

# Update on COVID-19 Initiatives and Request for Additional Funding

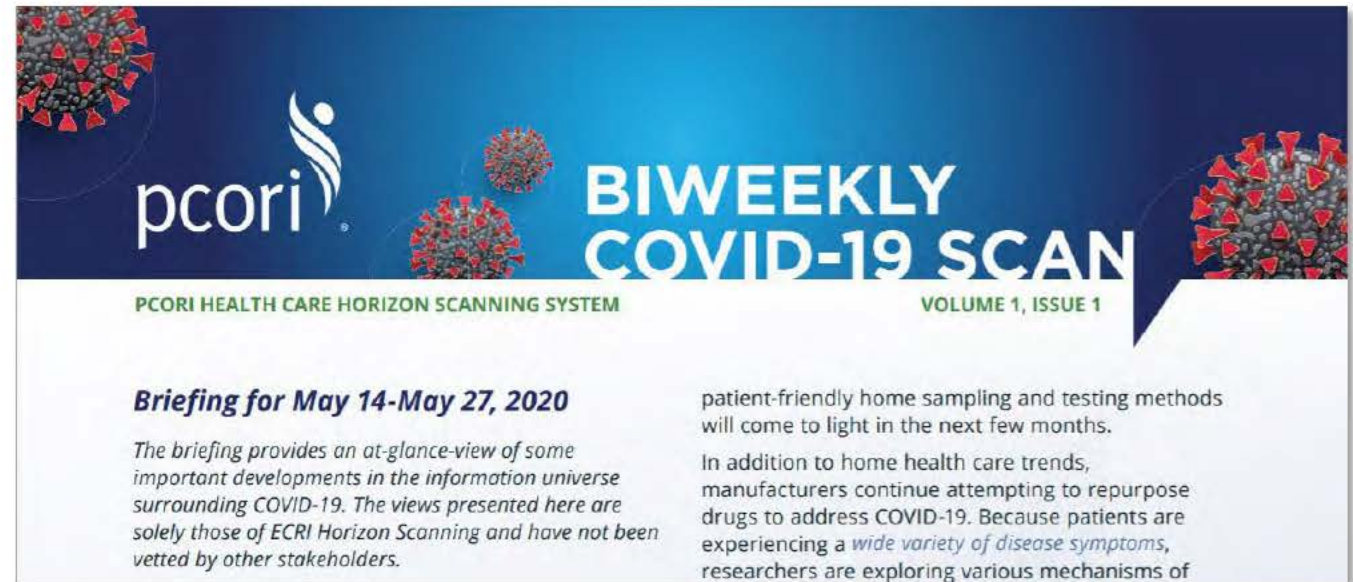
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Nakela Cook, MD, MPH  
Executive Director

# Bi-Weekly COVID-19 Horizon Scan



- PCORI has launched a new briefing on COVID-19-related topics that could potentially affect health care in the United States within the next 12 months
- Horizon scanning is a systematic process that serves as an early warning system to inform decision makers about possible future opportunities and threats.
- The first scan discusses a home testing kit and the potential repurposing of the drug anakinra for treating patients with COVID-19 who are experiencing acute respiratory distress syndrome and hyperinflammation



# PCORI-Funded HERO Research Program



**Project Title:** Preventing COVID-19 Infections: Healthcare Worker Exposure Response and Outcomes (HERO) Registry and Hydroxychloroquine (HERO-HCQ) Trial Program

**Principal Investigators:** Adrian Hernandez, MD, MHS; Emily O'Brien, PhD (HERO registry); Susanna Naggie, MD (HERO-HCQ trial)

**Awardee Institution:** Duke University

## HERO Registry

- Create a community of healthcare workers (HCWs) who may be at risk of COVID-19 infection
- Identify HCWs interested in engaging in upcoming clinical trials related to COVID-19 and obtain preferences and willingness regarding participation
- Create a dataset of basic clinical and environmental COVID-19 risk factors and clinical and emotional outcomes for analysis
- Recruitment goal for the HERO registry is 100,000 HCWs

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## HERO-HCQ Trial

- Will randomize 15,000 at-risk HCWs into a randomized clinical trial to evaluate the efficacy of hydroxychloroquine (HCQ) to prevent COVID-19 clinical infection in HCWs
- HCWs eligible for the HERO-HCQ trial will work at one of the 40 PCORnet sites participating in the trial
- Secondary aims:
  - To evaluate the efficacy of HCQ to prevent viral shedding of SARS-CoV-2 among HCWs
  - Evaluate safety and tolerability of HCQ

