



Patient-Centered Outcomes Research Institute Board of Governors Meeting

Hilton Garden Inn
2201 M Street, NW
Washington, DC 20037
Tel: (202) 974-6010
May 4, 2015

Board Members Present:

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

Board Member Absent:

Alicia Fernandez, MD

Methodology Committee Members Present:

Robin Newhouse, PhD, RN, *Chair*; Cynthia Girman, DrPH

Staff:

Joe Selby, MD, MPH, *Executive Director*; Rachael Fleurence, PhD; Laura Forsythe, PhD, MPH; Lori Frank, PhD; Mary Hennessey, Esq.; Susan Hildebrandt, MA; Kim Jackson, CPA, MBA; Bryan Luce, PhD, MBA; Kara Odom Walker, MD, MPH; Michele Orza, ScD; Bill Silberg; Sue Sheridan, MBA, MIM; Jean Slutsky, PA, MSPH; Hal Sox, MD; Regina Yan, MA

AGENDA ITEM	Related Minutes
Chairperson's Welcome; Call to Order; Roll Call <i>Grayson Norquist, MD, MSPH, Chairperson</i>	Dr. Norquist called the meeting to order at 10:15 a.m., welcomed the Board members present as well as the attendees, both in-person and on the phone.
Approval of the April 21st 2015 Minutes <i>Grayson Norquist, MD, MSPH</i>	The following motion was made and seconded: Motion: Approve the April 21, 2015 Board Meeting Minutes. <i>Approved by a majority vote of the Board by voice vote</i>
Executive Director's Report <i>Joe Selby, MD, MPH, Executive Director (ED) and Michele Orza, ScD, Senior Advisor to the ED</i>	Dr. Selby recognized Dr. Robin Newhouse, Chair of the PCORI Methodology Committee, who will be leaving the University of Maryland to become Dean at the Indiana University School of Nursing. She will continue to serve as Chair of the Methodology Committee. Continuing Education (CE) and Continuing Medical Education (CME): Dr. Selby discussed PCORI's vision to increase awareness of PCORI's research findings and methodology standards through high quality CE and CME. PCORI is partnered with Baylor and PRIME Education to create educational materials for health professionals. The program will begin with education on methodology standards for medical personnel and those in training. Also among the Initial educational activities, anticipated the end of May 2015, will be early findings about PCORI-funded research comparing IV and oral antibiotic treatment for osteomyelitis in children after a hospital stay. These educational activities will be provided free of charge and accessible through PCORI's website. Peer-Review and Public Release: Dr. Selby provided an update on the implementation of the Board-adopted peer-review and public release of research findings process, stating that PCORI is expecting to award a contract for peer review management in the near future. An RFP for a contract to manage lay summaries for the website will also be released soon. Existing PCORI research funding contracts will be modified to include details on the peer review process. The first funded projects to be peer reviewed are expected to release results by the end of 2015. 1st Annual Meeting: Dr. Selby announced that PCORI's first annual meeting will be held October 6-8, 2015 in suburban Washington, D.C. He outlined the goals of this meeting and the expected audience. The first day of the meeting will include a joint session with AHRQ and Academy Health focused on Dissemination and Implementation. Following the joint session will be a series of plenary and breakout sessions highlighting PCORI's research and initiatives and the state of patient-centered outcomes research and comparative clinical effectiveness research (PCOR/CER).

Mid-year Dashboard Review	1st Pragmatic Clinical Studies: Dr. Selby also reviewed the goals of the first 10 Pragmatic Clinical Studies and discussed PCORI's desire to increase the number of awards in subsequent cycles. Finally, Dr. Selby reviewed the agenda for today's meeting. Dr. Selby presented the mid-year Dashboard for the Board's review. The Q2 Dashboard addressed several of the yellow-flagged items (that is, items that are off target by more than 10%) and explained that staff believe they understand the reasons and are taking actions expected to get these items back on target. The mid-year Dashboard included no red-flagged items which indicate the need for the attention of or action by the Board. Dr. Selby highlighted this quarter's example of PCORI's influence on research (Goal 3): the creation of a patient-centered unit at UPMC to provide the infrastructure for conducting PCOR and to promote collaboration on CER. He also highlighted and the Board discussed several yellow-flagged items including: 1) Funds Committed to research were on target for Q1 but fell behind in Q2 as the result of an MOU that was not executed as planned and awarding less than the full amount made available for the first round of Pragmatic Clinical Studies; 2) Several pilot projects had not submitted their final reports as planned in Q2 but are close to submitting them; 3) The number of journal articles published appears to be declining, but we are examining the impact on this metric of delays of indexing in Medline; 4) The percent of Projects Meeting All Milestones continues to decline and we continue to try to understand the import of this and to refine our metrics for the progress of projects, with a focus on recruitment as a key indicator; 5) Uptake of PCORI's Methodology Standards appears to have leveled off, possibly as they have saturated the literature; 6) PCORnet's policies were not completed this quarter as planned, but are likely to be approved in Q3. Following-up on the Board's discussion of their Q1 Dashboard, Dr. Selby discussed how, in future quarters as more of PCORI's funded studies are completed, we will present more indicators of dissemination and early uptake, for example the impact factor of studies, the percent of articles in top tier journals, and the uptake of PCORI research into guidelines and systematic reviews.
Mid-year Budget Review <i>Larry Becker, Chair, Finance & Administration Committee and Regina Yan, MA, Chief Operating Officer</i>	Larry Becker gave summary remarks and introduced Chief Operating Officer Regina Yan who reviewed PCORI's financial position as of 2/28/15. The review included an overview of PCORI's cash balance and revenue, research contract obligations, a summary of PCORI's FY 2015 budget vs. actuals, cost savings as well as delayed expenses which resulted in expenditures 29% under budget. Ms. Yan highlighted several key factors in the variance. PCORI is currently updating its cash flow with the latest expenditure information to see how much additional funds made available from cost

