Patient-Centered Outcomes Research Institute Board of Governors Meeting

Almas Shriners Building
1315 K Street, NW
Washington, DC 20005
September 28, 2015

Board Members Present:
Grayson Norquist, MD, MSPH, *Chairperson*; Debra Barksdale, PhD, RN; Kerry Barnett, JD, *Vice Chairperson*; Lawrence Becker; 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; Richard Kronick, PhD; Harlan Krumholz, MD; Richard Kuntz, MD, MSc; Sharon Levine, MD; Freda Lewis-Hall, MD (via phone); Barbara McNeil, MD; Ellen Sigal, PhD; Harlan Weisman, MD (via phone); Robert Zwolak, MD, PhD

Board Member Absent:
Steve Lipstein, MHA

Methodology Committee Members Present:
Robin Newhouse, PhD, RN, *Chair;* Steven Goodman, MD, MHS, PhD, *Vice Chair*

Staff:
Joe Selby, MD, MPH, *Executive Director*; Rachael Fleurence, PhD; Laura Forsythe, PhD, MPH; Lori Frank, PhD; Romana Hasnain-Wynia, PhD; Mary Hennessey, Esq.; David Hickam, MD; Susan Hildebrandt, MA; Kim Jackson, CPA, MBA; Bryan Luce, PhD, MBA; Michele Orza, ScD; Sue Sheridan, MBA, MIM; Jean Slutsky, PA, MSPH; Hal Sox, MD; Regina Yan, MA

AGENDA ITEM	OBJECTIVE
Chairperson's Welcome; call to order *Grayson Norquist, MD, MSPH, Chairperson and Joe Selby, MD, MPH, Executive Director*	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. Dr. Joe Selby reviewed the agenda for today's meeting, and noted that five years ago the PCORI Board was named by GAO. He noted that 18 of the 21 members originally named by GAO are still serving on the PCORI Board of Governors. He congratulated the Board on the work it has done to make PCORI a reality and set it on the road to the successes we have seen and have yet to see.
Approval of the August 18, 2015 Board Meeting Minutes and Nomination of Chair and Vice-Chair of the Methodology Committee *Grayson Norquist, MD, MSPH*	Dr. Norquist introduced the Consent Agenda which included the August 18th Board meeting minutes and the nomination of Robin Newhouse as Chair, and Steve Goodman as Vice-Chair of the Methodology Committee, for a second term. The following motion was made by Robert Zwolak and seconded by Gail Hunt. **Motion:** Approve each of the motions on the Consent Agenda as reflected: -- the August 18, 2015 Board Meeting Minutes; and -- the nominations of Robin Newhouse to serve as Chair and Steve Goodman to serve as Vice-Chair of the Methodology Committee for a second term. *Approved by a majority vote of the Board by a voice vote (no opposed; no abstentions)*
Executive Director's Report and Q3 Dashboard Review *Joe Selby, MD, MPH and Michele Orza, ScD, Senior Advisor to the Executive Director*	Dr. Joe Selby opened by honoring Dr. Bryan Luce as PCORI's first Chief Science Officer (CSO), who is retiring at the end of September. He then introduced the new CSO, Evelyn Whitlock, who will join PCORI in January of 2016 from the Evidence-Based Practice Center at Kaiser Permanente Northwest. He highlighted PCORI's progress after five years, including how our funded study results are increasingly available on the PCORI website. Dr. Selby announced the Hypertension Awards awarded by NIH through collaboration between PCORI's Addressing Disparities program and the NIH (NHLBI, NINDS) with a total allocation of $23.5 million. These two patient-centered comparative effectiveness trials target improved outcomes in hypertension among rural and minority populations. The funded projects are: "Collaboration to Improve Blood Pressure in the US Black Belt –Addressing the Triple Threat" at the University of Alabama led by Dr. Monika Safford and "Comparative Effectiveness of Health System vs. Multi-level Interventions to Reduce Hypertension Disparities" at Johns Hopkins University led by Dr. Lisa Cooper. The board discussed the joint oversight roles of PCORI and the NIH for these awards. Dr. Selby then introduced the highlights and