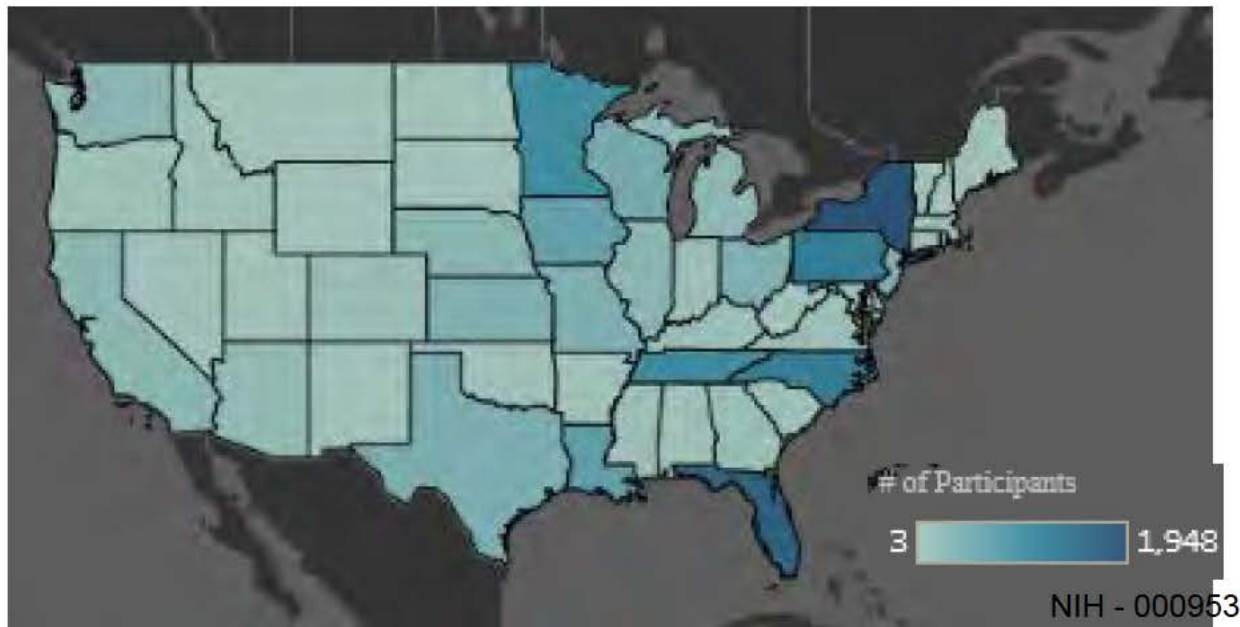


# HERO Registry Coverage and Trial Enrollment



## HERO Registry

- 14,535 participants have signed the registry consent
  - Covers all 50 states



## HERO-HCQ Trial

- 32 sites activated
- **28 sites have enrolled 918 participants**

As of June 15, 2020

# Oversight of the HERO-HCQ RCT

- The **HERO-HCQ** trial oversight mechanisms include the following:
  - Trial conducted under Investigational New Drug Safety FDA requirements
  - Data Safety and Monitoring Board established by the sponsor
    - DSMB is engaged with other DSMBs of large COVID-19 related trials
    - Recommend continuation, revision or discontinuation of protocol
  - Trial subject to Institutional Review Board (IRB) review
- Monitoring processes assure effectiveness, safety, or futility issues will be addressed promptly
- Consistent with best practices for RCT oversight, early termination is possible if indicated by either safety or futility
- PCORI Advisory Panel advises PCORI's ED about overall funding and monitoring questions and issues
- PCORI contractual mechanism and processes reduce financial impact of early termination

# PCORnet COVID-19 Common Data Model Background



- PCORnet is working to characterize the cohort of COVID-19 patients and provide detailed information on demographics and pre-existing conditions through weekly queries
- Purpose:
  - To support CDC surveillance and develop a strategy for longer-term COVID-19 research
- Approach:
  - PCORnet networks are creating a stand-alone version of the Common Data Model (CDM) that includes a subset of patients with respiratory illness since January 2020
  - Employing modified workflows to allow data refreshes much faster (days vs 3 months)
  - Query is reissued weekly, so sites have an opportunity to join once they are ready
- Inclusion criteria:
  - Diagnosis codes for COVID-19
  - COVID-19 antigen lab codes
- Query information:
  - Demographics and state
  - Care setting
  - Preexisting conditions and prescriptions for or medication administration of drugs of interest