	savings can be put to program activities. Furthermore, PCORI will incorporate the updated cost assumptions in its FY2016 budget planning.
Scientific Publications Committee Charter <i>Bill Silberg, Director of Communications</i>	Bill Silberg provided background on the history of the original scientific publications subcommittee charter that was established in 2011/2012, which addresses oversight of scientific articles developed on PCORI's behalf. He then went over the proposed updated model for the new committee charter and discussed next steps, including Board approval, appointing members, and regularly convening the committee. The Engagement, Dissemination, and Implementation Committee had previously recommended approval of this charter, and EDIC Chair, Dr. Debra Barksdale, briefly spoke to the Board about the old subcommittee and how this new proposed committee is an improvement. There was some brief discussion about the logistics of the committee. The following motion was made and seconded: Motion: To approve the Scientific Publications Committee Charter <i>Approved by a majority vote of the Board by voice vote</i>
Public Comment Period <i>Grayson Norquist, MD, MSPH</i> <i>Sue Sheridan, MIM, MBA, Director of Patient Engagement</i>	The Chairperson opened the meeting to the public, inviting comments from those attending the meeting in person and those attending remotely. There were no requests to make a public comment.
PCORnet Projects <i>Joe Selby, MD, MP, ED and</i> <i>Rachael Fleurence, PhD, Program Director CER Methods and Infrastructure</i>	Dr. Rachael Fleurence, Program Director for PCORI's CER Methods and Infrastructure team, presented an overview of the status of all PCORnet Research Demonstration Projects. She then addressed the PCORnet Aspirin Research Demonstration Project award, including the topic development, PFA development and merit review process. Members of the Board asked questions about the expertise of the study team and study monitoring, along with emphasizing the importance of a good process that results in a trial with strong consensus.
PCORnet Aspirin Demonstration Project Award	The following motion was made and seconded: Motion: To approve funding for the recommended PCORnet Aspirin Research Demonstration Project Award <i>Approved by a majority vote of the Board by a show of hands. 20 in favor, 0 opposed. (Dr. Fernandez had announced her intention to recuse herself prior to the meeting on this agenda item, but was not present for the vote).</i>
PPRN Demonstration Project PFA Development	Dr. Fleurence presented an overview of the PCORnet PPRN Research Demonstration Project. She outlined the project's potential scope and framework, which includes developing a limited PFA which will invite Letters of Intent from PPRNs that address patient-generated research questions. The Demonstration Project will encourage collaborating

PCORnet Project “NEXT-D” on Diabetes with CDC/NIH PFA Development	across PPRNs to conduct research on patient generated questions and testing the network’s capacity for conducting research on behalf of the patient community. The Board raised questions about the types of studies that will be funded by this initiative. The following motion was made and seconded: Motion: To approve the development of a limited PFA to fund up to nine PPRN research demonstration projects within PCORnet, not to exceed \$22 million in total costs. <i>Approved by a majority vote of the Board by a show of hands. 20 in favor, 0 opposed.</i> Dr. Selby, presented an overview of the Natural Experiments in Translation-for Diabetes (NEXT-D) initiative and the plans for PCORI involvement in the project. He outlined the rationale for PCORI to provide additional funding for CDRNs to participate in the initiative with the Centers for Disease Control (CDC) and NIH. The Board discussed the types of studies that will be funded within the initiative and the process for collaboration with CDC. The Board suggested adding evaluation criteria to the application. The following motion was made and seconded: Motion: To approve the development of a limited PFA to fund up to three CDRNs for participation in the CDC/NIH Next-D Network, not to exceed \$7.5 million (total cost) over five years. <i>Approved by a majority vote of the Board by a show of hands. 18 in favor, 0 opposed, 2 abstentions (Barbara McNeil and Ellen Sigal abstained)</i>
Evaluation Update <i>Lori Frank, PhD, Program Director, Evaluation & Analysis and Laura Forsythe, PhD, MPH, Associate Director, Evaluation & Analysis</i>	Dr. Lori Frank, Director of the Evaluation and Analysis Program, and Dr. Laura Forsythe, Associate Director, Evaluation and Analysis, presented results from a review of rare disease applications, and engagement efforts in PCORI research projects. Overall, the review indicates that applications for funding for projects involving rare diseases were not disadvantaged relative to applications for other conditions in terms of likelihood to be discussed at the panel meeting and likelihood to be funded. Absolute number of rare disease applications remains low, however, so PCORI instituted a rare disease set aside in Spring 2015 to ensure that rare diseases continue to be well represented within the portfolio. Results from ongoing information collection from awardees and research partners were presented next, with results from qualitative data analysis. Awardees expressed concerns about establishing partnerships while managing the uncertainty of application success. Many awardees reported that engagement with research partners enhanced recruitment methods. Awardees and research partners expressed interest in ongoing training for engagement in research. This early evidence suggests research engagement has an

