

Board of Governors Meeting via Teleconference / Webinar

Thursday, December 2, 2021

11:30 am-4:30 pm ET

MINUTES

Board Members Present:

Christine Goertz, DC, PhD, *Chairperson*; Sharon Levine, MD, *Vice Chairperson*; Kara Ayers, PhD; Kate Berry; Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Mike Herndon, DO; Russell Howerton, MD; James Huffman; Connie Hwang, MD, MPH; Karin Rhodes, MD, MS (designee for David Meyers, MD); James Schuster, MD, MBA; Kathleen Troeger, MPH; Danny van Leeuwen, MPH, RN; Robert Zwolak, MD, PhD

Board Members Absent: Tanisha Carino, PhD; Francis Collins, MD, PhD; Christopher Friese, PhD, RN; Michelle McMurry-Heath, MD, PhD; Barbara McNeil, MD, PhD; Eboni Price-Haywood, MD, MPH; Ellen Sigal, PhD; Janet Woodcock, MD

Agenda Item	PCORI Speakers
Welcome and Call to Order Consent Agenda: Consider for Approval: - Minutes of the October 26, 2021 Board Meeting - Nomination of Advisory Panel on Clinical Trials (CTAP) Member <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 reminded members that they were expected to complete the annual updating of their conflict of interest disclosures by the deadline. Goertz then introduced the two items on the Consent Agenda and gave the opportunity to Board members to discuss any of the matters on the Consent Agenda. She then reviewed the meeting agenda. <i>The following motion was made by Kathleen Troeger and seconded by Sharon Levine.</i> Motion: That the Board approve: - Minutes from the October 26, 2021, Board meeting - Nomination of Cristina Murray-Krezen as a member of the Advisory Panel on Clinical Trials to serve through August 2024, or until a successor is appointed. <i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions). Robert Zwolak was not present for this vote.</i> Goertz then recognized PCORI staff member Andrew Hu, Director, Public Policy and Government Relations, thanked him for his service during his tenure at PCORI, noted his many contributions to PCORI's

	mission and on behalf of the PCORI Board wished him success in his future endeavors.
Executive Director's Report • Dashboard • Year in Review <i>Nakela L. Cook, MD, MPH, Executive Director</i>	<u>Dashboard:</u> Dr. Cook presented the Q4-FY2021 Dashboard for the Board's review. The Dashboard presented 7 green-flagged metrics (those that are on track): Funds Committed, Research Project Performance, Time to Release of Research Findings, Final Research Reports Posted to PCORI.org, Uptake into Public/Patient Resources, Uptake into UpToDate®, and Other Examples of Uptake. There was one metric with a target that is not applicable: Results Published in the Literature. There were no yellow (those that are off target by more than 10%) or red ((items that are off-target and in need of attention or action by the Board) metrics. Cook gave an update relating to PCORI-funded project status. She reported that, for the most part, PCORI projects are on track, with 60% falling into the green (on-track) category and 31% in the yellow (on track but experiencing slight delays) category. While the percentage of green projects is slightly lower than in previous quarters, this is most likely attributable to COVID-19. Of the 93 projects with a yellow, orange, or red status, 88% had delays either mostly or partially due to COVID-19, with decreases in recruitment being the most common cause. These trends are similar to those from other funders that are evident in the emerging literature about research during the COVID-19 pandemic. Cook briefly presented the PCORnet Dashboard, noting that the full Dashboard is available on PCORI's website. These metrics are presented to the Research Transformation Committee for oversight, and their progress is closely monitored. In the future, Phase 3 funding of PCORnet will bring new infrastructure metrics to the Dashboard. She then discussed Dashboard metrics relating to outputs and uptake of PCORI-funded research results, including Final Research Reports available to the public, measures of attention, public availability of primary 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.org, provides complete and earlier availability of research results to the public. Cook highlighted the REGAIN Trial's October 2021 paper in the <i>New England Journal of Medicine</i> as an example of how study results can help patients with decision making.

