

Board of Governors Meeting via Teleconference / Webinar

Tuesday, February 26, 2019

12:00 pm - 1:30 pm ET

MINUTES

Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Christine Goertz, DC, PhD; *Vice Chairperson*; Kara Ayers, PhD; Larry Becker; Michael Lauer, MD (designee for Francis S. Collins, MD, PhD); Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Christopher Frieze, PhD, RN, AOCN, FAAN; Michael Herndon, DO; Russell Howerton, MD; Gail Hunt; Francis Chesley, Jr., MD (designee for Gopal Khanna, MBA); Sharon Levine, MD; Michelle McMurry-Heath, MD, PhD; Barbara McNeil, MD, PhD; Kathleen Troeger, MPH; Janet Woodcock, MD

Board Members Absent:

Trent Haywood, MD, JD; Freda Lewis-Hall, MD; Ellen Sigal, PhD; Robert Zwolak, MD, PhD

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 and read the Chair Statement on Conflict of Interest.
Consider for Approval: Minutes of the December 11, 2018 Board Meeting - Grayson Norquist, MD, MSPH	<i>The following motion was made by Larry Becker and seconded by Russell Howerton.</i> Motion: Approve the Minutes of the December 11, 2018 Board Meeting. <i>Approved by a majority vote of the Board by voice vote (no opposed, no abstentions)</i>
Consider for Acceptance: FY2018 Independent Financial Audit Report - Christine Goertz, DC, PhD, <i>Chair, Governance Committee</i> and Tom Sneeringer, CPA, <i>Partner, RSM US LLP</i>	Christine Goertz introduced this agenda item and reminded the Board that it is the responsibility of the Governance Committee to oversee PCORI's annual financial audit. She noted that the audit covered the 12-month period ending September 30, 2018, the preliminary field work was conducted September 26-28, 2018 and the on-site field work concluded November 30, 2018. The Governance Committee met several times with the RSM auditors throughout the audit to review its progress, each meeting accompanied by an executive session for direct communication. Goertz then introduced Tom Sneeringer, Senior Manager at RSM, who provided the overview of the FY2018 Independent Financial Audit. Sneeringer reported that PCORI received an unmodified or "clean" opinion, with no findings related to deficiencies or material weaknesses in internal controls over financial reporting and no

	findings related to non-compliance issues. Sneeringer noted that RSM auditors follow two sets of auditing standards for the PCORI audit: the industry standards from the American Institute of CPAs Audit Standards Board and the Government Auditing Standards. PCORI's audits are subject to review and submission to GAO. Sneeringer then reviewed PCORI's FY2018 statement of activities, including revenue, expenses, realized and unrealized loss on investments, and change in net assets, with a comparison to FY2017. He also reviewed PCORI's FY 2018 statement of financial position, including assets, liabilities and net assets compared to FY2017. He noted that PCORI's assets for FY2018 were \$1.15 billion, an increase of \$118 million over FY2017, due to excess of revenue over expenses in FY18. He stated that liabilities have remained consistent over the years. FY18 revenues increased by \$40 million due to an increase in PCOR fees, transfers from FHI and FSMI and \$9.8 million increase in interest income from investments in U.S. Treasury bills. Sneeringer further stated that PCORI's net assets (assets minus liabilities) as of September 30, 2018 were \$1.1 billion. Dr. Selby reminded the Board that PCORI has research contract commitments with associated expenses through FY2023 and the stated net assets are committed to cover those expenses. Sneeringer thanked the Governance Committee and PCORI management for their cooperation throughout the audit. Goertz asked whether any Board members had any questions. No discussion was requested. <i>The following motion was made by Kathleen Troeger and seconded by Michael Lauer.</i> Motion: Accept the FY2018 Independent Financial Audit Report <i>Approved by a majority vote of the voting Board members by roll call vote (16 in favor; 0 opposed; 0 abstentions); Alicia Fernandez was not present during this vote.</i>
Consider for Adoption: Request to Adopt New Methodology Standards - Robin Newhouse, PhD, RN, Chair, Methodology Committee	Dr. Robin Newhouse began her presentation by providing a brief background on the Methodology Committee (MC), its members, and PCORI's Methodology Standards. PCORI's Methodology Standards are required by PCORI's authorizing law and represent minimal standards for the design, conduct and reporting of comparative effectiveness research (CER) and patient-centered outcomes research (PCOR). These standards are developed by the MC and proposed to the Board for adoption after an opportunity for the public to comment.

