PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting via Teleconference / Webinar

Tuesday, May 5, 2020

11:00 am - 2:30 pm ET

MINUTES

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

Board Members Absent:
Alicia Fernandez, MD; Michael Herndon, DO; Ellen Sigal, PhD

Guest Speakers: Chris Forrest, MD, PHD, Children's Hospital of Philadelphia and Susanna Naggie, MD, Duke Clinical Research Institute

Executive Team: Nakela Cook, MD, MPH, *Executive Director*; Josie Briggs, MD; Mary Hennessey, Esq.; Michele Orza, ScD, Tasha Parker, Jean Slutsky, PA, MSPH; Regina Yan, MA

Agenda Item	Related Minutes
Call to Order, Roll Call, and Welcome - *Christine Goertz, DC, PhD, Chairperson and Nakela Cook, MD, MPH, Executive Director*	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. Dr. Goertz acknowledged the contributions of Dr. Josephine Briggs who served as the Acting Executive Director and is now serving as the Acting Chief Science Officer. She also welcomed the new Executive Director, Dr. Nakela Cook, who joined PCORI on April 15, 2020. She then reviewed the meeting agenda.
Consider for Approval: • Minutes of the March 2 and April 1, 2020 Board Meetings • Proposed Amendments to PCORI Bylaws - *Christine Goertz, DC, PhD, Sharon Levine, MD, Chair, Governance Committee, and Mary Hennessey, General Counsel*	*The following motion was made by Sharon Levine and seconded by Freda Lewis-Hall.* **Motion:** Approve minutes from the March 2, 2020 and April 1, 2020 Board of Governors meetings. *Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions); Jennifer DeVoe and Janet Woodcock were not present for this vote.*

	Dr. Goertz then asked Sharon Levine, Chair of the Governance Committee, to introduce the proposed amendments to PCORI's Bylaws. Dr. Levine noted that PCORI's reauthorizing law includes new and revised provisions addressing governance that should be reflected in PCORI's Bylaws to maintain consistency and accuracy. Mary Hennessey then summarized the proposed amendments which track language in the reauthorization law relating to: - GAO's appointment of Board members regarding the preserving of evenly staggered terms of Board members and the process for filling vacancies created by Board members who leave the Board before the end of their term; - Shift in authority for the appointment of Methodology Committee members from the Comptroller General of the United States to the PCORI Board; - Updating the legal citation referenced from the authorizing law to the reauthorizing legislation; and, - Clarifying language confirming that Committees, working groups and ad hoc committees shall not exercise the power of the Board except as authorized by the Board. *The following motion was made by Robert Zwolak and seconded by Gail Hunt.* **Motion:** Approve the Amended Bylaws *Approved by a majority vote of the voting Board members by roll call (15 in favor; no opposed; no abstentions); Jennifer DeVoe and Janet Woodcock were not present for this vote.*
Executive Director's Report - *Nakela Cook, MD, MPH*	Dr. Nakela Cook introduced herself as PCORI's new Executive Director. She shared information on her educational and career background, and how it has shaped her path to PCORI. She acknowledged the effective efforts of staff in working together remotely during the COVID-19 pandemic and of the Board in shifting its work and meeting to a virtual format. Cook provided background on what she envisions for PCORI 2.0, opportunities for PCORI's future, and how PCORI can learn during a public health crisis. She brought attention to PCORI's opportunities to leverage innovations in healthcare to promote the science of delivery for improved outcomes. She brought

