Patient-Centered Outcomes Research Institute
Board of Governors Meeting - Minutes

Marriott Scottsdale McDowell Mountain Hotel
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March 2, 2020

Board Members Present: Christine Goertz, DC, PhD, *Chairperson*; Sharon Levine, MD; *Vice Chairperson;* Kara Ayers, PhD; Larry Becker; Francis Collins, MD, PhD (*via phone*); Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Christopher Friese, PhD, RN; Michael Herndon, DO; Russell Howerton, MD; Gail Hunt; Gopal Khanna, MBA; Freda Lewis-Hall, MD; Michelle McMurry-Heath, MD, PhD; Barbara McNeil, MD, PhD; Grayson Norquist, MD, MSPH; Ellen Sigal, PhD; Kathleen Troeger, MPH; Janet Woodcock, MD; Robert Zwolak, MD, PhD

Executive Staff Present:
Josephine Briggs, MD, *Interim Executive Director and Acting Chief Science Officer;* Mary Hennessey, Esq.; Jean Slutsky, PA, MSPH; Regina Yan, MA, Michele Orza, ScD; including Directors, Steve Clauser, PhD; and Anne Trontell, MD, MPH

AGENDA ITEM	PCORI SPEAKERS
Welcome and Call to Order - *Christine Goertz, DC, PhD, Board Chairperson and Josephine Briggs, MD, Interim Executive Director and Acting Chief Science Officer*	Dr. Goertz chaired and opened the meeting, welcomed all to the March 2, 2020 meeting of the PCORI Board of Governors, and read the Chair Statement on Conflict of Interest. Goertz noted that there would be a public comment period later in the meeting, and also announced that Dr. Alicia Fernandez was reappointed by the Government Accountability Office (GAO) to serve a second six-year term on the Board of Governors through February 3, 2026. Fernandez also serves on the Science Oversight Committee and the Selection Committee. Goertz then reviewed the meeting agenda. Goertz also announced that the published agenda for this Board meeting had been accelerated to add time for discussion by the Board on PCORI's mission and strategic planning in light of PCORI's reauthorization directives.
Consider for Approval: Consent Agenda • Minutes of January 28, 2020 Board Meeting • Award Project Budget Increase Policy • CTAP Co-Chair - *Christine Goertz, DC, PhD*	Dr. Goertz introduced the Consent Agenda and gave the opportunity to Board members to discuss any of the matters on the Consent Agenda. No separate discussion was requested. *The following motion was made by Barbara McNeil and seconded by Larry Becker.* **Motion**: Approve each of the Motions on the Consent Agenda as reflected below: • Minutes of the January 28, 2020 Board Meeting • Appointment of Catherine (Kate) Crespi-Chun, as Co-Chair of the Advisory Panel on Clinical Trials to serve until August 31, 2021, or until a replacement is appointed • The proposed revised Award Project Budget Increase Policy *Approved by a majority vote of the voting Board members (no opposed; no abstentions; 0 recusals). Francis Collins was not present for the vote.*
Executive Director's Report - *Josephine Briggs, MD*	Dr. Briggs announced the resignation of Dr. David Hickam, the Director of PCORI's Clinical Effectiveness and Decision Science (CEDS) Department, effective in May, and thanked him for his contributions to PCORI's work. Briggs discussed transitions related to one of the organizations participating in PCORnet, the People-Centered Research Foundation (PCRF) which is a recipient of PCORI funding. Additionally, she informed the Board of two forthcoming JAMA publications of results from PCORI-

