pcori

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting via Teleconference / Webinar

Monday, September 14, 2020

1:30pm - 4:45 pm ET

MINUTES

Board Members Present:
Christine Goertz, DC, PhD, *Chairperson;* Sharon Levine, MD, *Vice Chairperson*; Kara Ayers, PhD; Larry Becker; Michael Lauer, MD (designee for Francis Collins, MD, PhD); Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Christopher Friese, PhD, RN; Michael Herndon, DO; Russell Howerton, MD; Gail Hunt; Freda Lewis-Hall, MD; David Meyers, MD (designee for Gopal Khanna, MBA); Michelle McMurry-Heath, MD, PhD; Barbara McNeil, MD, PhD; Grayson Norquist, MD, MSPH; Kathleen Troeger, MPH; Robert Zwolak, MD, PhD

Board Members Absent: Ellen Sigal, PhD and Janet Woodcock, MD

Methodology Committee Member present: Robin Newhouse, RN, PhD

Executive Team: Nakela Cook, MD, MPH, *Executive Director*; Josie Briggs, MD; Steve Clauser, MPA, PhD; Mary Hennessey, Esq.; Stanley Ip, MD; Michele Orza, ScD; Tasha Parker, Laura Rodriguez, Jean Slutsky, PA, MSPH

Agenda Item	PCORI Speakers
Welcome and Call to Order **Consider for Approval:** • Minutes of July 21, 2020 Board Meeting • Committee Leadership Nominations - *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. Dr. Goertz introduced the Consent Agenda, including the nominations for Committee Chair and Vice Chair and some Committee membership positions through September 22, 2022, and gave the opportunity to Board members to discuss any of the matters on the Consent Agenda. Gail Hunt inquired about the absence of a recommendation of a Vice Chair of the Selection Committee. Drs. Goertz and Cook noted that an appointment to this position goes through a different process and, while it will be addressed at a later date, it was not included under the umbrella of this motion. *The following motion was made by Larry Becker and seconded by Gail Hunt* **Motion:** Approve each of the motions on the Consent Agenda as reflected below: - Minutes from the July 21, 2020 Board meeting - The following nominations presented by the Governance Committee for the positions of Chair and Vice Chair of the specified Committees effective on September 23, 2020 for a two (2) year term, and the following nominations for Committee membership: - --- Engagement, Dissemination, and Implementation: Mike Herndon, Chair; Sharon Levine, Vice-Chair - --- Research Transformation Committee: Kathleen Troeger, Chair; Kara Ayers, Vice-Chair - --- Science Oversight Committee: Alicia Fernandez, Chair; Christopher Friese, Vice- Chair

	- --- Finance and Administration Committee: Russell Howerton, Chair; Robert Zwolak, Vice Chair; Christine Goertz, Member (Mike Herndon will no longer serve as a member of the FAC.) *Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions).*
Consider for Approval: • New Advisory Panelists, Chairs and Co-Chairs - *Kristin Carman, MA, PhD, Director, Engagement, Public and Patient Engagement; Steve Clauser, MPA, PhD, Program Director, Science, Healthcare Delivery & Disparities Research (HDDR) and Stanley Ip, MD, Interim Program Director, Clinical Effectiveness Decision Science (CEDS)*	Dr. Carman provided an overview of the Advisory Panel review process, which included the review timeline, the number of applications received per panel, and the maximum number of available openings on each panel. She noted that of the 153 applications received, 34 panelists were being put forth for Board approval. *(See Attachment A for list.)* Carman then thanked the staff for their efforts in making sure the panels represent multiple dimensions of diversity and noted the exceptional and numerous applications that were received for a limited number of open slots. Dr. Ip presented the proposed slates of new Advisory Panel members, which included their stakeholder type, organization, and term length for the Rare Disease Advisory Panel (RDAP), the Clinical Trials Advisory Panel (CTAP), and the Clinical Effectiveness and Decision Science Advisory Panel (CEDS AP). These slates were approved by the Science Oversight Committee (SOC) and Methodology Committee (MC) to be recommended to the full Board of Governors for service. Ip also presented a proposed co-chair for the RDAP and a chair for the CTAP. *(See Attachment A.)* Dr. Clauser presented the proposed slate of new Advisory Panel members for the Healthcare Delivery and Disparities Research Advisory Panel (HDDR AP). This slate was approved by the Science Oversight Committee (SOC) to be recommended to the Board of Governors for service. Clauser also presented a proposed chair and co-chair for the HDDR AP. *(See Attachment A.)* Dr. Carman presented the proposed slate of new Advisory Panel members for the Advisory Panel on Patient Engagement (PEAP). This slate was approved by the Engagement, Dissemination, and Implementation Committee (EDIC) to be recommended to the Board of Governors for service. Carman also presented a proposed chair and co-chair for the PEAP. After opening the floor for questions and discussion, some Board members indicated that Board members would find it valuable to attend Advisory Panel meetings. Larry Becker asked about the demographics of the applicant pool, which Carman provided. *The following motion was made by Russell Howerton and seconded by Sharon Levine* **Motion:** Approve the proposed slates of members, positions, and terms for the following Advisory Panels: CTAP, RDAP, CEDS AP, HDDR AP and PEAP. *Approved by a majority vote of the voting Board members by voice vote (no opposed, no abstentions).*

