

Board of Governors Meeting

Via Teleconference/Webinar

February 26, 2019
12:00 PM – 1:30 PM ET

Welcome and Introductions

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director

Agenda



12:00 PM

Call to Order, Roll call, and Welcome

12:00 – 12:05

Consider for Approval: Minutes of the December 11, 2018 Board Meeting

12:05 – 12:20

Consider for Acceptance: FY2018 Independent Financial Audit Report

12:20 – 12:35

Consider for Adoption: New Methodology Standards

12:35 – 1:05

Consider for Approval: Proposed Cycle 2 2018 Slate of Large Awards for the Limited Competition Dissemination and Implementation (D&I) PFA

1:05 – 1:20

Consider for Approval: Reissue Partnerships to Conduct Research (PaCR) within PCORnet PFA

1:20 PM

Wrap up and Adjournment

Board Vote

Call for a Motion to:

- **Approve** the Minutes of the December 11, 2018 Board Meeting

Call for the Motion to be Seconded:

- **Second** the Motion
- If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Voice Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions

FY2018 Independent Auditor's Report

Christine Goertz, DC, PhD

Chair, Governance Committee

Thomas J. Sneeringer, CPA

Partner, RSM US LLP



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

AUDITOR PRESENTATION

PCORI Board of Governors

February 26, 2019

FY2018 Independent Auditor's Report

PCORI received an unmodified opinion; the financial statements presented fairly, in all material respects, the financial position, the changes in its net assets, and its cash flows

- There are no findings related to deficiencies in internal control over financial reporting
- There are no findings related to compliance or other matters

Statement of Activities

Statement of Activities	FY2018	FY2017
Revenue	\$506,485,458	\$466,085,422
Expenses	\$384,523,987	\$400,343,278
Realized and unrealized loss on investments	\$ (502,360)	\$ (353,075)
Change in Net Assets	\$121,459,111	\$65,389,069

Statement of Financial Position

Statement of Financial Position	FY2018	FY2017
Assets	\$1,151,077,182	\$1,033,061,045
Liabilities	\$ 89,292,701	\$ 92,735,675
Net Assets	\$1,061,784,481	\$940,325,370

Board Vote

Call for a Motion to:

- **Accept** the FY2018 Independent Financial Audit Report

Call for the Motion to Be Seconded:

- **Second** the Motion
- If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Roll Call Vote:

- Vote to **Accept** the FY2018 Independent Financial Audit Report
- Ask for votes in favor, opposed, and abstentions

Methodology Committee: Request for Adoption of New Methodology Standards

Robin Newhouse, PhD, RN

Chair, PCORI Methodology Committee

PCORI Methodology Committee



Consistent with PCORI's authorizing law, the Methodology Committee works to develop and improve the science and methods of comparative clinical effectiveness research

Methodology Committee Members:

- Robin Newhouse, Chair
- Steven Goodman, Vice Chair
- Naomi Aronson
- Ethan Basch
- Stephanie Chang (AHRQ)
- David Flum
- Cindy Girman
- Mark Helfand
- Michael Lauer (NIH)
- David Meltzer
- Brian Mittman
- Sally Morton
- Neil Powe
- Adam Wilcox

PCORI's Methodology Standards



- Required by PCORI's authorizing law
- Developed by the Methodology Committee and proposed to the Board for adoption after opportunity for public comment
- Represent minimal standards for design, conduct, analysis, and reporting of comparative effectiveness research (CER) and patient-centered outcomes research (PCOR)
- Provide guidance to researchers and those who use research results
- Reflect generally accepted best practices
- Used by PCORI to assess the scientific rigor of funding applications, monitor conduct of research awards, and evaluate final research reports

Development & Adoption of New Methodology Standards



- Methodology Committee undertook a systematic process to draft, revise, and finalize eleven new Methodology Standards
- Board approved these standards for public comment in July 2018 (public comment ran from July – September 2018)
- Methodology Committee reviewed the public comments and revised the standards, as appropriate
- Methodology Committee approved three new categories of standards to be brought to the Board for adoption:
 - Standards for Qualitative Methods (4 standards)
 - Standards for Mixed Methods Research (3 standards)
 - Individual Participant-Level Data Meta-Analysis (IPD-MA) (4 standards)

