

Board of Governors Meeting via Teleconference / Webinar

Wednesday, April 1, 2020

11:15 am - 12:45 pm ET

MINUTES

Board Members Present:

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

Board Members Absent: Jennifer DeVoe, MD, DPhil

Agenda Item	PCORI Speakers
Call to Order, Roll Call, and Welcome - Christine Goertz, DC, PhD, <i>Chairperson</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.
Consider for Approval: PCORI Response to COVID-19, Requested Authorities and Funding Commitments - Larry Becker, <i>Chair, Finance and Administration Committee (FAC) and Josephine Briggs, MD, Interim Executive Director and Acting Chief Science Officer</i> • Funding a Large Research Project Using PCORnet® that Addresses Hydroxychloroquine (HCQ) for Prophylaxis	Larry Becker made opening remarks on behalf of the Finance and Administration Committee (FAC) and introduced the three initiatives PCORI is proposing to the Board relating to PCORI's response to COVID-19. The FAC reviewed these three proposals on March 27, 2020, and Becker confirmed that PCORI has available funding to support these proposals. Lastly, he emphasized the meaningful role PCORI could have in response to the coronavirus pandemic. Dr. Briggs began her presentation on the first proposal—PCORI funding of a large research project using PCORnet to address hydroxychloroquine (HCQ) for prophylaxis among healthcare workers (HCW). First, she noted that PCORI is uniquely positioned as a funder to produce and promote evidence-based information that matters to patients, clinicians, and the public. She indicated that existing infrastructure and mechanisms along with revised authorities granted by the Board will enhance PCORI's responsiveness to the global health crisis. PCORI could serve a leading role as a funder in the national research response to the coronavirus pandemic and address the many uncertainties that face the nation. She explained that the anticipated large research project would be conducted by the Duke Clinical Research Institute (DCRI) and leverage the PCORnet infrastructure. The research project funded by PCORI would include a registry study of HCWs and a randomized trial study to investigate if HCQ is effective compared with no HCQ for prophylaxis among HCWs. She explained that the mechanism

	through which PCORI would consider funding the proposed study would be through PCORI issuing a letter of invitation to DCRI to submit a proposal for the research project. She indicated that PCORnet is well equipped to be used for conducting a large research project of this magnitude due to its existing infrastructure, access to large numbers of HCWs and sites, large coordinating center, and ability to yield rapid results. Also, around 40 clinical research networks (CRNs) sites have already indicated their interest in participating in the registry and trial. Board discussion focused on: • how this large research project compares to other studies that are underway that will evaluate the effectiveness of HCQ use for prophylaxis • how the funded study is anticipated to address: • side effects and dosage of HCQ • when PCORI anticipates results from the funded study • whether the study team has considered the possibility of excluding HCWs who already have antibodies to the virus Briggs clarified that the study funded by PCORI will focus on pre-exposure prophylaxis. Also, she indicated that the funded study is expected to differ from other studies in its sample size (N=15,000 for the trial, N=100,000 for the registry), dosage of HCQ, and scientific issues raised. PCORI hopes that results from the research project will be available rapidly, ideally 3-4 months from the research project's start date. Finally, Briggs added that PCORI and the study team will be in close communication with others conducting or funding studies regarding HCQ to respond to findings and maximize flexibility. <i>The following motions were made by Robert Zwolak and seconded by Russell Howerton.</i> Motion: That the Board approve each of the Motions relating to funding a COVID-19 Large Research Project using PCORnet that Addresses HCQ for Prophylaxis as reflected below: • Use of the mechanism of a PCORI-issued invitation to submit a proposal for funding of this COVID-19 research project to be conducted using PCORnet, which PCORI would issue to the anticipated lead institution (which is a participant in PCORnet) and the related PI • Review, negotiation, and approval of the invited proposal and funding commitment under authority of the ED • A funding commitment up to \$50M total costs for funding the research project <i>Approved by a majority vote of the voting Board members by roll call vote (16 in favor; 0 opposed; 0 abstentions; 3 recusals: Christine Goertz, Freda Lewis-Hall and Barbara McNeil); Jennifer DeVoe</i>
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	<i>indicated earlier her intention to recuse but was not present at this meeting.</i>
Enabling Adaptation of Currently Funded Research and Other Projects with Additional PCORI Funding	Briggs turned to the second initiative for Board consideration, which would allow ongoing projects to adapt to the coronavirus pandemic. PCORI would allow investigators to modify their projects to accommodate necessary changes including moving to virtual environments, as well as to enhance their currently funded projects by adding new aims to address COVID-19. Potential topics for new aims include an evaluation of personal protection equipment for HCWs and the impact of COVID-19 on vulnerable populations. Briggs discussed the revisions to the typical approval processes for budget increases and the proposed modifications to the approval processes for increased funding and adding new aims relating to COVID-19. Board discussion focused on: - The need for rapid results - Outreach to awardees to alert them of new funding Larry Becker suggested that adding FY2020 to the motion would provide more clarity to the Board's intention. Members of the Board agreed. <i>The following motions were made by Larry Becker and seconded by Gail Hunt.</i> Motion: That the Board approve each of the Motions relating to Adaptation of Currently Funded Research and other Projects with Additional PCORI Funding for FY2020 as reflected below: - The ED be authorized to develop and implement a process for reviewing and approving all changes in scope, aims, or goals of research and other projects relating to the response to COVID-19 and/or to expand the research and other projects to result in info and/or findings relating to COVID-19 w/o approval by the relevant board-related committee for FY 2020 - The ED be authorized to approve budget increases for existing research and other projects relating to the response to COVID-19 and/or to expand the research and other projects to result in info and/or findings relating to covid-19, including in amounts that exceed \$1M, with notification of all approvals granted by the ED of over of over \$1M for a study or project provided to the relevant board-related committee and the FAC within 30 days of approval for FY2020 - A funding commitment of up to \$20M total costs for FY2020 for award funding increases for research and other projects related to the response to and addressing changes appropriate due to COVID-19 <i>Approved by a majority vote of the voting Board members by roll call vote (19 in favor; 0 opposed; 0 abstentions; 0 recusals)</i>

