



Patient-Centered Outcomes Research Institute Board of Governors In-Person Meeting

Almas Shriners Building
1001 14th Street, NW
Washington, DC 20005
Tel: (800) 914-8318

May 23, 2016

Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Debra Barksdale, PhD, RN; Kerry Barnett, JD, *Vice Chairperson*; Larry Becker; Andrew Bindman, MD; Francis Collins, MD, PhD; Allen Douma, MD (via phone); Alicia Fernandez, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Gail Hunt; Robert Jesse, MD, PhD; Harlan Krumholz, MD, SM; Richard Kuntz, MD, MSc; Sharon Levine, MD; Freda Lewis-Hall, MD; Steve Lipstein, MHA; Barbara McNeil, MD, PhD; Ellen Sigal, PhD; Harlan Weisman, MD (via phone); Robert Zwolak, MD, PhD

Board Members Absent:

None

Methodology Committee Member Present:

Robin Newhouse, PhD, RN, *Chair*; Michael Lauer, MD

Staff:

Joe Selby, MD, MPH, *Executive Director*; Rachael Fleurence, PhD; Mary Hennessey, Esq.; Susan Hildebrandt, MA; Kara Odom Walker, MD, MPH, MSHS; Michele Orza, ScD; Sue Sheridan, MBA, MIM; Bill Silberg; Erin Singhsinsuk, Jean Slutsky, PA, MSPH; Harold Sox, MD; Evelyn P. Whitlock, MD, MPH; Regina Yan, MA

MINUTES

Agenda Item	Related Minutes
Call to Order, Roll Call and Welcome - <i>Grayson Norquist, MD, MSPH, Chairperson, and Joe Selby, MD, MPH, Executive Director</i>	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: • Minutes of the April 26, 2016 Board Meeting • Committee Assignments for Andrew Bindman • Research and Infrastructure Project Budget Increase Policy - <i>Grayson Norquist, MD, MSPH</i>	Dr. Norquist introduced the Consent Agenda which included the April 26, 2016 Board meeting minutes, Committee Nominations, and the Research and Infrastructure Project Budget Increase Policy. <i>The following motion was made by Larry Becker and seconded by Steve Lipstein:</i> Motion: That the Board approve each of the following items on the Consent Agenda as follows: • Minutes from the April 26, 2016 Board Meeting; • Nomination by the Governance Committee of Andrew Bindman to serve on the Engagement, Dissemination and Implementation Committee (EDIC) and the Science and Oversight Committee (SOC); and, • Research and Infrastructure Project Budget Increase Policy. <i>Approved by a majority vote of the Board by voice vote (no opposed; no abstentions); Drs. Douma and Weisman were not present for this vote.</i>
Executive Director's Report and Q2 Dashboard Review - <i>Joe Selby, MD, MPH</i>	Dr. Selby welcomed Dr. Andrew Bindman to the PCORI Board of Governors. He then introduced the British Medical Journal's recent Patient Perspective initiative, which engages patients in their peer review process and incorporates into their publication how patients were involved. Dr. Selby also updated the Board of Governors on the Hepatitis C virtual stakeholder meeting, which took place on May 18, 2016 and was open to the public, as a follow-up to the original October 2014 meeting and engaged many of the original participants. The results of the stakeholder meeting are being synthesized and will be discussed by the Science Oversight Committee to determine next steps. Dr. Selby addressed the availability of PCORI funding for awarded projects continuing past 2019. He clarified that PCORI has confirmation from the Treasury Department that all funds in the PCOR Trust Fund up to and including September 30, 2019 will be available to PCORI and therefore all PCORI awarded research contracts will be funded through

