Patient-Centered Outcomes Research Institute Board of Governors Meeting Minutes

Renaissance Dupont Circle Hotel
1143 New Hampshire Avenue, NW
Washington, DC 20037
Tel: (202) 775-0800
December 8, 2014

Board Members Present:

Grayson Norquist, MD, MSPH, *Chair*; Debra Barksdale, PhD, RN; Kerry Barnett, JD; Lawrence Becker; Francis Collins, MD, PhD; Allen Douma, MD (by phone); Alicia Fernandez, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Gail Hunt; Robert Jesse, MD, PhD; Richard Kronick, PhD; Harlan Krumholz, MD; Sharon Levine, MD; Freda Lewis-Hall, MD; Steve Lipstein, MHA; Barbara McNeil, MD; Ellen Sigal, PhD; Harlan Weisman, MD; Robert Zwolak, MD, PhD

Board Members Absent:

Richard Kuntz, MD, MSc

Methodology Committee Members Present:

Robin Newhouse, PhD, RN, Chair

Staff:

Joe Selby, MD, MPH, *Executive Director*; Matt Burress; Rachael Fleurence, PhD; Laura Forsythe, PhD, MPH; Desiree Frank; Lori Frank, PhD; Orlando Gonzales, MPA; Pam Goodnow, CPA; Annie Hammel; Mary Hennessey, Esq., *General Counsel*; David Hickam, MD, MPH; Susan Hildebrandt, MA; Kim Jackson, CPA, MBA; Katie Jones; Jayne Jordan; Maggi LeDuc; Bryan Luce, PhD, MBA, *Chief Science Officer*; Ashley Pidal; Kara Odom Walker, MD, MPH; Michele Orza, ScD; Katie Rader; Bill Silberg; Jean Slutsky, PA, MSPH, *Chief Engagement and Dissemination Officer*; Christine Stencel, MA; Regina Yan, MA, *Chief Operating Officer*

AGENDA ITEM	RELATED MINUTES
Chair's Welcome *Grayson Norquist, Chairperson*	Dr. Norquist opened the meeting and welcomed the Board members present as well as the attendees, both in-person and on the phone.
Approval of the November 18, 2014 Minutes *Grayson Norquist, Chairperson*	The following motion was made and seconded: **Motion:** Approve the November 18, 2014 Board Meeting Minutes. *Approved by a majority vote of the Board by voice vote*
Reminder for Annual Update of Disclosures of Conflict of Interest Form *Larry Becker, Chair, Audit & Conflict of Interest Subcommittee*	Larry Becker reminded Board of Governor members and Methodology Committee members that they are required to complete annual Conflict of Interest Disclosures which will be included in PCORI's Annual Report to Congress. He asked that they be submitted quickly and, if possible, before the holidays. The deadline for submission of these disclosures is January 15, 2015.
Executive Director's Report End-of-year Dashboard Review *Joe Selby, Executive Director*	Dr. Selby provided an update on the first 5-Year GAO review of PCORI, which began in March 2014, and is drawing to a close. Several meetings with the GAO team were held throughout the summer and fall, and we expect our exit conference with GAO in December. GAO identified two primary questions for this review: (1) To what extent has PCORI established research priorities and funded research in accordance with its legislative requirements; and (2) To what extend has PCORI established plans and undertaken efforts to evaluate the effectiveness of its work? PCORI expects to have a chance to comment on GAO's draft report in mid-winter; the final report is due to be submitted to Congress by the GAO in March 2015. He gave an update on the proposed Policy on Peer Review of Primary Research and Public Release of Research Findings which was posted for public comment until November 7, 2014. PCORI received 835 comments from 63 individuals and organizations. The American Institute of Research (AIR) is synthesizing these comments to support PCORI's consideration of the comments and development of a final Policy. PCORI will also consider the Notice of Proposed Rulemaking for Clinical Trials Registration and Results Submission released by NIH to implement the requirements of the Food and Drug Administration Amendments Act (FDAAA). It is anticipated that the Policy will be presented to the Board at the February Board meeting. Dr. Selby also announced a multi-stakeholder PCORI Workshop on Research Dissemination and Implementation Framework and Toolkit to be held Wednesday, December 10, 2014 the purpose of which is to help focus on best practices, develop tools and identify innovative ways to disseminate tools and information in close collaboration with AHRQ. He further announced that PCORI's 1st Annual Meeting will be held October 6-8, 2015 in conjunction with AHRQ and its 2015 Annual Conference. Finally, Dr. Selby reviewed the agenda for today's meeting.

