

**Board of Governors Meeting via Teleconference / Webinar**

Tuesday, March 22, 2016

12:00 pm – 1:30 pm ET**Board Members Present:**

Larry Becker; FAC Chair (serving as Acting Chairperson for Meeting); Sharon Arnold, PhD; Debra Barksdale, PhD, RN; Francis Collins, MD, PhD; Allen Douma, MD; Alicia Fernandez, MD; Leah Hole-Marshall, JD; Gail Hunt; Richard Kuntz, MD, MSc; Steve Lipstein, MHA; Barbara McNeil, MD, PhD; Harlan Weisman, MD; Robert Zwolak, MD, PhD

Board Members Absent:

Grayson Norquist, MD, MSPH, *Chairperson*; Kerry Barnett, JD, *Vice Chairperson*; Christine Goertz, DC, PhD; Robert Jesse, MD, PhD; Harlan Krumholz, MD, SM; Sharon Levine, MD; Freda Lewis-Hall, MD; Ellen Sigal, PhD

Minutes

Agenda Item	Related Minutes
Call to Order, Roll Call, and Welcome - <i>Larry Becker, Finance and Administration Committee (FAC) Chair (serving as Acting Chairperson for Meeting)</i>	Larry Becker 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. Sharon Arnold, PhD, Acting Director of the Agency for Healthcare Research & Quality, was welcomed to her first PCORI Board meeting. Mr. Becker thanked Dr. Richard Kronick, the former AHRQ Director, for his work for PCORI and wished him well in his future endeavors. On behalf of the Board, Mr. Becker welcomed Dr. Arnold to the Board.
Approval of the February 23, 2016 Board Meeting Minutes - <i>Larry Becker, FAC Chair</i>	The following motion was made by Leah Hole-Marshall and seconded by Robert Zwolak: Motion: Approve the minutes of the February 23, 2016 Board of Governors meeting. <i>Approved by a majority vote of the Board by voice vote (no opposed; no abstentions)</i>
Consider for Approval: PCORnet Patient-Powered Research Networks (PPRN) Demonstration Projects - <i>Joe Selby, MD, MPH, Executive Director</i>	Joe Selby presented the request for approval of the PCORnet Patient-Powered Research Networks (PPRN) Demonstration Projects. He presented a brief overview of the project development to fund PPRN-initiated research, the merit review criteria used to evaluate the submitted research applications, the application process, the slate summary and proposed collaborations to conduct each research project, and the contributions these projects will have to the PCORnet Commons. During the presentation, he addressed questions around the quality of applications compared to other research proposals, the projected sample sizes, and the study

	lengths. The recommended slate included 5 recommended research projects (<i>see Attachment A for the slate of recommended and awarded PPRN Demonstration Projects</i>), representing a proposed total budget of \$12.5M. It was noted that the Selection Committee supported this request to approve research project funding of the recommended slate. The following motion was made by Francis Collins and seconded by Sharon Arnold: Motion: Approve funding for the recommended slate of awards for the Patient-Powered Research Networks (PPRN) Demonstration Projects. <i>Approved by a majority vote of the Board by roll call vote: 9 in favor; 0 opposed; 0 abstentions; 5 recused (Debra Barksdale, Alicia Fernandez, Steven Lipstein, and Barbara McNeil; Christine Goertz was not present for the meeting but indicated earlier her intention to recuse herself from this discussion and vote if she had been present).</i>
Consider for Approval: Management of Chronic Low Back Pain Targeted PCORI Funding Announcement (PFA) - Robert Zwolak, MD, PhD, Chair, Science Oversight Committee - Evelyn Whitlock, MD, MPH, Chief Science Officer	Robert Zwolak, Science Oversight Committee Chair, introduced this topic and Evelyn Whitlock, Chief Science Officer provided the Board with background on the proposed funding announcement. She noted that PCORI organized multiple stakeholder efforts on this patient-centered topic of chronic low back pain since 2013, including consideration by multiple groups, such as a Workgroup, Task Force, Advisory Panel, multi-stakeholder workshop and webinar, and endorsement by the SOC. She also reviewed related currently PCORI-funded research projects. Low back pain (LBP) is a large contributor to disability-adjusted life years in the United States. This targeted PFA will address the research question: “What is the comparative effectiveness of lumbar fusion surgery vs. an optimized multi-disciplinary non-surgical treatment program for chronic LBP?” Dr. Whitlock reviewed other elements of the proposed research question, including the proposed population, interventions, outcomes, study design, setting, time, and proposed research commitment of 1-2 studies for up to \$22M in total costs. The following motion was made by Leah Hole-Marshall and seconded by Robert Zwolak: Motion: Approve \$22M (total costs) for the Management of Chronic Low Back Pain targeted PFA development

