pcori

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting via Teleconference / Webinar

Tuesday, February 9, 2021, 1:00-3:15 pm Eastern

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 Friese, PhD, RN; Michael Herndon, DO; Russell Howerton, MD; James Huffman; Connie Hwang, MD, MPH; Barbara McNeil, MD, PhD; 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

Board Members Absent: Michelle McMurry-Heath, MD, PhD; Janet Woodcock, MD

Guest: Tom Sneeringer, CPA, Partner, RSM US LLP

AGENDA ITEM	PCORI SPEAKERS
Welcome and Call to Order **Consider for Approval:** • January 12, 2021 Board Minutes *Christine Goertz, DC, PhD, Board Chairperson*	Dr. Goertz chaired and opened the meeting, welcomed all to the February 9, 2021 meeting of the PCORI Board of Governors, and read the Chair Statement on Conflict of Interest. She then reviewed the agenda for the meeting. With no additions or corrections offered, Goertz then presented the minutes of the January 12, 2021 Board meeting for approval. *The following motion was made by Russell Howerton and seconded by Sharon Levine.* **Motion:** Approve minutes from the January 12, 2021 Board of Governors meeting. *Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions)*
Consider for Acceptance: • 2020 Financial Audit Report *Sharon Levine, MD, Chair, Governance Committee and Tom Sneeringer, CPA, Partner, RSM US LLP*	Dr. Levine introduced the audit report by reminding members that the Governance Committee, in accordance with its charter, is responsible for the oversight of PCORI's annual financial audit. She explained that the FY2020 independent audit was conducted by RSM under the charge of Tom Sneeringer, a partner at RSM, and covered the 12-month period ending September 30, 2020. The RSM auditors met with the Governance Committee five times to review the audit's progress and receive reports, and each meeting included the opportunity for an executive session between Governance Committee members and the auditors to provide for direct communication. Levine further noted that the audit would be provided to the Government Accountability Office and indicated, that the Governance Committee supports the acceptance of this

	audit, and introduced Tom Sneeringer to provide an overview of the FY2020 Independent Financial Audit to the Board. Sneeringer reported that RSM planned to issue an unmodified or "clean" opinion, that financial statements ending September 30, 2020 conform to generally accepted accounting principles with no findings related to deficiencies or material weaknesses in internal controls over financial reporting and no findings related to noncompliance issues. Sneeringer then reviewed PCORI's FY2020 statement of activities including revenue, expenses, realized and unrealized loss on investments, and change in net assets, with a comparison to FY2019. He also reviewed PCORI's FY2020 statement of financial position, including assets, liabilities and net assets compared to FY2019. He noted that PCORI's revenue for FY2020 was $455M compared to $615M in FY2019. He stated that expenses dipped slightly from $390M in FY2019 to $361M in FY2020, and that the vast majority of expenses relate to research awards and reflect the timing of when they were expensed by the awardees. He then explained that PCORI holds its assets and manages them in safe investments in U.S. Treasury notes and Treasury bills and are subject to market change. The investment balance reflects unrealized gain on investments. Net surplus in FY2020 amounted to $95M. Sneeringer then reviewed PCORI's financial positions which included assets of $1.5B, liabilities of $76M and net assets of $1.4B. He pointed out, however, that a number of funding commitments made for awards which have not yet begun are not reflected in these statements. Approximately $786M or 57% of PCORI's net equity is earmarked for these commitments. Sneeringer thanked the Governance Committee and PCORI management for their cooperation throughout the audit. He noted that RSM auditors had already met with GAO officials and GAO will issue its report to Congress by the end of March. Board members were asked if they had any questions. No discussion was requested. The following motion was made by Danny van Leeuwen and seconded by Michael Lauer: **Motion:** Accept the FY2020 Financial Audit Report *Accepted by a majority vote of the voting Board members by roll call vote (20 in favor; 0 opposed; 0 abstentions; 0 recusals). Ellen Sigal was not present for this vote.*
Discussion of Expedited Approach to Developing Targeted PFAs *Nakela L. Cook, MD, MPH, Executive Director*	Dr. Cook provided some background for expedited approach for the development of targeted PFA which will facilitate the ability to meet the commitment plan approved by the Board. She outlined the big picture for PCORI's Research Agenda, which includes three tracks that will occur simultaneously: Strategic Planning, Revitalizing the Topic Process, and Developing Targeted PCORI Funding Announcements (PFAs) while Strategic Planning is underway. She explained the rationale for an expedited approach in

