



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

Tuesday, November 20, 2018

**12:00 pm - 1:30 pm ET**

**Board Members Present:**

Grayson Norquist, MD, MSPH, *Chairperson*; Christine Goertz, DC, PhD; *Vice Chairperson*; Kara Ayers, PhD; Larry Becker; Francis S. Collins, MD, PhD; Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Christopher Friese, PhD, RN, AOCN, FAAN; Trent Haywood, MD, JD; Michael Herndon, DO; Russell Howerton, MD; Gail Hunt; Francis Chesley, Jr., MD (designee of Gopal Khanna, MBA); Sharon Levine, MD; Michelle McMurry-Heath, MD, PhD; Barbara McNeil, MD, PhD; Ellen Sigal, PhD; Kathleen Troeger, MPH; Janet Woodcock, MD; Robert Zwolak, MD, PhD

**Board Members Absent:**

Freda Lewis-Hall, MD

**AGENDA**

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.
<b>Consider for Approval:</b> Minutes of the October 29, 2018 Board Meeting - Grayson Norquist, MD, MSPH	<p><i>The following motion was made by Barbara McNeil and seconded by Ellen Sigal:</i></p> <p><b>Motion:</b> Approve the Minutes of the October 29, 2018 Board Meeting.</p> <p><i>Approved by a majority vote of the Board by voice vote (no opposed, one abstention: Kara Ayers)</i></p>
2018 Annual Meeting Debrief - Joe Selby, MD, MPH	<p>Dr. Selby reviewed the highlights of the 2018 PCORI Annual meeting. More than 950 individuals (excluding PCORI staff and undesignated attendees) attended the event, representing a diverse group of stakeholders including patients, caregivers, researchers, clinicians, and policy makers.</p> <p>Selby reminded everyone that the keynotes, plenary, and breakout sessions are available to watch via archived webcasts on PCORI's website.</p> <p>A survey was sent out to attendees to attain their views of the meeting, including questions about the impact of study results and quality of discussions. The Board of Governors will hear more about the survey's results at an upcoming Board meeting.</p> <p>Selby closed the agenda item by thanking everyone involved in its success including the Annual Meeting Steering Committee, Board, Methodology Committee and PCORI staff. In addition, attendees</p>

	<p>were thanked for their engagement during the meeting. Board members also expressed appreciation for the meeting’s content and overall theme, especially the presentation of results from PCORI-funded research studies during the poster session and plenary speakers.</p>
<p><b>Consider for Approval:</b>  Nominations of new Committee Members and Leadership</p> <ul style="list-style-type: none"> <li>- <i>Christine Goertz, DC, PhD, Chair, Governance Committee</i></li> </ul>	<p>Dr. Goertz presented the Governance Committee’s nominations of new members to the Strategy and other Board-related Committees. She indicated that the Governance Committee met several times to discuss the needs of the committees and consulted with Committee Chairs, other Board and Methodology Committee members and the Executive staff. Goertz then highlighted a few changes in Committee service of continuing Board and Methodology Committee members reassigned to round out needed skills on some Committees. These included:</p> <ul style="list-style-type: none"> <li>• The resignation of Naomi Aronson from the Research Transformation Committee due to her nomination to become a member of the Engagement, Dissemination and Implementation Committee to allow EDIC the benefit of the service of an MC Member;</li> <li>• The resignation of Russell Howerton from the Science Oversight Committee due to his nomination to become a member of the Finance and Administration Committee and to serve as FAC’s Vice Chair; and</li> <li>• Christine Goertz’s resignation from the RTC, FAC and Selection Committee in light of being named as Board Vice Chairperson.</li> </ul> <p>Goertz then reviewed for the Board the proposed nominations for the Committees as indicated.</p> <p><i>The following motion was made by Larry Becker and seconded by Gail Hunt.</i></p> <p><b>Motion:</b> that the Board of Governors approve the following nominations presented by the Governance Committee for the membership of these Committees:</p> <p><u>Engagement, Dissemination, and Implementation Committee</u>  Trent Haywood; Michael Herndon; Naomi Aronson (MC Member)</p> <p><u>Research Transformation Committee</u>  Kara Ayers; Michelle McMurry-Heath; Janet Woodcock</p> <p><u>Science Oversight Committee</u>  Jennifer DeVoe; Christopher Frieze</p> <p><u>Finance and Administration Committee</u>  Russell Howerton (as Vice Chair); Trent Haywood; Michael Herndon</p>

