



Board of Governors Meeting via Teleconference / Webinar

Tuesday, August 18, 2015

12:00 pm – 1:30 pm ET

Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Kerry Barnett, JD, *Vice Chairperson*; Debra Barksdale, PhD, RN; Lawrence Becker; Francis Collins, MD, PhD (Michael Lauer, MD, Francis Collins' designee was also present); Allen Douma, MD; Christine Goertz, DC, PhD; Harlan Krumholz, MD, SM; Leah Hole-Marshall, JD; Gail Hunt; Robert Jesse, MD, PhD; Robert Kaplan, PhD (participating in the meeting as designee for Richard Kronick, PhD); Richard Kuntz, MD, MSc; Sharon Levine, MD; Steve Lipstein, MHA; Barbara McNeil, MD, PhD; Ellen Sigal, PhD; Harlan Weisman, MD; Robert Zwolak, MD, PhD

Board Members Absent:

Alicia Fernandez, MD; Freda Lewis-Hall, MD;

MINUTES

Agenda Item	Related Minutes
Call to Order, Roll Call, and Welcome - <i>Grayson Norquist, MD, MSPH, Chairperson and Joe Selby, MD, MPH, Executive Director</i>	Dr. Grayson Norquist chaired and opened the meeting, welcomed all to the meeting of the PCORI Board of Governors and read the Chair Statement on Conflict of Interest. Dr. Joe Selby reviewed the agenda for today's meeting.
Approval of the July 21, 2015 Board Meeting Minutes - <i>Grayson Norquist, MD, MSPH</i>	The following motion was made and seconded: Motion: Approve the July 21, 2015 Meeting Minutes. <i>Approved by a majority vote of the Board by voice vote (no opposed; no abstentions)</i>
Consider for Approval: Slate of PCORnet Obesity Demonstration Awards - <i>Joe Selby, MD, MPH and Rachael Fleurence, PhD, Program Director CER Methods & Infrastructure</i>	Dr. Rachael Fleurence presented an overview of the PCORnet Obesity Demonstration Project, including the topic and PFA development process, goals of the initiative (which include supporting research on important clinical questions as well as testing and evaluating the PCORnet infrastructure), and application review process. The proposed slate included two projects: 1. A study focusing on bariatric surgery comparing weight loss and regain across three bariatric surgical procedures; and 2. A study comparing the Short- and Long-term Effects of Antibiotics on Childhood Growth. The study aims and budgets were presented for both proposed projects on the slate (<i>See Attachment A</i>). Christine Goertz, Chair of the Selection Committee, indicated that the

	Selection Committee had considered the slate and recommended that the Board approve it. The Board also discussed PCORI's conflict of interest management relating to Board voting on slates of awards. Gray Norquist, Chairperson, indicated that the Governance Committee plans to consider a Guidance memorializing PCORI's COI management, will consider PCORI's historic approach, and other options. The following Motion was made and seconded: Approve funding for the recommended slate of awards for the PCORnet Obesity Observational Research Initiative PFA. <i>Approved by a majority vote of the Board by roll call vote: 16 in favor; 0 opposed; 0 abstentions; 2 recused themselves (Dr. Richard Kuntz and Dr. Barbara McNeil). Harlan Krumholz, though present for the meeting later, was not present for this vote.</i>
Consider for Approval: Slate of Winter 2015 Large Pragmatic Studies Awards - Christine Goertz, DC, PhD and Bryan Luce, PhD, MBA, Chief Science Officer	Dr. Christine Goertz, Chair of the Selection Committee, introduced Dr. Bryan Luce who provided an overview of the processes used to arrive at the recommended slate of awards for funding relating to the Winter 2015 Pragmatic Clinical Studies PFA, along with a summary of the proposed slate, and how each award on the slate aligned with PCORI, IOM, and/or AHRQ priority topics. Dr. Luce summarized the process that led to the recommended slate of awards. Of the 132 Letters of Intent submitted, 32 (24%) were invited to submit a full application. From there, 24 applications were reviewed (75% of the invited). Luce reviewed each of the four proposed applications on the slate which totaled a proposed budget of up to \$56,731,907. Dr. Luce also provided a summary of each recommended project, generally addressing the proposed research question, study design, outcomes, budget, engagement plan, and potential impact for each recommended project. The Board discussed the slate. The following Motion was made and seconded: Approve funding for the recommended slate of awards from the Winter 2015 Cycle Pragmatic Studies PFA (see Attachment A for slate of recommended awards). <i>Approved by a majority vote of the Board by roll call vote: 14 in favor; 0 opposed; 0 abstentions; 5 recused themselves (Dr. Debra Barksdale, Dr. Robert Jesse, Dr. Barbara McNeil, Dr. Harlan Weisman and Dr. Robert Zwolak)</i>

Consider for Approval:

Targeted PCORI Funding Announcements (PFAs) Development

- Christine Goertz, DC, PhD and Bryan Luce, PhD, MBA, Chief Science Officer

- ### 1) Treatment-Resistant Depression

- ## 2) Long-term Opioid Treatment for Chronic Pain

Christine Goertz, Chair of the Science Oversight Committee, explained that the SOC recommended that the Board approve 3 topics for development of targeted PFAs. She indicated that additional topics were likely to be recommended by the SOC soon. Dr. Luce outlined the process that PCORI uses to review and approve questions for targeted PFAs. Dr. Luce highlighted the 6 targeted PFA topics that have already been approved for development. He then went through the three proposed targeted PFA topics.

