PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting via Teleconference / Webinar

Tuesday, August 16, 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; Lawrence Becker; Andrew Bindman, MD; Michael Lauer, MD (acting as designee for Francis Collins, MD, PhD); Allen Douma, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Gail Hunt; Robert Jesse, MD, PhD; Sharon Levine, MD; Steve Lipstein, MHA; Barbara McNeil, MD, PhD; Harlan Weisman, MD Robert Zwolak, MD, PhD

Board Members Absent:

Alicia Fernandez, MD; Harlan Krumholz, MD, SM; Richard Kuntz, MD, MSc; Freda Lewis-Hall, MD; Ellen Sigal, PhD

Minutes

Agenda Item	Related Minutes
Call to Order, Roll Call, and Welcome - *Grayson Norquist, MD, MSPH, Chairperson* and *Joe Selby, MD, MPH, Executive Director*	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.
Consent Agenda: **That the Board of Governors approve:** • Minutes of the July 19, 2016 Board Meeting • Rare Disease Advisory Panel (RDAP) Charter Revisions - *Grayson Norquist, MD, MSPH*	Dr. Norquist introduced the Consent Agenda which included approval of the July 19 meeting minutes and approval of the revised charter for the Rare Disease Advisory Panel (RDAP) brought to the Board by the Science Oversight Committee (SOC). Dr. Norquist gave the opportunity to Board members to discuss any of the matters on the Consent Agenda. No separate discussion was requested. The following motion was made by Kerry Barnett and seconded by Larry Becker: **Motion:** Approve each of the motions on the Consent Agenda as reflected below: • Minutes of the July 19, 2016 Board of Governors meeting, and • Revised Rare Disease Advisory Panel (RDAP) Charter *Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions)*
Consider for Approval: New Advisory Panelists and Chairs - *Evelyn Whitlock, MD, MPH, Chief Science Officer*	Dr. Selby reminded the Board that each year the terms for one third of the members of the PCORI Advisory Panels expire and a rigorous process to fill those vacancies takes place. This year, 405 applications were received to fill 45 open positions. While 3rd Party nominations, received from 41 organizations, were indicated, it was noted that a 3rd party nomination is not

	a requirement, and a lack of one does not weigh against an application. Dr. Whitlock then presented the 2016 proposed slate of new panelists, alternates, chairs and co-chairs for all seven of PCORI's Advisory Panels: Addressing Disparities; Assessment of Prevention, Diagnosis and Treatment Options; Clinical Trials; Communication and Dissemination Research; Improving Healthcare Systems; Patient Engagement; and Rare Disease. *The following motion was made by Harlan Weisman and seconded by Larry Becker:* ***Motion**:* Approve the proposed slates of new and reappointed members and terms for the following Advisory Panels: APDTO, IHS, AD, PEAP, CTAP, RDAP and CDR *Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions)* PCORI welcomes all appointed members and alternates to the respective Advisory Panels (See Attachment A for list of appointees and their terms)
Consider for Approval: PCORnet Patient-Powered Research Networks (PPRN) Research Demonstration Project - *Joe Selby, MD, MPH and Rachael Fleurence, PhD, Program Director, Research Infrastructure*	Dr. Fleurence introduced the request for funding of the PCORnet Patient-Powered Research Networks (PPRN) Research Demonstration Project. She discussed context surrounding the project and explained that this research project is in addition to five other PPRN Research Demonstration Projects that were previously awarded by the Board of Governors. This specific research project had required further methodological review that was completed and the research project was reviewed and recommended for approval by the Selection Committee. During the presentation, she addressed questions around how the disease populations were selected, the N-of-1 study methodology, the engagement of an external methodology consultation, and using PCORnet for studies and the purpose of the demonstration projects. *The following motion was made by Barbara McNeil and seconded by Debra Barksdale:* ***Motion**:* Approve funding for the recommended additional PPRN Research Demonstration Project Award. *Approved by a majority vote of the voting Board members by roll call (14 in favor; 0 opposed; 0*