Q2 Dashboard Review	their completion date even beyond 2019. PCORI has and will continue to set aside funds for these awarded projects through their completion, including beyond 2019. Dr. Selby also reminded all of the 2016 PCORI Annual Meeting to be held November 17-19, 2016 at the Gaylord National Resort and Convention Center in National Harbor, Maryland. Dr. Selby presented the Second Quarter Dashboard for the Board's review. The Dashboard demonstrated two yellow-flagged items (items that are off target by more than 10%): Funds Committed to Research, and Expenditures. He showed that PCORI is meeting our estimated funding amount, but are below the maximum budgeted funding for the quarter. There were no red-flagged items (items identified as off target and in need of attention or action by the Board). Dr. Selby highlighted examples of Radiology and Nephrology specialty physicians engaging with PCORI to drive a useful portfolio and facilitate uptake of results. He described an example of how PCORI is influencing research at Meharry-Vanderbilt Alliance, and cited a February 2016 JAMA article, <i>Improving Surgical Research by Involving Stakeholders</i>, outlining how stakeholder engagement in research helped improve enrollment and retention in a PCORI-funded research project. He reviewed the Measures of Progress of Research Projects for Pragmatic Clinical Studies (PCS), categorizing green, yellow, orange or red status for projects, and noted that all PCS projects are either green or yellow. He discussed that two PCS studies are behind on recruitment due to delayed recruitment initiation. PCORI staff are monitoring these studies closely. Dr. Selby provided an overview of the progress of PCORnet, including the current eight collaborative Research Demonstration projects underway, and stated that 25 of 33 networks are engaged in research projects. He indicated that the Front Door Policy (the way that external researchers and funders will approach PCORnet) had a soft launch in April 2016 and that a "public" opening of the Front Door is anticipated in summer 2016. He announced that PCORnet currently has 83 DataMarts, and that 6 DataMarts are already approved for research. Board members expressed interest in how PCORI sets benchmarks for projects on track, and in how long projects stay categorized as red. Additionally, there was discussion around how PCORI is planning to track speed of research, impact, and use of findings. Dr. Selby indicated that PCORI was monitoring trends and expected to be able to report more in the near future.
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Mid-Year Financial Review - <i>Regina Yan, MA, Chief Operating Officer, and Larry Becker, Chair of Finance and Administration Committee</i>	Larry Becker, Chair of the Finance and Administration Committee (FAC) and Regina Yan, Chief Operating Officer, presented the Mid-Year Financial Review for BOG discussion. The FY2016 Mid-Year Financial review included a review of the revenue and cash balances; research and other funding commitments; budget versus actuals review; funding commitment plan; and estimated revenue and expenditures for PCORI based on the first six months of FY2016 (October 1, 2015 – March 31, 2016). Ms. Yan noted the variance between the FY2016 budget and actuals for the period was 18%, down from 28% in FY2015 for the same period. This much smaller budget vs. actual variance signifies a refined ability to plan the budget and project expenses when compared to previous fiscal years. Larry Becker informed the board that the FAC reviews estimated revenue and expenditures monthly. Following the presentation, the Board of Governors expressed an interest in increased dissemination funding, to be discussed in more depth in the future, and adequate staffing resources.
Methodology Committee (MC) Update - <i>Robin Newhouse, PhD, RN, Chair of the Methodology Committee</i>	Robin Newhouse provided the Board with an update on the Methodology Committee's ongoing initiatives and activities including implementation of the PCORI Methodology Standards, an update on the public comment period for the draft revisions to the Methodology Standards, and the MC's coordination with the Clinical Trials Advisory Panel (CTAP). The three goals of implementation of the standards are to help investigators understand and use the standards, ensure methodological integrity of funded projects, and identify barriers to use of the standards. In the past, webinars and conferences helped investigators to understand the standards. These efforts are continued through the new online CME program launched last year and the academic curriculum launched approximately three months ago. Methodological integrity is addressed by incorporating the standards into the application (LOI and full application), pre-award (training of merit reviewers), and post-award (review of study protocol, progress reports and the final research report) processes. Board members identified the CME program and the curriculum as two areas where more outreach is needed. The members would like to see more work around dissemination of the standards. The public comment period on the draft revisions to the Methodology Standards was open between January and April of 2016. Eighty four comments were received from health researchers, industry, caregivers and family members,

