

Board of Governors Meeting

Via Teleconference/Webinar

July 24, 2018
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 June 19, 2018 Board Meeting

12:05 – 12:15

Consider for Approval: Nominations of Committee Chairs and Vice Chairs

12:15 – 12:45

Consider for Approval: Proposed Funding Slate for Cycle 3 2017 Limited PFA

12:45 – 1:15

Consider for Approval: Proposed New Methodology Standards for Public Comment

- IPD-MA
- Qualitative and Mixed Methods

1:15

Wrap up and Adjournment

Board Vote

Call for a Motion to:

- **Approve** the Minutes of the June 19, 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

Nominations for Chairs and Vice Chairs for PCORI Strategy and Board Committees

Sharon Levine, MD

Vice Chair, Governance Committee

Nominations for Chairs and Vice Chairs for PCORI Strategy and Board Committees



The Governance Committee is responsible for making nominations for consideration and vote by the Board of Governors for the Chairs and, if applicable, Vice Chairs of:

- Each of the three Strategy Committees -
 - Science Oversight Committee
 - Engagement, Dissemination and Implementation Committee
 - Research Transformation Committee
- Board Committee -
 - Finance and Administration Committee

Nominations for Chairs and Vice Chairs for PCORI Strategy and Board Committees



Appointment of new Committee leadership effective on September 23, 2018 from current Board members is expected to:

- Support effective transfer of knowledge from current leaders to anticipated new Committee leaders; and
- Help facilitate a smooth transition for PCORI's Strategy and Board Committees when new Board members appointed by the Government Accountability Office (GAO) join PCORI's Committees in Fall 2018

Nominations for Chairs and Vice Chairs for PCORI Strategy and Board Committees



Current status of Chairs/Vice Chairs of Strategy and Board Committees are as follows:

- **Science Oversight Committee**
 - Robert Zwolak, Chair – Eligible for reappointment to a 2nd term
 - Alicia Fernandez, Vice Chair – Eligible for reappointment to a 2nd term
- **Engagement, Dissemination and Implementation Committee**
 - Debra Barksdale, Chair – Rotating off Board Sept 2018
 - No current Vice Chair
- **Research Transformation Committee**
 - Freda Lewis-Hall, Chair – Final term as Chair ends Sept 2018
 - Allen Douma, Vice Chair – Rotating off Board Sept 2018
- **Finance and Administration Committee**
 - Lawrence Becker, Chair – Eligible for reappointment to a 2nd term
 - No current Vice Chair

Proposed Motion

That the Board of Governors approve the following nominations presented by the Governance Committee for the positions of Chair and Vice Chair of these Committees effective on September 23, 2018 for a two (2) year term:

- **Science Oversight Committee**
 - Robert Zwolak – Chair
 - Alicia Fernandez – Vice Chair
- **Engagement, Dissemination, and Implementation Committee**
 - Sharon Levine – Chair
 - Lawrence Becker – Vice Chair
- **Research Transformation Committee**
 - Kathleen Troeger – Chair
 - Freda Lewis-Hall – Vice Chair
- **Finance and Administration Committee**
 - Lawrence Becker – Chair
 - Christine Goertz – Vice Chair

Board Vote

Call for a Motion to:

- **Approve** the Proposed Motion

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

Proposed Funding Slate from the Limited PCORI Funding Announcement (Cycle 3 2017)

(Limited Competition Dissemination & Implementation PFA)

Debra Barksdale, PhD, RN

Chair, Engagement, Dissemination, and Implementation Committee

Jean Slutsky, PA, MSPH

Chief Engagement & Dissemination Officer

Cycle 3 2017 – Limited Competition (LC) Dissemination & Implementation PFA

Objective of the PFA



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 making their research results more useful, actionable, accessible, and available to targeted end users

Note:

- D&I Awards requesting budgets less than \$500k are approved for funding by the Chief Engagement and Dissemination Officer
- D&I Awards requesting budgets of \$500k or larger are presented to the Engagement, Dissemination, and Implementation Committee (EDIC) and approved for funding by the Board of Governors

