pcori

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting via Teleconference / Webinar

Tuesday February 15, 2022

1:00pm – 2:30pm Eastern

MINUTES

Board Members Present:
Sharon Levine, MD, *Vice Chairperson*; Kara Ayers, PhD; Kate Berry; Jennifer DeVoe, MD, DPhil; Christopher Friese, PhD, RN; Mike Herndon, DO; Russell Howerton, MD; James Huffman; Connie Hwang, MD, MPH; Barbara McNeil, MD, PhD; Karin Rhodes (designee for David Meyers, MD); Eboni Price-Haywood, MD, MPH; James Schuster, MD, MBA; Ellen Sigal, PhD; Michael Lauer, MD (designee for Lawrence Tabak, DDS, PhD); Kathleen Troeger, MPH; Danny van Leeuwen, MPH, RN; Robert Zwolak, MD, PhD

Board Members Absent: Christine Goertz, DC, PhD, *Chairperson;* Alicia Fernandez, MD; Janet Woodcock, MD

Guests: Tom Sneeringer, CPA, Partner, RSM US LLP; Steve Marconi, Senior Manager, RSM US LLP

Agenda Item	PCORI Speakers
Welcome and Call to Order **Consider for Approval:** • December 2, 2021, Board Meeting Minutes *Sharon Levine, MD, Board Vice Chairperson*	Dr. Levine chaired and opened the meeting, welcomed all to the meeting of the PCORI Board of Governors. She announced that the following members of the PCORI Board of Governors had recently transitioned off the Board due to career changes: Francis Collins, Michelle McMurry-Heath and Tanisha Carino. She welcomed Dr. Lawrence Tabak, DDS, PhD, who is currently serving as the Acting NIH Director replacing Collins, to the PCORI Board. Levine indicated that GAO intends to fill the Board seats vacated by McMurry-Heath and Carino during its regular Board appointment cycle this year. GAO expects to formally announce the nomination period beginning in April 2022 with appointments expected to be made by GAO in late September 2022. On behalf of PCORI and the Board of Governors, Levine thanked these former Board members for their contributions to PCORI and wished them well in their future endeavors. Levine then read the Chair Statement on Conflict of Interest and reviewed the meeting agenda. With no additions or corrections to the minutes offered, Levine then presented the minutes of the December 2, 2021 Board meeting for approval.

	The following motion was made by Barbara McNeil and seconded by Kara Ayers. **Motion**: Approve the December 2, 2021 Board Minutes *Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions). Eboni Price-Haywood was not present during this vote.*
Consider for Acceptance: • 2021 Financial Audit Report *Sharon Levine, MD, Chair, Governance Committee and Tom Sneeringer, CPA, Partner, RSM US LLP*	Dr. Levine introduced the agenda item on the audit report by reminding the Board that the Governance Committee is responsible for the oversight of PCORI's annual financial audit. She explained that the FY2021 independent audit was conducted by RSM under the charge of Tom Sneeringer, a partner at RSM, and Steve Marconi, Senior Manager at RSM, and that the Governance Committee met with these auditors at five Governance Committee meetings held between September 2021 and January 2022 to review the audit's progress and receive reports. Further Levine noted that each meeting included an executive session between Governance Committee Board members and auditors to provide for direct communication. Levine further stated that the RSM had met with the Government Accountability Office about the audit. She indicated that the Governance Committee supports the acceptance of this audit and she introduced Tom Sneeringer to provide an overview of the FY2021 independent Financial Audit to the Board. Sneeringer noted that he has served as the RSM engagement partner for PCORI's annual audits for several years. In keeping with RSM's partner rotation framework, for the FY2022 audit, he will no longer serve as the engagement partner; the engagement partner for the PCORI audit will be Steve Marconi, the current Senior Manager. Marconi introduced himself to the Board. Sneeringer reported on the FY2021 audit which covered the 12-month period from October 1, 2020 through September 30, 2021. He informed the Board that RSM planned to issue an unmodified or "clean"

	opinion, that PCORI's financial statements ending September 30, 2021 conform to generally accepted accounting principles with no findings related to deficiencies in internal controls over financial reporting and no findings related to noncompliance issues. He also stated that PCORI follows the accounting standards for non-profit organizations. He indicated that the audit was also performed in accordance with Government Auditing Standards. Sneeringer reviewed PCORI's FY2021 statement of activities including revenue, expenses, realized and unrealized loss on investments, and change in net assets, with a comparison to FY2020. He also reviewed PCORI's FY2021 statement of financial position, including assets, liabilities and net assets compared to FY2020. He noted that PCORI's revenue for FY2021 was $493M compared to $455M in FY2020. He stated that expenses dipped very slightly from $361M in FY2020 to $356M in FY2021, and that the vast majority of expenses relate to research awards and reflect the timing of when they were expensed by the awardees. He explained that PCORI holds its investments in U.S. Treasury notes and Treasury bills, which are subject to market change. For FY2021, PCORI's recorded investment balance reflects an unrealized loss of $3M which is not an actual loss but reflects a tracking of the portfolio. He explained that losses and gains are based on market value and current yields in the market, not actual losses and gains. Net assets in FY2021 amounted to $134M. Sneeringer then reviewed PCORI's financial positions, or balance sheet, which included assets of $1.6 billion, liabilities of $71 million and net assets of $1.5 billion. He stated that as of September 30, 2021, PCORI's assets, liabilities and net assets reflected a very strong financial position. Board members were asked if they had any questions. No discussion was requested. *The following motion was made by Russell Howerton and seconded by Michael Lauer.* **Motion**: Accept the FY2021 Audit Report

