PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting

Tuesday, December 13, 2022

1:00pm – 3:00pm Eastern

MINUTES

Board Members Present:
Russell Howerton, MD, *Chairperson;* Jennifer DeVoe, MD, DPhil, *Vice Chairperson*; Kara Ayers, PhD; Kate Berry; Christopher Boone, PhD; Ryan Bradley, ND, MPH; Alicia Fernandez, MD; Zoher Ghogawala, MD; James Huffman, MSc; Connie Hwang, MD, MPH; Mike Lauer, MD (NIH Director Designee); Barbara McNeil, MD, PhD; Debbie Peikes, PhD, MPA; Eboni Price-Haywood, MD, MPH; Kimberly Richardson, MA; James Schuster, MD, MBA; Kathleen Troeger, MPH; Robert Valdez, PhD, MHSA (AHRQ Director); Danny van Leeuwen, MPH, RN; Christopher White, Esq.

Board Members Absent: Christopher Friese, PhD, RN; Mike Herndon, DO; Janet Woodcock, MD

Agenda Item	PCORI Speakers
Welcome and Call to Order **Consider for Approval:** • September 20, 2022, Board Meeting Minutes *Russ Howerton, MD, FACS, Board Chairperson*	Dr. Howerton chaired and opened the meeting, welcoming all to the meeting of the PCORI Board of Governors, at this his first Board meeting as Board Chairperson, and especially welcomed the new PCORI Board members who were appointed by GAO in September 2022. The new Board members are Christopher Boone, PhD, Ryan Bradley, ND, MPH, Zoher Ghogawala, MD, Kimberly Richardson, Debbie Peikes, PhD, MPA, and Christopher White, JD. Howerton read the Chair Statement on Conflict of Interest and noted that Board members are asked to complete the annual updating of COI Disclosures before January 31, 2023. He then reviewed the meeting agenda. With no additions or corrections to the minutes offered, Howerton then presented the minutes of the September 20, 2022, Board meeting for approval. *The following motion was made by Robert Valdez and seconded by James Schuster.* **Motion**: Approve the Minutes of the September 20, 2022, Board of Governors Meeting *Approved by a majority vote of the voting Board members by voice vote (no opposed; Ryan Bradley abstained). Christopher Boone was not present for this vote.*
Consider for Approval:	Dr. Howerton reviewed the new governance framework approved by the Board on September 20, 2022, created to advance the new PCORI Strategic Plan, enable the Board to provide strategic oversight, and enable the staff to implement and lead

• Items Relating to Implementation of the New Governance Framework *Russ Howerton, MD, FACS, Chair, Governance Committee* *Mary Hennessey, Esq., General Counsel*	PCORI's programs to advance PCORI's mission. This framework included retaining essential standing committees, such as the Finance and Administration Committee (FAC), Governance Committee, etc.; creating a new Strategy Committee; expanding the current standing Selection Committee to include consideration of additional award types; incorporating ad hoc workgroups into the governance framework; pausing convenings of three strategic committees, i.e., EDIC, RTC, SOC; and assessing the new governance framework to evaluate if it is achieving the desired outcomes. Howerton then introduced Mary Hennessey to review the proposed new and amended governance documents being recommended by the Governance Committee to implement the new governance framework and address outdated language. Hennessey reviewed the proposed governance documents and highlighted some of the key elements in each of the proposed documents that the Board was asked to consider. These included: •New Strategy Committee Charter • Will consider strategic issues as assigned by the Board or Board Chairperson •Amended Standing Selection Committee and Special Selection Committees Charter • Will consider slates of awards from all programmatic award initiatives • Special Selection Committee(s) can be established by Board Chairperson as needed due to volume of award decisions, timing of award cycles, or other factors • Amended Governance Committee Charter • Increased number of members to up to 7 Board members • Added language that in making nominations to Committees, the Governance Committee will consider the needs of PCORI and Committees, length of service on Board and on Committees, and other considerations • Amended Finance and Administration Committee Charter • Increased number of Board members to up to 7 Board members • Amended Executive Committee Charter • Changed membership composition to the following ex-officio members: Board Chairperson, Board Vice Chairperson, Chairs of the Governance Committee, FAC, Strategy Committee, and Standing Selection Committee • New Nominating Committee for Members of the Methodology Committee Charter • Recommend slates of nominations to the Board for MC appointments • Membership appointed by Board Chairperson, includes Board members, senior staff membership and MC members • Amended Board and Methodology Committee Compensation and Reimbursement Policy • Updated to include work groups • Provided for retroactive compensation for Chairs and Vice Chairs of prior and existing work groups • Amended PCORI Bylaws • Amendments relating to Committees to align with amended charters • Paused historic three strategic committees (EDIC, RTC, SOC) and provided they can only be convened upon the authorization of the Board

