



Board of Governors Meeting

via Teleconference/Webinar

April 22, 2014

12:00-1:00 p.m. ET

Patient-Centered Outcomes Research Institute

Welcome and Introductions

Steven Lipstein, MHA

Vice Chair, Board of Governors

Joe Selby, MD, MPH

Executive Director

Agenda

Time	Agenda Item
12:00– 12:10 p.m.	Call to Order and Welcome • Consider for Approval: Minutes from March 25, 2014 Meeting • Consider for Approval: Methodology Committee ex officio members for the Advisory Panel on Clinical Trials • Consider for Approval: Revisions to Research Transformation Committee Charter Approved 2/25/14
12:10– 12:25 p.m.	Science Oversight Committee (SOC) Priority Objectives for 2014
12:25– 12:40 p.m.	Engagement, Dissemination, and Implementation Committee (EDIC) Priority Objectives for 2014
12:40– 12:55 p.m.	Research Transformation Committee (RTC) Priority Objectives for 2014
12:55 – 1:00 p.m.	General Discussion
1:00 p.m.	Wrap up and Adjournment

Board Vote: March 25, 2014 Board Meeting Minutes

Call for a Motion to:

- **Approve** March 25, 2014 Board Meeting Minutes

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/ Roll Call Vote:

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



Methodology Committee Ex Officio Members for the Advisory Panel on Clinical Trials

Joe Selby, MD, MPH
Chief Science Officer

Patient-Centered Outcomes Research Institute

Charter Language and Proposed Members

- *“In addition to the 10-14 members, the Board may appoint up to two members of the Methodology Committee, ex officio.”*
- The Methodology Committee agreed to the two following members to join the Advisory Panel on Clinical Trials:
 - Dr. Steve Goodman, MD (Methodology Committee vice-chair)
 - Mary Tinetti, MD

Board Vote: Approve Ex Officio Members

Call for a Motion to:

- **Approve** Advisory Panel on Clinical Trials Ex Officio members

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/ Roll Call Vote:

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



Revisions to Research Transformation Committee Charter

Freda Lewis-Hall, MD

Chair, Research Transformation Committee

Patient-Centered Outcomes Research Institute

Revisions to Research Transformation Committee Charter

The Research Transformation Committee (RTC) proposes revisions to its charter, which was approved by the Board on February 25, 2014. The proposed revisions are primarily to reflect the overall purpose of the RTC in more detail:

The Research Transformation Committee (the “Committee”) of the Patient-Centered Outcomes Research Institute (“PCORI”) shall advise and assist the Board of Governors and PCORI on *encouraging clinical and health care research, including research funded by others, to be more patient-centric by promoting open science, the development of transformative research platforms, and the conduct of more patient-centric and methodologically rigorous research*, as set forth in the “Responsibilities” section of this Charter.

Board Vote: Approve the Revised Charter

Call for a Motion to:

- **Approve** the Charter of the Research Transformation Committee as revised

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/ Roll Call Vote:

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



Science Oversight Committee Priority Objectives for 2014

Christine Goertz, PhD
Chair, Science Oversight Committee

Patient-Centered Outcomes Research Institute

Science Oversight Committee (SOC) Responsibilities

Oversight of:

- Research and scientific program priorities and topics
- Merit review process for applications
- Designation of specific research projects for funding
- Active portfolio management by staff

Including:

- Coordinating projects with partners (including AHRQ and NIH)
- Identification of process and prioritization of topics for PCORnet
- Strategizing on use of PCORnet to advance the PCORI portfolio
- Developing criteria to ensure transparency, high-quality oversight of standard operating procedures
- Developing optimal strategies for engaging stakeholders relative to research portfolio
- Collaborating with Methodology Committee on areas of common interest
- Coordinating meaningful collaborations with strategy committees.

SOC Goals

1. Establish a plan with key metrics to describe and assess the significance and potential impact of PCORI's research portfolio (SHARED OBJECTIVE WITH THE EDIC)

- a. This objective focuses on issues such as the significance to patients and other stakeholders of individual studies, clusters of studies as well as the overall research portfolio
- b. This objective also includes developing a plan and metrics to evaluate merit review and the research portfolio, with a particular focus on understanding the effects of greater patient involvement on the outcomes of the process.

2. Develop and institute a plan, SOPs, and metrics for the following processes:

- a. Topic Selection
- b. Merit Review
- c. Selection Committee Process
- d. Monitoring and Evaluating the Research Portfolio
 - Fiduciary aspects
 - Identifying scientific gaps and opportunities

3. Develop priority topics for consideration including approval of two new targeted funding announcements for large priority-driven CER trials (December 2014).





