Patient-Centered Outcomes Research Institute Board of Governors Meeting Minutes

The Hilton Alexandria, Old Town
1767 King Street
Alexandria, VA 22314
May 5, 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; Alicia Fernandez, MD; Christine Goertz, DC, PhD; Gail Hunt; Robert Jesse, MD, PhD; Richard Kronick, PhD; Harlan Krumholz, MD; Richard Kuntz, MD, MSc; Sharon Levine, MD; Freda Lewis-Hall, MD; Ellen Sigal, PhD; Harlan Weisman, MD; Robert Zwolak, MD, PhD

Board Members Absent:

Arnold Epstein, MD; Leah Hole-Marshall, JD; Steven Lipstein, MHA, *Vice Chair*

Methodology Committee Members Present:

Robin Newhouse, PhD, RN, Chair; Michael Lauer, MD

Staff:
Joe Selby, MD, MPH, *Executive Director*; Celeste Brown; Matt Burress; Desiree Frank; Lori Frank, PhD; Orlando Gonzales, MPA; Pam Goodnow, CPA; Annie Hammel; Romana Hasnain-Wynia, PhD; Mary Hennessey, *Esq., General Counsel*; Susan Hildebrandt, MA; Jayne Jordan; Kristen Kanopka; Maggi LeDuc; Katie Lewis; Bryan Luce, PhD, MBA, *Chief Science Officer*; Kara Odom Walker, MD, MPH; Michele Orza, ScD; Katie Rader; Sue Sheridan, MBA; Bill Silberg; Jean Slutsky, PA, MSPH, *Chief Engagement and Dissemination Officer*; Christine Stencel, MA; Regina Yan, MA, *Chief Operating Officer*

AGENDA

AGENDA ITEM	RELATED MINUTES
Chair's Welcome - *Grayson Norquist, MD, MSPH, Chair*	Dr. Norquist opened the meeting and acknowledged which Board members were present.
Executive Director's Report - *Joseph Selby, MD, MPH, Executive Director*	Dr. Norquist invited Dr. Selby to give the Executive Director's report. Dr. Selby discussed: (1) the progress of PCORnet, (2) the current status of the Pragmatic Clinical Studies, (3) the recent meetings of the two new Advisory Panels for Rare Disease and Clinical Trials, and (4) the GAO review. (1) Dr. Selby described the timeline and organizational structure of PCORnet including its 11 Task Forces, with an emphasis on three of them - the Task Forces on Data Standards & Security, Health Systems Interaction and Data Privacy. (2) The first Pragmatic Clinical Study was announced in February and 217 applications were received which will be reviewed in November to be awarded January 15. Another funding announcement will go out in May. (3) The Rare Disease Advisory Panel expressed interest in assisting with data standards and registries for rare disease in PCORnet, among other issues. They will coordinate with PCORnet Task Force on Rare Diseases. The Clinical Trials Advisory Panel is closely linked to the Methodology Committee and will work with them to maintain up-to-date standards, to provide guidance on innovative methods for trials and to advise on data and safety monitoring. (4) Dr. Selby informed the Board that the first GAO 5-year review of PCORI has begun and the Board will be kept apprised of developments. He then announced Jean Slutsky, PA, MPH as the new Chief Engagement and Dissemination Officer, and reviewed the agenda for the meeting.
Approval of the April Minutes - *Grayson Norquist, MD, MSPH, Chair*	The following motion was made and seconded: **That the Board of Governors approve the minutes of the April 22nd, 2014 teleconference meeting of the PCORI Board of Governors** *Approved by a majority vote of the Board by voice vote*
Update on Science Processes: • Implementing the Methodology Standards • Award Selection • Topic Selection - *Bryan Luce, PhD, Chief*	**Implementing the Methodology Standards** Dr. Luce reviewed PCORI's implementation of the Methodology Standards, the timeline, the pre-post award requirements, the checklist, and changes to the research template. All 53 projects in the August 2013 cycle were reviewed using the adherence process, and staff will be reviewing previously funded projects for adherence as well. PCORI has developed a curriculum to train reviewers. PCORI Staff will begin training later this month.

