

Board of Governors Meeting via Teleconference / Webinar

Tuesday, June 23, 2020

1:00 – 3:00 pm ET

MINUTES

Board Members Present:

Christine Goertz, DC, PhD, *Chairperson*; Sharon Levine, MD, *Vice Chairperson*; Kara Ayers, PhD; Larry Becker; Francis Collins, MD, PhD; Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Christopher Frieze, PhD, RN; Michael Herndon, DO; Russell Howerton, MD; Gail Hunt; Freda Lewis-Hall, MD; Michelle McMurry-Heath, MD, PhD; David Meyers, MD (designee for Gopal Khanna, MBA); Barbara McNeil, MD, PhD; Grayson Norquist, MD, MSPH; Ellen Sigal, PhD; Kathleen Troeger, MPH; Robert Zwolak, MD, PhD

Board Members Absent:

Janet Woodcock, MD

Methodology Committee Chair: Steve Goodman, MD, MHS, PhD

Agenda Item	Related Minutes
Call to Order, Roll Call, and Welcome - Christine Goertz, DC, PhD, <i>Chairperson</i> and Nakela Cook, MD, MPH, <i>Executive Director</i>	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. She then reviewed the meeting agenda.
Consider for Approval: • Minutes of the May 5, 2020 Board Meeting - Christine Goertz, DC, PhD	<i>The following motion was made by Kathleen Troeger and seconded by Kara Ayers.</i> Motion: Approve minutes from the May 5, 2020 Board of Governors meeting. <i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions); Freda Lewis-Hall and Michelle McMurry-Heath were not present for this vote.</i>
Executive Director's Report - Nakela Cook, MD, MPH	<u>Dashboard</u> Dr. Cook presented the Q2-FY2020 Dashboard for the Board's review. The Dashboard demonstrated that the following 7 areas are green-flagged s (those that are on track): funds committed; research project performance; altmetric/attention to PCORI results; uptake into UpToDate®; other examples of update; results viewed on PCORI.org; and front door requests to PCORnet. Two areas are yellow-flagged (those that are off target by more than 10%): operational expenses; and speed of PCORI peer review. There were no red-flagged items (items that are off-target and in need of attention or action by the Board).

Cook provided an example of a completed PCORI-funded study, covering the sequence from results to uptake of findings. The PCORI-funded study compared the effectiveness of two behavioral health home approaches. The study found that both approaches significantly increased patient activation in care, engagement in primary and specialty care, and perceived mental health status. The success of this behavioral health home intervention in improving important outcomes and the use of novel diffusion strategies led to its uptake by forty-three additional providers across Pennsylvania. The completed study also led to PCORI funding two other awards for dissemination and implementation of the findings.

Board members expressed interest in shortening the time for PCORI's peer review process and proposed incorporating lessons learned from the recently funded COVID-19 initiatives on efforts to reduce timelines.

Mid-Year Financial Review

Cook presented the Mid-Year Financial Review for Board discussion. The FY2020 Mid-Year Financial review included a review of PCORI's estimated revenues and expenditures, the FY2020 revenue through March 31, 2020, cash balance and outstanding award obligations as of March 31, 2020, and FY2020 budget versus actuals based on the first six months of FY2020 (October 1, 2019 – March 31, 2020). Cook noted additional revenue from the PCORI Trust Fund was expected in August of FY2020 and the total revenue received may be affected by the unemployment rate which would impact the number of lives covered. PCORI is continuing to watch this. There were no additional questions following the presentation.

Overview of Funding Opportunities

Cook then provided an overview of current and future PCORI funding opportunities, including two slates of awards being considered at today's Board meeting. Several open funding opportunities were listed including the Phased Large Awards for Comparative Effectiveness Research. Cook noted consideration was given to the release of that funding announcement due to the COVID-19 pandemic and concerns about the research community's ability to respond. The upcoming Cycle 3 2020 Broad PCORI Funding Announcement was highlighted. The announcement will include special emphasis topics that align with PCORI's new legislatively mandated priorities: material mortality and intellectual and development disabilities.

