PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting via Teleconference / Webinar

Tuesday, August 21, 2018

12:00 pm – 1:30 pm ET

Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Kerry Barnett, JD, *Vice Chairperson;* Larry Becker; Francis Collins, MD, PhD; Allen Douma, MD; Alicia Fernandez, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Russell Howerton, MD; Gail Hunt; Francis D. Chesley, Jr., MD (*designee for Gopal Khanna); S*haron Levine, MD; Barbara McNeil, MD, PhD; Kathleen Troeger, MPH; Robert Zwolak, MD, PhD

Board Members Absent:

Debra Barksdale, PhD, RN; Harlan Krumholz, MD, SM; Richard Kuntz, MD, MSc; Freda Lewis-Hall, MD; Ellen Sigal, PhD

MINUTES

Agenda Item	PCORI Speakers
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. Selby then reviewed the meeting agenda.
Consider for Approval: Minutes of the July 24, 2018 Board Meeting - *Grayson Norquist, MD, MSPH*	*The following motion was made by Russell Howerton and seconded by Kerry Barnett:* **Motion:** Approve the Minutes of the July 24, 2018 Board Meeting. *Approved by a majority vote of the Board by voice vote (no opposed, no abstentions)*
Consider for Approval: Proposed Advisory Panel Members • Rare Disease • Clinical Trials • Clinical Effectiveness and Decision Science • Healthcare Delivery and Disparities Research • Patient Engagement - *Sharon Levine, MD, Incoming Chair, Engagement, Dissemination and Implementation Committee,* - *Jean Slutsky, PA, MSPH, Chief Engagement & Dissemination Officer,* - *Robert Zwolak, MD, Chair, Science Oversight Committee,*	Dr. Levine introduced the annual process of appointing new members to PCORI's Advisory Panels, thanking the panelists whose terms had ended for their service, and thanking all those who applied to serve on a PCORI Advisory Panel. Dr. Levine, as chair of the Engagement, Dissemination and Implementation Committee (EDIC), indicated EDIC's support for the proposed new panelists to the Patient Engagement Advisory Panel (PEAP), its new chair, David White, and co-chair, Thomas Scheid, and the proposed 1-year term extensions for several existing panelists to ensure balance in the staggered terms of Advisory Panel members. Ms. Slutsky then reviewed the timeline and application and review process that takes place to fill the vacancies. Following Ms. Slutsky's presentation, Dr. Zwolak noted the Science Oversight Committee's support for the proposed members of the Advisory Panels on Rare Disease (RDAP); Healthcare Delivery and Disparities Research (HDDR); and Clinical Effectiveness and Decision

- *Diane Bild, MD, MPH, Acting Chief Science Officer*	Science (CEDS). He also noted the Methodology Committee's support for the proposed members of the Advisory Panel on Clinical Trials (CTAP). Dr. Bild then presented the slates of proposed panelists for the Advisory Panels on Rare Disease (RDAP), Healthcare Delivery and Disparities Research (HDDR), Clinical Effectiveness and Decision Science (CEDS) and the Advisory Panel on Clinical Trials (CTAP). Staff going forward will present additional information that showcases the diversity of stakeholders selected to serve on the Advisory Panels. *(Proposed and approved panelists, positions and terms are listed in Attachment A.)* *The following motion was made by Robert Zwolak and seconded by Barbara McNeil:* **Motion:** Approve the proposed slates of members, positions, and terms for the following Advisory Panels: PEAP, RDAP, CTAP, CEDS, and HDDR**.** *Approved by a majority vote of the voting Board members by voice vote (0 opposed; 0 abstentions)*
Consider for Approval: Proposed Slates - Cycle 2 2017 Strategies to Prevent Unsafe Opioid Prescribing in Primary Care Among Patients with Acute or Chronic Noncancer Pain - *Christine Goertz, DC, PhD, Chair, Selection Committee, and Diane Bild, MD, MPH*	Dr. Goertz thanked all applicants and awardees, and then introduced Dr. Bild who introduced the proposed slate for the Cycle 2, 2017 Targeted PFA. The goal of this PCORI Funding Announcement (PFA) is to fund studies that compare two or more alternatives to prevent unsafe opioid prescribing in primary care among patients with acute or chronic non-cancer pain, while ensuring adequate or improved pain management. This was a reissued PFA from Cycle 2, 2017. Of the 20 Letters of Intent submitted to this reissued PFA, 11 (55%) were invited to submit a full application. Of these, 9 applications were submitted. The Selection Committee recommended that the Board approve funding this project for a proposed total commitment of $5M of the posted $20M. The slate consisted of the following research project: • Comparative Effectiveness of Two State Payer Strategies to Prevent Unsafe Opioid Prescribing This research project is a prospective cohort study including >10,000 patients comparing two state workers' compensation programs that use different approaches to prior authorization for opioid prescriptions. The total project cost is $5M. This project adds to a portfolio of 15 existing projects that address opioid use and addiction totaling $84M. *The following motion was made by Barbara McNeil and seconded by Larry Becker:*

