Patient-Centered Outcomes Research Institute Board of Governors Meeting

The Westin Georgetown
2350 M Street
Washington, DC 20037
September 23, 2013

Board Members Present:

Eugene Washington, MD, MSc, *Chair*; Steven Lipstein, MHA, *Vice Chair*; Debra Barksdale, PhD, RN; Kerry Barnett, JD; Lawrence Becker; Leah Hole-Marshall, JD; Allen Douma, MD; Arnold Epstein, MD; Christine Goertz, DC, PhD; Gail Hunt; Robert Jesse, MD, PhD; Richard Kronick, PhD; Harlan Krumholz, MD; Richard E. Kuntz, MD, MSc; Freda Lewis-Hall, MD; Grayson Norquist, MD, MSPH; Ellen Sigal, PhD; Harlan Weisman, MD; Robert Zwolak, MD, PhD; Michael Lauer, MD (designee to Francis Collins)

Board Members Absent: Francis Collins, MD, PhD; Sharon Levine, MD

Methodology Committee Members Present:
Robin Newhouse, PhD, RN, *Chair*; Steven Goodman, MD, MHS, PhD, *Vice-Chair*; Naomi Aronson, PhD; Michael Lauer, MD; Brian Mittman, PhD; Jean Slutsky, Mary Tinetti, MD; Sally Morton, PhD

Staff:
Anne Beal, MD, MPH, *Deputy Executive Director and COE;* Marla Bolotsky; Chad Boult, MD, MPH; Rachael Fleurence, PhD; Desiree Frank; Mark Freeman; Orlando Gonzales, MPA; Pamela Goodnow, CPA; Annie Hammel;

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Romana Hasnain-Wynia, PhD; Mary Hennessey, Esq., *General Counsel*; David Hickam, MD, MPH; Susan Hildebrandt, MA; MD; Katie Jones; Aingyea Kellom; Bryan Luce, PhD, MBA, *Chief Science Officer*; Gregory Martin; Kara Odom-Walker, MD, MPH; Michele Orza, ScD; Katie Radar; Suzanne Schrandt; Joe Selby, MD, MPH, *Executive Director*; Sue Sheridan, MBA; William Silberg; Scott Solomon; Regina Yan, *Chief Operating Officer*

Additional Staff: Ayodola Anise; Rochelle Bent; Diane Bild; Celeste Brown; Lynne Disney; Kelly Dunham; Lee-Lee Ellis; Laura Forsythe; Jason Gerson; Kathy Gurgol; Alex Hartzman; Lauren Holuj; James Hulbert; Stanley Ip; Kim Jackson; Maggi LeDuc; Katie Lewis; Julie McCormack; Christine Stencel; Jaye Smalley; Victoria Szydlowski; Sarita Wahba; Nichole Walton; Rachel Witsaman

Consultants: Marla Bobowick (Starpower); Deborah Hechinger (Hechinger Group); Richard Schmitz (Golin Harris)

Guests: Nancy Miller; Margaret Darling, Nueva Vida; Matthew Davis, University of Michigan; Kristi Graves, Georgetown University; Adam Hartman, Johns Hopkins School of Medicine; Clarissa Hsu, Group Health Research Institute; Roberto Londono, Nueva Vida; David Loring, Emory University; Marci Nielsen, Patient-Centered Primary Care Collaborative; Brandy Parker, My Epilepsy Story; Janice Tufte, Group Health Research Institute; Christopher Yang, Drexel University

Public Commenters: None

AGENDA		
MONDAY SEPTEMBER 23	**AGENDA ITEM**	**MINUTES**
7:00 – 8:00 AM	Breakfast	
TAB 1 8:00 – 8:05 AM	Welcome and Approval of May 5th , June 18th and September 10th, 2013 Board Minutes - *Eugene Washington, Chair*	Dr. Washington opened the meeting. The May 5th, June 18th and September 10th 2013 meeting minutes were unanimously approved by the Board.
TAB 2 8:05 – 8:45 AM	Executive Director's Report - *Joe Selby*	Dr. Selby noted that at the conclusion of this Board meeting, Dr. Washington will step down as Chair of PCORI's Board and that Dr. Gray Norquist would become the new Chair. Vice Chair, Mr. Lipstein, expressed his gratitude to Dr. Washington for his service on behalf of the Board. Dr. Selby reviewed the dashboard and highlighted several areas. By the end of 2014, PCORI anticipates staff growth in order to align with strategic decisions, including employing active portfolio management, growth in size of portfolios, committing more funding in early years, and phasing out of consultants to be replaced primarily with full time staff. Dr. Selby reported on the infrastructure program and then reviewed several questions with the Board, with discussion primarily focused on