	• Added language to refer to Working Groups • Sunsetting of the Award Project Budget Increase Policy as a Board-approved policy to align with the revised authority relating to approval of awards. There were no questions or further discussion by the Board. Christopher Boone logged onto the meeting after roll call and was present for the following vote. *The following motion was made by Barbara McNeil and seconded by Robert Valdez.* **Motion**: Approve: ○ The proposed new Strategy Committee Charter ○ The proposed amendments to the: ▪ Selection Committee ▪ Governance Committee Charter ▪ Executive Committee Charter ▪ Finance and Administration Committee Charter ▪ Board and Methodology Committee Compensation and Reimbursement Policy • Implementation of the Compensation and Reimbursement Policy relating to Chairs and Vice Chairs of Work Groups will be effective retroactively as of the beginning of their service on prior and existing Work Groups ▪ PCORI Bylaws ▪ The proposed new Nominating Committee for Members of the Methodology Committee Charter ▪ The sunset of the Award Project Budget Increase Policy as a Board-approved policy *Approved by a majority vote of the voting Board members by roll call vote (20 in favor, 0 opposed, 0 abstained).*
Consider for Approval: • FY 2023 to FY 2025 Commitment Plan *James Huffman, MSc, Chair, Finance and Administration Committee* *Brian Trent, MPA, Deputy Executive Director for Operations*	James Huffman introduced the proposed FY 2023 to FY 2025 Commitment Plan for Board discussion and consideration for approval and noted that the 3-year proposed commitment plan continues to align with the Board-approved model for Commitment Planning. Brian Trent reviewed a comparison of PCORI's FY 2022 actual commitments to the target, noting that PCORI committed under target in FY 2022 and the associated key drivers, which included continued effects of COVID-19 and a lower than expected number of applications and anticipated engagement awards. Trent also provided an overview of the proposed 3-Year Commitment Plan for FY 2023 – FY 2025, which includes an increase in FY 2025 from $500M reflected in the long-term model to $600M using the uncommitted funds from FY 2022. It also includes allocating $50M of the increase to Infrastructure in anticipation of PCORnet Phase 4 commitments. Members of the Board asked several questions and made comments related to the allocation of funds, changes to commitments between fiscal years, meeting commitment targets (including relating to dissemination and implementation) and considering the infrastructure and needs of PCORnet. The proposed FY2023 to FY2025 is attached as Attachment A.

	The following motion was made by Barbara McNeil and seconded by Zoher Ghogawala. **Motion**: Approve the FY 2023 to FY 2025 Commitment Plan *Approved by a majority vote of the voting Board members by voice vote (0 opposed, 0 abstained). James Schuster was not present for this vote.*
Update from the Healthcare Cost and Value Workgroup *Eboni Price-Haywood, MD, MPH, Chair, Healthcare Cost and Value Workgroup* *Greg Martin, Acting Chief Engagement and Dissemination Officer*	Dr. Eboni Price-Haywood outlined the work of the Board-related Healthcare Cost and Value Workgroup, which was created in response to the provision in the 2019 reauthorization of PCORI's funding clarifying that PCORI-funded research should collect, as appropriate, potential burdens and economic impacts. The Workgroup focused on developing a framework to guide PCORI's activity in implementing this statutory provision. In particular, the Workgroup addressed the framework pillar around informing the conversation, engaging patients and other stakeholders to understand their unique perspective on value in health and healthcare, with a driving emphasis towards patient-centered value. Greg Martin reviewed the purpose, approach and process, and findings and work coming out of the Workgroup's efforts. He reported on an initial landscape review that served as the foundation for further engagement with patients and stakeholders, with the goal of understanding which attributes of patient-centered value are essential to whom and how the attributes can be measured. The work informed a second report summarizing patient and stakeholder perspectives on patient-centered value in health and health care, which includes 48 attributes across seven domains. The purpose of the draft report is to enable stakeholders and applicants to consider an inventory of attributes of patient-centered value and help support and bridge conversations between and among patients, stakeholders, and the broader healthcare community. Martin outlined next steps for the draft report, which include posting it for public input. The aim is to solicit and glean the broadest and deepest possible volume of perspectives on the attributes of patient-centered value. From there, the aim is to make the document, and particularly its inventory of attributes, a resource for PCORI applicants and the broader healthcare community. The Workgroup is also considering what follow-on products may be helpful after the report is finalized. Martin sought the Board's comments, including consideration of the following questions. • What considerations should be kept in mind regarding additional engagement of patients and stakeholders to provide input on the draft report on Patient and Stakeholder Views on Components of "Patient-Centered Value" in Health and Health Care? • What additional steps might we take to have the report meet the informational needs of the stakeholder community and our applicants? • What additional considerations should be kept in mind as we continue to inform conversations around patient-centered value? Board discussion focused on: • clarifications regarding how factors such as socioeconomic status and other access barriers were considered, additional opportunities to leverage community organizations or other trusted intermediary groups to encourage

