



[PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE](http://www.pcori.org)

Board of Governors Meeting via Teleconference / Webinar

Tuesday, April 21, 2015

12:00 pm – 2:00 pm ET

Board Members Present:

Debra Barksdale, PhD, RN; Lawrence Becker; Francis Collins, MD, PhD; Allen Douma, MD; Alicia Fernandez, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Gail Hunt; Robert Jesse, MD, PhD; Richard Kronick, PhD; Richard Kuntz, MD, MSc; Steve Lipstein, MHA; Barbara McNeil, MD, PhD; Harlan Weisman, MD; Robert Zwolak, MD, PhD

Board Members Absent:

Kerry Barnett, JD, *Vice Chairperson*; Harlan Krumholz, MD; Sharon Levine, MD; Freda Lewis-Hall, MD; Grayson Norquist, MD, MSPH, *Chairperson*; Ellen Sigal, PhD

MINUTES

Agenda Item	Related Minutes
Call to Order, Roll Call, and Welcome - <i>Steven Lipstein, MHA, Acting Chairperson, and</i> - <i>Joe Selby, MD, MPH, Executive Director</i>	Given the absence of Chairperson Dr. Grayson Norquist and Vice Chairperson Kerry Barnett, Steven Lipstein chaired the meeting and welcomed all to the meeting of the PCORI Board of Governors. Dr. Selby reviewed the agenda for today's meeting.
Consent Agenda: That the Board of Governors: - Approve minutes from the March 24, 2015 Board meeting - Approve to sunset select Governance-related policies	Steve Lipstein introduced the Consent Agenda which included approval of the March 24 meeting minutes and a proposal to sunset three Governance-related PCORI policies which had been deemed to be either outdated or duplicative of language in our bylaws or other governing documents. The Governance Committee recommended the policies on Appointment of the Board, Bylaws, and Committees of the Board be sunset. Mr. Lipstein gave the opportunity to Board members to separately discuss any of the matters on the Consent Agenda. No separate discussion was requested. The following motion was made and seconded: Motion: That the Board of Governors approve the proposed Consent Agenda Items as reflected below: – Approve minutes from the March 24, 2015 Board meeting – Approve sunset of the following select Governance-related policies: - o Policy on Appointment of Board - o Policy on Bylaws - o Policy on Committees of the Board <i>Approved by a majority vote of the Board by voice vote</i>

Consider for Approval: Slate of Fall 2014 Broad PFA Awards - <i>Christine Goertz, DC, PhD, Chair, Science Oversight Committee and Selection Committee, and</i> - <i>Bryan Luce, PhD, MBA, Chief Science Officer</i>	Dr. Christine Goertz thanked investigators for their submission and interest, and Board members and staff for their participation. Dr. Bryan Luce provided an overview of the processes used to arrive at recommendations for funding the Fall 2014 Broad PFA slate of awards, along with a summary of the proposed slate, and how each application aligned with PCORI, IOM, and/or AHRQ priority topics. Of the 833 Letters of Intent submitted, 290 (34.8%) were invited to submit a full application. From there, 114 applications were reviewed (39.3% of the invited). Dr. Luce reviewed each of the 29 (25.4% of 114) proposed from the Fall 2014 Cycle (<i>See Appendix A for titles</i>) using a proposed total budget of \$62,147,094. The following motion was made and seconded: Motion: Approve funding for the recommended slate of awards from the Fall 2014 Broad PFA Studies. <i>Approved by majority vote of the Board by roll call vote: 15 in favor; 0 opposed.</i>
Consider for Approval: Slate of Fall 2014 Pragmatic Studies Awards - <i>Christine Goertz, DC, PhD and</i> - <i>Bryan Luce, PhD, MBA</i>	Christine Goertz thanked investigators for their submission and interest, and Board members and staff for their participation. Bryan Luce provided an overview of the processes used to arrive at recommendations for funding the Fall 2014 Pragmatic Clinical Studies slate of awards, along with a summary of the proposed slate, and how each application aligned with PCORI, IOM, and/or AHRQ priority topics. Of the 169 Letters of Intent submitted, 21 (12.4%) were invited to submit a full application. From there, 16 applications were reviewed (76% of the invited). Luce reviewed each of the four (25% of 16) proposed applications and 1 application from the Fall 2014 Cycle using a proposed total budget of \$58,475,220. The five applications which were approved are titled as follows: 1. Anti-tumor necrosis factor (TNF) Monotherapy versus Combination Therapy with Low Dose Methotrexate in Pediatric Crohn's Disease 2. MOBILITY: Improving Patient-Centered Outcomes Among Overweight and Obese Youth with Bipolar Spectrum Disorders Treated with Second-Generation Antipsychotics