# COVID-19 Enhancement – Use Cases

## Research Ready COVID-19 CDM



- PCORnet Coordinating Center and networks are expanding scope of work to:
  - Add non-CDM data of interest
    - COVID-19+ flag
    - SARS-CoV-2 test results (antigen & antibody)
    - Select medication use: e.g., Remdesivir use (order / administration)
    - Admission to ICU / Use of mechanical ventilation
- Partnership with CDC to support weekly information refresh needed for CDC surveillance activities
  - Broad network participation
- Partnership with Reagan-Udall and the COVID-19 Evidence Accelerator
  - Utilize vanguard sites
  - Optimize and rigorously validate key COVID-19 elements
  - Curate and validate to establish Research Ready Data fit for purpose
  - Proposed use case: treatment and outcomes associated with COVID-19 coagulopathy
- Partnership with NHLBI and NICHD on MIS-C

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# Posting of COVID-19 PFAs for New Awards



- In May 2020, PCORI posted a COVID-19 **Targeted Funding Announcement** for new research studies, with three priority areas:
  - Adaptations to healthcare delivery
  - Impact of COVID-19 on vulnerable populations
  - Impact of COVID-19 on healthcare workforce well-being, management, and training
- PCORI also posted an **Engagement Award** Special Funding Award Opportunity to support projects that help communities increase their capacity to participate across all phases of the PCOR/CER process, while responding to contextual changes as a result of the COVID-19 pandemic.
- Both PFAs attracted significant interest, received a robust response, and applications are currently under review



# Update on Applications Submitted in Response to COVID-19 PFAs for New Awards

Obtained via FOIA by Judicial Watch, Inc.



- Both COVID-19 PFAs attracted significant interest
- Targeted **Research** Funding Announcement for COVID-19:
  - Hundreds of applications submitted
  - 2 rounds of Merit Review planned
- **Engagement Award** Special Funding Award Opportunity:
  - Robust response, now under review

# COVID-19 Targeted PFA: Research Award Examples

Obtained via FOIA by Judicial Watch, Inc.



- Promising applications propose research on topics that include:
  - Psychological distress among healthcare workers
  - Prevention of COVID-19 in nursing homes
  - Homelessness, supportive housing, and COVID-19
  - Strategies for infection control (e.g., shelter-in-place)
  - Interventions to mitigate impact of COVID-19 among vulnerable/racial minority populations

# Update on Enhancements for Currently Funded Projects



- 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**
- PCORI has already received a high volume of proposals that offer exciting ways to transform existing funded awards that serve the award's original aims and result in findings related to COVID-19
- **Over 150 awards have submitted proposals** for Enhancements to date, with proposals from all award types (Research, D&I, and Engagement)
  - Approved Enhancements total \$16.9M to-date
    - \$11.1M in Research Enhancements
    - \$2.8M in D&I Enhancements
    - \$3.0M in Engagement Enhancements