	engagement with marginalized groups, and an interest in including perspectives from complementary integrative health community • the observation that the draft report focuses on peripheral costs, as opposed to dollar costs, which does not reflect what was previously discussed related to PCORI's expanded mandate and ability to consider costs • the need to keep Congressional leaders and other key stakeholders informed on PCORI work in this area Price-Haywood clarified that in considering comments of stakeholders, the Workgroup was struck by the idea of cost and value and what is meant by cost. What was revealed was that, in fact, there are many costs or burdens that patients and family caregivers experience in addition to monetary costs. Dr. Nakela Cook further clarified that the Workgroup previously spoke with the Board about principles to summarize how PCORI would interpret the provision in the law reauthorizing PCORI's funding and that the Board had approved the "Principles for the Consideration of the Full Range of Outcomes Data in PCORI-Funded Research" in March 2021. Activities under the framework developed by the workgroup are ongoing and will focus on the other two pillars of the framework, which includes collection of data on costs and economic burdens. The Board recommended that the report on patient and stakeholder views of attributes of patient-centered value be explicit about its priority being monetary costs to patients, as a clear statement to support understanding of the research community who will be conducting this work.
End of Year Dashboard Review *Nakela Cook, MD, MPH, Executive Director*	Dr. Cook presented the Q4-FY2022 Dashboard highlighting that the Dashboard will be transitioning in the future to align with the new strategic plan (including related outputs, uptake, and progress on strategic goals). The Dashboard presented eight metrics that report on PCORI's performance, including aspects of process, uptake, and use. Of the metrics, three were green-flagged (those that are on track): Time to Release of Research Findings, CER Results Publicly Available, and CER Results: Altmetric Scores in Context. Funds Committed was the sole metric with a yellow flag (off target by more than 10%). Four metrics do not have an applicable target: Uptake into Public Patient Resources, Uptake of Results into UpToDate, Other Examples of Uptake, and Patients Reached via Dissemination & Implementation (D&I) Awards (new metric for Q4FY2022). There were no red-flagged metrics (items that are off-target and in need of attention or action by the Board). Cook then highlighted a PCORI-funded project, entitled 'Reducing Health Disparities for Black Women in the Treatment of Insomnia' project, an example of PCORI's effort to increase information for health decision making. This study found that a culturally tailored CBT for insomnia program was more effective at engaging participants than a standard version of CBT for insomnia. This example highlights the opportunity to learn more about culturally tailored interventions across PCORI's portfolio. Cook next discussed Dashboard metrics relating to outputs and uptake of PCORI-funded research results. These metrics included PCORI-funded study results in the literature, measures of attention to and influence of CER results, and uptake into both clinical and public-facing resources. She also shared that PCORI's award funding process, which includes posting results abstracts on PCORI's website, provides complete and earlier availability of research results to the public than

