



Board of Governors Meeting via Teleconference / Webinar

Tuesday July 26, 2022

1:00pm – 2:30pm Eastern

MINUTES

Board Members Present:

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; Barbara McNeil, MD, PhD; Eboni Price-Haywood, MD, MPH; James Schuster, MD, MBA; Michael Lauer, MD (designee for Lawrence Tabak, DDS, PhD); Kathleen Troeger, MPH; Robert Valdez, PhD, MHSA; Danny van Leeuwen, MPH, RN

Board Members Absent: Christine Goertz, DC, PhD, *Chairperson*; Christopher Friese, PhD, RN; Ellen Sigal, PhD; Janet Woodcock, MD; Robert Zwolak, MD, PhD

Agenda Item	PCORI Speakers
Welcome and Call to Order Consider for Approval: June 14, 2022, Board Meeting Minutes <i>Sharon Levine, MD, Board Vice Chairperson</i>	Dr. Levine chaired and opened the meeting, welcoming all to the meeting of the PCORI Board of Governors. Levine read the Chair Statement on Conflict of Interest. She also welcomed Dr. Harv Feldman, who was participating in his first Board meeting since joining PCORI's staff as Deputy Executive Director for Patient-Centered Research Programs. With no additions or corrections to the minutes offered, Levine then presented the minutes of the June 14, 2022, Board meeting for approval. <i>The following motion was made by Michael Herndon and seconded by Robert Valdez.</i> Motion: Approve the Minutes of the June 14, 2022, Board of Governors Meeting <i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions). Barbara McNeil was not present during this vote.</i> <i>Barbara McNeil joined the Board meeting following this agenda item.</i>
Consider for Approval: Advisory Panel Members, Chairs and Co-Chairs <i>Kristin Carman, MA, PhD</i>	Dr. Carman provided an overview of the advisory panel recruitment and selection process. She noted that applications were accepted from September 2021 until March 1, 2022. She then summarized the review process prior to nominations being submitted to the Board for approval. Carman indicated that staff conducted outreach to various stakeholder groups through multiple avenues of communication, including developing enhanced promotional materials, hosting a town hall and office

<i>Director, Public & Patient Engagement</i> <i>Steve Clauser, PhD, MPH Program Director</i> <i>Kim Bailey, MS Associate Director</i> <i>Anne Trontell, MD, MPH Associate Director</i>	hours, developing blog postings by current and former Advisory Panelists describing their experiences, explaining why they were motivated to join PCORI and encouraging others to apply to serve on an Advisory Panel. Carman indicated that PCORI solicited feedback on the application process and will implement changes to respond to suggestions. Carman presented the panel of proposed panelists, positions, and terms for the Advisory Panel on Patient Engagement, including the proposed Chair and Co-Chair. <i>(See Attachment A)</i> Dr. Clauser reviewed the panels of proposed panelists and chairs for the Advisory Panel on Healthcare Delivery and Disparities Research and the Advisory Panel on Rare Disease. <i>(See Attachment A)</i> Ms. Bailey reviewed the proposed panelists, positions, and terms for the Advisory Panel on Clinical Effectiveness and Decision Science. <i>(See Attachment A)</i> Dr. Trontell reviewed the proposed panelists, positions, and terms for the Advisory Panel on Clinical Trials. <i>(See Attachment A)</i> Board members expressed support for the presented slates. <i>The following motion was made by Barbara McNeil and seconded by Robert Valdez.</i> Motion: Approve the proposed slates of members, positions, and terms for the following Advisory Panels: PEAP, HDDR AP, RDAP, CEDS AP, and CTAP <i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions).</i>
Consider for Approval: Set of Candidate Topic Themes for Focused Funding <i>Nakela L. Cook, MD, MPH, Executive Director and Harv Feldman, MD, MSCE, Deputy Executive Director for Patient-Centered Research Programs</i>	Drs. Cook and Feldman presented a set of candidate topic themes for consideration for further development over the next several funding cycles. Cook thanked the Board and stakeholders for their input to date which allowed PCORI to identify a rich set of themes for near term focus. Cook highlighted the Board-approved strategic plan which has the National Priorities for Health at its center and includes a holistic approach to addressing these National Priorities through a range of activities, including patient-centered outcomes clinical effectiveness research, dissemination and implementation, engagement, and infrastructure activities. Focusing on the patient-centered CER activities, Cook reminded the Board that PCORI releases two general categories of research funding announcements: 1) Broad funding announcements that draw on research teams' best ideas, through the Broad Pragmatic Studies and PLACER funding announcements, and 2) focused funding announcements that begin through stakeholder identification of topics and are addressed through targeted funding announcements and Special Area of Emphasis topics. Cook explained that last year, PCORI piloted an Expedited and Enhanced Approach which expanded the range of approaches for focused funding announcements and provided advance notice to the research and stakeholder community through early announcement of candidate topics in development. During 2021, this approach resulted in the release of six Special Areas of Emphasis and twelve Targeted Funding Announcements (which were met with robust responses from the community), and four approved candidate topics still under development. Cook shared that this year,