	the short-term is to be responsive and relevant to stakeholders, and to meet the PCORI commitment plan. She described how the interim approach would converge with the updated National Priorities and Research Agenda. Cook described how PCORI would utilize a full range of approaches for expedited development of Targeted PFAs for the next several cycles, including typical Targeted PFAs (moderately to highly specified questions), expanded Targeted PFAs (moderately specified issues/conditions), and one or two large studies (highly specified questions). Cook provided the timeline for developing Targeted PFAs over the next several cycles while Strategic Planning is ongoing. She provided a summary of the three main features of the expedited approach: substantial reduction in time, consideration of a set of topics (versus one at a time), and expansion and utilization of the full range of types of Targeted PFAs. Board Members expressed interest in several areas which Cook addressed. She indicated that to implement the commitment plan, there will likely be an increase of staffing in some areas. Cook also indicated that the Science Oversight Committee (SOC) would continue to provide input while being nimbler and on a faster timeline. She also indicated that the expedited approach would provide more time for researchers to prepare for new PFAs, and addressed how the process would incorporate new topic suggestions. In response to discussion about the timeline for the projected completion of Strategic Planning, and when new Targeted PFAs would reflect new National Priorities, Cook indicated that if strategic planning finishes in late 2021, related topics and Targeted PFAs would likely be scheduled to occur approximately in mid-2022.
Cost Data Principles Update *Andrew Hu, Director, Public Policy and Government Relations and Joanna Siegel, ScD, Program Director, Engagement, Dissemination and Implementation*	Mr. Hu and Dr. Siegel presented an update on the status of PCORI's implementation of its the new obligation in the reauthorizing law that PCORI-funded research consider, as appropriate, the full range of outcomes data, including burdens and economic impacts. They also shared a synthesis of the feedback received during the public comment period on PCORI's proposed Principles for the Consideration of the Full Range of Outcomes data. Hu offered an overview of PCORI's cost data implementation plan and outlined the following objectives and activities of each of the three Pillars. Pillar 1 aims to establish Principles that PCORI will use as a reference point when developing guidance for future PFA applicants. Activities already undertaken under this pillar include the development of proposed Principles which were disseminated for public comment and the inclusion of initial guidance in PCORI's Cycle 1 PFA. Ongoing work includes revisions to the proposed Principles based on input received from the public comment period and the development of additional guidance for future PFAs. A final set of Principles will be presented to the PCORI Board of Governors for consideration in March. Pillar 2 includes efforts to develop or update methodology standards as they relate to the consideration of burdens and economic impact data in PCORI-

	funded studies. This work will be done in coordination with the Methodology Committee and will reflect input received from the public comment period. Pillar 3 will focus on identifying opportunities for PCORI to further advance the implementation of this mandate and support the needs of patients, caregivers and other stakeholders, including informing public policy discussions related to healthcare cost and value. Currently, staff are working to identify opportunities for PCORI to play a proactive role. Hu presented a synopsis of the public input PCORI received through stakeholder convenings, a 60-day public comment period, and a series of PCORI-hosted webinars. PCORI also requested feedback from internal resources, namely, PCORI Advisory Panels, the Methodology Committee, and PCORI's Board of Governors. PCORI, with the support of a contractor, analyzed comments from individuals and organizations representing the full spectrum of the healthcare community, with 32 unique written submissions representing hundreds of individuals and organizations as well as verbal input from the webinar series. Based on the analysis of public comments, the overarching themes and potential considerations for PCORI include: • Ensure patient-centeredness in implementation; • Conduct ongoing stakeholder engagement; • Capture of cost and economic data should only be done when appropriate; • Provide additional guidance for research community; • Include focus on social risk factors and social determinants of health; and • The role of PCORI. Implications for PCORI are categorized by considerations that will inform the finalization of the Principles, and considerations for further implementation activities and goals. Hu presented a description of each theme and accompanying considerations for PCORI. In addition to the input received on the proposed Principles, commenters also noted opportunities for PCORI to consider in further implementation actions, including taking a leadership role in advancing scientific methods on the collection of cost and economic impact data and supporting patient-centered discussions on healthcare costs and value. In terms of next steps and further implementation activities, he noted that staff will continue to revise and update the proposed Principles based on public input, and in coordination with the Methodology Committee, begin Pillar Two activities related to updating methodology standards. He also discussed the establishment of a Resource Center that will aid in the process of implementation of the mandate to consider the full range of outcomes data. Board members commented that many patient groups are seeking improved methodology on how to consider the impacts of costs and social risk factors and appreciated its inclusion in the analysis, noting that PCORI should establish a

	leadership role in the consideration of caregiver costs. It was questioned how the Principles will impact the merit review process. Hu confirmed that a need for additional guidance to the research community was expressed, including whether PCORI will prioritize outcomes and clarity on the types of analysis permitted. It was further asked if guidance could be formed on an iterative basis. Hu noted Cycle 1 PFA's included an initial high-level guidance and additional guidance will be forthcoming for future funding cycles.
Strategic Planning Update *Sharon Levine, MD, and Nakela L. Cook, MD, MPH*	Dr. Cook provided a brief update on the various activities encompassed in strategic planning such as identification of the National Priorities and Research Agenda; scenario planning based on the changes in landscape and environment; and advancing priorities from PCORI's reauthorizing legislation.
Wrap-up *Christine Goertz, DC, PhD*	Board meeting ended at 2:21 pm Eastern

Minutes were approved by the PCORI Board of Governors 03-16-2021