Strategic Planning Process

Cook presented an overview of the planned activities and timeline that are expected to comprise the strategic planning process, including engaging stakeholders, refreshing the National Priorities, developing the Research Agenda, and commitment planning and related discussions. She indicated that it is anticipated the process will extend into the Fall of 2021, when the Board is expected to be

	presented with a strategic plan for adoption. Board members acknowledged there were new opportunities and challenges for public engagement via virtual platforms and other formats given the current public health environment. Board members also commented that the timeline was realistic and allowed for it to be a meaningful process to get important stakeholder input at every stage of the process. In addition to the timeline and general activities needed for planning, the creation of a Strategic Planning Working Group was discussed. The working group is intended to be comprised of Board members and senior staff. Working collaboratively, the group's purpose is to brainstorm, generate, review, and refine options during the planning process and bring their recommendations to the whole Board for wider discussion and consideration. Board members expressed support for such a working group and the ability to collaborate with staff during the process. The Board discussed ideas on how to make this initiative optimally successful. It was noted that the full Board should be involved in the overall process, with asynchronous timing for Board input as the strategic plan is being developed. The Chairperson invited Board members interested in participating in the Strategic Planning Work Group to respond to the subsequent email request.
Update on COVID-19 Initiatives • HERO Registry and Trial • COVID-19 Enhancements to Existing Projects • COVID-19 Targeted PFAs Consider for Approval: Additional Funding for COVID-19 Enhancements and Targeted PFAs - <i>Nakela Cook, MD, MPH</i>	Dr. Cook noted PCORI had launched a new biweekly horizon scan series on COVID-19-related topics, part of its Health Care Horizon Scanning System initiative. At the time of presentation, two scans had been made publicly available through PCORI's website. Cook presented an update on the PCORI-funded HERO Registry and Trial Program, led by investigators at Duke University. The presentation included an update on participant recruitment for both the registry and trial; a description of the oversight mechanisms of the HERO trial such as a Duke-formed study Data Safety Monitoring Board (DSMB) and an Advisory Panel on PCORI's funding ; and how the PCORnet® common data model was being used to provide information on demographics and pre-existing conditions for COVID-19 for a cohort of patients to support Center for Disease Control surveillance and development of a strategy for subsequent research. Discussion took place about how other studies looking at hydroxychloroquine (HCQ) have factored in on the continuation of the HERO Trial, which studies the effectiveness of hydroxychloroquine (HCQ) in preventing COVID-19 infections in U.S. healthcare workers. Cook noted the oversight entities will consider data generated by other studies which will inform whether the HERO trial will continue. The DSMB is considering relevant information from other HCQ trials and will continue to do so as it advises on the trial's proceeding. There is currently no safety signal requiring termination of the trial and Cook noted the oversight process