Proposed New Standards: Qualitative Methods

Rationale

- Qualitative methods can enable a more robust capture and understanding of information from patients, caregivers, clinicians, and other stakeholders in research, thereby improving the strength, quality, and relevance of findings. Additional guidance is needed to ensure the appropriate use of qualitative methods in the context of PCOR/CER

Title of proposed new standards

- **QM-1:** State the qualitative approach to research inquiry, design, and conduct
- **QM-2:** Select and justify appropriate qualitative methods sampling strategy
- **QM-3:** Link the qualitative data analysis, interpretations, and conclusions to the study question
- **QM-4:** Establish trustworthiness and credibility of qualitative research

Proposed New Standards: Mixed Methods Research



Rationale

- Mixed methods research requires the **integration** of methods, data, findings, and interpretations. Additional guidance is needed to ensure the appropriate design, conduct, analysis, and reporting of PCOR/CER studies proposing a mixed methods approach

Title of proposed new standards

- **MM-1:** Specify how mixed methods are integrated across design, data sources, and/or data collection phases
- **MM-2:** Select and justify appropriate mixed methods sampling strategy
- **MM-3:** Integrate data analysis, data interpretation, and conclusions

Proposed New Standards: IPD-MA

Rationale

- Additional guidance is needed to ensure the appropriate design, conduct, analysis, and reporting of IPD-MA, which can provide more robust insights about differences in the benefits and risks of treatments for individual patients

Title of proposed new standards

- **IPD-1:** Specify the research question(s) that will be addressed through the IPD-MA and describe the specific information it will provide that other approaches would not
- **IPD-2:** Describe the proposed governance structure for the IPD-MA in the protocol and study reports
- **IPD-3:** Use systematic, reproducible methods to identify studies for inclusion in the IPD-MA
- **IPD-4:** Specify the design and planned analyses of the IPD-MA in a protocol, document any changes, and report significant amendments and modifications

Next Steps

- Methodology Committee is recommending that the Board adopt eleven new Methodology Standards today
 - Updated Methodology Standards will include a total of 65 standards in 16 categories
- Upon adoption, the new Methodology Standards will be implemented for the Cycle 2 2019 funding cycle
 - PCORI will update the Methodology Report (expected late spring 2019)

Call for a Motion to:

- **Adopt** eleven new PCORI Methodology Standards

Standards for Qualitative Methods

- **QM-1:** State the qualitative approach to research inquiry, design, and conduct.
- **QM-2:** Select and justify appropriate qualitative methods sampling strategy.
- **QM-3:** Link the qualitative data analysis, interpretations, and conclusions to the study question.
- **QM-4:** Establish trustworthiness and credibility of qualitative research.

Standards for Mixed Methods Research

- **MM-1:** Specify how mixed methods are integrated across design, data sources, and/or data collection phases.
- **MM-2:** Select and justify appropriate mixed methods sampling strategy.
- **MM-3:** Integrate data analysis, data interpretation, and conclusions.

Standards for IPD-MA

- **IPD-1:** Specify the research question(s) that will be addressed through the IPD-MA and describe the specific information it will provide that other approaches would not.
- **IPD-2:** Describe the proposed governance structure for the IPD-MA in the protocol and study reports.
- **IPD-3:** Use systematic, reproducible methods to identify studies for inclusion in the IPD-MA.
- **IPD-4:** Specify the design and planned analyses of the IPD-MA in a protocol, document any changes, and report significant amendments and modifications.

