PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting via Teleconference / Webinar

Tuesday, January 12, 2021

1:00-3:00 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; David Meyers, MD (designee for Gopal Khanna, MBA); Barbara McNeil, MD, PhD; 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

Agenda Item	PCORI Speakers
Welcome and Call to Order **Consent Agenda: Consider for Approval:** • Minutes of the Dec 7 and 8, 2020 Board Meeting • Nominations for New Committee Membership *Christine Goertz, DC, PhD, Board Chairperson*	Dr. Goertz chaired and opened the meeting, welcomed all to the January 12, 2021 meeting of the PCORI Board of Governors, and read the Chair Statement on Conflict of Interest. Goertz reminded Board members and Methodology Committee members to complete their annual updating of conflict of interest disclosures. She then reviewed the agenda for the meeting. Goertz then introduced the Consent Agenda and gave the opportunity to Board members to discuss any of the matters on the Consent Agenda. No separate discussion was requested. *The following motion was made by Sharon Levine and seconded by Kara Ayers.* **Motion**: That the Board: • Approve Minutes of the December 7 and December 8, 2020 Board Meeting • Appoint the nominated Board members to the specified PCORI Board and Board-related Committees: <u>Engagement, Dissemination, and Implementation Committee</u> Tanisha Carino, James Huffman, Connie Hwang, Danny van Leeuwen <u>Research Transformation Committee</u> Kate Berry, Eboni Price-Haywood <u>Science Oversight Committee</u> James Schuster

	Finance and Administration Committee Kate Berry, James Huffman Governance Committee James Schuster, Danny van Leeuwen *The motion was approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions).*
Consider for Approval: • Addition to the Cycle 1 2020 Broad PFA Slate of Awards *Barbara McNeil, MD, PhD, Chair, Selection Committee, Nakela Cook, MD, MPH, Executive Director and Steve Clauser, MPA, PhD, Program Director, Healthcare Delivery & Disparities Research (HDDR)*	Dr. McNeil made introductory remarks on behalf of the Selection Committee, noting that the Board approved the Cycle 1 2020 Broad PFA Slate of Awards on November 17, 2020 and, after programmatic review, the Selection Committee is now recommending to the Board funding an additional award for this slate. She then introduced Dr. Cook and Dr. Clauser to provide details regarding the proposed addition to the Cycle 1 2020 Broad PFA slate of awards. Clauser then introduced the additional proposed award. The additional award comes from the Improving Healthcare Systems priority area and is titled "Helping Patients Achieve Kidney Transplants through Health System Change". With the additional project, the proposed total award for the Cycle 1 2020 Broad PFA Awards is $40.5M. This leaves $249.5M available to fund research awards for all PFAs in Cycle 2 and Cycle 3 2020. Cook noted that this cycle was unusual due to high number of deferrals of applications granted due to the COVID-19 pandemic. Nineteen applications were deferred from Cycle 1 2020 and are currently under review. *The following motion was made by Russell Howerton and seconded by Robert Zwolak.* **Motion**: Approve funding for the addition of the recommended project to the slate of awards from the Cycle 1 2020 Broad PFAs. *The motion was approved by a majority vote of the voting Board members by roll call vote: 18 approved, none opposed, none abstained, 2 recused (Michael Lauer and Christine Goertz). Ellen Sigal was not present for this vote.*
Consider for Approval: • PCORI Prioritizing Principles for Infrastructure Funding Relating to PCORnet®	Dr. Zwolak introduced to the Board a recommendation to approve the *Prioritizing Principles for Infrastructure Funding Relating to PCORnet* as proposed by the PCORnet Priorities Workgroup. Zwolak summarized that the charge of the PCORnet Working Group, composed of members of the PCORI Board and Methodology Committee, was to propose a set of