	Motion: Approve funding for the recommended award from the Cycle 2 2017 Strategies to Prevent Unsafe Opioid Prescribing in Primary Care among Patients with Acute or Chronic Noncancer Pain PFA *Approved by a majority vote of the voting Board members by roll call vote (12 in favor; 0 opposed; 0 abstentions; 1 recusal: Leah Hole-Marshall). Francis Collins and Alicia Fernandez were not present for this vote.*
Consider for Approval: Cycle 3 2017 Pragmatic Clinical Studies Award Slate - *Christine Goertz, DC, PhD, Chair, Selection Committee, and Diane Bild, MD, MPH*	Dr. Bild continued her presentation by introducing the proposed slate of awards for the Cycle 3, 2017 Pragmatic Clinical Studies PFA. The goal of this PFA is to fund pragmatic clinical trials, large simple trials, or large-scale observational studies that compare two or more alternatives for addressing prevention, diagnosis, treatment, or management of a disease or symptom; improving healthcare system-level approaches to managing care; or for eliminating health or healthcare disparities. Of the 65 Letters of Intent submitted, 26 (40%) were invited to submit a full application. Of these, 21 applications were submitted. On July 16, 2018, the Selection Committee recommended to fund a slate of three applications for a proposed total commitment of $37.6M out of the posted $41M. The slate consisted of the following three research projects: • Comparative Effectiveness Randomized Trial to Improve Stroke Care Delivery: C3FIT: Coordinated, Collaborative, Comprehensive, Family-Based, Integrated, and Technology-Enabled Care • CISTO: Comparison of Intravesical Therapy and Surgery as Treatment Options for Bladder Cancer • Remote Cognitive Behavior Therapy for Major Depression (RTD) in Primary Care The first research project is a cluster randomized controlled trial that compares a neurologist-based comprehensive/primary stroke center care program and an integrated team-based stroke practice unit program in improving functional outcomes for stroke victims with a sample size of 1,800 patients diagnosed with stroke. The total project cost is $15.7M. The second research project is a prospective observational cohort study that compares the effectiveness of intravesical versus surgical therapy for patients with non-muscle-invasive bladder cancer (NMIBC) that recurs after initial non-surgical treatment using a sample size of 900 patients (300 cystectomy and 600 intravesical therapy). The total project cost is $8.5M. The third research project is a cluster randomized controlled trial that compares usual care with guided and unguided electronic cognitive

	behavioral therapy for patients with major depressive disorder, utilizing a sample size of 8,000 patients. The total project cost is $13.3M. *The following motion was made by Kerry Barnett and seconded by Sharon Levine:* **Motion:** Approve funding for the recommended slate of awards from the Cycle 3 2017 Pragmatic Clinical Studies PFA. *Approved by a majority vote of the voting Board members by roll call vote (12 in favor; 0 opposed; 0 abstentions; 2 recusals: Barbara McNeil, Grayson Norquist). Francis Collins was not present for this vote.*
Consider for Approval: Cycle 3 2017 Broad PFAs Award Slate - *Christine Goertz, DC, PhD, Chair, Selection Committee, and Diane Bild, MD, MPH*	Dr. Bild began the presentation of the proposed slate for the Cycle 3, 2017 Broad PFA awards by providing an overview of the process and budget for the Cycle 3, 2017 Broad PFAs. Of the 208 Letters of Intent submitted, 92 (44%) were invited to submit a full application. Of these, 65 applications were submitted. On July 16, 2018, the Selection Committee recommended to fund a slate of twelve applications for a proposed total commitment of $43.2M out of the posted $76M. The Broad slate consists of 12 research projects from different priority areas (*See Attachment B*): Addressing Disparities (2 recommended projects); Assessment of Prevention, Diagnosis, and Treatment Options (2 recommended projects); Communication and Dissemination Research (1 recommended project); Improving Healthcare Systems (4 recommended projects); and Improving Methods for Conducting PCOR (3 recommended projects). The proposed total award for this slate is $43.2 million. *(See Attachment B for the list of Cycle 3, 2016 Broad PFA projects funded.)* *The following motion was made by Sharon Levine and seconded by Larry Becker:* **Motion:** Approve funding for the recommended slate of awards from the Cycle 3 2017 Broad PFAs. *Approved by a majority vote of the voting Board members by roll call vote (12 in favor; 0 opposed; 0 abstentions; 2 recusals: Alicia Fernandez, Barbara McNeil); Francis Collins was not present for this vote.*
Consider for Approval: Planning for Implementation of the FY18 Funding Commitment Plan for PCORnet Network Support - *Joe Selby, MD, MPH*	Dr. Selby introduced the request to commit an additional $16 million from the FY2018 funding commitment plan to the People-Centered Research Foundation (PCRF) to largely provide ongoing funding support for nine PCORnet Clinical Data Research Networks (CDRNs). The PCORI Board previously approved funding of $25.4 million in FY2017 for PCRF

