

Board of Governors Meeting

Teleconference/Webinar

April 1, 2020

11:15 AM – 12:45 PM EST

Welcome and Introductions

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Agenda



11:15 –11:20 am

Call to Order, Roll Call, and Welcome

Consider for Approval: PCORI Response to COVID-19, Requested Authorities and Funding Commitments

11:20 – 12:45

- Funding a Large Research Project Using PCORnet[®] that Addresses Hydroxychloroquine (HCQ) for Prophylaxis
- Enabling Adaptation of Currently Funded Projects with Additional PCORI Funding
- Utilizing Existing PCORI Authorities and Programs to Address COVID-19

12:45 pm

Wrap up and Adjournment

PCORI Response to COVID-19 FAC-Recommended Authorities and Funding Commitments

Larry Becker, Chair

Finance and Administration Committee (FAC)

Josephine Briggs, MD

Interim Executive Director and Acting Chief Science Officer

Responding to COVID-19



- PCORI is uniquely positioned to produce and promote evidence-based information that matters to patients, clinicians, and the public. Currently-funded work has resulted in infrastructure and mechanisms that facilitate a rapid response. New authorities will help to enhance PCORI's responsiveness to pressing needs.
- The following presentation:
 - Outlines ways PCORI could serve a leading and meaningful role in the national research response and help address the many uncertainties that face the nation
 - Recommends for the Board's consideration a suite of opportunities PCORI could quickly act upon to enhance and support understanding of this novel pandemic
- Plans and priorities have been informed by knowledge of other US and international funders that are similarly planning to support responsive research.

Key Themes and Decision Points for This Meeting



- COVID-19 response as a priority for PCORI
- Funding allocation for COVID-19 of a total of \$110M
- Enhanced authorities to support flexibility of PCORI-funded COVID-19 Response projects

Overview

Opportunity	Activity	Requested Authority & Funding Commitment*
Funding a large research project	Funding a large research project: registry study of healthcare workers and randomized trial addressing hydroxychloroquine (HCQ) for prophylaxis	• Use of proposal-invitation mechanism to institution participating in PCORnet • Executive Director authority to review, negotiate, and approve proposal and funding • Up to \$50M
Enabling existing projects to address COVID-19	Enabling adaptation of currently funded projects	• Executive Director authority to review and approve changes to research and project plans • Executive Director authority to approve budget increases for (>\$1M) and/or expand existing research and other projects; notifying relevant Board-related Committee and FAC w/in 30 days • Up to \$20M
Utilizing existing authorities and programs to address COVID-19	Using the current Board-approved Executive Director authority for Rapid Response funding	• No New Authority Requested • Up to \$10M
	Current programs for funding new research studies, dissemination and implementation projects, engagement projects, and projects using PCORnet	• No New Authority Requested • Up to \$30M

Funding a Large Research Project: Registry Study of Healthcare Workers and Randomized Trial Study Using PCORnet[®] that Addresses HCC for Prophylaxis

Proposed Large Research Project: Significance



- **Ongoing international concerns of risks to healthcare workers (HCW)**
 - Reported rates of HCW conversion to COVID-19 positive status ~20%
 - Need to protect frontline HCW from clinical infection or becoming transmission vectors
 - High risk HCW (e.g., those in intensive care unit at time of intubation or resuscitation) when larger amounts of aerosolized virus present
- **No existing prophylactic therapy for COVID-19**
- **Complements ongoing research efforts from other US and international funders** (e.g., post-exposure prophylaxis)
- **PCORI has the opportunity to produce and promote actionable evidence in response to the emerging public health crisis**
 - This is a test of our ability to meet this priority rapidly

Proposed Large Research Project: Healthcare Worker Exposure Response and Outcomes (HERO) Registry and Trial



- PCORnet infrastructure will enable the **rapid** establishment of a large-scale **registry** and **randomized controlled trial**
 - Anticipated prime awardee Duke Clinical Research Institute (DCRI) serves as PCORnet Coordinating Center
- **Guiding Principles:**
 - Integrates fully with HCW lives to minimize burden and disruptions to workflow
 - Super rapid enrollment and reporting
 - Regulatory compliant and ethically sound
- **Targeted start date for research project: Early April**
 - Target start date for registry: Early April
 - Target start date for trial: Late April

Proposed Large Research Project: Healthcare Worker Exposure Response and Outcomes (HERO) Registry and Trial



