



# PCORI Funding Opportunity Overview

Improving Methods for Conducting Patient-Centered Comparative  
Clinical Effectiveness Research

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# My PCORI Experience

- 1. Propensity Score-based Methods for CER Using Multilevel Data: What Works Best When, 2016-2019**
- 2. New Methods for Integration of Individual Participant and Aggregate Data in CER Meta-Analysis, 2021-2024**
  - AI/ML Supplement, 2024-2025
- 3. Review Panel Services**



# UNLOCKING PCORI: EXPLORING STATISTICAL METHODOLOGY RESEARCH OPPORTUNITIES



## Panelists



**Kelley Kidwell**

University of Michigan



**Fan Li**

Yale University



**Daniel Scharfstein**

University of Utah

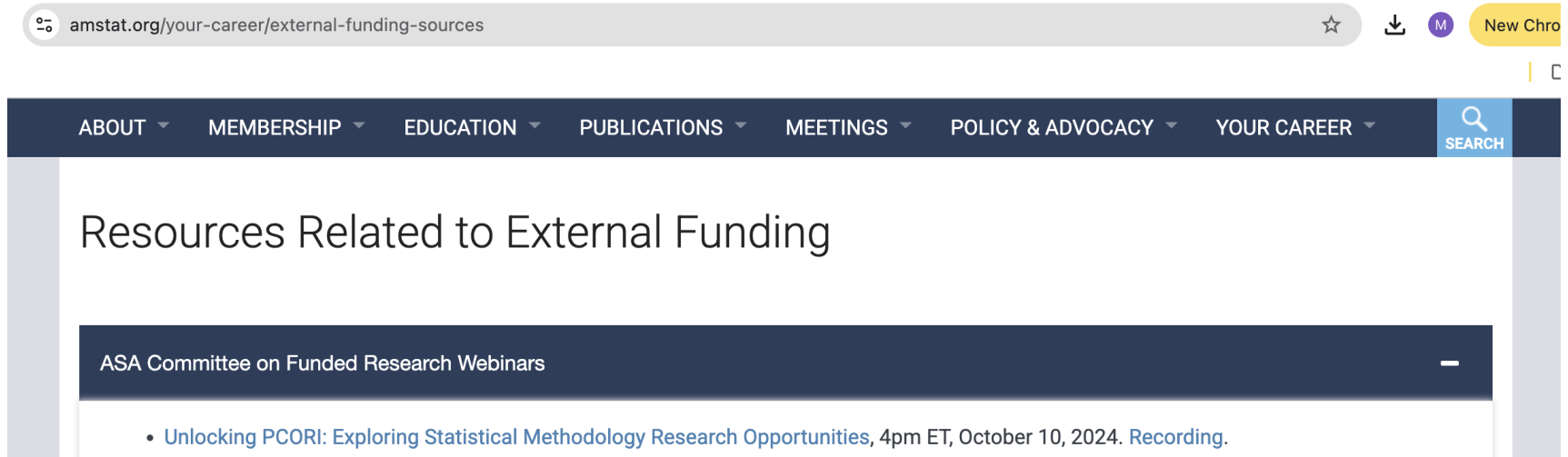


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Sponsored by  
ASA Committee  
on Funded  
Research

# <https://www.amstat.org/your-career/external-funding-sources>



The screenshot shows a web browser window with the address bar displaying [amstat.org/your-career/external-funding-sources](https://www.amstat.org/your-career/external-funding-sources). The browser's address bar includes a star icon for bookmarks, a download icon, and a profile icon labeled 'M'. A yellow 'New Chro' button is visible on the right. The website's navigation bar is dark blue with white text for 'ABOUT', 'MEMBERSHIP', 'EDUCATION', 'PUBLICATIONS', 'MEETINGS', 'POLICY & ADVOCACY', and 'YOUR CAREER', each followed by a dropdown arrow. A 'SEARCH' button with a magnifying glass icon is on the right. The main content area has a white background with the heading 'Resources Related to External Funding'. Below this, a dark blue banner contains the text 'ASA Committee on Funded Research Webinars' and a minus sign icon. A list of resources is shown below the banner, starting with 'Unlocking PCORI: Exploring Statistical Methodology Research Opportunities, 4pm ET, October 10, 2024. Recording.'

