PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting via Teleconference / Webinar

Tuesday, September 15, 2020

1:30pm - 4:45 pm ET

MINUTES

Board Members Present:
Christine Goertz, DC, PhD, *Chairperson;* Sharon Levine, MD, *Vice Chairperson*; Kara Ayers, PhD; Larry Becker; 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; Gail Hunt; Freda Lewis-Hall, MD; David Meyers, MD (designee for Gopal Khanna, MBA); Barbara McNeil, MD, PhD; Grayson Norquist, MD, MSPH; Ellen Sigal, PhD; Kathleen Troeger, MPH; Robert Zwolak, MD, PhD

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

Executive Team: Nakela Cook, MD, MPH, *Executive Director*; Josie Briggs, MD; Steve Clauser, MPA, PhD; Mary Hennessey, Esq.; Stanley Ip, MD; Michele Orza, ScD; Tasha Parker; Laura Rodriguez, PhD; Jean Slutsky, PA, MSPH

Agenda Item	PCORI Speakers
Welcome and Call to Order - *Christine Goertz, DC, PhD Board Chairperson*	Dr. Goertz chaired and opened the meeting, welcomed all to the meeting of th PCORI Board of Governors and read the Chair Statement on Conflict of Interest She then reviewed the meeting agenda.
PCORnet Update • **Consider for Approval:** PCORnet Extension Funding - *Josie Briggs, MD, Senior Advisor to the Executive Director* - *Kim Marschhauser, PhD, Senior Program Officer, Research Infrastructure* - *Claudia Grossman, PhD, Senior Program Officer, Research Infrastructure*	Dr. Briggs introduced a proposal to approve up to $17 million in funding to extend infrastructure projects of the PCORnet networks and the PCORnet Coordinating Center. She explained the PCORI Board approved the FY2020 budget in September 2020 which included $37 million in funding for PCORnet. She described the current request to commit $17 million of the allocated $37 million to extend the current PCORnet infrastructure projects. Briggs stated that this request for extension and reallocation of funds was reviewed by the PCORI Research Transformation Committee, which recommended that the Board approve the extension funding. She explained that the proposed extension funding would allow time for an internal and external evaluation of the PCORnet Network Partners as well as provide time for the Board to develop a strengthened strategic vision for PCORI's funding of PCORnet. Next, Dr. Marschhauser provided an update on PCORnet dashboard metrics to highlight the activity of the PCORnet Network Partners. She explained that over the last five years the PCORnet Network Partners have authored over 300 publications. She also described several dashboard metrics related to the PCORnet Front Door including the number of visitors, types of visitors, as well as their reason for visiting the Front Door. Marschhauser also noted that the PCORnet Front Door team is tracking the number of successful collaborations that result in funded studies and that updated information in this area will be shared in the coming months.