	and patients. Standards on Formulating Research Questions, Patient-Centeredness, and Causal Inference Methods received the most comments. Dr. Newhouse updated the Board on the collaborative relationship between the MC and the CTAP. CTAP advises PCORI and staff on best practices for conducting clinical trials through the MC. Two MC members serve as ex officio members of the CTAP. The MC is striving for a more enhanced relationship with the CTAP in the future. Dr. Newhouse also introduced new MC member Stephanie Chang, the AHRQ Director’s designee. Dr. Chang is the Director of the AHRQ Evidence-based Practice Center (EPC) Program.
Consider for Approval: PCORnet Cross-PPRN Research Project Award - <i>Joe Selby, MD; Rachael Fleurence, PhD; and Freda Lewis-Hall, MD, Chair of the Research Transformation Committee</i>	Dr. Joe Selby introduced this request for funding of the PCORnet Cross-PPRN Research Project Award and announced that this involves all 20 of the current PPRNs. Dr. Fleurence presented a brief overview of the funding announcement, and the purpose of the project, entitled Healthy Mind Healthy You, which is to compare the effectiveness to improve patients’ well-being of one 8 session mindfulness-based cognitive behavioral therapy (MBCT) to a 3 session “mindfulness light” MBCT. The proposed total budget for this project is \$4M. Dr. Fleurence stated that this demonstration project is intended to see how engaged but diverse communities in different areas of the country work together on a common research project. A documentation of “lessons learned” was suggested by the Board. Dr. Fleurence stated that all PCORnet studies have an evaluation component incorporated with an interim report and an evaluation report, which will be made available to the Board. It was noted that during its May 9, 2016 meeting, the Selection Committee (SC) recommended that the Board approve the funding of this award. . <i>The following motion was made by Sharon Levine and seconded by Gail Hunt:</i> Motion: Approve funding for the Cross-Patient-Powered Research Networks (PPRN) Demonstration Project, subject to PCORI review and negotiation of final terms. <i>Approved by a majority vote of the Board members by a show of hands and roll call for those on the phone: 15 in favor, 0 opposed, 0 abstentions; the following 5 Board members recused themselves: Debra Barksdale, Andrew Bindman, Alicia Fernandez, Steve Lipstein, and Barbara McNeil; (Ellen Sigal was not present for this vote)</i>

Report on Application Enhancement Efforts - <i>Evelyn Whitlock, MD, MPH; Jean Slutsky, PA, MSPH, Chief Engagement and Dissemination Officer; Regina Yan, MA; and Bob Zwolak, MD, PhD, Chair of Science Oversight Committee</i>	Regina Yan, Chief Operating Officer, Jean Slutsky, Chief Engagement and Dissemination Officer, and Bob Zwolak, Chair of the Science Oversight Committee (SOC), provided an overview of the work undertaken in regards to recent application enhancement efforts. Ms. Slutsky provided an overview of the work done to date, noting that our application enhancement efforts began in 2015 with four workgroups/ committees and one commissioned external review, which resulted in 45 recommendations for improvement focused across the application process. An Application Enhancement Steering Committee made up of key PCORI staff has reviewed the recommendations and has prioritized them into immediate (for August 2016 PFA posting) and short-term (for February 2017 PFA posting) categories for implementation. Ms. Yan reviewed the implementation of the recommendations in the two categories with the BOG. The Application Enhancement Steering Committee will report back on their progress regularly to the Science Oversight Committee (SOC). Following the presentation, members of the Board of Governors requested an update on this work in the fall of 2016.
Stakeholder Panel: Specialty Physicians - <i>Christopher Cox, MD, MPH, MHA, American Thoracic Society, Duke University Medical Center</i> - <i>Neil Kirschner, PhD, Senior Associate, Health Policy and Regulatory Affairs, American College of Physicians</i> - <i>Richard Schilsky, MD, FACP, FASCO, Senior Vice President and Chief Medical Officer, American Society of Clinical Oncology (ASCO)</i> Moderator: <i>Bob Zwolak, MD, PhD</i>	Representatives of three medical specialty societies appeared before the Board. All three had been asked to provide feedback to the Board on PCORI from their specialty's perspective. The panelists made a number of observations, including their support for comparative effectiveness research, the need to translate science into actual practice, the fact that PCORI has engaged physicians in a number of ways and their desire for involvement with dissemination. Finally, they engaged in a discussion with the Board around the best way to involve physician specialty societies in PCORI efforts. The Board concluded the discussion by thanking them for their input and indicating that this was an ongoing conversation.
Dissemination Strategy - <i>Jean Slutsky, PA, MSPH; Joanna Siegel, SM, ScD; and Debra Barksdale, PhD, RN, Chair, Engagement, Dissemination, and Implementation Committee</i>	Debra Barksdale, Chair, Engagement, Dissemination, and Implementation Committee, and Jean Slutsky, Chief Engagement and Dissemination Officer introduced Joanna Siegel, Director of PCORI's Dissemination and Implementation Program and noted that this presentation follows discussions with the Engagement, Dissemination, and Implementation Committee this spring. Dr. Siegel described plans for PCORI's Dissemination and Implementation Program, designed to support compliance with PCORI's authorizing legislation and uptake of research findings, and highlighted current activities including the