Q3 Dashboard Review	goals of PCORI's first Annual Meeting, which will be via webcast for public viewing. Dr. Selby presented the Quarter 3 Dashboard for the Board's review. The Q3 Dashboard demonstrated two yellow-flagged items (items that are off target by more than 10%), Funds Committed to Research and Expenditures. Dr. Selby discussed Funds Committed to Research with the Board, and explained that PCORI awards on average less funds than announced, but for Targeted studies, PCORI awards more. The Q3 Dashboard included no red-flagged items. Dr. Selby presented the Q3 examples of progress on all three of PCORI's strategic goals. To highlight progress on Goal 1, Dr. Selby presented the results of three PCORI-funded studies. For Goal 2, Dr. Selby presented dissemination details of the first PCORI-funded Continuing Education program, and altmetrics (alternative publication metrics) demonstrating uptake and use of one PCORI-funded study. To demonstrate progress on Goal 3, Dr. Selby shared the increased support for PCOR at the University of Texas Health Science Center at San Antonio. Dr. Selby reviewed the Measures of Progress of Research Projects, including the new metric in development for progress of projects, categorizing green, yellow, orange or red status for projects. He shared data on recruitment progress of PCORI funded studies. Board members expressed interest in seeing more details about projects with delayed recruitment, and learning more about how long projects are in red zone before pursuing termination.
Consider for Approval: Annual Budget FY 2016 - *Larry Becker, Chair, Finance and Administration Committee and Regina Yan, MA, Chief Operating Officer*	Larry Becker and Regina Yan presented PCORI's Proposed FY2016 Budget. Key items presented included: • PCORI has proposed an operating budget of $423 million for FY2016. Program expense will be at 78%, Program Support at 13% and Administrative Support at 9% of the total budget. • These categories of Program, Program Support and Administrative Support are consistent with best practices used by nonprofits in their financial reporting and on the 990 nonprofit tax form. • The proposed staffing level for FY2015 is 257, an increase of 33 positions, most of which is in the Science department. The additional staff are needed to support new activities such as PCORI's management of the Pragmatic Clinical Studies portfolio, dissemination, peer review and its growing portfolio. • For FY2016, the projected funding commitment is $579 million and is allocated between: 88% Research awards; 7% Infrastructure (PCORnet) awards, and 4% Engagement/ Dissemination awards. These levels may change based on Board of Governors (BOG) further conversations and approval. These levels will not be final until the awards are approved by

	the Board. • PCORI expects to have a cash balance of $737 million at the end of FY2015, all of which is already committed. The cash balance includes funds in the PCOR Trust Fund and in the operating account with PCORI's banking account. • For the period of FY2012 through FY2019, based on the Funding Commitment Plan that totals about $2.5 billion, the allocation is projected to be about 84% Research, 11% Infrastructure (PCORnet), and 5% Engagement/Dissemination. Board members asked clarifying questions about the arch of PCORI's funding as well as PCORI's dissemination work. The following motion was made by Richard Kuntz and seconded by Robert Jesse. **Motion:** Approve the Annual Budget FY 2016. *Approved by a majority vote of the Board by a voice vote (no opposed; no abstentions). Dr. Collins and Dr. Weisman were not present for the vote.*
Consider for Approval: Spring 2015 Broad Awards *Christine Goertz, DC, PhD, Chair, Selection Committee, and Bryan Luce, PhD, MBA, Chief Science Officer*	Dr. Christine Goertz opened the conversation and introduced Dr. Bryan Luce. Dr. Luce summarized the process that led to the recommended slate of awards. Of the 483 Letters of Intent submitted, 227 (47%) were invited to submit a full application. From there, PCORI received 179 responsive applications. Dr. Luce reviewed the titles of the 24 proposed applications on the slate, which totaled a proposed budget of up to $54,041,349. He pointed out a special budgetary set aside for rare disease applications, the diseases/conditions and populations being studied. The Board discussed the slate. The following motion was made by Larry Becker and seconded by Robert Zwolak. **Motion:** Approve funding for the recommended slate of awards from the Spring 2015 Cycle Broad PFAs (see Attachment A for slate of recommended awards). *Approved by majority vote of the Board by a show of hands and roll call for those on the phone: 17 in favor; 0 opposed; no abstentions; 1 recusal (Alicia Fernandez). Dr. Collins and Dr. Weisman were not present for the vote.*
Stakeholder Perspectives: Health Plans *Kerry Barnett, JD, Moderator* *Lewis Sandy, MD* Senior Vice President, Clinical	Kerry Barnett introduced the panel. The panelists shared information on stakeholder vs. researcher generated models of research and thoughts about PCOR, PCORI, and suggestions for improvement. Discussion by the panelists focused on using PCORI's research results