	Briggs then provided an overview of PCORnet infrastructure utilization in current PCORI funding opportunities. She highlighted two comments that have been expressed including the notion that PCORI was not using the PCORnet infrastructure for research as much as they could and that PCORI should be doing more comparison studies. Briggs emphasized three PCORI solicitations which aim to mitigate these concerns: PLACER, Rare Disease, and Observational Analyses of Second-Line Pharmacological Agents in Type 2 Diabetes. These funding initiatives aim to utilize the power of the PCORnet resources. Briggs then discussed the PCORnet Network Partner data and research efforts to facilitate COVID-19 related research. Next, Briggs discussed PCORI's investment in the development of the PCORnet infrastructure. She began by outlining the original vision in creating PCORnet, highlighting how it was an ambitious effort to improve the nation's capacity to conduct research. Briggs explained that PCORI's focus this year was to optimize the infrastructure to facilitate research to answer important COVID-19 related research questions. She noted that to date, PCORI has invested $131.3 million in PCORnet research and $357.4 million to support the PCORnet infrastructure. Briggs explained that infrastructure funding was the highest when the infrastructure was being developed but ongoing maintenance costs should be approximately $25 million a year. Briggs outlined a plan for evaluating the performance of the PCORnet Network Partners and the PCORnet Coordinating Center. She noted that the internal PCORI evaluation is underway to analyze Clinical Research Network site performance including data quality, linkage performance, population diversity, network management, and level of participation in research. Briggs stated that she believes this assessment will inform future funding decisions as well as inform merit review for a Phase 3 PFA. She also discussed the external Coordinating Center evaluation that is currently underway. Dr. Grossmann outlined the timeline and proposed next steps for a Phase 3 of PCORnet. She noted that the goal would be to have new network and Coordinating Center funding award contracts finalized by late summer 2021. Grossmann then discussed the FY2020 budget allocations for PCORnet as discussed earlier by Dr. Briggs. She explained that this request to commit $17 million to extend funding for the current Network contracts to 2021 will allow the necessary time for these evaluations and a Phase 3 merit review process. Following the presentation, a Board member inquired about the completion of the PCORnet ADAPTABLE pragmatic trial. Marschhauser noted that recruitment has been completed and the study team is analyzing the data. She reminded the Board that this is a demonstration project with a PCORnet evaluation aim. PCORI staff will provide the results of this evaluation to the Board. Another Board member discussed the strategic work ahead for the PCORI Board and explained that the strategic vision for PCORnet needs to align with the overall PCORI strategic plan. There was also a recommendation to expand the PCORnet dashboard metrics to look at user satisfaction with the Front Door rather than just tracking the number of visitors. There was also a clarifying question on whether the request for extension funding would be for all currently funded Clinical Research

	Networks and Health Plan Research Networks. Briggs explained that the extension funding would not be competitive and that the process for competing and reconfiguration of PCORnet would take place in the next phase after an external merit review. *The following Motion was made by Kathleen Troeger and seconded by Ellen Sigal:* **Motion:** Approve up to $17 million in funding to extend infrastructure projects of PCORnet networks and the PCORnet Coordinating Center. *Approved by a majority vote of the voting Board members by roll call vote: 13 in favor; 0 opposed; 1 abstained: Christopher Friese; 3 recusals (Jennifer DeVoe, Christine Goertz, and Barbara McNeil. Michelle McMurry-Heath indicated earlier her intention to recuse but was not present at this meeting. Alicia Fernandez was not present during this vote.*
Consider for Approval: • Commitment Plan - *Nakela Cook, MD, MPH Executive Director*	**Commitment Plan:** Dr. Cook shared four options for the 2021-2030 Commitment Plan Model, which include a consistent steady-state model, a rapid ramp up/ramp down model, and two models that combine an early peak in commitments with subsequent steady-state. She provided details on the four models, including considerations for operations, flexibility for large commitments, cash flow, and timing of results. Cook provided an example of Commitment Plan materials that will be developed when a model is selected. She shared the projected 3-year Commitment Plan for the model called Hybrid Model #2, which includes details on the line items for Research, Dissemination and Implementation, Infrastructure/Accelerating PCOR, and New Initiatives. She provided further details on staffing and operations considerations, and potential metrics and targets for tracking PCORI's progress. Board Members expressed interest in both Hybrid Models #1 and #2 (referred to as "Hybrid Model #1.5), which offer both an early peak in research and flexibility for funding in later years. Board members coalesced around an approach that was between the two hybrid models. The key characteristics of the model recommended by the Board was an early peak of $600M in commitments, flexibility in later years for dissemination and implementation, and flexibility for PCORI staff to be adaptive as needed. *The following motion was made by Larry Becker and seconded by Mike Herndon:* **Motion:** Approve the development of a proposed 3-year Commitment Plan consistent with "Hybrid Model #1.5," with key elements characterized as: • Early peak of $600M in commitments • Flexibility in later years for dissemination and implementation • Flexibility for PCORI staff to be adaptive *Approved by a majority vote of voting Board members by voice vote (no opposed; no abstentions).*