	establishment of the PCOR Translation Center that will assist PCORI in preparing the lay and clinician abstracts to be posted on PCORI's website, initiatives to advance public access to PCORI funded research findings published in peer-reviewed journals, and the Limited Competition Dissemination and Implementation Award program. She also described a strategy for early identification of potentially high-impact findings and highlighted the collaborative work that PCORI will undertake in collaboration with AHRQ in dissemination of these findings and promoting their implementation. Board members emphasized the importance of PCORI encouraging Awardees to submit their findings to PCORI and to journals promptly so as to expedite their dissemination and uptake, and commented on the importance of involving the stakeholder partners that are critical for successful implementation. Dissemination and implementation will be further discussed at the next in-person BOG meeting.
Targeted PCORI Funded Announcements - Evelyn P. Whitlock, MD, MPH, Chief Science Officer, and Bob Zwolak, MD, PhD Sickle Cell Disease	Dr. Evelyn Whitlock introduced the agenda item and outlined the process that PCORI uses to review and approve questions for targeted PFAs. Dr. Whitlock highlighted the 8 previously released targeted PFAs and 5 approved targeted PFA topics for development. She then presented the three targeted PFA topics recommended by the SOC to the Board for approval. Management of Sickle Cell Disease (SCD) Based on the results of advisory panel discussions, a multi-stakeholder workgroup, internal staff discussions, and support from the Science Oversight Committee (SOC), Dr. Whitlock presented a recommendation for a targeted PFA focusing on the comparative effectiveness of established transition coordination models for emerging adult SCD population (16-26 years of age) as they transition from pediatric to adult care. The emerging adult population is particularly vulnerable to worsened health outcomes during the time of transition from pediatric to adult care. PCORI is interested in funding up to 3 studies using a cluster randomized controlled trial (RCT) with sufficient sample size and/or clusters to power study in outpatient settings, including primary care practice, patient-centered medical homes, or specialty clinic for SCD patients. <i>The following motion was made by Barbara McNeil and seconded by Kerry Barnett:</i> Motion: Approve \$25M (total costs) for Management of Sickle Cell Disease targeted PFA development