	<i>Approved by a majority vote of the Board by roll call vote: 13 in favor; 0 opposed; 0 abstentions.</i>
Review of Q1 FY-2016 Dashboard - Joe Selby, MD, MPH and Michele Orza, ScD, Senior Advisor	Dr. Selby presented the First Quarter Dashboard for the Board's review, which demonstrated no items that are off target (yellow) or in need of attention or action by the Board (red) and that the percentage of research projects categorized as on-target (green) has been increasing. He introduced new metrics for PCORnet: research projects underway in PCORnet and the number of networks engaged in research projects. He highlighted published results from two PCORI-funded research projects: a health plan initiative to mitigate chronic opioid therapy risks, and a trial aiming to reduce low-value test ordering in primary care. And he drew attention to a published study that exemplified the impact of the engagement of patients in research, and led to the design of a peer-driven intervention for treatment of sleep apnea.
Informational Item: Re-release of the Clinical Management of Hepatitis C Infection Targeted PFA - Robert Zwolak, MD, PhD	Robert Zwolak, the Science Oversight Committee Chair, gave an overview of the history of this agenda item. In December 2014, the Board approved the development of the Clinical Management of Hepatitis C Infection targeted PFA for a commitment of up to \$50M in total costs for up to four studies with a proposed maximum for any single study of \$20 million. In February 2015, the Hepatitis C targeted PFA was released. In September 2015, the Board awarded two projects under this PFA, awarding a total of \$29M. The Science Oversight Committee recently revised the remaining unfunded research questions and endorsed a re-release of this targeted PFA, for award of up to \$21M of the remaining funds allocated to this targeted PFA. Funding will be available for up to two large clinical comparative effectiveness studies to: 1) assess the short-term patient-centered outcomes relative to timing of treatment (e.g., quality of life, cognitive function, depression, satisfaction, fatigue); and 2) ascertain risk for disease progression in early disease patients who have no access to direct-acting antiviral (DAA) treatment. The proposed studies are to focus on the disproportionately disadvantaged patient populations.
Wrap up and Adjournment - Larry Becker, FAC Chair	The meeting adjourned at 1:20 pm



Attachment A to the Minutes of the March 22, 2016 PCORI Board of Governors Meeting

Recommended Slate of Awards for the PCORnet Patient-Powered Research Networks
Demonstration Projects

Project Title	Total Budget
Comparative effectiveness of specific carbohydrate and Mediterranean diets to induce remission in patients with Crohn's disease	\$2.50M
Resiliency Education to Reduce Depression Disparities	\$2.50M
Harnessing PCORnet to Study Comparative Effectiveness and Safety of Biologic Therapies	\$2.50M
Healthy Hearts Healthy Minds: A PPRN Demonstration Pragmatic Trial	\$2.50M
Monitoring and Peer Support to Improve Treatment Adherence and Outcomes in Patients with Overlap Chronic Obstructive Pulmonary Disease and Sleep Apnea via a Large PCORnet Collaboration	\$2.48M

**All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.*

Minutes were approved by the PCORI Board of Governors 04-26-2016