PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting

Tuesday September 20, 2022

9:00am – 12:00pm Eastern

MINUTES

Board Members Present:
Christine Goertz, DC, PhD, *Chairperson;* Sharon Levine, MD, *Vice Chairperson*; Kara Ayers, PhD; Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Mike Herndon, DO; Russell Howerton, MD, FACS; James Huffman, MSc; Connie Hwang, MD, MPH; Barbara McNeil, MD, PhD; James Schuster, MD, MBA; Kathleen Troeger, MPH; Robert Valdez, PhD, MHSA; Danny van Leeuwen, MPH, RN; Robert Zwolak, MD, PhD

Board Members Absent: Kate Berry; Christopher Friese, PhD, RN; Eboni Price-Haywood, MD, MPH; Ellen Sigal, PhD; Lawrence Tabak, DDS, PhD; Janet Woodcock, MD

Methodology Committee Members: Robin Newhouse, PhD, RN, Vice Chair

Agenda Item	PCORI Speakers
Welcome and Call to Order **Consider for Approval:** • July 26, 2022, Board Meeting Minutes *Christine Goertz, DC, PhD, Board Chairperson*	Christine Goertz chaired and opened the meeting at 9:03 am, welcoming all to the meeting of the PCORI Board of Governors (Board). Dr. Goertz read the Chair Statement on Conflict of Interest and outlined the agenda for the meeting. With no additions or corrections to the minutes offered, Goertz presented the minutes of the July 26, 2022, Board meeting for approval. *The following motion was made by Robert Valdez and seconded by Barbara McNeil.* **Motion**: Approve the Minutes of the July 26, 2022, Board of Governors Meeting *Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions). Russell Howerton was not present for this vote.*
Consider for Approval: • Committee Nominations Relating to Board Transitions *Sharon Levine, MD, Chair, Governance Committee*	Sharon Levine reported that the Governance Committee has considered the implications of the upcoming Board transition, including making sure that Board Committees continue to be in compliance with their charters and have the requisite leadership and number of members to fulfill their duties. Therefore, the following nominations for Board approval were presented:

	Motion #1: The Board appoints the following Board members to serve on the specified committees in the specified roles: • Finance and Administration Committee: o James Huffman, Vice Chair o Kate Berry, Member o James Schuster, Member • Engagement, Dissemination, and Implementation Committee o Connie Hwang, Vice Chair The increase in the number of FAC members was noted and Dr. Zwolak, an outgoing FAC member, expressed support for the increase in membership on this committee. Levine and Goertz thanked each of these members for their interest in being nominated to serve on these committees and in these positions. In addition, the Board was asked to consider for approval a motion to enable a leadership succession plan and prevent a gap in committee chair positions in the event a Committee Chair is no longer able or available to fulfill the duties of the position by appointment of the Vice Chair to the position of Chair. Motion #2: The Board resolves that: • If the Chair of a Board-related Committee resigns or is no longer able or available to fulfill the responsibilities of the Chair position, the Vice Chair of that Committee is appointed to the position of Chair of the Committee, unless otherwise appointed by the Board. *The following motion was made by Mike Herndon and seconded by Barbara McNeil.* **Motion**: Approve Motion #1 relating to Committee Appointments and Motion #2 relating to Committee Chair Succession *Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions). Russell Howerton was not present for this vote.*
Executive Director's Report *Nakela L. Cook, MD, MPH, Executive Director*	**Welcome Mieke Martinez** Dr. Cook welcomed Mieke Martinez, MBA, PCORI's new Chief Financial Officer who began August 1, 2022. **PCORI Updates: Ad Hoc Committee and Work Group Activities Relating to the Board** Cook reviewed the Board's ad hoc committee and work group activities and noted that the following groups have been charged by the Board with addressing high-priority items: Strategic Planning Committee, PCORnet® Priorities Work Group, Work Group to Optimize Effective Governance and Board Engagement, and the Healthcare Cost and Value Work Group. She noted that the Strategic Planning Committee's work is concluded, the PCORnet Priorities Work Group is making recommendations to the Board today, and the Work Group to Optimize Effective Governance and Board Engagement will report to the Board today with a proposed new governance model.