1. Importance of research results in the context of the existing body of evidence
2. Readiness of the research results for dissemination
3. Technical merit (project design, outcomes, and evaluation)
4. Project personnel and environment
5. Patient-centeredness
6. Patient and stakeholder engagement

Application overview:

- 14 Letters of Intent (LOIs) submitted
- 9 LOIs invited to submit a full application – 65% of submitted LOIs
- 6 applications received – 67% of invited LOIs

Overall funding rate is **33** percent

- We are proposing to fund 2 applications* out of 6 received applications



**Recommended by the Engagement, Dissemination, and Implementation Committee (EDIC) on July 10th 2018*

Project Title
Disseminating & Implementing Patient and Family Centered I-PASS to Improve Patient Safety
Dissemination and Implementation of Effective Childhood Obesity Treatment Innovations

- Average requested budget per project is \$2M
- All proposed projects, including requested budgets and project periods, approved by the Board of Governors are subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

PFA	Amount Budgeted per Year	Proposed Total Award*
Dissemination and Implementation of PCORI-Funded Patient-Centered Outcomes Research Results	\$9M	\$4M

Note: Budgeted amount is for up to 3 cycles per year. \$3.6M has been awarded to date in FY18

Board Vote

Call for a Motion to:

- **Approve** funding for the recommended slate of awards from the Cycle 3 2017 Dissemination and Implementation of PCORI-Funded PCORI 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

Methodology Committee: Proposed New Methodology Standards for Public Comment

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
- David Flum
- Cindy Girman
- Mark Helfand
- Michael Lauer
- David Meltzer
- Brian Mittman
- Sally Morton
- Neil Powe
- Adam Wilcox

PCORI 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, 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

Methodology Committee: Proposing 11 New Standards



The Methodology Committee is recommending that the Board approve, for release for public comment, eleven new Methodology Standards:

- Standards for Individual Participant-Level Data Meta-Analysis (IPD-MA)
 - New category, 4 standards
- Standards for Qualitative Methods & Mixed Methods Research
 - New category, 7 standards

The Methodology Committee has taken a systematic approach to develop these new standards:

- Workgroups (PCORI staff & Methodology Committee members) developed an early draft of standards, based on the scientific literature in this area
- Draft standards were revised in response to feedback from the Methodology Committee and external experts
- The Methodology Committee approved proposed standards to send to the Board for approval for release for public comment

Proposed New Standards: Individual Participant-Level Data Meta-Analysis (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

Titles of proposed new standards:

- **IPD-1:** Specify the research question(s) that will be addressed through IPD-MA and describe the specific information the IPD-MA 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

Proposed New Standards: Qualitative Methods & Mixed Methods Research

Rationale:

- Qualitative methods and mixed methods approaches can enable more robust capture, understanding, and integration 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 design, conduct, analysis, and reporting of these approaches in PCOR/CER studies

Titles of proposed new standards:

- **QM-1:** State the qualitative approach to research inquiry, design, and conduct
- **QM-2:** Select and justify an 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
- **MM-1:** Specify how mixed methods are integrated across design, data sources, and/or data collection phases
- **MM-2:** Select and justify an appropriate mixed methods sampling strategy
- **MM-3:** Integrate data analysis, data interpretation, and conclusions

Next Steps

- The Methodology Committee is seeking Board approval to release the eleven new Methodology Standards for public comment
 - Proposed new Methodology Standards will be made available on PCORI's website for public comment for a period of 60 days
- Following the public comment period, PCORI and the Methodology Committee will read, process, and categorize public comments
 - If indicated, the proposed new Methodology Standards will be revised based on public comments
- The Methodology Committee will seek Board approval to adopt the revised new Methodology Standards
- Expected timeline: July 2018 through December 2018

Board Vote

Call for a Motion to:

- **Approve** the release for public comment of the proposed new Methodology Standards for IPD-MA and Qualitative Methods & Mixed Methods Research

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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