Advancement UnitedHealth Group *Sam Nussbaum, MD* Executive Vice President, Clinical Health Policy Anthem, Inc.	to inform the treatment options that health plans cover. Panel members' comments included that a key priority for health plans is having therapies that actually benefit the patient. Panel members recognized that under PCORI's legislation, PCORI cannot fund research focused on cost, just outcomes. Panel members commented that if there is a superior treatment, health plans will opt for that treatment and the cheaper option is used when the outcomes are uncertain. It was suggested that PCORI create a "sales sheet" explaining who PCORI is, what PCORI does, and why it's important. This will help to showcase the value of PCORI's work.
Consider for Approval: Clinical Management of Hepatitis C Infection Awards *Christine Goertz, DC, PhD and Bryan Luce, PhD, MBA*	Dr. Christine Goertz, Chair of the Selection Committee, introduced the topic and reminded the Board of Governors that this initiative was identified through PCORI's prioritization process and this topic was approved by the Board in December 2014. Dr. Luce gave an overview of the four unique research questions listed in the PFA. Of the 55 Letters of Intent (LOI) submitted, 26 were accepted and 17 applications were discussed at Merit Review. At this time the Selection Committee unanimously recommended funding two applications, using a proposed budget of $29,390,836. Luce walked through the research questions, study design, sample size and population, outcomes, budget, engagement, and potential impact of each proposed study. Several additional applications remain under consideration by staff and the Selection Committee. Future awards may be made under this initiative. The following motion was made by Francis Collins and seconded by Robert Jesse. **Motion:** Approve funding for the recommended slate of awards from the Clinical Management of Hepatitis C Infection Targeted PFA (see Attachment B for slate of recommended awards). *Approved by majority vote of the Board by a show of hands and roll call for those on the phone: 15 in favor; 0 opposed; no abstentions; 4 recused themselves (Debra Barksdale, Alicia Fernandez, Richard Kronick, and Harlan Krumholz). Dr. Lewis-Hall was not present for the vote*
Consider for Approval: Targeted PCORI Funding Announcements (PFAs) Development *Christine Goertz, DC, PhD and Bryan Luce, PhD, MBA* Clinical Strategies for Managing and Reducing Long-Term Opioid Use for Chronic Pain	Dr. Bryan Luce outlined the process that PCORI uses to review and approve questions for targeted PFAs. Dr. Luce highlighted the ten targeted PFA topics that have already been approved for development. He then went through the two proposed targeted PFA topics. Christine Goertz, Chair of the Science Oversight Committee, explained how the SOC and staff had incorporated the Board's comments from the August 18 meeting about the proposed topics, including significant SOC discussion which led to the revised research questions presented. Luce presented the two revised research questions and Dr. Joe Selby indicated the support from the National Institute on Drug Abuse. The