	<p><u>Governance Committee</u> Michelle McMurry-Heath</p> <p><i>Approved by majority vote of the Board by voice vote (no opposed; no recused, no abstentions).</i></p> <p>Following the vote, Dr. Norquist reminded the Board that appointments to the Selection Committee are made by the Board Chairperson. He then announced his new appointments to the Selection Committee: Kara Ayers, Jennifer DeVoe and Janet Woodcock.</p>
<p><b>Consider for Approval:</b> Cycle 1 2018 Dissemination and Implementation (D&amp;I) Limited Competition PFA Awards</p> <ul style="list-style-type: none"> <li>- Sharon Levine, MD, Chair, Engagement Dissemination, and Implementation Committee (EDIC), and Joanna Siegel, ScD, Director, D&amp;I Program</li> </ul>	<p>Dr. Levine, briefly described the purpose of the Limited Competition Implementation of PCORI-Funded Patient-Centered Outcomes Research Results PFA and then introduced Dr. Siegel to present the recommended slate of awards for the Cycle 1 2018 PFA. Siegel provided some additional details about the PFA and funding slate approval process for D&amp;I awards requesting budgets of \$500k or more.</p> <p>Of the 27 Letters of Intent submitted, 20 (74%) were invited to submit a full application. Of these, 13 applications were received. On October 30, 2018, the Engagement, Dissemination and Implementation Committee recommended to fund a slate of three applications (23%) for a proposed total commitment of \$3.9M out of the posted \$9M. EDIC convened with appointed members whose Board service continued beyond September 23, 2018,</p> <p>The slate included the following three projects proposed for funding, were</p> <ul style="list-style-type: none"> <li>• SAFE CT: Software, Actionable Feedback, and Education for CT: To Help Institutions Optimize Their Radiation Doses</li> <li>• Disseminating Community Health Worker Training; and</li> <li>• Rethink the Strip: De-adoption of Glucose Monitoring for Non-Insulin Treated Type 2 Diabetes in Primary Care</li> </ul> <p><i>The following motion was made by Russell Howerton and seconded by Kathleen Troeger.</i></p> <p><b>Motion:</b> Approve funding for the recommended slate of awards from the Cycle 1 2018 Limited Competition Implementation of PCORI-Funded Patient-Centered Outcomes Research Results PFA.</p> <p><i>Approved by a majority vote of the voting Board members by roll call vote (19 in favor; 0 opposed; 0 abstentions, 1 recusal: Alicia Fernandez)</i></p>

**Consider for Approval: Proposed Cycle 1 2018 Slates of Awards**

- Broad PFA
- Pragmatic Clinical Studies (PCS) PFA
- *Barbara McNeil, MD, PhD, Chair, Selection Committee and Diane Bild, MD, MPH, Acting Chief Science Officer*

**Cycle 1 2018 Broad PFAs**

Dr. McNeil thanked all applicants and awardees, and introduced Dr. Bild who introduced the proposed slate of awards for the Cycle 1 2018 Broad PFAs.

Before Bild began her presentation of the proposed slate, she provided an update on the Cycle 1-2018 targeted PFA on Pediatric Anxiety and indicated that there are no proposed awards for this targeted PFA and that this targeted PFA will be reposted for Cycle 1 2019.

Bild then provided an overview of the process and budget for the Cycle 1 2018 Broad PFAs.

Of the 224 Letters of Intent submitted, 107 (48%) were invited to submit a full application. Of these, 80 applications were received. On October 15, 2018, the Selection Committee recommended to fund a slate of nine applications (11%) for a proposed total commitment of \$25.7M out of the posted \$76M. 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.

