Patient-Centered Outcomes Research Institute Board of Governors Meeting

The W Atlanta-Downtown Hotel
45 Ivan Allen Jr., Blvd.
Atlanta, GA 30308
November 18-19, 2013

Board Members Present:
Grayson Norquist, MD, MSPH, *Chair*, Steven Lipstein, MHA, *Vice Chair*; Debra Barksdale, PhD, RN; Kerry Barnett, JD; Lawrence Becker; Francis Collins, MD, PhD; Allen Douma, MD; Arnold Epstein, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Gail Hunt; Robert Jesse, MD, PhD; Sharon Levine, MD; Freda Lewis-Hall, MD; Ellen Sigal, PhD; Harlan Weisman, MD; Robert Zwolak, MD, PhD

Board Members Absent: Richard Kronick, PhD; Harlan Krumholz, MD; Richard Kuntz, MD, MSc

Methodology Committee Members Present:
Robin Newhouse, PhD, RN, *Chair*; Jean Slutsky

Staff Members Present:
Joe Selby, MD, MPH, Executive Director; Anne Beal, MD, MPH, *Deputy Executive Director and Chief of Engagement;* Desiree Frank; Mark Freeman; Pamela Goodnow, CPA; Orlando Gonzales, MPA; Annie Hammel; Mary Hennessey, Esq., *General Counsel*; David Hickam, MD, MPH; Susan Hildebrandt, MA; MD; Bryan Luce, PhD, MBA, *Chief Science Officer*; Gregory Martin; Kara Odom-Walker, MD, MPH; Michele Orza, ScD; Katie Radar; Suzanne Schrandt; Sue Sheridan, MBA; William Silberg; Jaye Bea Smalley; Christine Stencel; Regina Yan, *Chief Operating Officer*

AGENDA

MONDAY NOVEMBER 18: MEETING OF THE BOARD		
TIME	**AGENDA ITEM**	**OBJECTIVE**
7:30 – 8:30 AM	Breakfast	
TAB 1 8:30 – 8:45 AM	Welcome Approval of September 2013 Board Meeting Minutes - *Grayson Norquist*	Dr. Norquist opened the meeting at 8:34 am. The September 23rd meeting minutes were unanimously approved by the board.
TAB 2 8:45 – 9:15 AM	Executive Director's Report - *Joe Selby*	Dr. Norquist invited Dr. Selby to give the Executive Director's report. Dr. Selby discussed the progress of the National Clinical Research Network, indicating that 28 CDRN and 61 PPRN applications were submitted, with a broad diversity in terms of geography and focus. It is anticipated that the Board will vote on the CDRN and PPRN slates on December 17, 2013. It is anticipated that participants in the NCRN will have the opportunity to participate in a large, pragmatic trial in 2014. Dr. Selby also reviewed improvements in the merit review process and the decrease in the time from award to contract execution for research funding.
TAB 3 9:15 – 10:00 AM	Strategic Plan (Goals 1, 2, and 3) - *Joe Selby*	Dr. Selby reviewed the evolution of PCORI's Strategic Plan, beginning in July 2011 with the Board's approval of PCORI's Mission Statement, which substantially frames the Strategic Plan. He reviewed the imperatives addressed in the Strategic Plan and how the strategic priorities lead to outputs and enable PCORI to reach its goals. He gave an overview of the strategic plan cycle, which reflects an ongoing process that includes strategic planning, leading to strategic questions, leading to implementation, leading to strategic questions, and leading back to strategic planning. Strategic questions will continue to develop over time. Board Member Levine moved to approve the proposed PCORI strategic plan and Board Member Becker seconded. After the motion, the Board discussed the importance of having the PCORI committees organized to give input on strategic goals and provide recommendations to the Board. The Chair

