Patient-Centered Outcomes Research Institute
Board of Governors Meeting

Marriott Wardman Park Hotel
2660 Woodley Road, NW
Washington, DC 20008

October 29, 2018

Board Members Present:
Grayson Norquist, MD, MSPH, *Chairperson;* Christine Goertz, DC, PhD; *Vice Chairperson;* Larry Becker; 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; Francis Chesley, Jr., MD (designee of Gopal Khanna, MBA); Sharon Levine, MD; Freda Lewis-Hall, MD; 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:
Kara Ayers, PhD; Trent Haywood, MD, JD

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

AGENDA ITEMS	RELATED MINUTES
Welcome and Call to Order	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.
Consider for Approval: Minutes of September 18, 2018 Board Meeting - *Grayson Norquist, MD, MSPH, Chairperson*	Members were asked if anyone had any additions or edits to the September 18, 2018 Board of Governors minutes. One edit was offered to correct the time of adjournment from 11:47 pm to 11:47 am. *The following motion was made by Russell Howerton and seconded by Ellen Sigal.* **Motion:** Approve the Minutes of the September 18, 2018 Board Meeting as corrected. *Approved by a majority vote of the voting Board members (no opposed; 3 abstentions: Jennifer DeVoe, Christopher Friese and Michael Herndon); Michele McMurry-Heath and Janet Woodcock were not present for this vote.*
Executive Director's Report - *Joe Selby, MD, MPH, Executive Director*	Dr. Selby opened the report by welcoming the seven newly appointed Board of Governors members and the new Vice Chairperson, Dr. Christine Goertz. The report then highlighted PCORI's 2018 Annual Meeting that was to take place on October 31, 2018 to November 2, 2018. The Annual Meeting will highlight results from dozens of PCORI-funded patient-centered clinical effectiveness research studies and explore opportunities to use this evidence in ways that patients and other healthcare stakeholders found useful. Selby noted that over 1000 members of the PCORI community were expected to attend the event. Selby gave an update on the jointly-funded 5-year, $40 million learning health system (LHS) traineeship initiative between PCORI and AHRQ. Recently, 11 LHS Centers of Excellence were selected; their aim is to produce the next generation of LHS researchers to conduct patient-centered outcomes research. Selby reported that PCORI received two recognitions for its investments in palliative care research by two stakeholder organizations. The 2018 Champion's Award presented by the Coalition to Transform Advanced Illness Care (C-TAC), and the AAHPM Presidential Citation Award presented by American Academy of Hospice and Palliative Medicine (AAHPM, recognized PCORI's leadership and significant

	contributions to support and develop the research field of advanced illness care. **Q3-2018 Dashboard** The Q3-2018 Dashboard presented by Selby demonstrated 2 green-flagged items (items that are on track) and 4 yellow-flagged items (items that are off target by more than 10%-15%, depending on the metric). The two metrics that are green are research using PCORnet and PCORI abstracts posted to the website. Two metrics have provisional targets, so they are not flagged as green or yellow: results published in the literature and Altmetric (a measure of attention to publications). The Funds Committed to Research metric is yellow due in part to a much smaller than expected slate for Targeted research in low back pain and symptom management for advanced illness in Q3. The Expenses metric is yellow because expenses were below the goal of 85% of the budgeted amount. The project performance metric is yellow because more than 10% of projects are considered off track. The PCORI Peer Review metric is yellow because early data show that the process has not yet met the established target. There were no red-flagged items (items that are off-target and in need of attention or action by the Board). **Research Results** Selby highlighted published results from PCORI-funded research studies on the topics of smartphone-based treatment for people with serious mental illness, and frequency of colorectal cancer screening on long-term health outcomes. These publications had high Altmetric scores. As an example of uptake of study results, he noted that results from a PCORI-funded study on community health workers in veteran care was awarded a 2018 Veterans Health Administration Shark Tank Competition Diffusion of Excellence award. He also shared that PCORI is credited with inspiring the Ontario Ministry of Health and Long-Term Care (MOHLTC) in engagement of patients in reviewing applications from competitive research calls. **Projects Progress Report** Selby introduced the Q3 focus on progress of projects, with an attention to recruitment. He shared that half of PCORI's funded research projects are entering PCORI Peer Review or have their results posted to PCORI.org, He stated that while the majority of PCORI-funded research projects are on track, the proportion off track has increased slightly over the past year. Selby noted that Pragmatic Clinical Studies, usually larger, longer, and more complex, are more likely to