The MC undertook a systematic process to draft, revise, and finalize eleven new Methodology Standards. The Board approved these standards for public comment on July 24, 2018 (60-day public comment period: July 24 – September 21, 2018). After this period, the MC reviewed the public comments and revised the standards, where appropriate. The MC approved a total of 11 standards across 3 new categories (Qualitative Methods (4 standards); Mixed Methods Research (3 standards); Individual Participant-Level Data Meta-Analysis (IPD-MA) (4 standards)) to be brought to the Board for adoption (as reflected in the motion considered by the Board below).

A question was asked about the potential applicant burden given that the total number of standards is now 65. Dr. Newhouse explained that the standards, required under PCORI's authorizing law, represent minimal and necessary requirements for sound science and that not every standard will apply to a particular study (e.g., many of the standards are specific to a particular study design). Dr. Newhouse noted that PCORI surveys have also shown that applicants and reviewers view the standards favorably. In response to a question, Dr. Newhouse clarified that the standards are used by both reviewers and PCORI staff to evaluate the quality of research applications and identify and address methodological concerns prior to awarding and executing contracts for research.

Motion: Adopt eleven new PCORI Methodology Standards:

- *Standards for Qualitative Methods*
 - **QM-1:** State the qualitative approach to research inquiry, design, and conduct.
 - **QM-2:** Select and justify appropriate qualitative methods sampling strategy.
 - **QM-3:** Link the qualitative data analysis, interpretations, and conclusions to the study question.
 - **QM-4:** Establish trustworthiness and credibility of qualitative research.
- *Standards for Mixed Methods Research*
 - **MM-1:** Specify how mixed methods are integrated across design, data sources, and/or data collection phases.
 - **MM-2:** Select and justify appropriate mixed methods sampling strategy.
 - **MM-3:** Integrate data analysis, data interpretation, and conclusions.
- *Standards for Individual Participant-Level Data Meta-Analysis (IPD-MA)*
 - **IPD-1:** Specify the research question(s) that will be addressed through the IPD-MA and describe the specific information it will provide that other approaches would not.

	○ IPD-2: Describe the proposed governance structure for the IPD-MA in the protocol and study reports. ○ IPD-3: Use systematic, reproducible methods to identify studies for inclusion in the IPD-MA. ○ IPD-4: Specify the design and planned analyses of the IPD-MA in a protocol, document any changes, and report significant amendments and modifications. <i>The following motion was made by Barbara McNeil and seconded by Larry Becker.</i> Motion: Adopt eleven new PCORI Methodology Standards. <i>Approved by a majority vote of the voting Board members by roll call vote (15 in favor; 1 opposed; 0 abstentions, 0 recusals); Alicia Fernandez was not present during this vote.</i>
Consider for Approval: Proposed Cycle 2 2018 Slate of Large Awards for the Limited Competition Dissemination and Implementation (D&I) PFA - Sharon Levine, MD, Chair, Engagement Dissemination and Implementation Committee (EDIC), and Jean Slutsky, PA, MSPH, Chief Engagement and Dissemination Officer	Dr. Sharon Levine briefly introduced the proposed slate of large D&I awards from the <i>Limited Competition Implementation of PCORI-Funded Patient-Centered Outcomes Research Results</i> PFA and noted the role of the EDIC in the funding approval process for D&I awards requesting budgets of \$500k or more. Levine then introduced Ms. Jean Slutsky to provide additional details about the PFA and to present the EDIC-recommended slate of D&I awards for Cycle 2 2018. Slutsky outlined the purpose of this funding initiative, the applicable merit review criteria, and provided an overview of the PFA review process. She reviewed the numbers of letters of intent submitted, of LOIs invited to submit a full application and of applications received and reported that the overall funding rate tied to the recommended slate is 25%. She then provided a brief description of the two projects on the proposed slate: • “Implementation of the IMPaCT Community Health Worker Intervention”; and, • “Implementing Peer-Driven Care for Patients with Sleep Apnea”. This slate of awards represents a total investment of approximately \$2.8M. <i>The following motion was made by Kara Ayers and seconded by Gail Hunt.</i> Motion: Approve funding for the recommended slate of awards from the Cycle 2 2018 Limited Competition Implementation of PCORI-Funded Patient-Centered Outcomes Research Results PFA. <i>Approved by a majority vote of the voting Board members by roll call vote (15 in favor; 0 opposed; 0 abstentions, 1 recusal: Sharon</i>