Robert Zwolak, MD, PhD, Chair, PCORnet Priorities Workgroup *Lesley Curtis, PhD, Duke Clinical Research Institute and Co-Principal Investigator, PCORnet Coordinating Center* *Neely Williams, EdD, PCORnet Steering Committee Patient Partner* *Tom Carton, PhD, MS, Louisiana Public Health Institute and PCORnet Steering Committee Chair*	prioritizing principles that align closely with PCORI's overall strategic planning and be used by the PCORI Board and staff to guide decision-making about PCORI infrastructure funding for future stages of PCORnet. Additionally, he stated that these principles would be used to inform the development of performance metrics that will be built into funding announcements and utilized for contract monitoring. Zwolak emphasized that the PCORnet Priorities Working Group was not asked to complete a comprehensive analysis of governance nor to develop a list of research topic priorities for PCORnet. Zwolak then summarized three defining characteristics of PCORnet. He first explained that PCORnet is national in scope and represents a federated network of networks, which allows for representation of a large segment of the American population in large-scale research studies. The second defining characteristic of PCORnet is patient-centricity, where patients are at the center of PCORnet. PCORnet participants promote a culture of patient-centeredness at every level of the network. The third defining characteristic he highlighted was the unique data structures that set PCORnet infrastructure apart from other prominent research networks through its common data model and ability to facilitate connections to patients . He emphasized that the success of PCORnet is rooted in an established trust among network partners and stakeholders, which acts as the foundation of the network. Zwolak then introduced three leaders actively involved in the governance structure of PCORnet and invited them to share their experiences and perspectives on PCORnet. Lesley Curtis, PhD, Co-Principal Investigator (PI) of the PCORnet Coordinating Center noted that PCORnet data infrastructure is optimized for trust, and clinicians and patients are actively engaged. She emphasized that a key feature of the data infrastructure is the data curation, which is centralized and coordinated, keeping data quality as the major focal point. Neely Williams, EdD, PCORnet Steering Committee Patient Partner, added that being a PCORnet patient partner has been a learning experience has opened her eyes to the importance of the patient's role in research and supporting a national network. Williams highlighted the strengths of patient partner participation in PCORnet and how this has built a strong partnership and trust with those involved. Lastly, Tom Carton, PhD, MS, PI of REACHnet CRN, provided a brief overview of the governance role of the PCORnet Steering Committee emphasizing the network representation and voting structure that includes stakeholder voices during decision-making processes. He also highlighted the numerous PCORnet Workgroups that network partners can participate in and explained that PCORnet is governed with the intention for learning and has fostered a culture of trust among network partners.

	Zwolak then presented the eight *Prioritizing Principles for Infrastructure Funding Relating to PCORnet* proposed by the PCORnet Priorities Working Group and asked for Board questions or comments. He explained that the eight prioritizing principles fall under three themes: patient-centeredness, national scope, and governance and partnerships. Regarding the national scope focused principles, one Board member asked for clarification on what is meant by "national scope" and whether the intention is to expand PCORnet beyond the current Clinical Research Networks (CRNs). Curtis responded that the PCORnet infrastructure provides unique opportunities for collaborations for large definitive studies. Carton added that while some CRNs have smaller geographic footprints, others have participating sites across the country. Zwolak provided additional clarification by stating national scope is also an effort to get a better cross-sectional representation within research. Several Board members inquired if previous multi-network studies that used the PCORnet infrastructure have been seamless or if there were delays and challenges faced. Curtis responded by mentioning the ADAPTABLE study, indicating that this was the first time the PCORnet networks mobilized on such a large scale for a research study. She acknowledged that this first experience was not seamless and emphasized this experience led to the establishment of processes and approaches that enable the Network Partners to work through problems quickly. She also noted that the launch of the HERO Research Program demonstrated how the Network Partners subsequently leveraged these processes as well as existing relationships and trust to initiate the research program quickly. Board members noted that producing results quickly will remain a critical metric for PCORnet. Lastly, a member of the PCORnet Priorities Working Group, added that the value of a national scope and multi-network participation is that the infrastructure builds engagement capacity. Next, the Board discussed prioritizing principles related to governance and partnerships. One Board member asked for clarification regarding the prioritizing principle that recognizes, enables, and promotes the value of PCORnet to contribute to a learning health care system through effective partnerships with all stakeholders and the need for educational resources needed to achieve this goal. Zwolak explained that the underlying concept refers to the need for educational materials that can engage many types of stakeholders utilizing the network. Board members also requested clarification regarding the development of a shared governance model, what principles or metrics would guide this effort, and how the principles would be operationalized to achieve a more nuanced governance model. Cook responded by stating that development of the prioritizing principles was just the first step in the

	process and that the principles would inform the creation of metrics to achieve the goals outlined. A member of the PCORnet Priorities Working Group commented that their view of the principles is that they are aspirational and act as guidance for the work that still must be done. Zwolak agreed that the focus of the prioritizing principles is to guide the Board and PCORI staff. Board members emphasized the importance of ensuring PCORnet is utilized to truly benefit people and explained the need for safeguards to meet this goal. One Board member added that participation in the governance model of other stakeholders external to PCORnet may be one strategy to ensure that PCORnet continues to work for the public good. Another Board member added that another strategy to achieve this goal could be inclusion of PCORI as a voting member in PCORnet governance. Zwolak reiterated that the PCORnet Priorities Working Group was not charged with reviewing the current governance model and Board members agreed that there should be further discussion on the structure of oversight and monitoring of PCORI funding relating to PCORnet. There was a recommendation to charge the Research Transformation Committee to continue these conversations regarding PCORnet governance. Dr. Nakela Cook, PCORI's Executive Director, added that PCORI will have consultations with external parties and this analysis can be brought to the PCORnet Priorities Working Group and PCORI strategic committees to formulate next steps. A Board member stated that they believe a Continuous Quality Improvement (CQI) analysis of PCORnet would be beneficial. Zwolak added that PCORI has contracted with an organization to evaluate the functions and role of the PCORnet Coordinating Center, which may provide information about some of the questions posed. Cook added that the evaluation and expected report are not focused on PCORnet governance but rather the structure and function of the Coordinating Center. *The following motion was made by Kathleen Troeger and seconded by Barbara McNeil:* **Motion:** Approve the PCORI Prioritizing Principles for Infrastructure Funding Relating to PCORnet as proposed by the PCORnet Priorities Workgroup. *Approved by majority vote of the voting Board members by roll call vote: 17 in favor, 2 abstained (Christopher Friese and Alicia Fernandez), 1 recusal (Jennifer DeVoe). David Meyers was not present during this vote.*
Consider for Approval: • Funding Opportunities for Infrastructure	Ms. Troeger introduced to the Board a request to approve the development and release of infrastructure funding opportunities related to Phase 3 of PCORnet. She noted that the Research Transformation

