

**Board of Governors Meeting via Teleconference / Webinar**

Tuesday, January 28, 2020

12:00 pm - 1:30 pm ET**MINUTES****Board Members Present:**

Christine Goertz, DC, PhD, *Chairperson*; Kara Ayers, PhD; Larry Becker; Francis S. 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; Kathleen Troeger, MPH; Janet Woodcock, MD; Robert Zwolak, MD, PhD

Board Members Absent:

Grayson Norquist, MD, MSPH; Sharon Levine, MD, *Vice Chairperson*; Ellen Sigal, PhD

Agenda Item	PCORI Speakers
Call to Order, Roll Call, and Welcome - <i>Christine Goertz, DC, PhD, Chairperson and Josephine Briggs, MD, Interim Executive Director and Acting Chief Science Officer</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. Goertz noted that this meeting marks the first meeting since the signing of PCORI's reauthorization legislation that extended PCORI's funding through 2029. She thanked all the advocates and stakeholders that worked across the healthcare community that highlighted the importance of PCORI's work. Goertz also expressed gratitude for the bipartisan support PCORI received in Congress led by PCORI's champions in the House and Senate: Congresspersons Diana DeGette and Don Beyer and Senators Mark Warner, Bill Cassidy, Chris Van Hollen and Shelly Moore Capito. She also thanked the PCORI staff and expressed PCORI's intent to honor the continued trust that patients, payers, caregivers, physicians, purchasers and Congress have placed in PCORI. Goertz then identified highlights in the new mandate, such as advancing patient-centered research to address new research priorities of maternal mortality and intellectual and developmental disabilities, and to continue to work with patients and other stakeholders to disseminate and implement PCORI's research findings to change healthcare practice. Goertz also announced the selection of PCORI's new Executive Director, Nakela Cook, MD, MPH, FACC, a cardiologist active in the research field with a keen interest in engaging patients and other stakeholders in key research initiatives. Dr. Cook will begin her tenure as Executive Director on April 15, 2020. Goertz also thanked Dr. Joe Selby, PCORI's inaugural Executive Director, and Dr. Josie Briggs, who has served as PCORI's interim Executive Director for the past several months. Dr. Josie Briggs then reviewed the meeting agenda.

Consider for Approval: Minutes of the December 9, 2019 Board Meeting - Christine Goertz, DC, PhD	<i>The following motion was made by Freda Lewis-Hall and seconded by Russell Howerton.</i> Motion: Approve the Minutes of the December 9, 2019 Board Meeting. <i>Approved by a majority vote of the voting Board members (no opposed; no abstentions).</i>
Consider for Approval: Additional Applications from Cycle 1 2019 Slate of Awards • Improving Healthcare Systems • Addressing Disparities • Treatment Options for Age-Related Hearing Loss - Barbara McNeil, MD, PhD, Chair, Selection Committee and Josephine Briggs, MD	Dr. McNeil made introductory remarks on behalf of the Selection Committee and introduced Dr. Briggs to provide details regarding the proposed slates of awards being presented to the Board for approval. Briggs noted that the proposed awards were in addition to the Cycle 1 2019 awards the Board approved on November 19th, 2019. The additional proposed awards were initially considered and approved by the Selection Committee on October 1, 2019, but not brought before the Board in November 2019 due to PCORI's limited funds as it waited for reauthorization. Briggs then introduced the proposed Slate of additional awards for the Cycle 1 2019 Broad PFAs Awards. She provided a brief overview of the process and budget for the Cycle 1 2019 Broad PFAs. Of the 74 applications received for Cycle 1 2019, the Board approved 12 in November 2019, and with the additional three applications put forward today, PCORI would fund 15 applications (20%) for a proposed total commitment of \$43.1M out of the budgeted \$76M. The slate of additional Broad Awards consists of three research projects from two different priority areas: Addressing Disparities (1 recommended project) and Improving Healthcare Systems (2 recommended projects). <i>See Attachment A for the list of Cycle 1 2019 Broad PFA additional projects funded.</i> To address questions raised during the Board's discussion on the first slate of awards, Steve Clauser, PCORI's Program Director of the Healthcare Delivery and Disparities Research Program, was invited to provide additional details about the three additional awards. <i>The following motion was made by Barbara McNeil and seconded by Gail Hunt.</i> Motion: Approve funding for the recommended additional awards from the Cycle 1 2019 Broad PFA.