	allowed for diverse perspectives and expertise to be provided and deliberative consideration be given as the HERO Trial progresses. The presentation continued with a review of the other activities underway as part of PCORI's response to COVID-19 initiatives. Two PCORI funding announcements (PFAs) had been posted, a targeted announcement soliciting new research applications focused on COVID-19, and an Engagement Award Special Funding Award Opportunity. Cook reported both funding announcements attracted significant interest, received robust responses, and applications were currently under review. Cook also reported on the number of enhancements to existing PCORI-funded awards. In April 2020, PCORI posted three funding announcements to seek investigator-initiated proposals to address the COVID-19 public health crisis for current awardees in the form of enhancements. Over 150 awards have submitted proposals for enhancements to date, with proposals from all award types (research, dissemination and implementation, and engagement). Approved enhancements total \$16.9M at the time of presentation, with \$11.1M for research award enhancements, \$2.8M for dissemination and implementation award enhancements, and \$3.0M for engagement award enhancements. Additionally, awarded enhancements ranged across various health conditions and intervention strategies. The presentation highlighted three awards with funded enhancements, one from each of the research, dissemination and implementation, and engagement portfolios. The Board previously approved funding of \$20M) for COVID-19 related enhancements of currently funded projects and funding of \$30M for new projects from the targeted COVID-19 funding announcements. To fund meritorious proposals submitted to those announcements without delay, Cook then presented, for the Board's consideration, a request for additional funding of up to \$50M in additional funding for COVID-19-related enhancements to currently-funded projects and new projects funded via targeted PFAs. Cook noted additional funding was needed for several reasons including the rapidly-evolving nature of the COVID-19 pandemic; the high volume of meritorious applications from the research community for new projects submitted in response to Targeted PFAs; the high volume of meritorious proposals from current awardees for project enhancements; and PCORI's unique position to fund projects that provide answers to the challenging COVID-19 related dilemmas facing patients, caregivers, providers, health systems, and policymakers. Discussion took place around the need for PCORI to be connected to other funders' work in the COVID-19 space and be informed of efforts by others so PCORI-funded work could be collaborative and
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	cohesive rather than duplicative. Additionally, the idea that PCORI could synthesize the many COVID-19 initiatives that were underway as a kind of landscaping exercise was discussed. Although the Board commented that such a role (i.e., that of a data synthesizer) is difficult and complex. Board members encouraged PCORI to focus on other areas it was in a unique position to support. Board members also recommended consideration be given to application timelines as the research community's ability to respond to PFAs may be adversely impacted by the pandemic. The Board also encouraged consideration for funding longer-term questions related to COVID-19. <i>The following motion was made by Larry Becker and seconded by Robert Zwolak.</i> Motion: Approve an additional funding commitment of up to \$50M to fund COVID-19 related enhancements to existing projects and to fund new COVID-19 related projects, subject to the approval processes previously authorized by the Board at its April and May 2020 meetings for COVID-19 related enhancements to existing projects and new COVID-19 projects, to apply in FY2020 and FY2021. <i>Approved by a majority vote of the voting Board members by roll call (18 in favor; no opposed; no abstentions); Grayson Norquist was not present for this vote.</i>
Consider for Approval: Funding Announcement - Targeted PFA on Suicide Prevention: Brief Interventions for Youth - Robert Zwolak, MD, PhD, Chair, Science Oversight Committee and Els Houtsmuller, PhD, Associate Director, Healthcare Delivery and Disparities Research (HDDR)	Dr. Zwolak made introductory remarks on behalf of the Science Oversight Committee, which recommended that the Board approve this PFA for development and release, in June 2020, before turning it over to Dr. Houtsmuller to present the Targeted PFA. Houtsmuller explained the steps taken to select and develop this topic, including stakeholder interviews, meetings, and workshops, background research, literature reviews and discussions with other funders. She explained that studies under this PFA would compare the effectiveness of different brief interventions to reduce suicidality and improve outcomes for youth at increased risk for suicide, with a particular interest in tailored brief interventions for subpopulations at increased risk for suicidality. PCORI expects to fund 2-4 studies with a maximum project duration of 5 years, with a total amount requested of \$30M. Board discussion focused on: - the 5-year project duration period, - whether interventions will consider a participant's access to lethal means (ex. firearms), and - including youth with disabilities to the PFA as a vulnerable population. <i>The following motion was made by Russell Howerton and seconded by Freda Lewis-Hall.</i>