PCORI will build on the approach and learnings to advance the National Priorities for Health while also working to refine the Research Project Agenda setting process, a next step in strategic planning.

Cook indicated that the topic themes under consideration emerged from a multi-step process, including landscape review, stakeholder engagement, analysis of engagement awards, and consideration of public comment on the National Priorities for Health. She noted that all of the input coalesced into eight themes that align with PCORI's National Priorities for Health, are high burden conditions or issues, resonate with multiple stakeholder groups, and reflect areas where PCORI funding would make an impact.

Dr. Feldman explained that the topic candidates represent three topic themes, and intentionally intersect and overlap. Feldman indicated that if the Board approves the recommended topics, PCORI would engage with more stakeholders to refine the thematic areas and topics.

The Recommended Set of Candidate Topic Themes for Further Development are:

Populations

- Promoting healthy children and youth
- Promoting health for older adults

Health Behavior

- Addressing violence and trauma
- Addressing substance use

Health Conditions

- Improving cardiovascular health
- Managing pain
- Promoting sleep health
- Improving mental and behavioral health

These recommended candidate topic themes would join the ongoing research priority areas of Intellectual and/or Developmental Disabilities, Maternal Morbidity and Mortality, Rare Disease, and COVID-19. Feldman then presented two themes with examples of inputs that led to creation of the theme.

Board members expressed enthusiasm for the range of medical themes and systems issues and encouraged PCORI to consider cross-cutting areas, such as caregiving and workforce. A Board member noted that promoting sleep health is not only a health condition but a health behavior. Board members encouraged PCORI to consider upstream issues that impact patient health and may lead to a latter diagnosis, such as substance use. Board members recognized the importance of focus on substance use and promoting healthy youth. Within the theme of healthy youth, prevention generally and prevention of unintended pregnancy were highlighted as topics of importance. Board members encouraged PCORI to consider evidence needs related to oral health care for children and restorative dental care for older adults. Board members encouraged PCORI to consider evidence needs related to positive health behaviors generally, in addition to sleep hygiene. Board members expressed enthusiasm about bringing a focus on health equity and underrepresented populations into refinement activities across the themes.