	<i>Approved by a majority vote of the Board members by a show of hands and roll call for those on the phone: 19 in favor, 0 opposed, 0 abstention; (Freda Lewis-Hall and Ellen Sigal were not present for this vote)</i>
Opioids	Strategies to Prevent Unsafe Opioid Prescribing in Primary Care among Patients with Acute or Chronic Non-cancer Pain This is a sequential targeted PFA, following another targeted PFA on managing and reducing long-term opioid use, which was approved for development by the Board in September 2015 and released in October 2015. The goal of this targeted PFA is to generate evidence to prevent unsafe opioid prescribing while ensuring adequate pain management using either payer or health system strategies, or patient and provider communication interventions addressing benefits and harms of various treatments. It includes two research questions: one looking at the comparative effectiveness of different payer or health system strategies that aim to prevent unsafe opioid prescribing while ensuring access to non-opioid methods for pain management with the goal of reducing pain and improving patient function and quality of life outcomes, while reducing patient harm; and the second, looking at the comparative effectiveness of different patient and provider facing interventions that facilitate improved knowledge, communication and/or shared decision making about the harms and benefits of opioids and alternative treatments on prevention of unsafe prescribing and improved patient outcomes. Dr. Whitlock summarized the proposed population, outcomes, study design, setting, time, and sample size for each proposed question. PCORI is interested in funding up to 6 studies. <i>The following motion was made by Steve Lipstein and seconded by Robert Jesse:</i> Motion: Approve \$30M (total costs) for Preventing Unsafe Opioid Prescribing targeted PFA development <i>Approved by a majority vote of the Board members by a show of hands and roll call for those on the phone: 20 in favor, 0 opposed, 0 abstentions; (Ellen Sigal was not present for this vote)</i>
Palliative Care	Community-based Palliative Care Delivery for Adult Patients with Advanced Illnesses and their Caregivers Based on the results of advisory panel discussions, a multi-stakeholder workgroup, internal staff discussions, and support from the SOC, Dr. Whitlock presented a recommendation for the development a targeted PFA with

	two research questions focusing on geographically and racial/ethnically diverse patients living at home with any serious, advanced illness and who experience a high symptom burden and/or functional limitations and their caregivers. Both research questions would take place in multi-site community-based settings such as hospital-based clinics, solo or group physician practices, and the patient's home. The first research question is "what is the comparative effectiveness of different patient, caregiver, and clinician-directed and combination approaches to facilitating advance care planning conversations between adult patients living with advanced illnesses, their caregivers, and clinicians on patient-centered and other outcomes over time?" The second research question, "what is the comparative effectiveness of different established models of palliative care in community settings on improving patient-centered and other outcomes among adult patients with advanced illnesses and their caregivers" considers established palliative care models to be evaluated through head-to-head comparisons. Dr. Whitlock summarized the proposed population, intervention and comparators, timing, setting, design, sample size, and proposed commitment associated with each proposed research question. PCORI seeks to fund up to 8 studies. <i>The following motion was made by Kerry Barnett and seconded by Alicia Fernandez:</i> Motion: Approve \$48M (total costs) for Palliative Care targeted PFA development <i>Approved by a majority vote of the Board members by a show of hands and roll call for those on the phone: 19 in favor, 0 opposed, 0 abstentions; (Freda Lewis-Hall and Ellen Sigal were not present for this vote)</i>
Additional Awards from the 2015 Cycle 1 Large Pragmatic Studies and 2015 Cycle 2 Broad PFAs - Evelyn P. Whitlock, MD, MPH	2015 Cycle 1 Pragmatic Clinical Studies Funding Slate On behalf of Dr. Evelyn Whitlock, Dr. David Hickam, Director of the Accelerating Methods for PCOR program, presented an overview of this additional study (Comparative Effectiveness of Breast Cancer Screening and Diagnostic Evaluation by Extent of Breast Density) to the 2015 Cycle 1 slate. With this addition, six projects would be funded under this cycle, increasing the budget to \$67M (from \$59M) out of an allotted \$90M. <i>The following motion was made by Sharon Levine and seconded by Christine Goertz:</i> Motion: Approve funding the recommended additional award ["Comparative Effectiveness of Breast Cancer Screening and Diagnostic Evaluation by Extent of Breast

