Patient-Centered Outcomes Research Institute
Board of Governors Meeting

Park Hyatt Hotel
1201 24th Street, NW
Washington, DC 20036
Tel: (202) 789-1234

December 9-10, 2019

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

Board Members Absent:
Francis Collins, MD, PhD; Grayson Norquist, MD, MSPH

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

Executive Staff Present:
Josephine Briggs, MD, *Interim Executive Director and Acting Chief Science Officer;* Mary Hennessey, Esq.; Michele Orza, ScD; Jean Slutsky, PA, MSPH; Regina Yan, MA

TIME	AGENDA ITEM
Welcome and Call to Order **Consider for Approval:** • Minutes of November 19, 2019 Board Meeting - *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 meeting of the PCORI Board of Governors and read the Chair Statement on Conflict of Interest. Goertz reminded members that annual update of conflict of interest disclosures is due by January 31. She also informed Board members that Trent Haywood has resigned from the Board and indicated that he is no longer serving in the healthcare payer sector. She thanked Joe Selby for his work as the founding Executive Director of PCORI. Dr. Briggs then reviewed the meeting agenda. Dr. Goertz then asked if anyone had any additions or edits to the November 19, 2019 Board of Governors minutes. Dr. Robert Zwolak pointed out a typographical error in Attachment A where the minutes should say "inference". There were no other additions or edits offered. *The following motion was made by Robert Zwolak and seconded by Larry Becker.* **Motion:** Approve minutes from the November 19, 2019 Board of Governors meeting as amended. *Approved by a majority vote of the voting Board members by show of hands and voice vote (for members via phone) (no opposed; no abstentions); Christopher Friese, Russell Howerton, Freda Lewis-Hall, Michelle McMurry-Heath, and Janet Woodcock were not present for this vote.*
Executive Director's Report and FY2019 Dashboard • Executive Director's Remarks • End-of-Year Dashboard Report • PCORI as of 2019: The Foundation We've Built - *Josephine Briggs, MD*	Dr. Briggs introduced the Executive Director's Report by describing her early experiences as PCORI's Interim Executive Director, becoming familiar with PCORI processes, research studies, challenges, and accomplishments. Briggs presented the Q4-2019 Dashboard for the Board's review. The Dashboard demonstrated 8 green-flagged metrics (those that are on track), and 1 yellow-flagged metrics (those that are off target by more than 10%-15%, depending on the metric). There were no red-flagged items (items that are off-target and in need of attention or action by the Board). For an end-of-year summary, Briggs reported that PCORI has committed a total of $2.51 billion as of FY-2019. She provided information showing that PCORI-funded research projects have performed as well as or better than published benchmarks, in terms of recruitment and time to publish results. She described that there are nearly 300 completed research projects with results posted to PCORI.org, and provided information about a new $90M NIH-funded study called the PREVENTABLE study, that will utilize PCORnet®. She provided an overview of PCORI at the end of FY-2019, including commitments, total number of

	studies, studies with results, and early uptake of research findings. Briggs provided an example of a completed PCORI-funded study, covering the sequence from results to impact, highlighting a study that compared broad and narrow spectrum antibiotics for children with ear, sinus and throat infections. Results from the study were published in JAMA and on PCORI.org that showed that narrow-spectrum antibiotics were associated with better outcomes than broad-spectrum antibiotics. The presentation concluded with an estimate of the potential impact of these findings, which if implemented widely, could, it is believed, reduce societal costs by $131M per year. As Interim Executive Director, Briggs asked the Board what short-term goals she should pursue to help the Board prepare for PCORI 2.0. Board members expressed interest in seeing the potential return-on-investment from the highlighted PCORI-funded study. They discussed the importance of dissemination and implementation, uptake into policy documents, and the need for investigators to publish all findings in the literature. Board members expressed interest in framing a more meaningful topic selection process and exploring data on time from application to results, to identify potential process areas for improvement, and having more consolidated stakeholder input.
Patient-Centeredness and Engagement: What Have We Learned? - *Kristin Carman, MA, PhD, Director, Public & Patient Engagement* - *Laura Forsythe, PhD, MPH, Director, Evaluation & Analysis* - *Lia Hotchkiss, MPH, Program Director, Eugene Washington PCORI Engagement Awards Program*	Dr. Goertz introduced Ms. Hotchkiss and Drs. Carman and Forsythe, who presented on what PCORI has learned about patient-centeredness and engagement. Hotchkiss began the presentation with a background on PCORI's authorizing legislation, and its purpose to advance research that is more accessible and relevant to ease the burden of health care decision-making, engage patients and stakeholders and address questions that are important to them. Carman provided an overview of PCORI's conceptual model, and described PCORI's efforts to develop a body of evidence about engagement to improve the engagement of individuals and organizations, better support PCORI awardees, and answer questions about the influence of engagement in research. She indicated that, in addition to practice-based experience, PCORI has conducted and commissioned observational studies about engagement in PCORI projects that include: over 120 confidential in-depth interviews with researchers and partners, a review of over 125 peer reviewed articles by PCORI awardees, hundreds of surveys, and analysis of programmatic and administrative data required project progress reports.

