



Board of Governors Meeting via Teleconference / Webinar

Tuesday, April 16, 2019

12:00 pm - 1:30 pm ET

MINUTES

Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Kara Ayers, PhD; Larry Becker; Francis S. Collins, MD, PhD; Jennifer DeVoe, MD, DPhil; Christopher Friese, PhD, RN, AOCN, FAAN; Trent Haywood, MD, JD; Michael Herndon, DO; Russell Howerton, MD; Gail Hunt; David Meyers, MD (designee for Gopal Khanna, MBA); Freda Lewis-Hall, MD; Ellen Sigal, PhD; Kathleen Troeger, MPH; Janet Woodcock, MD; Robert Zwolak, MD, PhD

Board Members Absent:

Christine Goertz, DC, PhD; *Vice Chairperson*; Alicia Fernandez, MD; Sharon Levine, MD; Michelle McMurry-Heath, MD, PhD; Barbara McNeil, MD, PhD

Agenda Item	PCORI Speakers
Call to Order, Roll Call, and Welcome - Grayson Norquist, MD, MSPH, <i>Chairperson</i> and Joe Selby, MD, MPH, <i>Executive Director</i>	Dr. Norquist 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.
Consider for Approval: Minutes of the March 19, 2019 Board Meeting - Grayson Norquist, MD, MSPH	<p><i>The following motion was made by Russell Howerton and seconded by Larry Becker.</i></p> <p>Motion: Approve the Minutes of the March 19, 2019 Board Meeting.</p> <p><i>Approved by a majority vote of the Board by voice vote (no opposed, no abstentions)</i></p>
Consider for Approval: Proposed Revised Charters for PCORI Committees and Advisory Panels - Grayson Norquist, <i>Board Chairperson and Member, Governance Committee</i> and Mary Hennessey, Esq., <i>General Counsel</i>	<p>Dr. Norquist reminded the Board of the annual review of Committee and Advisory Panel charters to ensure they remain current and accurate and that they support a consistent and effective governance structure. This year, while there were no recommended changes to the charters of the Advisory Panels, amendments are proposed for several Committee charters to include language addressing voting by written consent to reflect the historic practice of the Committees and requirements of DC nonprofit law. These Committee charters include the Engagement, Dissemination and Implementation Committee (EDIC), Research Transformation Committee (RTC), Science Oversight Committee (SOC), Selection Committee (SC), Methodology Committee (MC), Finance and Administration Committee (FAC), and Governance Committee.</p> <p>Additionally, some Committees recommended amendments to their charters to enhance clarity and consistency, such as revisions</p>

	<p>to the FAC charter to include its oversight of the Board and Methodology Committee Compensation and Reimbursement Policy, revisions to the Governance Committee charter to refine the description of its role in advising GAO on the appointment process for Board and MC members, and revisions to the SC and MC charters to reorganize sections and make their charters consistent with other charters.</p> <p><i>The following motion was made by Gail Hunt and seconded by Freda Lewis-Hall.</i></p> <p>Motion: Approve the amended charters of the EDIC, RTC, SOC, Selection Committee, Methodology Committee, FAC and Governance Committee</p> <p><i>Approved by a majority vote of the Board by voice vote (no opposed, no abstentions)</i></p>
<p>Consider for Approval: Proposed Cycle 2 2018 Slates of Awards</p> <ul style="list-style-type: none"> • Broad PFA - <i>Gail Hunt, Vice Chair, Selection Committee and Diane Bild, MD, MPH, Acting Chief Science Officer</i> 	<p>Ms. Hunt thanked all applicants and awardees, and then introduced Dr. Bild who introduced the proposed slate for the Cycle 2 2018 Broad PFAs Award Slate.</p> <p>Dr. Bild provided an overview of the process and budget for the Cycle 2 2018 Broad PFAs.</p> <p>Of the 182 Letters of Intent submitted, 96 (53%) were invited to submit a full application. Of these, 65 applications were received. At its March 22nd and April 3, 2019 meetings, the Selection Committee recommended to fund a slate of seven applications (11%) for a proposed total commitment of \$21.3M out of the posted \$76M. Dr. Bild provided an overview of the slate, summarizing the amount posted and proposed total award amounts by priority area. Dr. Bild noted that all proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.</p> <p>The Broad slate consists of 7 research projects from different priority areas (<i>See Attachment A</i>): Addressing Disparities (1 recommended project); Assessment of Prevention, Diagnosis, and Treatment Options (2 recommended projects); Improving Healthcare Systems (1 recommended project); and Improving Methods for Conducting PCOR (3 recommended projects).</p> <p><i>(See Attachment A for the list of Cycle 2 2018 Broad PFA projects funded.)</i></p> <p><i>The following motion was made by Ellen Sigal and seconded by Mike Herndon.</i></p> <p>Motion: Approve funding for the recommended award slate</p>

