



Patient-Centered Outcomes Research Institute

Board of Governors Meeting via Teleconference / Webinar

Tuesday, September 30, 2014

12:00 p.m. – 1:30 p.m. ET

Board Members Present:

Grayson Norquist, MD, MSPH, *Chair*; Steven Lipstein, MHA, *Vice Chair*; Debra Barksdale, PhD, RN; Lawrence Becker; Francis Collins, MD, PhD; Allen Douma, MD; Leah Hole-Marshall, JD; Gail Hunt; Robert Jesse, MD, PhD; Richard Kronick, PhD; Richard Kuntz, MD, MSc; Harlan Weisman, MD; Robert Zwolak, MD, PhD

Board Members Absent:

Kerry Barnett, JD; Alicia Fernandez, MD; Christine Goertz, DC, PhD; Harlan Krumholz, MD; Sharon Levine, MD; Freda Lewis-Hall, MD; Ellen Sigal, PhD

MINUTES

AGENDA	
AGENDA ITEM	RELATED MINUTES
Call to Order, Roll Call, and Welcome - Grayson Norquist, MD, MSPH, <i>Chair and</i> - Joseph Selby, MD, MPH, <i>Executive Director</i>	Dr. Norquist welcomed all to this meeting of the PCORI Board of Governors. Dr. Selby announced the new Methodology Committee members appointed by the GAO: Cynthia Gorman, DrPH; Sally Morton, PhD (who has served as a statistical methodology expert to the Committee since 2012); and Neil R. Powe, MD, MPH, MBA. GAO continues to search to fill the one remaining vacancy. He noted that NIH has issued a notice of intent to publish a Funding Opportunity Announcement (FOA) for the Hypertension in Racial/Ethnic and Rural Populations Study approved in July by the PCORI Board to do in collaboration with NIH. This FOA will be published in November with applications expected to be due in January 2015. This pre-announcement will be posted to PCORI's web in the near future. Dr. Selby also announced that GAO appointed a new PCORI Board member to fill the vacancy left by Arnold Epstein – Barbara J. McNeil, MD, PhD. Dr. McNeil is a national leader in quality of care and quality assessment with a deep understanding of PCORI. All look forward to meeting her at the December in-person Board meeting. Finally, Dr. Selby reviewed the agenda for today's meeting.
Summary of Proposed Slates of Awards - Bryan Luce, PhD, MS, MBA, <i>Chief Science Officer</i>	Dr. Bryan Luce provided an overview of the processes used to arrive at recommendations for funding the slate of awards relating to the Broad PFA for the Spring 2014 Cycle Awards, along with a summary of the proposed slate related to conditions, populations, and geographic locations. An overview of the allotted budget versus proposed budget and project budget averages was presented per PFA. There was a 50% increase in responsive applications for the

	Spring 2014 cycle. The IHS and Methods programs used a competitive LOI screen this cycle. Over 19% of the slate were resubmissions. For this cycle, program staff recommended funding an average of 9.2% of responsive applications (45/490 applications). Three targeted applications were proposed to the Committee using a total budget of \$34,907,503. Forty-three broad applications were proposed to the Committee using a total budget of \$67,058,573. This includes one project from the Winter 2014 Cycle.
Targeted Awards for Obesity Treatment Options Set in Primary Care for Underserved Populations - <i>Romana Hasnain-Wynia, MS, PhD, Director, Program in Addressing Health Disparities</i>	Dr. Romana Hasnain-Wynia presented the recommended slate for the targeted funding announcement for Obesity Treatment Options In Primary Care for Underserved Populations. The announcement solicited proposals for multi-site pragmatic clinical trials to test the comparative effectiveness of multi-component behavioral therapy interventions set within primary care for achieving weight loss in obese patients who are at risk for experiencing disparities in outcomes. The recommendation is a slate of two projects for funding: The Louisiana Trial to Reduce Obesity in Primary Care and the Midwestern Collaborative for Treating Obesity in Rural Primary Care. The projects total just under \$20M (~\$10M each), the budgeted amount for this targeted PFA. The following motion was made and seconded: That the Board of Governors approve funding for the recommended slate from the Obesity Treatment Options Targeted PFA. <i>Approved by majority vote of the Board by roll call vote: 12 in favor; 0 opposed.</i>
Targeted Award for the Effectiveness of Transitional Care - <i>Steven Clauser, PhD, MPA, Program Director, Improving Healthcare Systems</i>	Dr. Steven Clauser provided an overview of the Effectiveness of Transitional Care targeted PFA and the project recommended for funding, Project ACHIEVE (Achieving Patient-Centered Care and Optimized Health in Care Transitions by Evaluating the Value of Evidence). The presentation was followed by supportive comments and a discussion of the importance of incorporating multiple patient populations and communities (e.g., low socioeconomic status, low health literacy, comorbidities), care settings (e.g., rural vs. urban, hospital vs. community) and contexts (e.g., dual eligible, managed care) in the study. The following motion was made and seconded: That the Board of Governors approve funding for the recommended slate from the Transitional Care Targeted PFA. <i>Approved by majority vote of the Board by roll call vote: 12 in favor; 0 opposed. Sharon Levine had announced her intention to recuse herself ahead of the meeting on this agenda item, but was not present for the vote.</i>
Slate of Awards for Broad Spring 2014 Funding - <i>Bryan Luce, PhD, MS, MBA, Chief Science Officer</i>	Dr. Bryan Luce presented an overview of the five national priority areas and each program. He noted that all projects on the slate presented today are subject to acceptance of PCORI's contract terms and conditions and were recommended for