	<i>Levine); Trent Haywood indicated earlier his intention to recuse but was not present at this meeting.</i>
Consider for Approval: Reissue Partnerships to Conduct Research (PaCR) within PCORnet PFA - Joe Selby, MD, MPH	Dr. Joe Selby presented a proposal to reissue the Partnerships to Conduct Research within PCORnet (PaCR) funding announcement. The issuance of the original PaCR PCORI Funding Announcement (PFA) was originally approved by the Board on June 17, 2018 as part of Cycle 2 2017. The PaCR PFA was originally directed towards research projects of the Patient-Powered Research Networks (PPRNs) who were receiving PCORnet Phase II funding. There were four distinct requirements for the research projects that were funded under the original PaCR PFA including a requirement to develop external partnerships (with some level of co-funding), advance data integration, generate comparative clinical effectiveness research evidence, and leverage existing PCORnet resources. Ultimately, there were four research projects funded by PCORI from the original issuance of the PaCR PFA, which Dr. Selby summarized for the Board. Dr. Selby explained that the request being considered by the Board today is to approve reissuance of the PaCR PFA for a total of \$6 million for research funding with several distinct requirements. The request is within the Board-approved FY19 funding commitment plan for research conducted in PCORnet and was endorsed by the Research Transformation Committee (RTC) on January 17, 2019 and the Science Oversight Committee (SOC) on February 8, 2019. The reissued PaCR PFA will be directed towards research projects of the Clinical Research Networks (CRNs) and Health Plan Research Networks (HPRNs) that are continuing in PCORnet 2.0. Applicants will be required to comply with all PCORnet 2.0 study designation requirements and utilize all relevant PCORnet 2.0 governance structures, policies, and resources. Applicants will be required to secure a commitment of at least 50 percent of direct project funding from another funding source that has potential for a future partnership with the network. Potential research projects will be required to further the development of linkages between data from electronic health records/clinical data, registry data, sources that capture patient-reported outcomes data. PCORI will require non-competitive Letters of Intent (LOIs) from applicants to inform Merit Reviewer recruitment requirements. The applicants will also be required to submit a Letter of support from the PCORnet 2.0 Steering Committee with the LOI. PCORI will fund up to two individual research projects (expected to be up to a 3-year time frame), with direct costs up to \$4 million from PCORI and \$6 million in total costs from PCORI. After the presentation, there was a question to clarify whether any uncommitted infrastructure funds were being requested for the issuance of this PFA. Selby noted that this request is for \$6 million for research funding, not infrastructure funding. To ensure clarity

	about the amount and nature of the funding related to the reissuance of the PaCR PFA, the proposed motion was amended to clarify the total amount of funding (\$6M) and the nature of the funding (research, not infrastructure). There was also a question as to whether PCORI was placing too many stipulations on a small amount of research funds. Dr. Selby acknowledged that while there are certainly larger hurdles for this funding announcement, PCORI views these requirements as beneficial for PCORnet to improve capacity to conduct high quality research and enhance prospects for financial sustainability. <i>The following motion was made by Larry Becker and seconded by Barbara McNeil.</i> Motion: Reissue the Partnerships to Conduct Research (PaCR) within PCORnet PFA with a budget of up to \$6M in research funding. <i>Approved by a majority vote of the voting Board members by roll call vote (15 in favor; 0 opposed; 0 abstentions, 1 recusal, Jennifer DeVoe). Michael Lauer was not present during this vote</i>
Wrap up and Adjournment - Grayson Norquist, MD, MSPH	Meeting ended at 1:16 pm

Minutes were approved by the PCORI Board of Governors 03-19-2019