# Funded Enhancements

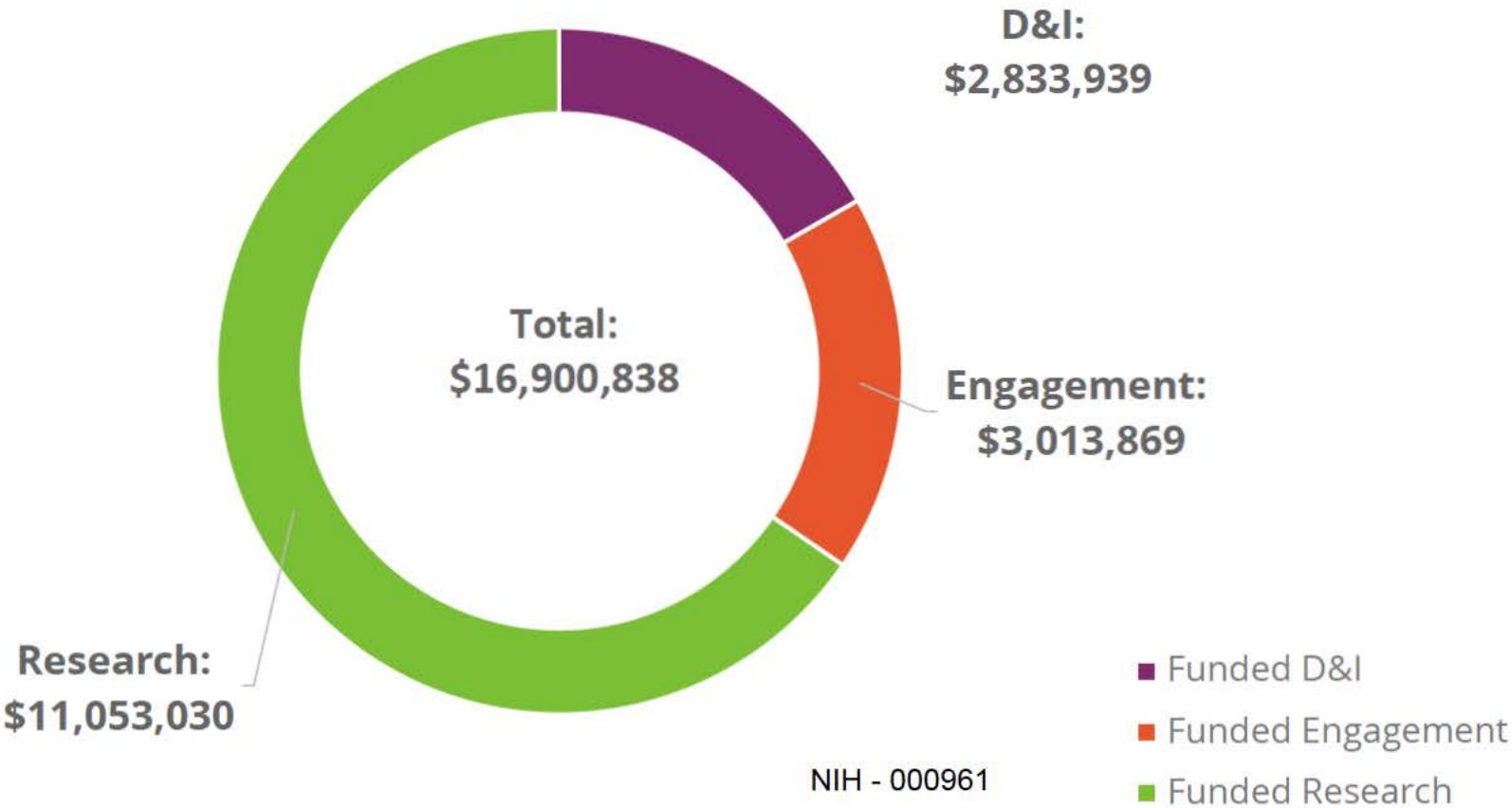
Total Budget = \$20M

Obtained via FOIA by Judicial Watch, Inc.



## Estimated Total Approved Dollars for Enhancements

Last updated: June 12, 2020



# COVID-19 Enhancements – Current PCORI Funding

Obtained via FOIA by Judicial Watch, Inc.

Health Condition	Research Awards & Intervention Strategy									Dissemination & Implementation Awards	Engagement Awards
	Drug	Other Clinical	Health Services	Tele-medicine	Training & Education	Screening	Tech-nology	Behavioral Inter-ventions	N/A		
Cancer											
Cardiovascular Diseases											
Gastrointestinal Disorders											
Genetic Disorders											
Infectious Diseases											
Mental/Behavioral Health											
Muscular & Skeletal Disorders											
Neurological Disorders											
Nutritional & Metabolic Disorders											
Rare Disease											
Reproductive & Perinatal Health											
Respiratory Diseases											
Other or Non-Disease Specific											



# A Stakeholder-Driven Comparative Effectiveness Study of Treatments to Prevent Coronary Artery Damage in Patients with Resistant Kawasaki Disease



## Enhancement Research Question

- Seeks to characterize and compare a significant new pediatric inflammatory condition with similarities to Kawasaki disease (KD) and which has emerged in communities heavily affected by COVID-19. The team will compare clinical data and laboratory samples from three groups of patients: typical KD prior to Covid-19, typical KD during Covid-19, and PIMS patients.