	funding by the Selection Committee. The CER program proposed 11 projects. Improving Healthcare Systems split their announcement for two sizes of projects - one type for \$1.5 million for three years, and the other type for \$5 million for five years, and proposed five projects total. Addressing Disparities proposed four projects. Communication and Dissemination Research proposed five projects. Improving Methods for Conducting PCOR proposed 10 projects. The Methods PROMIS announcement, developed in partnership with NIH, proposed eight projects. The slate in total included 43 projects, which includes one project from the Winter 2014 Cycle. Attached is a list identifying the titles of all projects on the slate. There was some discussion about why some portfolios were not meeting funding targets. It was explained that the merit review process, designed to PCORI Methods and requirements, eliminated many applications. However, 26.7% of applications recommended for funding were resubmissions. Some of the under-funding can also be attributed to the Large Pragmatic Trials PFA cycles. The following motion was made and seconded: That the Board of Governors approve funding for the recommended slate of awards from the Spring 2014 Cycle Broad PFA. <i>Approved by majority vote of the Board by roll call vote: 12 in favor; 0 opposed.</i>
Update on PCORI/AHRQ Treatment Options for Uterine Fibroids Funding Announcement - Joseph Selby, MD, MPH, Executive Director, and - Richard Kronick, PhD, Board Member and Director, Agency for Healthcare Research and Quality (AHRQ).	Dr. Selby noted that this is one of the original high priority topics approved by the PCORI Board of Governors in early 2013. PCORI committed \$20,000,000 to the initiative. PCORI convened a multi-stakeholder workgroup to refine the important evidence gaps and opportunities for new research. He noted that new research in this area is important; uterine fibroid is a condition that disproportionately affects working age women and African American women. Using the input from this multi-stakeholder process, the decision was reached to establish a registry for uterine fibroids to conduct comparative effectiveness research. PCORI's founding legislation directs PCORI to look for opportunities to collaborate with AHRQ. PCORI contracted with AHRQ in 2013 to undertake making the funding announcement and award, and manage the funded project. Dr. Kronick announced that Duke University (PI: Evan Myers) has been awarded the 5-year grant. Project Title: Comparing Options for Management: Patient-Centered Results for Uterine Fibroids (COMPARE-UF). This project will establish a prospective registry. The project also includes a research and data coordinating center at Duke Clinical Research Institute and 9 clinical centers across the country. It is expected that comparative effectiveness research based on the registry will be conducted to look at management options and outcomes important to patients with substantial stakeholder involvement. Further information will be available on both AHRQ and PCORI's websites.
Wrap up and Adjournment - Grayson Norquist, MD, MSPH, Chair	The meeting adjourned at 1:30 pm.