Treatment of Multiple Sclerosis	recommendation included two research questions: comparing the effectiveness of strategies to reduce/eliminate opioid use while managing pain, and to prevent dose escalation, in patients with chronic non-cancer pain, in up to four studies. The following motion was made by Kerry Barnett and seconded by Barbara McNeil. **Motion:** Approve $40M (total costs) for Long-Term Opioid Treatment for Chronic Pain for targeted PFA Development. *Approved by majority vote of the Board by a show of hands and roll call for those on the phone: 19 in favor; 0 opposed; 0 abstentions. (Dr. Francis Collins was not present for this vote).* Dr. Luce introduced Multiple Sclerosis, explaining the three approaches to treatment, major impact of this illness, evidence gaps, and results from the multi-stakeholder workgroup. The recommendation included three research questions on different disease-modifying therapies (DMTs) or therapeutic strategies, non-DMT symptomatic therapies, and conventional direct care vs tele-rehabilitation to fund up to eight studies. The following motion was made by Ellen Sigal and seconded by Robert Jesse. **Motion:** Approve $50M (total costs) for Treatment of Multiple Sclerosis for targeted PFA Development. *Approved by majority vote of the Board by a show of hands: 19 in favor; 0 opposed; 0 abstentions. (Dr. Francis Collins was not present for this vote).*
Methodology Committee Update *Robin Newhouse, PhD, RN*	Dr. Robin Newhouse, Chair of the Methodology Committee, provided an update on recent and ongoing activities of the Methodology Committee and engaged in a discussion of the key issues as they relate to the Board of Governors. The updates included activities related to: (1) Decision Sciences, (2) new Methodology Standards on designs using clusters and complex interventions, (3) Methodology Standards review and revision, and (4) Methodology Standards dissemination activities. Brian Mittman, Steve Goodman, and Sally Morton provide additional supporting information on the activities underway. The Methodology Committee will review all the revised standards at its in-person meeting on October 29th and pending the Committee's approval, will request that the Board of Governors authorize making them available for public comment. The Methodology Committee will present an update to the Board of Governors at the next in-person Board of Governors meeting.

Evaluation Update: Results of Applicant Analyses *Lori Frank, PhD, Program Director, Evaluation & Analysis and Laura Forsythe, PhD, MPH, Associate Director*	Dr. Lori Frank and Dr. Laura Forsythe presented findings to support Board discussion about the PCORI applicant pool. Information was provided from three evaluation efforts: (1) analysis of the characteristics of funded versus unfunded applicants; (2) a landscape review of recently published CER researchers and their connection to PCORI; and (3) findings from a survey of health outcomes and health services researchers on their experience with CER. The information presented has been discussed by the SOC Application Enhancement Workgroup, to identify areas for application and funding enhancement. An analysis of PCORI applicant characteristics found few differences between funded and unfunded applicants with the exception that slightly more PCORI applicants had received prior funding from NIH, AHRQ, and PCORI. Board members noted that PCORI is attracting applications from junior researchers although the majority of applicants are highly experienced. Suggestions for further analyses include conducting a subgroup analysis to look at differences between generalist and specialist clinicians, as well as to further examine resubmission rates. The Board was interested to learn that based on specific literature searches for recently published CER, the majority of authors of that published work had some connection to PCORI, mostly as awardees, applicants, or reviewers. Staff has been contacting those researchers with no connection to PCORI to understand why they have not pursued PCORI funding. Preliminary findings suggest some intend to apply in future cycles, while others described the challenge of switching funders. Some of these researchers indicated that they did not know their work would fit with PCORI's funding requirements. Suggestions were made which would expand a literature search to capture more researchers. Results from the PCORI survey of health services and outcomes researchers were briefly reviewed to address experience and qualifications for CER of a pool of potential applicants. Implications for outreach to potential applicants and for training were discussed by the Board. Together, these findings suggest that PCORI has already attracted experienced researchers, and the pool of potential applicants may be smaller than some initially estimated. . Board members recommended: conducting additional analyses to evaluate connections to former AHRQ grantees who received prior CER funding; a more focused review of researchers within a subset of NIH institutes who have conducted CER; a consideration of ways to strengthen investigator training in collaboration with AHRQ; and new funding mechanisms within PCORI to support young or inexperienced CER researchers. PCORI's Research Transformation Committee is actively considering additional training needs for health systems workers in collaboration with AHRQ. These findings also suggest there may be an additional opportunity for PCORI to leverage the interest of non-clinical researchers to conduct more clinical CER.