		called for a vote on the motion. The Board of Governors approved the proposed Strategic Plan unanimously.
10:00 – 10:15 AM	Break	
TAB 4 10:15 – 11:15 AM	Strategic Issues: Research Funding Planning (Goal 1) Decision Support Research (Goal 1) - *Joe Selby*	Dr. Selby gave an overview of the strategic question of how PCORI should optimize its funding commitments over the next six years to best fulfill its mission, recognizing that expenditures follow commitments with a lag of one to two years. He summarized PCORI's authorizing legislation, including provisions addressing access to the PCORI Trust Fund through September 30, 2019. He also summarized how funds from the Trust Fund are provided to PCORI and that PCORI has the ability to responsibly project the amount of such funding for budgeting and planning purposes over the next six years. He reviewed different approaches to making commitments and expenditures over the next 6 years, including: • both committing and expending all projected funding by September 30, 2019, which would require a significant ramp-up of spending right away, presenting challenges • Committing a similar amount of funding each year, on a steady basis, which would potentially leave significant funds committed, but unexpended in 2019; or • a middle path of committing funding at somewhat higher levels in the next few years, but with all commitments made by September 30, 2019 and with trailing expenditures, including some beyond 2019. Under this approach, more research results would be available earlier, which will help identify research gaps and trends. The Board recognized the importance of appropriately and responsibly stewarding PCORI's funds. It encouraged PCORI to fund projects that are high-impact and will support advancement of PCORI's mission. The Board discussed the importance of being engaged with these long term strategic issues and to consult with GAO, Treasury, and Congress on the long term options. The Board recognized that the 2014 Budget includes projections for funding during FYE 2014, which will be

		part of the approved budget. At the same time, the Board felt it was important for PCORI to have a research funding plan on a 2 year basis, rather than an annual basis, in order to ensure that high-impact projects will be funded. Dr. Selby discussed the strategic question of the appropriate ratio of funding of decision support and primary comparative effectiveness research. He summarized PCORI's first three funding cycles and overview of awards. He noted that PCORI has funded 37 projects which incorporate decision making tools. Dr. Selby also addressed different ways of understanding the challenges faced by patients: that there may be large gaps in knowledge and therefore a need for more and better quality research (which tends to align with pursuing primary comparative effectiveness research projects); or, that there is significant information, but it is not synthesized or presented in a useful way to support shared decision making (which tends to align with pursuing decision support projects). Dr. Selby said that PCORI recognizes both and believes its mandate includes addressing both evidence generation and evidence synthesis and decision support. The Board discussed the importance of both approaches and the role that active portfolio management should take in ensuring high quality in both areas, the right ratio, and in evaluating how decision support tools are adopted. PCORI can consider conceptual and operational framework for comparative effectiveness research in decision support.
TAB 5 11:15 – 12:15 PM	2014 Budget (Goals 1, 2, and 3) - *Regina Yan*	The November 18, 2014 Board of Governors Meeting was the first opportunity for the Board to approve the new 2014 year fiscal year budget since a change of the fiscal year was approved by the Board in September 2013. The new fiscal year 2014 began on October 1, 2013. In the interim, PCORI had been operating under the previous fiscal year's budget, which was approved through December 31, 2013. The 2014 Budget, when approved, would be effective immediately. Future year budgets will be presented to the Board for approval prior to the beginning to the fiscal year.