	Forsythe outlined findings from the body of evidence on the science of engagement, and specifically how engagement influences study conceptualization and execution, how engagement is designed and practiced, and researchers' understanding of the needs of people and organizations. Forsythe noted engagement influences all aspects of CER design and conduct and focused on the way engagement influences research focus, design, recruitment and retention. Supporting examples of each theme were provided. Forsythe went on to describe several high-level, interdependent themes on how engagement affects PCORI-funded studies: user-orientation and acceptability; feasibility; quality; relevance, and engagement scope and quality. Carman discussed some of the challenges of engagement including those related to infrastructure and resources, people and teams, organizations, and balancing views. Carman outlined future actions to build on PCORI's accomplishments by advancing the science of engagement including measurement of engagement, how engagement enhances dissemination, implementation and uptake to practice, and to continue to share what PCORI has learned and innovate in how best to do it. To inform future directions, Board members suggested that PCORI staff continue to track influence of PCORI within external organizations and the field more broadly, continue to develop and provide tailored training and support for engagement, and ensure and enhance stakeholder engagement in dissemination efforts. In addition, Board members urged continued publication on PCORI's engagement findings. Finally, Board members emphasized that uptake is a very complicated area in which engagement may have an impact, and recommended PCORI put resources into tools that target stakeholders and specific contexts to facilitate engagement and uptake of findings into practice.

Research Portfolio Exploration Series: Focus on Cancer - *Neeraj Arora, PhD, Associate Director, Healthcare Delivery and Disparities Research Program (HDDR) and* - *Sarah Daugherty, PhD, MPH, Senior Program Officer, Clinical Effectiveness and Decision Science Program (CEDS)*	Dr. Goertz introduced Drs. Arora and Daugherty, who presented on PCORI's cancer portfolio. Their presentation began with an overview of the high prevalence and burden of cancer in the U.S. Arora provided an overview of PCORI's cancer portfolio. PCORI has invested $313 million to fund 80 CER studies on cancer, representing nearly one-fifth of PCORI's entire research portfolio. Many of these studies (77%) were funded through PCORI's Broad Funding Announcements, in which investigators partner with stakeholders to address important decisional dilemmas. The portfolio also includes 11 pragmatic clinical studies and 7 targeted awards. Arora then described key characteristics of the cancer portfolio which includes a broad range of cancer types and interventions, including both clinical and care delivery-related interventions. Many studies (70%) are randomized controlled trials (RCTs), and 25% enroll caregivers. In addition, the portfolio addresses key decisional dilemmas across the patient's cancer journey, with 18 studies focused on cancer prevention and early detection, 50 studies focused on cancer treatment (including 15 on advanced cancer care), and 12 studies focused on post-treatment survivorship. Daugherty highlighted notable findings from four completed studies across the patient's cancer journey. The first study was an RCT within the prevention and early detection category. The study found that tailored decision support with a patient navigator significantly increased colorectal cancer screening rates (78%) compared to mailed educational information (44%) among Hispanic patients. She then presented key findings from two prospective observational studies within the treatment phase. The first study compared the side effects of three treatments for localized prostate cancer (surgery, radiation, and active surveillance). The study found that men who had surgery reported a greater decline in sexual function and worse urinary incontinence compared to those who had radiation or active surveillance at 3 years. Several dissemination activities have extended the reach of this study's results, including a recent PCORI-funded Dissemination & Implementation award to update an existing prostate cancer treatment decision aid using the more representative data generated by this study. The second treatment-related study examined how mental and social well-being was affected by surgical treatment choice among sporadic breast cancer patients. Compared with women who kept the healthy breast, women who had both breasts removed had more concerns about body image, a lower quality of life, and the same amount of worry about their cancer after surgery.

	The last study presented by Daugherty focused on post-treatment surveillance within the survivorship phase and compared the effectiveness of different surveillance intensities among lung cancer survivors following surgical resection. The study found that, compared with receiving an imaging test every 12 months, receiving tests at 3- or 6-month intervals made no difference in how soon doctors detected a recurrence, or how likely patients were to live five years after their first surgery. Arora then highlighted some of the key lessons learned from the ongoing large pragmatic trials on cancer that have been funded by PCORI. These trials required extra time and resources during study start up, particularly to communicate equipoise in a way that minimizes provider bias, and to integrate system interventions into routine clinical workflow. In addition, significant coordination and relationship-building between the awardee team and study sites was critical for the trial's success. Arora and Daugherty concluded the presentation by noting that studies within the cancer portfolio emphasize the full spectrum of outcomes that matter to patients and caregivers. Many studies build on prior efficacy trials, taking projects to scale in real world settings, and leverage existing registries and clinical trial infrastructure to address questions that are important to stakeholders. In addition, PCORI recently released two research areas of interest related to cancer in the Cycle 3 2019 Broad Funding Announcement: 1) Dosing of anti-neoplastic agents in adults, and 2) Genetic sequencing to guide cancer treatment. To inform future directions, Board members suggested exploring strategies to work more synergistically with other funders, particularly with the National Cancer Institute, as well as ways to leverage PCORnet for cancer studies. In terms of specific topics to examine for future funding, they recommended exploring studies on gene therapy and studies that include individuals who have multiple primary cancers. They also suggested that PCORI should consider funding multiple studies on a few cancer topics in order to make a significant impact (e.g., increasing uptake of colorectal cancer screening; integrating palliative care as part of routine cancer therapy). Lastly, Board members emphasized the importance of evaluating the impact of out-of-pocket costs on patients and their caregivers and families during cancer treatment and throughout survivorship.
Public Comment – *Kristin Carman, MA, PhD, Director, Public & Patient Engagement*	No members of the public requested the opportunity to make a public comment. Thus, there were no public comments presented during this time.
Wrap-up and Adjourn Meeting of the Board – *Christine Goertz, DC, PhD*	The meeting adjourned at 1:00 pm

Minutes were approved by the PCORI Board of Governors 01-28-2020