• FY2021 Expense Budget - *Larry Becker, Chair,* - *Finance and Administration Committee (FAC) and Nakela Cook, MD, MPH, Executive Director*	**FY2021 Expense Budget:** Mr. Becker and Dr. Cook presented the Proposed FY2021 Budget of $399 million, as recommended by the FAC, for Board approval. Cook explained key terms relating to the budget, including the difference between award commitments and award payments, and noted that only award payments are expenses and included in the budget. She summarized the projected FY2020 and FY2021 fund balances and then presented the major components of the FY2021 budget, which include Award Payments (representing 80% of the total FY2021 Budget or $317 million), Other Direct Program Costs (8% or $33.3 million), Program Support Services (5% or $19.2 million), and Administrative Support (7% or $29.1 million). She also noted the differences between the FY2021 budget, FY2020 projections and FY2020 approved budget. Board members were invited to ask questions and discuss the proposed FY2021 budget. No additional questions were raised. *The following motion was made by Larry Becker and seconded by Mike Herndon:* **Motion:** Approve the Proposed FY2021 Budget. *Approved by a majority vote of the voting Board members present by roll-call vote (17 in favor; no opposed; no recused, no abstentions). Ellen Sigal was not present during this vote.*
Report from Strategic Planning Committee - *Sharon Levine, MD and Nakela Cook, MD, MPH*	Dr. Cook presented the proposed approach for strategic planning on behalf of the Strategic Planning Committee (SPC). The presentation included review of the purpose of the SPC; review of a revised strategic framework; the expected sequencing of activities throughout strategic planning; consideration of the inputs received thus far on the process; and discussion on additional inputs the Board would find useful as it develops PCORI's strategy. Cook walked through the original strategic planning framework developed in 2013; this was followed by review of a proposed new strategic framework. The revisions included making the strategic goals mid-term goals and shifting the National Priorities to long term goals for health, not just research. This shift, Cook explained, would cover the range of activities that PCORI pursues inclusive of research, engagement, and dissemination and implementation. The proposed framework also focuses on an emphasis on impact for the next phase for PCORI. Board members coalesced around the revised strategic framework and the concept to shift the National Priorities from specific to research to relating more broadly to health. Board members provided other sources of inputs to the strategic planning process and made recommendations for engaging with various entities. A theme emerged to discuss and engage with groups not generally included such as researchers who have yet to engage with PCORI and care providers in unique settings like socioeconomically challenged rural or urban settings. In regard to identification of the National Priorities, which is the first large

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	component encompassed in strategic planning, the Board commented on the opportunity to impact health and healthcare through a Priority related to care delivery and focusing on the quality of care. Discussion took place on the need for the strategic plan to provide a flexible approach for PCORI to achieve its mission given the potential for changes in the health landscape over the next several years.
Panel Discussion with Outgoing Board Members • Reflections on 10 years of Board service and vision for the future - *Larry Becker, Gail Hunt, Freda Lewis-Hall, MD, and Grayson Norquist, MD, MSPH*	The Board members whose terms will end on September 22, 2020, all of whom were appointed by the GAO to the PCORI Board in 2010, were asked to present on their thoughts and experiences from serving on the PCORI Board, and what advice they would pass onto future Board members. These members were Larry Becker, Gail Hunt, Freda Lewis-Hall, and Grayson Norquist. The panel discussed the importance of engaging with and listening to the full range of PCORI's stakeholders, from patients and caregivers to policy-makers. It was said that diverse opinions can work together in a collegial manner and stressed the importance of balancing stakeholder input. The panel was asked what role they held during their PCORI Board service that resonated with them the most. Responses included chairing the first Conflict of Interest Committee, chairing the Research Transformation Committee, and the opportunity to speak with stakeholders across the country. A highlight for two outgoing members was a visit by the Board to New Orleans to visit a health clinic. PCORI Staff were given the opportunity to ask questions of the outgoing Board members which included questions related to advice for PCORI staff, and in what areas PCORI should make progress on in the next 10 years. Members expressed interest in further progress in implementation, evidence synthesis, communications with patients, and research related to public health.
Public Comment Period - *Kristin Carman, MA, PhD, Director, Engagement, Public and Patient Engagement*	No members of the public requested the opportunity to make a public comment. Thus, there were no public comments presented during this time.
Wrap up and Adjournment - *Christine Goertz, DC, PhD*	Meeting adjourned at 3:54 pm

Minutes were approved by the PCORI Board of Governors 11-17-2020