Treatment Options for Age-Related Hearing Loss	<i>Approved by a majority vote of the Board members by roll call vote (16 in favor; 0 opposed; 0 abstentions; 0 recusals); Alicia Fernandez was not present during this vote.</i> Dr. Briggs introduced the proposed slate of additional awards for the Cycle 1 2019 Treatment Options for Age-Related Hearing Loss Targeted PFA. She discussed the priority research question of this targeted PFA as well as the previous studies the Board approved for fund at its November 19, 2019 meeting. The slate consisted of the following additional research project: Addressing the Clinical Dilemma and Patient Preference for Unilateral versus Bilateral Hearing Aids Briggs then discussed some highlights of the proposed research project, such as the study's research question, population/setting, comparators, outcomes, and potential impact. To elaborate on the study and address questions raised during the Board's discussion, David Hickam, PCORI's Program Director of the Clinical Effectiveness and Decision Science Program, and Thu-Vy Do, the program officer for this PFA, were invited to provide additional details about the additional award. Board discussion focused on the length of follow up and measurement of patient preference. <i>The following motion was made by Kara Ayers and seconded by Francis Collins.</i> Motion: Approve funding for the recommended additional award from the Cycle 1 2019 Treatment Options for Age-Related Hearing Loss PFA <i>Approved by a majority vote of the Board members by roll call vote (15 in favor; 0 opposed; 0 abstentions; 1 recusal: Christine Goertz) Alicia Fernandez was not present during this vote.</i>
Consider for Approval: PCORnet Coordinating Center Extension Josephine Briggs, MD	Kathleen Troeger, MPH, Chair of the Research Transformation Committee, introduced to the Board of Governors a proposal to approve \$6.1 million to extend the Duke University PCORnet Coordinating Center contract. She noted that the Research Transformation Committee (RTC) reviewed this proposal during its January 16, 2020 meeting. The RTC concluded that the proposed extension is essential to enable the work of PCORnet. Ms. Troeger explained that the requested funds were included in the funding commitment plan reviewed by the Board in September 2019.

Next, Dr. Briggs provided information on PCORnet Coordinating Center expenditures. She noted that annual Coordinating Center expenditures were highest in 2017 due to a focus on network expansion and development of novel tools for data querying and analysis. She explained that over the last two years, however, Coordinating Center expenditures have decreased due to the ability of PCORnet networks to leverage reusable data infrastructure. She added that the budget request for this extension holds costs essentially constant with last year's allocation with a modest increase in scope. PCORI staff anticipate that the expanded scope for the Coordinating Center will enable PCORI to better understand the return on investment at the network site-level, provide a more streamlined process to monitor Clinical Research Network (CRN) data quality and linkage performance, and allow for better assessment of site-level research performance.

Briggs noted that there are important transitions underway by the People-Centered Research Foundation (PCRF) Board. The PCRF Board has decided to wind down PCRF's role in PCORnet over the next several months. She explained that PCRF funding of CRNs, which PCRF awarded through funding that PCRF received from PCORI, will be able to continue through new direct funding contracts by PCORI to CRNs. PCORI staff believe this can be accomplished cooperatively with PCRF with minimal disruption to network progress. Briggs explained that this process should be completed by April of this year.

One Board member noted the emphasis being placed on PCORnet CRNs and asked for clarification on PCORI funding of Patient-Powered Research Networks (PPRNs). Jean Slutsky, PCORI's Chief Engagement and Dissemination Officer, clarified that PCORI used the engagement award mechanism to support projects of a subset of the PPRNs. Another Board member asked whether PCORI has completed a formal assessment of the PPRNs and if there were any continued or future planned relationships with patient engagement groups within PCORnet. Dr. Marschhauser, a Senior Program Officer at PCORI, explained that a formal evaluation of PCORnet was conducted at the end of Phase I to inform PCORI funding for Phase II. Briggs added that patients are engrained in the governance of PCORnet with several serving on its Steering Committee.

The Board noted that there is a need to be more regularly informed of PCORnet progress. Briggs agreed and added that direct contracting with the CRNs and expanding the scope of work for the Coordinating Center will put PCORI in a position to assess PCORnet progress, successes and areas for improvement. A Board member stated that there is also a need to set expectations for PCORnet, set benchmarks for performance, and better understand PCORnet governance. The Board also discussed the need for PCORnet to be useful for both public and private sector funders and the need for

	future conversations regarding the long-term sustainability plan for PCORnet. Briggs concluded her presentation by stating that the \$6.1 million request will support PCORnet Coordinating Center activities including data management, program support, quality improvement efforts, research support, communications and CRN performance monitoring. <i>The following Motion was made by Russell Howerton and seconded by Larry Becker:</i> Motion: Approve \$6.1 million total cost to extend the Duke University Coordinating Center contract. <i>Approved by majority vote of the Board by roll call vote: (13 in favor; 1 opposed, Christopher Frieze; 3 recusals Freda Lewis-Hall, Christine Goertz, and Barbara McNeil).</i>
Wrap up and Adjournment - Christine Goertz, DC, PhD	Meeting ended at 1:13 pm

Minutes were approved by the PCORI Board of Governors 03-02-2020



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ATTACHMENT A: Additional Projects Approved for the Cycle 1 2019 Broad PFA Awards

Program	Awarded Project
Addressing Disparities	Examination of the Evidence-Based Care Transitions Intervention Enhanced with Peer Support to Reduce Racial Disparities in Hospital Readmissions and Negative Outcomes Post Hospitalization
Improving Healthcare Systems	Comparative Effectiveness of Readmission Reduction Interventions for Individuals with Sepsis of Pneumonia
	Improving Family-Centered Pediatric Trauma Care: The Standard of Care versus the Virtual Pediatric Trauma Center