	abstentions; 2 recusals: Andrew Bindman and Steve Lipstein). Alicia Fernandez had earlier indicated her intent to recuse, but was not present for the meeting.
Report from the Science Oversight Committee: Enhanced Funding Opportunities - *Evelyn Whitlock, MD, MPH and Robert Zwolak, MD, PhD, Chair, Science Oversight Committee*	Dr. Zwolak provided an overview of the previously approved studies, noting that the Board approved $153M in commitments for studies at its meeting in July. He noted that despite these approvals, there were still un-awarded funds available under the relevant PFAs compared to the maximum amount of funds previously allocated to the PFAs by the Board. Dr. Zwolak outlined for the Board some of the possible reasons and addressed expanded strategic funding opportunities that are recommended by the SOC. The expanded funding opportunities are intended to enhance the submission of meritorious applications and benefit PCORI and researcher applicants. He explained the two Science Oversight Committee (SOC) endorsed strategies for Board consideration.
Consider for Approval: Re-opening of selected targeted PCORI Funding Announcements (PFA)	The first strategy that the SOC has endorsed reopening targeted PFAs. Dr. Whitlock reviewed the information on the following three topic areas tied to targeted PFAs that had previously been approved by the Board for development: New Oral Anticoagulants, Long-term Opioid Treatment for Chronic Pain and Multiple Sclerosis. She remarked that the SOC and staff believe additional studies in these three areas would complement and extend studies that have already been approved. It was reiterated that the Board has already approved the budgets tied to these targeted PFAs, and that funds were recently not fully committed and thus remain available. Dr. Whitlock noted that this is an opportunity to reopen these specific funding announcements for researchers to resubmit applications or submit new applications in these three target areas. Dr. Whitlock confirmed that the re-opening of any specific funding announcement would be subject to due diligence to ensure new research areas remain and avoid duplication. The Board discussed the option to reopen up to three of the targeted PFAs subject to the limit of the amount originally allocated by the Board for the relevant funding announcement for the specific topic.

	The following motion was made by Steve Lipstein and seconded by Allen Douma: ***Motion**:* Approve re-opening of one or more of the Cycle 3 2015 targeted PFAs (NOACs in the Extended Treatment of Venous Thromboembolic Disease, Long-term Opioid Treatment for Chronic Pain, Treatment of Multiple Sclerosis), for up to the total allocated amount for the specific topic *Approved by a majority vote of the voting Board members by roll call (16 in favor; 0 opposed; 0 abstentions)*
Consider for Approval: Special emphasis topics for Pragmatic Clinical Studies (PCS) PFA	The second strategy for allocation of un-awarded (and uncommitted) funds outlined by the Science Oversight Committee was to call out Special Emphasis (SE) topics within the Pragmatic Clinical Studies (PCS) PCORI Funding Announcements (PFAs). The focus would be on enhancing work that PCORI is already doing by building on the established topic pathway and tying those topics to PFAs for pragmatic clinical studies. The funding for these special emphasis PCS topics would be from allocated, but uncommitted, PCS funds. Dr. Whitlock reminded the Board of the Board-recognized process for priority topic pathways. The SOC undertook an explicit prioritization and evaluation process for considering PCS topics for special emphasis. After SOC evaluation, two special emphasis topics were selected by the SOC: Community-acquired Pneumonia and Pelvic Organ Prolapse. (The SOC approved including these as special emphasis topics for Cycle 3 2016 PCS PFA). During the discussion, Dr. Whitlock reminded the Board that, unlike a targeted PFA, this is a one-time request and applications could be awarded up to $40M per topic. She confirmed that there would be no obligation for PCORI to fund research projects on these special emphasis topics. Dr. Zwolak further reminded the Board that the purpose of this strategy is to try and entice more applications in these clinically important topics and fund up to $343M in fiscal year 2017. *The following motion was made by Sharon Levine and seconded by Gail Hunt:*

