PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting via Teleconference / Webinar

Tuesday, February 24, 2015
12:00 p.m. – 2:00 p.m. ET

Board Members Present:
Kerry Barnett, JD, *Vice Chairperson;* Sharon Arnold, PhD (designee for Richard Kronick); Lawrence Becker; Francis Collins, MD, PhD; Allen Douma, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Gail Hunt; Robert Jesse, MD, PhD; Harlan Krumholz, MD; Richard Kuntz, MD, MSc; Sharon Levine, MD; Steve Lipstein, MHA; Barbara McNeil, MD, PhD; Harlan Weisman, MD; Robert Zwolak, MD, PhD

Board Members Absent:
Grayson Norquist, MD, MSPH, *Chairperson*; Debra Barksdale, PhD, RN; Alicia Fernandez, MD; Freda Lewis-Hall, MD; Ellen Sigal, PhD

MINUTES

Agenda Item	Related Minutes
Call to Order, Roll Call, and Welcome - *Kerry Barnett, JD, Vice Chairperson ar* - *Joe Selby, MD, MPH, Executive Director*	Given the absence of Dr. Grayson Norquist, Chairperson, Kerry Barnett, Vice Chairperson chaired the meeting and welcomed all to the meeting of the PCORI Board of Governors. Dr. Selby reviewed the agenda for today's meeting.
Consent Agenda: That the Board of Governors: - Approve minutes from the January 27, 2015 Board meeting - Approve the Committee nominations and Committee changes as recommended by the Governance Committee	Kerry Barnett reviewed the matters being presented to the Board for approval as consent agenda items and gave the opportunity to Board members to separately discuss any of the matters. No separate discussion was requested. The following motion was made and seconded: That the Board of Governors approve the proposed Consent Agenda Items as reflected below: – Approve minutes from the January 27, 2015 Board meeting – Approve the Committee nominations and Committee changes as recommended by the Governance Committee o Approve Committee Chairs, Vice Chairs, and Members as nominated by the Governance Committee *(as reflected in the attached document)* o Approve transfer of responsibilities of the Audit and Conflict of Interest Subcommittee of the Governance Committee to the Governance Committee effective at the conclusion of the FY 2014 audit o Sunset the Audit and Conflict of Interest Subcommittee effective at the conclusion of the FY 2014 audit

	Motion: Approve each of the Motions on the Consent Calendar, as reflected. *Approved by a majority vote of the Board by voice vote*
Consider for Acceptance: FY2014 Audit Report - *Larry Becker, BS, Chair, Audit and Conflict of Interest Sub-Committee,* - *Regina Yan, MA, Chief Operating Officer, Tom Sneeringer, Audit Partner and Client Service Coordinator, McGladrey*	Mr. Becker, Chair of the Audit and Conflict of Interest Sub-Committee (ACOI) summarized ACOI's oversight of the comparative FY 2014 and FY 2013 audit engagements and recommended the audit report for acceptance. Thomas Sneeringer, CPA and managing partner, McGladrey LLP, presented the FY2014 and FY 2013 financial highlights. Mr. Sneeringer explained that the audit was conducted on the records of two fiscal years ending September 30, 2014 and 2013, respectively, because PCORI elected a new fiscal year end in 2013 and management wanted to provide 12-month comparative financial statements for both years. McGladrey, LLP will issue an unmodified opinion on the financial statements as a whole. The following motion was made and seconded: **MOTION**: That the Board accept the Fiscal Year 2014 Audit Report. *Approved by a majority vote of the Board by voice vote.*
Consider for Approval: Slate of Spring 2014 Pragmatic Studies Awards - *Christine Goertz, DC, PhD, Bryan Luce, PhD, MBA, Chief Science Officer*	Christine Goertz, Chair of the Selection Committee, thanked investigators for their submission and interest, Board members and staff for their participation. Bryan Luce, Chief Science Officer, provided an overview of the processes used to arrive at recommendations for funding the Spring 2014 Pragmatic Clinical Studies slate of awards, along with a summary of the proposed slate, and how each application aligned with PCORI, IOM, and/or AHRQ priority topics. Of the 231 Letters of Intent submitted, 40 (17%) were invited to submit a full application. From there, 35 applications were submitted (88% of the invited). Luce reviewed each of the five proposed applications on the slate with a proposed total budget of $64,140,036. The five applications which were approved are titled as following: (1) Enabling a Paradigm Shift: A Preference-Tolerant RCT of Personalized vs. Annual Screening for Breast Cancer; (2) Early Supported Discharge for Improving Functional Outcomes After Stroke; (3) A Pragmatic Trial to Improve Colony Stimulating Factor Use in Cancer;