	funded studies with potential to change practice: 1) a 5-year outcomes report on common bariatric surgeries; and 2) a report from a large study to reduce radiation doses associated with CT scans. Board members expressed interest in receiving more information on the forthcoming study results and requested a status update about the Patient-Powered Research Networks (PPRNs).
Consider for Acceptance: 2019 Independent Financial Audit Report - *Sharon Levine, MD, Chair, Governance Committee and Tom Sneeringer, CPA, Partner, RSM US LLP*	Dr. Levine introduced this agenda item by reminding members that the Governance Committee, in accordance with its charter, is responsible for the oversight of PCORI's annual financial audit. She explained that the FY2019 independent audit was conducted by RSM under the charge of Tom Sneeringer, a partner at RSM, and covered the 12-month period ending September 30, 2019. The planning field work at PCORI was conducted by the RSM auditors in September 2019 and the final audit field work took place November 11-29, 2019. The RSM auditors met with the Governance Committee four times, to review the audit's progress, and each meeting included the opportunity for an executive session between Governance Committee members and the auditors to provide for direct communication. Levine further noted that the Governance Committee supports the acceptance of this audit and introduced Tom Sneeringer to provide an overview of the FY2019 Independent Financial Audit to the Board. Sneeringer reminded the Board that, in addition to conducting the audit at its behest, under the auspices of the Governance Committee, RSM also reports to the GAO which reviews the audit in accordance with PCORI's authorizing law. Sneeringer reported that RSM was prepared to issue an unmodified or "clean" opinion, that financial statements ending September 30, 2019 conform to generally accepted financial principles with no findings related to deficiencies or material weaknesses in internal controls over financial reporting and no findings related to non-compliance issues. Sneeringer then reviewed PCORI's FY2019 statement of activities including revenue, expenses, realized and unrealized loss on investments, and change in net assets, with a comparison to FY2018. He also reviewed PCORI's FY2019 statement of financial position, including assets, liabilities and net assets compared to FY2018. He noted that PCORI's revenue for FY2019 was $615 million. He stated that expenses, largely made up of research award expenses, remained consistent over FY2019 and FY2018. He then explained that PCORI's $1 billion investments in U.S. Treasury notes and Treasury bills were reported at its fair market value as of 9/30/19, and explained how the market changes for PCORI's investment are reported under accounting standards for nonprofits, including that these investments are actually realized at maturity. Sneeringer further stated that PCORI's net assets (assets minus liabilities) as of September 30, 2019 were $1.29 billion,

	compared to $1.06 billion in FY2018, an increase of $227.6 million. PCORI's overall total net assets were $1.4 billion, largest portion being from short-term investments, up $225 million. Liabilities are consistent with FY2018. Sneeringer thanked the Governance Committee and PCORI management for their cooperation throughout the audit. Board members were asked if they had any questions. No discussion was requested. *The following motion was made by Ellen Sigal and seconded by Larry Becker:* **Motion:** Accept the FY2019 Financial Audit Report *Accepted by a majority vote of the voting Board members present by a show of hands (19 in favor, 0 opposed; 0 abstentions; 0 recusals). Francis Collins was not present for the vote.*
The following two award slates were considered for approval in a combined motion and vote. **Consider for Approval:** Broads PFA Cycle 2 2019 Awards Slate • Addressing Disparities • Assessment of Prevention, Diagnosis and Treatment Options • Improving Healthcare Systems - *Barbara McNeil, MD, PhD, Chair, Selection Committee and Josephine Briggs, MD, Interim Executive Director and Acting Chief Science Officer* Limited Competition Dissemination and Implementation PFA Cycle 2 2019 Awards Slate - *Larry Becker, Chair, Engagement Dissemination and Implementation Committee (EDIC), and Joanna Siegel, SM, ScD, Director,*	Dr. Goertz announced that the two upcoming agenda items - consideration of the Broads Cycle 2 2019 Awards Slate and the Cycle 2 2019 Dissemination and Implementation (D&I) Awards Slate - would be combined into one agenda item. Dr. Briggs noted that the first slate of research awards was reviewed by the Selection Committee under the chairmanship of Dr. McNeil, and the second slate of three D&I awards was reviewed by the Engagement, Dissemination and Implementation Committee (EDIC) under the chairmanship of Dr. Becker. She stated that each Committee has recommended its applicable slate of awards to the Board for approval. The slate of broad research awards recommended by the Selection Committee consisted of four research projects from three different priority areas: Addressing Disparities (1 recommended project), Assessment of Prevention, Diagnosis, and Treatment Options (1 recommended project) and Improving Healthcare Systems (2 recommended projects). *(See Appendix A for the list of Cycle 2 2019 Broad PFA research projects funded.)* The second slate recommended by the Engagement, Dissemination, and Implementation Committee consisted of three limited competition dissemination and implementation awards. *(See Appendix B for the list of D&I award projects funded.)* Briggs stated that these slates have been very carefully reviewed by each of these two Committees and reminded Board members that more detailed information regarding these awards was included in the slides provided the Board which also have been posted to PCORI's website. The Board had no questions and did not ask for any further information.

