

**Board of Governors Meeting via Teleconference / Webinar**

Tuesday, September 28, 2021

2:30-4:30 pm ET**MINUTES****Board Members Present:**

Christine Goertz, DC, PhD, *Chairperson*; Sharon Levine, MD, *Vice Chairperson*; Kara Ayers, PhD; Kate Berry; Tanisha Carino, PhD; Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Christopher Friesse, PhD, RN; Mike 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: Francis Collins, MD, PhD; Michelle McMurry-Heath, MD, PhD; Janet Woodcock, MD

Guest: The Honorable Senator Bill Cassidy, MD (R-LA)

Agenda Item	PCORI Speakers
Welcome and Call to Order - <i>Christine Goertz, DC, PhD, Board Chairperson</i>	Dr. Goertz chaired and opened the meeting, welcomed all to the meeting of the PCORI Board of Governors and read the Chair Statement on Conflict of Interest. She then reviewed the meeting agenda.
Consider for Approval: Award Slates - <i>Nakela, L. Cook, MD, MPH, Executive Director</i>	Dr. Cook provided contextual information regarding the three award slates to be considered by the Board: the addition to the slate of awards for the Cycle 3 2020 Phased Large Award for Comparative Effectiveness Slate (PLACER) (Table A); the slate of awards for the Cycle 1 2021 Dissemination & Implementation Limited Competition PFA, and the slate of awards for Clinical Research Award infrastructure projects for the Cycle 1 2021 PCORnet Phase 3. Cook noted that the PLACER slate was approved by the Board of Governors on July 27, 2021, which totaled \$135M. With the addition of this proposed award to this slate, the amount awarded will total \$168M. Cook indicated that PCORI will see the second round of PLACER awards in Cycle 3 2021. Cook also provided information about the D&I award slate, highlighting the numbers of LOIs submitted, LOIs invited, applications submitted, and applications proposed for funding, with historic information.

Addition to the Slate of Awards from the Cycle 3 2020 Phased Large Awards for Comparative Effectiveness Research (PLACER) - <i>Anne Trontell, MD, MPH, Associate Director, Clinical Effectiveness and Decision Science</i>	Cook indicated that the PCORnet Phase 3 PFA was meant to focus on optimization of previously funded networks, following Phase 1, which focused on Design and Phase 2, which focused on Building Capacity. Cook noted the current slate of proposed Clinical Research Network infrastructure projects comprises \$61M. Cook indicated that the total funding for all the proposed slates of awards brought to the Board today will result in exceeding the targeted funding for this fiscal year in the Commitment Plan. She indicated that the applications for these funding announcements were strong and that overall there is sufficient funding for these awards, given that the anticipated commitments are intended to ramp up in the years following PCORI's reauthorization. ***** <u>PLACER: Colonoscopy versus stool-based testing for older adults with a history of colon polyps Application</u> Dr. Trontell introduced the additional proposed application to the PLACER slate, stating that additional time was needed before the Selection Committee recommended this application to be approved by the Board. Trontell gave a brief overview of the application and noted how the application would complement the slate approved by the Board in July. Discussion included clarification of endpoints of the study and Trontell confirmed the study will be 6.5 years including a yearlong feasibility phase. Each patient's participation begins when scheduled for their surveillance colonoscopy. Further discussion included questions regarding economic impact to the patient. Dr. Thuy-Vy Do, PCORI Science Program Officer, noted that this aspect was not included in the application but could be discussed during contract negotiations with the study team. <i>See Table A for the addition to the PLACER slate.</i> <i>The following motion was made by Mike Herndon and seconded by Jennifer DeVoe.</i> Motion: Approve funding for the recommended additional project to the slate of awards from the Cycle 3 2020 Phased Large Award for Comparative Effectiveness Research (PLACER) PFA
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**Cycle 1 2021 Limited Competition
Dissemination and Implementation PFA**

- *Michael Herndon, DO, Chair, Engagement, Dissemination, and Implementation Committee (EDIC) and Joanna Siegel, SM, ScD, Director, Dissemination and Implementation (D&I)*

The motion was approved by a majority vote of the voting Board members by voice vote: none opposed, none abstained, 1 recused (Sharon Levine); Barbara McNeil was not present during this vote.

Dr. Herndon made introductory remarks on behalf of the Engagement, Dissemination, and Implementation Committee, noting that at its September meeting, the committee discussed and voted to recommend that the Board approve the Limited Competition D&I funding slate. He then introduced Dr. Siegel to provide details on the slate.

Dr. Siegel provided an overview of the Limited Competition funding announcement which provides awardee teams, who have completed a PCORI-funded study, the opportunity to take the next steps in promoting uptake of the evidence into practice. The implementation project on the slate, "Implementation of an Online Weight Management Program in Clinical and Community Settings," is proposing to implement findings from a study funding through PCORI's Improving Health Systems priority area. The total funds requested for the proposed slate is \$2.1M.

A Board member asked if there were opportunities to get more researchers to submit applications to implement findings from PCORI-funded research. Siegel noted there are processes in place to attract more applicants. When asked how success was measured, Siegel noted the D&I program has consistent program evaluation. Additionally, funded D&I projects are expected to include both measures of implementation and outcomes. Projects are typically three years. Now, the D&I program is considering how stakeholder groups can take the intervention beyond the project period. The D&I award program now includes a supplemental award opportunity that focuses on the cost of implementation, which is intended to have a broader impact.