	3. A Practical Intervention to Improve Patient-Centered Outcomes After Hip Fractures Among Older Adults (Regain Trial) 4. Integrating Patient-Centered Exercise Coaching into Primary Care to Reduce Fragility Fracture 5. Pragmatic Randomized Trial of Proton vs. Photon Therapy for Patients with Stage II or III Breast Cancer The following motion was made and seconded: Motion: Approve funding for the recommended slate of awards from the Fall 2014 Pragmatic Studies PFA. <i>Approved by majority vote of the Board by roll call vote: 13 in favor; 0 opposed; 2 recused themselves (Ms. Barksdale and Mr. Lipstein); Dr. Norquist had announced his intention to recuse himself ahead of the meeting but was not present for the meeting or vote.</i>
Consider for Approval: Proposed Amendments to PCORI Bylaws and Charter Revisions for Select PCORI Committees and Advisory Panels - Mary Hennessey, Esq., General Counsel	Mary Hennessey presented to the Board revised versions of various governing documents for PCORI, its Committees and its Advisory Panels. Bylaw revisions reflected a shift in responsibilities for some Committees approved by the Board in February as well as streamlined and updated language. Additionally, PCORI Committees completed their annual review of their charters as well reviewing the charters of the Advisory Panels for accuracy, consistency and updated language. The following motion was made and seconded: Motion: That the Board of Governors approve the proposed amendments to the PCORI Bylaws. <i>Approved by the Board by roll call vote: 14 in favor, 0 opposed (Dr. Robert Zwolak, MD, PhD did not participate in the vote).</i> The following motion was made and seconded: Motion: That the Board of Governors approve each of the proposed revised charters for the • Governance Committee • Methodology Committee • Research Transformation Committee • Advisory Panel on Clinical Trials • Advisory Panel on Rare Disease, and • Advisory Panel on Communication, Dissemination and Research

	<i>Approved by a majority vote of the Board by voice vote</i>
Consider for Approval: Appointment of Advisory Panelists - Jean Slutsky, PA, MSPH, Chief Engagement and Dissemination Officer, and - Bryan Luce, PhD, MBA	Jean Slutsky presented the proposed slate of new panelists for the Communication and Dissemination Research (CDR) Advisory Panel and the Patient Engagement Advisory Panel (PEAP). The slate for the Inaugural CDR Advisory Panel consists of 21 proposed members and 3 alternates. The PEAP has 7 proposed new members and 2 alternates. Dr. Bryan Luce presented the slate of new panelists for the five Advisory Panels on: Assessment of Prevention, Diagnosis & Treatment Options (4 new members and 4 alternates); Improving Healthcare Systems (6 new members, 5 alternates and 1 new co-chair, Michael Dueñas); Addressing Disparities (6 new members, 4 alternates); Clinical Trials (10 reappointed members); and Rare Disease (13 reappointed members, 2 new members and 1 alternate). Staggered 1, 2, and 3 year terms were assigned to each newly appointed member. PCORI welcomes all appointed members and alternates to its Advisory Panels (<i>See Addendum B for list of appointees and terms.</i>) Dr. Selby thanked all those panelists whose terms had ended for their stellar work and dedication to PCORI's mission. The following motion was made and seconded: Motion: Approve the appointment of the proposed panelists <i>Approved by a majority vote of the Board by voice vote</i> PCORI welcomes all appointed members and alternates to its Advisory Panels (<i>See Addendum B for list of appointees.</i>) Dr. Selby thanked all those panelists whose terms had ended for their stellar work and dedication to PCORI's mission. The following motion was made and seconded: Motion: Approve the appointment of the proposed panelists <i>Approved by a majority vote of the Board by voice vote</i>