	focus to the urgency of addressing health disparities in the United States. She then outlined the opportunities that PCORI has to accelerate its impact on care delivery and patient health outcomes. Cook shared her vision for PCORI 2.0, as a cycle of evidence to implementation, integrating research and health care while leveraging data and technology. She stated that her first year focus will be on shared principles, onboarding, PCORI's response to the COVID-19 pandemic, National Priority setting, topic generation process, and other priorities stemming from PCORI's authorizing law. She outlined a collaborative strategy to advance this vision. Cook provided an overview of PCORI's approach in response to the COVID-19 health crisis. She shared PCORI's three priority areas: health care delivery, vulnerable populations, and health care workers. She described PCORI's approach including funding new awards, enhancing of existing awards, information sharing, and adapting existing processes for awardees and applicants. Board members expressed interest in what PCORI is hearing from awardees on how COVID-19 is affecting their research and other projects, and how PCORI is helping address the impact.
COVID-19 Response Update • Progress on COVID-19 Targeted PFA ○ **Consider for Approval** – alternative review and approval framework for awards under this PFA - *Nakela Cook, MD, MPH and Jason Gerson, PhD, Senior Program Officer, Clinical Effectiveness and Decision Science (CEDS)*	Dr. Gerson began the presentation by providing a brief update on PCORI's COVID-19 Targeted Funding Announcement. On April 1, 2020, the Board approved $30M for funding new research studies, dissemination and implementation projects, engagement projects, and projects using PCORnet. Now, PCORI plans to release a targeted research funding announcement on May 5, 2020 with 3 priority areas: 1. Adaptations to Healthcare Delivery 2. Impact of COVID-19 on vulnerable populations 3. Impact of COVID-19 on healthcare workforce well-being, management, and training Next, Dr. Cook provided some details on the accelerated timeline for this PFA. She explained that unlike others, this targeted PFA will not require an LOI from applicants and will receive expedited programmatic screening and merit review. The timeline for this award is as follows: • Preannouncement released 4/21/20 • PFA opens 5/5 • Applications due 5/26 • Merit Review on 6/23

	• Selection Committee on 6/30 • If needed, a Board meeting would be scheduled in early July. • The maximum project duration is 2 years, with primary outcomes reported within 12 months. Given the expedited timeline relating to this PFA, Dr. Cook provided the Board with three alternative approval options for awards under this solicitation: • Option 1: The Selection Committee approves slates of awards from the COVID-19 PFA • Option 2: The Executive Director approves slates of awards from the COVID-19 PFA after receiving recommendations from the Selection Committee. • Option 3: The Board of Governors approves slates of awards from the COVID-19 PFA after receiving recommendations from the Selection Committee. Board discussion focused on: • A general preference for Option 2 • A need for timely decisions for awards under this PFA • The possibility of adding more Board members to the Selection Committee for review of these awards • The opportunity for this new approval framework to inform the Board's approval alternatives for slates of awards in the future • The Executive Director's role in Option 1 vs Option 2 • The expertise of the Selection Committee and PCORI Science Staff to make informed decisions regarding the selection of these awards Cook and Gerson confirmed that applications will still undergo a rigorous merit review with external subject-matter experts. PCORI's merit review team is already identifying reviewers with expertise in relation to COVID-19. PCORI's secondary programmatic review would only look for the application's alignment with the PFA's goals and PCORI's portfolio and priorities. Regarding the Executive Director's role in Option 1 vs Option 2, Dr. Cook noted that the Executive Director would be kept informed of developments under Option 1 but would not conduct any pre-approvals or screenings of applications. *The following motion was made by Grayson Norquist and seconded by Gail Hunt.*