He introduced the first proposed targeted PFA by defining severe depression and treatment-resistant depression, the major impact of this illness, evidence gaps, and results from the multi-stakeholder workgroup. The recommendation included funding two to three studies to compare the effectiveness of augmentation strategies versus switching to other treatments for patients with treatment-resistant depression.

The following motion was made and seconded:

Approve development of a targeted PFA addressing Treatment-Resistant Depression for up to \$30M.

Approved by majority vote of the Board by roll call vote: 18 in favor; 0 opposed; 0 abstentions. Dr. Debra Barksdale was not present for this vote.

Dr. Luce explained that this proposed targeted PFA looks at the use of opioids as a treatment by patients who suffer chronic pain, which has significant harms and risks. He identified evidence gaps in treatment options and dosing strategies, misuse, and risk mitigation strategies, as well as results from the multi-stakeholder workgroup. The first recommended question for a targeted PFA compared the effectiveness and harms of continuing opioid therapy alone vs. opioid therapy plus non-opioid interventions (pharmacological and/or non-pharmacological) among patients on high-dose long-term opioid therapy. The second recommended question for a targeted PFA compared the effectiveness and harms of strategies used to limit dose escalation, among patients on moderate/low-dose long-term therapy. The Board discussion identified concerns regarding reducing dosage of high-dose opioids, the heterogeneous population, and perceived lack of evidence. Christian Goertz suggested that based on the concerns raised during the Board's discussion, this topic should be taken back to the SOC for further discussion. Thus, no motion was made for the Board to approve the development of a targeted PFA on this topic.

3) New Oral Anti-coagulants	For the last targeted PFA recommendation, Dr. Luce discussed the various uses of oral anticoagulants, impact of new oral anticoagulants, evidence gaps, and results from the multi-stakeholder workgroup. The recommendation included developing a targeted PFA to fund two to three studies to compare different strategies for extended anticoagulation treatment for patients who have completed a course of treatment after an initial episode of deep vein thrombosis or pulmonary embolism. The following motion was made and seconded: Approve development of a targeted PFA addressing New Oral Anticoagulants for up to \$30M. <i>Approved by majority vote of the Board by roll call vote: 18 in favor; 0 opposed; 0 abstentions. Dr. Debra Barksdale was not present for this vote.</i>
Annual Meeting Update - <i>Bill Silberg, Director of Communications</i>	Bill Silberg provided an update on the status of the PCORI Annual Meeting planned for this October 6-8, 2015. He indicated that all sessions are now posted on PCORI's Annual Meeting website. Board members were reminded if they have not registered yet to please do so. For any information or questions, contact Orlando Gonzales.
Wrap up and Adjournment - <i>Grayson Norquist, MD, MSPH</i>	The meeting adjourned at 1:29 pm

See Attachment A for **Slate of PCORnet Obesity Observational Research Initiative Awards**

Approved by the PCORI Board of Governors 09-28-2015



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Attachment A to the Minutes of the August 18, 2015 PCORI Board of Governors Meeting

**THE BOARD OF GOVERNORS OF
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE**
(Slates approved by the Board of Governors on August 18, 2015)

Slate of PCORnet Obesity Observational Research Initiative Awards

Project Title	Total Budget	Announced Budget
Bariatric Study	\$4,499,999	
Short- and Long-term Effects on Antibiotics on Childhood Growth	\$4,499,142	
Total (direct & indirect)	\$8,999,141	\$9,000,000

Slate of Awards for the Winter 2015 Pragmatic Studies

Project Title	Total Budget	Announced Budget
Comparing Outcomes of Drugs and Appendectomy (CODA)	\$12,911,011	
Integrated Versus Referral Care for Complex Psychiatric Disorders in Rural Federally Qualified Health Centers (FQHCs)	\$11,736,419	
Comparative Effectiveness of Pulmonary Embolism Prevention after Hip and Knee Replacement (PEPPER): Balancing Safety and Effectiveness	\$13,535,266	
Integrating Behavioral Health and Primary Care	\$18,509,211	
Total (direct & indirect)	\$56,691,907	\$90,000,000