		All of the PCORI subcommittees (FAAC, COEC, PDC, etc.) had reviewed their portion of the budget. Executive Director Selby stated a periodic review would be incorporated on a quarterly basis with the organizational dashboard, as well as a semi-annual financial report to the Board. In addition, if there are major changes to budget assumptions, mid- year modifications will be presented to the Board for approval. Board Member Goertz moved to approve the 2014 budget and Board Member Lipstein seconded. The organizational budget of $182.5 million for FY2014 was unanimously approved by the board. The Board also approved a research funding commitment of $1.28 billion over a 2 year period for 2014 and 2015.
12:15 – 1:15 PM	Lunch	
TAB 6 1:15 – 1:45 PM	Clinical Trials Advisory Panel Charter (Goal 1) Rare Disease Advisory Panel Charter (Goal 1) - *Bryan Luce*	PCORI Chief Science Officer, Bryan Luce, presented the charters for the Clinical Trials Advisory Panel (CTAP) and Rare Disease Advisory Panel (RDAP), which are both required in the authorizing legislation, for the Board's review and approval. The CTAP charter was discussed by the Board at its September 23rd 2013 meeting and the recommendation was made to have the charter reflect more explicitly that the CTAP work directly with the Methodology Committee. The charter was thus revised to address the Board comments, and then reviewed and approved by the Methodology Committee and Program Development Committee and accepted by the Board. Following a motion to approve the CTAP charter, which was seconded, the Board voted to approve the CTAP Charter. Dr. Luce also presented the charter for the Rare Disease Advisory Panel. He reviewed the steps PCORI took to develop the Charter, including hosting a Rare Disease Roundtable. Dr. Luce gave an overview of the requirements of the enabling law, which envisions a panel for each rare disease study. Dr. Luce explained that PCORI decided to go beyond the legislative requirement by having a standing, overarching advisory panel on rare disease, as well as having ad hoc panels tailored to specific rare disease studies. Discussion of the RDAP charter focused on the definition of 'rare disease' and that the panel should harmonize alternate definitions of rare disease (FDA,

		National Organization of Rare Diseases, etc). Following a motion to approve the RDAP charter, which was seconded, the Board voted to approve the RDAP Charter. Dr. Luce explained that the application process for both panels will open in the coming months, with the first meetings to take place in Spring 2014. Individuals and organizations are invited to self-nominate or nominate others in the community. PCORI will target specific groups and communities to ensure breadth and diversity of experience on the panel.
TAB 7 1:45 – 2:00 PM	Modifications to Decision Matrix - *Regina Yan*	Chief Operating Officer Yan presented modifications to the organizational decision matrix, specifically on the topic of the Rapid Response Fund. This modification would allow the Executive Director to approve spending in Procurement and Spending on Research and Other Program Activities for contracts up to and including $500,000 in consultation with the Chair and Vice-Chair. For contracts greater than $500,000, the approval rests on the Board Chair, Vice-Chair and Chair of FAAC. Board Member Barnett moved to accept the recommendation and that motion was second by Board Member Zwolak. The motion was unanimously approved.
TAB 8 2:00 – 3:00 PM	Methodology Report: Submission to Board Plan for Dissemination and Implementation - *Robin Newhouse, David Hickam,*	Robin Newhouse, Chair of the Methodology Committee, presented the revised Methodology Report to the Board for acceptance and the Dissemination and Implementation Plan for the Standards for Board discussion. Minor, editorial revisions to the Methodology Standards that had been approved by the Methodology Committee were also presented to the Board for adoption. Dr. Newhouse offered thanks to many who contributed to the revision of the document and reviewed the multiple steps taken to develop the Methodology Report, including the draft report presented to the Board and the public comment period in response to the draft Report (over 1,480 unique comments), which took place from July-September 2012, and led to substantial changes in the report, such as the creation and inclusion of stories and examples, which bring to light the impact of Methodology Standards. The Dissemination and Implementation Plan includes multiple, concurrent phases that outline the identification and development of tools and tactics to get the Report and Standards into the field. The plan also clearly identifies audiences and stakeholders, in

		order to leverage individual and professional relationships. Under development is a preliminary check list to demonstrate whether applications are in compliance with the standards. The Board discussed the Methodology Report and Dissemination and Implementation Plan including the importance of adherence to the Standards. Following a motion, which was seconded, the Board voted and approved the following motion: That the Board accepts the revised Methodology Report and adopts editorial revisions to the Methodology Standards as endorsed by the Methodology Committee.
3:00 – 3:30 PM	Public Comment	
3:30 PM	Wrap-up and Adjourn Meeting of the Board	Board Member Becker reminded the Board that a request will go out to declare their Conflict of Interest soon. Executive Director Joe Selby reminded the Board about the upcoming webinars.