Consider for Approval: Appointment of Secretary and Treasurer - <i>Allen Douma, MD, Member, Governance Committee, and</i> - <i>Mary Hennessey, Esq.</i>	Allen Douma reminded members that, in accordance with PCORI's Bylaws, the Governance Committee is responsible for recommending to the Board the appointment of a Treasurer and Secretary. The Governance Committee discussed various options, including appointment of select Board members for these positions, and recommended that the Board appoint the Chief Operating Officer to serve ex officio as the Treasurer and the General Counsel to serve ex officio as Secretary. Mary Hennessey outlined for the Board legal and governance issues, including the requirement of DC nonprofit law for nonprofits to designate a Treasurer and a Secretary. She explained that in PCORI's early years, the Board appointed the Board Chairperson to serve ex officio as Treasurer and the Board Vice Chairperson to serve ex officio as Secretary. Given the evolution of PCORI, the Governance Committee considered various options and made its recommendation. The following motion was made and seconded: Motion: That the Board of Governors approve the appointment of the Chief Operating Officer as the PCORI Treasurer, ex officio, and the General Counsel as the Secretary, ex officio. <i>Approved by a majority vote of the Board by voice vote</i>
Wrap up and Adjournment - <i>Steven Lipstein</i>	The meeting adjourned at 1:46 pm

Approved by the PCORI Board of Governors 05-04-2015

Appendix A

(Accompanying Minutes for the PCORI Board of Governors Meeting, April 21, 2015)

Fall 2014 Broad Cycle Award Slate* (29 Projects)

Addressing Disparities (4 Projects):

- **Pain Coping Skills Training for African Americans with Osteoarthritis**
- **Comparative Effectiveness of a Low-Cost Virtual Reality Gaming Platform for Neuro-Rehabilitation of Hemiparesis**
- **Get With The Guidelines® (GWTG) Interventions to Reduce Disparities in Acute Heart Failure (AHF) Patients Discharged from the Emergency Department (ED) (GUIDED HF)**
- **Clinician Language Concordance and Interpreter Use: Impact of a Systems Intervention on Communication and Clinical Outcomes**

Assessment of Prevention, Diagnosis, and Treatment Options (9 Projects):

- **Treatment Alternatives in Adult Rare Disease; Assessment of Options in Idiopathic Subglottic Stenosis**
- **The Patient-Reported Outcomes Project of Hepatitis C (HCV-TARGET (PROP up TARGET)**
- **Intervention and Outcomes in Duarte Galactosemia**
- **Home or Away from Home: Comparing Clinician and Patient/Family-Centered Outcomes Relevant to the Care of Pediatric Acute Myeloid Leukemia during Periods of Neutropenia**
- **Comparative Effectiveness of CARRA Treatment Strategies for Polyarticular Juvenile Idiopathic Arthritis**
- **Comparative Effectiveness Trial to Reduce Child Maltreatment, Improve Client Outcomes and Examine Client Burden**
- **Cancer of the Uterus and Treatment of Stress Urinary Incontinence**
- **Improving Outcomes of Opioid Addicted Prisoners With Extended Release Injectable Naltrexone Before Reentry**
- **Patient Reported Outcomes for Bladder Management Strategies in Spinal Cord Injury**

Communication and Dissemination Research (2 Projects):

- **Cardiopulmonary Resuscitation (CPR) Education for Families of Cardiac Patients before Hospital Discharge: Comparing Methods for Real-World Dissemination**
- **Communication to Improve Shared Decision Making in Attention Deficit/Hyperactivity Disorder (ADHD)**

Improving Healthcare Systems (6 Projects):