	impact on many aspects of the research process. Results suggest several potential courses of action for PCORI, including managing expectations of applicants about application success and compensation, learning more about viable technology supports to manage research relationships, enhancing training, and continuing to share learned Evidence.
Methodology Committee Update <i>Robin Newhouse, PhD, RN, NEA-BC, FAAN, Chair, Methodology Committee</i>	Dr. Robin Newhouse provided the Board with an overview of the Methodology Committee's (MC) strategic priorities. Priorities related to the Methodology Standards: A group of experts, along with MC members and staff, drafted new standards on designs using clusters at a workshop on April 7th. The standards will be presented to the entire Committee at the May 6 meeting. A group of MC members and staff will draft new standards for research on complex interventions, beginning with a literature review of definitions and current guidance. Four of the Methodology Standards categories are currently under review. It is anticipated that the review of all eleven categories will occur by fall 2015. Priorities related to identifying methods gaps: A sub group of Committee members was formed to identify and prioritize methods for PCORnet, including methods for data networks and missing data. A group is also working on the related topic of PROs in EHRs. A sub group has also been formed to define a clear statement on "usual care". This may be a topic on which the MC and SOC can work together. The Committee is conducting a "deep-dive" into decision science including patient preference. A workshop is planned for June to help plan a larger workshop in the fall. The Board identified patient involvement as an important component of this initiative. Priorities related to disseminating Methodology Standards: A CME/CE initiative with Baylor College of Medicine is underway with the deliverable expected at the end of May. Several members are involved with module development. The Standards academic curriculum development has been awarded to Johns Hopkins. The deliverable is expected in September 2015. The Committee will communicate the scope of work and deliverables to the Board at a future meeting. Other updates: The GAO has appointed Adam Wilcox, PhD from Intermountain Healthcare as a new Methodology Committee member. Dr. Wilcox is a noted leader in the field of healthcare informatics. Dr.

	Newhouse expressed her enthusiastic welcome on behalf of the entire Committee.
CDR Program Overview <i>Jean Slutsky, PA, MSPH, Chief Engagement and Dissemination Officer and Program Director, Communication & Dissemination Research</i>	Jean Slutsky, Program Director of the Communication and Dissemination Research program (CDR) presented an overview of the CDR program including a rationale regarding the need for CDR, explanation of the CDR program portfolio priorities, and explanation of the CDR program goals for 2015. She also described three projects CDR has funded to date. She gave an overview of the evolution of PCORI's approach to funding decision aids and of the work currently underway to analyze PCORI's funding portfolio relating to decision aids.
Topic Prioritization Process <i>Christine Goertz, DC, PhD Chair of the Science Oversight Committee and Joe Selby, MD, MPH</i>	Dr. Christine Goertz, made a presentation on the topic prioritization process, during which she explained the pathway to a funding announcement and whether that results in a targeted PFA or the priority topic list in the Pragmatic Clinical Studies PFA. The process graphic identifies staff, SOC, and Advisory Panel roles throughout each step and the criteria used to make decisions as topics progress from one list to another. The Board of Governors voted to approve this process last July. The refinements to this approach allows for more frequent and timely interaction with the SOC, as the SOC selects or rejects topics for further development. Soliciting the SOC's feedback early and often will save time and resources, as well as streamline the process. This refined process and the seven lists of topics are available on the website; the goal is to increase transparency to PCORI stakeholders.
Public Comment Period <i>Grayson Norquist, MD, MSPH</i> <i>Sue Sheridan, MIM, MBA, Director of Patient Engagement</i>	The Chairperson opened the meeting to the public, inviting comments from those attending the meeting in person and those attending remotely. There were no requests to make a public comment.
Wrap-up and Adjournment of the Meeting of the Board <i>Grayson Norquist, MD, MSPH</i>	The meeting was adjourned at 5:40 pm

Approved by the PCORI Board of Governors 06-16-2015