

Board of Governors Meeting via Teleconference / Webinar

Tuesday, November 19, 2019

12:00 pm - 1:30 pm ET

MINUTES

Board Members Present:

Christine Goertz, DC, PhD, *Chairperson*; Sharon Levine, MD, *Vice Chairperson*; 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; David Meyers, MD (designee for Gopal Khanna, MBA); Michelle McMurry-Heath, MD, PhD; Barbara McNeil, MD, PhD; Grayson Norquist, MD, MSPH; Ellen Sigal, PhD; Kathleen Troeger, MPH; Robert Zwolak, MD, PhD

Board Members Absent:

Kara Ayers, PhD; Trent Haywood, MD, JD; Freda Lewis-Hall, MD; Janet Woodcock, MD

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.
Interim Executive Director Introduction and Remarks - <i>Josephine Briggs, MD, Interim Executive Director</i>	Dr. Goertz welcomed Dr. Josephine Briggs as PCORI's new Interim Executive Director and Acting Science Officer as of November 1, 2019. Dr. Briggs expressed her enthusiasm to be working with PCORI's Board and staff. She then reviewed the meeting agenda.
Consider for Approval: Consent Agenda • Minutes of the September 18, 2019 Board Meeting • Nominations for: ○ Chair of the Advisory Panel on Rare Disease (RDAP) ○ Chair and Vice Chair of the Engagement, Dissemination, and Implementation Committee (EDIC) ○ Governance Committee Member - <i>Christine Goertz, DC, PhD</i>	Dr. Goertz introduced the Consent Agenda, and gave the opportunity to Board members to discuss any of the matters on the Consent Agenda. No separate discussion was requested. <i>The following motion was made by Barbara McNeil and seconded by Sharon Levine.</i> Motion: Approve each of the motions on the Consent Agenda as reflected below: • Minutes from the September 18, 2019 Board meeting • Appointment of Scott Berns, MD, MPH, as Chair of the Rare Disease Advisory Panel to serve until August 31, 2021, or until a replacement is appointed • Appointment of Larry Becker as Chair of the Engagement, Dissemination and Implementation Committee to complete the current term of Sharon Levine, MD (until Sept 30, 2020)

	• Appointment of Michael Herndon, DO, as Vice-Chair of the Engagement, Dissemination and Implementation Committee to complete the current term of Larry Becker (until Sept 30, 2020) • Appointment of Grayson Norquist, MD, MSPH, to serve as a member of the Governance Committee. <i>Approved by a majority vote of the voting Board members (no opposed; no abstentions).</i>
Consider for Approval: • Proposed Cycle 1 2019 Slate of Large Awards for the Limited Competition Dissemination and Implementation (D&I) PFA - Sharon Levine, MD, Chair, Engagement Dissemination and Implementation Committee (EDIC), and Joanna Siegel, ScD, Program Director, Dissemination & Implementation	Dr. Levine introduced the agenda item relating to EDIC's recommendation that the Board approve funding for two slates of awards relating to the Cycle 1 2019 dissemination and implementation PFAs. Levine then introduced Dr. Joanna Siegel to present the first EDIC-recommended slate for the <i>Limited Competition Implementation of PCORI-Funded Patient-Centered Outcomes Research Results</i> PFA. Siegel provided additional details about the purpose of this funding initiative, the applicable merit review criteria, and an overview of the PFA review process. She reviewed the numbers of letters of intent submitted, of LOIs invited to submit a full application and of applications received and reported that the overall funding rate tied to the recommended slate is 33%. She then provided a brief description of the two projects on the slate proposed for funding: • "Using the Child Health Ratings Inventories (CHRIS) to Improve Diabetes Care for Children" and • "Effective Dissemination Approach for a Successful Asthma Self-Management Support Intervention." This slate of awards represents a total investment of approximately \$2.6M out of the amount budgeted (per year) of \$9.0M. This is the first of cycle of proposed funding relating to this year's budget. <i>The following motion was made by Larry Becker and seconded by Gail Hunt:</i> Motion: Approve funding for the recommended slate of awards from the Implementation of PCORI-funded Patient-Centered Outcomes Research Results PFA <i>Approved by a majority vote of the voting Board members by roll call vote (16 in favor; 0 opposed; 0 abstentions; 0 recusals); Ellen Sigal was not present during this vote.</i> Dr. Levine then turned back to Dr. Siegel to present the second slate of awards recommended by EDIC to the Board for the <i>Implementation of Findings from PCORI's Major Research Investments</i> PFA, noting that this initiative supports implementation of specific, published, peer-reviewed evidence

