



Patient-Centered Outcomes Research Institute

Board of Governors Meeting via Teleconference / Webinar

Tuesday, March 25, 2014

12:00 p.m. – 1:00 p.m. ET

MINUTES

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 (*Michael Lauer*); Allen Douma, MD; Arnold Epstein, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; 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; Robert Zwolak, MD, PhD

Board Members Absent:

Alicia Fernandez, MD; Harlan Weisman, MD

Time	Agenda Item	Results
12:00-12:03	Call to Order, Roll Call, and Welcome <i>Grayson Norquist</i> , Board Chair, and <i>Joe Selby</i> , Executive Director	Grayson Norquist called the meeting to order and a roll call of the Board was conducted. Joe Selby presented an overview of the agenda.
12:03-12:10	Consider for Approval: February 25, 2014 Board Meeting (via Teleconference/Webinar Minutes and Withdrawal of Outdated Committee Charters <i>Grayson Norquist</i>	The following motion was made and seconded: That the Board of Governors approve the minutes of the February 25, 2014 meeting <i>Vote: Approved by a majority vote of the Board by voice vote</i> Grayson Norquist explained that the Board's approval of revised and new charters for committees to implement the governance transition at its February 25, 2014 rendered several existing committees and charters outdated. To further implement the governance transition, several committees should be sunset and their charters withdrawn. The following motion was made and seconded: That the Board of Governors approve the sunset of the following committees and the withdrawal of their charters: • Communications, Outreach, and Engagement Committee (COEC) • Program Development Committee (PDC) • Nominating Committee • Standing Committee on Conflict of Interest (SCCOI)

		<i>Vote: Approved by a majority vote of the Board by voice vote</i>
12:10-12:15	Revisions to Research Transformation Committee Charter Approved 2/25/14	Chairperson Freda Lewis-Hall requested that this item be withdrawn from the agenda for this meeting and postponed pending further discussion with the Chairs of the other strategy committees. There were no objections from the Board.
12:15-12:25	Revised Institutional Policies: Whistleblower Policy Record Retention Policy	Chief Operating Officer Regina Yan presented proposed revisions to both the current Whistleblower Policy and Record Retention Policy Primary proposed revisions to the whistleblower Policy included the incorporation of the General Counsel's role as well as refining a few procedures and definitions. The primary proposed revisions to Record Retention Policy included updating timeframes to reflect current best practices and adding differentiation between records for funded and unfunded projects. The Board asked several questions about the proposed revised Record Retention Policy and suggested further clarifications were needed. The following motion was made and seconded: That the Board of Governors approve the revised Whistleblower Policy. <i>Vote: Approved by a unanimous vote of the Board by roll call vote</i> The following motion was made and seconded: That the Board of Governors table the consideration of approval of the proposed revised Record Retention Policy until further clarifications are complete. <i>Vote: Approved by a majority vote of the Board by voice vote</i>
12:25-12:55	New Advisory Panel Slates: - Advisory Panel on Clinical Trials - Advisory Panel on Rare Disease	Joe Selby gave an overview of PCORI's two new Advisory Panels, the Advisory Panel on Clinical Trials and the Advisory Panel on Rare Disease, by briefly reviewing the process for establishing the panels and seeking members, including addressing background, legislation, charters, number of applications received, and timeline. He also gave clarification about the role of potential future "sub-panels" and the role of the proposed alternates.

		The Board discussed the benefits of having a FDA representative on the Advisory Panel on Rare Disease. Joe Selby advised that the charter indicates that the panel may invite outside experts (which would include FDA representatives) to a panel meeting and that in the future, PCORI can consider whether to propose to add a FDA representative as a formal member. The following motion was made and seconded: That the Board approve the slate of members for the Advisory Panel on Clinical Trials <i>Vote: Approved unanimously by the Board by roll call vote</i> The following motion was made and seconded: That the Board approve the slate of members for the Advisory Panel on Rare Disease <i>Vote: Approved unanimously by the Board by roll call vote</i>
12:55-1:00	Wrap up and Adjournment	Grayson Norquist

Approved by the PCORI Board of Governors 4/22/2014