Approved by the PCORI Board of Governors 11-18-2014

PCORI Spring 2014 Cycle Broad Slate Project Titles*

**Approved for funding by PCORI Board of Governors September 30, 2014*

1. Stopping Anti-Tumor Necrosis Factor Agents in Rheumatoid Arthritis (STARA) Clinical Trial
2. Patient-Centered CER of Home-Based Interventions to Prevent CA-MRSA Infection Recurrence
3. Optimization of Home Oxygen Weaning in Premature Infants
4. Comparing Mobile Health (mHealth) and Clinic-Based Self-Management Interventions for Serious Mental Illness: Patient Engagement, Satisfaction, and Outcomes
5. CHoosing Options for Insomnia in Cancer Effectively (CHOICE): A Comparative Effectiveness Trial of Acupuncture and Cognitive Behavioral Therapy
6. Preventive sexual health screening among female-to-male (FTM) transgender adult patients
7. Randomized Comparison of Evidence-Based Protocols for Adolescents with ADHD in Specialty Care: Behavioral Only versus Integrated Behavioral and Medication Interventions
8. Comparative Effectiveness of Rehabilitation Interventions for Traumatic Brain Injury
9. Comparative Efficacy of Therapies for Eosinophilic Esophagitis
10. Anterior versus posterior entry site for cerebrospinal fluid shunt insertion
11. North Carolina Prostate Cancer Comparative Effectiveness & Survivorship Study (NC ProCESS):Stakeholder-Driven, Population-Based Prospective Cohort Study
12. Patient-centered physical activity coaching to improve outcomes in COPD: A pragmatic trial
13. Peer support after NICU discharge: Can parent navigation improve parental mental health and infant outcomes?
14. Delivering patient-centered adolescent preventive care with training and technology
15. Improving specialty care delivery in chronic skin care
16. Comparing patient-centered outcomes in the management of pain between emergency departments and dedicated acute care facilities for adults with sickle cell disease
17. Active and Healthy Brotherhood: a program for chronic disease self-management for Black men
18. A Comparative Trial of Improving Care for Underserved Asian Americans Infected with Hepatitis B (HBV)

19. Acupuncture Approaches to Decrease Disparities in Outcomes of Pain Treatment -A Two Arm Comparative Effectiveness Trial (AADDOPT-2)
20. Programa Esperanza (Project Hope)
21. Describing the comparative effectiveness of colorectal cancer screening tests: The impact of quantitative information
22. Aligning the visit priorities of complex patients and their primary care providers
23. Using question prompt lists during asthmatic visits to increase adolescent involvement
24. The comparative effectiveness of patient-and provider-directed strategies for increasing shared decision making in reproductive health care
25. Improving communication between cancer patients and oncologists using patient feedback on actual conversations and the ABIM maintenance of certification
26. Causal analyses of electronic health record data for assessing the comparative effectiveness of treatment regimens
27. Engaging Stakeholders in Building Patient-centered, N-of-1 Randomized and Other Controlled Trial Methods
28. Methods for Heterogeneity of Treatment Effects: Random Forest Counterfactual Machines
29. Technology-Assisted Qualitative Research: How Does Modality Affect Outcome?
30. Privacy-preserving analytic and data-sharing methods for clinical and patient-powered data networks
31. Better Rehabilitation Through Better Characterization of Treatments: Development of the Manual for Rehabilitation Treatment Specification
32. Patient-Centered Approaches to Research Enrollment Decisions in Acute Cardiovascular Disease
33. Estimation of multi-treatment effects from observational data with application to diabetes mellitus
34. Propensity Score-Based Methods for CER Using Multilevel Data: What Works Best When
35. Development of a Patient-Directed Queries Network to engage Patients and Prioritize their Questions to inform the PCORI Research Agenda
36. Making PROMIS Meaningful to Patients and Providers in Clinical Practice
37. Expanding PROMIS Item Bank Development to the Pregnant Population
38. Expanding PRO assessment integrated into routine clinical care of patients with HIV to new PROMIS domains

- 39. Extending PROMIS Pain Item Banks: Pain Self-efficacy and Pain Catastrophizing
- 40. Feasibility of Implementing Patient-Reported Outcome Measures
- 41. Measuring the Context of Healing: Using PROMIS in Chronic Pain Treatment
- 42. Development of the PROMIS Pediatric Sleep Health Item Banks
- 43. Incorporating PROMIS Symptom Measures into Primary Care Practice