<ul style="list-style-type: none"> Medication-Assisted Treatment Delivery for Pregnant Women with Substance Use Disorders Involving Prescription Opioids and/or Heroin Targeted PFA 	<p>from the Cycle 2 2018 Broad PFAs.</p> <p><i>Approved by a majority vote of the voting Board members by roll call vote (13 in favor; 0 opposed; 1 abstention, Kathleen Troeger; 2 recusals: Jennifer DeVoe and Robert Zwolak)</i></p> <p><i>Alicia Fernandez and Christine Goertz informed us earlier of their intention to recuse but were not present at this meeting.</i></p> <p>.....</p> <p>Dr. Bild introduced the proposed slate of awards for the Cycle 2 2018 Medication-Assisted Treatment Delivery for Pregnant Women with Substance Use Disorders Involving Prescription Opioids Targeted PFA.</p> <p>Dr. Bild explained that this PFA adds to the existing portfolio that looks at studies across the spectrum for preventing inappropriate opioid use and reducing harm from opioid use disorder. This is a re-issue of a targeted PFA originally released during Cycle 2 2017. The original PFA included two priority research questions, of which 2 studies were funded responding to the question regarding comparative effectiveness of alternative models of comprehensive opioid use disorder treatment on maternal and neonatal outcomes. There were no studies funded answering the second question, prompting a re-issue of the PFA.</p> <p>Of the 4 Letters of Intent submitted, 4 (100%) were invited to submit a full application. Of these, 2 applications were received. On April 3, 2019, the Selection Committee recommended to fund a slate of 1 application (50%) for a proposed total commitment of \$5.6M out of the budgeted \$6M.</p> <p>The slate consisted of the following research project:</p> <ul style="list-style-type: none"> Support Models for Addiction Related Treatment <p>Dr. Bild explained that the research project is a matched-pair cluster randomized control trial that seeks to compare a collaborative care model with a care manager supporting an obstetrician to a tele-support model. The study will utilize a sample size of 480 (12 clusters) pregnant women with opioid use disorder.</p> <p><i>The following motion was made by Gail Hunt and seconded by Larry Becker.</i></p> <p>Motion: Approve funding for the recommended award slate from the Cycle 2 2018 Medication-Assisted Treatment Delivery for Pregnant Women with Substance Use Disorders Involving Prescription Opioids and/or Heroin PFA.</p>
--	---

- Symptom Management for Patients with Advanced Illness Targeted PFA

Approved by a majority vote of the voting Board members by roll call vote (16 in favor; 0 opposed, 0 abstentions)

Barbara McNeil informed us earlier of her intention to recuse herself but was not present at this meeting.

.....

Dr. Bild introduced the proposed slate of awards for the Cycle 2 2018 Symptom Management for Patients with Advanced Illness Targeted PFA.

Dr. Bild explained that this PFA was a re-issue of a targeted PFA originally released during Cycle 2 2017. The original PFA received 9 applications and funded 1 study. The PFA seeks to examine the long-term outcomes for the comparison of evidence-based treatments for symptoms experienced by patients with advanced illness and a life expectancy of > 6 months. The re-issue included several modifications, such as allowing non-pharmacological interventions (i.e. non-pharmacological approaches, combination, or complementary therapies), as well as removing depression from the symptom list.

Of the 13 Letters of Intent submitted, 5 (38%) were invited to submit a full application. Of these, 5 applications were received. On March 22, 2019, the Selection Committee recommended to fund a slate of 1 application (20%) for a proposed total commitment of \$2.8M out of the budgeted \$15M.

The slate consisted of the following research project:

- Integrative Medicine for Pain in Patients with Advanced Cancer Trial (IMPACT)

The research project is a two-arm randomized control trial that seeks to compare acupuncture to massage therapy, using a sample size of 300 patients that have a diagnosis of advanced cancer, presence of musculoskeletal pain for at least one month, and moderate to severe pain rating in the preceding week.

