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PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting via Teleconference / Webinar

Tuesday, January 26, 2016
12:00 pm – 1:30 pm ET

Board Members Present:
Grayson Norquist, MD, MSPH, *Chairperson*; Kerry Barnett, JD, *Vice Chairperson;* Debra Barksdale, PhD, RN; Francis Collins, MD, PhD; Allen Douma, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Gail Hunt; Richard Kronick, PhD; Harlan Krumholz, MD, SM; Sharon Levin, MD; Freda Lewis-Hall, MD; Barbara McNeil, MD, PhD; Harlan Weisman, MD; Robert Zwolak, MD, PhD

Board Members Absent:
Lawrence Becker; Alicia Fernandez, MD; Robert Jesse, MD, PhD; Richard Kuntz, MD, MSc; Steve Lipstein, MHA; Ellen Sigal, PhD

MINUTES

Agenda Item	**Related Minutes**
Call to Order, Roll Call, and Welcome - *Grayson Norquist, MD, MSPH, Chairperson*	Dr. Grayson 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.
Consent Agenda: That the Board of Governors approve: • Minutes of the December 7, 2015 Board Meeting • Committee Assignments - *Grayson Norquist, MD, MSPH, Chairperson*	Dr. Norquist introduced the Consent Agenda which included the December 7, 2015 Board meeting minutes and Committee nominations put forth by the Governance Committee (see below for nominations). The following motion was made by Kerry Barnett and seconded by Barbara McNeil. **Motion:** Approve each of the motions on the Consent Agenda as reflected: • Approval of the December 7, 2015 Board Meeting Minutes; and • Nominations put forth for approval from the Governance Committee: o Board Member Robert Zwolak to serve out the remaining term as Chair for Christine Goertz on the Science Oversight Committee (SOC) to 9/30/2016; o Board Member Alicia Fernandez to serve out the remaining term as Vice Chair for Bob Zwolak on the Science Oversight Committee (SOC) to 9/30/2016; o Board Member Richard Kronick to serve as a member of the Science Oversight Committee;

	o Removal of Methodology Member Robert Kaplan from the Science Oversight Committee due to his resignation; and o Board Member Christine Goertz to replace Alicia Fernandez as a member on the Finance and Administration Committee (FAC). After the Governance Committee elected to bring these Committee assignment changes to the Board, the Governance Chair was made aware that Christine Goertz also requested to be named to the Research Transformation Committee (RTC), and was further made aware that the RTC Chair, the BOG Chairperson and the Executive Director were in accordance. With this knowledge, the Board was asked to approve the appointment of Christine Goertz to the Research Transformation Committee in addition to the above requests. *Approved by a majority vote of the Board by voice vote (no opposed; no abstentions).*
Consider for Approval: ADAPTABLE (Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-term Effectiveness): Supplemental Funding Request	Rachael Fleurence, Program Director of CER Infrastructure at PCORI, presented the request for supplemental funding for the first pragmatic clinical trial that will use the PCORnet infrastructure, the ***PCORnet Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-Term Effectiveness (ADAPTABLE).*** She outlined that the Board had previously approved $14M in total funding for the ADAPTABLE study in May 2015. She presented a brief overview of the trial, justification for supplemental funding, and budget requests. The justifications for funding included implementing recommendations of the Clinical Trials Advisory Panel, inclusion of patients with no internet access, recruitment and retention of patients and the addition of two CDRNs, ensuring complete ascertainment for events occurring outside of the CDRN networks, and an endpoint validation plan. It was noted that both the RTC and SOC supported this request to robustly improve science and using the demonstration project as an opportunity to continue developing the PCORnet infrastructure. The following motion was made by Francis Collins and seconded by Robert Zwolak. **Motion**: Approve $3.81M total funds in additional funding for critical activities for ADAPTABLE. *Approved by a majority vote of the Board by roll call vote:* *13 in favor; 0 opposed; 0 abstentions; Gail Hunt and Harlan Krumholz were absent for this vote.*
Consider for Approval: Awards for The Natural Experiments Network (NEN) A Collaborative Initiative	Dr. Christine Goertz, chair of the Selection Committee, introduced Dr. Evelyn Whitlock, PCORI's new Chief Science Officer. Natural Experiments Network (NEN) is a Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH)/