- **Putting Patients at the Center of Kidney Care Transitions**
- **Impact of High Deductible Health Plans on Patients with Bipolar Disorder**
- **Comparative Effectiveness of State Psychotropic Oversight Systems for Children in Foster Care**
- **Integrating Online Weight Management with Primary Care Support: Patient-Centered Strategies for Addressing Overweight and Obesity in Primary Care**
- **Simplifying Survivorship Care Planning: Comparing the Efficacy and Patient Centeredness of Three Care Delivery Models**
- **Does Outpatient Palliative Care Improve Patient-Centered Outcomes in Parkinson's Disease?**

Improving Methods for Conducting PCOR (8 Projects):

- **Patient Centered Adaptive Treatment Strategies (PCATS) using Bayesian Causal Inference**
- **Matching Complex Patients to Treatments: Innovative Statistical Scoring Methods for Treatment Selection**
- Bayesian Hierarchical Models for the Design and Analysis of Studies to Individualize Healthcare
- **Developing Bayesian Methods for Noninferiority Trial in Comparative Effectiveness Research**
- **Visual Displays of Qualitative Data to Advance PCOR**
- Research Ethics in Patient-Centered Outcomes Research
- Mapping and Resourcing Patient and Stakeholder Engagement Along 10-step PCOR Continuum Framework
- Measuring and Talking to Patients about the Accuracy of Data Used in PCOR

*Subject to the acceptance of PCORI's contract terms and conditions.

Resubmission in bold

Addendum B

New and Reappointed Advisory Panel Members April 2015 (Terms in years)

- **Advisory Panel on Assessment of Prevention, Diagnosis, and Treatment Options:** Leslie Levine (3), Robert Bonomo (3), Jonathan Klein (3), Michael Herndon (3)
- **Advisory Panel on Improving Healthcare Systems:** Carolyn Peterson (3), Lisa Freeman (3), Ravi Govila (3), Jim Bellows(3), Bonnie Clipper (3), Timothy Daaleman(3); New Chair: Doris Lotz (2013-2016); New Co-Chair: Michael Dueñas (2014-2017)
- **Advisory Panel on Addressing Disparities:** Cheryl Pegus (3), Danielle Pere (3), Sinsi Hernandez-Cancio (3), Barbara Kornblau (3), Elinor Schoenfeld (3), Kenneth Mayer (3), Ronald Copeland (3)
- **Advisory Panel on Patient Engagement:** Anjum Khurshid (3), Jane Perlmutter (3), Philip Posner (3), Veronica Todara (3), Jimmy Lin (3), Bennett Levitan (3), Mark Mishra (3)
- **Advisory Panel on Communication and Dissemination Research:** Robert Volk (3), Sandi Smith (2), Lauren McCormack (3), Nancy Perrin (1), Michael Pignone (3), Neela Goswami (2), Ashish Atreja (1), LaRita Jacobs (3), Ruth Parker (2), Frank Rider (1), Helen Osborne (2), Kristin Vorhees (1), Janice Buelow (3), Andy Rosenberg (2), Janice Radak (1), Danny van Leeuwen (1), Clifford Ko (3), Nancy Blake (2), Alan Whippy (1), Giovanna Devercelli (3), and Cornell Wright (2)
- **Advisory Panel on Clinical Trials:** Sanford Jeames (1), Margo Micheals (2), Jason Connor (3), Elizabeth Stuart (chair) (3), Anne McTiernan (1), Craig Nichols (1), Frank Rockhold (2), Robert Temple (1), Merrick Zwarenstein (3), John Lantos (co-chair) (2)
- **Advisory Panel on Rare Disease:** Jacqueline Alikhaani (1), Vincent Del Gaizo (co-chair) (3), Kate Lorig (2), Marc Skinner (2), Russell Teegarden (1), Marilyn Bull (2), Mardi Gomberg-Maitland (1), Marshall Summar (chair) (3), Sindy Escobar Alvarez (2), Yaffa Rubenstein (3), Philip Ruff (1), James Wu (3), Uday Deshmukh (2), Patricia Furlong (3), Lisa Heral (3)