	<i>The following motion was made by Barbara McNeil and seconded by Michael Herndon.</i> Motion: Approve the Recommended Set of Candidate Topic Themes for Further Development <i>Accepted by a majority vote of the voting Board members by voice vote (no opposed; Robert Valdez abstained from the vote).</i>
Update on Research Awards and Dissemination and Implementation Awards <i>Nakela L. Cook, MD, MPH, Executive Director</i>	Dr. Cook introduced the agenda item by providing a summary of the awards made under several different PCORI Funding Announcements (PFAs), including the name of the PFA and the total funding per PFA, with a total amount awarded under all PFAs of \$261M (subject to programmatic and budget approval by PCORI). She reported that 28 research and dissemination/implementation (D&I) projects were approved this cycle. Cook noted that three research PFAs, Broad, Methods, and PLACER, were open to investigator-initiated ideas and three were targeted. The D&I funding announcement focused on implementation of PCORI-funded PCOR results. It was noted that the Broad announcement was the last issuance in this format and that PCORI has transitioned to a combined Broad-Pragmatic announcement for upcoming funding cycles. Cook highlighted two awards that focus on PCORI's priority areas. One study addresses intellectual and developmental disabilities (IDD) as well as disparities and tests the effectiveness of a future planning tool to ease the burden on caregivers. This award will broaden PCORI's IDD award portfolio to include a project that includes black and Latinx study participants. Cook noted that the other study, in the maternal morbidity and mortality (MMM) area, addresses factors that contribute to maternal suicide and overdose and will complement PCORI's award portfolio of over thirty studies in MMM. Cook noted that the five PLACER studies are large scale, high impact, randomized trials. The studies range in size from 1500-3700 participants. Four studies include drug comparisons, and all are focused on high impact conditions. Cook described the four Methods awards, noting that they include work related to artificial intelligence, machine learning, and data networks. Cook introduced the Healthy Aging targeted awards. She reminded the Board that this PFA was different than typical targeted ones, with a broader approach focused on domains for research in this specified area. She noted that there was a very robust response with over forty letters of intent received. PCORI was able to fund four awards for a total of \$25 million, and plans to re-issue this PFA as there is substantial interest in the topic. Cook described one award for the Migraine targeted PFA, which focuses on comparing combined therapy with amitriptyline to cognitive behavioral therapy. One award was also made for the Osteoporotic Fracture targeted PFA, which will examine the effectiveness of a multimodal intervention for care transitions for those with lower limb fractures. Cook informed the Board that both funding

	announcements will be re-issued as originally planned to fulfill the full intent of these announcements. Cook presented the Dissemination and Implementation Awards for Cycle 3 2021 that were approved from the Limited Competition (LC) PFA and which totaled \$4M. The project titles are: the TRIAD (Treatment Individualized Appendicitis Decision-making) Implementation Program; and Technology-Assisted Implementation of a Mobile Health Intervention for Serious Mental Illness Cook provided additional context for the awards with respect to the FY2022 Commitment Plan. She stated that with the addition of these awards, PCORI will have committed \$380 million in research funding in FY2022. While a few additional awards are expected to be made, it is not expected that funding will quite reach the \$500 million target by the end of FY2022 but will reach close to that amount. She also stated that while the committed funding of \$16M for D&I awards did not attain the \$40M target for FY2022, a robust response to another funding opportunity bodes well for meeting targets in future funding cycles. Cook noted that all commitments will be presented at the upcoming September Board of Governors meeting at the end of FY2022, with more discussion anticipated in December when the multi-year plan and any anticipated adjustments will be discussed. Board members discussed the need to ensure that the migraine studies include recently approved medications. There was also a desire to include community partners in addition to awardee institutions in future award presentations to the Board. Cook indicated that the discussed need to post announcements for a sufficient time to allow researchers time to prepare better applications has been part of the planning for these candidate topics. Dr. Levine reminded the Board that these awards were approved by the Executive Director under delegated authority from the Board under the new awards approval authority approved by the Board at its June 14, 2022, meeting.
FY 2022 Mid-Year Financial Results <i>Russell Howerton, MD, FACS Finance and Administration Committee Chair</i> <i>Brian Trent, MPA Deputy Executive Director for Operations</i>	Dr. Howerton introduced the Mid-Year Financial Review which reports on the status of PCORI's financials and includes a report on financial performance comparing actuals and budget between October 1, 2021, and March 31, 2022. He noted that the FAC has reviewed these financials and informed the Board that the budget variance of 6% is within the variance target of 10%. Howerton then introduced Brian Trent to present the FY2022 Mid-Year Financial review. Trent presented to the Board the financials as of March 31, 2022, which included total revenues (\$231.8M), cash balance (\$1,613.2M) and outstanding award obligations (\$1,222.5M). He reported that unobligated cash available is \$390.7M. He outlined the budget versus actuals for FY2022 stating that the actuals for the timeframe reviewed was \$181.7M, which is 6% under budget. Board members asked what accounted for the variance of \$11M in award payments, which Trent explained is usually a timing issue relating to payments for award expenses but that he expected that variance gap to lessen in future months. He also noted that PCORI's Administrative Support costs which are 8% of PCORI's total expenses were equal to or lower than comparable research funders.

