

Board of Governors Meeting via Teleconference / Webinar

Tuesday, June 20, 2017

12:00 pm – 1:30 pm ET

Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Kerry Barnett, JD, *Vice Chairperson*; Debra Barksdale, PhD, RN; (Mike Lauer, MD (designee for Francis Collins, MD, PhD); Allen Douma, MD; Alicia Fernandez, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Russell Howerton, MD; Gail Hunt; Gopal Khanna, Harlan Krumholz, MD, SM; Richard Kuntz, MD, MSc; Sharon Levine, MD; Freda Lewis-Hall, MD; Barbara McNeil, MD, PhD; Ellen Sigal, PhD; Kathleen Troeger, MPH; Robert Zwolak, MD, PhD

Board Members Absent:

Larry Becker; Robert Jesse, MD, PhD

Minutes

Agenda Item	PCORI Speakers
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, introduced the new board member, Gopal Khanna, the recently appointed Director of the Agency for Healthcare Research and Quality, who replaced Andy Bindman, who resigned this post in January 2017. He then read the Chair Statement on Conflict of Interest.
Consider for Approval: Consent Agenda • Minutes of the May 8, 2017 Board Meeting • CTAP and RDAP Charter Revisions - Grayson Norquist, MD, MSPH	Dr. Norquist introduced the Consent Agenda which included the approval of the May 8, 2017 meeting minutes, and approval of the proposed amended Charter for the Advisory Panel on Clinical Trials (CTAP) as recommended by the Science Oversight Committee and Methodology Committee and the Charter of the Advisory Panel on Rare Disease (RDAP). The Charter for RDAP was reviewed by the Science Oversight Committee and was provided to the Board with no recommended revisions. 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 Harlan Krumholz and seconded by Kerry Barnett: That the Board approve: • Minutes from the May 8, 2017 Board meeting • Proposed amended Charter for the CTAP and Charter for RDAP Motion: Approve the Consent Agenda

	<i>Approved by a majority vote of the Board by voice vote (no opposed; no abstentions)</i>
Consider for Acceptance: PCORnet Research PFA - Joe Selby, MD, MPH	Dr. Selby introduced the proposal for an off-cycle 2017 limited-competition PCORI Research Funding Announcement (PFA) targeted to PCORnet Patient-Powered Research Networks (PPRNs). He informed the Board that this request was for a total of \$21.0 million and would come out of the \$37 million that had been approved by the Board for PCORnet Research in FY17. He then explained that the purpose of this research funding announcement is to answer important patient and stakeholder-driven clinical effectiveness research (CER) questions that fall within PCORI's national priority areas. The funding announcement emphasizes the necessity of funder collaborations and data linkages, which are key factors for PCORnet sustainability. Dr. Selby discussed how this is the next step in PCORI's strategy to achieve the Board's vision of a sustainable National research infrastructure that attracts a diverse set of public and private funders of research. The PFA is a limited-competition funding announcement where only PPRNs will be invited to submit Letters of Intent (LOIs). Applicants will be required to secure partner funding from industry and/or other organization collaborators prior to submitting full applications. Through this PFA, PCORI will fund up to 5 individual research projects over 3 years, with direct costs up to \$5 million per research project with total costs to PCORI for the initiative being \$21 million. Finally, Dr. Selby discussed the tentative timeline for the PFA. The full announcement will be released in July, while LOIs will be due in September, and applications will be due in December 2017. Following the presentation, discussion took place around the amount of funding that has been awarded to PPRNs and the number of awards. It was discussed that this PFA would, at most, only award research awards to up to 5 of 20 PPRNs. It was emphasized that PPRNs are also encouraged to apply for other PCORI PFAs for CER studies on their own and there have been several that have applied for PCORI awards through full competition broad and targeted PFAs. Conversation also took place surrounding the flexibility in the PFA and whether more flexibility would allow the PPRNs to be more innovative and continue to move towards "research done differently," which was the vision for PPRNs. Some concerns were raised from some Board members about requiring applicants to secure partner funding, including collaborating with industry funders, while other Board members encouraged this

	innovative funding plan to require partner funding. It was discussed that potential interested funders could include disease foundations as well as industry. Finally, the chairs of both the SOC and RTC expressed support of the development of the PFA and informed the Board that both committees had endorsed it. <i>The following motion was made by Kathleen Troeger and seconded by Robert Zwolak:</i> Motion: Approve the development of a limited PFA for collaborative research within PCORnet, not to exceed \$21 million in total costs <i>Approved by a majority vote of the voting Board members by roll call (18 in favor; 1 opposed (Harlan Krumholz); 0 abstentions and 0 recusals)</i>
Open Science Update - Parag Aggarwal, PhD	Dr. Aggarwal provided an update on the status of the draft Policy for Data Access and Data Sharing (the Policy) which is a component of PCORI's Open Science Initiative. The presentation included a description of the activities to-date that have helped inform the evolution of the draft Policy and a summary of key issues that had been discussed by the Research Transformation Committee. Board members noted additional considerations when crafting the Policy, including governance issues related to data user agreements; sequencing and timing of the release of data; soliciting input from additional stakeholder types; resolving issues related to other health system data like EHR and claims data. PCORI will continue work on the draft Policy, which will incorporate findings from the PCORI funded Pilot Data Sharing Initiative that is underway. The considerations noted by the Board will be incorporated during the finalization process.
Wrap up and Adjournment - Grayson Norquist, MD, MSPH	Meeting ended at 1:16 pm

Minutes were approved by the PCORI Board of Governors 07-18-2017