Dissemination an Implementation .	*The following motion was made by Sharon Levine and seconded by Jennifer DeVoe.* **Motion**: Approve funding for the recommended awards from the Broads PFA Cycle 2 2019 Awards Slate and the Limited Competition Implementation of PCORI-Funded Patient-Centered Outcomes Research Results PFA Cycle 2 2019 Awards Slate. *The motion was approved by all those in attendance by a show of hands: 0 opposed, 0 abstained, 3 recused (Alicia Fernandez, Barbara McNeil, Christopher Friese). Francis Collins was not present for the vote.*
The development of the following three PCORI Funding Announcements (PFAs) were considered for approval in a combined motion and vote. **Consider for Approval:** Phased Large Awards for Comparative Effectiveness Research (PLACER) PFA - *Robert Zwolak, MD, PhD, Chair, Science Oversight Committee (SOC) and Anne Trontell, MD, MPH, Associate Director, Clinical Effectiveness and Decision Science (CEDS)*	Dr. Zwolak made introductory remarks on behalf of the Science Oversight Committee. He briefly drew attention to the Phased Large Awards for Comparative Effectiveness Research (PLACER) funding announcement proposal and stated that its key is the inclusion of PCORI funding of a feasibility phase that allows investigators the opportunity to test and refine complex interventions in challenging research settings to enhance the likelihood of successful recruitment, followed by a focused PCORI Go/No Go approval step for ongoing funding of the full refined study. PLACER is designed to allow for more confidence that these complex studies with larger award amounts will yield scientific results that are valuable to scientists, patients, and their caregivers. Then Zwolak introduced Dr. Briggs and Dr. Trontell to provide more details on PLACER. Briggs thanked Zwolak and the SOC for its thoughtful discussion on this complex endeavor. She introduced Trontell who noted that this initiative was presented earlier to the Science Oversight Committee and the Research Transformation Committee. She described PLACER's potential ability to remove roadblocks to funding highly important research questions of large scale and scope. PLACER is different than PCORI's other awards, because of its (1) ability to allow for greater uncertainty and (2) large scale and scope. The first phase of a research study funded under the PLACER PFA will allow investigators to test the feasibility of the research study. It will last for a maximum of 18 months and cost between $1-2 million (direct costs only). After this phase, a Go/No-Go Decision will be made by PCORI's Executive Director with the advice of senior PCORI staff and an external advisory panel. Finally, studies approved in the Go/No Go decision stage will progress into funding for the full-scale study phase, where studies have maximum budget of $20 million (direct costs only) for up to 5 years. Investigators will be expected to use an independent data coordinating center throughout the duration of the study and the use of PCORnet for the conduct of the study is strongly encouraged.

	After describing the lifecycle of PLACER, Trontell discussed some of the award's finer details, as they pertain to the merit review process, go/no-go decision, and full-scale study execution phase. The requested amount for this PFA is $150M in total costs. PCORI expects to fund up to 5 studies with a maximum project duration of 7 years. The Board asked clarifying questions and asked about possible topics that would apply to PLACER. While Zwolak clarified that researchers would have relative autonomy on what topics to study, Josie Briggs added that PCORI is developing a list of exemplar topics to help guide applicants. Also, PCORI has certain standards for appropriate research questions that stem from its authorizing legislation. A pre announcement is expected to go out March 3rd, and the PFA is expected to be announced in early May 2020 to align with PCORI's Cycle 2 2020 PFAs timeline. Applications are expected to be due in September 2020.
Observational Analyses of Second-Line Pharmacological Agents in Type 2 Diabetes Mellitus PFA - *Robert Zwolak, MD, PhD, Chair, Science Oversight Committee and Kim Bailey, Senior Program Officer, Clinical Effectiveness and Decision Science (CEDS)* PCORnet Rare Disease PFA - *Robert Zwolak, MD, PhD, Chair, Science Oversight Committee (SOC) and Josephine Briggs, MD and Penny, Mohr, Senior Advisor, Healthcare Delivery and Disparities Research (HDDR)*	Briggs then provided an overview of the Observational Analyses of Second-line Pharmacological Agents in Type 2 Diabetes Mellitus (T2DM) Targeted PFA, the development of which being presented to the Board for approval. This PFA will address the question: What is the comparative effectiveness of older versus newer second-line agents among individuals with T2DM at moderate cardiovascular (CV) risk? The requested amount for this PFA is $20M in total costs. PCORI expects to fund 2-3 studies with a maximum project duration of 3 years. Finally, Briggs briefed the Board on the Conducting Rare Disease Research in PCORnet Targeted PFA. This PFA would fund observational analyses that study rare diseases through the use of PCORnet. The goals of this targeted PFA are to (1) utilize PCORnet resources to perform an observational research study that will answer one or more important research questions about the care of patients with rare disease and to (2) enhance the capabilities for the conduct of multi-site rare disease research by creating partnerships, methods, tools, and linkages that will facilitate future comparative effectiveness studies. The requested amount for this PFA is $25M in total costs. PCORI expects to fund 5 studies with a maximum project duration of 3 years. One Board member noted that while they supported a robust PCORnet platform moving forward, they felt the Board needed to develop a more contemporary revisit of PCORI's mission for PCORnet. *The following motion was made by Larry Becker and seconded by Robert Zwolak.* **Motion**: Approve the development of three PFAS: • Phased Large Awards for Comparative Effectiveness Research (PLACER) PFA • Observational Analyses of Second-line Pharmacological Agents in Type 2 Diabetes Mellitus Targeted PFA