The Broad slate consists of 9 research projects from different priority areas (*See Attachment A*): Addressing Disparities (4 recommended projects); Communication and Dissemination Research (1 recommended project); Improving Healthcare Systems (1 recommended projects); and Improving Methods for Conducting PCOR (3 recommended projects). Bild provided a very brief overview of the research projects on the slate.

*The following motion was made by Barbara McNeil and seconded by Larry Becker.*

**Motion:** Approve funding for the recommended slate of awards from the Cycle 1 2018 Broad PFAs.

*Approved by a majority vote of the voting Board members by roll call vote (19 in favor; 0 opposed; 0 abstentions, 1 recusal: Sharon Levine)*

**Cycle 1 2018 Pragmatic Clinical Studies PFA**

Dr. Bild introduced the proposed slate of awards for the Cycle 1 2018 Pragmatic Clinical Studies PFA.

The goal of this PFA is to fund pragmatic clinical trials, large simple trials, or large-scale observational studies that compare two or more alternatives for addressing prevention, diagnosis, treatment, or management of a disease or symptom; improving healthcare system-level approaches to managing care; or for eliminating

	<p>health or healthcare disparities. Of the 91 Letters of Intent submitted, 38 (42%) were invited to submit a full application. Of these, 25 applications were received. On October 15, 2018, the Selection Committee recommended to fund a slate of three applications (12%) for a proposed total commitment of \$28M out of the posted \$37M.</p> <p>The slate consisted of the following three research projects:</p> <ul style="list-style-type: none"> <li>• Comparing Smoking Cessation Interventions among Underserved Patients Referred for Lung Cancer Screening</li> <li>• Comparison of Surgery and Medicine on the Impact of Diverticulitis (COSMID) Trial</li> <li>• A Multi-Site Study to Compare the Outcomes of Psychiatric Treatment of Suicidal Adolescents in Different Treatment Settings</li> </ul> <p>The first research project is a randomized control trial that seeks to compare scalable interventions across four large health care systems without requiring increased staffing in Low-dose Computed Tomography (LDCT) screening centers, utilizing a sample size of 3,200 active smokers as participants.</p> <p>The second research project is an individually randomized control trial with a parallel observational cohort study that compares the impact on quality of life of elective surgical colectomy versus best medical management for patients with diverticulitis confirmed by CT scan, using a sample size of 700 patients (500 RCT and 200 observational cohort).</p> <p>The third research project is a multi-site randomized controlled trial utilizing 1000 adolescents that compares the outcomes of psychiatric treatments in adolescents at risk for suicide in different treatment settings: outpatient versus inpatient.</p> <p><i>The following motion was made by Robert Zwolak and seconded by Barbara McNeil.</i></p> <p><b>Motion:</b> Approve funding for the recommended slate of awards from the Cycle 1 2018 Pragmatic Clinical Studies PFA.</p> <p><i>Approved by a majority vote of the voting Board members by roll call vote (18 in favor; 0 opposed; 0 abstentions, 2 recusals: Kara Ayers, Sharon Levine)</i></p>
<p><b>Consider for Approval:</b> Targeted PFAs</p> <ul style="list-style-type: none"> <li>• Treatments for Posttraumatic Stress Disorder (PTSD) in Adults</li> </ul>	<p><b><u>Treatment for Posttraumatic Stress Disorder (PTSD) in Adults</u></b></p> <p>Dr. Zwolak introduced the presentation by discussing the important public health nature of the topic and expressing the Science Oversight Committee’s interest in the proposed targeted PFA. He concluded by introducing Dr. Bild, who noted</p>