Board Vote

Call for the Motion to be Seconded:

- **Second** the Motion
- If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Roll Call Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions

Proposed Funding Slate from the Limited Competition PCORI Funding Announcement (Cycle 2 2018):

Implementation of PCORI-Funded Patient-Centered
Outcomes Research Results

Sharon Levine, MD

Chair, Engagement, Dissemination,
and Implementation Committee (EDIC)

Jean Slutsky, PA, MSPH

Chief Engagement and Dissemination Officer



Cycle 2 2018 – Limited D&I PFA

Purpose of this funding initiative

- To give PCORI awardee teams an opportunity to
 - Propose **investigator-initiated** strategies for disseminating and implementing findings from their PCORI funded studies in the context of existing evidence
 - Undertake the **next step(s)** for promoting the uptake of their findings in practice

Cycle 2 2018 – Limited D&I PFA

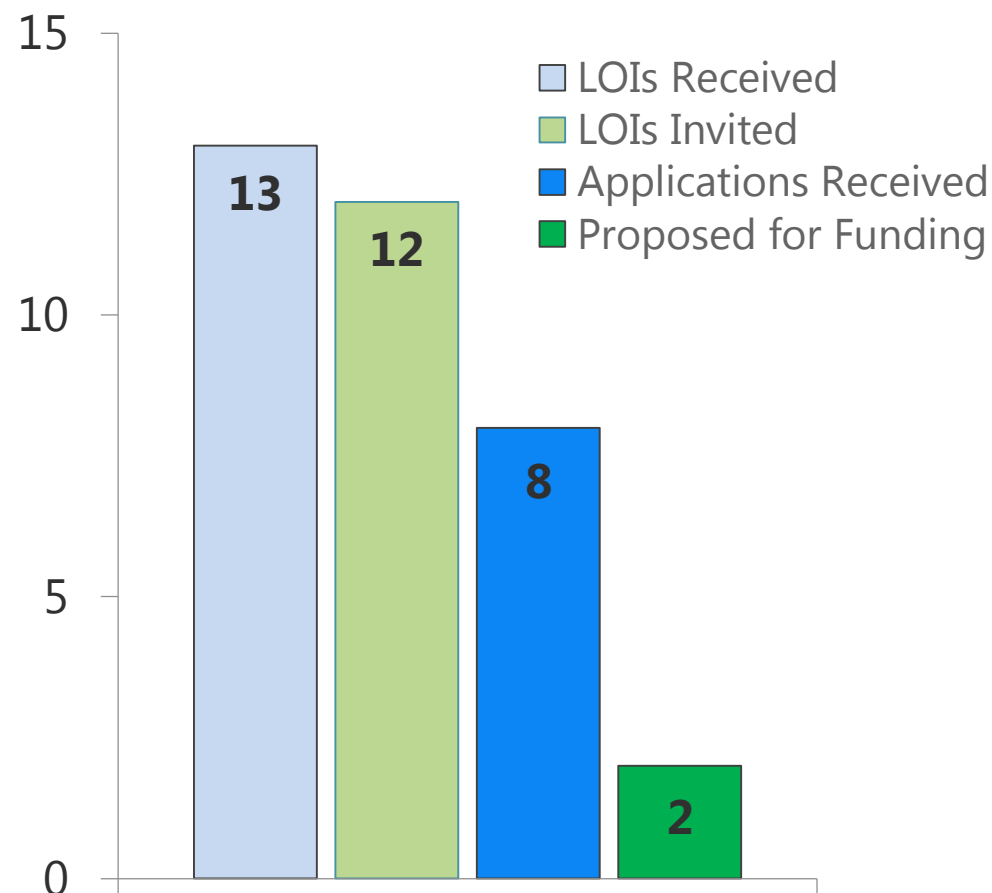
Merit Review Criteria

1. Importance of research results in the context of the existing body of evidence
2. Readiness of the research results for implementation
3. Technical merit of the proposed implementation project
4. Project personnel and environment
5. Patient-centeredness
6. Patient and stakeholder engagement

Cycle 2 2018 – Limited D&I PFA

Process Overview

- **Application overview**
 - 13 Letters of Intent (LOIs) submitted
 - 12 LOIs invited to submit a full application (92% of submitted LOIs)
 - 8 applications received (67% of invited LOIs)
- **Overall funding rate is 25 percent**
 - EDIC is proposing to fund 2 applications out of 8 received applications
- **Proposed funding slate is recommended by the Engagement, Dissemination, and Implementation Committee (EDIC)**