	• Conducting Rare Disease Research in PCORnet Targeted PFA *Approved by a majority vote of the voting Board members in attendance by a show of hands and Francis Collins via phone.*
Portfolio Overview – PCORI's Community Health Worker Synthesis - *Steve Clauser, PhD, Program Director, Healthcare Delivery and Disparities Research (HDDR) and Cathy Gurgol, MS, Senior Program Officer, HDDR* **Guest Speakers:** • *Vallabh Shah, PhD, Professor, Department of Biochemistry and Molecular Biology and Internal Medicine, School of Medicine, UNMHSC* • *Kevin English, Dr.P.H, Director, Albuquerque Area Southwest Tribal Epidemiology Center, Indian Health Board, Inc.* • *Shreya Kangovi, MD, MSHP, Associate Professor, Medicine, Perelman School of Medicine* • *Keysha Brooker, MSW, Penn Center for Community Health Workers*	Dr. Goertz introduced Dr. Clauser, who presented information about PCORI's Community Health Worker (CHW) portfolio. Clauser began the presentation by describing the challenges associated with addressing health disparities in the United States (US). He explained that reports from the National Academies of Sciences and the Agency for Healthcare Research and Quality, as well as recent systematic reviews, have recommended CHWs as a strategy for addressing health disparities. He also described that CHWs are a rapidly growing profession in the US. However, more evidence is needed to support the wider adoption of CHWs by payers, health care systems, and other stakeholders. Clauser then provided an overview of PCORI's CHW portfolio. The portfolio includes two types of CHWs: CHWs who are trained lay people who come from the same community as patients they work with; and peers, who are trained lay people who share patient's diagnosis and treatment experiences. PCORI has invested $275 million to fund 76 CER studies that include a traditional CHW or peer in the intervention. Nearly half of studies in the portfolio (45%) are focused on addressing health disparities, and the majority of the portfolio (95%) are randomized controlled trials (RCTs). The portfolio includes a broad range of health conditions and outcomes, including health services utilization outcomes, health behavior outcomes, clinical outcomes, care experience outcomes, and health status and wellbeing outcomes. Next, Clauser presented key findings from four completed studies in the portfolio that address health disparities. The studies found that CHW and peer interventions can improve health outcomes and reduce disparities by increasing access to care and enhancing care quality. Specifically, the first two studies found that peer navigators can increase access to appropriate care for Hispanic patients with serious mental illness. Compared to usual mental health care, peer navigation increased appropriate health service use, quality of life, and other health-related indices (e.g., chronic disease detection). The third study presented found that tailored decision support with a patient navigator increased colorectal cancer screening rates among low-income Hispanic patients compared to mailed educational information. Lastly, the fourth study found that a risk-reduction intervention delivered by trained CHWs reduced cardiovascular disease risk factors among at-risk adults living in rural Appalachian Kentucky compared to usual care.