The following motion was made by Larry Becker and seconded by Kara Ayers.

Motion: Approve funding for the recommended award slate from the Cycle 2 2018 Symptom Management for Patients with Advanced Illness PFA.

Approved by a majority vote of the voting Board members by roll call vote (15 in favor; 0 opposed; 0 abstentions, 0 recusals); Trent Haywood was not present during this vote.

.....

- Psychosocial Interventions with Office-Based Opioid Treatment for Opioid Use Disorder Targeted PFA

Dr. Bild introduced the proposed slate of awards for the Cycle 2 2018 Psychosocial Interventions with Office-Based Opioid Treatment (OBOT) for Opioid Use Disorder Targeted PFA.

This PFA seeks to examine the comparative effectiveness of psychosocial interventions versus standard medical management for patients who receive office-based opioid treatment with buprenorphine.

Of the 15 Letters of Intent submitted, 11 (73%) were invited to submit a full application. Of these, 8 applications were received. On March 22, 2019, the Selection Committee recommended to fund a slate of 3 applications (38%) for a proposed total commitment of \$14.9M out of the budgeted \$20M.

The slate consisted of the three following research projects:

- Comparative Effectiveness of Family-Enhanced OBOT and OBOT in Primary Care
- Identifying Optimal Psychosocial Interventions for Patients Receiving Office-Based Buprenorphine
- Contingency Management to Enhance Office-Based Buprenorphine Treatment for Opioid Use Disorder

The first research project is a randomized control trial that seeks to compare usual care-OBOT with OBOT and Community Reinforcement and Family Training (CRAFT) in order to inform OBOT delivery in community health centers and other settings. The study will include 1000 participants, or 500 dyads, of predominantly low-income, uninsured, and racial/ethnic minority adults in urban areas with opioid use disorder and their cohabitating significant other.

The second research project is a four-arm randomized control trial comparing: OBOT (usual care) vs. OBOT with cognitive behavioral therapy (CBT) vs. OBOT with peer support by a certified recovery specialist (CRS) vs. OBOT with CBT and CRS. The study sample size is 440 patients, predominantly racial/ethnic minority adults with opioid use disorder living in urban areas.

The final research project is a 3-arm study that looks to compare usual care-OBOT to OBOT and contingency management – one arm for contingency management for buprenorphine adherence and the other for contingency management for buprenorphine adherence and opiate abstinence. This study has a sample size of 375 adults with opioid use disorder, predominantly of racial/ethnic minorities.

The following motion was made by Mike Herndon and seconded by Russell Howerton.



	<p>Motion: Approve funding for the recommended award slate from the Cycle 2 2018 Psychosocial Interventions with Office-Based Opioid Treatment for Opioid Use Disorder PFA</p> <p><i>Approved by a majority vote of the voting Board members by roll call vote (15 in favor; 0 opposed; 0 abstentions)</i></p> <p><i>Alicia Fernandez informed us earlier of her intention to recuse herself but was not present at this meeting. Trent Haywood was not present during this vote.</i></p>
Wrap up and Adjournment - Grayson Norquist, MD, MSPH	Meeting ended at 12:56 pm

See Attachment A

Minutes were approved by the PCORI Board of Governors 05-13-2019



**ATTACHMENT A to minutes for April 16, 2019 PCORI Board of Governors Meeting:
Slate Approved of Cycle 2 2018 Broad PFA Awards**

Program	Awarded Project
Addressing Disparities	Comparing Approaches to Enhanced Prenatal Care to Improve Maternal and Child Health in Central California
Assessment of Prevention, Diagnosis, and Treatment Options	Comparative Effectiveness of Zolpidem and Cognitive Behavioral Therapy for Insomnia in Rural Adults (COZi-R)
	Cognitive Behavioral Therapy and Real-time-pain-management Intervention for Sickle Cell via Mobile Applications (CaRISMA)
Improving Healthcare Systems	Comparative Effectiveness of Direct Admission and Admission through Emergency Departments for Children
Improving Methods for Conducting PCOR	Comparing “Just-in-Time” to Conventional Consent for Randomized Trials with Usual Care Controls
	Validating and Generalizing Personalized Treatment Rules by Leveraging Different Data Sources
	Methods for the Design and Conduct of Subgroup Analysis in Observational Studies