

# Notice of Recording



**Please note this meeting is being recorded. The recording will be posted to PCORI's website.**

# Methodology Committee Teleconference

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Steven Goodman, MD, MHS, PhD  
Chair, PCORI Methodology Committee

Robin Newhouse, PhD, RN  
Vice-Chair, PCORI Methodology Committee

December 13, 2021

# Introduction: Acknowledgement of COI Statement & Overview of Agenda

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**Steven Goodman, MD, MHS, PhD**

Chair, PCORI Methodology Committee

# COI Statement: Methodology Committee



Welcome to the Methodology Committee meeting. I want to remind everyone that disclosures of conflicts of interest of members of the Methodology Committee are publicly available on PCORI's website and are required to be updated annually. Members of the Methodology Committee are also reminded to update your conflict of interest disclosures if the information has changed. You can do this by contacting your staff representative.

If the Methodology Committee will deliberate or take action on a matter that presents a conflict of interest for you, please inform the Chair so we can discuss how to address the issue. If you have questions about conflict of interest disclosures or recusals relating to you or others, please contact your staff representative, **Vita Pierzchala**.

# Meeting Agenda & Topics



Agenda Item	Discussion Lead
<b>Introduction</b> <ul style="list-style-type: none"><li>• Welcome, acknowledgement of COI Statement, and review of agenda</li></ul>	Steve Goodman
<b>Science of Engagement Discussion</b>	Kristin Carman, Laura Forsythe
<b>Consensus Vote: Minutes of the Previous Meeting Recap, Updates, &amp; Agenda Items for Upcoming Meetings</b>	Steve Goodman

Please review the attached **meeting minutes**. An approval by a **consensus vote** will be called for towards the end of this meeting.

# Science of Engagement Funding Initiative

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Kristin L. Carman, PhD, MA  
Director, Public & Patient Engagement

Laura Forsythe, PhD, MPH  
Director, Evaluation & Analysis

Methodology Committee, December 13, 2021



# The Science of Engagement



- The systematic **study of methods for and outcomes of engagement** to inform high-quality, patient-centered research
- Intended to help inform engagement practice, guidance, and resources to achieve meaningful engagement and inclusion of diverse and representative partners

# Science of Engagement Initiative



## The new initiative aims to:

- Expand the evidence base on the approaches for effectively engaging diverse patients and stakeholders throughout the research process
- Identify the ultimate outcomes of engagement or the impact of engagement
- Implement resources and facilitators necessary to successfully support studies that address these research topics

## Request for Information

- PCORI issued an RFI that was open from September 27, 2021 to November 19, 2021
- Currently in the process of analyzing and synthesizing feedback from 54 responses

# PCORI's Engagement Evidence To Date



- Engagement is **feasible in all phases of CER and PCOR** and with a variety of stakeholders
- Engagement can **influence the design and conduct of research studies** in meaningful ways including acceptability, feasibility, quality, and relevance
- Engagement can **benefit** the patient and stakeholder partners, communities, and researchers involved
- There are **known challenges** to address, including those related to infrastructure and resources, people and teams, organizational policies, and balancing views and priorities

# Patient-Centeredness Methodology Standards



- PC-1: Engage people representing the population of interest and other relevant stakeholders in ways that are appropriate and necessary in a given research context.
- PC-2: Identify, select, recruit, and retain study participants representative of the spectrum of the population of interest and ensure that data are collected thoroughly and systematically from all study participants.
- PC-3: Use patient-reported outcomes when patients or people at risk of a condition are the best source of information for outcomes of interest.
- PC-4: Support dissemination and implementation of study results.

**Awardees have looked for guidance from PCORI  
on *how* and *when* to engage**

# SoE Potential Topic Areas for Study



**What defines successful engagement, and for whom?**

**How can engagement be measured? What indicates that a study is patient-centered?**

**What are the approaches that support and achieve successful engagement?**

**Which approaches should be combined to achieve engagement aims?**

**Under which conditions do approaches work best and how should they be modified and resourced for different contexts, settings, and communities?**

# Key Characteristics of the Engagement Evidence Needed



- **Actionable results** about how to effectively do engagement
- Generalizable or **transferable knowledge**
- **Variety of robust designs and methods** (experimental, including quasi-experimental; observational, including natural experiments; well-designed comparative case studies, etc.)
- Studies potentially including:
  - **Assessment** of existing engagement methods
  - **Development and testing** of new engagement methods
  - **Development and validation** of engagement process and outcome measures

# SoE RFI Sample Questions



Includes request for input on questions including:

- In reference to the topics in the “Topics of Inquiry to Understand the Science of Engagement” table, **do you feel these are the right topics?** Are there other topics or areas of inquiry that are missing? How would you prioritize or stage addressing these topics?
- What **outcomes are important and appropriate for studies of engagement?** What **measures are most important to develop, validate, and use** to quantify and to understand the quality and impacts of patient and stakeholder engagement in health research?
- What should PCORI keep in mind to ensure that these potential research opportunities (Stand-alone Research Awards on the Science of Engagement and Studies Within a Study) are **inclusive of and accessible to all types of organizations and communities?** How can we best support the community to ensure high-quality applications?

# Discussion



- Do you have any questions or areas where you need clarification?
- What is key for us to consider as we move forward in developing this initiative?
- What specific information do you need to inform the development of methodology standards or to inform other Methodology Committee work?

# Consensus Vote: Meeting Minutes



**Approve** the minutes of the previous meeting

Or

Propose **edits** to the minutes of the previous meeting

# Recap, Updates, & Agenda Items for Upcoming Meetings

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**Steven Goodman, MD, MHS, PhD**

Chair, PCORI Methodology Committee