Patient-Centered Outcomes Research Institute
Board of Governors Open Meeting Minutes

Eaglewood Conference Center
1401 Nordic Road
Itasca, IL 60143
May 6, 2013

Board Members Present:

Eugene Washington, MD, MSc, *Chair;* Steven Lipstein, MHA, *Vice Chair;* Kerry Barnett, JD; Lawrence Becker; Carolyn Clancy, MD; Leah Hole-Curry, JD; Allen Douma, MD; Arnold Epstein, MD; Christine Goertz, DC, PhD; Gail Hunt; Robert Jesse, MD, PhD; Harlan Krumholz, MD; Richard E. Kuntz, MD, MSc; Sharon Levine, MD; Grayson Norquist, MD, MSPH; Ellen Sigal, PhD; Harlan Weisman, MD; Robert Zwolak, MD, PhD
Via phone - Francis Collins, MD, PhD
Absent: Debra Barksdale, PhD, RN; Freda Lewis-Hall, MD

Methodology Committee Members Present:
Sherine Gabriel, MD, MSc, *Chair*; Robin Newhouse, PhD, RN, *Vice-Chair*; Naomi Aronson, PhD; Brian Mittman, PhD; Jean Slutsky, Mary Tinetti, MD; Sally Morton, PhD

Staff
Adaeze Akamigbo, PhD; Anne Beal, MD, MPH, *Deputy Executive Director and COE;* Chad Boult, MD, MPH; Kelton Chapman; Martin Duenas, MPA; Jordan Elliker; Rachael Fleurence, PhD; Desiree Frank; Lori Frank, PhD; Mark Freeman; Orlando Gonzales, MPA; Pamela Goodnow, CPA; Sean Grande; Annie Hammel; Romana Hasnain-Wynia, PhD; David Hickam, MD, MPH; Susan Hildebrandt, MA; Stanley Ip, MD; Bryan Luce, PhD, MBA, incoming *CSO*; Gregory Martin; Kara Odom-Walker, MD, MPH; Michele Orza, ScD; Suzanne Schrandt; Joe Selby, MD, MPH, *Executive Director*; Sue Sheridan, MBA; William Silberg; Christine Stencel; Regina Yan, Chief Operating Officer

Consultant: Richard Schmitz (Golin Harris)

Public Commenters:

Andrew Auerbach, UCSF School of Medicine
Regina Greer-Smith, Member of the PCORI Patient Engagement Advisory Panel
Mary Alice Lawless, Foundation for Health Smart Consumers

Board of Governors Open Meeting

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Agenda (Central Time)

MONDAY MAY 6	AGENDA ITEM OPEN MEETING	OUTCOME
7:00 – 8:00 AM	**Breakfast**	
8:00 – 8:09	**Welcome and Approval of February and March 2013 Board Minutes** - *Eugene Washington* The February and March 2013 meeting minutes were unanimously approved.	February 4 and March 12 and 26, 2013 board minutes approved.
8:09 – 8:57	**Executive Director's Report** - *Joe Selby* Dr. Selby updated the Board on recent progress in our research funding and in other areas, including engagement. He mentioned that, in response to questions from applicants, PCORI is examining funded applications for examples of how successful applicants presented their patient and stakeholder engagement so that we can share these examples with future applicants. Chair Washington, Vice Chair Lipstein, and Dr. Selby recognized departing Board Member Carolyn Clancy for her exemplary engagement, commitment, and participation. Dr. Selby introduced PCORI's new Chief Science Office Dr. Bryan Luce and new Chief Operating Officer Regina Yan.	
8:57 – 10:35	**Strategic Planning** - *Joe Selby* Dr. Selby presented the draft strategic plan, 2013 priorities, and plans for progress reporting to the Board. Staff continues to work on metrics and milestones and on developing a "Dashboard" the Board can use to monitor progress toward goals. Chair Washington said that the Board is going to want high level reporting on each of the strategic plan goals. Dr. Selby also discussed with the Board in detail two strategic issues: 1) the implementation of portfolio planning, management, and evaluation, and 2) the	The Board endorsed the strategic plan for finalization

