



Patient-Centered Outcomes Research Institute Board of Governors Meeting

The Wink Hotel
1143 New Hampshire Ave, NW
Washington, DC 20036

September 7, 2018

Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Kerry Barnett, JD, *Vice Chairperson*; Debra Barksdale, PhD, RN; Larry Becker; Francis S. Collins, MD, PhD; Allen Douma, MD (via phone); Alicia Fernandez, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Russell Howerton, MD, FACS; Gail Hunt; Harlan Krumholz, MD, SM; Sharon Levine, MD; Freda Lewis-Hall, MD; Barbara McNeil, MD, PhD; Ellen Sigal, PhD; Kathleen Troeger, MPH; Robert Zwolak, MD, PhD

Board Members Absent:

Gopal Khanna, MBA; Richard Kuntz, MD, MSc

Methodology Committee Members Present:

Robin Newhouse, PhD, RN

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 Consider for Approval: • Minutes of August 21, 2018 Board Meeting – Grayson Norquist, MD, MSPH	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 <i>The following motion was made by Robert Zwolak and seconded by Larry Becker.</i> Motion: Approve the Minutes of the August 21, 2018 Board Meeting. <i>Approved by a majority vote of the voting Board members (no opposed, no abstentions); Francis Collins, Allen Douma, Gail Hunt, Harlan Krumholz, and Freda Lewis-Hall were not present for this vote.</i>
Executive Director's Report – Joe Selby, MD, MPH	Dr. Selby opened the report by noting that six of the founding PCORI Board of Governors members were rotating off the PCORI Board later this month. He highlighted the accomplishments those six members, as well as the larger Board, and what they helped to achieve during the past eight years since PCORI's founding. Highlights mentioned included funding over \$2.3 billion dollars for research studies and \$471 million dollars to support research infrastructure, engagement awards, and dissemination and implementation awards; releasing dozens of funding cycles to fund awards; building PCORnet, the National Patient-Centered Clinical Research Network, a large national data network; establishing standards and resources, such as the Methodology Standards and Engagement Rubric; and generating results from its funded research which now includes over 1300 publications associated with PCORI-funding. Selby presented on the efforts underway for the public reporting of PCORI peer-reviewed results. Several descriptive statistics were provided to demonstrate the progress made to make findings publicly available. At the time of presentation, 242 draft final research reports had been submitted, 101 abstracts of peer-reviewed findings had been posted, and 16 full final research reports were posted to PCORI's website. Selby reported on early results of PCORI funded-studies that were already being taken up into practice. Noted examples included PCORI-funded research studies cited in evidence-based clinical recommendations and policy documents. A PCORI-funded study was cited as a notable example of a shared decision-making tool in a Center for Medicaid and Medicare national coverage decision on implantable cardiac defibrillators, and another PCORI-funded study regarding peer mentoring among individuals with spinal cord injury was credited with influencing accreditation standards for rehabilitation facilities. Board members commented that the uptake of PCORI's early results was encouraging and that the examples provided gave evidence to the aspirations planned for PCORI's work.

	Selby acknowledged and thanked the six outgoing PCORI Board members. Debra Barksdale, Kerry Barnett, Allen Douma, Leah Hole-Marshall, Harlan Krumholz, and Richard Kuntz were thanked individually for their unique and valuable contributions to PCORI's continued efforts to support patient-centered research.
Consider for Approval: Policy for Data Management and Data Sharing - <i>Jason Gerson, PhD</i>	Dr. Gerson presented the final draft of the Policy for Data Management and Data Sharing for the Board of Governors' consideration and approval. The Policy is the third component of PCORI's Open Science Initiative which intends to make scientific research widely accessible to the public. The companion activities to the Policy include PCORI's Process for Peer Review of Primary Research and Public Release of Research Findings, which outlines the process for reviewing PCORI-funded primary research, and PCORI's Public Access to Journal Articles Presenting Findings from PCORI-Funded Research, which provides funding for public access to journal articles that present results. Gerson provided an overview of the Policy's creation and noted that deliberate input had been sought throughout its development. Activities to support solicitation included a public comment period, meetings with an Expert Advisory Group, discussions with peer funders and regulatory agencies, and regular interaction with PCORI's Research Transformation Committee. Additionally, a pilot project was conducted that brought together data repository organizations with PCORI awardees to assess technical and operational challenges related to implementing this Policy. Gerson provided an overview of the Policy's content. The Policy specifies data and data documentation to be shared; articulates expectations for data management and data sharing to awardees; provides funding to support PCORI awardees' time and effort to prepare data; specifies when data would be made available for third-party requests; describes the third-party data request review process; articulates criteria and review process regarding exemptions from Policy requirements. Gerson stressed that significant consideration had been given to the privacy and ethical protections of clinical research participants and the data intended for sharing would be only data that was de-identified in accordance with the HIPAA Privacy Rule. Board members discussed the various components outlined in the Policy. Discussion took place on the implementation issues that could arise for research studies whose informed consent was not broad enough to allow for sharing of participant data. Gerson noted that this was considered, and PCORI would work with awardees to discuss the considerations involved with and barriers to informed consent. For previously-funded research studies where participant information has already been collected, PCORI will review on a case-by-case basis. Regarding the timeframe for when data generated from PCORI-funded research studies would be made available for third-party requests, Board members inquired about the proposed sequencing. Gerson noted that under