Utilizing Existing PCORI Authorities and Programs to Address COVID-19	Dr. Briggs presented the third initiative PCORI is proposing to the Board. The first part of this opportunity would use current Board-approved authority for Executive Director Rapid Response Funding. The second part would allow for planning for funding new research studies, dissemination and implementation projects, engagement projects, and projects using PCORnet. These two funding commitments would allow for rapid response activities and others that could respond to the current public health crisis. Board members highlighted PCORI's unique ability to bring patients into the discussion, and the potential to study how patients coped with the adjustment to telehealth. <i>The following motions were made by Ellen Sigal and seconded by Freda Lewis-Hall.</i> Motion: That the Board approve Motions relating to Utilizing PCORI Authorities and Programs to Address COVID-19: Executive Director Rapid Response and Programs for Funding Research and other projects with appropriate funding commitments as reflected below: - An additional commitment of \$10M for the FY2020 budget for the ED's Rapid Response Award authority for rapid response awards relating to COVID-19 - A commitment of \$30M to be available for funding COVID-19 related research, dissemination and implementation, and engagement projects to be funded in FY2020 and FY2021 <i>Approved by a majority vote of the voting Board members by roll call vote (19 in favor; 0 opposed; 0 abstentions; 0 recusals)</i>
Wrap up and Adjournment <i>Josephine Briggs, MD</i> - - <i>Christine Goertz, DC, PhD</i>	Dr. Goertz and Dr. Norquist recognized that this meeting was Dr. Briggs' last Board meeting as Interim Executive Director. They expressed heartfelt gratitude to Dr. Briggs for the tremendous job she has done as PCORI's Interim Executive Director. Briggs announced that the Government Accountability Office has just released a notice in the Federal Register requesting nominations for the PCORI Board of Governors. She encouraged everyone to think about who would be well suited to contribute to the PCORI Board and PCORI mission and encourage self-nomination or nominations by organizations. GAO has indicated that it will accept nominations until May 13, 2020. Meeting ended at 12:19 pm

Minutes were approved by the PCORI Board of Governors 05-05-2020