

Board of Governors Meeting via Teleconference / Webinar

Tuesday, December 13, 2016

12:00 pm – 1:30 pm ET

Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Kerry Barnett, JD, *Vice Chairperson*; Debra Barksdale, PhD, RN; Larry Becker; Sharon Arnold, MD (acting as designee for Andy Bindman, MD; Michael Lauer, MD (acting as designee for Francis Collins, MD, PhD); Alicia Fernandez, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Russell Howerton, MD; Gail Hunt; Robert Jesse, MD, PhD; Harlan Krumholz, MD, SM; MHA; Sharon Levine, MD; Kathleen Troeger, MPH; Robert Zwolak, MD, PhD

Board Members Absent:

Allen Douma, MD; Richard Kuntz, MD, MSc; Freda Lewis-Hall, MD; Barbara McNeil, MD, PhD; Ellen Sigal, PhD

Minutes

Agenda Item	Related Minutes
Call to Order, Roll Call, and Welcome - <i>Gray Norquist, MD, MSPH, Chairperson</i> and <i>Joe Selby, MD, MPH, Executive Director</i>	Dr. 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.
Consent Agenda • Minutes of the October 31, 2016 Board Meeting • Committee Appointments - <i>Gray Norquist, MD, MSPH</i>	Dr. Norquist introduced the Consent Agenda which included approval of the October 31, 2016 meeting minutes and approval of the nominations for Committee appointments for Russell Howerton and Kathleen Troeger brought to the Board by the Governance Committee. Russell Howerton is nominated to serve on the Science Oversight Committee, and Kathleen Troeger is nominated to serve on the Research Transformation Committee. Dr. Norquist gave the opportunity to Board members to discuss any of the matters on the Consent Agenda. No separate discussion was requested. The following motion was made by Robert Zwolak and seconded by Kerry Barnett: Motion: Approve each of the motions on the Consent Agenda as reflected below: • Minutes of the October 31, 2016 Board Meeting and • Approval of the nomination of Russell Howerton to serve on the Science Oversight Committee (SOC) and Kathleen Troeger to serve on the Research Transformation Committee (RTC) <i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions)</i>

Consider for Approval: 2016 Cycle 1 Broad - Evelyn Whitlock, MD, MPH, Chief Science Officer	Dr. Goertz introduced the agenda item on the recommended slate of awards relating to the Cycle 1 2016 Broad PFAs. Dr. Whitlock summarized the process that led to the recommended slate of awards. Of the 233 Letters of Intent submitted, 93 (40%) were invited to submit full applications. Of these, 66 were submitted, deemed responsive, and proceeded to Merit Review (of which 29% were resubmissions). The Selection Committee recommended funding 17 of the submitted applications and 2 additional projects from Cycle 2 2015 for a proposed total commitment of \$42M in total costs (direct and indirect costs). Dr. Whitlock summarized the conditions and PCORI populations of interest reflected in the awards on the slates and reviewed the titles of the 19 proposed studies by National Priorities, which are listed in <i>Attachment A</i>. <i>The following motion was made by Robert Jesse and seconded by Larry Becker:</i> Motion: <i>Approve funding for the recommended slate of awards from the Cycle 1 2016 Broad PFA Awards</i> <i>Approved by a majority vote of the voting Board members by roll call vote (11 in favor; 0 opposed; 0 abstentions; 4 recusals: Debra Barksdale, Andy Bindman, Alicia Fernandez and Harlan Krumholz). Barbara McNeil had earlier indicated her intent to recuse, but was not present for this meeting.</i>
Consider for Approval: Policy Delegating to Science Oversight Committee (SOC) the authority to reopen Targeted PCORI Funding Announcements (PFAs) and Special Emphasis Topics - Evelyn Whitlock, MD, MPH	Dr. Whitlock presented the Policy on Reissuing Targeted PFAs and Special Emphasis Topics. (<i>See Attachment B</i>). She described the purpose of the policy is to set forth the circumstances under which the Board of Governors delegates to the Science Oversight Committee (SOC) the review and approval of requests from the PCORI Science Staff to either reissue a targeted PFA or approve the inclusion of Special Emphasis topics in Pragmatic Clinical Studies PFAs. The SOC may approve reissuance of a targeted PFA when the relevant targeted PFA has not used the maximum available Board-allocated funding due to insufficient number of meritorious and programmatically relevant applications. <i>The following motion was made by Russell Howerton and seconded by Kathleen Troeger:</i> Motion: <i>Approve the Policy Delegating to Science Oversight Committee (SOC) the authority to reopen Targeted PCORI Funding Announcements (PFAs) and Special Emphasis Topics</i>

