



Board of Governors Meeting via Teleconference / Webinar

Tuesday, April 26, 2016

12:00 pm – 1:30 pm ET

Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Sharon Arnold, PhD; Debra Barksdale, PhD, RN; Larry Becker; Francis Collins, MD, PhD; Allen Douma, MD; Alicia Fernandez, MD; Leah Hole-Marshall, JD; Gail Hunt; Harlan Krumholz, MD, SM; Freda Lewis-Hall, MD; Ellen Sigal, PhD; Harlan Weisman, MD

Board Members Absent:

Kerry Barnett, JD, *Vice Chairperson*; Christine Goertz, DC, PhD; Robert Jesse, MD, PhD; Richard Kuntz, MD, MSc; Sharon Levine, MD; Steve Lipstein, MHA; Barbara McNeil, MD, PhD; Robert Zwolak, MD, PhD

Minutes

Agenda Item	Related Minutes
Call to Order, Roll Call, and Welcome - Grayson Norquist, MD, MSPH, <i>Chairperson</i> and Joe Selby, MD, MPH, Executive Director	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.
Consent Agenda: • Minutes of the March 22, 2016 Board Meeting • Committee Assignments for Sharon Arnold • Revisions to Committee and Advisory Panel Charters - Grayson Norquist, MD, MSPH	Dr. Norquist introduced the Consent Agenda which included the March 22, 2016 Board meeting minutes, Committee Nominations, and Charter Revisions. The following motion was made by Allen Douma and seconded by Ellen Sigal: Motion: That the Board approve each of the following items on the Consent Agenda as follows: • Minutes from the March 22, 2016 Board Meeting; • Nomination by the Governance Committee of Sharon Arnold to serve on the Engagement, Dissemination and Implementation Committee (EDIC) and the Science and Oversight Committee (SOC); • Proposed amended Charters for the: - o Research Transformation Committee, - o Science Oversight Committee, - o Engagement, Dissemination and Implementation Committee, - o Methodology Committee, - o Advisory Panel on Assessment of Prevention, Diagnosis and Treatment Options, - o Advisory Panel on Addressing Disparities,

	- o Advisory Panel on Improving Healthcare Systems, - o Advisory Panel on Communication and Dissemination Research, and the - o Patient Engagement Advisory Panel. <i>Approved by a majority vote of the Board by voice vote (no opposed; no abstentions)</i>
Consider for Approval: 2015 Cycle 2 Broad - Evelyn Whitlock, MD, MPH, Chief Science Officer	Dr. Evelyn Whitlock introduced the agenda item on the recommended slate of awards relating to the Cycle 2 2015 Broad PFAs. She summarized the process that led to the recommended slate of awards. Of 369 Letters of Intent submitted, 184 (49%) were invited to submit full applications. Of these, 132 were submitted, deemed responsive, and proceeded to Merit Review (of which 34% were resubmissions). The Selection Committee recommended funding 21 of the submitted applications for a proposed total commitment of \$45M 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 21 proposed studies by National Priorities, which are listed in <i>Attachment A</i>. The following motion was made by Larry Becker and seconded by Leah Hole-Marshall. Motion: Approve funding for the recommended slate of awards from the 2015 Cycle 2 Broad PFAs <i>Approved by a majority of voting members of the Board by roll call: 9 in favor; 0 opposed; no abstentions; and 4 recusals (Debra Barksdale, Alicia Fernandez, Harlan Krumholz, and Freda Lewis-Hall). Prior to the meeting, Christine Goertz, Steve Lipstein, and Barbara McNeil announced their intention to recuse, but were not present at the meeting.</i>
Plan for Application Enhancement Effort - Evelyn Whitlock, MD, MPH; Jean Slutsky, PA, MSPH, Chief Engagement and Dissemination Officer and Program Director for Communication and Dissemination Research and Regina Yan, MA, COO	Dr. Whitlock explained that this effort to improve PCORI research applications started more than one year ago and has invited input from several internal and external workgroups. The three overarching principles from the workgroup/committee reports are to (1) ensure PCORI culture supports applicant success, (2) implement change management process, and (3) improve and increase communication with external stakeholders.