		merit review. The Board made several comments on merit review, including noting that PCORI's process includes a focus on engagement.
TAB 3 8:45 – 9:30 AM	Charter for Clinical Trials Advisory Panel - *Bryan Luce, Chief Science Officer*	Bryan Luce provided an update on the status of the legislatively mandated Clinical Trials Advisory Panel. PCORI staff has been working closely with the Methodology Committee and the PDC to develop a draft charter for the Advisory Panel Key points highlighted by Dr. Luce focused on the scope and function of the panel, especially in relation to the other PCORI advisory panels and the Methodology Committee, and the need for the panel to meet the requirements of the legislation. Members of the Board raised a number of questions and provided comments, primarily focused on the original intent of the legislation, appropriate oversight and reporting structure for the panel, the need for clarity on the advisory role of the panel, and potential interaction with the Methodology Committee. Once revised, the charter will come back to the Board in the November meeting for vote on approval.
TAB 4 9:30 – 10:30 AM	PCORI's Research Portfolio: Planning and Investment Strategy - *Bryan Luce, Chief Science Officer*	Dr. Luce presented the current and future plans for research funding to the Board. Staff with the PDC continues to work on targeted funding areas, the funding mix to encourage greater impact and paths to creating more responsiveness to patient and stakeholder guidance. He also noted the proposed research funding and commitments from 2013-2015. He presented funding to date, along with details on FY2014 research funding and the gradation of targeted funding approaches. Dr. Luce also discussed with the Board three strategic issues**:** 1) the anticipated shift in the balance of PCORI's portfolio from broad to targeted funding, 2) ways to speed up the PFA process, including fast-track PFAs and inserting "carve-outs" in the broad announcements, 3) reallocating projects to larger, longer studies. The Board expressed general support of shifting the balance from broad to targeted funding and recognized that some topics will need to move forward more quickly. There is also interest in better describing the formal criteria for selecting

		targeted topics. The PDC is also interested in becoming more targeted, but determining how to narrow down topics to clear specific questions is very time-intensive. The Board expressed interest in funding research that impact important outcomes and our strategic goals. Board members encouraged each other to think about what success looks like and evaluate our current funding efforts through a prospective evaluation of the difference in outcomes between broad and targeted funding approaches, including the infrastructure awards. Chair Washington summarized that the Board agreed with the proposed general shift toward more targeted funding and that we need to move more quickly, but continue to include a rigorous process for selecting topics. The greatest challenge is defining success to ensure that we select topics that are most likely to have the greatest impact and require that our applicants provide a rationale for funding that includes impact.
10:30 – 10:45 AM	Break	
TAB 5 10:45 – 11:30 AM	Dissemination and Implementation Action Plan - *Anne Beal, Deputy Executive Director and Chief Officer of Engagement*	Dr. Beal presented an update on the development of PCORI's action plan for the dissemination of clinical comparative effectiveness research. Dr. Beal described the roundtable that was held on July 29, 2013, in Washington, DC. Dr. Beal reviewed information on where patients go to seek information. She also reviewed AHRQ's role in dissemination under the statute and the need to avoid duplication. The Board discussed the difference between doing dissemination "for" implementation and facilitating dissemination and implementation efforts and whether PCORI should emphasize dissemination, making information available and usable to those who are implementing, or pursue implementation science activities. The approach taken by PCORI will have implications, including budgetary implications. Discussion will be continued with the COEC, which can then make a recommendation to the full Board. The

		Chair requested that COEC and staff provide the Board with information on the scope of PCORI's D&I efforts and how they complement AHRQ's activities or fill in to address activities that AHRQ does not engage in.
TAB 6 11:30 – 12:15 PM	Engagement Awards - *Anne Beal, Deputy Executive Director and Chief Officer of Engagement*	Dr. Beal presented an informational overview of the Eugene Washington Engagement Awards and provided examples of each category: Knowledge, Training and Development, and Dissemination. The awards will honor Chair Washington's service to PCORI and the Board and his efforts to ensure that our work is inclusive and transparent. Dr. Beal sought Board comments on how to measure the success of the engagement awards. Board discussion included focus on the role of the intermediate funder, the impact on Engagement team staffing, and coordination with AHRQ dissemination efforts. Vice Chair Lipstein summarized that the Board was broadly supportive of the Eugene Washington PCORI Engagement Awards. He requested that the Board be provided with more details on the scale of the Engagement Awards, how they will be coordinated with AHRQ, and how the awards will build and support the scientific research agenda.
12:15 – 1:15 PM	Lunch	
TAB 7 1:15 – 1:45 PM	PCORI Methodology Committee Update - *Robin Newhouse, Methodology Chair* - *David Hickam, Director, Program on the Assessment of Prevention, Diagnosis, and Treatment Options*	Robin Newhouse, Chair of the Methodology Committee discussed the development of the Methodology Report and noted that a draft is under review by a subgroup of the Committee and will be finalized for submission to the Board at its November meeting. The Report includes innovations, including examples of how the Methodology Standards are applied. Dr. Newhouse also identified some areas that have are being considered for the development of new standards. The Board discussed the dissemination of the methodology standards, with the need to have plans for different audiences.
TAB 8	Operations Report	A mid-year financial review, contracts process

1:45 – 2:15 PM	- *Regina Yan, Chief Operating Officer*	improvements, the addition of several new systems, and the development of staffing plan were presented. The Board suggested a 5-year financial forecast as well as a financial summary with additional details for future reports. For the development of the proposed staffing plan, it was recommended to reference metrics used by peer organizations. The Board also noted its expectation of a transition away from contractors by the end of the year as PCORI builds up its own internal staff capacity.
2:15 – 2:45 PM	Public Comment	The Chair opened the meeting to public comment, inviting comments from those attending the meeting in person and those attending remotely.
3:00 – 4:30 PM	Awardees and Stakeholder Panel	Three different PCORI awardees gave presentations on their research projects. Members of the Board asked several questions about the projects. ***Group Health Research Institute*** Clarissa Hsu, Janice Tufte ***Georgetown University; Nueva Vida*** Kristi Graves, Margaret Darling, Roberto Londono ***Emory University – My Epilepsy Story*** David Loring, Brandy Parker
4:30 PM	Wrap-up and Adjourn	The Chair adjourned the meeting