	anticipated shift in the balance of PCORI's portfolio from broad to targeted funding.	
10:35 – 11:00 AM	**Break**	
11:00 – 12:17	**Targeted PFAs** - *Joe Selby, Chad Boult, Romana Hasnain-Wynia,* Chad Boult and Romana Hasnain-Wynia, reported to the Board on the recommendations from the work groups regarding targeted PFAs. Board approval was sought for two PFAs that have been endorsed by the Program Development Committee. PDC Chair Goertz voiced the committee's support of moving forward with both PFAs. Chair Washington emphasized that the PFAs were a result of a concerted effort to create more focused funding announcements. Following Board discussion, Chair Washington called for a vote on moving forward to develop the PFA related to falls prevention in the elderly. This PFA would provide up to $30 million for a large intervention trial and would be developed in partnership with the National Institute on Aging. Subsequent to Board discussion, Member Barnett moved and Member Hole-Curry seconded a motion to approve $17 million to spend on a PFA for severe asthma treatment options in African-Americans and Hispanics/Latinos.	Approved: the development of PFA related to falls prevention in the elderly. Votes: 17 in favor, 0 opposed, 1 abstention. Approved: PFA for severe asthma treatment options in African-Americans and Hispanics/Latinos. Votes: 17-0-0 (unanimous with one recusal)
12:17 – 1:11 PM	**Lunch**	
1:11 – 2:08	**Advisory Panels Update: Post Training & Kick-Off Amend Charters to allow for Co-Chair** - *Rachael Fleurence* Dr. Fleurence updated the Board on the advisory panels that met on April 19-20, 2013 in Alexandria, Virginia. Dr. Fleurence sought Board comments on the management and outcome of the panels as well as recommendations for future activities. A Member suggested that more of the landscaping work should go up prior to the prioritization process. Chair Washington urged the Board to weigh what it is giving up when it defines what the focus areas are through its landscapes up front before going out to a broader group. Dr. Selby agreed that the use and timing of landscape reviews to sharpen the focus of	Approved: amendment to advisory panel charters to allow for co-chairs. Votes: 17-0-0 (unanimous)

	the question will vary from one question to another. A question was raised about the role of the Board committees in relation to that of the advisory panels. Dr. Selby said that the Board and the PDC receive the recommendations of the Advisory Panels and then work with staff to determine what next steps are appropriate: a further landscape assessment, a systematic review, a multi-stakeholder working group, or possibly moving directly to a funding announcement. Dr. Fleurence presented an amendment to the advisory panel charters to allow the appointment of co-chairs on the advisory panels. Member Zwolak moved for approval of the amendment and Member Clancy seconded.	
2:08 – 2:36	**Active Portfolio Management** - *Joe Selby, David Hickam, Lori Frank* Dr. Frank and Dr. Hickam presented to the Board the staff's thinking on active portfolio management and the insights gained from work with the PCORI pilot project program. Internal staff discussions regarding portfolio management revolve around assessing and balancing risks and rewards of specific potential and funded projects. The staff was cautioned against excessive bureaucracy in the management of the portfolio which might reduce effectiveness. Staff will report on the progress at coming Board meetings.	
2:36 – 3:02	**Public Comment Period** Public comments were received from Mary Alice Lawless, Regina Greer-Smith, and Andrew Auerbach.	
3:02 – 4:03	**Methodology Committee's Recommended Actions** *Sherine Gabriel, Robin Newhouse, David Hickam* Methodology Committee chair Gabriel updated the Board on the activities of the Committee. For incorporating the standards as part of the application requirements, there was a necessary six-month lag between publication of the revised Methodology Committee standards and PCORI's ability to require adherence to them in the review process. This ensures that MC members are not advantaged by	