	Motion: Approve the development and release of Suicide Prevention: Brief Interventions for Youth Targeted PFA <i>Approved by a majority vote of the voting Board members by roll call (16 in favor; no opposed; no abstentions); David Meyers, Michelle McMurry-Heath, Grayson Norquist were not present for this vote.</i>
Consider for Approval: Award Slates • Cycle 3 2019 Broad PFAs Award Slate - <i>Barbara McNeil, MD, PhD, Chair, Selection Committee, and Stanley Ip, MD, Interim Program Director, Clinical Effectiveness and Decision Science (CEDS) and Steve Clauser, PhD, MPA, Program Director, Healthcare Delivery and Disparities Research (HDDR)</i> • Limited Competition Dissemination and Implementation PFA - <i>Lawrence Becker, Chair, Engagement, Dissemination, and Implementation Committee (EDIC) and Joanna Siegel, SM, ScD, Director, Dissemination and Implementation Program</i>	Dr. McNeil made introductory remarks on behalf of the Selection Committee and introduced Dr. Ip and Dr. Clauser to provide details regarding the proposed slate of awards being presented to the Board for approval. These projects were reviewed by the Selection Committee and recommended for Board approval in June 2020. Ip and Clauser then introduced the proposed slate for the Cycle 3 2019 Broad PFA Awards. The slate consists of ten research projects from four different priority areas: Addressing Disparities (3 recommended projects), Assessment of Prevention, Diagnosis, and Treatment Options (1 recommended project), Improving Healthcare Systems (4 recommended projects), and Improving Methods for Conducting PCOR (2 recommended projects). <i>The following motion was made by Larry Becker and seconded by Christopher Friese.</i> Motion: Approve funding for the recommended slate of awards from the Cycle 3 2019 Broad PFAs <i>Approved by a majority vote of the voting Board members by roll call (12 in favor; no opposed; no abstentions; 2 recusals – Sharon Levine and Barbara McNeil). Kara Ayers, David Meyers, Michelle McMurry-Heath, Grayson Norquist and Robert Zwolak were not present for this vote.</i> ***** Dr. Goertz then turned to Mr. Becker and Dr. Siegel to discuss the proposed funding slate for the Cycle 3 2019 <i>Limited Competition Implementation of PCORI-Funded Patient-Centered Outcomes Research Results</i> PFA. After Becker provided a brief description of the PFA, Siegel introduced the slate of D&I awards recommended by the EDIC. She then provided a brief description of the one project proposed for funding, “Implementing Best-Practice, Patient-Centered Venous Thromboembolism Prevention in Trauma Centers”. This award slate represented a total investment of \$1.4M out of the amount budgeted (per year) of \$9.0M. This was the third cycle of proposed funding related to this year’s budget. <i>The following motion was made by Sharon Levine and seconded by Gail Hunt.</i>

	Motion: Approve funding for the recommended award slate from the Cycle 3 2019 Limited Competition Implementation of PCORI-Funded Patient-Centered Outcomes Research Results PFA <i>Approved by a majority vote of the voting Board members by roll call (15 in favor; no opposed; no abstentions; 1 recusal – Jennifer DeVoe). David Meyers, Michelle McMurry-Heath, and Grayson Norquist were not present for this vote.</i>
Wrap up and Adjournment - Christine Goertz, DC, PhD	In order to adjourn in a timely manner, Dr. Goertz noted that time did not allow the Executive Director, Nakela Cook, to make her usual closing comments, and asked instead that Dr. Cook post any comments she would have wanted to make to the PCORI website. Meeting adjourned at 3:00 pm

Minutes were approved by the PCORI Board of Governors 07-21-2020

Attachment A: Projects Approved for the Cycle 3 2019 Broad PFA Awards

Program	Awarded Project
Addressing Disparities	Comparative Effectiveness of Individual Versus Group-level Interventions to Reduce HIV Risk among African Immigrant Women
	Diabetes Medical Nutrition Therapy in Southeastern African American Women
	Online Cognitive Behavioral Therapy for Depressive Symptoms in Rural Patients with Coronary Heart Disease
Assessment of Prevention, Diagnosis, and Treatment Options	Addressing Anxiety among Low-Risk Chest Pain Patients in the Emergency Department Setting
Improving Healthcare Systems	Elders Preserving Independence in the Community (EPIC)
	Comparing the Effectiveness of Two Approaches to Preventing Severe Hypoglycemia
	Comparing Fingerstick Blood Glucose Monitoring versus Continuous Glucose Monitoring in Primary Care
	Comparative Effectiveness Trial of Perioperative Telemonitoring for Functional Recovery and Symptoms
Improving Methods for Conducting PCOR	Missing Data When Transporting Treatment Effects from Clinical Trials to a Target Population
	An Efficient Distributed Learning Framework for Integrating Evidence In Clinical Research Networks