	(4) Pragmatic trial of more vs. less intensive strategies for active surveillance of patients with small pulmonary nodules; and, (5) Targeted interventions to Prevent Chronic Low Back Pain in High Risk Patients: A Multi-Site Pragmatic RCT. The following motion was made and seconded: **Motion:** Approve funding for the recommended slate of awards from the Spring 2014 Pragmatic Studies PFA. *Approved by a majority vote of the Board by roll call vote: 15 in favor; 0 opposed; Sharon Arnold, representing Richard Kronick of AHRQ, recused herself; Grayson Norquist and Debra Barksdale had announced their intention to recuse themselves prior to this meeting, but were not present for this vote.*
Consider for Adoption: PCORI's Process fo Peer Review of Primary Research and Release of Research Findings - *Joe Selby, Bill Silberg, Director of Communications*	Dr. Selby began this presentation by talking about the components and timeline for developing PCORI's Process for Peer Review of Primary Research and Release of Research Findings process and proposal and its relationship to PCORI's move towards open science. The Engagement, Dissemination, and Implementation Committee (EDIC) provided guidance on the development of the process during its face-to-face meeting on January 20th while considering the input from public comments, PCORI's Methodology Committee (MC) and the National Institutes of Health (NIH). American Institutes for Research (AIR) was contracted to analyze the public comments that were submitted about the proposed process. This analysis resulted in nine recommended revisions in addition to two other recommendations from PCORI's MC and the NIH. Discussions with NIH produced a number of clarifying editorial suggestions that PCORI staff agreed would be helpful to incorporate into the revised process document, including language defining what is meant by a study's "completion date" under FDAAA. Staff also agreed to a follow-up discussion with NIH on the document's reference to HSRProj, a web-based registry for methods projects. Bill Silberg indicated the revisions and reminded them that the Process adopted by the Board will be finalized and made publicly available. The Board made two suggestions to be addressed when finalizing the document regarding language to harmonize PCORI's process with FDAAA. The first was to use, where applicable, the FDAAA language verbatim to make it clear that they are in concordance. The second was a clarification that the Process document can be revisited in the future for improvements. **Motion:** Adopt the revised Proposed Process for Peer Review of Primar Research and Public Release of Research Findings

	Approved by a majority vote of the Board by a roll call vote: 16 in favor, 0 opposed.
Wrap up and Adjournment - Kerry Barnett	The meeting adjourned at 1:45 pm

Approved by the PCORI Board of Governors 3-24-2015

2014 PCORI Committee Rosters
Approved by the Board of Governors

Updated by Board November 18, 2014

Nominations and Recommended Committee Changes of the Governance Committee
For Consideration by PCORI Board at February 24, 2015 Meeting (via Teleconference)

- **Science Oversight Committee**
  - Christine Goertz, DC, PhD, Chair
  - Alicia Fernandez, MD
  - Leah Hole-Marshall, JD
  - Richard E. Kuntz, MD, MSc
  - Michael S. Lauer, MD
  - Barbara McNeil, MD, PhD
  - Ellen Sigal, PhD
  - Robert Zwolak, MD, PhD, Vice Chair *(name as Vice Chair of SOC)*
  - *Add: Steve Lipstein*
  - Robert Kaplan, PhD (Methodology Committee Member)