	The approved slates of members, positions, and terms for the Advisory Panels is reflected in Attachment A.
Revised Methodology Committee and Governance Committee Charters - *Sharon Levine, MD, Chair, Governance Committee and Mary Hennessey, Esq., General Counsel*	Dr. Levine introduced the agenda item to revise PCORI's Methodology and Governance Committee Charters, and explained that due to PCORI's reauthorizing legislation shifting the authority to appoint members of PCORI's Methodology Committee (MC) from the GAO to the PCORI Board, the Governance Committee has developed a proposed governance structure with input from the Methodology Committee that will enable the Board to appoint MC members. The Governance Committee recommended that the Board approve proposed amendments to the MC Charter that reflect this proposed governance structure. Levine also noted that the Governance Committee recommends that the Board approve the proposed amendments to the Governance Committee charter which strikes language about advising the GAO regarding the process of appointment of MC members since that authority is now with the PCORI Board. Mary Hennessey then explained the amendments to the Methodology Committee charter which include: - Implementing six-year terms with staggered term structure; - Term limits: MC members may be appointed to a second term to the extent necessary to fulfill the functions of the MC, requirements of the authorizing law, and/or the needs of PCORI, but no more than two full consecutive 6-year terms; - Appointment to the MC to fill a premature vacancy for the remainder of a predecessor's term; and - Confirmation that an appointed MC member is eligible to serve until a successor is appointed. Hennessey also pointed out the proposed amendments to the Governance Committee charter that delete language which became outdated given the changes in the reauthorizing legislation that Levine outlined. She also noted that if the Board approved this new governance framework for the Methodology Committee, then planning for next steps will proceed, including for a regular cycle of appointments in odd years (e.g. 2021, 2023, etc.) (to avoid confusion and competition with GAO's regular cycle of Board appointments which takes place in even years). A Board member asked whether the current MC members would be assigned according to terms and was assured that under next steps, an appropriate transition plan for current MC members would be addressed. *The following motion was made by Sharon Levine and seconded by Barbara McNeil.* **Motion:** Approve the proposed amended Methodology Committee Charter and the proposed amended Governance Committee charter. *Approved by a majority vote of the voting Board members by voice vote (no opposed, no abstentions).* .