	Motion: That the Board approve: • That the Executive Director be authorized to approve slates of awards in FY20 recommended for funding by the Selection Committee from the COVID-19 PFA, consistent with the Board-approved funding commitment relating to COVID-19 projects (Option 2 above) *Approved by a majority vote of the voting Board members by roll call vote (15 in favor, 0 opposed; 0 abstained; 0 recusals). Jennifer DeVoe and Janet Woodcock were not present during this vote.*
Additional COVID-19 Response Updates • PCORnet HERO Registry and Trial *Josephine Briggs, MD, Acting Chief Science Officer, Christopher Forrest, MD, PhD, Children's Hospital of Philadelphia; Susanna Naggie, MD, Duke Clinical Research Institute*	Dr. Briggs began the update by noting that on April 1, 2020 the Board approved use of the mechanism of a PCORI-issued invitation to submit a proposal for funding of the Healthcare Worker Exposure Response and Outcomes (HERO) Registry and Hydroxychloroquine (HERO-HCQ) Trial and authorized the Executive Director to review, negotiate, and approve funding up to $50 million in total costs. PCORI issued the invitation and ultimately funded a strong application from Adrian Hernandez, MD at Duke University. The study team has assembled a Steering Committee to oversee the HERO Research Program co-chaired by Judith Currier, MD, MSc from the University of California, Los Angeles and Russell Rothman, MD, MPP from Vanderbilt University Medical Center. Briggs explained that PCORI convened an Advisory Panel to provide advice to the Executive Director about overall funding and monitoring questions and issues related to the HERO Research Program. She explained that the Panel does not serve the function of a Data and Safety Monitoring Board (DSMB) as establishing and overseeing the DSMB is the responsibility of the study sponsor, Duke University. Next, Briggs discussed the role of the HERO Registry. She explained that the role of the Registry is to facilitate the participation of health care workers (HCWs) as partners in research on COVID-19 issues. She noted that while studies of novel therapies and vaccines are outside of PCORI's legislative mandate, partnerships with other funders and collaborators on such studies is part of the Registry mandate. Briggs then introduced the Chair of the HERO Registry Sub-Committee, Christopher Forrest, MD, PhD, to provide more information on the Registry design and goals.

	Forrest began by noting that the Registry was launched on April 10, 2020 and currently has over 10,000 participants from all 50 states. Forrest echoed Briggs' remarks by stating that the Registry will not be limited to the HERO-HCQ trial but will facilitate future research opportunities within a community of healthcare workers to evaluate future tools and novel therapies. He explained that the Registry has three objectives including building a community of HCWs, offering participants opportunities to participate in research, and returning results to all participants. Forrest noted that eligibility for the registry is broad and meant to capture anyone over 18 who works in a healthcare facility and can read English or Spanish. He explained that the registry collects core information via periodic surveys to understand COVID-19 exposures and illness, access to personal protective equipment, and HCW concerns and burnout. Forrest also presented preliminary data including demographics, use of Personal Protective Equipment (PPE), concerns on the impact of the pandemic on HCW health and wellbeing, and other concerns about risk to exposure. He concluded his presentation by noting that these early aggregate Registry results will be returned to participants through email, the Registry website, and an interactive Town Hall event. Next, Briggs addressed the HERO-HCQ trial by explaining why studying hydroxychloroquine (HCQ) remains a priority. She explained that the combination of extensive use of HCQ combined with weak clinical evidence and safety concerns creates an urgent public health need for definitive studies. Briggs then introduced HERO-HCQ trial co-principal investigator Susanna Naggie, MD. Naggie provided additional background information on HCQ. She explained that HCQ has a long history of use and is widely prescribed with over 5 million prescriptions in the US in 2017. Naggie explained that while no large-scale studies comparing HCQ to other disease-modifying anti-rheumatic drugs (DMARDs) have been conducted, observational studies suggest it is generally safe. Additionally, the American College of Rheumatology identified HCQ as the DMARD with the least contraindications. She also noted that concerns over HCQ safety are regarding chronic usage. She explained that there is an increased risk of cardiovascular events when used in combination with Azithromycin. Naggie also stated that the most common side effects include nausea (at high dose), rash, and retinopathy (with prolonged use). Naggie noted that there are 15 treatment and 19 prevention studies in ClinicalTrials.gov. She added that there is a lack of

