

## Board of Governors Meeting via Teleconference / Webinar

Tuesday, September 26, 2017

12:00 pm – 1:30 pm ET

### Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Kerry Barnett, JD, *Vice Chairperson*; Debra Barksdale, PhD, RN; Larry Becker; Michael Lauer, MD (Acting as Designee for Francis Collins, MD, PhD); Allen Douma, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Russell Howerton, MD; Gopal Khanna; Harlan Krumholz, MD, SM; Richard Kuntz, MD, MSc; Sharon Levine, MD; Barbara McNeil, MD, PhD; Kathleen Troeger, MPH; Robert Zwolak, MD, PhD

### Board Members Absent:

Alicia Fernandez, MD; Gail Hunt; Freda Lewis-Hall, MD; Ellen Sigal, PhD

## MINUTES

| Agenda Item                                                                                                                                                                                                                                                   | PCORI Speakers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
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| <p>Call to Order, Roll Call, and Welcome</p> <ul style="list-style-type: none"> <li>- <i>Grayson Norquist, MD, MSPH, Chairperson and Joe Selby, MD, MPH, Executive Director</i></li> </ul>                                                                    | <p>Dr. Norquist opened the meeting, thanked all who joined the call and welcomed all to the meeting of the PCORI Board of Governors. He then read the Chair Statement on Conflict of Interest.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <p><b>Consider for Approval: Consent Agenda</b></p> <ul style="list-style-type: none"> <li>• Minutes of the September 12, 2017 Board Meeting</li> <li>• Nomination for Advisory Panel Member Position</li> <li>- <i>Grayson Norquist, MD, MSPH</i></li> </ul> | <p>Dr. Norquist introduced the Consent Agenda which included the approval of the September 12, 2017 meeting minutes, and the nomination of Kevin Weinfurt to serve as a member of the Advisory Panel on Clinical Trials (CTAP) as an ethicist through Fall 2020. Kevin Weinfurt is nominated to serve on CTAP instead of Elisa Hurley, who had previously been approved by the Board to serve on CTAP but who declined the invitation to serve due to unforeseen competing commitments. Dr. Norquist gave the opportunity to Board members to discuss any of the matters on the Consent Agenda. No separate discussion was requested.</p> <p><i>The following motion was made by Sharon Levine and seconded by Michael Lauer:</i></p> <p>That the Board approve:</p> <ul style="list-style-type: none"> <li>• Minutes from the September 12, 2017 Board meeting</li> <li>• Nomination of Kevin Weinfurt to serve as a member of the Advisory Panel on Clinical Trials (CTAP) as an ethicist through Fall 2020</li> </ul> <p><b>Motion:</b> Approve each of the Motions on the Consent Agenda</p> <p><i>Approved by a majority vote of the Board by voice vote (no opposed; no abstentions)</i></p> |

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| <p><b>Consider for Approval:</b><br/>FY 2018 Budget</p> <ul style="list-style-type: none"> <li>- <i>Larry Becker, Chair, Finance and Administration Committee (FAC) and Regina Yan, MA, Chief Operating Officer</i></li> </ul> | <p>Larry Becker and Regina Yan presented the proposed FY2018 Budget of \$478.6 million, as recommended by the FAC, for Board approval. Mr. Becker indicated that the proposed FY 2018 Budget represented the culmination of the work of PCORI departments and relevant strategy committees, each of which had reviewed and discussed the proposed budget relating to their oversight area. Ms. Yan explained key terms relating to the budget, including the difference between award commitments and award payments. She summarized PCORI's current estimated revenue through FY2019 (\$3,245M) and the breakdown of current estimated expenditures through FY2024 by program expenses, program support and general administration, as well as the current and cumulative funding commitment plan through FY2018. She reviewed the actual and projected revenue versus expenditures from PCORI inception through FY2024, and highlighted the projected FY2017 and FY2018 fund balances (\$935M and \$937, respectively). She outlined the annual budget development process, which is guided by the Board approved strategic plan and priority activities, and includes review and input from staff and Board-related strategy committees. She presented the key themes and major components of the FY2018 budget of \$478.6 million focusing on expected increases in award payments, peer review of PCORI-funded research findings, and dissemination and implementation initiative, and summarized the FY2018 budget vs. the FY2017 projection.</p> <p><i>The following motion was made by Barbara McNeil and seconded by Christine Goertz:</i></p> <p><b>Motion:</b> Approve the Proposed FY2018 Budget</p> <p><i>Approved by a majority vote of the voting Board members by roll call (15 in favor; 0 opposed; 0 abstentions and 0 recusals). Allen Douma was not present for this vote.</i></p> |
| <p><b>Consider for Approval:</b><br/>PCORnet Coordinating Center Task Order Set-aside Usage</p> <ul style="list-style-type: none"> <li>- <i>Joe Selby, MD, MPH</i></li> </ul>                                                  | <p>Dr. Joe Selby introduced the topic of the PCORnet Coordinating Center (CC) Phase II set aside funding. He explained that when the Board approved Phase II CC funding, it approved funding that included set aside funds to allow for activity-by-activity funding through task orders given the need for flexibility to meet evolving needs. Dr. Selby informed the Board that the set aside funds were intended by PCORI staff for use by either of the CC organizations: Duke or Genetic Alliance. During Phase II, new CC activity is identified by PCORI through programmatic management and oversight of the CC and the PCORnet networks. He then explained that the set aside funds were formally approved by the PCORI Board at its meeting on February 23, 2016 as part of Duke's funding, rather than as funding that could be used flexibly for</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

