Patient-Centered Outcomes Research Institute
Board of Governors Meeting

Park Hyatt Hotel
1201 24th Street, NW
Washington, DC 20035

May 13, 2019

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

Board Members Absent:
Trent Haywood, MD, JD; Michelle McMurry-Heath, MD, PhD

Methodology Committee Member Present:
Mark Helfand, MD, MS, MPH

Executive Staff Present:
Joe Selby, MD, MPH, *Executive Director;* Yen-Pin Chiang, PhD, MPA; Mary Hennessey, Esq.; Michele Orza, ScD; Jean Slutsky, PA, MSPH; Regina Yan, MA

AGENDA ITEM	RELATED MINUTES
Welcome and Call to Order **Consider for Approval: Consent Agenda** o Minutes of the April 16, 2019 Board Meeting o Amended Committee Charter - *Grayson Norquist, MD, MSPH, Chairperson*	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. Norquist asked if anyone had any additions or edits to the April 16, 2019 Board of Governors minutes, and gave the opportunity to Board members to discuss any of the matters on the Consent Agenda. There were no additions or edits offered and no separate discussion was requested. It was noted that the proposed amended Governance Committee Charter was to correct an inadvertent error from the last Board meeting when the Board was inadvertently provided with an incomplete version of the proposed amended Charter. This proposed amended Charter correctly captures the intended proposed amendments. *The following motion was made by Larry Becker and seconded by Christopher Friese.* **Motion:** Approve each of the motions on the Consent Agenda as reflected below: • Minutes from the April 16, 2019 Board Meeting • Amended Governance Committee charter with provisions addressing the process by which a Vice-Chair is named; and voting by written consent on audit matters to be consistent with DC nonprofit law *Approved by a majority vote of the voting Board members (no opposed; no abstentions); Kara Ayers, Russell Howerton, David Meyers, Freda Lewis-Hall and Janet Woodcock were not present for this vote.*
Executive Director's Report and Q2 Dashboard Review - *Joe Selby, MD, MPH, Executive Director*	Dr. Selby opened the report by reviewing discussion areas anticipated for upcoming Board of Governors meetings. The Board identified several topics of interest to be presented in the coming year as PCORI begins revising its strategic plan. Discussion areas expected included the following: revitalizing, enhancing and making the stakeholder-driven topic generation process more transparent; exploring the research portfolios as one way to generate the next round of targeted research topics; and enhancing the focus and activities for promoting worthy research findings through dissemination and implementation. The latter two, Selby noted, would be discussed later in the meeting. Selby described a new, regularly occurring portfolio exploration series that will be added to future Board meetings. The series will delve into the current set of funded projects in PCORI's portfolio. The first topic portfolio set for exploration is the telehealth

	portfolio with expected future subsequent portfolio explorations to address opioids, multiple sclerosis, mental health, and cancer. Board members expressed interest in adding additional topics to the exploration series such as community health workers and health care delivery. Board members also inquired about learning more about validation of new health technologies (e.g., mobile health applications) and how the PCORI-supported evidence synthesis maps were being employed. **Dashboard** Selby presented the Q2-2019 Dashboard for the Board's review. The Dashboard demonstrated 8 green-flagged metrics (those that are on track), and 2 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). Selby presented examples of results on PCORI's goals: to increase information, to speed uptake, and to influence research. He shared two publications with comparative effectiveness research (CER) results from PCORI-funded studies, published in *Annals of Internal Medicine* and *Journal of General Internal Medicine.* He then shared an example of results from a PCORI-funded study being taken up into the Infectious Diseases Society of America (IDSA) clinical practice guidelines for the management of outpatient parenteral antimicrobial therapy. He provided an example of how PCORI is influencing the way research is conducted by sharing review articles published in *F1000 Research* and *JAMA Network Open*. For the first of two Q2 Dashboard features, Selby provided a focused view of PCORI Peer Review. As of Q2, 213 studies have completed PCORI Peer Review, and the median time in Peer Review has been steadily decreasing over time. For the second of two Q2 Dashboard features, Selby provided an in-depth look at the progress of PCORnet with a focus on network data improvements, study highlights, and future opportunities. Board Members expressed interest in learning more about time for application review and for study start-up, following studies to estimate impact, and publication of manuscripts within the timeline of PCORI Peer Review. On the topic of PCORnet, Board Members discussed conducting research using observational data, completeness of lab test data, and the disposition of front door requests from past years.
Research Portfolio Exploration Series: Portfolio Overview - *Joe Selby, MD, MPH*	Dr. Selby shared an overview of the PCORI CER portfolio. He described the portfolio in terms of funding commitment and number of studies by disease/condition area, populations of interest, study design, outcome themes, high-cost conditions, and other study elements.