	Members of the Board asked questions about the use of Altmetric scores, including how they drive PCORI's topic selection, how results are disseminated to the public and external audiences, and how the Strategic Planning Committee can assist with selection of new metrics and benchmarks for the Dashboard. It was noted that PCORI can continue to consider dashboard elements. <u>Year in Review:</u> Cook introduced new members of the PCORI Leadership Team: Sri Mishra, MBA (Chief Information Officer), Yolanda Hutchins, MA (Chief People Officer), and Carolyn Best, PhD (Program Operations Chief). She then discussed PCORI's new website, which launched in November and includes improved infrastructure, new features, and analytic capabilities. She then highlighted other PCORI achievements in FY2021, including the MarCom Gold Award PCORI received for its Annual Report for the third year in a row, and PCORI's successful second Virtual Annual Meeting, which took place in November. She congratulated PCORI's Communications team on this achievement. Cook then discussed other achievements relating to how PCORI has fulfilled its mission, and how PCORI works, including collaboration & teamwork and diversity, equity & inclusion efforts. Highlights noted included PCORI's strategic planning activities, which culminated in the Board's adoption of National Priorities for Health in Fall 2021, efforts related to PCORI's COVID-19 response, and PCORI Next. Building on the successes of FY2021, Cook forecast a busy FY2022 agenda, which includes adoption of a new strategic plan, a new year in PCORI's commitment plan, and continued work on topic development. Cook also reported on PCORI's anticipated office relocation to 1333 New Hampshire Avenue, NW, Washington, DC, with an expected move in the Summer of 2022.
Consider for Approval: FY2022 to FY2024 Commitment Plan <i>Nakela L. Cook, MD, MPH</i>	Dr. Cook gave a recap of the 3-year Commitment Plan approved by the Board for FY2021-FY2023, at the December 8, 2020 Board meeting. The Board-approved Commitment Plan included a plan for total commitments of \$600M in FY2022. The FY2013-2018 average had been \$388M. The 3-Year Commitment Plan is subject to annual review and update by the Board. Cook outlined funding commitment projections for upcoming years, including commitment targets for Research, Dissemination & Implementation, Infrastructure/Accelerating PCOR, and New Initiative/Emerging Issues. This plan also will require a 15% increase in staffing to support these new commitments.

	Cook detailed how PCORI met the FY2021 target for commitments, with a commitment of \$494M compared to its target of \$482M. PLACER was a driver of this funding, while D&I and Infrastructure funding was lower than projected, due to a shift in timing of Health Systems Implementation Initiative (HSII) and PCORnet Coordinating Center awards. Cook presented the Proposed 3-Year Commitment Plan for FY2022-2024, including targeted commitments in the funding areas of Research, Dissemination & Implementation, Infrastructure/Accelerating PCOR, and New Initiatives. Members of the Board discussed the potential impact of National Priorities on the future Commitment Plan and challenges and opportunities facing Dissemination & Implementation funding. <i>The following motion was made by Michael Herndon and seconded by Karin Rhodes.</i> Motion: Approve the Proposed 3-year Commitment Plan for FY2022-2024, subject to annual review and update by the Board. <i>Approved by a majority vote of the Board by voice vote (no opposed; no abstentions).</i>
Consider for Approval: Proposed Research Agenda for Posting for Public Comment <i>Nakela L. Cook, MD, MPH and Sharon Levine, MD, Board Vice Chairperson and Chair, Strategic Planning Committee</i>	Dr. Levine introduced this agenda item for the Strategic Planning Committee (SPC) and thanked its members and the Board for the input provided to the initial draft Research Agenda that led to the revisions being presented today with the goal of approving the proposed Research Agenda for posting for Public Comment. She then introduced Dr. Cook to provide an overview. Cook provided an overview of the proposed Research Agenda including how it was created. PCORI received input from a range of stakeholders to identify and inform the proposed Research Agenda in addition to holding discussions at Board of Governors meetings. At its October 26, 2021, meeting, the Board held focused discussions on the proposed Research Agenda which generated several areas for refinement. Cook reviewed the Board's feedback from the October meeting which was used to update the proposed Research Agenda. Feedback included considering if the Research Agenda should consist of statements and descriptive characteristics or if the characteristics could be used as examples; possibly combining complementary statements; and simplifying the content of the proposed Research Agenda while retaining precise terminology.

	Based on the Board's feedback, the Strategic Planning Committee revised the proposed Research Agenda. Cook presented the proposed revised Research Agenda which was comprised of six Statements: • Fund research that fills patient- and stakeholder-prioritized evidence gaps and is representative of diverse patient populations and settings • Fund research that aims to achieve health equity and eliminate health and healthcare disparities • Fund research that builds the evidence base for emerging interventions by leveraging the full range of data resources and partnerships • Fund research that examines the diverse burdens and clinical and economic impacts important to patients and other stakeholders • Fund research that focuses on health promotion and illness prevention by addressing health drivers that occur where people live, work, learn, and play • Fund research that integrates implementation science and that advances approaches for communicating evidence so the public can access, understand, and act on research findings Cook reviewed how each Statement was revised based on Board feedback. Cook also noted that following approval of the proposed Research Agenda for posting for public comment, PCORI expected the public comment period to last from early December 2021 to late January 2022. <i>The following motion was made by Daniel van Leeuwen and seconded by Sharon Levine.</i> Motion: Approve the Proposed Research Agenda for Posting for Public Comment <i>Approved by majority vote of the voting Board members by voice vote (no opposed; no abstentions).</i>
Break	
Consider for Approval: Award Slates <i>Nakela Cook and Jennifer DeVoe, MD, MPhil, MCR, DPhil, Vice Chair, Selection</i>	Dr. Cook introduced the agenda item by giving an overview of the award slates to be considered for approval and providing context for the Research and Infrastructure Slates including how they compare to historical averages for each PFA. The total funding amount being presented to the Board was \$67.5M.