	<i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions).</i>
Q4 Dashboard Review - Joe Selby, MD, MPH	Dr. Selby presented the end of FY-2016 Dashboard for the Board's review. The Dashboard demonstrated 4 green-flagged items (items that are on track) and 3 yellow-flagged items (items that are off target by more than 10%). The metric for Projects on Track is yellow in Q4, to acknowledge that not all projects are meeting 100% of recruitment milestones. He highlighted that we are now tracking the Draft Final Research Reports on the Dashboard. There were no red-flagged items (items that are off target and in need of attention or action by the Board). Dr. Selby presented an example of a PCORI-funded project with three published CER results that found that use of intravenous antibiotics is associated with higher rates of all-cause hospital revisits than oral antibiotics (Project PI: Ron Keren, Children's Hospital of Pennsylvania). To demonstrate how PCORI is influencing the way others are doing research, he highlighted that CMS Quality Measure Development Plan now recognizes PCORI's engagement framework as a best practice for partnering with patients. To demonstrate the impact of engagement in research, he highlighted the first Pipeline to Proposal project that was approved for a PCORI research project. Dr. Selby showed a cumulative look at funds committed to research projects over time, and demonstrated that PCORI is making progress on the strategic priority to increase the proportion of research funding going to focused and targeted topics. He discussed the number and total investment in Engagement awards. Dr. Selby highlighted proposed changes for the FY-2017 Dashboard, including a larger focus on CER results and uptake. He discussed the ways that uptake of study results will be tracked, including web statistics for posted abstracts, altmetrics to gauge attention, bibliometrics for citations, and uptake into clinical guidelines.
PCORI Funds Management Planning - Larry Becker	Larry Becker, Chair of the Finance and Administration Committee (FAC), informed the Board that over the past year the PCORI Executive staff, in consultation with the FAC has been working to develop a plan so that PCORI can efficiently and closely manage its funds to ensure its ability to meet its funding commitment obligations. This includes being able to draw down the entire PCORI portion of the PCOR Trust Fund as the funds are available in fiscal year 2017, and continuing to do so each year through the deposit of the last allotment of the Trust Fund in 2019.

	Mr. Becker stated that as PCORI’s research investments grow in size and number and continue to do so, this will enable PCORI to more efficiently and closely manage its financial commitments. All of the funds in PCORI’s portion of the PCOR Trust Fund are committed, thus PCORI believes it is appropriate and wise to drawn down the entire PCORI portion of the Trust Fund each year so that PCORI can meet its financial commitments. PCORI has discussed our funding commitment and our drawdown plans in routine communications with GAO, Department of Treasury and the Office of Management and Budget (OMB), and have consulted external expert legal counsel to ensure that PCORI’s drawdown of the Trust Fund funds to fulfill PCORI’s statutory mission and that PCORI’s receipt of passive interest on the funds are consistent with PCORI’s authorizing law and in compliance with D.C. nonprofit law. PCORI staff and the FAC are currently developing a funds management and investment policy, which will be brought to the Board in short order for approval. The Board will routinely be updated on funds management matters. Dr. Selby emphasized to the Board that all funds allocated to PCORI in the PCOR Trust Fund are committed to projects underway which have associated expenses. PCORI’s drawdown plans are intended to protect the funding and to address uncertainties around the long term viability of the PCOR Trust Fund. Gray Norquist, Board Chairperson, commended the work underway and asked whether any Board members had any questions or whether any Board members were opposed or abstained from supporting the plan. No Board member present voiced any opposition or any desire to abstain, and the FAC Chair was encouraged to move forward on this plan.
Annual Meeting Debrief - <i>Joe Selby, MD, MPH</i>	Joe Selby provided preliminary information summarizing the PCORI Annual Meeting, which took place November 17-19, 2016 at the Gaylord Hotel and Convention Center. Selby noted that there were 881 attendees (1,083 with staff), of which researchers, patients/caregivers, and clinicians were the top three represented stakeholder groups. There was additional significant participation via Twitter, with 6,500 tweets and a reach of over 12.3 million. One of the breakout sessions entitled “Smarter, More Appropriate Use of Antibiotics” was held as a Facebook Live event with 360 unique participants. Selby also highlighted the Board and Methodology Committee’s (MC) involvement in the planning of the meeting. This included the

	Engagement, Dissemination, and Implementation Committee's oversight and participation by Board and MC members on the Steering Committee. Numerous Board and MC members also served as moderators, discussants or panelists during the meeting. Board feedback included suggesting an expanded ability to have virtual participation and to increase the amount of time allotted for questions from the audience. Lastly, the Board suggested that, as next year's meeting will place greater emphasis on highlighting results from PCORI-funded research, background information might be shared with attendees in advance so they can come prepared to discuss findings with investigators, research teams, and partners.
Wrap up and Adjournment - <i>Grayson Norquist, MD, MSPH</i>	Meeting ended at 1:11 pm

Minutes were approved by the PCORI Board of Governors 01-10-2017

Additional Materials: Attachments A and B

Attachment A – Cycle 1 2016 Broad PFAs Slate of Awards Approved by the Board of Governors:

Program	Project Title
Addressing Disparities	Improving Outcomes for Low-Income Mothers with Depression: A Comparative Effectiveness Trial of Two Brief Interventions in the Patient-Centered Medical Home
	A Randomized Controlled Trial to Compare the Reach, Effectiveness and Maintenance of Two Family-based Childhood Obesity Treatment Programs in a Medically Underserved Region
	Comparative Effectiveness of Diabetes Prevention Programs
	Addressing Childhood Hearing Loss Disparities in an Alaska Native Population: A Community Randomized Trial
Assessment of Prevention, Diagnosis & Treatment Options	SETPOINT2: A Pragmatic Trial to Test the Effectiveness of Early vs. Delayed Percutaneous Tracheostomy in Patients with Severe Stroke and Respiratory Failure
	Acupressure Intervention to Reduce Treatment-related Symptoms in Children with Cancer
	A Stakeholder-driven Comparative Effectiveness Study of Treatments to Prevent Coronary Artery Damage in Patients with Resistant Kawasaki Disease
Communication and Dissemination Research	Smoker-to-Smoker Peer Marketing and Messaging to Disseminate Tobacco Interventions
	Integrating the Patient Voice into a Comparative Effectiveness Trial of Communication Strategies in the Management of Chronic Pain
Improving Healthcare Systems	Expanding Access to Home-based Palliative Care through Primary Care Medical Groups
	Ambulatory Cancer Care Electronic Symptom Self-Reporting (ACCESS) for Surgical Patients
	Improving Patient-Centered Communication in Primary Care: A Cluster Randomized Controlled Trial of the Comparative Effectiveness of Three Interventions
	Comparing Patient-Centered Outcomes for Adults and Children with Asthma in High-Deductible Health Plans with and without Preventive Drug Lists
Improving Methods for Conducting PCOR	Statistical Methods for Development, Validation and Implementation of Absolute Risk Models
	Development of Computational Methods for Evaluating Doctor-Patient Communication
	Privacy Preserving Interactive Record Linkage (PPIRL) via Information Suppression
	Improving Study Design and Reporting for States Choice Experiments
	Development of Reporting Guidelines for Psychometric Research on Patient Reported Outcome Measures
	How Well do Clinical Prediction Models (CPMs) Validate? A Large-Scale Evaluation of Cardiovascular Clinical Prediction Models

Attachment B – Policy on Reissuing Targeted PFAs and Special Emphasis Topics:

Patient-Centered Outcomes Research Institute
Policy on Reissuing Targeted PFAs and

Including Special Emphasis Topics in Pragmatic Clinical Studies PFAs

Approved by the SOC October 4, 2016

Presented for approval by the PCORI Board of Governors December 13, 2016

PCORI issues several types of PCORI Funding Announcements (PFAs), including Targeted PFAs and Pragmatic Clinical Studies PFAs. Targeted PFAs are issued to communicate funding opportunities in targeted research areas of interest, related funding allocations, applicable application and review processes and applicant resources. Pragmatic Clinical Studies PFAs are issued to communicate funding opportunities for the conduct of pragmatic clinical studies, related funding allocations, applicable application and review processes and applicant resources, which typically seek applications in multiple research areas of interest. This Policy sets forth the circumstances under which the Board of Governors delegates to the Science Oversight Committee (SOC) the review and approval of requests from the PCORI Science Staff to either reissue a targeted PFA or approve the inclusion of Special Emphasis topics in Pragmatic Clinical Studies PFAs.

As described in this Policy, the SOC may approve reissuance of a targeted PFA when the relevant targeted PFA has not used the maximum available Board-allocated funding due to insufficient number of meritorious and programmatically relevant applications. After final slates are approved by the Board of Governors relating to the original targeted PFA, staff will review outstanding research project applications that are under review. Research questions may be slightly modified in the targeted PFA based on staff review of the awarded applications. If no additional research projects are likely to be recommended to the Board for approval after the Board's initial slate approval, the staff will make a formal recommendation to the Science Oversight Committee to re-open the targeted PFA during the next open cycle.

Additionally, approval of the inclusion of Special Emphasis topics for a Pragmatic Clinical Studies PFA must be similarly reviewed and approved by the Science Oversight Committee with a related specific funding allotment and cycle assignment. Special Emphasis topics must align with specific criteria as outlined below.

The following criteria must be met in order for the SOC to approve the Special Emphasis topics:

- 1) **Criterion 1: Programmatic Priority.** Topic represents an area of emphasis for PCORI (e.g. a drug, device or procedure head-to-head comparison, a precision medicine intervention, or represents a unique funding niche for PCORI). Topic builds on previous investment or fills an important gap in the portfolio;
- 2) **Criterion 2: Significant Disease Burden.** Disease or condition represents a significant burden in the U.S. population in terms of prevalence, loss of productivity and/or individual suffering;

- 3) Criterion 3: Significant Cost. Topic addresses high-cost treatments or is a significant financial burden for the U.S. population; and
- 4) Criterion 4: Stakeholder Interest. Topic is of interest to multiple stakeholders and/or was noted as an urgent and timely research gap by multiple sources (e.g. IOM 100, AHRQ future research needs, etc.)

The Science Staff will prepare and present relevant briefing materials for the SOC to review and consider approving the reissuance of targeted PFAs and the inclusion of Special Emphasis Topics in PCS PFAs on an as needed basis throughout the cycles of funding.

Approved by the Board of Governors December 13, 2016