	Health Care Cost and Value Work Group Cook reported that the Health Care Cost and Value Work Group continues to make progress on developing a framework for PCORI's approach to the full range of outcomes data and helping to inform the broader value conversation. Outputs thus far include a landscape review summarizing patient and stakeholder perspectives and a multistakeholder workshop focused on engagement. This work, which began in October 2021, will continue through December 2022. **Year In Review** Cook highlighted several accomplishments of FY2022 and progress on advancing several goals. *Leadership Team and New Office Space* Cook recognized the new leadership team members that joined PCORI over the last year. Additionally, she expressed excitement for PCORI's new consolidated office space at 1333 New Hampshire Ave NW, Washington DC. *PCORI Strategic Plan* Cook provided an overview of the Strategic Plan, which the Board approved in June 2022. She noted that it reflects a bold vision and summarized the five National Priorities of Health that will guide future PCORI work: Increase Evidence for Existing Interventions and Emerging Innovations in Health; Enhance Infrastructure to Accelerate Patient-Centered Outcomes Research; Advance the Science of Dissemination and Health Communication; Accelerate Progress Toward an Integrated Learning Health System; and Achieve Health Equity. *Methodology Committee Framework and Nomination of New Members* Cook reviewed the Board-approved Methodology Committee framework and highlighted several accomplishments to date, including amending the Methodology Committee charter, revising the *Conflict of Interest Policy Relating to Funding for Members of the Board, Members of the Methodology Committee and Employees*, and approving a framework for nominating and appointing new Methodology Committee members. She noted a robust response to PCORI's solicitation for new Methodology Committee member applications and that the Board will consider appointments at a future meeting. *New Updates* Cook shared that, for the third year in a row, PCORI's Annual Report received the MarCom Gold Award, an international creative competition that recognizes outstanding achievement in marketing and communication. She provided updates on planning for the 2022 Virtual Annual Meeting and noted enhancements to PCORI's website. *Innovative Initiatives* Cook reported on several of PCORI's Innovative Initiatives, which align with the National Priorities for Health: • The **Health Systems Implementation Initiative (HSII)** provides funding opportunities to participating healthcare delivery systems and provider-

	affiliated health plans to undertake implementation projects in their care delivery settings. The goal of HSII is to promote the uptake of specific PCORI-funded evidence in practice. Applications have been received from organizations across the nation. PCORI expects to announce HSII participants in February 2023 and these organizations can apply for funding opportunities for specific implementation projects. • The **Health Equity Initiative** will focus on comparing multi-component, multi-level interventions that simultaneously address clinical conditions and social determinants of health to improve maternal health outcomes. The *Partnering Research and Community Organizations for Novel Health Equity Research: Addressing Social and Clinical Determinants of Maternal Health Targeted PCORI Funding Announcement (Partner Targeted PFA),* which supports PCORI's National Priorities for Health, including Achieve Health Equity, intends to fund high-quality, comparative clinical effectiveness studies in which community organizations are full partners in the work, are in leadership roles, and are partners in critical decision making alongside research organizations. • The **Science of Engagement** funding opportunity seeks to fund research that builds an evidence base on engagement in research and to strengthen the infrastructure to create actionable evidence. Through mechanisms and engagement, PCORI desires to generate evidence to support improving efforts. • The Agency for Healthcare Research and Quality (AHRQ) and PCORI are continuing their strong partnership to support training of researchers to conduct patient-centered outcomes research within **Learning Health Systems** and with an emphasis on addressing health inequities. • Cook also reported on the eight topic themes approved by the Board in July 2022 and noted that the goal of posting two to three PFAs per cycle has been achieved, with a total of 11 Targeted PFAs posted this year. *FY 2022 Funding Commitments Relative to Target & Context* Cook reported on funding commitments for FY 2022. She reported that Cycle 3 will be the largest funding cycle and that PCORI will end FY 2022 with an estimated funding commitment of $476-$511M of the FY2022 target of $600M. Cook reviewed the funds committed for FY 2022 against those committed in FY 2020 and FY 2021, projected funding commitments for FY 2022, and estimated funding commitments for FY 2023. She indicated that the Board will consider the next three-year commitment plan at its meeting in December. *Results Coming to Fruition* Cook reviewed publication highlights for six PCORI-funded CER studies with Altmetric scores ranging from 362 to 894; she indicated that an Altmetric score ≥ 300 is considered a very high score. All publications are in the top 5% of all research outputs scored by Altmetric. Cook then reported on publications from three specific studies that were funded by PCORI or that were conducted using PCORnet® with very high scores: Cardiac Complications after SARS-CoV-2 Infection and mRNA COVID-19 Vaccination, BP-