	the Policy, data would be made available when the Final Research Report is made available on PCORI's website or when the research project's primary results are published in a peer reviewed journal, whichever comes first. Questions were asked about the definition of a "primary result" and what would prompt the process to start. Gerson noted that "primary results" applied to the pre-specified primary aim(s) as found in the research application. In cases where more than one primary aim is specified, upon the publication of one primary aim, data would be made available for third-party requests. Board members recommended PCORI consider and refine its approach to ensure data are made available in a timely manner and minimize the likelihood that principal investigators can unduly postpone making data available for third-party requests. The exemptions and waivers included in the Policy were also discussed. Board members recommended there be transparency around the research projects that are exempt from part or all of the Policy. Suggestions for promoting transparency included providing aggregate-level statistics on the number of research projects that received exemptions and waivers. In closing the presentation, Board members recommended collecting information and conducting performance improvement analyses to support PCORI's ability to learn from the Policy's implementation. Additionally, Board members encouraged PCORI to continue refining the Policy based on learnings from implementation and to position itself to inform other peer funders' experience with data sharing. Gerson noted that learning and refinement of the Policy would take place and expressed confidence for PCORI's place in the data sharing landscape. <i>The following motion was made by Ellen Sigal and seconded by Alicia Fernandez:</i> Motion: Approve the Policy for Data Management and Data Sharing <i>Approved by a majority vote of the voting Board members (no opposed, no abstentions and no recusals). Francis Collins was not present for this vote.</i>
Consider for Approval: PCORnet PPRN Special Emphasis Engagement PFA - Joe Selby, MD, MPH	Dr. Selby introduced the request to develop and release a limited competition Engagement Award PFA open to all Phase 2 PCORnet Patient-Powered Research Networks (PPRNs), which is being recommended for Board approval by both the Engagement, Dissemination and Implementation Committee and the Research Transformation Committee. He explained that the PPRNs have been an integral part of PCORnet and are clear examples of sophisticated patient-driven organizations. He reviewed a number of their achievements including the recently awarded Partnering to Conduct Research with PCORnet (PACR) awards. He noted that while the PPRNs are not part of the current PCORnet sustainability plans of the People-Centered Research Foundation (PCRF), PCORI has a strong interest in continuing a relationship with the PPRNs. To enable continued evolution of PPRNs, EDIC and RTC are recommending the development of a PFA for a limited competition Engagement Award PFA to be released in late October 2018 for awards up to \$350k for an 18-24-month period. The goals of this PFA would include: to help grow the PPRN research portfolios, further develop their