	be off track, and that as of Q3, primary results of 84 CER projects have been peer-reviewed and are publicly available, either by publication or by posting to PCORI.org. He also noted that the speed of PCORI Peer Review is steadily improving. **<u>Recruitment</u>** Regarding recruitment, Selby showed that early results from PCORI's initial funding indicate that PCORI-funded studies are doing better on recruitment than available benchmarks. Of the 204 projects that completed recruitment as planned, 70% completed projects on time or early, and 96% achieved greater than 90% of their target enrollment. Selby discussed the roles of contract modifications and extensions: 40% of studies required an extension of their timeline, with an average extension of 6 months. The average time to complete recruitment was 138% of the planned recruitment timeline. Board Members expressed interest in the study of community health workers in veterans' health and in how PCORI compares to other funders in terms of terminated studies and studies with suspended enrollment.
Transforming Research The Future of Health Research - *Robert M Califf, MD, MACC, Vice Chancellor for Health Data Science, Duke University*	Dr. Califf presented on the future of health research and learning health systems. He noted that US health systems are experiencing a paradigm shift where there is a surplus of patient information available and systems are greatly needed to properly utilize this data. He presented several descriptive statistics regarding life expectancy and mortality in the United States by county and then showed the national trend over the past several years. Califf also described US life expectancy and health expenditure compared to other countries. He then posed a question of "Why is the US different and moving in the opposite direction of other nations?" He posits that it could range from a variety of factors including the lag time between research knowledge generation and implementation. He noted that organizations like PCORI and initiatives like PCORnet, with strong stakeholder engagement, can impact health outcomes by streamlining clinical research, helping to disseminate new information more quickly, and aiding in implementation. Califf then discussed how research and health monitoring is improving and becoming more efficient in the digital age. He noted that health monitoring technology is becoming more available due to the increased use of electronic health records. Califf

	added that, in the future, predictive analytics could potentially enable surveillance of diseases, aid in early detection and diagnosis of conditions, predict a patient's risk of being hospitalized, and assist payers in predicting health care costs. He indicated that while there are significant advantages to this information surplus, given the current landscape of data breaches, privatization of personal data, and privacy concerns, policies governing use is needed. The Board then discussed the significant challenge in the lag time from clinical research result generation to implementation into practice. The Board also discussed the need to develop data privacy policies to govern the use of patient data.
PCORnet – ADAPTABLE Update - *Adrian F. Hernandez, MD, MHS and Elizabeth Shenkman, PhD, Co-Principal Investigators*	Dr. Hernandez presented an update on the PCORI-funded ADAPTABLE study, one of the PCORnet demonstration projects, which compares the effectiveness and safety of two daily doses of aspirin (81mg and 325 mg) in reducing major cardiovascular events in patients with a history of coronary artery disease. A secondary aim of the study is to develop, refine, and evaluate the PCORnet infrastructure for the conduct of clinical trials. Hernandez noted that ADAPTABLE is a large pragmatic trial aiming to enroll 15,000 patients across 40 PCORnet sites. After the initial year, the ADAPTABLE team updated the enrollment curve. The average monthly enrollment for the last 6 months has been 530 participants per month. Trial enrollment will continue until May 2019. He presented information on the demographics of enrolled participants and noted that only 1.7% of randomized participants have withdrawn consent. He also discussed the study team's approach to understanding patient outcomes. Hernandez also discussed early successes from the ADAPTABLE study including successful electronic approach of approximately 400,000 patients, continued recruitment of 500 participants per month, integration of Health Plan Research Networks, and successful virtual follow-up. Several challenges include migration of health encounters, inconsistent self-reporting of events, and difficulties as PCORnet transitions. He also noted that PCORnet investigators are beginning to build upon the groundwork laid by ADAPTABLE. PCORnet network partners are participating in an NHLBI funded study called INVESTED. This pragmatic trial is comparing outcomes of high versus low dose influenza vaccine in 9,300 high-risk cardiovascular patients. PCORnet is using a