<ul style="list-style-type: none"> <li>• Treatment Options for Age-Related Hearing Loss</li> <li>- <i>Robert Zwolak, MD, PhD, Chair Science Oversight Committee and Diane Bild, MD, MPH, Acting Chief Science Officer</i></li> </ul>	<p>the significance of PTSD expressed by relevant stakeholder communities and the proposed development of the Treatment for Posttraumatic Stress Disorder (PTSD) in Adults Targeted PFA. She summarized the steps taken to identify the evidence gaps in this area and the consultations with different stakeholders.</p> <p>It was emphasized during the Board’s discussion that interventions should be population-specific, as a common misconception is that all trauma responds similarly. There is a variety of different traumas, sometimes compounded by comorbidities, which require specific interventions. Additionally, when asked about potential confounding scenarios, Bild responded that PCORI has engaged in several discussions with the Department of Defense and is open to considering other possibilities.</p> <p>The total commitment requested for this PFA is up to \$15M in total costs, with an estimated number of 2 studies and a maximum project duration of 3.5 years.</p> <p><i>The following motion was made by Gail Hunt and seconded by Russell Howerton.</i></p> <p><b>Motion:</b> Approve the development and release of Treatment for Posttraumatic Stress Disorder (PTSD) in Adults Targeted PFA.</p> <p><i>Approved by a majority vote of the voting Board members by roll call vote (20 in favor; 0 opposed; 0 abstentions)</i></p> <p><b><u>Treatment Options for Age-Related Hearing Loss</u></b></p> <p>Dr. Zwolak and Dr. Bild described stakeholder interest in hearing loss research and the need for comparative effectiveness research and the considerable discussions of the Science Oversight Committee on this topic. Bild explained the evidence gap in this area and summarized the proposed focus of the Treatment Options for Age-Related Hearing Loss Targeted PFA.</p> <p>The total commitment requested for this PFA is up to \$12M in total costs, with an estimated number of 4-5 studies and a maximum project duration of 3 years. It was also proposed to release the PFA over the course of 2 cycles – Cycles 1 and 2 2019. This is to account for the rapidly developing landscape of hearing devices and potential changes in the field due to legislative and regulatory action.</p> <p>The concern regarding who would provide payment for the devices, especially as multiple kinds of hearing devices are currently in the beginning stages of being released, was expressed. Bild indicated that applicants would be required to explicitly address this issue in their application. As insurance coverage varies from state to state, applicants may need to</p>
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	<p>confine their population of interest to insured populations or approach vendors for donations themselves to gain access to devices.</p> <p>Dr. Zwolak reminded members that this is a cutting-edge proposal and that the SOC recommends the approval of the development of this targeted PFA</p> <p><i>The following motion was made by Barbara McNeil and seconded by Robert Zwolak.</i></p> <p><b>Motion:</b> Approve the development and release of Age-Related Hearing Loss Targeted PFA.</p> <p><i>Approved by a majority vote of the voting Board members by roll call vote (20 in favor; 0 opposed; 0 abstentions)</i></p>
Wrap up and Adjournment Grayson Norquist, MD, MSPH	Meeting ended at 12:58 pm

**Minutes were approved by the PCORI Board of Governors 12-11-2018**



**ATTACHMENT A to the Minutes of the  
PCORI Board of Governors Meeting Held November 20, 2018:  
Slate Approved of Cycle 1 2018 Broad PFA Awards**

Program	Awarded Project
<b>Addressing Disparities</b>	Peer Online Motivational Interviewing for Sexual and Gender Minority Male Survivors
	Reducing Oral Health Disparities of Older Adults: Comparative Effectiveness of 2 Treatments
	Leveraging mHealth and peers to Engage African-American and Latinos in HIV Care (LEAN)
	Reducing Disparities in Behavioral Health Treatment for Children in Primary Care
<b>Communication and Dissemination Research</b>	Comparing Strategies for Implementing Primary HPV Testing for Routine Cervical Cancer Screening
<b>Improving Healthcare Systems</b>	Patient-Centered Enhancements in School Behavior Health: A Randomized Trial
<b>Improving Methods for Conducting PCOR</b>	Evaluation of Complex Interventions on Drug (Re)Fill Behavior Using Electronic Healthcare Data
	Natural Language Processing for Medication Adherence: Complex Semantics and Negation
	Incremental Privacy-Preserving Record Linkage (iPPRL) to Improve Data Quality