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|                                                                                                                                                                                                                                                                                                                                                                  | <p>new CC activities by either Duke or Genetic Alliance. Dr. Selby discussed the current use of the set aside funds explaining that Duke has received set aside funds for one contract modification and Genetic Alliance has received set aside funds for 2 contract modifications and 5 new task orders. As of 7/25/17 there is still \$2,970,808 remaining in the Phase II set aside funds. Dr. Selby indicated that the FAC and RTC had been made aware of the use of the Phase II set aside funding by both Duke and Genetic Alliance and recommended that the Board approve a formal motion indicating that the Phase II Coordinating Center set aside funds could be used for funding either Duke or Genetic Alliance.</p> <p><i>The following Motion was made by Larry Becker and seconded by Kerry Barnett:</i></p> <p><b>Motion:</b> Approve the use of PCORnet Coordinating Center set aside funding for either Duke or Genetic Alliance.</p> <p><i>Approved by a majority vote of the Board members by voice vote (no opposed; no abstentions; 2 recusals, Sharon Levine and Barbara McNeil). Freda Lewis-Hall had earlier indicated her intent to recuse, but was not present for this meeting.</i></p>                                                                                                                                                                                                                                                                        |
| <p><b>Consider for Approval:</b><br/> American Heart Association (AHA)-PCORI Collaboration: Shared Decision Making and Patient Care for those with Atrial Fibrillation at Risk for Stroke</p> <ul style="list-style-type: none"> <li>- Robert Zwolak, MD, PhD, Chair, Science Oversight Committee and Evelyn Whitlock, MD, MPH, Chief Science Officer</li> </ul> | <p>Dr. Zwolak introduced the agenda item and indicated that the Science Oversight Committee enthusiastically recommended that the Board approve funding to the American Heart Association (AHA) for the collaborative initiative. Dr. Whitlock explained that the collaboration originated through the Research Transformation Committee in the fall of 2015. The Phase I goal was to conduct crowdsourcing challenges to identify critical, patient-centered, comparative effectiveness cardiovascular disease research questions that would further precision medicine approaches for cardiovascular disease treatment and prevention and for AHA to create a blueprint with recommendations for using the crowdsourcing mechanism to identify CER questions for the future, which AHA had developed.</p> <p>Following the Phase I activities, a PCORI-commissioned ECRI Institute topic brief documented the underuse of anticoagulants in patients with atrial fibrillation (A-fib) and found that the lack of both clinician adherence to guidelines and patient adherence to medication contributed to underuse. A recent systematic review about research on decision aids for treatment options found only one published study that included newer oral anticoagulants and that no decision aids were currently available for clinical use. The AHA proposed taking advantage of a planned program for a Strategically-Focused Research Network (SFRN) on A-Fib for a project.</p> |

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|                                                                                                                                                                                                                                                    | <p>The current proposal for a collaborative funding initiative with AHA, “Decision-making and Choices to Inform Dialogue and Empower A-Fib Patients (DECIDE),” aims to have AHA fund a center within the AHA SFRN to develop, or adapt, and test a decision aid to enable patients and clinicians to choose oral anticoagulant options to prevent stroke in the setting of A-Fib and to enable shared decision making around OAC options. The DECIDE center would collaborate with other centers in the SFRN to test the tool in appropriate patients and compare it with existing decision strategies. Under the proposed collaboration, PCORI would provide \$2.5 funding to AHA to enable AHA to fund one 4-year project and PCORI would additionally fund AHA \$250K to support AHA’s administrative costs relating to the initiative. AHA would also contribute \$2.5M to fund the one 4-year project. Under the collaborative initiative, AHA will issue the funding announcement and will manage the award, assuring PCORI requirements for stakeholder engagement, Merit Review, Peer Review of research findings, and public availability of results.</p> <p>Members of the Board had questions regarding why clinical outcomes were considered secondary and whether this is because the study would not be powered to look at clinical outcomes. Dr. Whitlock noted that Science staff will clarify the wording to assure that clinical outcomes, including stroke and bleeding, be included. Board members also commented that the importance of anticoagulation should be emphasized. Dr. Whitlock noted that there are multiple opportunities for PCORI to participate in the selection and monitoring of projects. She extended an invitation to Board members to inform staff if they would like to participate in this process.</p> <p><i>The following Motion was made by Robert Zwolak and seconded by Michael Lauer:</i></p> <p><b>Motion:</b> Approve PCORI funding up to \$2.75M to support the AHA-PCORI Collaboration: DECIDE, a 4-year project, subject to terms of agreement between PCORI and AHA</p> <p><i>Approved by a majority vote of the voting Board members by roll call (16 in favor; 0 opposed; 0 abstentions and 0 recusals).</i></p> |
| <p><b>Consider for Approval:</b><br/>Process for Dissemination and Implementation (D&amp;I) Awards greater than \$500,000</p> <ul style="list-style-type: none"> <li>- Debra Barksdale, PhD, RN, Chair, Engagement, Dissemination &amp;</li> </ul> | <p>Dr. Debra Barksdale thanked Jean Slutsky and staff for work to bring the proposed process for approval of Dissemination and Implementation Awards greater than \$500,000 (including awards for dissemination and implementation and for implementation of shared decision making) to the Board for</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