	computable phenotype approach to electronically identify patients. Additionally, PCORnet is being used in a prospective cohort study of approximately 400 chronic heart failure patients to compare outcomes in patients initiated on sacubitril/valsartan compared to a cohort of similar chronic heart failure patients. Dr. Shenkman discussed future opportunities for PCORnet by building on the lessons from the demonstration studies. She noted that the network has strong engagement from important stakeholders including patients, clinicians, researchers, and health systems. She also discussed PCORnet capabilities for future studies by leveraging curated data, building on experience from demonstration projects and partnerships, developing real work evidence for observational studies, and focusing on implementation of evidence into practice. Following this presentation, a question was asked about the quality of the medication and laboratory data in PCORnet used for the ADAPTABLE study. Hernandez noted that PCORnet has data curation cycles to assess data quality. Despite differences in quality of the medication and laboratory data across networks participating in PCORnet, he noted the quality is improving over time.
Funding Commitment Plan - *Joe Selby, MD, MPH*	Dr. Selby introduced the proposed FY2019 funding commitment plan for consideration by the Board. The plan describes how PCORI expects to allocate funds based on revenues expected through FY2019. The plan provides guiderails for FY2019 commitments, not an immutable allocation of dollars, and significant departures from the plan would go back to the Board of Governors for approval. Additionally, Selby explained that for a large portion of the commitments planned for FY2019, the activities that would result in them began in FY2018, such as funding announcements made in FY2018 with letters of intent, applications, merit review, and selection committee already in process. Selby reviewed the overall commitment plan and each of the plan's funding categories. The proposed plan includes a total commitment through FY2021 of $2.75 billion. The proportion of funding was: 4 percent ($109 million) for engagement; 77 percent ($2,111 million) for research, including research in programs and research conducted in PCORnet; 4 percent ($122 million) for dissemination; and 15 percent ($413 million) for infrastructure (PCORnet and workforce development).

	Selby continued the presentation by reviewing the sub-categories that comprise each of the above categories of the commitment plan. Jean Slutsky, PCORI's Chief Engagement and Dissemination Officer, confirmed that the Pipeline to Proposal program is under evaluation and would be reviewed for additional funding upon PCORI's reauthorization. The presentation concluded with an overview of the commitment plan. No questions were posed by Board members. Selby turned the approval item over to Grayson Norquist, Board Chairperson, for consideration by the Board. *The following motion was made by Russell Howerton and seconded by Alicia Fernandez.* **Motion:** Approve the Proposed FY2019 Funding Commitment Plan. *Approved by a majority vote of the voting Board members (no opposed; no abstentions; no recusals). Ellen Sigal was not present for this vote.*
Strategic Plan Update - *Jean Slutsky, PA, MSPH, Chief Engagement and Dissemination Officer*	Ms. Slutsky presented an update on PCORI's strategic plan to fund shorter-term research products to meet decision maker needs. Themes that emerged from previous stakeholder convenings to assist individuals in making better-informed health care decisions include timely information sharing on emerging technologies and therapeutics, knowing what is on the horizon to help frame decision making and research priorities, and evidence from shorter-term research projects. Slutsky provided additional details, stating that horizon scanning will help payers, patients, clinicians, researchers, and PCORI identify new therapeutics and technologies before they enter the market. Reports on these technologies will provide clarity about available evidence and areas of uncertainty for decision makers. The first of the PCO-funded emerging technology reports will be on gene therapies. Rapid-cycle research and projects utilize PCORnet Collaborative Research Groups to answer useful questions for stakeholders. Evidence maps and systematic reviews will be used to identify research gaps and to help with evidence-informed decision making.

Public Comment - *Kristin Carman, MA, PhD*	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 4:28 pm

Minutes were approved by the PCORI Board of Governors 11-20-2018