Science Officer	Dr. Luce stated that the Methodology Standards are required to be used, and a rigorous monitoring process is in place. The Board expressed an interest in providing feedback to applicants who did not adhere to the MC standards to improve their methodology for any future applications. There was also a discussion regarding methodological standards for projects not carried out in an academic setting, the number of questions pragmatic and randomized controlled trials can answer, and the inclusion of observational studies. A suggestion for the creation of a PCORI Methodology Standards toolkit was put forth for researchers and teaching institutions, among other uses, including to improve the dissemination of these standards. Dr. Luce noted there is a checklist in the works that will be made available. These standards will also be made more prominent on the PCORI website. In response to Board suggestions regarding funding economical research and innovative solutions to conducting research, Dr. Luce mentioned that the Advisory Panel on Clinical Trials will work to improve study designs. **Award Selection:** Dr. Luce reviewed the funding slate selection process, the exception criteria and the guidelines for considering projects outside of the merit review scores. The Board recommended the exception criteria be addressed in the SOPs being developed, as exceptions are rare. Dr. Luce noted that the BOG will be invited to comment on the SOPs through an informal review process. **Topic Selection:** Dr. Luce gave an overview of the SOC's work as a Committee the next day on topic selection which included two key issues: the timing and nature of SOC and BOG involvement, and the extent of information for SOC and BOG review. He then went over the process improvement steps, intended to shorten the vetting process and make it more efficient by including the SOC and experts earlier in the process. Among other improvements, the SOC will review topics prior to the Advisory Panels to shorten the process. Topics will be sorted into buckets for targets. The Board recommended clear definitions of PCTs, RCTS, tPFAs. etc.
Lunch	
Overview of Addressing Disparities Program - *Romana Hasnain-Wynia, MS, PhD, Addressing Disparities Program, Program Director*	Dr. Hasnain-Wynia provided an overview of the Addressing Disparities program and portfolio, and presented a program-specific Driver Model being used to better understand and guide the program. She presented a "snapshot" of the portfolio, including a breakdown of studies by research topic area, target population, and study design. She highlighted that projects addressing disparities exist not only in the Addressing Disparities portfolio, but throughout all of the PCORI's program areas. Dr. Hasnain-Wynia described the underpinning of the Addressing Disparities Driver Model, a conceptual framework created by Cooper et al. that delineates barriers to and mediators of equitable health care for populations likely to experience disparities. The Addressing Disparities Driver Model is conceptualized as an overlay to this framework, and outlines primary, secondary, and tertiary drivers of the program goal to reduce or eliminate disparities in health care outcomes. Dr. Hasnain-Wynia demonstrated how the program has mapped the portfolio to this model to visualize topic areas that are well-funded, and gaps in the portfolio. The Board discussed issues around metrics for success, generalizability of findings, and

	sustainability of projects, recognizing that these are challenges faced by many studies. The Board also discussed how to leverage the potential knowledge that is being generated. Dr. Hasnain-Wynia reiterated the importance of examining themes and topics across PCORI's entire portfolio in order to best leverage findings that result from the research. The Board expressed an interest in developing messaging around "the big picture" at PCORI and developing a better and deeper understanding of PCORI's research.
Methodology Committee Update - *Robin Newhouse, PhD, RN, Methodology Committee, Chair*	Dr. Newhouse provided an update on the following activities of the Methodology Committee: **Methodology Standards:** The MC is developing two new sets of standards in the area of research designs that use clusters and complex interventions. The MC will hold an expert workshop on Research Designs using Clusters in the fall 2014, date TBD. Public recommendations for topic areas for new standards are now being solicited and collected via the PCORI website. **PCORnet Methods Task Force:** A new group of staff, MC, and PCORnet Coordinating Center members has formed to identify and address methods gaps that evolve from PCORnet. **Open Science Work Group**: Led by Steve Goodman and Harlan Krumholz, and with oversight from the RTC, a work group has formed to consider open science and data sharing. The group will be presenting a proposal to the MC and RTC, with the goal of presenting a proposal to the Board. **Decision Sciences Initiative**: A work group of PCORI staff and MC members has developed a framework for decision sciences and is planning a workshop for the fall to convene experts in this area, both inside and outside the health/healthcare arena. The framework includes elements such as: improving decision options for patients/systems, decisions when patient cannot be actively involved, and shared decision making. **MC Update**: The GAO's call for nominations for the four anticipated vacant seats on the MC closed on April 11th. The MC thanked Sharon-Lise Normand, Sherine Gabriel, John Ioannidis, and Al Berg, for their service.
Engagement Update - *Jean Slutsky, PA, MSPH, Chief Engagement and Dissemination Officer*	Ms. Slutsky provided an update on the Engagement Department since starting on March 17, 2014. She noted her goal, working in collaboration with the Chief Science Officer, to bring together Engagement, Communications, and Dissemination more closely. She was pleased to note the recent hiring of key staff in her Department, and the expansion of the PCORI Engagement Awards to include conference funding support. And, lastly, she reported that the PCORI Patient and Family Engagement Rubric has been completed and is being made available on the PCORI web site to guide researchers and patients/caregivers with promising practices of engagement within our first three funding cycles. Training for the Engagement Rubric is also being planned.
Evaluation Framework and Activities - *Michele Orza, ScD, Senior Advisor to the Executive Director*	Dr. Orza provided an overview and update on PCORI's evaluation work, involving a large cross-cutting team of staff who are assisted by the PCORI Evaluation Group, composed of Board and Methodology Committee members and external experts. She described PCORI's focus on three main evaluation tasks: building the evaluation framework; determining how to measure our goals; and, assessing the impact of engagement on PCORI's processes and the early phases of PCORI-funded research.