- **Engagement, Dissemination, and Implementation Committee**
  - Debra Barksdale, PhD, RN, Chair
  - Robert Jesse, MD, PhD, Vice Chair
  - Lawrence Becker
  - Allen Douma, MD
  - Gail Hunt
  - Richard Kronick, PhD
  - Sharon Levine, MD
  - Naomi Aronson, PhD (Methodology Committee Member)
  - Brian Mittman (Methodology Committee Member)

- **Research Transformation Committee**
  - Freda Lewis-Hall, MD, Chair
  - ~~Kerry Barnett, JD~~ *(Kerry Barnett leaves RTC given new role as Vice Chairperson of the Board)*
  - Francis Collins, MD, PhD
  - Allen Douma, MD
  - Gail Hunt
  - Harlan Krumholz, MD
  - Harlan Weisman, MD
  - Steven Goodman, MD, MHS, PhD (Methodology Committee Member)
  - Clyde Yancy, MD, MSc (Methodology Committee Member)

- **Finance and Administration Committee**
  - Kerry Barnett, JD, ~~Chair~~ *(Kerry Barnett stays on FAC as a member, but leaves role as Chair of FAC)*

- Larry Becker, Chair (Name as Chair of FAC)
- Alicia Fernandez, MD
- Bob Zwolak, MD, PhD

Governance Committee (*Transfer responsibilities of Audit and Conflict of Interest Subcommittee to Governance Committee upon conclusion of FY 2014 audit)*

- ~~Steve Lipstein, MHA, Chair (Vice Chairperson of the Board)~~ *(Steve Lipstein leaves GC as Chair and Member)*
- *Kerry Barnett, JD, Chair (Vice Chairperson of the Board). Designated to serve as GC Chair by Gray Norquist, Board Chairperson.[1]*
- Grayson Norquist, MD, MSPH (Chairperson of the Board)
- Allen Douma, MD
- Sharon Levine, MD
- Robin Newhouse, PhD, RN (Methodology Committee Member)

- ~~**Audit and Conflict of Interest Sub-Committee of the Governance Committee**~~ *(Sunset A/COI Sub-committee due to realignment of responsibilities and members) (Responsibilities transferred to Governance Committee;*
  - ~~Larry Becker, Chair~~
  - ~~Robert Zwolak, MD, PhD, Vice Chair~~
  - ~~Kerry Barnett, JD~~

- **Executive Evaluation and Compensation Sub-Committee** (All ex-officio members)[2]
  - Steve Lipstein, MHA, Chair (*Steve Lipstein will continue to serve as EECSC Chair due to designation by Gray Norquist, Board Chairperson).*
  - Grayson Norquist, MD, MSPH *(continues as Chairperson of Board)*
  - Larry Becker *(continues, but in his new status as Chair of the FAC)*
  - Kerry Barnett, JD *(continues, but in his new status as Board Vice Chairperson)*

[1] PCORI's Bylaws state that the Governance Committee must have the Board Chairperson and Vice Chairperson of the Board, up to 3 other members of the Board, and one Methodology Committee member. Chairs of the FAC, the Strategy Committees, and the A/COI Subcommittee are not eligible to be on the Governance Committee. The Bylaws also provide that the Chair of the Governance Committee is the Board Chairperson, or his/her designee from among the Board Vice Chairperson and current Board members who have previously served as either the Board Chairperson or Board Vice-Chairperson.

[2] PCORI's Bylaws state that the EECSC is composed of the Board Chairperson, Board Vice Chairperson, Chair of the FAC, and the Chair of the ACOI Sub-Committee. The Bylaws also provide that the Chair of the EECSC is the Board Chairperson or his/her designee from among the Board Vice Chairperson and current Board members who have previously served as either the Board Chairperson or Board. If the Board Chairperson names someone who previously served as the Board Chairperson or Vice Chairperson to serve as Chair of the EECSC, that person serves on the EECSC as well.