PCORnet Phase II - *Rachael Fleurence, PhD and Joe Selby, MD, MPH*	Dr. Rachael Fleurence, Program Director for PCORI's CER Methods and Infrastructure team, presented an overview of plans for Phase II of PCORnet, including a brief overview of new CDRNs and PPRNs, research demonstration projects, and the PCORnet Common Data Model. Governance and operational work was also discussed, including work groups and the work of PwC (under a contract with PCORI) to develop a business plan for PCORnet with the input of PCORnet stakeholders. Members of the Board asked clarifying questions regarding the governance structure moving forward and sustainability.
Public Comment - *Sue Sheridan, MIM, MBA, Director of Patient Engagement*	There were no requests to make a public comment.
Wrap-up and Adjournment *Grayson Norquist, MD, MSPH*	Dr. Norquist thanked all who joined the meeting and reminded attendees that PCORI welcomes any feedback. The meeting adjourned at 5:43 pm.

Approved by the PCORI Board of Governors 11-17-2015

Attachment A - Recommended Slate of Awards from the Spring 2015 Cycle Broad PFAs (approved by the Board of Governors):

Program	Project Title
Addressing Disparities	Addressing Racial Disparities in Implantable Cardioverter Defibrillator Therapy Via Innovative Designs (VIVID)
	Reducing Health Disparities in Unintended Pregnancies Among Hispanic Adolescents Using a Patient-Centered Computer-Based Clinic Intervention
Assessment of Prevention, Diagnosis, and Treatment Options	Comparative Effectiveness of Metabolic and Bariatric Surgery Using Patient-Reported Outcome Measures (PROMs)
	Optimizing the Effectiveness of Routine Post-treatment Surveillance in Prostate Cancer Survivors
	Comparative Effectiveness of Therapy in Rare Diseases: Liver Transplantation vs. Conservative Management of Urea Cycle Disorders
	Posterior Fossa Decompression with or without Duraplasty for Chiari Type I Malformation with Syringomyelia
	Comparative Effectiveness and Safety of Inhaled Corticosteroids and Antimicrobial Compounds for Non-Cystic Fibrosis Bronchiectasis
	Comparing the Effectiveness of Guideline-Concordant Care to Active Surveillance for Ductal Carcinoma in Situ (DCIS): an Observational Study
	Rivaroxaban vs. Low-Molecular Weight Heparin or Coumadin for Treatment of Venous Thromboembolism (VTEs) in Cancer Patients
	Discontinuation of Disease Modifying Therapies (DMTs) in Multiple Sclerosis (MS)
Communication and Dissemination Research	Navigating High-Risk Surgery: Empowering Older Adults to Ask Questions that Inform Decisions about Surgical Treatment
	Enhancing Patient Ability to Understand and Utilize Complex Information Concerning Medication Self-management
	Comparative Effectiveness of Decision Support Strategies for Joint Replacement Surgery

Improving Healthcare Systems	3D Team Care for Cognitively Vulnerable Older Adults
	Acute Community Care to Avoid Unnecessary Emergency Department Visits
	Using a Teachable Moment Communication Process to Improve Outcomes of Quitline Referrals
	Enhancing the Cardiovascular Safety of Hemodialysis Care: A Cluster-randomized, Comparative Effectiveness Trial of Multimodal Provider Education and Patient Activation Interventions
	Enhancing Mental Health Care by Scientifically Matching Patients to Providers' Strengths
Improving Methods for Conducting PCOR	Advancing Patient Centered Outcomes Research in Survival Data with Unmeasured Confounding to Improve Patient Risk Communication
	Causal Inference Guidelines for Pragmatic Clinical Trials
	Concept Mapping as a Scalable Method for Identifying Patient-Important Outcomes
	Patient-Centered Research for Standards of Outcomes in Diagnostic Tests (PROD)
	A Model for Improving Patient Engagement and Data Integration with PCORnet Patient Powered Research Networks and Payer Stakeholders
	Making Better Use of Randomized Trials: Assessing Applicability & Transporting Causal Effects

Attachment B – Recommended Slate of Awards from the Spring 2015 Cycle, Clinical Management of Hepatitis C Infection Targeted PFA (approved by the Board of Governors):

Clinical Management of Hepatitis C Infection	Patient-Centered Models of Hepatitis C Care for People Who Inject Drugs
	THE PRIORITIZE STUDY: A Pragmatic, Randomized Study of Oral Regimens for Hepatitis C: Transforming Decision-Making for Patients, Providers, and Stakeholders