

Board of Governors Meeting via Teleconference/Webinar

Tuesday, May 25, 2021

12:45 pm - 4:30 pm ET

MINUTES

Board Members Present:

Christine Goertz, DC, PhD, *Chairperson*; Sharon Levine, MD, *Vice Chairperson*; Kara Ayers, PhD; Kate Berry; Tanisha Carino, PhD; Michael Lauer, MD (designee for Francis Collins, MD, PhD); Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Christopher Frieze, PhD, RN; Mike Herndon, DO; Connie Hwang, MD, MPH; Michelle McMurry-Heath, MD, PhD; Barbara McNeil, MD, PhD; Karin Rhodes (designee for David Meyers, MD); David Meyers, MD; Eboni Price-Haywood, MD, MPH; James Schuster, MD, MBA; Ellen Sigal, PhD; Kathleen Troeger, MPH; Danny van Leeuwen, MPH, RN; Robert Zwolak, MD, PhD

Methodology Committee Chair Present: Steve Goodman, MD, MHS, PhD

Board Members Absent: Russell Howerton, MD; James Huffman; Janet Woodcock, MD

Facilitator: Sonja Armbruster, MA

Agenda Item	Speakers
Welcome and Call to Order Consent Agenda: Consider for Approval: - Minutes of April 13, 2021 Board Meeting - Proposed Revised Supplemental Conflict of Interest Policy for PCORI Staff - Christine Goertz, DC, PhD, Board Chairperson	Dr. Goertz chaired and opened the meeting, welcomed all to the second day (May 25, 2021) of the two-day meeting of the PCORI Board of Governors, and read the Chair Statement on Conflict of Interest. She then reviewed the agenda for the meeting. Goertz then introduced the two items on the Consent Agenda and gave the opportunity to Board members to discuss any of the matters on the Consent Agenda. <i>The following motion was made by James Schuster and seconded by Sharon Levine.</i> Motion: That the Board approve: - Minutes from the April 13, 2021 PCORI Board Meeting - The proposed revised Supplemental Conflict of Interest Policy for PCORI Staff <i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions).</i>