amstat.org/your-career/external-funding-sources

ABOUT ▾ MEMBERSHIP ▾ EDUCATION ▾ PUBLICATIONS ▾ MEETINGS ▾ POLICY & ADVOCACY ▾ YOUR CAREER ▾ SEARCH

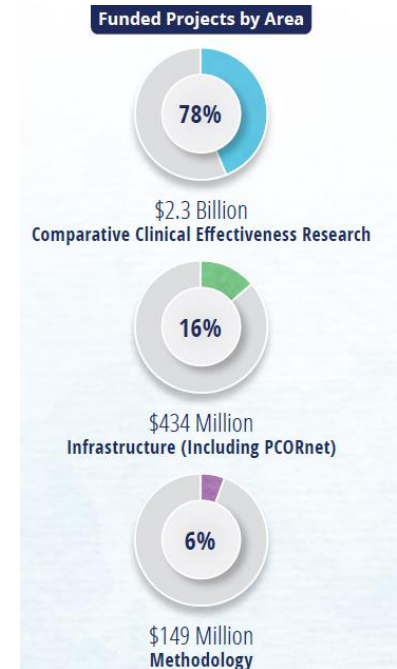
## Resources Related to External Funding

ASA Committee on Funded Research Webinars

- [Unlocking PCORI: Exploring Statistical Methodology Research Opportunities](#), 4pm ET, October 10, 2024. [Recording](#).

# What is PCORI?

- Non-profit, non-governmental institution authorized by congress in 2010, reauthorized for 10 years in 2019
- Largest public research funder focusing on CER & CER Methods and Infrastructure
- ~ 3 cycles of funding per year
- Improving Methods: up to 3 years, 750K total DC
- Review Criteria
  - Study identifies critical methodological gap(s) in patient-centered CER
  - Potential for the study to improve patient-centered CER methods
  - Scientific merit (research design, analysis, and outcomes)
  - Investigator(s) and environment
  - Patient centeredness
  - Patient and stakeholder engagement



# Application & Funding Process



- PCORI Funding Announcement (PFA)
  - Cycle Specific
  - Programmatic Priority Areas.
  - LOI & Merit Review
  - General Requirements & PCORI Policies

## Update for the 2023 Methods PFA

- **To Improve the Use of Artificial Intelligence (AI) and Machine Learning (ML) in Clinical Research:**
  - Beginning in Cycle 1 2023, PCORI will consider projects that develop disease- or condition-specific predictive models to be nonresponsive.
- **To Improve Study Design:**
  - Beginning in Cycle 2 2023, PCORI will no longer consider applications in the area of the design and conduct of cluster randomized trials, including stepped-wedge trials. PCORI is currently funding several projects in this area. We may reintroduce cluster randomized trials as a priority in future funding cycles.
  - Beginning in Cycle 2 2023, this programmatic priority includes a call-out regarding methods to improve the design and conduct of decentralized clinical trials (DCTs).

# Letter of Intent (LOI)

- Short proposal (~2 pages + references)
  - Title
  - Specific aims
  - Background
  - Significance
  - Approach
- Templates available at each PFA website
- Sufficient detail and scientific rigor of proposed methods
- Responsiveness to PFA- priority areas, Programmatic fit and balance (not overlapping with previously funded studies)
- LOIs Invited depends on PFA and year: 22-77%
  - Rates published in Board of Governor Meeting Slides

# Full Application & Review

- Research Strategy (12 pages)
  - Objectives, Background, Significance, Study Design/Approach, Study Population
  - **Engagement Approach**
- Research Team and Environment, Return of Aggregate Study Results
- **Dissemination and Implementation Potential**
- Start early, try to end early- navigating PCORI system can be difficult
- 2 Day Review Panel Meeting
  - Selected subset discussed: 11 out of 24 applications
  - Five assigned reviewers (three scientific/two stakeholder reviewers)
  - 1~3 Readers
  - Panel Members At-Large



# Patient & Stakeholder Engagement

- **Advisory Board**

- Clinicians, statisticians, patients & patient advocates (4-8 members)
- Meet regularly (quarterly or bi-annually), mostly virtually but may meet in person
- Review project, ask for feedback
  - Interpretation of methods and results
  - Broad disseminate beyond statistical communities
- Included in proposal via letters of support/biosketches



# My Reflections on PCORI Methods Funding

## Opportunities

- Dedicated funding for methods development
- Disease-agnostic scope, enabling broad methodological applicability across clinical areas
- Flexible and collaborative project management
- Stakeholder engagement to broaden real-world impact

## Challenges

- Two-stage review process: longer time from application to funding
- Contract mechanism (rather than a grant): greater oversight and reporting requirements
- Student tuition is not an allowable cost
- Lay-language final report requires additional effort and may extend project closeout
- Meaningful stakeholder engagement can be challenging to design and implement for methodological research