• Cycle 1 2019 Implementation of Findings from PCORI's Major Research Investments PFA	selected from major PCORI-funded comparative clinical effectiveness research and other PCORI-identified studies. Siegel provided some additional details about this PFA, highlighted some differences from the previous PFA in the merit review criteria and applicant eligibility, and noted that two LOIs were submitted, one was invited to submit a full application and one application was received. The project on the proposed slate for funding, which represents an overall funding rate of 100%, was "Broad Implementation of Outpatient Stewardship." Dr. Siegel provided some additional details about the recommended project in response to questions from the Board about the project's goals and activities. This slate of awards represents a total investment of \$2.5M out of the amount budgeted (per year) of \$8.0M. This is the first of cycle of proposed funding relating to this year's budget. It was recommended that the names of projects on slates be more descriptive of the focus on the project to enhance understanding and clarity. <i>The following motion was made by Larry Becker and seconded by Russell Howerton:</i> Motion: Approve funding for the recommended slate of awards from the Implementation of Findings from PCORI's Major Research Investments PFA <i>Approved by a majority vote of the voting Board members by roll call vote (17 in favor; 0 opposed; 0 abstentions; 0 recusals)</i>
Consider for Approval: Proposed Cycle 1 2019 Selection Committee Slates of Awards - Barbara McNeil, MD, PhD, Chair, Selection Committee and Josephine Briggs, MD, Interim Executive Director and Acting Chief Science Officer • Broad PFA	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 PCORI had received a large number of meritorious applications this cycle for the Broad and Targeted announcements. She indicated that, due to the limited funds at this time until PCORI awaits reauthorization, several applications have been put on hold and are not proposed for funding at this time. She also announced that, unfortunately, the Cycle 1 2019 re-issue of the Partnerships to Conduct Research within PCORnet (PaCR) announcement did not receive any sufficiently meritorious applications to put forward to the Board for funding. Briggs then introduced the proposed Slate 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 153 Letters of Intent submitted, 96 (63%) were invited to submit a full application. Of these, 74 applications were received. On October 1, 2019, the Selection Committee recommended to fund a slate of twelve applications (16%) for a proposed total commitment of \$33.5M out of the budgeted \$33.4M.

The Broad slate consists of twelve research projects from different priority areas: Addressing Disparities (2 recommended projects); Assessment of Prevention, Diagnosis, and Treatment Options (3 recommended projects); Communication and Dissemination Research (1 recommended project); Improving Healthcare Systems (2 recommended projects); and Improving Methods for Conducting PCOR (4 recommended projects).

(See Attachment A for the list of Cycle 1 2019 Broad PFA projects funded.)

Due to the number of expected Board member recusals, the Board first discussed and voted on the slate of awards for the 4 National Priorities of Addressing Disparities (AD), Assessment of Prevention, Diagnosis, and Treatment Options (APDTO), Communication and Dissemination Research (CDR), and Improving Health Systems (HIS); and then later, the Board discussed and voted on the slate of awards for the National Priority of Improving Method for Conducting PCOR.

Broad PFA: National Priority Areas for AD, APDTO, CDR, IHS

To address questions raised during the Boards' 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 focus of one of the proposed Addressing Disparities awards, remarking that it involved physician training on communication impairments, and including patient-preferred communication styles.

The following motion was made by Robert Zwolak and seconded by Kathleen Troeger.