Strategic Planning – Facilitated Discussions - <i>Sonja Armbruster, MA, Facilitator</i>	Ms. Armbruster led a facilitated discussion that addressed the opportunities created by the overlapping interests of the National Priorities, an operational Research Agenda, and what is needed to ensure progress on all the National Priorities. Armbruster reviewed the main themes that developed from the previous day’s discussion of the National Priorities by the Board. The themes included: ensuring that health equity is examined across the National Priorities but also remains as a distinct priority; generating strategic partnerships with traditional and non-traditional entities as well as multisectoral partners for engagement in PCOR; reaching locally through more community-based research projects; changing the culture of research and promoting trust in the research community; mindfulness surrounding the unintended consequences related to impact, outcomes, and implementation; and identifying and understanding PCORI’s unique role and potential contribution to each priority. She indicated that the draft National Priorities are intended to be aspirational long-term goals, and the Research Agenda will focus on more measurable strategies to achieve those goals. Based on the dynamic Board discussion that took place during the prior day’s discussion, Cook returned to the dialogue on the draft <i>Advancing a Learning Health System</i> National Priority. It was recognized that this area is relevant for PCORI’s unique role and mission, and that solely focusing on the ‘healthcare system’ could be limiting, and there is a need to further refine the boundaries and PCORI’s niche within this National Priority. Board members were given the opportunity to suggest areas for further refinement. Board members suggested that a visual component, such as a conceptual model, could inform what is encompassed in the priority. Furthermore, since PCORI is promoting learning health systems, Board members suggested that PCORI reflect the concept of learning and continuous improvement within its internal processes. Board members also suggested highlighting a feasible, high-risk, high-reward research question when the National Priorities are finalized to help promote PCORI’s research funding activities. There was some discussion about whether major disruptions in the existing health system to change existing practices would be necessary for PCORI to make progress on the National Priorities or if developing research questions that target specific weaknesses in the health system would suffice. For example, moving from a healthcare system to a system that cares for people may require shifts in existing practices like reimbursement policies to spur progress. Board members noted that PCORI would need to partner with and convene relevant entities for improvements in health to be accomplished given the large-scale nature of health. Board members confirmed that the
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	five draft National Priorities were appropriate to consider at the June Board meeting for approval for posting for public comment. In regard to a potential Research Agenda, Board members suggested examining primary incentives to care for patients with complex medical and social needs, effective primary care delivery across the United States, how to increase research participation among underserved populations, and identifying the needs of groups PCORI is looking to partner with in the future. Board members agreed that to advance the National Priorities, PCORI needs to utilize existing partnerships and build new partnerships with non-traditional and community-based entities. Board members also mentioned that this is the time for PCORI to take risks and promote the implementation of research findings.
Executive Director's Report - <i>Nakela L. Cook, MD, MPH, Executive Director</i>	Dr. Cook presented the FY2021 Midyear Dashboard for the Board's review (as of Q2-21). The Dashboard demonstrated 7 green-flagged metrics (those that are on track): Funds Committed, Research Project Performance, Posting of Results to PCORI.org, Final Research Reports Posted to PCORI.org, Uptake into Public/Patient Resources, Uptake into UpToDate®, and Other Examples of Uptake. There were no yellow-flagged metrics (those that are off target by more than 10%), and no red-flagged items (items that are off-target and in need of attention or action by the Board). Cook shared that the PCORI-funded ADAPTABLE trial, which was the first randomized trial to utilize PCORnet®, had published results in the <i>New England Journal of Medicine</i>. She also provided an example of a completed PCORI-funded AHRQ Systematic Review, from results to uptake of findings. The systematic review had results published in <i>JAMA Oncology</i> and <i>JAMA Network Open</i>. Findings were taken up by the American Society of Clinical Oncology into their 2021 Clinical Practice Guideline for Management of Dyspnea in Advanced Cancer. Cook shared an example of how PCORI and its engagement resources influenced the creation of a national Veteran Engagement Board. She provided an update on what PCORI has learned via project monitoring during COVID-19, including details on disruptions to ongoing studies. She shared that since this data was last collected for the Q3-20 Dashboard, about half as many research studies are experiencing pauses in study activity or are amid adaptations to their interventions. Cook highlighted six publications with high Altmetric scores, indicating attention in news articles, social media, blogs, and other sources. She also provided more details on a new metric on the Dashboard, uptake of CER results into public/patient-facing resources.

	Board members expressed interest in data on application resubmissions and the time it takes from application to award. They also expressed interest in continuing to monitor time in PCORI Peer Review. To further inform PCORI metrics for uptake of results into public/patient-facing resources, members suggested that we work with ambassadors, advisory panels, advisory committees and other resources. Cook provided an overview of her first year in her role as Executive Director, beginning with changes to Board membership, PCORI's first virtual Annual Meeting, and the 2020 GAO Review. She outlined the framework for what PCORI does and how PCORI works. To provide an update on advances made to support PCORI's Mission, she reviewed progress on Strategic Planning activities and updates to funding approaches. She recapped progress made on new areas introduced in PCORI's reauthorizing law, including two new research priority areas (Maternal Mortality and Intellectual and Developmental Disabilities), and developing principles for the consideration of the full range of outcomes data. Cook described PCORI's response to the COVID-19 pandemic, which also advanced PCORI's fast funding approaches. She recapped the 3-year Commitment Plan, and the expedited approach to PFA development while Strategic Planning is underway. To provide an update on PCORI's approach to collaboration and teamwork, Cook described progress made on PCORI culture, workforce, and workplace, and shared the framework for returning staff to the office. She outlined the PCORI organizational transformation effort, referred to as <i>PCORI Next</i>, and the high-priority recruitments underway. To provide an update on PCORI's Diversity, Equity, and Inclusion (DEI) Initiative, Cook referred the Board to PCORI's strategy for DEI. To start, Cook discussed the impetus for this type of initiative by providing information from seminal reports that highlighted concepts like health equity and quality of care. She also amplified the notion that 30 years past these reports we are still grappling with some of those same issues of health equity as evident from recent experiences with COVID-19. Cook continued by re-articulating PCORI's commitment to DEI and how it is critical to our mission both internally (focusing on the workforce) and externally (focusing on how we fund). Additionally, Cook discussed that PCORI is not immune to any of these challenges but that we are motivated to change the scope
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	by committing to three main goals of our DEI Strategy: Learn, Expand, and Engage, which also correlate to the three pillars of PCORI as an Organization, PCORI as a Funder, and PCORI as a Partner. To further articulate our strategy, Cook shared corresponding initiatives and activities to each one of these pillars and articulated that our ultimate goal is to deliver on PCORI's mission, but recognize that we cannot do so without incorporating diversity, equity and inclusion.
Consider for Acceptance: - PCORI Methodology Report revised to incorporate new previously-adopted PCORI Methodology Standards - <i>Steve Goodman, MD, MHS, PhD, Chair, Methodology Committee</i>	Dr. Goodman provided introductory remarks and gave a brief overview of background information: in 2019, the Board adopted QM, MM, IPD-MA methodology standards, as well as accepted the Methodology Report prepared at that time. However, the Board did not vote on the explanatory text for the standards, which elaborates motivation and intent for these standards. In addition, the explanatory text addresses the public comments on these Methodology Standards received by PCORI. These additions are included in the updated Methodology Report being considered for acceptance by the Board today. Goodman also highlighted the other updates to the Report: the suggestion that applicants can use either SPIRIT or NIH drafting tools for drafting research protocols, and updates about Methodology Committee membership and reauthorization language. Dr. Goertz thanked the Methodology Committee and called for Board members to offer comment. A Board member stated that he would be interested in information about gaps in evidence outside of scientific literature to incorporate the questions and concerns of the patients and caregivers who are not also researchers. <i>The following motion was made by Barbara McNeil and seconded by Danny van Leeuwen.</i> Motion: Accept the Updated PCORI Methodology Report. <i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions). Connie Hwang, Mike Lauer, and Michelle McMurray-Heath were not present during this vote.</i>
Consider for Approval: Funding for Partnership with AHRQ for Conduct of Systematic Reviews	Dr. Cook discussed PCORI's mandate to conduct systematic reviews and PCORI's long-standing partnership with AHRQ as a primary means to meet this mandate. She summarized the history of the PCORI-AHRQ program, including providing information about the range of topics, addressed updates of existing AHRQ