	Q4 Dashboard Review: Dr. Selby presented the Q4 Organizational Dashboard, highlighting new and noteworthy items (green) and items more than 10% off target (yellow). The 'New and Noteworthy Items' highlighted were 1) the influencing research example, 2) Journal articles by awardees, 3) Completion of research projects, and 4) Responsiveness to Help Desk inquiries. The 'Yellow-flagged Items' highlighted were 1) Percent of projects meeting all milestones, 2) Funds to be committed to research and 3) Expenditures. Board members raised questions and comments, including: • Ongoing discussions about research strategy should be used to inform the development of targets and goals for items like the care continuum and the balance of targeted and broad PFAs. • Further information was requested about the difference between the acceptance rates for resubmissions. • Members recommended an indication of whether the variation in off-target items was due to natural variance in timeline, a shift in strategy or a programmatic issue. Next steps: • The Dashboard will be discussed again at an upcoming Board meeting.
Committee Reports: Governance Committee *Steve Lipstein, Chair, Governance Committee*	Steve Lipstein, Chair, **Governance Committee**, recounted that in 2013 external consultants, Marla Bobowick and Debbie Hechinger, worked with the Board to evaluate PCORI governance and presented findings upon which the Board acted. In accordance with the findings, a Strategic Plan was developed and approved, the governance structure was recrafted, meetings structure was redesigned, and communication avenues were strengthened. Additionally, Strategy Committees were formed to streamline efforts into the goals of our Strategic Plan. The Governance Committee continues to evaluate our performance for any other potential areas of evolution and improvement.
Science Overview Committee (SOC) *Christine Goertz, Chair, Science Oversight Committee (SOC)*	Christine Goertz, Chair of the **Science Oversight Committee (SOC)**, presented a brief overview of the committee's objectives and how they were accomplished throughout the year. The SOC used a portfolio analysis to drive its efforts in evaluating the research strategy. The SOC oversaw the development of SOPs for topic selection, merit review, selection committee process, and monitoring and evaluating the research portfolio. The Committee advised on the development of the Selection Committee charter, which was approved by the Board. The Board appointed members of the Board and Methodology Committee to the Selection Committee. As part of its objectives for the year, the SOC recommended that the Board approve the development of three tPFAs. (The Board also approved the development of a fourth tPFA, recommended by the SOC on Hepatitis C later in the day of the Board meeting.)
Engagement, Dissemination and Implementation Committee (EDIC) *Debra Barksdale, Chair, Education, Dissemination, and*	E**ngagement, Dissemination and Implementation Committee (EDIC)** Chair, Debra Barksdale, presented an update on the EDIC's 5 goals for the past year. Details surrounding the activities in these goals were presented later during Jean Slutsky's Engagement Update.

Implementation Committee (EDIC) Research Transformation Committee (RTC) *Freda Lewis-Hall, Chair, Research Transformation Committee (RTC)* Finance and Administration Committee (FAC) *Kerry Barnett, Chair, Finance and Administration Committee*	 Freda Lewis-Hall, Chair of the **Research Transformation Committee (RTC)**, provided an update on the progress of the RTC in its first year. The major project for the RTC in 2014 was to advance the work of PCORnet. The RTC has also taken an active role in activities to promote open science. The committee, Board and staff have considered a framework and are working to align activities with internal PCORI processes. Finally, the RTC created and endorsed a set of Collaboration Principles designed to guide PCORI's approach to collaborations with other research funders. Work on all these initiatives will continue in 2015. Kerry Barnett, Chair of the **Finance and Administration Committee (FAC),** described the critical bridge between the program and the administrative capacities necessary to accomplish strategic goals. • FY2014 primary goals include: o Passage of Annual Budget and provide oversight on key financial matters; o Overseeing employee hiring and annual employee survey result; o Oversight on development and revisions to key institutional policies; o Guide and support in developing its strategy specific to the financial issues related to PCORI's governing legislation. The FY2015 Budget was approved by the PCORI Board of Governors in September of 2014 and work is ongoing regarding the progress made on the rest of the goals.
Public Comment Period *Bill Silberg, Director, Communications*	The Chairperson opened the meeting to the public comment, inviting comments from those attending the meeting in person and those attending remotely. There were no requests to make a public comment.
PCORI Research Strategy Update *Christine Goertz, Chair, Science Oversight Committee (SOC)*	Christine Goertz, chair of the Science Oversight Committee (SOC), presented the proposed funding strategy's continuous evolution of PCORI's shift to larger, targeted, more stakeholder-based patient-centered outcomes research. Recommendations included: (1) continue but taper Broad investigator-initiated research program, (2) continue Large Pragmatic Clinical Studies program, (3) continue to target key topics, with increasing emphasis on comprehensive studies of selected Priority Topics, and (4) encourage the use of PCORnet, when appropriate. She also discussed the proposed percent distribution of annual funding commitment and the advantages and caveats of this strategy. The Board's discussion reflected the Board's consensus that these recommendations reflect a balanced approach for the funding research strategy between organizational priorities and investigator-initiated research.