	Check Study (PCORI Study), and Clinical Features and Burden of Post-acute Sequelae of SARS-CoV-2 Infection in Children and Adolescents (NIH Supported). **Celebrating their Service** Cook expressed gratitude for the service of four founding board members rotating off the PCORI Board on September 22, 2022: Christine Goertz, DC, PhD, Sharon Levine, MD, Ellen Sigal, PhD, and Robert Zwolak, MD, PhD. **Board Discussion** Board members provided comments and asked questions on the Executive Director's report, including relating to planning for emerging health care issues (e.g., monkey pox, polio, etc.), increasing the number of projects and amount of funding committed for Dissemination & Implementation projects, and the scope of what is considered "workforce," confirming that it includes patients and caregivers. Board members also commented on approaches for dissemination and implementation.
Consider for Approval: • Proposed FY 2023 Budget *Russell Howerton, MD, Chair, Finance and Administration Committee* *Brian Trent, MPA, Deputy Executive Director for Operations*	Dr. Goertz introduced Dr. Robert Zwolak, Vice Chair, Finance and Administration Committee (FAC), indicating that he would address the proposed FY 2023 on behalf of the FAC given that Russ Howerton, the FAC Chair, was not able to lead this part of the agenda. Zwolak and Brian Trent presented the Proposed FY 2023 Budget of $451 million, as recommended by the FAC. Trent summarized the projected FY 2022 and FY 2023 fund balances PCORI's projected fund balance as of 9/30/2022 is $1,663M; PCORI's Projected Fund Balance as of 9/30/2023 is $1,819M; PCORI's Projected Outstanding Award Obligations at 9/30/2023 is $1,625M. The Net Funds Available at 9/30/2023 is $194M. Trent explained the difference between award commitments and award payments, noting that only award payments are expenses and included in the budget. Trent then presented the Proposed FY 2023 PCORI Budget by Major Budget Component and Funding Area (see Attachment A), which includes Award Payments (representing 78% of the total FY 2023 budget or $351 million), Programs & Program Support (14% or $63 million), and Administrative Support (8% or $37 million). He also noted differences between the FY 2023 budget and FY 2022 projections. Board questions related to PCORI's fund balances, the impact of inflation on PCORI's research community, and the funds projected to be available at the end of FY 2023. Members of the FAC shared their perspective that PCORI's projected fund balances at the end of FY 2023 are reasonable and reflect PCORI's efforts to achieve the aggressive targets laid out in PCORI's Funding Commitment Plan. *The following motion was made by Sharon Levine and seconded by Alicia Fernandez.* **Motion**: Approve the Proposed FY 2023 PCORI Budget *Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions).*
Consider for Approval: • Proposed Governance Framework	Dr. Goertz reminded the Board that the Work Group to Optimize Effective Governance and Board Engagement (Work Group), which was created in March 2022, aimed to develop an evolved approach for the Board's strategic oversight that advances PCORI's new Strategic Plan and reauthorization priorities.

