

Board of Governors Meeting via Teleconference / Webinar

Tuesday, March 21, 2017

12:00 pm – 1:30 pm ET

Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Kerry Barnett, JD, *Vice Chairperson*; Sharon Arnold, PhD; Debra Barksdale, PhD, RN; Larry Becker; Francis Collins, MD, PhD; Allen Douma, MD; Alicia Fernandez, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Gail Hunt; Freda Lewis-Hall, MD; Barbara McNeil, MD, PhD; Ellen Sigal, PhD; Kathleen Troeger, MPH; Robert Zwolak, MD, PhD

Board Members Absent:

Russell Howerton, MD; Robert Jesse, MD, PhD; Harlan Krumholz, MD, SM; Richard Kuntz, MD, MSc; Sharon Levine, MD;

MINUTES

Agenda Item	Related Minutes
Call to Order, Roll Call, and Welcome - Grayson Norquist, MD, MSPH, <i>Chairperson</i> and Joe Selby, MD, MPH, <i>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.
Consider for Approval Minutes of the February 28, 2017 Board Meeting - Grayson Norquist, MD, MSPH	<i>The following motion was made by Kerry Barnett and seconded by Freda Lewis-Hall</i> Motion: Approve the minutes of the February 28, 2017 Board of Governors meeting. <i>Approved by a majority vote of the Board by voice vote (no opposed; no abstentions)</i>
Consider for Approval: 2016 Cycle 2 PCS Slate - Christine Goertz, DC, PhD, <i>Chair, Selection Committee</i> and Evelyn Whitlock, MD, MPH, <i>Chief Science Officer</i>	Dr. Goertz introduced the agenda item on the recommended slate of awards relating to the Cycle 2 2016 Large Pragmatic Clinical Studies PFA. Dr. Whitlock summarized the process that led to the recommended slate of awards. Of 82 Letters of Intent submitted, 23 (28%) were invited to submit full applications. Of these, 15 applications were submitted. On February 7, 2017, the Selection Committee reviewed three applications and recommended to fund them for a proposed total commitment of \$33.3M out of the allotted \$90M. The project titles of the proposed applications are: A Simple Large Trial of Patient-Centered Care for Opioid Use Disorders in Federally Qualified Healthcare Centers and Specialty Care Settings

Additional 2015 Cycle 3 Methods Application	• Operative versus Non-Operative Treatment for Atraumatic Rotator Cuff Tears: A Multicenter Randomized Controlled Pragmatic Trial • Improving Transition from Acute to Post-Acute Care following Traumatic Brain Injury Dr. Whitlock summarized the conditions and PCORI populations of interest reflected in the awards on the slates and reviewed the titles of the 3 proposed studies. <i>The following motion was made by Larry Becker and seconded by Robert Zwolak.</i> Motion: Approve funding for the recommended slate of awards from the Cycle 2 2016 Large Pragmatic Clinical Studies PFA. <i>Approved by a majority vote of the voting Board members by roll call (13 in favor; 0 opposed; 0 abstentions and 2 recusals, Alicia Fernandez and Barbara McNeil)</i> The Board approved 7 projects for the Cycle 3, 2015 Improving Methods for Conducting PCOR Funding Slate during the Board of Governors meeting on July 19, 2016. The total award for the 7 projects was \$6.4M. Dr. Whitlock's explained that the Methods PFA is proposing to add one additional project from Cycle 3, 2015. This project (Realization of a standard of Care for Rare Disease Using Patient-Engaged Phenotyping) was first brought to the Selection Committee during the July 7 and 8, 2016 meeting as a Not To Fund exception application, and then again in the November 1, 2016 Selection Committee Meeting where it was Approved for Further Programmatic Review. The new proposed total award for the Cycle 3, 2015 Methods PFA, which includes the 7 projects already approved during the July 19, 2016 Board Meeting, is \$7.1M. <i>The following motion was made by Christine Goertz and seconded by Debra Barksdale.</i> Motion: Approve funding for the recommended additional award from the 2015 Cycle 3 Improving Methods for Conducting PCOR PFA. <i>Approved by a majority vote of the voting Board members by roll call (14 in favor; 0 opposed; 0 abstentions and 1 recusal, Barbara McNeil).</i>
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Consider for Approval:

Funding for PCORnet Sustainability

- Joe Selby, MD, MPH and Rachael Fleurence, PhD, Program Director, Research Infrastructure

Dr. Rachael Fleurence introduced the request for implementing the FY2017 funding commitment plan. She informed the Board that PCORI's goal is to provide infrastructure resources to develop a sustainable PCORnet by the end of Phase II. She also discussed how a workgroup was formed within PCORnet to implement the business plan, which recommended establishing a new entity to support the sustainability of PCORnet. The new entity incorporated in the District of Columbia under the name the People-Centered Research Foundation (the Foundation) on March 16, 2017 and is a nonprofit (501c3). The Foundation's goal is to advance and support PCORnet's legacy of Patient/People-Centered research.

Dr. Fleurence then discussed the implementation of the FY2017 funding commitment plan. This request was within the approved PCORnet FY2017 funding commitment plan and was endorsed by the Research Transformation Committee (RTC) on December 19, 2016. She described that the funds will be used to support PCORI's goal for a sustainable PCORnet through infrastructure funding to the Foundation. Funds will be awarded through a cost-reimbursable master contract with associated statements of work. The funding will support both the Program Office and the Data and Network Nodes. Initial statements of work will be for the program office for up to \$2.0 million and will cover areas such as governance, operations, the research portfolio, engagement, and the Data Network.

Following the presentation, discussion took place surrounding the fact that it would be the foundation hiring staff for the program office and not PCORI. Conversation also took place around the National Center for Advancing Translational Sciences (NCATS) Trial Innovations Network and how leaders from PCORI, PCORnet and NCATS have been working to make sure that PCORnet and NCATS share insights and resources. Finally it was discussed that the first new contract will be launched quickly, hopefully within 6 weeks, and the rest will be over the next 12 months with scopes of work and milestones. The Board expressed that it was thankful for all the work that has been put in over the last few months.

The following Motion was made by Larry Becker and seconded by Ellen Sigal:

Motion: Approve up to \$25.4 million to support the Foundation program office and infrastructure expansion over the next two-years, subject to negotiation of final terms and conditions.

Approved by a majority vote of the Board by roll call vote: 13 in favor; 0 opposed; 2 abstentions, Allen Douma and Kathleen Troeger; (Christine Goertz was not present for this vote)

Q1 Dashboard Review - <i>Joe Selby, MD, MPH</i>	Dr. Selby presented the Q1-2017 Dashboard for the Board's review. He highlighted that we are now showing budget for funds committed to research, rather than maximum amount available. The Dashboard demonstrated 4 green-flagged items (items that are on track) and 1 yellow-flagged items (items that are off target by more than 10%). The metric for Draft Final Research Reports turned in on time is yellow in Q1 because we were under the target of 90% turned in on time. There were no red-flagged items (items that are off-target and in need of attention or action by the Board). Dr. Selby presented results of PCORI-funded research study of shared decision making in the emergency department for evaluation of low risk chest pain. The study found that use of a decision aid increased patient knowledge about risk, increased engagement, and safely decreased the rate of admission to an observation unit for cardiac testing. Dr. Selby highlighted a recently-funded PCORI Dissemination and Implementation award that plans to scale up the implementation of venous thromboembolism (VTE) prevention education in hospitals. To demonstrate how PCORI is influencing the way others are doing research, Dr. Selby highlighted that Henry Ford Health System credits PCORI with serving as a model for patient engagement in research as they developed their Patient Engagement Research Center (PERC). Board members expressed interest in developing quarterly targets for journal publications resulting from PCORI-funded projects.
Wrap up and Adjournment - <i>Grayson Norquist, MD, MSPH</i>	Meeting ended at 1:27 pm

Minutes were approved by the PCORI Board of Governors 05-08-2017