Development of a Targeted PCORI Funding Announcement on Hepatitis C *Joe Selby, Executive Director* *Bryan Luce, Chief Science Officer*	Joe Selby, Executive Director, and Bryan Luce, Chief Science Officer, presented an overview of Hepatitis C's clinical impacts, current and pending treatment options, input from PCORI's Assessment of Options Advisory Panel and results from the multi-stakeholder workgroup. Though these activities key questions emerged, resulting in a recommendation of staff, which was endorsed by the SOC that PCORI issue a targeted PFA to fund up to four large clinical studies to test the comparative effectiveness of alternative approaches to screening in various patient populations, care delivery choices for treatment, timing of treatment, and active treatment choices. The recommendation included committing up to $50 million total to fund up to four studies, with a proposed maximum for any single study of $20 million. Board members engaged in discussion, with different perspectives articulated about PCORI issuing a targeted PFA in this area. The following motion was made and seconded. **Motion:** Approve issuance of a targeted PCORI Funding Announcement on Hepatitis C to fund up to 4 studies for a total of up to $50M. *Approved by majority vote of the Board by voice vote.*
Release of PCORI Funding Announcement for PCORnet Phase II *Joe Selby, Executive Director* *Rachael Fleurence, Program Director, CER Methods and Infrastructure*	Rachael Fleurence, PCORI's CER Methods and Infrastructure Program Director, presented an overview of the PCORnet Phase II PCORI Funding Announcements for Clinical Data Research Networks (CDRNs) and Patient-Powered Research Networks (PPRNs). She presented the overarching goals for Phase II along with the number of anticipated awards and a reminder of the budget commitment already made by the Board. She emphasized PCORnet as a national network and the planned capacity for the network for research during Phase II. Several clarifying questions were asked regarding the application criteria, the review process, sustainability, and clinician engagement. The Funding Announcement would reflect a commitment to fund up to 13 CDRN awards and up to 22 PPRN awards. Current Phase I CDRN and PPRN awardees are eligible to apply and new applicants may apply, but must meet baseline requirements within 6 months of the start of Phase II. An overview of the application review process was presented. The following motion was made and seconded. **Motion:** Approve the release of a PCORI Funding Announcement for PCORnet Phase II for CDRNs and PPRNs *Approved by a majority vote of the Board by voice vote*
Methodology Committee Update *Robin Newhouse, Chair, Methodology Committee*	Robin Newhouse, Methodology Committee Chair, presented an update on the Committee's work to include advising on dissemination and implementation of the Methodology Standards through training and a work group, ongoing monitoring of the Methods Program portfolio, and piloting the Methods Consultation Panels with the Spring 2014 Large Pragmatic Studies applications. In 2014, the Methodology Standards were cited 134 times in peer review journals. Sebastian Schneeweiss, a member of the Methodology Committee, presented an update from the Network Research

	Methods Work Group activities on distributed analyses, which will result in a white paper. In 2015, the Methodology Committee will review existing Methodology Standards and work to develop standards for research designs with clusters and standards for complex interventions. Other updates include a Decision Science Expert meeting will be held in April 2015, and the committee will discuss opportunities in Value of Information with the Board in the future.
Break	
Engagement Update *Jean Slutsky, Chief Engagement and Dissemination Officer*	PCORI's Chief Engagement and Dissemination Officer, Jean Slutsky, presented updates on Engagement's major programs and activities. She emphasized the ongoing evaluation of all of these programs and the importance of maintaining close ties and communication with PCORI's Science group. The Board asked several strategic questions and what she thinks needs to be done at PCORI now that she's been with the organization for close to a year. She stressed the importance of making PCORI a learning organization, involving a wide variety of stakeholders in our work, and examining the mechanics of what we do.
Preliminary Results of WE-ENACT *Lori Frank, Program Director* *Laura Forsythe, Senior Program Officer* *Research Integration and Evaluation*	Lori Frank, Director of the Research Integration and Evaluation Program, and Laura Forsythe, Senior Program Officer, presented preliminary results from data collection on engagement in PCORI research projects. Information on engagement is collected from both Principal Investigators and their patient and stakeholder partners at annual intervals. This information will be used to describe engagement in PCORI funded projects, to support project success, to evaluate the impact of engagement, to inform PCORI funding requirements, and to guide those interested in conducting PCOR.
Improving Methods for Conducting PCOR Program Overview *Rachael Fleurence, Program Director, CER Methods and Infrastructure*	Given the minimal available time remaining in the Board meeting, the Chairperson indicated that this agenda item would be moved to another Board meeting.
Public Comment Period *Bill Silberg, Director, Communications*	The Chairperson opened the meeting for public comment, inviting comments from those attending the meeting in person and those attending remotely. Contributing with comments were: - Sara van Geertruyden, Partnership to Improve Patient Care (PIPC) - Brian Edlin, National Development and Research Institute (NDRI)
Wrap-up and Adjournment of the Meeting of the Board *Grayson Norquist, Chairperson*	The meeting was adjourned at 5:45 pm

Approved by the PCORI Board of Governors 1-27-2015