- **Registry component (N=100,000):**
 - Create a **dataset of basic clinical and environmental COVID-19 risk factors** and clinical and emotional outcomes **for future analysis**
 - Identify HCWs interested in engaging in upcoming clinical trials related to COVID-19 and obtain preferences and willingness regarding randomization
 - Create a community of HCWs who may be at risk of COVID-19 infection
- **Trial component (N=15,000):** Evaluate the efficacy of hydroxychloroquine (HCQ) to prevent COVID-19 clinical infections in healthcare workers (HCW) as compared to placebo

~40 PCORnet CRN sites are interested in participating



Proposed Large Research Project: Trial Details

PICOTS	Details
Population	Healthcare workers (N=15,000)
Intervention	Hydroxychloroquine (HCQ) for pre-exposure prophylaxis
Comparators	Usual Care + Placebo versus Usual Care + HCQ
Outcomes	<i>Primary:</i> Prevention of clinical infection with COVID-19 <i>Secondary:</i> Efficacy of HCQ to prevent viral shedding of COVID-19 and to describe safety of HCQ
Timing	Testing as warranted by clinical presentation; seroconversion measured at 1 month
Setting	Hospitals and clinics

Proposed Large Research Project: MOTION



That the Board approve:

- 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 the authority of the Executive Director
- A funding commitment up to \$50M total costs for funding the research project

Proposed Large Research Project: Board Vote

Call for a Motion to:

- **Approve** each of the Motions relating to funding a COVID-19 Large Research Project using PCORnet that Addresses HCQ for Prophylaxis

Call for the Motion to be Seconded:

- **Second** the Motion
- If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Roll Call Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions

Enabling Adaptation of Currently Funded Projects



Adapting Current Projects

While the current health care crisis presents significant challenges for research plans, it also provides **opportunities for testing new approaches and measuring the effects of resultant changes to care provision and study execution**

- Investigators have already been inquiring about opportunities to modify their plans to address COVID-19, including adapting plans for virtual environments and/or including new arms or aims that address COVID-19.
- Some examples of topics for new aims might include an evaluation of:
 - Efficient use of personal protective equipment in healthcare workers
 - The effect of COVID-19 in patients with immunocompromised conditions
 - The challenges of rapid implementation of telemedicine encounters
 - The impact of COVID-19 in vulnerable populations

Adapting Current Projects: MOTION



That the Board approve:

- The Executive Director 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 information and/or findings relating to COVID-19 without approval by the relevant Board-related Committee
- The Executive Director 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 information and/or findings relating to COVID-19, including in amounts that exceed \$1M, with notification of all approvals granted by the Executive Director of over \$1M for a study or project provided to the relevant Board-related Committee and the FAC within 30 days of approval
- 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

Adapting Current Projects: Board Vote

Call for a Motion to:

- **Approve** each of the Motions relating to Adaptation of Currently Funded Research and other Projects with Additional PCORI Funding

Call for the Motion to be Seconded:

- **Second** the Motion
- If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Roll Call Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions

Utilizing Existing PCORI Authorities and Programs to Address COVID-19

- Executive Director Rapid Response
- Programs for Funding Research and Other Projects

Utilizing Existing PCORI Authorities and Programs to Address COVID-19



- PCORI's existing funding framework includes authorities and programs that can be utilized to address COVID-19 with appropriate Board-approved funding commitments:
 - **Current Executive Director Rapid Response**
 - \$500K or less—Executive Director approves with consultation with the Board Chairperson and Board Vice Chairperson; and
 - Over \$500K—approval of one of: Board Chairperson, Board Vice Chairperson or Chair of FAC—with consultation with the Executive Director.
 - Opportunities may include rapid-response studies that can provide quick answers to pressing questions related to COVID-19
- **Current Programs for Funding Research and Other Projects**
 - PCORI has well-established funding programs for research studies, dissemination and implementation projects, engagement projects, and projects using PCORnet that can be utilized for topics relating to the COVID-19 response
 - Opportunities may include a comparison of approaches to population-level screening and topics may also be proposed to PCORI by stakeholders involved in the country's response

Utilizing Existing PCORI Authorities: MOTION



That the Board approve:

- An additional commitment of \$10M for the FY2020 budget for the Executive Director'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

Utilizing Existing PCORI Authorities: Board Vote



Call for a Motion to:

- **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

Call for the Motion to be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Roll Call Vote:

- Vote to **Approve** the **Final** Motion
 - Ask for votes in favor, opposed, and abstentions

Wrap Up and Adjournment

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