Kathleen Troeger, MPH, Chair, Work Group to Optimize Effective Governance and Board Engagement *Christine Goertz, DC, PhD, Vice Chair, Work Group to Optimize Effective Governance and Board Engagement* *Nakela L. Cook, MD, MPH*	Work Group Chair Kathleen Troeger recognized the Work Group members and thanked them for their sustained efforts and active participation to advance this work. She expressed the Work Group's support for and endorsement of the proposed governance framework to be considered by the Board. Dr. Cook provided an overview of the proposed governance framework, which would: • **Retain the following standing committees**: Governance Committee, Finance and Administration Committee (FAC), Executive Evaluation and Compensation Subcommittee (EECSC), and Executive Committee • **Create a new standing Strategy Committee** • **Pause the convenings of the three current standing Strategy Committees** (Engagement, Dissemination, and Implementation Committee; Research Transformation Committee; Science Oversight Committee) • **Expand the standing Selection Committee** to include consideration of additional award types • **Formally incorporate ad hoc work groups** into the governance framework • **Assess the new governance framework** to determine if it is achieving the desired outcomes Goertz noted that the Work Group's proposal stemmed from the Board's focus over the past 2.5 years on advancing PCORI's governance culture and enabling the Board's governance structure to support PCORI. She expressed her appreciation to the Work Group and then opened the floor for discussion. Board members commented on the implications of the new governance framework on other committees, including the existing strategic related committees and the Executive Committee. It was noted that if the proposed governance framework is approved by the Board, the Governance Committee would consider implementation and transition issues and make recommendations to the Board. *The following motion was made by James Schuster and seconded by Kathleen Troeger.* **Motion**: Approve the Proposed Governance Framework *Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions).*
Consider for Approval: • Proposed Strategies to Leverage PCORnet® to Advance PCORI's National Priorities for Health and Evaluate PCORnet Performance	Dr. Zwolak and Dr. Kara Ayers, Chair and Vice Chair of the PCORnet® Priorities Work Group – Stage Two, respectively, provided introductory remarks, and thanked Work Group members for their engagement and collaboration. Dr. Erin Holve thanked Zwolak and Ayers for their leadership of the Work Group and added that the focus of the Stage Two Work Group was to build on the Board-approved PCORI Prioritizing Principles for Infrastructure Funding Relating to PCORnet (recommended by Work Group Stage 1) to: (1) propose strategies to inform PCORI's evaluation framework for PCORnet and guide future Board consideration of the accomplishments of PCORnet that are due to PCORI infrastructure funding and to inform decisions about future PCORI investments to maintain and enhance PCORnet; (2) propose cross-cutting strategies to integrate and leverage PCORnet to advance PCORI's National Priorities for Health; and, (3) provide information, reports, and

Robert Zwolak, Chair, MD, PhD, PCORnet Priorities Work Group *Kara Ayers, PhD, Vice Chair, PCORnet Priorities Work Group* *Erin Holve, PhD, MPH, MPP, Chief Research Infrastructure Officer*	recommendations to inform deliberations by the Strategy Committees, the Board Strategic Planning Committee, and the Board. Holve reviewed four crosscutting strategies recommended by the Work Group to leverage PCORnet to advance PCORI's National Priorities for Health: • **Fund Research that uses the PCORnet infrastructure** to conduct definitive studies that advance the National Priorities for Health. In addition to other patient-centered CER priorities, special attention should be given to intellectual and/or developmental disabilities, maternal morbidity and mortality, health equity, and rare disease research. • **Invest in PCORnet infrastructure to continuously learn and improve** by: o Maintaining baseline network functions and enhancing data quality and network research capacity to ensure effective study execution; o Accelerating participation of diverse, underrepresented and underserved populations, including in network governance and among investigators using PCORnet; o Supporting PCORnet coverage that is comparable to the general United States population; o Innovating to advance PCORI's National Priorities for Health, including enhancing data capacity (e.g., non-clinical data) and open science to accelerate progress toward an integrated learning health system; o Enhancing engagement infrastructure to support meaningful patient and stakeholder partnership in network governance and all stages of the research process and contribute to advancing the science of engagement. • **Expand the use of PCORnet** by enhancing: o Visibility and stakeholder understanding of the unique capabilities of PCORnet as a disease-agnostic network capable of supporting the full trajectory of research and a range of study designs (e.g., platform trials, pragmatic trials, high-quality observational studies) that facilitate the development and execution of patient-centered CER studies; o Access and use by researchers, patients, caregivers, communities, health systems, and other health stakeholders; o Partnerships with other organizations to support conduct of research aligned with PCORI strategic priorities. • **Increase the use of PCORnet** for PCORI's operational and strategic priorities. Holve then reviewed three strategies recommended by the Work Group to evaluate performance of PCORnet: • **Use continuous monitoring and evaluation** to: o Contribute to PCORnet Network Partners' capacity to continuously learn and improve; o Inform Board's strategic planning and decision-making about 1) baseline network functions and maintenance and 2) innovation and expansion of network functions; and o Assess performance of the Network as a whole and all participating Network Partners – CRNs and Coordinating Center – and sites. • When evaluating PCORnet performance: o In considering the network research capacity to ensure efficient and effective study execution, prioritize better and faster over cheaper;

