

Board of Governors Meeting via Teleconference / Webinar

Tuesday, November 21, 2017

12:00 pm – 1:30 pm ET

Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Debra Barksdale, PhD, RN; Larry Becker; Allen Douma, MD; Leah Hole-Marshall, JD; Russell Howerton, MD; Gopal Khanna; Sharon Levine, MD; Freda Lewis-Hall, MD; Barbara McNeil, MD, PhD; Ellen Sigal, PhD Kathleen Troeger, MPH; Robert Zwolak, MD, PhD

Board Members Absent:

Kerry Barnett, JD, *Vice Chairperson*; Francis Collins, MD, PhD; Alicia Fernandez, MD; Christine Goertz, DC, PhD; Gail Hunt; Harlan Krumholz, MD, SM; Richard Kuntz, MD, MSc

MINUTES

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 October 30, 2017 Board Meeting - Grayson Norquist, MD, MSPH	<i>The following motion was made by Barbara McNeil and seconded by Sharon Levine.</i> Motion: Approve the minutes of the October 30, 2017 Board of Governors meeting. <i>Approved by a majority vote of the Board by voice vote (no opposed; no abstentions)</i>
Consider for Approval: Proposed Slate for Cycle 1 2017 Broad PFA Awards - Leah Hole-Marshall, JD, <i>Vice Chair, Selection Committee</i> and Evelyn Whitlock, MD, MPH, <i>Chief Science Officer</i>	Leah Hole-Marshall introduced the agenda item on the recommended slate of research awards relating to the Cycle 1 2017 Broad PFAs. Dr. Whitlock reminded the Board of the Merit Review criteria applied to the national priorities under the Broad PFAs. She then gave a summary of the process that led to the recommended slate of awards. Of the 197 Letters of Intent (LOIs) submitted, 99 (50%) were invited to submit a full application. Of these, 77 (78% of invited LOIs) applications were submitted, deemed responsive, and proceeded to Merit Review. The Selection Committee recommended funding 11 of the submitted applications, 2 of which are resubmissions, for a proposed total commitment of \$25.2M (total costs) of the budgeted \$46M.

	Dr. Whitlock summarized the health conditions and PCORI populations of interest reflected in the awards on each slate and reviewed the titles of the 11 proposed studies grouped by the National Priority topics, which are listed in <i>Attachment A</i>. <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 Cycle 1 2017 Broad PFAs. <i>Approved by a majority vote of the voting Board members by roll call vote (10 in favor; 0 opposed; 0 abstentions; and 3 recusals: Sharon Levine, Barbara McNeil and Robert Zwolak). Alicia Fernandez indicated earlier her intention to recuse, but was not present at this meeting.</i>
Consider for Approval: Proposed Slate for Cycle 1 2017 Pragmatic Clinical Studies (PCS) Awards - Leah Hole-Marshall, JD and Evelyn Whitlock, MD, MPH	Dr. Whitlock introduced the proposed awards for the Cycle 1 2017 Pragmatic Clinical Studies (PCS) PFA and reminded the Board of the Merit Review criteria for the pragmatic clinical studies. Of the 50 Letters of Intent (LOIs) submitted, 21 (42%) were invited to submit a full application. Of these, 18 (86% of invited LOIs) applications were submitted and proceeded to Merit Review. The Selection Committee recommended funding 3 of the submitted applications for a proposed total commitment of \$32.1M (total costs) of the budgeted \$41M. The three projects presented were: • A Prospective Comparative Study of Outcomes with Proton and Photon Radiation in Prostate Cancer • Comparative Effectiveness of Health System-Based versus Community-Based Dementia Care • Comparative Effectiveness of System Interventions to Increase HPV Vaccine Receipt in Federally Qualified Health Centers The first project is a prospective non-randomized parallel cohort comparison with a nested randomized trial. It aims to study the comparative effectiveness of two modalities for delivering radiation therapy as treatment for prostate cancer within adult men, ages 30-80 years, who are diagnosed with localized prostate cancer. The total project cost is \$11.9M. The second project is a two-arm pragmatic randomized clinical trial that aims to study whether dementia care, based within the health system, is superior to dementia care that is based in the community. The total project cost is \$13.6M. The third project is a four-arm stepped wedge cluster randomized clinical trial. It aims to study whether a parent-focused, clinic-focused,

