PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting via Teleconference / Webinar

Tuesday, September 27, 2016

12:00 pm – 1:30 pm ET

Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Debra Barksdale, PhD, RN; Larry Becker; Andy Bindman, MD; Francis Collins, MD, PhD; Allen Douma, MD; Alicia Fernandez, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Russell Howerton, MD; Gail Hunt; Robert Jesse, MD, PhD; Richard Kuntz, MD, MSc; MHA; Kathleen Troeger, MPH; Robert Zwolak, MD, PhD

Board Members Absent:

Kerry Barnett, JD, *Vice Chairperson;* Harlan Krumholz, MD, SM; Sharon Levine, MD; Freda Lewis-Hall, MD; Barbara McNeil, MD, PhD; 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. Dr. Norquist then welcomed the two newest Board members to PCORI, Russell Howerton, MD, Chief Medical Officer and Vice President of Clinical Operations at Wake Forest Baptist Medical Center, and Kathleen Troeger, Director of Outcomes Research at Hologic, Inc. He also took the opportunity to thank Steve Lipstein and Harlan Weisman for their years of service to PCORI and wish them well in their future endeavors.
Consent Agenda: • Minutes of the August 16, 2016 Board Meeting • Committee Nominations • PEAP Chair - *Grayson Norquist, MD, MSPH*	Dr. Norquist introduced the Consent Agenda which included approval of the August 16 meeting minutes and approval of the Committee Chair and Vice Chair nominations, as well as the nomination for the Chair of the Patient Engagement Advisory Panel (PEAP) put forth by the Governance Committee *(See Attachment A)*. 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 presented for Board approval: **Motion:** Approve each of the motions on the Consent Agenda as reflected below: • Minutes of the August 16, 2016 Board of Governors meeting • Nominations for Chairs, Vice Chairs for the Engagement, Dissemination and Implementation Committee (EDIC), Research Transformation Committee (RTC), Science Oversight Committee (SOC), and the Finance and Administration Committee (FAC) *(see Attachment A)* • Nomination for Chair of the Patient Engagement Advisory Panel (PEAP) *(see Attachment A)*

	Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions)
Consider for Approval: FY 2017 Budget - *Larry Becker, Chair, Finance and Administration Committee (FAC) and Regina Yan, MA, Chief Operating Officer*	Larry Becker and Regina Yan presented the Proposed FY2017 Budget, as recommended by the FAC, for Board approval. Ms. Yan explained key terms relating to the budget, including the difference between commitments and payments. She summarized PCORI's estimated revenue through FY 2019 and estimated expenditures through FY 2024 as well as the current and cumulative funding commitment plan through FY 2017. She outlined the budget development process, which ties to the Board approved strategic plan, and includes review and input from staff and Board-related strategy committees. She presented the major components of the FY 2017 budget, highlighted the key drivers of budget increases, and summarized the FY2017 budget vs. the FY 2016 projection. Board members were invited to ask questions and discuss the Proposed FY2017 Budget and no further discussion was deemed necessary. The following motion was made by Gail Hunt and seconded by Leah Hole-Marshall: **Motion:** Approve the Proposed FY2017 Budget. *Approved by majority vote of the voting Board members by roll call vote (13 in favor; no opposed; no recused, no abstentions). Bob Jesse was not present for this vote.*
Consider for Approval: Revised Delegation of Authority and Sunset of Record Retention Policies - *Larry Becker, Mary Hennessey, Esq General Counsel, and Regina Yan, MA*	Larry Becker and Mary Hennessey presented the revised Delegation of Authority and Expenditure Policy and the Record Retention Policy to the Board, as recommended by the FAC: Mary Hennessey outlined the history of the Board's approval of the Delegation of Authority Policy and the Record Retention Policy in PCORI's early years. She explained that PCORI has evolved into a more complex organization and the early-adopted policies are now outdated and do not contemplate the Board's later adoption of other policies, resolutions, and governing documents. She explained that the revised Delegation of Authority and Expenditure Approval Policy addresses the circumstances under which an officer, director, employee or other representative of PCORI may legally bind PCORI, authorize payments, and/or commit to expenditures on behalf of PCORI. This revised policy addresses substantive areas from the 2011 Board approved policy as well as parts of the 2013 Board approved Decision Matrix. She also explained that the updated Record Retention Policy establishes standards for the retention and destruction of core corporate and governance records of PCORI. To implement these two new policies, the FAC recommends that the Board sunset the 2011 Record Retention Policy and affirm that the

