implementation Potential: 2 pages**
  - Describe how you will make study results available to study participants after you complete the analyses.
  - Describe possible barriers to disseminating and implementing the results of this research in other settings.
- **Consortium Contractual Arrangements: 10 pages**
  - Describe the proposed components of the research project that will be performed by subcontracted organizations.
    - Explain the strengths that these partners bring to the overall project to ensure successful submission of contract deliverables in accordance with the milestone schedule.

Research Plan Template
Continued

- **Protection of Human Subjects: 5 pages**
- **References: 10 pages**
- **Appendices (optional)**: **10 pages**
  - 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: (NEW)**
  - Applicants must complete each column of this checklist, as appropriate, and include it with the Research Plan PDF upload

People and Places Template

- **Leadership Plan Template (Dual PI application): 5 pages**
  - Describe the governance and organizational structure of the leadership team and the research project;
  - Delineate the administrative, technical, scientific, and engagement responsibilities for each PI and the rationale for submitting a dual-PI application;
  - Discuss communication plans and the process for making decisions on scientific and engagement direction;
  - Describe the procedure for resolving conflicts.

- Note: If this template is applicable, it should be uploaded as the first section of the People and Places Template

People and Places Template
Continued

- **Professional Profile/Biosketch: 5 pages per person**
  - Required for all key personnel
    - Use NIH biosketch or PCORI's format
    - List all partners within the Key Personnel section

- **Patient and/or stakeholder biosketches: 5 pages per person**

- **Project/Performance Site(s) and Resources: 15 pages**
  - Provide a description of the facilities that will be used during the project, including capacity, capability, characteristics, proximity, and availability to the project

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

- Letters of support should be organized in the following manner:
  - Letters of organizational support
  - Letters of collaboration
  - Letters confirming access to patient populations, data sets, and additional resources

Milestones/Deliverables

- **Milestones**
  - Significant events, deliverables, tasks, and/or outcomes that occur over the course of the project that mark progress toward the project's overall aims
- **Deliverables**
  - Measurable and verifiable outcomes or products that a project team must create and deliver according to the contract terms
- See Appendix 1 of the Application Guidelines for examples of milestones.
- Milestones/Deliverables must be entered into PCORI Online

Budget

- 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. Include the federally negotiated or independently audited indirect cost rate letter (prime contractor) and fringe benefit rate policy verification document (prime contractor)

Using the PCORI Online System

- Navigate to PCORI Online (https://pcori.force.com/engagement)
- Log into the PCORI system early
- Please only use **Chrome, Safari, and Firefox browsers** to access the system
- The PI and the AO cannot be the same individual
- PCORI Online Training Slides
- PCORI Online Application Cheat Sheet

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**

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

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Merit Review

Carolyn Mohan
Merit Review Officer

An Inclusive Merit Review

- Each review panel includes three reviewer types to bring diverse perspectives.
- Each application is reviewed by three scientists, one patient, and one other stakeholder.

Patients

Scientists, including methodologists

Other Stakeholders

The Merit Review Process

- Overview
  - Full applications screened by committee of PCORI merit review staff for responsiveness to PFA and consistency with LOI
  - Preliminary (online) review
  - In-Person review
  - Post-Panel review (PCORI program staff)

- PCORI guides reviewers to use the bullet points under each merit review criterion to evaluate their assigned applications (see Merit Review Section in PFA)

Merit Review Criteria

Crosswalk of PCORI Merit Review Criteria with NIH Criteria	
SIGNIFICANCE	1. Potential for the study to fill critical gaps in evidence 2. Potential for the study findings to be adopted into clinical practice and improve delivery of care
APPROACH	3. Scientific merit (research design, analysis, and outcomes) NEW 4. Investigator(s) and environment

PCORI-only Merit Review Criteria	
PATIENT-CENTEREDNESS/ ENGAGEMENT	5. Patient-centeredness 6. Patient and stakeholder engagement

The Potential for the Study to Fill Critical Gaps In Evidence

- Does the application convincingly describe the clinical burden?
- Does the application identify a critical gap in current knowledge as noted in systematic reviews, clinical practice guidelines, or previous research prioritizations?
- Does the application identify a critical gap in current knowledge, evidenced by inconsistency in clinical practice and decision making?
- Would research findings from the study have the potential to fill these gaps?

The Potential of the Study Findings to Be Adopted Into Clinical Practice and Improve Delivery of Care

- Does the application identify who will make the decision (i.e., the decision maker) or use (i.e., the end-user) the study findings (not the intervention) this study produces, such as local and national stakeholders?
- Does the application identify potential end-users of study findings—such as local and national stakeholders—and describe strategies to engage these end-users?
- Does the application provide information that supports a demand for this kind of a study from end-users?
- Would this study's research findings have the potential to inform decision making for key stakeholders? If so, provide an example. How likely is it that positive findings could be reproduced by others, resulting in improvements in practice and patient outcomes? Identify the potential barriers that could hinder adoption of the intervention by others.
- Does the application describe a plan for how study findings will be disseminated beyond publication in peer-review journals and at national conferences?