	o Consider the evaluation needs and perspectives of the different stakeholders in the PCORnet ecosystem (e.g., PCORI, PCORnet governance, CRN leaders and staff, patients, clinicians, health systems, PCORnet users and potential users) as well as stakeholders' roles and how they contribute to PCORnet success; o Benchmark PCORnet performance against appropriate comparators whenever possible. • Align evaluation of PCORnet with: o PCORI's Strategic Plan, National Priorities for Health, Research Agenda, and organization-wide strategy for monitoring progress and measuring success; o Maturity of PCORnet, by developing and leveraging a maturity model that defines expectations for PCORnet performance at multiple levels of maturity (e.g., emerging, intermediate, advanced) for a set of key domains (e.g., research, data and technology, engagement). Following Holve's presentation, several Work Group members expressed their strong endorsement of the proposed strategies. Zwolak commented that it was appropriate for PCORI to continue to lead the advancement of PCORnet and noted that it will be important for the Board to consider where strategic consideration of PCORI's next phases of funding PCORnet fits within PCORI's evolving governance model. The Board's discussion focused on a variety of issues such as planning for strategic discussions regarding the next phases of PCORI funding of PCORnet, evaluation factors, considering how PCORnet enables CER tied to PCORI priorities, whether PCORnet could be leveraged to understand patient outcomes based on payment models, addressing challenges related to accessing social determinant health data, and engaging underserved populations. Board members also requested additional information on demographic data of PCORnet at a future meeting. *The following motion was made by Sharon Levine and seconded by Mike Herndon.* • **Motion**: Approve the Strategies to Leverage PCORnet® to Advance PCORI's National Priorities for Health and Evaluate PCORnet Performance *Approved by a majority vote of the voting Board members by voice vote: no opposed; no abstentions; 1 recusal (Kathleen Troeger)*
Fond Farewell to Outgoing Board Members *Nakela L. Cook, MD, MPH, Executive Director*	Dr. Goertz noted that this would be the last Board meeting for four founding Board members including herself, along with Sharon Levine, Ellen Sigal, and Robert Zwolak. Dr. Nakela Cook then expressed her appreciation for their contributions to PCORI and to the advancement of PCORI's mission during their 12 years of service. Cook then reviewed each outgoing Board member's service and contributions to PCORI and invited each outgoing Board member to share brief reflections on their service and advice for the future. Each outgoing Board member provided comments and reflections.

Wrap-up and Adjourn *Christine Goertz, DC, PhD, Board Chairperson*	Dr. Goertz thanked all who joined the meeting and noted that the meeting agenda, slides, and archived webinar from today's meeting, and minutes from the previous meeting would be posted to the PCORI website within the week. Goertz then reminded Board members that the next Board meeting will be held on December 13, 2022. She noted that no individuals had registered to speak during the public comment period of the Board meeting and thus no public comments will be received. The meeting was adjourned at 12:05pm.

Attachment A:

Proposed FY 2023 PCORI Budget
By Major Budget Component and Funding Area
$ in millions

EXPENSES	FY 2023 Proposed Budget			FY 2022 Year-End Projection			Increase/ (Decrease)		
PROGRAM SERVICES									
Award Payments									
Research*	$	263.6	59%	$	225.0	59%	$	38.6	17%
Dissemination & Implementation		27.7	6%		20.9	5%		6.8	32%
Infrastructure		59.4	13%		49.2	13%		10.2	21%
Total Award Payments		**350.7**	**78%**		**295.1**	**77%**		**55.6**	**19%**
Total Programs & Program Support		**63.2**	**14%**		**54.5**	**14%**		**8.7**	**16%**
TOTAL PROGRAM SERVICES		**413.9**	**92%**		**349.6**	**91%**		**64.3**	**18%**
Total Administrative Support		**37.1**	**8%**		**35.7**	**9%**		**1.4**	**4%**
TOTAL EXPENSES	**$**	**451.0**	**100%**	**$**	**385.3**	**100%**	**$**	**65.7**	**17%**

* Includes $1 million in Rapid Response payments