	Board Members discussed the list of highest-cost clinical conditions, and suggested a few areas that may also be considered. In addition to the number of funded studies, it was suggested that PCORI look at the number of submitted applications that addressed high-cost conditions.
Research Portfolio Exploration Series: Focus on Telehealth Portfolio - *Penny Mohr, MA, Senior Advisor, Healthcare Delivery and Disparities Research*	Dr. Selby introduced Ms. Penny Mohr, who serves as PCORI's staff lead for PCORI's telehealth portfolio. The presentation began with a brief background and definition of the term 'telehealth', including 'telemedicine' and 'mHealth'. Mohr explained how the research gaps in telehealth reflect PCORI's mission through addressing barriers to patient-centered care. Mohr went on to characterize the PCORI telehealth portfolio. The portfolio includes approximately $352 million supporting 84 studies of comparative clinical effectiveness research in telehealth. As of April 2019, there are 74 projects classified as telehealth, 23 projects classified as telemedicine (consultative and curative care), and 56 projects classified as mHealth (using mobile devices in medical care). These categories are not exclusionary, and projects may be classified as more than one type. Over half of the studies have completed research, and 14 studies have completed the draft final research report (DFRR) and peer review process. While a handful have shown positive findings, others are not as conclusive. Nearly all telehealth projects are randomized control trials, and most are of a moderate sample size. The Board questioned if the interventions are facilitated via caregivers, or if they are individually based. Mohr noted that this varies across the portfolio; however, early results are showing the importance of having a caregiver present to work with the patient who is interacting with the technology. Mohr highlighted a few studies from the telehealth portfolio, including a study comparing the effectiveness of early integration of palliative care delivered via telemedicine versus in-person visits for advanced lung cancer patients in rural areas. Another highlighted study sought to evaluate the feasibility, effectiveness, and satisfaction associated with tele-healthcare visits for patients with Parkinson's Disease. This investigator has additionally been awarded a PCORI Dissemination & Implementation award. The Board posed a question wondering if projects examined physician satisfaction with telehealth in addition to patient satisfaction as it is important for implementation purposes. Mohr answered that some projects in the portfolio do, while others do not. Mohr concluded her presentation describing what PCORI is doing with the telehealth findings. The PCORI website has

	evidence maps on mHealth for the self-management of chronic disease. A stakeholder workshop was held in May 2018 during which the key message was that the patient and clinician experience and context are critical to telehealth's success. Investigator communities have been established. Certain gaps still remain, including head-to-head trials of mobile apps, cancer treatment, maternal and child health, and the management of serious pediatric conditions. The Board noted the richness of the telehealth portfolio and questioned whether putting together a toolkit, CME credits, or seminars for various audiences to educate stakeholders had been considered. Mohr noted that PCORI's Engagement Award program has made three awards available with these intents in mind. Additionally, PCORI has held a webinar addressing the issues with implementation at multiple sites. In response to questions related to adherence, specifically monitoring. Mohr responded that the portfolio includes several ongoing studies that are looking at HIV medication adherence as well as nutrition and behavioral change adherence. In reply to questions concerning what PCORI should do in the telehealth research field going forward, Mohr responded that this is something to be considered by PCORI when doing portfolio analyses to avoid being duplicative.
Consider for Approval: Funds to Support Implementation of the PCORnet Common Data Linkage Method - *Kathleen Troeger, MPH, Chair, Research Transformation Committee (RTC) & Maryan Zirkle, MD, MS, MA, Senior Program Officer*	Dr. Zirkle, Senior Program Officer on PCORI's Research Infrastructure team, presented to the Board a proposal to approve infrastructure funding for the development and implementation of a common linkage method in PCORnet. Linking data across disparate sources at the patient level can yield more complete datasets allowing for higher quality research. Zirkle provided background information about the evolution of advancing common linkage methods in PCORnet, including 2016 efforts using a secure and private method called privacy-preserving record linkage (PPRL) and PCORI funding of Health Plan Research Networks (HPRNs) to participate in PCORI funded PCORnet demonstration projects to link data with Clinical Research Networks (CRNs) and work through barriers and challenges. Through these demonstration projects, the need for more a more efficient record linkage was identified in lieu of the time intensive and expensive one-off linkages conducted on a project by project basis. Participants in PCORnet advanced a robust search and review process to identify a vendor to supply a PPRL common linkage method that all Network Partners would use to perform linkages, which is envisioned to be funded as part of the recommended infrastructure award. The RTC is recommending that the Board approve up to $2 million to fund infrastructure development for implementation of a common linkage method in PCORnet. This request is within the approved Research Infrastructure FY2019 funding commitment plan and was