	Accepted by a majority vote of the voting Board members by voice vote (no opposed; no abstentions).
Strategic Planning Committee Report *Nakela L. Cook, MD, MPH, Executive Director and Sharon Levine, MD, Board Vice Chairperson and Co-Chair, Strategic Planning Committee*	Dr. Levine introduced Dr. Cook. Cook provided an overview of the public comment period for the proposed Research Agenda, which was held from December 10, 2021, to January 31, 2022. Cook outlined some of the emerging themes from the analysis of stakeholder input including: the importance of engagement and cross-sector collaboration, being responsive to change, leveraging opportunities to enhance data infrastructure, and promoting health equity within health and healthcare research. She noted that analysis of stakeholder input was underway and will inform revisions to the proposed Research Agenda (RA). The Strategic Planning Committee (SPC) is expected to consider revisions to respond to stakeholder input at its February meeting. A proposed revised Research Agenda is anticipated to be brought before the Board in March for consideration for adoption. Cook then introduced the next steps in the Strategic Plan development process. Drafts of the Strategic Plan (the Plan) will be reviewed by the SPC during April and May, 2022, and then the proposed Plan is expected be presented to the Board for consideration for approval in June 2022. Cook noted that there were several purposes of the Plan including to show how PCORI will achieve its vision, serve as a communications tool, form the basis for operational plans, and provide an opportunity for stakeholders to see themselves in PCORI's vision. The Plan is expected to be complemented by a digital format with clickable, interactive webpages, as well as, by printable, "at-a-glance" handouts. Cook provided an overview of the outline of the proposed Plan, and how the contents match the scope of strategic planning activities. Cook highlighted that a large portion of the Plan will describe PCORI's unique, holistic approach to achieving progress on the National Priorities for Health including strategies related to engagement, research, infrastructure, methods, and dissemination and implementation. Levine further elaborated that the Plan would outline strategies, but PCORI's work to

	carry out the plan will be critical for putting the strategies into action. Board members voiced support for the Plan's initial outline and complementary digital format. Feedback provided included taking time to prepare for carrying out the Plan and evaluating progress. Discussion took place around how the Plan would allow for pivoting and being responsive to changes in the healthcare landscape. Cook noted that the breadth of the National Priorities and Research Agenda would allow PCORI to adapt to an evolving healthcare and research landscape.
Healthcare Cost and Value Workgroup Report *Dr. Nakela Cook, Executive Director and Greg Martin, Acting Chief Engagement and Dissemination Officer*	Dr. Cook provided a recap of PCORI's four Principles for the Consideration of the Full Range of Outcomes Data, which the Board approved in 2021. Cook indicated that the Healthcare Cost and Value Workgroup, comprised of Board members, Methodology Committee members, and PCORI staff, is considering how PCORI can address the intersection of health care cost and value. Cook then introduced Greg Martin, Acting Chief Engagement and Dissemination Officer, to provide further detail. Martin noted that stakeholders have voiced their desire for PCORI to help advance considerations of healthcare cost and value. Martin outlined the workgroup's phased approach to addressing the implementation of the PCORI Principles. He outlined the three pillars of PCORI's efforts: Addressing the Collection of the Full Range of Outcomes; Informing the Value Conversation; and Supporting Policy Priorities. He indicated that the primary focus of the "Informing the Value Conversation" phase will be a landscape review and convening patients and other stakeholders to understand what patient-centered value means to them, such as understanding what aspects of value should be monitored and measured over time. Martin noted that the workgroup anticipates bringing forward a report on these activities to the Board for public input this summer. The Board will continue to receive regular updates as work progresses.

	Board members' discussion focused on several themes. They suggested that PCORI should define terminology more precisely, such as "patient-centered costs," particularly when convening stakeholders to ensure there is a shared understanding during conversations. Board members inquired as to how "value" would be defined, when considering aspects such as value in relation to an individual vs. value across a group of individuals to get an average value. Other factors raised in defining value included ensuring diversity within stakeholder groups. Board members further focused on the need to ensure this project has real-world value to patients rather than becoming a primarily academic exercise. The point was raised that PCORI's most valuable contribution to existing literature is patient-centeredness. Board members also recommended that PCORI identify the ultimate desired output of this work and use that as a guide when creating a framework and capturing stakeholders' perspectives. It was also noted that PCORI's mandate in the authorizing law is to collect and disseminate information on this topic, rather than be the arbitrator of what value means.
Closing Remarks *Nakela L. Cook, MD, MPH*	Dr. Cook reviewed the Board meeting highlights. She thanked all the Board members for their helpful and insightful input on these important topics and thanked all that joined the call. Cook then reminded the Board members of the upcoming March meeting.
Wrap-up and Adjourn *Sharon Levine, MD*	Dr. Levine thanked all who joined the meeting and noted that the meeting agenda, minutes from the previous meeting, slides and archived webinar would be posted to the PCORI website within the week. The meeting was adjourned at 2:25 pm.

Minutes were approved by the PCORI Board of Governors 03-08-2022