	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)-funded 5-year multi-center study based in five health systems. Its aim is to study the natural variation within and between systems in policies and clinical interventions aimed at preventing or managing diabetes mellitus. The CDC invited PCORI to join with CDC and NIH in co-funding the second cycle of this initiative in order to add some of PCORnet's EHR-based networks to the 5 centers that CDC/NIH fund. PCORI funding will serve entirely to expand the NEN beyond 5 sites by adding Clinical Data Research Networks (CDRNs). The CDC/NIH funded five sites at $450k/year and a coordinating center at $250K/year. In 2015, the Board authorized funding for up to three additional NEN projects through a limited PCORI funding announcement; three PCORnet CDRNs applied to this limited PFA and were recommended for funding by the Selection Committee. With the Selection Committee's recommendation, Dr. Whitlock presented the proposed projects: • **The Impact of Medicaid Health Homes on Patients with Diabetes** • **A Patient-Centered Path to Addressing Diabetes: Impact of State Health Policies on Diabetes Outcomes and Disparities** • **Natural Experiments of the Impact of Population-targeted Health Policies to Prevent Diabetes and Its Complications** The recommended slate of awards used a proposed budget of $6.75M, which was also the allotted budget. The following motion was made by Sharon Levine and seconded by Harlan Weisman. **Motion**: Approve the recommended slate of awards from the Natural Experiments Network Limited PFA. *Approved by majority of the Board by roll call: 14 in favor; 0 opposed; 0 abstentions; Gail Hunt was absent for this vote.*
Consider for Approval: Slate of Cycle 1 2015 Large Pragmatic Studies Award	Dr. Christine Goertz, Chair of the Selection Committee, introduced the agenda item on the recommended slate of awards relating to the Cycle 1 2015 Large Pragmatic Studies PFA and invited Dr. Evelyn Whitlock to provide an overview to the Board. Whitlock summarized the process that led to the recommended slate of awards. The Board previously approved development of a PFA to fund large pragmatic studies, with funding up to $10M in direct costs and up to 5 years duration, with a total available funds of $90M in total costs, Of 116 Letters of Intent submitted, 43 (37%) were invited to submit full applications. Of these, 36 were submitted and 34 applications were deemed responsive and proceeded to Merit Review. The Selection Committee reviewed six applications and recommended to fund five of those applications for a proposed total commitment of $59M in total costs (direct and indirect costs).

	Dr. Whitlock provided a summary of each of the five proposed studies, listed below: • **Determining the Optimal Treatment Strategy for Patients who have Chronic Migraine with Medication Overuse** • **RofLumilast or Azithromycin to preveNt Chronic Obstructive Pulmonary Disease (COPD) Exacerbations (RELIANCE)** • **Dissemination of Effective Smoking Cessation Treatment to Smokers with Serious Mental Illness** • **Patient-Empowered Strategy to Reduce Asthma Morbidity in Highly Impacted Populations** • **Comparison of Operative versus Medical Endocrine Therapy for Low Risk Ductal Carcinoma in Situ (DCIS): The COMET Trial** Dr. Whitlock gave an overview of how the topics of the studies on the recommended slate fit within PCORI's current funded portfolio and relate to PCORI priority topics. Board members asked several questions about the slate, which were addressed. The following motion was made by Sharon Levine and seconded by Harlan Weisman. **Motion**: Approve the recommended slate of awards from the Cycle 1 2015 Large Pragmatic Studies PFA *Approved by majority vote of the Board by roll call: 9 in favor; 0 opposed; no abstentions; 4 recusals (Debra Barksdale, Barbara McNeil, Gray Norquist, and Bob Zwolak recused themselves from voting on the slate; Steve Lipstein was not present but indicated earlier his intention to recuse himself from this vote). Gail Hunt and Freda Lewis-Hall were not present for this vote.*
Consider for Approval: Addition to the Slate of Spring 2015 Cycle Broad Awards	Dr. Evelyn Whitlock reminded the Board that the original Spring 2015 Cycle Broad slate was approved by the Board on September 28, 2015, which included 5 projects in the Improving Healthcare Systems program. Since then, the Selection Committee had more time to consider an additional study from that cycle for this program that needed more internal discussion and information. The Selection Committee recommended funding this additional project: **Improving Self-Care Decisions of Medically Underserved African Americans with Uncontrolled Diabetes: Effectiveness of Patient-Driven Text Messaging versus Health Coaching.** Dr. Whitlock gave an overview of this study's elements. This study increased the Improving Healthcare Systems program's total budget relating to the Spring 2015 Cycle for Broad PFAs to $24M (compared to the $18.7M total budget previously approved), which is within the overall Spring 2015 Cycle's budget of $88M. The following motion was made by Harlan Weisman and seconded by Debra Barksdale.

	Motion: Approve the recommended addition to the Spring 2015 Broad Cycle awards *Approved by majority of the Board by roll call: 14 in favor; 0 opposed; 0 abstentions; 0 recusals. (Freda Lewis-Hall and Gail Hunt were absent for this vote.)*
2016 Annual Meeting Update	Due to time constraints, the Board elected to table this update to a later Board meeting.
Wrap up and Adjournment	Dr. Norquist thanked all who joined the meeting and reminded attendees that PCORI welcomes any feedback. The meeting adjourned at 1:30 pm.

Approved by the PCORI Board of Governors 02-23-2016