	Motion: Approve designating two special emphasis topics (Community-acquired Pneumonia and Pelvic Organ Prolapse) in a future PCS PFA, each topic with set aside funding of up to $40M remaining from previously approved PCS budgets *Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions)*
Discussion: Future Process relating to Reopening Targeted PFAs and Special Emphasis Topics in PCS PFAs	Dr. Norquist opened a discussion about the Board's delegation of authority to the SOC and staff to reopen targeted PFAs and designate PCS Special Emphasis Topics under similar circumstances, such as when there are remaining uncommitted funds under a PFA; and when the topics are deemed important and relevant to PCORI's mission and meet the scientific rigor and merit review standards. Board members discussed that with these examples, the Board has already authorized the development of the PFAs and related funding amounts. Additionally, the Board has recognized the topic development process overseen by the SOC. The Board recognized the value of these strategies to enhance the applications submitted to PCORI through efficient mechanisms such as these when there are uncommitted funds related to a targeted PFA and PCS PFA. <u>Action Item:</u> The SOC in conjunction with staff will develop a draft policy memorializing the Board's delegation of authority to the SOC to identify and reopen targeted PFAs and designate PCS Special Emphasis Topics. The SOC will bring a draft policy to the Board at an upcoming Board meeting for its approval.
Wrap up and Adjournment - *Grayson Norquist, MD, MSPH*	The meeting adjourned at 1:30 pm

Additional Materials: Attachment A

Minutes were approved by the PCORI Board of Governors 09-27-2016

Attachment A: Advisory Panel Appointees (August 2016)

New and Reappointed Advisory Panel Members, Alternates and Chairs, August 2016 (Term in Years)

- **Advisory Panel on Addressing Disparities**: Terrie Black (3), Deidra Crews (3), Christine Joseph (3), Donald Klepser (3), Ana Maria Lopez (3), Umbereen Nehal (3), Tung Nguyen (3)
  - Alternate: Tamarah Deuperval-Brownlee (3)
  - Chair: Cheryl Pegus
  - Vice Chair: Elizabeth A. Jacobs
- **Advisory Panel on Assessment of Prevention, Diagnosis, and Treatment Options:** Zeeshan Butt (3), Rafael Alfonso-Cristancho (3), Felix Fernandez (3), Jeff Hersh (3), Susan Lin (3), Michael Schneider (3), Nancy White (3)
  - Alternates: Cheryl Holly (3), Elaine Larson (3), Jeff Quinlan (3)
  - Chair: Margaret Clayton
- **Advisory Panel on Clinical Trials:** Kaleab Abebe (3), Patrick Archdeacon (3), Seth Morgan (3), Carole Treston (3)
  - Alternates: Mei Lu (3), Karen Jackson (3), Jeffery Jarvik (3), John Laschinger (3)
- **Advisory Panel on Communication and Dissemination Research:** Emilie Johnson (3)
  - Alternates: Marta Brooks (3), Elizabeth Krause (3)
  - Reappointed Members: Ashish Atreja (3), Danny van Leeuwen (3), Nancy Perrin (3), Janice Radak (3), Frank Rider (3), Kristin Voorhees (3)
- **Advisory Panel on Improving Healthcare Systems:** Rebecca Aslakson (3), Leah Backhus (3), Ignatius Bau (3), James Perrin (3), Alexis Snyder (3), Craig Umscheid (3), Mitzi Wasik (3), Nancy Yedlin (3)
  - Alternates: Marian Grant (3), Amy Houtrow (3), Jacqueline Merrill (3), Elizabeth Rubinstein (3), Kimberly Saverno (3)
- **Advisory Panel on Patient Engagement:** John Chernesky (2), Emily Creek (2), Libby Hoy (2), Megan Lewis (2), Suzanne Madison (2), Ting Pun (2), John Westfall (2), David White (2)
  - Alternate: Michael Siegel (2)
- **Advisory Panel on Rare Disease**: Matt Cheung (3), Kathleen Gondek (3), Michael Kruer (2), John Mulvihill (2), Maureen Smith (3), Penelope Strauss (1)
  - Alternate: John Gearhart (3)