	Dr. Orza described how PCORI's evaluation framework organizes the questions important to PCORI and to stakeholders and outlines how we will go about getting the answers. She briefly described each of the three kinds of questions included in the framework and the activities underway to answer them. The first set of questions is about PCORI's day-to-day work. The second set relates to PCORI's three strategic goals – to increase useful information, speed its uptake and use, and to influence research to be more patient-centered. The primary activities related to this set of questions are the development of metrics for usefulness, uptake and use, and influence. The third set focuses on the unique elements of the PCORI approach, especially Engagement. The Evaluation Team is focused on getting rich and detailed descriptions of engagement in PCORI-funded projects to determine its impact on results of the research. The Board discussed and asked questions about the role of external evaluation, the development and application of usefulness criteria, the assessment of engagement, and appropriate comparators for PCORI.
Break	
Mid-year Dashboard Review - *Joe Selby, MD, MPH, Executive Director*	Dr. Selby presented the PCORI Board of Governors' Dashboard at mid-year FY 2014. The primary visuals are arrows and bar charts that, whenever possible, show progress relative to targets and over time. Several metrics shown on the Dashboard are still in development, and there are placeholders for additional metrics for which we expect to have data to show in Q3 or Q4. Dr. Selby highlighted the following: • There are over 40 topics in the priority topics pipeline. Two areas have been funded (Asthma and Uterine fibroids), fifteen topics were included in the Pragmatic Clinical Studies PFA, and two specific PFAs have been issued (Obesity and PROMIS). • Currently, PCORI anticipates committing funds in the $400 million range by Q4. • The spread of projects across the categories treatment, prevention, diagnosis and screening has seen very moderate shifts over the funding cycles, with the majority of projects funded falling into the treatment category. • Projects were reported as meeting 67% and 62% of their milestones in Q1 and Q2, respectively. • Projects were 74% adherent to the Methodology Standards in Q2, based on their application. • PCORnet was slightly behind the target for goal Q1 to have all the contracts signed. Because the contracts were new and very complex, they took more time to execute. • Staffing is behind target for Q2, but still expected to reach our target by the end of Q4. The Board reviewed and asked questions about what the target balance should be among treatment, prevention, diagnosis, and screening, what other ways PCORI could consider cutting and analyzing the portfolio, how to give publications by awardees a more prominent space on the dashboard and how to consider tracking adherence to the Methodology Standards.

Approval to Authorize a cash-secured Letter of Credit for Additional Office Space Lease - *Grayson Norquist, MD, MSPH, Chair* - *Regina Yan, MA, Chief Operating Officer*	Ms. Yan explained that Bank of America requires the Board of Governors to approve a resolution that authorizes a letter of credit as a form of security deposit for the new office lease at 1919 M St NW. The funds required for lease of the new space were part of the approved FY2014 Budget The following motion was made and seconded: **That the Board of Governors approve each resolution in "A Resolution of the Board of Governors of the Patient-Centered Outcomes Research Institute to Authorize a Letter of Credit".** *Approved by a majority vote of the Board by voice vote*
Financial Review as of 2/28/2014 - *Regina Yan, MA, Chief Operating Officer*	Ms. Yan provided a 5 month financial report of FY2014 which compared the budget and the actual spending through February 28, 2014. She reported PCORI is underspending its year-to-date budget by 61%, the majority of which is in research spending. The cost reported by awardees has been coming in at a much slower pace than expected. Other factors which contributed to the underspending included cost savings as well as other delayed expenses, such as projects moving expected completion date to later in the year and slower than targeted staff hiring. Director of Finance Pam Goodnow is reviewing financial reports and invoices from awardees to adjust model for projection of research spending. A re-forecasted spending for FY2014 will be reviewed with the Board. Board members inquired about assumptions used for the current forecast, what adjustments could be made and what metrics could be added to the organizational dashboard to help the Board keep more apprised of the research spending, administrative ratios and hiring. The Finance and Administration Committee (FAC) will work with the staff in further refining its analysis and report.
Public Comment - *Susan Sheridan, MBA, MIM, Director, Patient Engagement*	The Chair opened the meeting to public comment, inviting comments from those attending the meeting in person and those attending remotely. Those contributing with comments were: – Sara van Geertruyden, Partnership to Improve Patient Care (PIPC) – Gunes Aygok, MD, North Shore-LIJ Health System
Wrap-up and Adjournment of the Meeting of the Board - *Grayson Norquist, MD, MSPH, Chair*	The meeting was adjourned at 4:50 pm.