	relevant benchmarks. Three new metrics were introduced to the Board: Return of Aggregate Results to Research Participants, Relative Citation Ratios of CER Articles from PCORI-funded Studies, and Patients Reached via D&I Awards. These metrics address whether and how PCORI research findings reach people who can benefit from them. Cook also featured an example of a recently completed project from PCORI's D&I award program to demonstrate how PCORI is promoting uptake and use of PCORI-funded research results in practice. Cook described history of the project, beginning with the early PCORI-funded study entitled 'Generating Critical Patient-Centered Information for Decision Making in Localized Prostate Cancer,' which generated results that were published in *JAMA*, incorporated into PCORI Evidence Updates, and cited in UpToDate®, and Clinical Guidelines. The subsequent PCORI-funded implementation project, 'Improving Shared Decision Making for Men with Prostate Cancer that Has Not Spread,' incorporated findings from this early study into an existing effective decision aid to bring information on prostate cancer treatment choices to patients across three health systems representing diverse patient populations. After reviewing the tool, 30% of patients changed their mind about treatment, and one study site reported that the percentage of patients needing multiple visits to choose a treatment decreased from 46% to 13%. The study team plans to use this data to advocate for implementation of the decision aid throughout Los Angeles County health system, the second largest public health care system in the country. Members of the Board raised questions and comments about the need for a deeper understanding of the meaning of public uptake of PCORI-funded study results, and how to assess PCORI's success in pursuing its strategy around equity and inclusion in research.
Latest Additions to PCORI's Portfolio of Funded Awards *Nakela Cook, MD, MPH, Executive Director*	Dr. Cook presented the Research and Dissemination & Implementation awards recently approved from Cycle 1 2022, including 20 projects from 6 PFAs totaling just over $100M. Cook spoke to the approved slate from the *Broad Pragmatic Studies* PFA, noting the projects' alignment with PCORIs National Priorities for Health. The *Improving Methods for Conducting PCOR* PFA aims to address methodological gaps and best practices and Cook highlighted 1 of the 6 projects from this PFA that will look at weighting methods for large data sets. In addition, 6 projects were awarded from Targeted PFAs (TPFA). From the *Brief Interventions for Adolescent Alcohol Use* TPFA, Cook spoke to a project that will focus on screening and referral to treatment with a large patient reach. The *Comparing Effectiveness of Interventions Targeting Mental Health in Individuals with Intellectual and Developmental Disabilitie*s TPFA includes projects that will compare mindfulness to Cognitive Behavioral Therapy for Autistic adults. Cook also highlighted a research award from the *Prevention, Early Identification, and Treatment of Delirium in Older Adults* TPFA that will compare Hospital Elder Life care versus Family Augmented Help to bridge evidence gaps to inform decision making. Cook also announced two Dissemination & Implementation awards funded in Cycle 1 2022. Cook put these awards into context, noting the alignment with the FY2023 Commitment Plan, which aims for PCORI to fund $500M for Research awards. She indicated that this cycle totals $96M with 2 cycles remaining for this year and that the last cycle historically is the most robust. She indicated that Dissemination & Implementation awards reach $5M from this cycle, and with 2 cycles remaining, it is anticipated that D&I award funding will reach up to $40M this year. Cook indicated that an in-depth portfolio discussion is slated for a future Board meeting next year.

Wrap-up and Adjourn *Russell Howerton, MD, FACS, Board Chairperson*	The meeting was adjourned at 3:00pm.

Minutes were approved by the PCORI Board of Governors February 14, 2023.

See Attachment A

Attachment A:

Proposed 3-Year Commitment Plan
2023-2025

Funding Line (4 Larger Categories)	FY 2023 Target ($M)	FY 2024 Target ($M)	FY 2025 Target ($M)
Research	**500**	**500**	**460**

• **Includes:**
  • **Balance of broad and focused funding opportunities**
  • **Full range of study types, size, and duration from evidence synthesis to large clinical trials**
  • **Projects to address short-term and long-term information needs**			

Dissemination & Implementation	**60**	**60**	**60**

• **Includes:**
  • **Several lines of D&I Awards**
  • **Full range from Translation Center to large scale implementation projects**
  • **Other D&I Activities, such as supporting Open Access**			

Infrastructure	**40**	**40**	**80**

• **Includes:**
  • **Engagement Awards**
  • **PCORnet® Infrastructure Awards**
  • **Workforce Awards**			

New Initiatives	***50***	***50***	***50***
• **Includes the Executive Rapid Response Fund of $10M**			
Total Commitments	**600** ***(Up to 650)***	**600** ***(Up to 650)***	**600** ***(Up to 650)***