	Executive Staff have authority to approve updated and future versions of the policy, keeping the FAC informed, to ensure that the policy can be updated as needed to comply with legal and governance PCORI needs. The FAC also recommends that the Board sunset two prior policies addressing delegation of authority and approve the updated version of the Delegation of Authority and Expenditure Policy. The following motion was made by Gail Hunt and seconded by Robert Zwolak. **Motion:** Sunset the following Board-approved policies: • Record Retention Policy (approved 1.20.11) and affirm that Executive Staff have the authority to approve revised versions, keeping the FAC informed • Delegation of Authority Policy (approved 3.8.11) • PCORI Decision Making Matrix – Responsibility by Functional Area (approved 11.18.2013) And, Approve the proposed revised Delegation of Authority and Expenditure Approval Policy. *Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions)*
Consider for Approval: Addition to the 2015 Cycle 3 New Oral Anticoagulants (NOACs) in the Extended Treatment of Venous Thromboembolic Disease Targeted PFA Award Slate - *Evelyn Whitlock, MD, MPH, Chief Science Officer*	Dr. Whitlock began the presentation by reiterating that this is an opportunity to add to the slate already approved for this targeted PFA for up to $30M. (In July 2016, the Board approved funding for a slate of two research projects for a total of $6.5M). A recap was presented on what was approved previously. A third application for $14.8M on Warfarin vs. Direct Oral Anticoagulants for Secondary Prevention of Recurrent Venous Thromboembolism: a randomized comparative effectiveness trial was presented and discussed. This project addresses the research question: Are all direct oral anticoagulants/regimens equivalent for efficacy and safety for long term treatment of venous thromboembolism (VTE)? It was noted that will be a three drug study comparing two of the NOAC/DOACs with warfarin, and there are now four of these agents. The previously approved observational studies are complementary studies comparing all four of the newer drugs to warfarin. This is complementary across the range of agents. The two study drugs for this project (rivaroxaban and apixaban) were chosen based on availability and use, focusing on most commonly used agents. The following motion was made by Larry Becker and seconded by Robert Jesse.

	Motion: Approve funding for the recommended additional award from the Cycle 3, 2015 New Oral Anticoagulants (NOACs) in the Extended Treatment of Venous Thromboembolic Disease Targeted PFA. *Approved by a majority vote of the voting Board members by roll call. (12 in favor; 0 opposed; 1 abstention (Kathleen Troeger) and 0 recusals). Gail Hunt was not present for this vote.*
Update on the STRIDE Falls Prevention Trial - *Steve Clauser, PhD, MPA, Program Director, Science and David Reuben, MD, and Thomas Gill, MD*	Steve Clauser introduced the agenda item and explained the importance of Falls Prevention as a PCORI targeted funding priority as it was an Institute of Medicine top tier comparative effectiveness research priority topic and endorsed by the Board of Governors. He noted this was the first targeted priority topic implemented as a partnership with the National Institutes of Health and commented on the excellent collaboration between the leadership of the National Institute on Aging and PCORI in the solicitation, award and oversight of this trial. A presentation was made on STRIDE: A Multisite Pragmatic Trial to Reduce Serious Falls-related Injuries by Drs. Thomas Gill and David B. Reuben. The STRIDE study is funded by PCORI and the National Institutes on Aging with three joint principal investigators: Shalender Bhasin, M.D. (Harvard/Partners); Thomas Gill, M.D. (Yale) and David B. Reuben, M.D. (UCLA). The study is conducted in 14 Pepper Centers with the Data Coordinating Center at Yale. It addresses the research question “What is the comparative effectiveness of nurse co-management of falls risk factors and enhanced physician management of falls risk factors in reducing serious falls-related injuries and improving other outcomes (all falls-related injuries, falls efficacy, physical function and disability, anxiety) among elders at risk of falls-related injuries? The presenters provided an update of the trial including the research question, study design, clinical trial site locations and other important data, as well as progress to date, future plans, challenges and barriers. It was noted that this trial represents the single largest PCORI investment to date. The projected recruitment completion date is March 31, 2017. A final report is expected in June 2019.The Board will continue to be kept informed on the progress of this project as the trial continues.
Wrap up and Adjournment - *Grayson Norquist, MD, MSPH*	The meeting adjourned at 1:22 pm

Additional Materials: Attachment A

Minutes were approved by the PCORI Board of Governors 10-31-2016

Attachment A to Minutes of
Board of Governors Meeting via Teleconference / Webinar
Tuesday, September 27, 2016
12:00 pm – 1:30 pm ET

PCORI Committee Chair and Vice Chair Appointments
(Terms effective September 23, 2016 – September 22, 2019)

The Board approved the following nominations made by the Governance Committee for Committee Chair and Vice Chair appointments:

- Engagement, Dissemination and Implementation Committee (EDIC)
  – Chair, Debra Barksdale (Reappointment for 2nd term)
  Vice Chair, Bob Jesse (Reappointment for 2nd term)

- Research Transformation Committee (RTC)
  – Chair, Freda Lewis-Hall (Reappointment for 2nd term)
  Vice Chair, Allen Douma (Nominated for 1st term – no previous Vice Chair served)

- Science Oversight Committee (SOC)
  – Chair, Robert Zwolak* (Nominated for 1st term)
  Vice Chair, Alicia Fernandez* (Nominated for 1st term)

- Finance and Administration Committee (FAC)
  – Chair, Larry Becker* (Nominated for 1st term)

*previously appointed to serve remaining term of previous Chair, Vice Chair

Patient Engagement Advisory Panel Chair
The Board approved the following for the Patient Engagement Advisory Panel for a one-year term as Chair. Ms. Perlmutter has served as a member of this advisory panel for the past two years.

Name	Stakeholder Group	Primary Affiliation	Term of Chair position (In Years)
Jane Perlmutter	Patients, Caregivers, Patient Advocates	Self-employed (Gemini Group)	1