	Clauser then introduced four guest speakers, Drs. Shah, English, Kangovi, and Ms. Brooker, who presented their PCORI-funded research and implementation (Kangovi/Brooker) projects to implement CHW interventions. Shah and English presented their research on the use of a CHW intervention to improve health outcomes among Zuni Indian adults with chronic kidney disease living on the Zuni Reservation in rural New Mexico. The randomized controlled trial, *Reducing Health Disparity in Chronic Kidney Disease in Zuni Indians,* compared the effectiveness of an at-home education and point of care program delivered by community health representatives to usual care at the Indian Health Services clinic. The study found that patients who received the at-home program delivered by community health representatives had better activation in their own health and healthcare and a greater reduction in some risk factors for kidney disease, such as blood sugar levels and weight. Kangovi and Brooker then presented their PCORI-funded research that assessed whether a CHW intervention called *Individualized Management for Patient-Centered Targets (IMPaCT)* improves health outcomes for low-income patients with multiple chronic conditions. The randomized controlled trial, *Effectiveness of Collaborative Goal-Setting Versus IMPaCT Community Health Worker Support for Improving Chronic Disease Outcomes,* found that patients who received the CHW intervention reported higher quality of primary care and had lower odds of repeat hospitalizations compared to patients who did not receive the CHW intervention. Kangovi has also received a PCORI Dissemination & Implementation award to scale the *IMPaCT* CHW intervention in three new healthcare organizations. Board members, Clauser, and the panelists then discussed the challenges associated with bringing CHW interventions to scale across the US. For example, they discussed the issues around sustainable reimbursement for CHWs. In addition, Board members noted the need to extend CHW programs for specific populations, such as rural and LGBTQ populations. Shah and English explained that CHWs need continuous training to successfully implement programs that address various health conditions in different settings. Kangovi and Brooker emphasized that a key ingredient for sustainability of CHW programs is to empower patients to take control of their own health. Lastly, Board members and panelists noted the importance of conducting return-on-investment analyses to support the wider adoption of CHW programs.
Public Comment - *Jean Slutsky, PA, MSPH, Chief Engagement and Dissemination Officer*	<u>Brendaly Rodriguez, MA, CPH</u> <u>University of Miami</u> Ms. Rodriguez expressed support for the funding of Community Healthcare worker studies. She encouraged PCORI to invest more in efforts to disseminate results from CHW studies, and for PCORI to help

	clarify roles of CHWs in addressing social determinants of health and access to care.
Discussion of PCORI Governance and Future Planning - *Christine Goertz, DC, PhD*	Christine Goertz introduced this agenda item by In December 2019, legislation was passed by Congress, reauthorizing PCORI's funding for 10 years; in response to this, the Board plans on revisiting PCORI's strategic plan. The Board opened discussions with a preliminary review of PCORI's existing mission and initial discussion of some of the changes reflected in the reauthorizing legislation. Some Board members expressed the need to discuss the existing mission and vision statement as those serve as foundational pieces for developing PCORI's strategy. There was a general consensus the entire Board of Governors should be involved in guiding strategy for PCORI and consider carefully the necessary elements needed for PCORI's success in the next 10 years. Board members expressed that substantive discussion would be needed in the coming months to outline PCORI's strategy for positively impacting patient-centered research. The Board previewed one such discussion, that of PCORI's role in providing information to people and whether PCORI should also support the adoption of the information into clinical practice and in decision-making by patients. Board member expressed that these and similar questions could provide deep insight into PCORI's future work and help guide PCORI's strategy. Additional comments were made on the future primary lines of work for PCORI and how critical it was to align those (and organizational resources) with the mission and vision. Infrastructure development and dissemination and implementation activities were mentioned as needing to be discussed in future and how they would complement funding patient-centered comparative effectiveness research. Several themes for future consideration emerged during this discussion. Subsequent discussion took place on next steps related to strategic planning. The Board noted the importance of staffing the planning process appropriately and including senior executive staff. Concluding the discussion, enthusiasm was expressed for the opportunity to think about PCORI's accomplishments in the next 10 years.
Wrap-up and Adjourn Meeting of the Board - *Christine Goertz, DC, PhD*	The meeting concluded at 5:00 pm Mountain time.

Minutes were approved by the PCORI Board of Governors 05-05-2020

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Appendix A: *Broads PFA Cycle 2 2019 Awards Slate*

Program	Award
Addressing Disparities	Comparing Mobile Health Strategies to Improve Pre-exposure Prophylaxis Use (PrEP) for HIV Intervention
Assessment of Prevention, Diagnosis and Treatment Options	Randomized Trial Comparing MRI-Targeted Transperineal vs Transrectal Prostate Biopsy
Improving Healthcare Systems	Comparative Effectiveness of Perinatal Psychiatric Access Programs on Treatment Engagement
	Using Mobile Integrated Health and Telehealth to Support Transitions of Care among Heart Failure Patients

Appendix B: *Dissemination and Implementation Cycle 2 2019 Awards Slate*

Award
Implementing Team-based Outpatient Palliative Care in Parkinson Foundation Centers of Excellence
Innovative Implementation of a Robust Executive Function Intervention Delivered in Schools
Learning Collaborative to Improve the Quality of Elective Orthopedic Surgery Decisions