Cycle 1 2020 D&I Large Awards Slate (1 award) - *Larry Becker, Chair, Engagement, Dissemination, and Implementation Committee (EDIC) and Joanna Siegel, SM, ScD, Director, Dissemination & Implementation (D&I) Program*	Dr. Goertz turned to Mr. Becker and Dr. Siegel, to discuss the proposed funding slate for the Cycle 1 2020 *Limited Competition Implementation of PCORI-Funded Patient-Centered Outcomes Research Results* PFA. After Becker introduced the PFA, Siegel presented the D&I award slate recommended by the EDIC and briefly described the one project proposed for funding, "Implementation of Effective Home Oxygen Weaning Strategies in Premature Infants". This award slate represented a total investment of $1.3M out of the amount budgeted (per year) of $9.0M. This was the first cycle of proposed funding related to this year's budget. *The following motion was made by Gail Hunt and seconded by Jennifer DeVoe.* **Motion:** Approve funding for the recommended award slate from the Cycle 1 2020 Limited Competition Implementation of PCORI-Funded Patient-Centered Outcomes Research Results PFA. *Approved by a majority vote of the voting Board members by roll call vote (13 approved, 0 opposed, 0 abstained, 2 recusals: Kara Ayers and Robert Zwolak). Michael Lauer, David Meyers, and Michelle McMurry-Heath were not present during this vote.*
Executive Director's Report • Highlights from the First 5 Months • COVID-19 Initiatives Update *Nakela Cook, MD, MPH, Executive Director*	Dr. Cook shared highlights from her first 150 days as Executive Director at PCORI. She shared details on PCORI's Office Reopening Plan, PCORI's updated leadership team, and PCORI activities around diversity, equity, and inclusion. She highlighted her first 150 days with the Board of Governors and Committees, and shared themes from a listening tour with diverse stakeholder groups. She provided an update on PCORI's efforts towards meeting our new Congressional mandates, starting with an update on the topic areas in maternal morbidity and mortality and intellectual and developmental disabilities. She also discussed PCORI's efforts toward balancing long- and short-term priorities, and changes to the Methodology Committee charter in response to PCORI's reauthorizing law. Cook provided an update on PCORI's COVID-19 response, covering new award funding, information sharing, and adaptations to existing awards. She shared that PCORI has committed $114M toward COVID-19-related funding to-date. She provided updates on the PCORI-funded HERO Research Program and on COVID-19-related enhancements to existing awards. Cook highlighted enhancements to three PCORI-funded projects: a research award on extended treatment for venous thromboembolism, a dissemination and implementation award on a decision aid for lupus, and an engagement award for engaging with African immigrants in PCOR/CER. Cook shared the titles of the 9 awards funded under the COVID-19 Targeted PFA, and the research areas that the studies address. She provided an update on what PCORI has learned via project monitoring during COVID-19: an early trend that a percent of projects which may not be able to meet objectives within project period is increasing due to COVID-19 delays, and she provided details around the type of disruptions and delays due to COVID-19. She concluded by sharing activities for her next 150 days, including PCORI's operations, future funding opportunities, engaging with stakeholders, efforts around strategic planning, and welcoming new Board members.

	Board Members expressed interest in Cook's strategy for prioritizing efforts in her next 150 days, and in the impact of COVID-19 on participant enrollment and recruitment. They discussed PCORI's challenges relating to public health and to eliminating health disparities.
Consider for Approval for Posting for Public Comment: Cost Data Principles for Researchers - *Jean Slutsky, PA, MSPH, Chief Engagement and Dissemination Officer, Andrew Hu, Director, Engagement, Public Policy, and Joanna Siegel, SM, ScD, Director, D&I Program*	Dr. Goertz introduced the discussion of the approval for posting Cost Data "Principles" for Researchers for public comment and then turned it over to Mr. Hu and Dr. Siegel. Hu provided an overview of PCORI's proposed "Principles for the Consideration of the Full Range of Outcomes Data". He offered additional context on PCORI's reauthorizing law as well as the Congressional and stakeholder intent for the new cost data provision. He also discussed the stakeholder input on the cost data provision received by PCORI. The implementation plan for this provision was explained including the timing and opportunities for public comment. He went over the three pillars of implementation; Pillar 1- providing guidance to PIs in future PFAs on how they should interpret this policy and incorporate it into their research proposals; Pillar 2- establishing methodology standards to inform how PCORI-funded studies should capture relevant data; and Pillar 3-convening discussions on how this information can/should be used. Pillar 1 of implementation, set to begin upon approval of proposed "Principles", includes the posting of the "Principles" for a 60-day public comment period, a series of webinars for further stakeholder feedback and comment, and the presentation of a revised set of "Principles" to the Board for final approval following public comment. Hu then introduced the proposed "Principles", and the feedback received on them to date in the process of readying for public comment; he also introduced open questions for input on the "Principles" for which PCORI will seek feedback during the public comment period. Principle #1 – PCORI-funded research may consider the full range of outcomes important to patients and caregivers, including burdens and economic impacts. Principle #2 – PCORI-funded research may consider the full range of outcomes relevant to other stakeholders, when these outcomes have a near-term or longer-term impact on patients. Principle #3 – The collection of data on burdens and economic impacts of treatment options must be appropriate and relevant to the clinical aims of the study. Principle #4 – Beyond the collection of burden and economic impact data, PCORI may support the conduct of certain types of economic analyses as part of a funded research study, to enhance the relevance and value of this information to health care decision-makers.

	Ms. Hunt commented that family out-of-pocket costs and work impacts were not included and requested that family impacts and caregiver impacts for caring for patients (such as driving) be included. Dr. Zwolak expressed support for the efforts made to address economic impact with tools that reflect true real-world impacts and applauded PCORI's approach. *The following motion was made by Jennifer DeVoe and seconded by Larry Becker* **Motion:** Approve the Draft Principles for the Consideration of the Full Range of Outcomes Data for Posting for Public Comment. *Approved by a majority vote of the voting Board members by roll call vote (17 approved, 0 opposed, 0 abstained, 0 recusals). David Meyers was not present during this vote.*
Wrap up and Adjournment - *Christine Goertz, DC, PhD*	Dr. Goertz reminded attendees that the Public Meeting of the PCORI Board would continue tomorrow and invited attendees to join at that time. Meeting adjourned at 3:56 pm.