<i>Committee</i>	Cook then reviewed the LOIs, applications and funding rates for each of the slates. She noted that this cycle was the first issuance of the Pragmatic Clinical Studies (PCS) PFA since 2018. She indicated that PCORI expected to receive fewer PCS applications due to the Phased Large Awards for Comparative Effectiveness Research (PLACER) PFA that was issued one cycle prior. Cook also noted that for the upcoming Cycle 2 2021, PCORI has issued multiple Targeted PFAs which is also reflected in the LOI and applications received for this PCS cycle. Cook then discussed the Broad PFA, noting that PCORI received higher than average LOIs and applications in the previous cycle, Cycle 3 2020, as this PFA was not offered in Cycle 2 2020 due to implications of COVID-19. Cycle 2 2021 and Cycle 3 2021 are (so far) similar to historical averages. Cook also noted that PCORI has historically seen a dip in Cycle 2 Broad applications, and PCORI continues to investigate the reasoning behind this. Cook then addressed the Coordinating Center Functions to Advance Phase 3 of PCORnet®, the National Patient-Centered Clinical Research Network, PFA, noting the historical averages relating to PFAs addressing Coordinating Center Functions in Phase 1- the Design phase and Phase 2- which focused on Capacity Building. She compared this information to the current phase, Phase 3- which focuses on Optimization. This PFA was a limited competition offered to currently funded PCORnet participants. Cook reviewed the Proposed Award Slates in the context of the Commitment Plan, noting the \$450M targeted for Research Funding and \$60M targeted for Infrastructure. The reviewed the cumulative FY22 funding commitments with today's proposed slates: \$49.5M for the Research slate and \$18M for the Infrastructure slate, leaving funds available for the following cycles. Dr. DeVoe then made introductory remarks on behalf of the Selection Committee, noting that the Committee met in October and November 2021, and recommended three slates of awards for Board approval. She then introduced PCORI staff to present the slates. <u>Cycle 1 2021- Pragmatic Clinical Studies (PCS):</u> Dr. Khan introduced the proposed slate of awards for the Cycle 1 2021 - PCS PFA. Khan reviewed details of the PFA noting the direct cost cap of \$10M. The Selection Committee recommended a slate with the following 3 awards for funding for a total of \$23.5M: Expanding first-line Options for Depression & Matching Treatments: Hatha Yoga vs Behavioral Therapy
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<i>Carly Khan, PhD, MPH, RN, Associate Director, Healthcare Delivery and Disparities Research (HDDR)</i>	• Comparative Effectiveness of Online Cognitive Behavioral Therapy vs. an Online Single-Session Pain Relief Skills Class for Chronic Pain • Comparative Effectiveness of Mobile Health Smoking Cessation Approaches among Underserved Patients <i>The following motion was made by Alicia Fernandez and seconded by Robert Zwolak.</i> Motion: Approve funding for the recommended slate of awards from the Cycle 1 2021 Pragmatic Clinical Studies PFA. <i>Approved by a majority vote of the voting Board members by voice vote: none opposed, none abstained. Barbara McNeil had earlier announced her intent to recuse but was not present for the meeting. (Kate Berry, Connie Hwang and Kathleen Troeger were not present for this vote).</i>
<i>Steve Clauser, PhD, MPA, Program Director, HDDR; Holly Ramsawh, PhD, Senior Program Officer, Clinical Effectiveness and Decision Science (CEDS)</i>	<u>Cycle 1 2021 - Broad PFAs</u> Dr. Clauser introduced the slates for the Cycle 1 2021 - Broad-Addressing Disparities and Improving Healthcare Systems PFAs, noting brief descriptions of each of the slates including their relevance to Congressionally mandated Special Areas of Emphasis (SAE) as well as their complements to the PCORI research portfolio. Dr. Ramsawh introduced the slates for the Cycle 1 2021 – Broad Assessment of Prevention, Diagnosis, and Treatment Options (APDTO) and Improving Methods for Conducting PCOR PFAs, also noting brief descriptions of the proposed slates. The Selection Committee recommended a total of 6 applications for funding with a total of \$26M, including: Addressing Disparities Slate (3 projects (total \$13.8M)); Improving Health Systems Slate (1 project (total \$7M)); Assessment of Prevention, Diagnosis, and Treatment Options Slate (1 project (total \$4M)); and Improving Methods for Conducting PCOR Slate (1 project (total \$1M)). (See Attachment A) <i>The following motion was made by Mike Herndon and seconded by Robert Zwolak.</i> Motion: Approve funding for the recommended slate of awards from the Cycle 1 2021 Broad PFAs. <i>Approved by a majority vote of the voting Board members by voice vote: none opposed, none abstained, 5 recused: Kara Ayers, Sharon</i>