Cycle 2 2018 – Limited D&I PFA

Slate of 2 Recommended Projects



Project Title
Implementation of the IMPaCT Community Health Worker Intervention
Implementing Peer-Driven Care to Patients with Sleep Apnea

- Average requested budget per project is \$1.4M
- All proposed projects, including requested budgets and project periods, if approved by the Board, will be subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Project 1:

Implementation of the IMPaCT Community Health Worker Intervention

This D&I project will

- Adapt and customize an award-winning Community Health Worker program, shown in a PCORI-funded study to improve patient satisfaction and decrease hospitalization among low-income chronically ill patients
- Implement this program to a larger patient population receiving care in VA and Medicaid managed care organizations in Pennsylvania and North Carolina
- Evaluate the continued success of the program and its impact on healthcare and health outcomes

Project 2: Implementing Peer-Driven Care to Patients with Sleep Apnea

This D&I project will

- Adapt and customize an interactive phone-based peer support program, shown in a PCORI-funded study to improve continuous positive airway pressure (CPAP) adherence among patients with obstructive sleep apnea
- Implement the program in a large healthcare system that cares for a significant number of dual-eligible Medicaid and Medicare patients across Arizona
- Evaluate the continued success of the program and its impact on healthcare and health outcomes

Cycle 2 2018 – Limited D&I PFA

Slate of 2 Recommended Projects



PFA	Amount Budgeted per Year	Proposed Total Award*
Implementation of PCORI-Funded Patient-Centered Outcomes Research Results	\$9M	\$2.8M

*Note: Budgeted amount is for up to 3 cycles per year. This is the second cycle for FY 2019

Board Vote

Call for a Motion to:

- **Approve** funding for the recommended slate of awards from the Cycle 2 2018 Limited Competition Implementation of PCORI-Funded Patient-Centered Outcomes Research Results PFA

Call for the Motion to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Roll Call Vote:

- Vote to **Approve** the **Final** Motion
 - Ask for votes in favor, opposed, and abstentions

Partnerships to Conduct Research within PCORnet (PaCR) - Reissue

Joe Selby, MD, MPH
Executive Director



Initial PaCR Awards: Cycle 2 2017 – Partnerships to Conduct Research within PCORnet (PaCR)



The original funding opportunity was directed solely to PPRNs (as prime responders). It was intended to support the Board's vision of a sustainable national research infrastructure. The announcement had 4 key requirements:

- **Develop External Partnerships:** Applicants must collaborate with external stakeholders—industry sponsors or other funding organizations—to secure direct or in-kind support
- **Advance Data Integration:** Applicant PPRNs must describe proposed data linkage(s), how linkages will serve study needs and be accomplished (e.g., using de-identified or identifiable data linkages); and approaches to Institutional Review Board (IRB) oversight of those linkages
- **Generate CER Evidence:** Studies must generate CER evidence relevant to specific conditions, treatments, and patient communities or to clinical care for broader populations
- **Leverage Existing PCORnet Resources:** Applicants must use all appropriate existing PCORnet resources such as other PPRNs, CRNs (previously CDRNs), Health Plans (HPRNs), the Coordinating Center (PCORnet CC), the PCORnet Common Data Model (CDM), and others

PFA Development Approved by Board: June, 17, 2018

Total Approved: \$21M Total Costs

Cycle 2 2017 – Partnerships to Conduct Research within PCORnet (PaCR) – 4 Awarded Projects