Minutes were approved by the PCORI Board of Governors 11-17-2020

See Attachment A for list of Advisory Panel nominees approved by the Board.

<u>Attachment A: New Advisory Panelists, Chairs and Co-Chairs</u>

Approved nominations to the Advisory Panel on Clinical Trials (CTAP):

- <u>Nominations (3-year term):</u>
  - Rowena Dolor, MD *(Researchers)*
  - Ilana Gareen, PHD, MPH *(Researchers)*
  - Larry Kessler, ScD *(Researchers)*
  - William Tierney, MD *(Researchers)*
  - Susan Lin, ScD, OTR/L (*Patients, Caregivers, and Patient Advocates)*
  - Michael L. Jones, PhD, MBA, RN *(Payers)*
- <u>Chair Nomination (1-year term):</u>
  - Catherine Crespi-Chun, PhD, MS *(Researchers)*

Approved nominations to the Advisory Panel on Rare Disease (RDAP):

- <u>Nominations (3-year terms):</u>
  - Danielle Boyce, MPH *(Patients, Caregivers, and Patient Advocates)*
  - Laura Tosi, MD *(Clinicians)*
  - Mathew Edick, PhD *(Patients, Caregivers, and Patient Advocates)*
  - Nancy Rose, MD *(Clinicians)*
  - Salman Hussain, MPH *(Industry)*
  - Sarah Bacon, MS *(Patients, Caregivers, and Patient Advocates)*

- <u>Co-Chair Nomination (2-year term):</u>
  - Doug Lindsay, BS (Patients, Caregivers, and Patient Advocates)

Approved nominations to the Advisory Panel on Clinical Effectiveness and Decision Science (CEDS):

- <u>Nominations (3-year terms):</u>
  - Danielle Bargo, MSc *(Industry)*
  - Samantha Harden, PhD *(Researchers)*
  - Karen Giuliano, PhD, MBA, RN *(Researchers)*
  - Michael Philbin, PhD *(Patients, Caregivers, and Patient Advocates)*
  - Kari Gali, DSC *(Clinicians)*
  - William Bennett, MS, MD (*Researchers)*
  - Helen M. Beady, EdD, MEd *(Patients, Caregivers, and Patient Advocates)*
  - Joey Mattingly, PhrmD, MBA, PhD *(Researchers)*
  - Rick Rader, MD *(Researchers)*
  - Adjoa Adofo Kyerematen, MS *(Policy Makers)*
  - Mychal Weinert, BS *(Patients, Caregivers, and Patient Advocates)*
  - Lisa Goldman Rosas, MPH, PhD *(Researchers)*
  - Susan Johnson, BS, MBA *(Clinicians)*
  - Julie Eller, BS *(Patients, Caregivers, and Patient Advocates)*

Approved nominations to the Advisory Panel on Healthcare Delivery and Disparities Research (HDDR):

- Nominations (3-year terms):
  - Brandi Ring, MD (*Clinicians)*
  - Kristina M. Cordasco, MD, MPH, MSHS (*Researchers)*
  - Varleisha Gibbs, PhD, OTD, OTR/L (*Researchers)*
  - Jeffrey Oliver, MBA *(Patients, Caregivers, and Patient Advocates)*

- Chair & Co-Chair Nominations (2-year terms):
  - **Chair:** Jane Kogan, PhD *(Payers)*
  - **Co-Chair:** Alicia Arbaje, PhD, MD, MPH *(Researchers)*

Approved nominations to the Advisory Panel on Patient Engagement (PEAP):

- Nominations (3-year terms):
  - Karen L. Fortuna, PhD, MSW, LICSW *(Researchers)*
  - Margarita Holguin, MPA *(Patients, Caregivers, and Patient Advocates)*
  - Alma McCormick *(Patients, Caregivers, and Patient Advocates)*
  - Alan Richmond, MSW *(Patients, Caregivers, and Patient Advocates)*
- Chair & Co-Chair Nominations (1-year terms):
  - **Chair:** Gwen Darien *(Patients, Caregivers, and Patient Advocates)*
  - **Co-chair:** Neely Williams, EdD *(Patients, Caregivers, and Patient Advocates)*