PCORnet Coordinating Center Functions

*Laura Lyman Rodriguez, PhD,
Interim Chief Program Support
Officer and Senior Advisor to the
Executive Director*

Levine, James Schuster. Michael Lauer and Christopher Frieze had earlier announced their intent to recuse, but were not present for the meeting, (Kate Berry, Connie Hwang and Kathleen Troeger were not present for the vote).

Cycle 2 2021 – Coordinating Center Functions to Advance Phase 3 of PCORnet®, the National Patient-Centered Clinical Research

Network PFA:

For this portion of the agenda, Dr. Goertz asked Dr. Sharon Levine to facilitate the discussion and vote due to conflict of interest considerations.

Dr. Rodriguez began with a recap of the work of the Board-related PCORnet Priorities Working Group, which proposed Prioritizing Principles for Infrastructure Funding Relating to PCORnet, which were approved by the Board on January 12, 2021. The Board also approved the development of funding opportunities for Phase 3 infrastructure funding of \$78M over three years on January 12, 2021, including funding opportunities of a total of \$60M over three years for Clinical Research Network infrastructure projects and funding opportunities of \$18M over three years specifically for the Coordinating Center infrastructure. Rodriguez provided an overview of the structure of the PFA, with 5 Functional Scopes of Work considered and awarded individually. The Selection Committee recommended a slate of 5 awards for all 5 Functional Scopes with a total of \$18M:

Coordinating Center Functional Scope	Project Title
Scope 1: PMO	PCORnet Coordinating Center: Program Management, Collaboration and Coordination
Scope 2: CDM	PCORnet Coordinating Center: Common Data Model Maintenance, Expansion and Linkage
Scope 3: Query	PCORnet Designated Study Consultation and Query and Analytic Tool Development to Enable Multi-network PCORnet Research
Scope 4: Comms	Strengthening Communications to Support the PCORnet Research Community
Scope 5: Engagement	PCORnet Engagement Coordinating Center

	<i>The following motion was made by Russell Howerton and seconded by Robert Zwolak.</i> Motion: Approve funding for the recommended slate of awards from the Cycle 2 2021 – Coordinating Center Functions to Advance Phase 3 of PCORnet®, the National Patient-Centered Clinical Research Network PFA. <i>Approved by a majority vote of the voting Board members by voice vote: none opposed, none abstained, 3 recused: Jennifer DeVoe, Christine Goertz, James Schuster. Michael Lauer, Michelle McMurry-Heath, and Barbara McNeil had earlier expressed their intent to recuse but were not present for the meeting. (Kate Berry, Connie Hwang and Kathleen Troeger were not present for this vote).</i>
Consider for Approval: Cycle 1 2022 Targeted PFAs <i>Nakela Cook, Alicia Fernandez, MD, Chair, Science Oversight Committee, Els Houtsmuller, PhD, Associate Director, HDDR and Yewande Akinbami, MD, MPH, Program Officer, CEDS</i>	Dr. Cook provided an overview of Targeted PFA development to be considered for approval in the context of the expedited and enhanced process She then introduced Dr. Fernandez to make introductory remarks on behalf of the Science Oversight Committee. Fernandez indicated that the Science Oversight Committee recommended that the Board approve the development of two PFAs, and then turned the presentation over to Dr. Houtsmuller to present the recommended Targeted PFAs. Houtsmuller explained that studies under the recommended Targeted PFA on Brief Interventions for Adolescent Alcohol Use would compare the effectiveness of brief behavioral interventions, adapted for adolescents ages 12-17, to address alcohol use. The total requested funding under the PFA is \$30M, through an estimated up to 3 cycles, to fund an estimated 3-5 studies, with a maximum project duration of \$30M. <i>The following motion was made by Kara Ayers and seconded by Michael Herndon.</i> Motion: Approve the development of “Brief Interventions for Adolescent Alcohol Use” Targeted PFA with funding up to \$30M in total costs <i>Approved by majority vote of the voting Board members by voice vote (no opposed; no abstentions). Kate Berry, Connie Hwang, and Kathleen Troeger were not present during this vote.</i> Dr. Fernandez then made introductory remarks on behalf of the Science Oversight Committee, which recommended that the Board

