

Board of Governors Meeting via Teleconference / Webinar

Tuesday, June 15, 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; Mike Herndon, DO; Russell Howerton, MD; James Huffman; Connie Hwang, MD, MPH; Barbara McNeil, MD, PhD; Karin Rhodes (designee for David Meyers, MD); 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: Michelle McMurry-Heath, MD, PhD; Janet Woodcock, MD

Agenda Item	PCORI Speakers
Welcome and Call to Order Consider for Approval: - Minutes of the May 24-25, 2021 Board Meetings - <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. With no additions or corrections to the minutes offered, Goertz then presented the minutes of the May 24-25, 2021 Board meeting for approval. <i>The following motion was made by Barbara McNeil and seconded by Sharon Levine.</i> Motion: Approve the Minutes from the May 24-25, 2021 PCORI Board Meetings. <i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions).</i>
Consider for Approval: Targeted PFAs for Cycle 3 2021 - <i>Alicia Fernandez, MD, Science Oversight Committee (SOC) Chair and Nakela L. Cook, MD, MPH, Executive Director</i>	Dr. Fernandez made introductory remarks regarding the development of the three targeted PFAs which included consultation with NIH, AHRQ, and other relevant agencies and noted the recommendation of the Science Oversight Committee. Dr. Cook then explained that these three Targeted PFAs for Cycle 3 2021 are under the enhanced and expedited approach for development of PFAs to implement the Commitment Plan goal while strategic planning is underway. All three topics are part of the large set of candidate topics that the Board

Comparative Effectiveness of Novel Pharmacologic and Evidence-Based Nonpharmacologic Treatments for Migraine Prevention - Stanley Ip, MD, Interim Program Director, Clinical Effectiveness and Decision Science (CEDS)	approved in April 2021. She also indicated that two of the PFAs will reflect focused areas within the topics, the Health Aging PFA will be a pilot that reflects an expanded approach that enables more flexibility from applicants within the topic to enable research teams to propose novel research questions. All three PFAs will reflect an interest in a wide range of study duration and funding levels and are expected to be offered through multiple cycles, which is expected to accelerate portfolio development. The total funding request relating to all three PFAs is up to \$130M, well within the Commitment Plan for 2022 and 2023. She then introduced Dr. Stanley Ip to introduce the first PFA topic. Dr. Ip explained that studies under the <i>Comparative Effectiveness of Novel Pharmacologic and Evidence-Based Nonpharmacologic Treatment for Migraine Prevention</i> PFA would compare the effectiveness of novel pharmacologic options and/or evidence-based nonpharmacological interventions with established efficacy or in common use for migraine prevention in patients with episodic and/or chronic migraine in primary and/or specialty-care clinics. PCORI expects to fund 3-5 studies of up to 5 years duration through up to 3 cycles of funding with a total amount requested of \$40M. Board discussion focused on the opportunity to consider cost impact and cost effectiveness through guidance for investigators to apply in applications, and flexibility in comparing therapies (such as comparing novel and traditional treatments). Cook noted that PCORI has developed the <i>Principles for the Consideration of the Full Range of Outcomes Data in PCORI-Funded Research</i> and is actively working through guidance for investigators on how to apply these Principles, such as lost workdays, etc. Board members noted that studies on migraines lend themselves to considering outcomes such as lost days of work and other outcomes and burdens. Board members also noted that there are a number of new therapies for migraines, and staff confirmed that both traditional and non-traditional therapies would be considered. <i>The following motion was made by Russell Howerton and seconded by Mike Herndon.</i> Motion: Approve the development of a PFA on “Comparative Effectiveness of Novel Pharmacologic and Evidence-based Nonpharmacologic Treatments for Migraine Prevention” with funding up to \$40M in total costs.
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	<i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions). Tanisha Carino and James Schuster were not present during this vote.</i>
Healthy Aging: Optimizing Physical and Mental Functioning Across the Aging Continuum - <i>Neeraj Arora, PhD, Associate Director, Healthcare Delivery and Disparities Research (HDDR)</i>	Dr. Arora explained that the Healthy Aging PFA is a pilot given that it is expected to be a relatively broader PFA. The key aspects of the proposed PFA were presented to the Board, including goal, domains, populations, example outcomes and settings. Studies funded under this PFA would compare the effectiveness of interventions to optimize the physical and mental functioning of community-dwelling older adults and their caregivers across the aging continuum within four domains: maintaining functioning and independence, managing chronic conditions, supporting individuals with significant functional impairment, and reducing caregiver burden. This PFA is expected to focus on older adults predominantly age 60 and beyond with chronic disease issues, although applications justifying targeting of younger, middle aged populations will be considered. PCORI expects to fund a total of between 9-12 studies (about 3-4 studies per cycle) for up to 3 cycles with a total amount requested of \$50M. The maximum project duration for studies funded under this PFA is expected to be 5 years. The Board discussed how the age of 60 was chosen as the baseline age for older adults, whether a distinction will be made between well-managed and sub optimally-managed care for chronic disease. Staff informed the Board that after interactions with multiple stakeholders, including the National Institute of Aging, it was decided to primarily focus on adults age 60 and older. It was recognized that from a disparities lens, it may be appropriate to consider below age 60 to capture those who experience premature aging. Staff also stated that they do not plan to focus on populations in the extremes of well-managed aging or end-of-life care; and may consider the novel Alzheimer's disease drug in the context of dementia in. <i>The following motion was made by Christopher Frieze and seconded by Sharon Levine.</i> Motion: Approve the development of a PFA on "Healthy Aging: Optimizing Physical and Mental Functioning Across the Aging Continuum" with funding up to \$50M in total costs. <i>Approved by a majority vote of the voting Board members by voice vote (no opposed; Ellen Sigal abstained). James Schuster was not present during this vote.</i>
Multimodal Interventions to Prevent Osteoporotic Fractures	Dr. Warren presented the Multimodal Interventions to Prevent Osteoporotic Fractures PFA, noting that studies under this PFA would