	or combined parent- and clinic-focused intervention is more effective than usual care at increasing uptake of prophylactic HPV vaccine among underserved, ethnic minority adolescents receiving care through Federally Qualified Health Centers. The total project cost is \$6.6M. In response to a question regarding the first project's study design relating to the intensity-modulated radiation therapy (IMRT) comparator and its sample size, Dr. Whitlock noted that PCS studies receive a methodology review after merit review to assess for any residual methodological problems with components like sample size, or any other issues that might come up during merit review. <i>The following motion was made by Leah Hole-Marshall and seconded by Freda Lewis-Hall:</i> Motion: Approve funding for the recommended slate of awards from the Cycle 1 2017 Pragmatic Clinical Studies PFA. <i>Approved by a majority vote of the voting Board members by roll call vote (10 in favor; 0 opposed; 0 abstentions and 3 recusals, Russell Howerton, Sharon Levine and Grayson Norquist). Harlan Krumholz indicated earlier his intention to recuse, but was not present at this meeting.</i>
Annual Meeting Debrief - Joe Selby, MD, MPH and Bill Silberg, Director, Communications	Dr. Selby provided an update for the Board on PCORI's recent Annual Meeting. An online follow-up survey of attendees is currently being conducted and the results are expected to be reported to the Board in early January. Dr. Selby reported that in attendance at the Annual Meeting were about 1,000 attendees from a variety of backgrounds, and noted the variety of ways attendees could access the meeting, including live streaming and reviewing the sessions that were recorded and can be found on PCORI's website. He also noted the record twitter traffic of approximately 8,500 Tweets using #PCORI2017 and the popularity of the Poster Board session. Some Board members who attended the 2017 PCORI Annual Meeting offered their reflections and observations garnered from their experiences and interactions. Dr. Selby noted that planning already is under way for the PCORI2018 Annual Meeting to be held October 31 – November 2, 2018 in Washington, D.C.
Wrap up and Adjournment - Grayson Norquist, MD, MSPH	Meeting ended at 1:03 pm

Minutes were approved by the PCORI Board of Governors 12-12-2017

Board of Governors Meeting via Teleconference / Webinar

Tuesday, November 21, 2017

MINUTES - Attachment A

Cycle 1 2017 Broad PFA Award Slate Approved

Program	Project Title
Addressing Disparities	Transgender Cohort Study of Gender Affirmation and HIV-Related Health
	Reducing Health Disparities for Black Women in the Treatment of Insomnia
	Comparative Effectiveness Research to Improve the Health of Sexual and Gender Minority (SGM) Patients through Cultural Competence and Skill Training of Community Health Center (CHC) Providers and Non-Clinical Staff
Assessment of Prevention, Diagnosis, and Treatment Options	Randomized Controlled Trial of Laser Hair Depilation in Adolescents with Pilonidal Disease
	Comparative Effectiveness of Mindfulness-Based Stress Reduction and Pharmacotherapy for Anxiety
Communication and Dissemination Research	Promoting Autonomy and improving Shared Decision-Making for Older Adults with Advanced Kidney Disease
Improving Healthcare Systems	Comparative Effectiveness of clinical Decision-Making Processes Required by Public Health Systems
	Comparison of Patient-Centered versus Provider-Centered Delivery of Cognitive Behavioral Treatment (CBT) for Pediatric Anxiety and Obsessive Compulsive Disorder (OCD)
	A Comparative Effectiveness Trial of an Information Technology Enhanced Peer-Integrated Collaborative Care Intervention for US Trauma Care Systems
Improving Methods for Conducting PCOR	Advancing Privacy Preserving Record Linkage Methods in the context of Real-World Data Networks & HIE
	Unlocking Clinical Text in EMR by Query Refinement Using Both Knowledge Bases and Word Embedding