	approve the development of a Targeted PFA on Early Identification & Treatment of Delirium, before turning it over to Dr. Akinbami to present the recommended Targeted PFA. Akinbami explained that studies under this recommended Targeted PFA would compare the effectiveness of evidence-based single and/or multicomponent interventions to improve prevention, early identification, or treatment of delirium in older adults. PCORI expects to fund 3-5 studies with a total amount requested of \$30M. The total requested funding under the PFA is \$30M, through an estimated up to 3 cycles, to fund an estimated 3-5 studies, with a maximum project duration of \$30M. Board discussion focused on: • The cause of delirium is commonly medications; • Evidence gaps are in this population aged 65 or older and diagnosed with or at risk of delirium in medical or long-term settings; and. • The Science Oversight Committee worked alongside staff to refine and narrow this topic to produce a topic that would result in meaningful CER results, <i>The following motion was made by Michael Herndon and seconded by Karin Rhodes.</i> Motion: Approve the development of “Prevention, Early Identification and Treatment of Delirium” Targeted PFA with funding up to \$30M in total costs <i>Approved by majority vote of the voting Board members by voice vote (no opposed; no abstentions). Kate Berry, Connie Hwang, and Kathleen Troeger were not present during this vote.</i>
Consider for Approval: • Health Systems Implementation Initiative (HSII) <i>Michael Herndon, DO, Chair, Engagement, Dissemination, and Implementation Committee (EDIC) and Joanna Siegel, ScD, Program Director, Dissemination, and Implementation (D&I)</i>	Dr. Herndon made introductory remarks on behalf of the Engagement, Dissemination, and Implementation Committee, which in November 2021 voted to recommend that the Board approve the proposed approval framework for HSII Implementation Projects and commitment of funds for HSII, before turning it over to Dr. Siegel to present HSII. Dr. Siegel explained what the Health Systems Implementation Initiative is and described its goals, three-step process, and other components (e.g., evaluation, HSII Learning Network). Dr. Siegel provided an overview of the proposed HSII Approval Framework, explaining the proposed review and approval framework for each of

	HSII's Three Steps: (Step 1: Selecting HSII Participants, Step 2: HSII Capacity Building Projects, and Step 3HSII Implementation Projects). In response to Board member questions about the initial capacity building award amount for HSII Capacity Building Projects (≤\$500K), Siegel explained that this amount was developed based on comments received by PCORI through PCORI's Request for Information (RFI) about the envisioned HSII. <i>The following motion was made by Sharon Levine and seconded by Alicia Fernandez.</i> Motion: Approve: • The Proposed Approval Framework for HSII Implementation Projects, including PCORI staff review of proposals, EDIC consideration of projects and recommendation of slates of awards, and Executive Director consideration and approval of slates of awards • The commitment of funding of up to \$15 million per fiscal year beginning in FY 2022 to fund projects awarded under the Health Systems Implementation Initiative, not to exceed a total of \$50 million for 5 fiscal years. <i>Approved by majority vote of the voting Board members by voice vote (no opposed; no abstentions). Kathleen Troeger was not present during this vote.</i>
Public Comment Period <i>Kristin Carman, MA, PhD, Director, Public & Patient Engagement</i>	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 Adjourn <i>Christine Goertz, DC, PhD</i>	Meeting ended at 3:10 pm

Minutes were approved by the PCORI Board of Governors 2-15-2022

Attachment to Minutes of the PCORI Board Meeting of December 2, 2021

Attachment A:

Cycle 1 2021 Broad PFA

Addressing Disparities	Equity-Enhancements to Reduce Disproportionate Unmet Mental Health Need of African American Children
	Comparative Effectiveness of Treating Genital Herpes Infection to Reduce Racial Disparities in the Risk of Severe Maternal Morbidity (SMM)
	Improving the health of adolescents and transition-age youth with IDD
Improving Health Systems	The Follow-up Automatically vs As-Needed Comparison (FAAN-C) Trial
Assessment of Prevention, Diagnosis and Treatment Options	The CARES Trial: Comparing Analgesic Regimen Effectiveness and Safety after surgery
Improving Methods	Improved Statistical Methods for Instrumental Variable Designs in CER