The following motion was made by Daniel Van Leeuwen and seconded by Robert Zwolak

Cycle 1 2021 PCORnet, The National Patient-Centered Clinical Research Network Phase 3 - Barbara McNeil, MD, PhD, Chair, Selection Committee and Penny Mohr, MA, Acting Program Director, Research Infrastructure	Motion: Approve funding for the recommended award slate from the Cycle 1 2021 Limited Competition Dissemination and Implementation PFA <i>Approved by a majority vote of the voting Board members present by voice vote. None opposed, none abstained. Barbara McNeil had indicated her intention to recuse from the deliberative discussion and vote, but not present during this vote.</i> ***** <u>Optimizing Infrastructure for Conducting Patient-Centered Outcomes Research: PCORnet®, The National Patient-Centered Clinical Research Network Phase 3, Cycle 1 2021:</u> Ms. Mohr outlined the objectives of the and noted that the PFA was posted as a limited competition that was only open to previously funded Clinical Research Networks. The Clinical Research Networks were encouraged to add additional sites to their application if those sites would aide in diversifying the patients they reach. Mohr noted that PCORnet covers about 40 states within the United States and the populations included are similar to the makeup of the population of the country as a whole. Mohr then gave a brief description of each of the eight Clinical Research Networks with infrastructure projects proposed for funding. Discussion included the importance of aligning PCORnet and its participating networks with the evolving PCORI National Priorities and the challenges of the timing of alignment given that the National Priorities are still under development. Mohr noted that the PFA emphasized the commitment to PCORI's strategic planning and that PFA had included an expectation that the proposed projects align with the Board-approved PCORI Prioritizing Principles for Infrastructure Funding Relating to PCORnet. <i>See Table B for the Phase 3 slate.</i> <i>The following motion was made by Sharon Levine and seconded by Mike Herndon.</i> Motion: Approve funding for the recommended slate of awards from the Cycle 1 2021 - PCORnet®, The National Patient-Centered Clinical Research Network - Phase 3 PFA <i>The motion was approved by a majority vote of the voting Board members by voice vote: none opposed, 1 abstained</i>
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	(Christopher Friese); 4 recused (Kara Ayers, Jennifer DeVoe, Eboni Price-Haywood, James Schuster); Russell Howerton was not present during this vote.
Consider for Approval: FY2022 Budget <i>Russell Howerton, MD, Chair, Finance and Administration Committee (FAC) and Nakela Cook, MD, MPH, Executive Director</i>	Dr. Zwolak, Vice Chair of the Finance and Administration Committee, introduced the proposed FY2022 Budget to the Board on behalf of the Committee, and introduced Dr. Cook to present the proposed FY2022 Budget of \$404 million, as recommended by the FAC, for Board approval. Cook explained the difference between award commitments and award payments, noting that only award payments are expenses and included in the budget. She summarized the projected FY2021 and FY2022 fund balances and then presented the major components of the FY2022 budget, which include Award Payments (representing 77% of the total FY2022 Budget or \$313 million), Programs & Program Operations (15% or \$59 million), and Administrative Support (8% or \$33 million). She also noted the differences between the FY2022 budget, FY2021 projections, and FY2021 approved budget. Board members were given the opportunity to ask questions regarding the proposed FY2022 budget, but there were no questions presented. <i>The following motion was made by Ellen Sigal and seconded by Barbara McNeil:</i> Motion: Approve the proposed FY2022 Budget <i>Approved by a majority vote of the voting Board members present by voice vote. None opposed, none abstained. Russell Howerton was not present during this vote.</i>
Congressional Panel <i>The Honorable Senator Bill Cassidy, MD (R-LA)</i>	Senator Bill Cassidy joined the Board meeting and provided his thoughts on ways PCORI can help advance healthcare quality and outcomes. He emphasized opportunities for PCORI to focus funding that results in evidence relating to mental health, pandemic preparedness, health disparities, what works and does not work in regard to telehealth, the opioid epidemic, and the need for better data to improve the patient experience in achieving value-based care. He also emphasized the importance of achieving value in healthcare and discussed drug pricing and the importance of balancing innovation and costs.

	Senator Cassidy answered several questions from PCORI Board members, including questions about how PCORI can respond to the needs of Americans, how PCORI can better align its research to meet the needs of Congress, how PCORI can help others understand the patient experience in the context of drug pricing, and how PCORI can play a role as states consider moves to address value-based care.
Wrap-up and Adjourn <i>Christine Goertz, DC, PhD</i>	Dr. Goertz adjourned the meeting at 4:33 pm

Minutes were approved by the PCORI Board of Governors 10-26-2021

Table A:

Addition to Cycle 3 2020 Phased Large Award for Comparative Effectiveness Research (PLACER) Slate	Colonoscopy versus stool-based testing for older adults with a history of colon polyps
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Table B:

PCORnet Phase 3	PEDSnet: Advancing Pediatric Patient-Centered Outcomes Research in PCORnet
	The Stakeholders, Technology and Researchers (STAR) Clinical Research Network: Phase 3
	Greater Plains Collaborative Optimizing Infrastructure for Conducting Patient-Centered Outcomes Research: PCORnet, The National Patient-Centered Clinical Research Network – Phase 3
	OneFlorida+ Partner Engagement Network
	INSIGHT Clinical Research Network
	Accelerating Data Value Across a National Community Health Center Network (ADVANCE) Clinical Research Network
	REACHnet 3.0: Optimizing Infrastructure for Conducting Patient-Centered Outcomes Research
	PaTH to Health: PCORnet Clinical Research Network