	A Steering Committee has been established with key PCORI staff from Science, Engagement, and Operations departments to develop implementation plans. They have identified immediate changes that can be implemented in the next cycle (to be posted in August 2016) and short-term changes that will be implemented in the following cycle (to be posted in February 2017), as well as long-term changes for future cycles. Staff is focusing on improving applicant experience, along with other initiatives, which could improve the quality and quantity of applications and Letters of Intent (LOI) submissions. Staff updates the Science Oversight Committee (SOC) monthly on the progress of this effort and will periodically update the Board of Governors, including at the May in-person Board meeting.
PCORnet Investment - <i>Joe Selby, MD, MPH</i>	Dr. Selby presented on the PCORI investment in PCORnet, the National Patient-Centered Clinical Research Network. He presented a brief overview of the cumulative investment in PCORnet and then highlighted Phase I and II network (CDRN and PPRN) investments, which totals \$237M. He then focused on the Clinical Data Research Networks (CDRNs) Phase II investment based on the following categories: Data Development, Administrative Streamlining, Network Management, Research Readiness, Engagement, and Business Development. During the discussion he clarified that this presentation highlighted projected CDRN spending and not prior spending.
Engagement in PCORnet - <i>Sharon Terry, President and CEO, Genetic Alliance; Co-Principal Investigator of PCORnet Coordinating Center; Principal Investigator of the Community-Engaged Network for All (CENA) PPRN; and Chair of the PCORnet Engagement Committee</i>	Sharon Terry presented an overview of engagement activities within PCORnet. She presented an overview of current PCORnet Engagement Committee initiatives and priority topics, how to ensure engagement in research, and highlights from the March 28-29, 2016 “Building Trustworthiness in PCORnet” meeting attended by 166 in-person attendees and 357 webcast viewers. Key recommendations from the meeting to integrate engagement principles among research funders were presented to the Board. During the discussion, Board members spoke of the importance of PCORnet reflecting the PCORI core values of engagement and dissemination.
Re-release of the Clinical Management of Hepatitis C Infection Targeted PFA - <i>Joe Selby, MD, MPH</i>	Joe Selby presented an update on the targeted PFA for a Hepatitis C study discussed at the March 22, 2016 Board of Governors meeting. He explained that the anticipated PFA would address a randomized trial focused on patients without access to expensive Hepatitis C

Open Access Policy - Joe Selby, MD, MPH, Jean Slutsky, PA, MSPH	treatment and measures patient-reported outcomes over a one-year follow-up period. The original stakeholder meeting in October 2014, which informed the original targeted funding announcement, did not support this particular study design. Stakeholders have expressed concerns with using randomized trials to test active surveillance for Hepatitis C, saying it is a departure from the October 2014 meeting. PCORI has decided to reconvene the same patients and stakeholders from the October 2014 meeting to discuss concerns on this topic. The public Virtual Web Meeting will take place on May 18, 2016 from 1:00-3:00pm ET. The public may listen in to the discussion and send in questions and comments. Jean Slutsky summarized PCORI's new Open Access Policy, which aligns with similar policies adopted by many major funders. Under the Policy, awardees with published peer-reviewed articles resulting from PCORI-funded research must deposit a copy of their manuscript in PubMed Central at the time of journal acceptance. PubMed Central will make them available 6-12 months after publication, depending on the policies and timelines of specific publications. Upon awardee request, PCORI will pay Public Access fees for one article presenting the primary findings from their research project. Payment for additional articles will be considered on a case-by-case basis, with special consideration given to projects with particularly robust findings or multiple components involved. Payments generally will not exceed \$3,500 per research project for publication of articles. PCORI will pay journals directly.
Wrap up and Adjournment - Grayson Norquist, MD, MSPH	The meeting adjourned at 1:25 pm

Minutes were approved by the PCORI Board of Governors 05-23-2016

Additional Materials: Attachment A

Attachment A - Cycle 2 2015 Broad PFAs Slate of Awards Approved by the Board of Governors:

Program	Project Title
Addressing Disparities	Comparing the Effectiveness of Clinicians and Paraprofessionals to Reduce Disparities in Perinatal Depression
	Virtual Evidence-based Healthcare for Underserved Patients with Down Syndrome
Assessment of Prevention, Diagnosis, and Treatment Options	Continued Anticonvulsants after Resolution of Neonatal Seizures: a Patient-centered Comparative Effectiveness Study
	Comparative Effectiveness Analyses among Conservative Treatment Strategies For Ductal Carcinoma In Situ
	Multi-institutional Trial of Non-operative Management of Uncomplicated Pediatric Appendicitis
	Improving Care for Veterans with Post-Traumatic Stress Disorder (PTSD): Comparative Effectiveness of Medications to Augment First-line Pharmacotherapy
	Longitudinal Comparative Effectiveness of Bipolar Disorder Therapies
Communication and Dissemination Research	Resetting the Default: Improving Provider-patient Communication to Reduce Antibiotic Misuse
	Comparing Effectiveness of Self-management and Peer Support Communication Programs amongst Chronic Obstructive Pulmonary Disease Patients and their Family Caregivers
	Ostomy Telehealth for Cancer Survivors
Improving Healthcare Systems	Healing through Education, Advocacy and Law (HEAL) in Response to Violence
	Patient Osteoarthritis Careplan to Inform Optimal Treatment
	Comparing Interventions to Increase Colorectal Cancer Screening in Low-Income and Minority Patients
	Pragmatic Trial Comparing Telehealth Care and Optimized Clinic-Based Care for Uncontrolled High Blood Pressure
Improving Methods for Conducting PCOR	Development and Evaluation of a Patient-Centered Approach to Assess Quality of Care: Patient-Reported Outcomes-based Performance Measures (PRO-PMs)
	Engaging Patients and Caregivers Managing Rare Diseases to Improve the Methods of Clinical Guideline Development
	Learning within Health Care Delivery Systems: Design, Analysis, and Interpretation of Longitudinal Cluster Randomized Trials
	Design and Methodological Improvements for Patient-Centered Small n Sequential Multiple Assignment Randomized Trials (snSMARTs) in the Setting of Rare Diseases
	Governance of Learning Activities in Learning Healthcare Systems
	Improving Methods of Incorporating Racial/Ethnic Minority Patients' Treatment Preferences into Clinical Care
	Stratified Regression Models for Case-Only Studies