PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Patient-Centered Outcomes Research Institute

Board of Governors Meeting via Teleconference / Webinar

Tuesday, August 26, 2014
12:00 p.m. – 1:30 p.m. ET

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

Board Members Absent:
Kerry Barnett, JD; Richard Kronick, PhD; Richard Kuntz, MD, MSc

MINUTES

Agenda Item	RELATED MINUTES
Call to Order, Roll Call, and Welcome *Steve Lipstein,* Board Vice-Chair, and *Joe Selby,* Executive Director	Steve Lipstein called the meeting to order and a roll call of the Board was conducted. Dr. Selby presented an overview of the agenda. The following motion was made and seconded. **Motion:** Approve the July 29, 2014 Board Meeting Minutes *Approved by a majority vote of the Board by voice vote.*
Consider for Approval: Posting for Public Comment of PCORI's Proposal for Peer Review and Release of Primary Research Findings *Joe Selby,* Executive Director	Executive Director Joe Selby provided an overview of PCORI's proposed process for peer review of primary research and making research findings publicly available as required by PCORI's authorizing legislation. The Board was to vote to approve the document for posting for public comment. The Board discussed the proposal and Dr. Selby brought to the Board's attention some initial comments provided by Board member Francis Collins, Director of the National Institutes of Health, particularly relating to the Food and Drug Administration Amendments Act (FDAAA) and timing of the final report. It was agreed that PCORI staff would consider these issues and the document would be presented at the next Board meeting for consideration of approval for posting for public comment. *Agenda Item was carried over to the next meeting.*
Consider for Approval: Revised PCORnet Coordinating Center Budget	Rachael Fleurence, Program Director for Methods and Infrastructure, provided background on the need for the PCORnet Coordinating Center's supplemental budget request. Due to increased scope of work, the Coordinating Center was invited to submit a supplemental budget

Rachael Fleurence, Program Director, CER Methods and Infrastructure Program	request for their two-year contract ending in October 2015. The total amount, $1.9 Million, was presented along with specific line items. Board members expressed strong support for evaluation to make sure the necessary deliverables and performance quality are met. The following motion was made and seconded. Motion: Approve the PCORnet Coordinating Center Supplemental Budget Request *Approved by majority vote of the Board by roll call vote: 14 in favor; 0 opposed, 2 recused themselves (Dr. Epstein, Dr. Lewis-Hall. 2 members present for the meeting did not participate in the vote (Dr. Douma, Dr. Levine)*

Review and Discuss Draft Open Science Framework
 	
Steve Goodman, Methodology Committee Vice Chair and Research Transformation Committee (RTC) Member, and
 	
Harlan Krumholz, Board and RTC Member
	On behalf of the Open Science Work Group, Steve Goodman and Harlan Krumholz provided the Board with an informational update on the group's progress in developing a comprehensive proposal to address open science for PCORI. The group feels that PCORI is in a position to have a major impact in this fast moving area. There is also significant work underway to investigate and understand the variety of operational and technical details involved**.**
	
	Goodman presented the main components of the proposed framework, some of which are also included in the proposed Process for Peer-Review of Primary Research and Making Research Findings Publicly Available. The other elements of the proposed framework include posting of the initial and final study protocols and preparing the study data and meta data for possible reproduction and data sharing requests. The work group recommended that PCORI require awardees to prepare for data reproduction and sharing and also discussed platforms that could potentially host data and metadata. The group will also take into consideration the recommendations and findings of the IOM report on Strategies for Responsible Sharing of Clinical Trial Data, which is expected to be released in December 2014.
	Board members raised questions and concerns related to the presentation, including:
	• What will the resource implications be for PCORI relating to the proposal? What are the resource implications for awardees being asked to prepare their work for possible reproduction and sharing?
	    o If awardees are asked to prepare their data throughout the course of the project, rather than retrospectively, this should drive down the costs significantly.
	• What fraction of PCORI awards would the group anticipate would be reproduced?
	    o The decision about which studies to reproduce is a question involving not only the proportion of studies but also which studies should be selected. The work

	group anticipates something in the range of 10% of high profile studies would be a reasonable guess. • How does this work fit into our strategic priorities and outcomes? o The work group encourages the Board to consider not only the ROI on the cost of preparing the data for sharing, but also on actually having the data sets available for public use.
Wrap up and Adjournment *Grayson Norquist*	The meeting adjourned at 1:27 pm.

Approved by the PCORI Board of Governors 09-15-2014