	information on the safety or efficacy of HCQ for prevention of COVID-19 in a well population. Naggie explained that the safety of HCW participants is of utmost importance. The HERO-HCQ trial is being conducted under an Investigational New Drug (IND) application with FDA oversight. Additionally, Duke has formed a DSMB for the trial that meets weekly to review safety events and to ensure severe unexpected events are identified and reported to the FDA. Naggie also noted that the HERO-HCQ trial protocol excludes any HCW at high risk for HCQ toxicity including HCW at high risk for QT prolongation, severe skin reactions, retinopathy, severe heart disease, or medications that can interact with HCQ. Briggs concluded the presentation by adding that the oversight and monitoring processes will enable safety and futility issues will be addressed promptly. She also explained that early termination is possible if indicated by either safety or futility. Lastly, Briggs described the rapid timeline for implementation of this study. After the presentation Goertz, opened the floor to discussion. The Board expressed enthusiasm for the rapid timeline for funding and implementation of the HERO Research Program. Several Board members noted concern regarding the lack of diversity among the initial Registry participants and inquired about strategies being employed to improve the diversity of Registry participants. Forrest explained that initial recruitment efforts were focused on hospitals participating in PCORnet and they are now reaching out to unions and professional societies as well as hospital leadership to get improve representation from those working in other roles in healthcare facilities. It was suggested that specific emphasis should be employees working in senior healthcare facilities and first line responders. There was also discussion about whether media coverage of HCQ has impacted trial enrollment. Naggie noted that they have not seen an impact yet and have successfully randomized 265 participants in just under two weeks. She also explained that they have created material for study sites to help facilitate discussions with participants. Naggie stated that the expectation for each site is to enroll 300 participants over a four to six-week period. She noted that one site has already enrolled over 150 participants. Lastly, one Board member noted that the HERO Research Program is an excellent example of why PCORI invested in developing PCORnet. PCORnet was always envisioned as a national resource to help answer important questions.

Enhancements of Existing Awards - *Steve Clauser, PhD, Program Director, HDDR*	********** PCORI is seeking ways to play a leading, meaningful, and responsive role in the national research response to the current threats of the novel coronavirus and COVID-19. On April 1, 2020, the Board approved up to $20M in funding allocation enabling the adaptation of currently funded research and other projects. In response to the Board's funding allocation, PCORI posted three funding opportunities to seek investigator-initiated proposals to address the COVID-19 public health crisis for active awardees under the Research, Engagement Awards, and Dissemination & Implementation award mechanisms. These enhancements must serve the original aims of the award and can include modest additions to existing aims and/or be an adjunct project that addresses COVID-19. The review will rely on existing departmental review and approval processes, with an added layer of cross-departmental input, to expedite review and approval of these enhancements. The Executive Director makes the final approval for all funding decisions following input and recommendations at the cross-departmental level. PCORI has already received proposals that offer ways to transform existing funded awards. It is anticipated that these enhancements will begin in mid-May. **********
Monitoring & Evaluating Impact of Pandemic on Our Work - *Laura Forsythe, PhD, MPH, Director, Evaluation and Analysis*	Dr. Forsythe presented on the expected effects of the COVID-19 pandemic on PCORI's award portfolio and the information that will be captured to understand and respond to those effects. Forsythe shared that the entire research enterprise, including PCORI, has been affected by the pandemic, particularly because of limits on in-person interactions and research activities. Forsythe outlined the metrics PCORI plans to track organized into two groups: those related primarily to the pandemic, and routine metrics part of the quarterly Dashboard that are likely to be affected by the pandemic. Metrics related to the pandemic include indicators about projects PCORI has already funded (e.g., changes to protocols and engagement plans and project delays or terminations related to the pandemic) and projects to be funded specifically to address the pandemic (e.g., quantity and quality of responses to COVID specific funding opportunities, dollars invested in projects to address the pandemic, expected impact of this body of studies). Routine metrics that may be affected include, as an example, the quantity and quality of

	response to typical funding announcements and project recruitment success. Forsythe noted that these metrics will capture both the challenges and the opportunities of the pandemic- for example, PCORI may see increased use of PCORnet in the context of the pandemic. Forsythe also noted that PCORI will capitalize on opportunities to learn about ways PCORI may improve its application and review processes going forward, based on efforts to expedite these processes in response to the pandemic.
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 Adjournment - *Christine Goertz, DC, PhD*	Meeting adjourned at 2:26 pm

Minutes were approved by the PCORI Board of Governors 06-23-2020