Funding Relating to PCORnet Phase 3 and Funding Commitment *Kathleen Troeger, MPH, Chair, Research Transformation Committee and Nakela Cook, MD, MPH, Executive Director and Kim Marschhauser, PhD, Senior Program Officer*	Committee voted on January 6, 2021 to recommend that the Board approve this funding commitment. Troeger then introduced Dr. Cook, who stated this request was consistent with PCORI's three-year funding commitment plan approved by the Board in December 2020. She also noted that this recommendation for Phase 3 infrastructure funding aligns with the Board-approved *PCORI Prioritizing Principles for Infrastructure Funding Relating to PCORnet*. Cook introduced Dr. Marschhauser who outlined the envisioned plan for the development and release of infrastructure funding opportunities for Phase 3 of PCORnet. Marschhauser explained that the "barebones" estimate of funding support needed to sustain the PCORnet research infrastructure is $20 million a year for nine Clinical Research Networks (CRNs) and $6 million a year for coordinating center functions. Marschhauser noted that the total estimated costs for each CRN is $1.5 to $2 million a year with a majority of the CRN budget supporting data and research readiness activities. She also noted that for Phase 3 of infrastructure funding for PCORnet, PCORI anticipates utilizing a limited competition solicitation to invite applications from CRNs currently funded to participate in PCORnet. Marschhauser noted that coordination of network resources and capabilities is also critical to the success of Phase 3 of PCORnet. She added that based on historical data, PCORI staff estimate the total yearly costs for coordinating center functions to be $6 million a year with the majority of the budget to support data infrastructure management including maintenance of the PCORnet Common Data Model, data curation, and query fulfillment. Marschhauser explained that PCORI staff anticipate utilizing separate funding solicitations in Phase 3 for each major coordinating center function to enable a strong merit review process and to facilitate effective funding of different coordinating center functions. After the presentation, several Board members asked for clarification to understand how the funding request to maintain PCORnet infrastructure in Phase 3 was aligned with the Board approved *PCORI Prioritizing Principles for Infrastructure Funding Relating to PCORnet.* Cook responded that the *PCORI Prioritizing Principles for Infrastructure Funding* serve as building blocks and implementation of the Prioritizing Principles will require further planning and consultation with external experts before they can be fully operationalized. PCORI staff will engage with Board strategy committees and the Board regarding future plans for expansion of the PCORnet infrastructure to operationalize the approved Prioritizing Principles.

	Several Board members asked whether CRN applicants would have to meet performance metrics, including for sites, for continued funding in Phase 3. Cook confirmed that Phase 3 solicitations will be competitive, and that funding will not be guaranteed. PCORI will utilize a multi-phase merit review process for selection and award of Phase 3 funding. Applications will be limited to current CRNs, but CRNs have the ability to add new sites or researchers to their existing networks. *The following motion was made by Michael Lauer and seconded by Robert Zwolak:* **Motion:** Approve the development and release of funding opportunities of up to $78 Million for infrastructure funding relating to Phase 3 of PCORnet *Approved by a majority vote of the voting Board members by roll call vote: 13 In favor, 1 abstention (Christopher Friese), 6 recusals (Jennifer DeVoe, Alicia Fernandez, Christine Goertz, Barbara McNeil, Eboni Price-Haywood and James Schuster). David Meyers was not present during this vote.*
Discussion: • Developing Targeted PFAs in the Short-Term while Strategic Planning is Underway *Nakela Cook, MD, MPH*	Time did not allow for the discussion of this agenda item, which instead will be included on the agenda for the February Board Meeting.
Wrap-up *Christine Goertz, DC, PhD*	Board meeting ended at 2:59 pm Eastern

Minutes were approved by the PCORI Board of Governors 02-09-2021