Project	Basic Study Information	Partnerships	Project Total Cost
Comparative Effectiveness of Pharmacogenomics for Treatment of Depression (CEPIO-D)	Compares pharmacogenomic guided psychiatric treatment with best practice guidelines among adults with major depressive disorder	- Assurex - Cogito	\$4.8M
Improving Outcomes in Limited Juvenile Idiopathic Arthritis	Compares early treatment with a biological agent to usual care (start with NSAIDS and glucocorticoid joint injections) among children within 6 months of diagnosis of juvenile idiopathic arthritis	- Arthritis Foundation - Bristol Myer Squibb - CARRA Registry	\$7M
Using PCORnet to Compare Blood Pressure Control Strategies	Compares blood pressure control programs and blood pressure monitoring strategies among clinics participating in the Target: Blood Pressure Improvement Program and patients diagnosed with hypertension	- American Medical Association (AMA) - American Heart Association (AHA)	\$6.5M
Comparative Effectiveness of Biologic or Small Molecule Therapies in Inflammatory Bowel Disease	Compares second line biologic agents and small molecule among Crohn's and Ulcerative Colitis patients who are anti-TNF primary or secondary non-responders	Crohn's & Colitis Foundation	\$2.4M

Cycle 2 2017 – External Partnerships

In the 4 Awarded Projects



- The 4 original awards brought in approximately **\$6M** in external funding:
 - In-kind support for:
 - Leadership, program staff support and travel
 - Provision of study drug
 - Data warehouse management
 - Software modifications and operational support
 - Software and app licenses
 - 12-genetic marker commercially available test
 - Direct financial support for:
 - Study management support
 - Patient and stakeholder engagement
 - Data infrastructure

Proposed Re-issue of PaCR Announcement

From FY19 Budget – for Research in PCORnet 2.0



Budget Line	Total FY19 Approved	Committed	Request	Remaining
Research	up to \$11.0 M	\$0.0 M	\$6.0 M	\$5.0 M
Infrastructure (capacity building)	up to \$32.5 M	\$1.0 M	\$0.0 M	\$31.5 M

Cycle 1 2019 PaCR Reissue - Requirements

- Prime institution must be a CRN or HPRN within PCORnet 2.0
- Study must comply with PCORnet 2.0 study designation requirements
- Must utilize PCORnet 2.0 governance, policies, and resources
- Co-funders should also have potential for future funding partnerships with PCORnet 2.0
- Studies must address an important CER question
- Must feature data linkages, between EMRs, claims, registry data

PaCR Reissue

Solicitation Plan and Funds Available



- PCORI will invite LOIs from **CRNs and HPRNs in PCORnet 2.0** with an investigator-initiated research question
 - LOIs will be required, but are not competitive
 - Rather, LOIs are meant to inform Merit Reviewer recruitment requirements
- PCORI would fund **up to 2 individual research projects**
 - Direct costs (PCORI): up to \$4 million available (\$2 million per project)
 - Total costs (PCORI): \$6 million available (\$3 million per project)
 - ≤ 3 year timeframe
 - Review criteria will assess data linkage, research, engagement, co-funder collaboration and potential to support sustainability

PaCR Reissue

Project Specifications



- Applicants required to secure **at least 50% partnered co-funding** from federal, industry, or other non-federal funder/collaborators prior to submitting full application
- Co-funding partnerships must demonstrate potential for additional future partnership/collaboration with the network
- Letters of support required including from PCORnet 2.0 Steering Committee (with LOI) and from Co-funder(s) (with full proposals)
- Require linkages between EHR/clinical data with existing claims data, registry data, or PROs using the **PCORnet 2.0 Common Linkage Method** if available
- Study must comply with PCORnet 2.0 governance policies including PCORnet's study intake process

Tentative Timeline

- ✓ January: RTC endorsement (January 17, 2019)
- ✓ February: SOC endorsement (February 8, 2019)
- February: Request PCORI Board of Governors approval and post pre-announcement
- March: Limited PFA released
- April: LOIs (non-competitive) due
- June: Applications due
- August: Merit Review
- October: Selection Committee
- October: Present proposed slate of research projects to the Board of Governors for consideration
- December: Earliest research project start date

Board Vote

Call for a Motion to:

- **Approve** reissue of Partnerships to Conduct Research within PCORnet PFA

Call for the Motion to be Seconded:

- **Second** the Motion
- If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Roll Call Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions

Wrap Up and Adjournment



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PCORI



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