	to support the sustainability of PCORnet. Dr. Selby informed the Board that this requested additional $16 million would be for a two-year period to fund activities such as maintaining and improving data quality, CDRN participation in PCORnet business development, CDRN participation in network governance, patient and stakeholder engagement activities, and data linkage for complete data. Dr. Selby explained that the infrastructure funds would be awarded to PCRF to provide network support for nine CDRNs that were selected by PCRF based on a competitive merit review conducted by PCRF. There was a question regarding whether the anticipated funding of maintaining CDRN data quality under this funding award to PCRF implies concern about CDRN data quality and its implications for the ADAPTABLE demonstration project. Dr. Selby explained that the CDRN networks will continue to refresh their data, send data extracts to the Coordinating Center for quality checks, and create new variables for Common Data Model expansion, which are the types of activities that will be funded under a funding award to PCRF. He also explained that the ADAPTABLE study has a careful data quality process and that there will be an update on ADAPTABLE during a future meeting to discuss the study's progress using electronic health records for recruitment and end point measurement. The Board discussed whether they should consider postponing this vote until they could review more detailed information related to PCRF and PCORnet. There was discussion about whether it would be problematic to delay this vote as PCRF cannot complete negotiations with the CDRN networks without this award. Dr. Selby noted there will be additional discussion regarding PCRF and PCORnet and funding during upcoming September 2018 Board of Governors meetings. *The following motion was made by Barbara McNeil and seconded by Christine Goertz:* **Motion:** Approve up to $16 million to support PCORnet network partner sustainability and network expansion over the next two years, subject to negotiation of final terms and conditions. *Approved by a majority vote of the voting Board members by voice vote (14 in favor; 0 opposed; 0 abstentions and 0 recusals). Russell Howerton was not present for this vote.*
Wrap up and Adjournment - *Grayson Norquist, MD, MSPH*	Meeting ended at 1:21 pm

Minutes were approved by the PCORI Board of Governors 09-07-2018

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Attachments for Minutes of the PCORI Board of Governors Meeting, August 21, 2018

ATTACHMENT A: Advisory Panel Appointees (August 2018)

New and Reappointed Advisory Panel Members, Alternates and Chairs, August 2018 (Term in Years)

- **Advisory Panel on Patient Engagement:** Jennifer Canvasser (3), Gwen Darien (3), Marilyn Geller (3), Jill Harrison (3), Anita Roach (3), Sandy Sufian (3), James Harrison (3), Matthew Hudson (3), Maureen Fagan (3), Sarah Donelson (3), Umair Shaw (3), Emily Creek (1), Ting Pun (1), Jack Westfall (1), Megan Lewis (1), David White (1); New Chair: David White (2018-2019), New Co-Chair: Thomas Scheid (2018-2020).

- **Advisory Panel on Rare Disease:** Roxanna Bendixen (3), Scott Berns (3), Sherene Shalhub (3), Kathleen Babich (3), Vanessa Boulanger (3), Julie Gortze (3), Tilicia Mayo-Gamble (3).

- **Advisory Panel on Clinical Trials:** Catherine Crespi (3), Nancy Dreyer (3), Elisa A. Hurley (3), Henry Sacks (3), Jane Perlmutter (3).

- **Advisory Panel on Clinical Effectiveness and Decision Science:** Evelyn White (3), Kate Houghton (3).

- **Advisory Panel on Healthcare Delivery and Disparities Research:** Carmen Pace (3), Kathy Phipps (3), Barbara Warren (3).

ATTACHMENT B: Slate Approved of Cycle 3, 2017 Broad PFA Awards

Program	Awarded Project
Addressing Disparities	Patient and Caregiver-Centered Diabetes Telemanagement Program for Hispanic/Latino Patients
	Effectiveness of Universal vs. Targeted School Screening for Adolescent Major Depressive Disorder
Assessment of Prevention, Diagnosis, and Treatment Options	Comparative Effectiveness of Metformin for Type 2 Diabetes with Chronic Kidney Disease
	Transseptal versus Retrograde Aortic Approach to Left Ventricular Catheter Ablation
Communication and Dissemination Research	A Randomized Trial to Promote Informed Decisions about Cancer Screening in Older Adults
Improving Healthcare Systems	Preventing Tipping Points in High Comorbidity Patients: A Lifeline from Health Coaches
	Specialty Medical Homes to Improve Outcomes for Patients with Inflammatory Bowel Disease (IBD) and Behavioral Health Conditions
	Primary Care and Community-Based Prevention of Mental Disorders in Adolescents
	System-Level Capture of Family History Data to Assess Risk of Cancer and Provide Longitudinal Care Coordination
Improving Methods for Conducting PCOR	Bayesian Additive Regression Trees for Causal Inference with Multiple Treatments and a Binary Outcome
	Enhancing Hybrid Study Designs for Comparative Effectiveness Research
	Improving CER/PCOR Methods for Analyzing Linked Data Sources in the Absence of Unique Identifiers