PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting via Teleconference / Webinar
Monday, September 27, 2021
1:00-3:15 pm ET

MINUTES

Board Members Present:
Christine Goertz, DC, PhD, *Chairperson;* Sharon Levine, MD, *Vice Chairperson*; Kara Ayers, PhD; Kate Berry; Michael Lauer, MD (designee for Francis Collins, MD, PhD); Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Mike Herndon, DO; Russell Howerton, MD; James Huffman; Connie Hwang, MD, MPH; Barbara McNeil, MD, PhD; Karin Rhodes (designee for 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: Tanisha Carino, PhD; Christopher Friese, PhD, RN; 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 July 27, 2021 Board Meeting *Christine Goertz, DC, PhD, Board Chairperson*	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 July 27, 2021 Board meeting for approval. *The following motion was made by Barbara McNeil and seconded by Sharon Levine:* **Motion**: Approve the Minutes of the July 27, 2021, Board Meeting *Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions).*
Executive Director's Report *Nakela L. Cook, MD, MPH, Executive Director*	Dr. Cook updated the Board on PCORI *Next* activities which had taken place since her last report in May 2021. PCORI *Next* is PCORI's organizational transformation effort to invest in operational, cultural and professional excellence. To help enable this effort, new positions at PCORI have been created, and two of these positions have recently been filled. Cook introduced these two new senior staff members to the Board: Sri Mishra, MBA, the Chief Information Officer, and Yolanda Hutchins, MA, the Chief People Officer. She asked that the Board join her in welcoming these new staff members to PCORI.

	Cook then reported on PCORI's response to the COVID-19 Pandemic across four domains: funding awards; collaborations and partnerships; information sharing; and embedding COVID-19 related topics into future PCORI funding announcements. Award funding was done through two mechanisms: Enhancements which allowed existing awards to add aims studying pandemic related outcomes while providing timely results (122 enhancements were awarded for a total of $34.8M); and new awards in both Research and Engagement using expedited targeted PCORI funding announcements (36 new awards were made for a total of $44.5 M). Cook then shared several publications that have already come out of the funded projects from the Enhancement portfolio including ones that illustrate surveying the Marshallese population on health resources in light of the pandemic; COVID-19 infection and increased risk of venous thromboembolism (VTE) among an ethnically diverse population; the risk of serious COVID-19 infection among patients with multiple sclerosis being treated with rituximab; effects of the pandemic on those being admitted for addiction treatment; and finally, a look into the socioeconomic disparities and differences in healthcare utilization in a diverse population in New York City. Cook provided a snapshot of some funded Dissemination & Implementation COVID-19 projects and reported on a project to support families and children with ASD/ADHD during the pandemic. She also gave an update on the HERO Research Program clinical trial and the Registry of Healthcare Workers. Cook then provided information on various COVID-19 targeted funded projects and related that $30M was awarded for 9 new research projects, and $4M was awarded for 25 new engagement projects. She then reported on the outcomes of several funded projects that studied various issues such as ways to engage community health workers in PCOR to address health disparities in the context of COVID-19, the impact of COVID-19 on the mental health of high-risk populations and increasing vaccine confidence among long-term care workers. Along with these new research and engagement awards and due to the rapidly evolving nature of the pandemic, Cook noted that PCORI staff are working on embedding COVID-19 outcomes in future PFAs particularly in post-acute COVID-19 infection, disproportionately affected populations, and social isolation. Cook noted that another component of PCORI's strategy has been collaboration with several federal agencies to leverage resources toward

	shared goals during the COVID-19 pandemic, including with the Centers for Disease Control and Prevention which funded PCORnet Network Partners to conduct continued surveillance; and the National Institutes of Health funded PCORnet Network Partners to conduct the ACTIV-6 trial, testing the efficacy of repurposed medications in treatment of mild to moderate COVID-19 infections. In addition, Cook noted that PCORI has been committed to actively sharing relevant information throughout the course of the pandemic and has done so via hosting webinars, a virtual briefing of Congress, and has funded bi-weekly horizon scannings as a mechanism for topic generation and information. She further noted that these bi-weekly horizon scan reports of COVID-19 related topics focused on six priority areas: devices, risk factor areas, diagnostics, health systems, treatments and vaccines, and many can be found on PCORI's website Cook then summarized that as the pandemic and PCORI's response continue to evolve, PCORI will be focused across four main areas: information sharing, award funding, partnerships and collaborations, and embedding COVID-19 related topics into future PCORI work. Dr. Goertz asked that since PCORI staff were able to reduce the overall PFA timeline for review of COVID applications, if there were any learnings that could be applied permanently moving forward to reduce the funding process timelines. Cook responded that PCORI staff were able to experiment out of necessity due to the realities of the pandemic and that during the first COVID-19 Targeted PFA solicitation there was a tradeoff with expedited applications and the quality of proposals, which was addressed during the second round of funding. She noted that one of the experiments that was very well received was the addition of a "Reverse Site Visit" instead of PCORI's traditional post-Merit Review Process, that allowed for real time answers by applicants to questions regarding aspects of applications. Cook noted that a formal evaluation of these funding processes is underway and that she would inform the Board when results became available.
Consider for Approval: New Advisory Panelists, Chairs and Co-Chairs Advisory Panel on: • Patient Engagement (PEAP)	Dr. Carman began the session with an overview of the advisory panel process, timeline, and this year's applicant pool. She noted that this year there was an expanded effort to reach out to various stakeholder groups to enhance the diversity of the panels, including relating to geography, viewpoint, and experience. She indicated that PCORI pursued outreach to communities that have traditionally been under-represented in research, including a focus on experience with intellectual and development disabilities (IDD) and maternal mortality. She indicated