	endorsed by the Research Transformation Committee on April 18, 2019. Zirkle described the expected roles of the Network Partners and the selected vendor (who will contract with the awardee) in implementation of the common linkage method. She explained that the PCORnet CRNs and HPRNs will need to amend existing governance and infrastructure including Institutional Review Board approvals and data sharing and data use agreements as well as expand the Common Data Model. The vendor will enable PPRL by remotely installing software at each CRN and HPRN site as well as at the Coordinating Center. The vendor will also provide technical support to ensure PPRL takes place behind each institution's firewall and all information is encrypted to ensure patient privacy. The Coordinating Center will expand existing query infrastructure and develop new approaches for data queries. Zirkle noted that implementation of a common linkage method in PCORnet would significantly increase the network's capacity and decrease the time and cost associated with linking disparate sources of data. She also explained that there is a plan to evaluate the common linkage method by using the PPRL method to perform an analysis to identify patient overlap among the Network Partners. In response to a question about preserving the privacy of patient records while being able to confidentially identify duplicate patient records, Zirkle explained that the review process conducted by the relevant PCORnet participants for the vendor highlighted the importance of privacy and security. She also noted that while the timeline for this proposed funded infrastructure project is two years, it is expected that there will be an extensive security review incorporated into the project within the first year. Zirkle also stated that patient data remains behind institutional firewalls. She indicated that the vendor provides technical support but will not receive patient data. With regard to Board questions regarding the vendor's software and methodology, Zirkle replied that PCORI infrastructure staff has high confidence that the PPRL method will work as this vendor has already implemented this method in the past and has previously worked with several PCORnet network partners. *The following motion was made by Kathleen Troeger and seconded by Janet Woodcock.* **Motion:** *Approve up to $2 million to fund infrastructure development for implementation of a common linkage method in PCORnet.* *Approved by a majority vote of the voting Board members present by a show of hands (14 in favor, no opposed, no abstentions, four recusals: Jennifer DeVoe, Christine Goertz, Freda Lewis-Hall, Barbara McNeil). Grayson Norquist was not present for this vote.*

Dissemination and Implementation Update o Overview o Project Focus - *Jean Slutsky, PS, MSPH, Chief Engagement and Dissemination Officer & John K. Cuddeback, MD, PhD, Chief Medical Informatics Officer, American Medical Group Association (AMGA)*	Ms. Slutsky provided a brief overview of PCORI's Dissemination and Implementation (D&I) program, noted the three available D&I Program funding initiatives, and provided a snapshot of currently funded D&I awards. She then introduced an example of a Dissemination & Implementation award. In this project, PCORI research awardee Dr. David Kent, at Tufts Medical Center, is working to move evidence from a recently-completed PCORI-funded study toward practical use in improving health care and health outcomes. In his original research project, Dr. Kent's team re-analyzed data from previous clinical trials and, based on these data, developed a model to predict the probability that an individual with prediabetes will develop diabetes in the near term. With a Limited Competition D&I award, Dr. Kent's team is partnering with the American Medical Group Association (AMGA) to incorporate this risk model into the electronic health record (EHR) and then implement the EHR-based tool in 50 AMGA member clinics from Mercy Health Systems and Premier Medical Associates. Guest speaker Dr. John Cuddeback, Chief Medical Informatics Officer at AMGA, described his organization's interest and role in the project. He outlined AMGA's National Diabetes Campaign, which has the goal of improving care for 1 million people with type 2 diabetes by 2021. One plank in this initiative is for clinics to conduct more practice-based screening, yet clinicians have reported reluctance to undertake more screening when they are already overwhelmed with the number of patients with diabetes, let alone prediabetes. Incorporating the risk prediction model developed in Dr. Kent's PCORI-funded study into the HER at AMGA member clinics can provide clinicians a way to manage this condition by personalizing risk estimates at the point of care. In the PCORI-funded Dissemination and Implementation project, AMGA has partnered in testing and implementing the risk prediction tool through the HER at the project's care clinic sites. Dr. Cuddeback presented early results for 670 high-risk patients at Premier Medical Associates. Among these patients, metformin use increased from 6% to 19%, and referral to a diabetes prevention program increased from 0% to 44%. Almost all clinicians working with these patients have accessed the tool to inform their conversations regarding treatment. Next steps for the project are to begin implementation at Mercy Health Systems. Following his remarks, Dr. Cuddeback responded to questions from members of the Board of Governors.
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 - *Grayson Norquist, MD, MSPH*	Meeting ended at 12:28 pm

Minutes were approved by the PCORI Board of Governors 06-18-2019