Motion: Approve funding for the recommended slate of awards from the Cycle 1 2019 Broad PFAs for: Addressing Disparities; Assessment of Prevention, Diagnosis, and Treatment Options; Improving Healthcare Systems; Communication and Dissemination Research.

Approved by a majority vote of the voting Board members by roll call vote (14 in favor; 0 opposed; 0 abstentions; 3 recusals: Jennifer DeVoe, Christopher Friese and Sharon Levine)

Broad PFA: Improving Methods for Conducting PCOR

Briggs then presented the proposed slate of awards for the Cycle 1 2019 Broad PFAs for Improving Methods for Conducting PCOR and

Treatment of Post-traumatic Stress Disorder (PTSD) in Adults Targeted PFA	invited discussion. The Board asked for a more detailed description of the focus of one award on the slate which was provided by Briggs and Clauser. <i>The following motion was made by Larry Becker and seconded by Ellen Sigal.</i> Motion: Approve funding for the recommended slate of awards from the Cycle 1 2019 Broad PFA for Improving Methods for Conducting PCOR. <i>Approved by a majority vote of the voting Board members by roll call vote (15 in favor; 0 opposed; 0 abstentions; 2 recusals: Christine Goertz, Barbara McNeil); Freda Lewis-Hall indicated earlier her intention to recuse herself but was not present at this meeting.</i> <u>Treatment of Post-Traumatic Stress Disorder in Adults</u> Dr. Briggs then introduced the proposed slate of awards for the Cycle 1 2019 Treatment of Post-Traumatic Stress Disorder (PTSD) in Adults Targeted PFA. She provided a brief overview of the process and budget for this announcement. Of the 28 Letters of Intent submitted, 16 (57%) were invited to submit a full application. Of these, 15 applications were received. On October 1, 2019, the Selection Committee recommended to fund a slate of two applications (13%) for a proposed total commitment of \$13.0M. The budgeted amount for this targeted PFA was \$10M. The slate consisted of the following research projects: - Comparative Effectiveness of Trauma-focused and Non-trauma-focused Treatment Strategies for PTSD Among Those with Co-Occurring SUD (COMPASS) - Comparative Effectiveness PTSD Trial of Sequenced Pharmacotherapy and Psychotherapy in Primary Care <i>The following motion was made by Gail Hunt and seconded by Alicia Fernandez.</i> Motion: Approve funding for the recommended slate of awards from the Cycle 1 2019 Post-Traumatic Stress Disorder in Adults PFA. <i>Approved by a majority vote of the voting Board members by roll call vote (17 in favor; 0 opposed; 0 abstentions; 0 recusals)</i> <u>Treatment of Anxiety Disorders in Children, Adolescents, and/or Young Adults</u>
---	---

Treatment of Anxiety in Children, Adolescents, and/or young Adults Targeted PFA	Briggs introduced the proposed slate of awards for the Cycle 2 2018 Treatment of Anxiety Disorders in Children, Adolescents and/or Young Adults Targeted PFA. She explained that this was a revised funding announcement. The previous funding announcement was in Cycle 1 2018, for which no awards were made. Briggs provided a brief overview of the process and budget for this announcement. Of the 12 Letters of Intent submitted, 10 (83%) were invited to submit a full application. Of these, 9 applications were received. On October 1, 2019, the Selection Committee recommended to fund a slate of two applications (22%) for a proposed total commitment of \$13.6M. The budgeted amount for this targeted PFA was \$10M. The slate consisted of the following research projects: - A Sequential Multiple Assignment Randomized (SMAR) Trial Assessing Medication and CBT Sequencing - Partners in Caring for Anxious Youth It was recommended that the research project title for the second award be more descriptive. <i>The following motion was made by Sharon Levine and seconded by Alicia Fernandez.</i> Motion: Approve funding for the recommended slate of awards from the Cycle 1 2019 Treatment of Anxiety Disorders in Children, Adolescents, and/or Young Adults PFA. <i>Approved by a majority vote of the voting Board members by roll call vote (16 in favor; 0 opposed; 0 abstentions; 1 recusal Barbara McNeil); Kara Ayers and Freda Lewis-Hall indicated earlier their intention to recuse themselves but were not present at this meeting.</i>
Treatment Options for Age-related Hearing Loss Targeted PFA	Treatment Options for Age-Related Hearing Loss Briggs concluded the agenda item by presenting the recommended slate of awards relating to the Treatment Options for Age-Related Hearing Loss targeted PFA. She provided a brief overview of the process and budget for this funding announcement. Of the 12 Letters of Intent submitted, 10 (83%) were invited to submit a full application. Of these, 7 applications were received. On October 1, 2019, the Selection Committee recommended to fund a slate of two applications (29%) for a proposed total commitment of \$4.7M. The budgeted amount for this targeted PFA was \$6M. The slate consisted of the following research projects:

	- HearCARE: Hearing for Communication and Resident Engagement - Comparison of Direct-to-Consumer Treatments Using Hearing Devices <i>The following motion was made by Russell Howerton and seconded by Larry Becker:</i> Motion: Approve funding for the recommended slate of awards from the Cycle 1 2019 Treatment Options for Age-Related Hearing Loss PFA. <i>Approved by a majority vote of the voting Board members by roll call vote (17 in favor; 0 opposed; 0 abstentions; 0 recusals)</i>
Brief Policy Update Jean Slutsky, PA, MSPH, Chief Engagement and Dissemination Officer	Jean Slutsky provided the Board with an update on the current status of PCORI's reauthorization. As of Tuesday, November 19, 2019, Congress is expected to pass legislation this week that includes another short-term extension of government funding – a continuing resolution – as well as extensions of various health care programs. This package will include a short-term extension of the expiration date for the PCOR Trust Fund from November 21 to December but does not include extension of the funding mechanisms. Slutsky also noted that Congress continues to advance bipartisan efforts to secure a long-term reauthorization of PCORI with the goal of passing legislation to do so by December 20. However, there is a possibility of another short-term extension until March of next year. PCORI will continue to work with Congress and our advocates to secure new funding in either long-term or short-term scenarios.
Wrap up and Adjournment Christine Goertz, DC, PhD	Meeting ended at 1:25 pm

Minutes were approved by the PCORI Board of Governors 12-09-2019

ATTACHMENT A: Slates Approved of Cycle 1 2019 Broad PFA Awards

Slate 1: Four National Priority Areas

Program	Awarded Project
Addressing Disparities	Improving Communication and Healthcare Outcomes for Patients with Communication Disabilities: the INTERACT Trial
	Care in the CCP Program vs. Care in the C4P Program vs. Care in Traditional Care Coordinator Program
Assessment of Prevention, Diagnosis, and Treatment Options	Patient-Clinic-Community Integration to Prevent Obesity Among Rural Preschool Children
	Prostate Cancer Comparative Outcomes of New Conceptual Paradigms for Treatment (PC CONCEPT)
	Opioid-sparing Pain Treatment in Myeloma and Lymphoma Patients Undergoing High-dose Chemotherapy: RCT
Communication and Dissemination Research	Reducing Treatment Risk in Older Patients with Diabetes: Comparative Effectiveness of Academic Detailing with and without Pre-Visit Patient Preparation
Improving Healthcare Systems	Comparative Effectiveness of Unobserved vs. In-Office Inductions for Medication Assisted Treatment
	Comparing Two Approaches to Care Coordination for High-Cost/High-Need Patients in Primary Care

Slate 2: Improving Methods for Conducting PCOR

Improving Methods for Conducting PCOR	Towards a New Generation of Matching Methods for Comparative Effectiveness Research
	Using Topic Segmentation to Enhance Concept Parsing and Identification of Negations
	Incomplete Stepped Wedge Designs: Methods for Study Planning and Analysis
	New Causal Inference Methods for Cluster Randomized Trials with Post-Randomization Selection-Bias