• Healthcare Delivery & Disparities Research (HDDR) • Rare Disease (RDAP) • Clinical Effectiveness and Decision Science (CEDS) • Clinical Trials (CTAP) *Kristin Carman, MA, PhD, Director, Engagement, Public and Patient Engagement;* *Steve Clauser, MPA, PhD, Program Director, Science (HDDR) and* *Stanley Ip, MD, Interim Program Director (CEDS)*	that due to these efforts, the number of applications to serve on advisory panels increased and there was a broader pool of applicants, including geographic. She presented the proposed slate of new advisory panel members and chairs for the Advisory Panel on Patient Engagement (PEAP). (See Attachment A.) Following Carman's presentation of the proposed PEAP slate, Dr. Clauser presented the proposed slate of new advisory panel members and chairs for the Advisory Panel on Healthcare Delivery & Disparities Research (HDDR AP) and the Advisory Panel on Rare Disease (RDAP). *(See Attachment A)* Dr. Ip then presented the proposed slate of new advisory panel members and chairs for the Advisory Panel on Clinical Effectiveness and Decision Science (CEDS AP) and the Advisory Panel on Clinical Trials (CTAP). *(See Attachment A)* Dr. Levine asked whether PCORI has a standardized process for how the feedback and deliberation of its advisory panels is folded into PCORI's work. She indicated that this question has been asked of her by individuals who are considering applying to serve on a PCORI advisory panel. Dr. Cook responded that PCORI has pathways that enable information from Advisory Panels to be considered by PCORI. Carman further explained that PCORI ensures that transcripts, an external summary, and an internal summary of each advisory panel meeting are prepared from each Advisory Panel meeting that enables information to be fed into PCORI processes, e.g., topic development processes. She explained further that Advisory Panels' input is incorporated into PCORI's work at various levels. For instance, she noted that PCORI has had very deliberate engagement of the Advisory panelists at key points in the strategic planning process where their input can be brought back internally to PCORI staff and the Strategic Planning Committee. This input has been incorporated into information presented to the Board to inform the Board's final decisions. *The following motion was made by James Schuster and seconded by Kara Ayers:* **Motion**: Approve the proposed slates of members, positions and terms for the following Advisory Panels: PEAP, HDDR AP, RDAP, CEDS AP, and CTAP.

	Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions); Connie Hwang was not present during this vote.
Strategic Planning Committee Report: National Priorities Updat and Research Agenda Discussion *Nakela L. Cook, MD, MPH and Sharon Levine, MD, Board Vice Chairperson*	Dr. Levine, Chair of the Strategic Planning Committee, introduced the agenda item and thanked members of the committee. She indicated that Dr. Cook would give an update on the status of strategic planning work. Cook noted that PCORI received input from a range of stakeholders to identify and inform the National Priorities for Health in addition to holding discussions at Board of Governors meetings and a 60-day public comment period on the proposed National Priorities between June 29-August 27, 2021. Preliminary analysis of the public feedback suggests strong support for the five proposed National Priorities. Some preliminary themes from the public feedback address considerations for conceptual points (e.g., distinguishing terms and clarifying concepts) and other areas (e.g., how to do the work and research directions and topics). She informed the Board that the Strategic Planning Committee (SPC) is in the process of reviewing the Research Agenda for proposed revisions. The process for revising the Research Agenda will be similar to the process for the National Priorities and includes opportunities for Board and SPC review and feedback as well as a public comment period. Cook indicated that the Research Agenda will establish the framework through which PCORI achieves progress on the National Priorities, specifically through the strategy of funding comparative clinical effectiveness research (CER); will support the ability to be responsive to stakeholders; and will fulfill PCORI's authorizing law. The Research Agenda will also inform the Research Project Agenda, which will define focused areas for funding. She noted other strategies necessary to accomplish the National Priorities, that may be in addition to the strategy of funding CER, will also be included in the final Strategic Plan. Key proposed parameters for the Research Agenda were presented to the Board, along with preliminary proposed elements for potential application within the Research Agenda, which were developed based on input from public guidance and SPC discussions. Board members commented that, at this point, a challenge is for PCORI to consider important questions to answer through its funded research and note how to utilize its unique role in the research funding landscape. Board members also suggested that the Research Agenda parameters provide clarity on the type of research PCORI may seek to fund, should be accompanied by a lay language translation when it is posted for public comment and, when appropriate, terms should be clarified for ease of understanding.