Scientific Merit

- A clear research plan with rigorous methods that adhere to PCORI's Methodology Standards and accepted best practices
- A clear justification for the study design and outcome measures
- Clearly described and justified comparators
- Sample sizes and power estimates based on careful evaluations of the anticipated effect size
- Feasibility
    - A carefully constructed and realistic timeline that includes specific scientific and engagement milestones
    - Realistic strategies for participant recruitment and retention

Investigators and Environment

- Demonstrate the team's experience, leadership approach, governance and organizational structure, as appropriate to achieving project goals
- Demonstrate resources and institutional support to conduct project as planned, with budget and on time
- Dual PIs must submit a leadership plan

Patient Centeredness

- Does the application include a thorough description about which outcomes (both benefits and harms) are important to patients? Are those outcomes included in the study plan?
- Does the application provide information that indicates that closing the evidence gap is important to patients and other stakeholders?
- Are the interventions being compared in the study available to patients now, and are they the best options for comparison (including whether they would be chosen by patients and their healthcare providers for managing the condition being studied)?

Patient and Stakeholder Engagement

- Does the application provide a well-justified description of how the research team incorporates stakeholder involvement? Does the study include the right individuals to ensure that the projects will be carried out successfully?
- Does the application show evidence of active engagement among scientists, patients, and other stakeholders throughout the research process? Is the frequency and level of patient and stakeholder involvement sufficient to support the study goals?
- Is the proposed Engagement Plan appropriate and tailored to the study?
- Are the roles and the decision-making authority of all study partners described clearly?
- Are the organizational structure and resources appropriate to engage patients and stakeholders throughout the project?

Key Dates

Action	Date
Online System Opens:	June 1, 2018
Pre-LOI Applicant Town Hall:	June 11, 2018
LOI Deadline:	June 28, 2018
LOI Decisions Announced:	July 23, 2018
Post-LOI Applicant Town Hall:	August 9, 2018 (Today)
Application Deadline:	September 25, 2018
Merit Review Dates	December 2018
Awards Announced:	April 2019
Earliest Project Start Date:	June 2019

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Tips for Success and Resources

Andrea Brandau

Program Officer

Healthcare Delivery and Disparities Research

Tips for Success
Preparing Your Application

- Read the funding announcement and review the PCORI Application Guidelines Document
- Review the PCORI Research Plan Template
- Have a copy of your approved LOI and LOI feedback provided by PCORI staff readily accessible

Tips for Success
Study Design/Approach

- Document how proposed study will fill the **evidence gap.**
- Include a clear **conceptual framework,** theory or model that anchors the background, significance, and informs the design, key variables, and relationships being tested.
- Clearly describe and justify **comparators,** including **usual care.**
- Document **efficacy/effectiveness** and/or **common use** of **proposed comparators** in clinical practice.
- Provide clear **justification** for the **study design** and **outcomes.**
- Include **clear rationale** for sample size, power estimates, and effect sizes, and support rationale with evidence or pilot work.

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Tips for Success
Programmatic

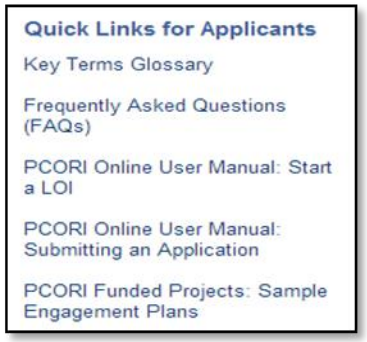
- Clearly demonstrate the **feasibility** of the study:
  - Team and expertise
  - Recruitment and retention
  - Committed sites
  - Realistic timelines
- Clearly describe **sustainability** and **scalability** of interventions
- Consider how your project meets **PCORI's unique** merit review **criteria** around Patient-centeredness and Patient and Stakeholder Engagement

Applicant Resources

- **MAT Pre-announcement:** http://www.pcori.org/funding-opportunities/announcement/medication-assisted-treatment-mat-delivery-pregnant-women
- **PFA:** http://www.pcori.org/funding-opportunities/announcement/medication-assisted-treatment-mat-delivery-pregnant-women
- **FAQs:** http://www.pcori.org/funding-opportunities/what-you-need-know-apply/have-question/medication-assisted-treatment-mat
- **Methodology Standards**: http://www.pcori.org/research-we-support/research-methodology-standards/
- **Engagement Rubric:** http://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)



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Q&A

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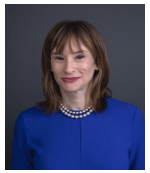
If we are unable to address your question during this time, e-mail the Helpdesk at pfa@pcori.org.

Thank You!

Els Houtsmuller
Associate Director, Healthcare Delivery and Disparities Research



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