- <i>Nakela L. Cook, MD, MPH</i>	systematic reviews, and a pilot process to support nominations from clinical guideline writing societies. Cook noted the dissemination efforts stemming from the past PCORI-AHRQ funded systematic reviews, including PCORI Evidence Updates, targeted PCORI Funding Announcements for research projects, PCORI Funding Announcements for implementation projects, AHRQ implementation funding announcement, and use to support new clinical guidelines. Cook reaffirmed the need to continue to fund systematic reviews and to increase annual output. She noted that the mechanism used to provide a framework for the partnership and funding is an MOU between PCORI and AHRQ that has historically reflected commitments on the order of \$1.5 to \$2.5 million. As PCORI seeks increased capacity, she recommended approval for a longer term commitment of up to \$6 million annually with a maximum of \$30 million over the next 5 years to collaborate with AHRQ on systematic reviews. Cook confirmed that topics would be discussed internally and with EDIC and SOC, as needed. it was acknowledged that pursuing systematic reviews on MMM and IDD topics was particularly important, given the reauthorizing law. In response to a question, Cook indicated that the average cost of a systematic review is generally between \$500K and \$750K, depending on size and scope of the review. <i>The following motion was made by Barbara McNeil and seconded by Kathleen Troeger.</i> Motion: Approve funding of up to \$6 M per fiscal year, not to exceed a total of \$30 M for 5 fiscal years, to the Agency for Healthcare Research and Quality (AHRQ) for PCORI’s partnership with AHRQ to fund the conduct of systematic reviews, subject to finalization of Memorandum(s) of Understanding between PCORI and AHRQ. <i>The motion was approved by a majority vote of the voting Board members by voice vote: none opposed, none abstained, 1 recusal, (Karin Rhodes, designee for AHRQ); Tanisha Carino, Michael Lauer, Connie Hwang, Michelle McMurry-Heath and Robert Zwolak were not present during this vote.</i>
Public Comment - <i>Greg Martin, Acting Chief Engagement and Dissemination Officer</i>	No members of the public requested the opportunity to make a public comment. Thus, there were no public comments presented during this time.

Wrap-up and Adjourn - <i>Christine Goertz, DC, PhD</i>	Meeting ended at 3:57 pm
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Minutes were approved by the PCORI Board of Governors 06-15-2021