	expertise in the area of participant-driven research, and better position the PPRNs to engage with Clinical Data Research Networks (CDRNs) and PCRF. He noted that this proposal had already been reviewed and endorsed by the Research Transformation Committee (RTC) and the Engagement, Dissemination, and Implementation Committee (EDIC), and that the scope will be developed in collaboration between the Engagement staff, Research Infrastructure staff, and in consultation with the PPRNs. Following the presentation, there was a clarifying question on the criteria of the Engagement Award opportunity and metrics that emphasize the importance of capacity and ability to execute. Selby explained that the PFA details will be developed over the course of the next several weeks. Board members also suggested that PCORI staff consider future PPRN-focused research initiatives as well as a descriptive summary of the PPRNs to capture their experiences, accomplishments, and lessons learned. It was also suggested that PCORI should consider future initiatives led exclusively by community groups. <i>The following motion was made by Debra Barksdale and seconded by Gail Hunt:</i> Motion: Approve Development of PPRN Limited Competition Engagement Award PFA up to \$4M <i>Approved by a majority vote of the voting Board members (no opposed, no abstentions and no recusals).</i>
Strategic Plan Update 2018: - Joe Selby, MD, MPH	Dr. Selby reviewed the proposals for updating PCORI’s strategic plan from the February 2018 Board of Governor’s Meeting, focusing on the proposal to move toward greater specificity in all PCORI solicitations and more focus in the research portfolio. He described ways that PCORI could move toward more specific stakeholder-driven research questions and described the need for PCORI to have a robust list of stakeholder-driven research questions in the topic pipeline. Selby described the potential advantages of specifying an initial set of high-priority areas of research, listed possible criteria to identify topic areas, and shared some examples of topics that would meet most of those initial criteria. He shared the potential advantages of pre-vetting a set of research teams to compete for high-specificity topics, given the challenges of funding large trials, with the goal of spending less time in the application and review phase. Board members expressed support for the proposal to move toward greater specificity in seeking research applications. Some Board members expressed concerns around the idea of pre-vetting research teams, while others supported the idea. Board members provided suggestions for topics areas of potential focus, including high cost conditions, diagnostic testing, telehealth, and healthcare delivery. Members suggested the importance of finding the unique contribution that PCORI can make in topic areas that are already well-funded by other research funding entities.

Research Synthesis Methods: Evidence Maps: - <i>Jennifer Croswell, MD, MPH</i>	Dr. Croswell introduced the concept of evidence maps, noting that evidence maps use the same methodology as systematic reviews to produce a visual product. She described that evidence maps aim to identify key research gaps and help promote evidence-informed decision making. She shared examples of early evidence maps from the IOM, the VA, and one funded by PCORI. Croswell described that PCORI funded the development of its first interactive evidence map, which has been conducted by the ECRI Institute on the “Impact of mHealth for Self-Management of Chronic Disease on Patient-Centered Outcomes,” exploring the evidence landscape of mHealth interventions (e.g., text messages, mobile applications, wearable devices) for self-management of chronic disease. She demonstrated the interactive evidence maps on mHealth, pointing out areas of evidence gaps, and areas where PCORI is actively funding research. Board members expressed interest in making PCORI-funded completed evidence maps available to the public and patients to aid in decision-making. Croswell noted that staff is working on making these visual tools available via the PCORI website.
Panel Discussion with Outgoing Board Members	The Board members whose terms will end on September 22, 2018 were asked to present on their thoughts and experiences from serving on the PCORI Board. These members were Debra Barksdale, Kerry Barnett, Allen Douma (via phone), Leah Hole-Marshall and Harlan Krumholz. Richard Kuntz, whose term also ends on September 22, 2018, was not present. The panel was asked to comment on whether PCORI’s achievements to date have reached or come close to their early achievement goals, what choices stood out for them and whether they ever questioned the commitment that PCORI has made in involving patients and other stakeholders into the research process. The outgoing members expressed great satisfaction with the impact PCORI has made on patient involvement in research - “Research Done Differently” - despite what some believed to be a slow start. Some remembered wondering in the beginning what the dynamics on the Board would be, given their diverse backgrounds and interests, but all felt the Board has worked collaboratively, which has made PCORI a strong organization. They also indicated that, despite outside entities expressing uncertainty about the value of patients as partners in research, the Board stayed committed to this goal. While there may have been uncertainty about how best to reach this goal, the Board wanted PCORI to provide information that the public and patients care about most. It was also stated that knowing what the public and patients care about most benefits not only patients, but also other PCORI stakeholders, including industry, payers and clinicians. The outgoing Board members also noted that the work of PCORI includes not just finding out information about what treatments work best for which patients, but how to get that information to the right people, especially those who are financially marginalized. It was stated that PCORI has a great opportunity to find new and innovative ways to disseminate and facilitate implementation of evidence in real world situations.

	Staff was given the opportunity to ask questions of the outgoing Board members which included questions related to the Board's working relationship with PCORI staff and any advice they had for the seven incoming Board members. The panel expressed their reliance on staff and gratitude for the work they accomplish. The advice offered to new Board members included being patient, always asking why, and to dream big. Selby reminded these outgoing Board members of the upcoming September 18 Board meeting, which is expected to be their final PCORI Board meeting.
Public Comment — <i>Kristin Carman, MA, PhD</i>	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 - <i>Grayson Norquist, MD, MSPH</i>	Meeting ended at 2:38 pm

Minutes were approved by the PCORI Board of Governors 09-18-2018