The current award seeks to test the superiority of infliximab to a second intravenous immunoglobulin (IVIG) infusion for treatment of persistent or recrudescant fever in children with KD, who fail to become afebrile after the first IVIG infusion.

## Potential Impact of Enhancement

- This will further characterize COVID-related PMIS and offers the opportunity to better understand two rare diseases with significant morbidity.

## Methods

- Observational study

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*Jane Burns, MD  
University of California, San Diego*

*Assessment of Prevention, Diagnosis, and  
Treatment Options,  
Awarded December 2016*

# Expanding access to the Infusion Center Model for People Living with Sickle Cell Disease (SCD)



## Enhancement Activities

- Aims include 1) conducting a robust evaluation of telemedicine on access to care, patient experience and health outcomes for adults with SCD; and 2) assessing barriers and facilitators, potential benefits and risks, and satisfaction with telemedicine visits using semi structured qualitative interviews with adults living with SCD.

## Potential Impact of Enhancement

- This enhancement includes an evaluation of telemedicine as a viable option to improve outcomes and broaden access to care for adults living with SCD. If telemedicine proves to be valuable for adults living with SCD, it will be incorporated into the implementation toolkit that is being developed as a component of the original award.

Current award aims to understand the barriers and facilitators to successful implementation of an infusion clinic (IC) model for adults with SCD diverse group of key stakeholders. The objective of this award is to identify the best strategies for broad implementation of the model and develop, test, and evaluate an implementation toolkit.

*Sophie Lanzkron, MD, MHS  
Johns Hopkins School of Medicine*

*Capacity Building,  
Awarded November 2019*

# Broad Implementation of Outpatient Stewardship (BIOS) Study



## Enhancement Activities

- Pediatric outpatient settings have seen a dramatic shift to telehealth. Evidence suggests that antibiotic stewardship is less effective in telemedicine than during in-person visits. This enhancement will adapt educational content for clinicians, audit-and-feedback reports, and practice facilitation to address appropriate antibiotic prescribing for acute respiratory illnesses (ARTIs) during telemedicine visits.

## Potential Impact of Enhancement

- Supports national goals for antibiotic stewardship, benefiting the public as well as children with ARTIs, for whom over-prescription of broad-spectrum antibiotics can cause unnecessary side effects such as diarrhea and vomiting. It is of immediate and ongoing relevance for improving outcomes for this target population.

Antibiotics are the most commonly prescribed medication for children, primarily in outpatient settings for treatment of acute respiratory tract infections (ARTIs). Contrary to current guidelines, many children are prescribed broad-spectrum rather than narrow-spectrum antibiotics as first-line treatment. The original D&I projects adapts and implements a tested antibiotic stewardship program to improve outpatient prescribing at 350,000 ARTI visits in diverse practice settings across 5 health systems.

*Jeffrey Gerber, MD, PhD  
Children's Hospital of Philadelphia*

*Implementation of PCORI's Major Research Investments  
Awarded November 2019*

# Consider for Approval: Additional Funding for COVID-19-Related Project Enhancements and COVID-19 Targeted PFAs

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Nakela Cook, MD, MPH  
Executive Director

# Background on COVID-19 Funding Approval



- On April 1, 2020, the Board approved up to \$110M in total for COVID-19-Related Funding:
  - \$50M for the HERO Registry and Trial
  - **\$20M for COVID-19-related enhancements of currently-funded projects**
  - **\$30M for funding new projects from targeted COVID-19 PFAs**
  - \$10M for Rapid Response Fund
- In order to be able to fund meritorious proposals without delay we request up to \$50M in additional funding for COVID-19-related:
  - Enhancements to currently-funded projects
  - New projects funded via targeted PFAs



# Rationale for Additional Funding for COVID-19-Related Project Enhancements and Targeted PFAs



- We are requesting up to \$50M in additional funding for COVID-19-Related Project Enhancements and the COVID-19 Targeted PFAs for the following reasons:
  - The rapidly-evolving nature of the COVID-19 pandemic
  - High volume of meritorious applications from the research community for new projects
  - High volume of meritorious proposals from our awardees for project enhancements
  - 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

# Board Vote

## Call for a Motion to:

- **Approve** Up to \$50M in additional funding for COVID-19-Related Project Enhancements and Targeted PFAs

## 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