- <i>Meghan Warren, PhD, MPH, Program Officer, CEDS</i>	compare the effectiveness of multimodal treatment interventions on patient-centered outcomes in people with osteoporosis and a history of fractures. Warren provided the Board with information regarding the anticipated interventions/comparators to be studied as well as the expected outcomes and timing of studies. PCORI expects to fund a total of 3-5 studies through up to 3 cycles with a total amount requested of \$40M. The maximum project duration for studies funded under this PFA is expected to be 5 years. The Board asked whether there is a potential role for the use of PCORnet in studies funded under this PFA. Warren indicated that PCORI plans to be flexible for how researchers would propose and design these studies, including with the use of PCORnet. She further noted that after discussions with stakeholders, the PFA was intentionally developed to be broad enough to consider fragility fractures vs. trauma fractures. In a discussion regarding the expanded PFA of Health Aging vs. the targeted PFA on osteoporotic fractures, Dr. Cook noted that if PCORI begins to see some strong proposed studies that would result in exceeding the funding commitment, the Board will be advised. Board members also noted that studies funded under this PFA topic may lend themselves to considering comparative burdens for patients. <i>The following motion was made by Barbara McNeil and seconded by Kara Ayers.</i> Motion: Approve the development of a PFA on “Comparative Effectiveness of Multimodal Interventions to Prevent Osteoporotic Fractures” with funding up to \$40M in total costs. <i>Approved by a majority vote of the voting Board members by voice vote (Kathleen Troeger abstained). James Schuster was not present during this vote.</i>
Consider for Approval for Posting for Public Comment: Proposed National Priorities for Health - <i>Nakela L. Cook, MD, MPH and Sharon Levine, MD, Co-Chairs, Strategic Planning Committee</i>	Dr. Levine introduced this agenda item: to consider for approval the posting for public comment PCORI’s Proposed National Priorities for Health. Levine commented that the Board had an extensive discussion of the proposed National Priorities for Health at its May 24-25, 2021 Board meeting, and the comments from that meeting have been incorporated into the version being considered today. She reminded the Board that they are not voting to approve the proposed National Priorities for Health, but are voting to post these proposed Priorities for Public Comment. Levine then introduced Dr. Cook who walked the Board through the five proposed Priorities:

- Increase Evidence for Existing Interventions and Emerging Innovations in Health
- Enhance Infrastructure to Accelerate Patient-Centered Outcomes Research
- Advance the Science of Dissemination, Implementation, and Health Communication
- Achieve Health Equity
- Accelerate Progress Toward an Integrated Learning Health System

Cook reviewed progress on PCORI's Strategic Planning Process to date, public input already received, and the discussions from the May Board meeting. Themes from the May Board meeting included the importance of identifying PCORI's unique role and contribution to each Priority, how progress may require system changes, the critical role of strategic partnerships, the need to get local in communities for place-based or population-specific strategies and sustainability, the importance of integrating the full range of outcomes, and the importance of nimbleness and adaptiveness in PCORI's processes. Cook stated two categories of input emerged from the Board's comments during the May meeting: 1) considerations for revisions to the proposed National Priorities, which included making the titles action-oriented and updating the Priority statements; and 2) considerations that may inform other areas of strategic planning including implementation and other tactics, which included ideas for the Research Agenda and evaluation tactics, how the priorities will be implemented, and improvements to internal processes. Cook reviewed the input gathered from the Board and described how the input was reflected in each of the updated proposed Priorities. Input provided by the Board during the May meeting included validating the priorities and relevance for PCORI's mission, refining parameters within the priorities, and informing potential strategies to progress the priorities.

Cook also commented on the anticipated next steps following the Board's consideration and approval of posting for public comment. The Priorities will be posted for a 60-day public comment period expected to start at the end of June, and the comments collected will be considered in finalizing proposed Priorities. A synthesis of the public comments will be presented to the Board and the proposed National Priorities for Health are expected to be provided to the Board for consideration and approval in September or October 2021.

Board members reinforced the importance of community engagement for achieving the Priorities' goals and added that PCORI may need to provide support to investigators to facilitate engagement throughout

	the research lifecycle. Comments from Board members addressed several specific items within the Priorities, including whether the Priorities would allow PCORI to fund the investigation of the effectiveness of newly approved medications, and reinforced the need to express the bi-directional nature of communication between communities and investigators. Cook replied that these approaches are possible through the proposed Priorities. Cook noted PCORI's goal of an increased emphasis on emerging innovations, drugs, devices, and therapeutics. <i>The following motion was made by Russell Howerton and seconded by Barbara McNeil.</i> Motion: Approve the Proposed National Priorities for Health for Posting for Public Comment. <i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions). Tanisha Carino, Connie Hwang, and Kathleen Troeger were not present during this vote.</i>
FY2021 Mid-year Financial Review - <i>Russell Howerton, MD, Chair, Finance and Administration Committee (FAC) and Nakela Cook, MD, MPH</i>	Dr. Howerton and Dr. Cook presented the Mid-Year Financial Review for Board discussion. The FY2021 Mid-Year Financial review included a review of the FY2021 revenue through March 31, 2021, cash balance and outstanding award obligations as of March 31, 2021, and FY2021 budget versus actuals based on the first six months of FY2021 (October 1, 2020 – March 31, 2021). Cook noted the variance between the FY2021 budget and actuals for the period was 7%, which is considered a minor variance. In response to a question, Cook reminded the Board about the planning process undertaken to build the FY2021 budget and reflect potential impacts of COVID-19.
Wrap-up and Adjourn - <i>Christine Goertz, DC, PhD</i>	Dr. Cook offered closing comments, reviewing the comments provided by the Board on all the agenda items, and thanked the Board for their comments relating to the National Priorities for Health. Meeting ended at 2:33 pm Eastern.

Minutes were approved by the PCORI Board of Governors 07-27-2021