	Density”] from the Spring 2015 Pragmatic Clinical Studies Cycle: <i>Approved by a majority vote of the Board members by a show of hands and roll call for those on the phone: 12 in favor, 0 opposed, 0 abstentions; 5 recused; Debra Barksdale, Andrew Bindman, Alicia Fernandez, Steve Lipstein and Robert Zwolak were recused for this vote. (Robert Jesse, Freda Lewis-Hall, Ellen Sigal and Gail Hunt were not present for this vote)</i> Additional Studies to Broad Cycle 2 2015 Slate Dr. Whitlock presented two additional studies to the Cycle 2 2015 Broad slate, which was originally approved by the Board on April 26, 2016. One study (High Intense Periodic vs. Every Week Therapy in Children with Cerebral Palsy (CP)) falls under the Assessment of Prevention, Diagnosis, and Treatment Options program, and the other study (Patient-Centered Hepatitis C Care via Telemedicine for Individuals on Opiate Substitution Therapy: A Stepped Wedge Cluster Randomized Control Trial) falls under the Improving Healthcare Systems program. With these additions, the total number of awarded projects for this cycle would be 23. The addition of these two studies would increase the budget to \$55M (from \$45M) out of an allotted \$76M for this cycle. <i>The following motion was made by Dr. Zwolak and seconded by Larry Becker:</i> Motion: Approve funding for the recommended two additional awards from the 2015 Cycle 2 Broad PFAs [High Intense Periodic vs. Every Week Therapy in Children with Cerebral Palsy (CP) and Patient-Centered Hepatitis C Care via Telemedicine for Individuals on Opiate Substitution Therapy: A Stepped Wedge Cluster Randomized Control Trial] <i>Approved by a majority vote of the Board members by a show of hands and roll call for those on the phone: 19 in favor, 0 opposed, 0 abstentions; (Freda Lewis-Hall and Ellen Sigal were not present for this vote)</i>
Portfolio Analysis – Depression, Pain, Sleep, and Fatigue Outcomes - Evelyn Whitlock, MD, MPH and Alicia Fernandez, MD	Dr. Evelyn Whitlock presented data, collected by staff from the portfolio data analysis to identify projects that were coded as having one of the following outcomes: depression, pain, sleep, and fatigue. The search reviewed the project plan in the applications, not the study protocol, and excluded Methods, Pilots, MOUs, PPRN, CDRN projects, and included 285 other research projects (through the Spring 2015 PCS cycle). The process identified 136 research projects that planned to report one or more outcome related to pain, depression or anxiety, sleep issues, or fatigue. Many of these 136 projects included more than one of the outcomes and

	outcome categories. Specifically, this identified 240 mentions of these four outcomes in the 136 projects. Through the 136 cases across the four outcomes—105 in depression or anxiety—60 in pain, 19 in fatigue, and 16 in sleep. Note that some PCORI projects included more than one of these outcomes and are represented multiple times in the 206 total. They were the primary outcome in 82 instances and the secondary outcome in 117 instances. She also presented the conditions and measures that are associated with each outcome in PCORI’s portfolio. While patient-important outcomes are commonly measured in PCORI’s portfolio and across different types of conditions or disease categories, measurement approaches are inconsistent, which limits the synthesis of findings across topics. Dr. Whitlock indicated that the judicious use of core outcome sets could improve the coherence of PCORI’s research portfolio, and even its uptake, if focused on measures applicable to clinical practice.
Public Comment - Sue Sheridan, MIM, MBA	There were no public comments.
Acknowledgment	Dr. Selby announced that it would be the last in-person Board meeting for two Board members, whose service on the PCORI Board of Governors will be completed in September: Steve Lipstein and Harlan Weisman. While these Board members will participate in Board meetings by teleconference, Dr. Selby said he wanted to take advantage of the opportunity of the in-person Board meeting to thank them for their significant service to PCORI, particularly being so instrumental in establishing PCORI in its early years.
Wrap-up and Adjourn Meeting of the Board - Grayson Norquist, MD, MSPH	The meeting adjourned at 5:25 pm

Minutes were approved by the PCORI Board of Governors 06-21-2016