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| <p><i>Implementation Committee (EDIC) and Jean Slutsky, PA, MSPH, Chief Engagement and Dissemination Officer</i></p>                                                                                                                                                | <p>approval. Ms. Slutsky noted that to date, PCORI's Dissemination and Implementation (D&amp;I) Program has proposed funding only for projects with total costs under \$500k; these have been approved by the CEDO, consistent with PCORI policy. At this point, however, the D&amp;I Program is reviewing and anticipates proposing larger projects for funding, requiring a formal mechanism for approving these projects. Under the proposed process, the D&amp;I Program will present slates of projects over \$500k recommended for funding to the Engagement, Dissemination and Implementation Committee (EDIC) for consideration and approval to move forward for presentation to the full Board of Governors. The slates of projects that the EDIC recommends to move forward will then be presented to the Board of Governors for approval.</p> <p><i>The following motion was made by Michael Lauer and seconded by Larry Becker:</i></p> <p><b>Motion:</b> Approve the Approval Process for Large Dissemination &amp; Implementation Awards.</p> <p><i>Approved by a majority vote of the voting Board members by roll call (16 in favor; 0 opposed; 0 abstentions and 0 recusals).</i></p>                                                                     |
| <p><b>Consider for Approval:</b><br/>Additional Application from the Cycle 3, 2016 Pragmatic Clinical Studies PFA</p> <ul style="list-style-type: none"> <li>- <i>Christine Goertz, DC, PhD, Chair, Selection Committee and Evelyn Whitlock, MD, MPH</i></li> </ul> | <p>Christine Goertz introduced this agenda item, noting that the Board would consider approving an additional research project that was being recommended for approval by the Selection Committee after staff had addressed questions of the Selection Committee. Dr. Whitlock then began her presentation by introducing the proposed additional award for the Cycle 3, 2016 Pragmatic Clinical Studies (PCS) PFA.</p> <p>She explained that on September 12, 2017, the Board had voted to approve the Selection Committee's (SC) recommendation to fund a slate of three PCS research projects for a proposed total commitment of \$32,751,663 out of the budgeted \$60M. Dr. Whitlock explained that the SC was now recommending funding one additional research project after questions identified by the Selection Committee had been addressed. The additional recommended research project is:</p> <ul style="list-style-type: none"> <li>• A Pragmatic Trial of Home versus Office Based Narrow Band Ultraviolet B Phototherapy for the Treatment of Psoriasis</li> </ul> <p>This project is a randomized, controlled study that aims to study whether home-based phototherapy is non-inferior to office-based phototherapy for the treatment of patients with</p> |

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|                                                                    | <p>moderate to severe psoriasis in terms of clinical and patient-reported outcomes, within adults with moderate to severe psoriasis. The total project cost is \$8.6M.</p> <p>The proposed total commitment for Cycle 3, 2016 PCS PFA, which includes the three applications already approved by the Board and this proposed application is \$41.4M out of the budgeted \$60M.</p> <p><i>The following motion was made by Russell Howerton and seconded by Barbara McNeil:</i></p> <p><b>Motion:</b> Approve funding for the recommended additional award from the Cycle 3 2016 Pragmatic Clinical Studies PFA</p> <p><i>Approved by a majority vote of the voting Board members by roll call (16 in favor; 0 opposed; 0 abstentions and 0 recusals).</i></p> |
| <p>Wrap up and Adjournment</p> <p>- Grayson Norquist, MD, MSPH</p> | <p>Meeting ended at 1:20 pm</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

**Minutes were approved by the PCORI Board of Governors 10-30-2017**