Closing Remarks <i>Nakela L. Cook, MD, MPH, Executive Director</i>	Dr. Cook reviewed the Board meeting highlights. She thanked all the Board members for their helpful and insightful input on these important topics and thanked all that joined the call. Cook then reminded Board members of the upcoming, in-person meeting, scheduled for September 19-20, 2022.
Wrap-up and Adjourn <i>Sharon Levine, MD, Board Vice Chairperson</i>	Dr. Levine thanked all who joined the meeting and noted that the meeting agenda, minutes from the previous meeting, slides and archived webinar would be posted to the PCORI website within the week. The meeting was adjourned at 2:38pm.

Attachment A:**Advisory Panel on Patient Engagement**

Name	Stakeholder Group	State	Term Length (or until replacements are appointed)
Agatha Onyinyechukwu Adigwe	Patients, Caregivers, and Patient Advocates	MA	3 years
Ramona Burress	Industry	IL	3 years
Gwen Cooper	Patients, Caregivers, and Patient Advocates	IN	3 years
Heidi Dohse	Patients, Caregivers, and Patient Advocates	ID	3 years
David Hwang	Clinicians	NC	3 years
Isabelle Lousada	Patients, Caregivers, and Patient Advocates	MA	3 years
Aracely Rosales	Patients, Caregivers, and Patient Advocates	FL	3 years
Chair			
Karen Fortuna	Researchers	NH	1 year
Co-Chair			
Jen Brown	Patients, Caregivers, and Patient Advocates	IL	1 year

Advisory Panel on Healthcare Delivery and Disparities Research

Name	Stakeholder Group	State	Term Length (or until replacements are appointed)
Billy Collins	Clinicians	MD	3 years
Mark Friedberg	Payers	MA	3 years
Venus Gines	Patients, Caregivers, and Patient Advocates	TX	3 years
Heather Himelhoch	Hospitals/Health Systems	IL	3 years
Dipti Itchhaporia	Clinicians	CA	3 years
Feylyn Lewis	Researchers	TN	3 years
Aasim Ilyas Padela	Researchers	WI	3 years
Katherine Sanchez	Hospitals/Health Systems	TX	3 years
Betty Scull	Patients, Caregivers, and Patient Advocates	AR	3 years
Jeffrey Tom	Payers	HI	3 years
Rosemary Veniegas	Hospitals/Health Systems	CA	3 years
Aileen Wong	Clinicians	AZ	3 years
Chair			
Varleisha Gibbs	Researchers	MD	1 year
Co-Chair			
Brandi Ring	Clinicians	TX	1 year

Advisory Panel on Rare Disease

Name	Stakeholder Group	State	Term Length (or until replacements are appointed)
Danielle Dong	Industry	MA	3 years
Aliza Fink	Patients, Caregivers, and Patient Advocates	MD	3 years
Meghan Halley	Researchers	CA	3 years
Christy Moore	Payers	CA	3 years
Richard Parad	Researchers	MA	3 years
Co-Chair			
Heather Adams	Researchers	NY	2 years

Advisory Panel on Clinical Effectiveness and Decision Science

Name	Stakeholder Group	State	Term Length (or until replacements are appointed)
Michael Fischer	Researchers	MA	3 years
Tom James	Payers	KY	3 years
Barry Liden	Researchers	MD	3 years
Yaara Zisman-Ilani	Researchers	PA	3 years
Chair			
Julie Eller	Patients, Caregivers, and Patient Advocates	MA	1 year
Co-Chair			
Michael Hoerger	Clinicians	LA	2 years

Advisory Panel on Clinical Trials

Name	Stakeholder Group	State	Term Length (or until replacements are appointed)
M. Khair ElZarrad	Policymakers	MD	3 years
Alexander Fiks	Researchers	PA	3 years
Kelley Kidwell	Researchers	MI	3 years
Greg Merritt	Patients, Caregivers, and Patient Advocates	MI	3 years