Engagement, Dissemination, and Implementation Committee Priorities

Debra Barksdale, PhD, RN

Chair, Engagement, Dissemination, and Implementation Committee

Patient-Centered Outcomes Research Institute

Engagement, Dissemination, and Implementation Committee (EDIC) Charter Responsibilities

- Primary focus on the strategic goal to **speed and implementation** and use of patient-centered outcomes research evidence.
- Establishment of **PCORI as a trusted leader in PCOR/CER**
- Development of a communications strategy** that enhances and supports PCORI's position as a trusted leader
- Engagement of stakeholders:** patients, caregivers, payers, clinicians, health systems, and others
- Coordination of **dissemination and implementation activities with the Agency for Healthcare Research and Quality (AHRQ)**
- Facilitation of dissemination and implementation of PCOR** through partnerships and a robust infrastructure created to engage stakeholder communities

EDIC Major Planned Accomplishments for 2014

The EDIC has prioritized programmatic responsibilities for the Engagement team. The top three include:

- **Engagement Awards Program**
- **Dissemination and Implementation**
- **Active Portfolio Management** with **Patient and Family Engagement Rubric** and implementation of **Engagement Officers** to monitor adherence and performance

Engagement Awards Program

- Enhancing our primary research efforts by expanding understanding of and connection to PCOR, cultivating a large PCOR-ready community, and working with key partners to encourage dissemination and implementation of the best patient engagement practices.
- **Proposed Accomplishments for 2014:**
 - ***Establish close oversight to build-on a series of awards that are strategically related to help advance engagement and science objectives.***

Dissemination and Implementation

- Facilitation of dissemination and implementation through partnerships and a robust infrastructure created to engage patients and other stakeholder communities in dissemination and implementation of PCOR
- Coordination of dissemination and implementation activities with the Agency for Healthcare Research and Quality (AHRQ)
- Proposed Accomplishment for 2014:**
 - Complete the development of the PCORI Dissemination and Implementation Action Plan***
 - Engage a wide and inclusive range of key patient and non-patient stakeholder groups such as nurses, payers, physicians, etc.***

Active Portfolio Management with Patient and Family Engagement Rubric

- The rubric is a response to frequent questions from the patient and research communities asking what we mean by “engagement in research.” The rubric is a framework that provides a variety of options for incorporating engagement, where relevant, into the research process. The rubric will be used as a guide for applicants, merit reviewers, awardees and Engagement Officers.
- **Proposed Accomplishments for 2014:**
 - *Integrate rubric into PFAs, Merit Review training, and applicant training*
 - *Hire, train, and implement the role of the Engagement Officers in monitoring research projects*

Other EDIC Responsibilities

- **Develop strategy for outreach to key non-patient Stakeholder groups.** The Engagement team, in collaboration with the Communications team, has developed an extensive strategy of activities and approaches to engage key non-stakeholder communities defined as 1) clinicians; 2) hospitals and health systems; 3) purchasers/business; 4) payers; 5) industry; 6) researchers; 7) policymakers and 8) training institutions.
 - ***For 2014: Provide input on the strategy for stakeholder outreach***
- **Develop targets and milestones to speed implementation.** To operationalize the 2014 priority activities into practice for speeding the implementation of PCORI research findings.
 - ***For 2014: Provide guidance on the development of policies and practices to speed implementation***



Research Transformation Committee (RTC) 2014 Objectives

Freda Lewis-Hall, MD

Chair, Research Transformation Committee

Patient-Centered Outcomes Research Institute

RTC's Objectives for 2014

Today the RTC proposes:

- An overarching objective that flows from its charge
- Objectives related to its top three priority responsibilities

Overarching Objective Related to the RTC's Charge:

- From the charter: "...advise and assist the Board of Governors and PCORI on encouraging clinical and health care research, including research funded by others, to be more patient-centric by promoting open science, the development of transformative research platforms, and the conduct of more patient-centric and methodologically rigorous research..."

Objective for 2014:

- Develop additional ideas for strategies that PCORI could pursue for transforming the clinical and health care research enterprise*

Objectives Related to RTC's Top Three Responsibilities

The RTC prioritized its several responsibilities and determined that its top three are:

- Provide direction for the development of **PCORnet**
- Promote **open science**
- Propose PCORI strategy for **co-funding** partnerships/alternative funding models, and evaluate the success of such models

Priority Responsibility: Provide Direction for the Development of PCORnet

From charter: “Encourage the development of transformative research platforms by creating an assessment of the short- and long-term opportunities PCORnet might fill; use this knowledge to craft a viable framework to support the infrastructure of a functional national network.”

Objective for 2014:

- *Oversee the implementation of Phase I and the development of a strategic plan for Phase II of PCORnet and for its long-term sustainability*

Priority Responsibility: Promote Open Science

From the Charter: “Develop a PCORI-specific approach to supporting and promoting open science and reproducible research, in concert with the Methodology Committee.”

Objective for 2014:

Coordinate the work of the Methodology Committee and the Open Science Work Group and oversee the development and implementation of policies for how PCORI will support open science

Priority Responsibility: PCORI strategy for co-funding partnerships/alternative funding models, and evaluation of such models

- From charter: “Evaluate the options for PCORI to co-fund or contract with other institutions to support the management of larger (e.g., \$1M+) projects, as a means of conducting these studies more efficiently and of encouraging other institutions or agencies to conduct large-scale patient-centric research.”

Objectives for 2014:

- Delineate the principles and guidelines for co-funding, contracting, and other arrangements that would be transformational*
- Oversee the development of an operational plan for such collaborations, including their evaluation, based on the guidelines and principles developed by RTC*
- Oversee the implementation of evaluations of on-going collaborations*



Wrap-up and Adjournment

Steven Lipstein, MHA
Chair, Board of Governors

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