	Cook noted that during the upcoming October 26th Board meeting, it is expected that the final analysis of the public input will be presented and that the proposed National Priorities will be considered by the Board for adoption. Additionally, it is expected that there will be a facilitated conversation on the draft Research Agenda. During the December Board meeting, the Board is expected to consider the proposed Research Agenda for approval for posting for public comment.
Public Comment Period *Kristin Carman, MA, PhD*	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 *Christine Goertz, DC, PhD*	Dr. Cook reviewed the highlights of the meeting including congratulating the new Advisory Panelists and providing a request to Board members to provide her with their thoughts on additional input as well as any questions for the Strategic Planning agenda before the October meeting. Dr. Goertz thanked those who joined the meeting and then adjourned the meeting. The meeting ended at 2:37 pm

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

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ATTACHMENT A:

Advisory Panel on Patient Engagement Panelists (PEAP)			
Name	***Stakeholder Group***	***State***	***Term Length (or until replacements are appointed)***
Donald Adams, Jr.	*Patients, Caregivers, and Patient Advocates*	*IL*	*3 years*
Geri Baumblatt	*Patients, Caregivers, and Patient Advocates*	*IL*	*3 years*
Russell Bennett	*Patients, Caregivers, and Patient Advocates*	*CA*	*3 years*
Jen Brown	*Patients, Caregivers, and Patient Advocates*	*IL*	*3 years*
Melody Goodman	*Researchers*	*NY*	*3 years*
Una Lee	*Clinicians*	*WA*	*3 years*
Lauren Lessard	*Researchers*	*AK*	*3 years*
Rupa Valdez	*Researchers*	*VA*	*3 years*
PEAP Chair			
Neely Williams	*Patients, Caregivers, and Patient Advocates*	*TN*	*1 year*
PEAP Co-Chair			
Karen Fortuna	*Researchers*	*NH*	*1 year*

Advisory Panel on Healthcare Delivery and Disparities Research Panelists (HDDR AP)			
Name	***Stakeholder Group***	***State***	***Term Length (or until replacements are appointed)***
Kelly Buckland	*Patients, Caregivers, and Patient Advocates*	*DC*	*3 years*
Diana Cejas	*Clinicians*	*NC*	*3 years*
Ashley Valentine	*Patients, Caregivers, and Patient Advocates*	*IL*	*3 years*

Advisory Panel on Rare Disease Panelists (RDAP)			
Name	***Stakeholder Group***	***State***	***Term Length (or until replacements are appointed)***
Heather Adams	*Researchers*	*NY*	*3 years*
Natario Couser	*Clinicians*	*VA*	*3 years*
Giovanna Devercelli	*Industry*	*NC*	*3 years*
Deanna Fournier	*Patients, Caregivers, and Patient Advocates*	*NJ*	*3 years*
Sonia Jain	*Researchers*	*CA*	*3 years*
Mileva Repasky	*Patients, Caregivers, and Patient Advocates*	*PA*	*3 years*
Bridget Reynolds	*Patients, Caregivers, and Patient Advocates*	*IL*	*3 years*
Jasvinder Singh	*Researchers*	*AL*	*3 years*
RDAP Chair			
Mathew Edick	*Patients, Caregivers, and Patient Advocates*	*MI*	*2 years*

Advisory Panel on Clinical Effectiveness and Decision Science Panelists (CEDS AP)			
Name	***Stakeholder Group***	***State***	***Term Length (or until replacements are appointed)***
Timothy Gong	*Clinicians*	*TX*	*3 years*
Michael Hoerger	*Clinicians*	*LA*	*3 years*
Christina Nyquist	*Patients, Caregivers, and Patient Advocates*	*VA*	*3 years*
Jennifer Olsen	*Patients, Caregivers, and Patient Advocates*	*GA*	*3 years*
Sarah Wang	*Patients, Caregivers, and Patient Advocates*	*VA*	*3 years*

Advisory Panel on Clinical Trials Panelists (CTAP)			
Name	***Stakeholder Group***	***State***	***Term Length (or until replacements are appointed)***
Jennifer B. Christian	*Industry*	*NC*	*3 years*
Angelica Geter	*Researchers*	*GA*	*3 years*
Janet Holbrook	*Researchers*	*MD*	*3 years*
Emily Largent	*Researchers*	*PA*	*3 years*
Elizabeth Turner	*Researchers*	*NC*	*3 years*
CTAP Chair			
Michael Jones	*Researchers*	*MS*	*2 years*