	prior knowledge of specific standards. Therefore, the application guidelines to be released in mid-May will include the requirement that applicants adhere to PCORI's methodology standards. There will be an active implementation plan proactively promote the methods. The plan will include training as well as periodic review and update of the standards.	
4:03 – 4:21 PM	**Break**	
4:21 – 5:19	**Proposed Awards December 2012 Cycle** - *Grayson Norquist, Martin Dueñas* Member Norquist presented an update on the Cycle II applications. Dr. Selby reported that the application and review process appeared to improve substantially from Cycle I to Cycle II, based on reports of review committee chairs. With time, applications should get better and receive higher funding scores. Staff is working to get reviewers back to review resubmitted applications, which will be received for the first time at the Cycle III review in mid-July. The most recent cycle of awards (Cycle II) was the first review at which elements of active portfolio management were part of the review process. That is, PCORI staff and the Board Selection Committee considered project fit with PCORI's priorities in addition to merit review scores. Chair Washington summarized the discussion on the PCORI approach to portfolio management: 1)Conduct an impact analysis by looking at the grant awards in order to understand whether or not PCORI is moving closer to its goals. 2) Proctively review our portfolio goals in selecting actual projects. 3) Active management of funded projects to ensure that PCORI is optimizing the return on the investment in those projects. The staff will develop a one-pager that defines PCORI's approach to active portfolio management. Member Norquist moved and Member Zwolak seconded a motion to accept the slate of applications for funding.	Approved: proposed slate of 51 awards . Votes 17-0-0 (unanimous)
5:19 – 5:36	**Institute Policies** - *Kerry Barnett, Regina Yan*	Approved: Updated decision matrix to

	Finance, Audit and Administrative Committee (FAAC) chair Barnett and Ms. Yan presented the effort to formalize some of PCORI's procedures to provide clear operational guidelines as well as to meet audit compliance requirements Member Zwolak moved and Member Kuntz seconded a motion to approve the updated decision matrix to reflect the new structure of the Office of the Executive Director. The vote was unanimous with 17 in favor, 0 opposed, and 0 abstentions. Chair Washington noted that the policies presented for the Board's approval were basically a formalization of how PCORI has already been operating. Vice Chair Lipstein moved and Member Douma seconded a motion to approve the Institute policies as reviewed by the legal counsel and approved by the FAAC. The motion also included Member Zwolak's amendment to strike the language in the post-approval section that permitted an investigator to unilaterally deviate from the adopted PCORI methodological standards by simply informing the staff.	separate out the roles of Deputy Executive Director and COO. Votes: 17-0-0 (unanimous) Approved: Institute policies as reviewed by legal counsel and recommended by the FAAC as amended. Votes: 17-0-0 (unanimous)
5:36 – 5:45	**Wrap-up and Adjourn** - *Joe Selby, Eugene Washington* Dr. Selby briefly presented a list of next-steps: 1) Continue to develop metrics for the strategic plan. 2) Dashboards to be developed and tailored to individual audiences. 3) Charters to be developed for the clinical trials advisory panel and the rare disease advisory panel. 4) Continuing work on PCORI's evaluation plan that builds on the metrics. 5) Continue to develop the dissemination and implementation blueprint. 6) Build into the strategic plan a more refined pre-award portfolio management strategy. 7) Develop a strategic publication plan. 8) Consider carving out a piece of future Board meetings for brain storming good research ideas. 9) Enhance the landscape data collection before the prioritization process and standardize the requests. 10) Identify the boundary between useful	

	involvement of staff and being overly bureaucratic in the active portfolio management process. 11)Develop methods for monitoring the implementation metrics. 12)Work with the Methodology Committee to develop training and tools for merit review panelists. 13) Consider strategies for increasing pre-award support, such as applicants consultation with staff. 14) Consider setting aside funds for and/or influencing how PCORI scores applications that might be completed in less than three years. Chair Washington thanked all the participants for joining the meeting and extended his special appreciation to the Board and staff for their hard work and preparation.	