

# **Healthcare Worker Exposure Response and Outcomes (HERO) Registry Study**

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## List of Abbreviations

<b>CCC</b>	Clinical Coordinating Center
<b>CFR</b>	Code of Federal Regulations
<b>DCC</b>	Data Coordinating Center
<b>GCP</b>	Good Clinical Practice
<b>HCW</b>	Healthcare Worker
<b>HIPAA</b>	Health Insurance Portability and Accountability Act
<b>ICF</b>	Informed Consent Form
<b>ICH</b>	International Conference on Harmonisation
<b>IRB</b>	Institutional Review Board

## Protocol Summary

- Title:** Healthcare Worker Exposure Response and Outcomes (HERO) Registry Study
- Précis:** The HERO Registry provides a resource for collecting information on Healthcare Workers (HCWs) currently working in the United States. The overall goal of the Registry is to create and engage a community of HCWs who may be eligible for participation in future research studies, including those of COVID-19 prophylaxis and treatment.
- Main Objectives:**
- Create a virtual community of adult HCWs in the United States
  - Identify HCWs interested in engaging in upcoming research studies, including those related to COVID-19
  - Create a dataset of health-related measurements, risk factors, and outcomes for future analysis
- Population:** Adult healthcare workers in the United States.
- Sites:** Participants will contribute data via an online portal.
- Duration:** The registry does not have a planned end date at this time.

## 1. Introduction

### 1.1 Background Information

In December, 2019, numerous patients in Wuhan, China were diagnosed with pneumonia caused by an unknown virus. By January 7, 2020, Chinese scientists had isolated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This is a novel betacoronavirus closely related to severe acute respiratory syndrome coronavirus (SARS-CoV-1). [1] In the subsequent months, the spread of the virus has caused a global pandemic. As of March 24, 2020, there were over 415,000 cases and over 18,000 deaths worldwide. [2]

Healthcare workers have been disproportionately affected by the current pandemic. As of March 2020, over 3,300 Chinese healthcare workers have been infected. In Spain, 5,400 healthcare workers have been infected, accounting for 14% of the country's total infections. In Brescia, the center of Italy's outbreak, 10-15% of doctors and nurses have been infected and are unable to work. [3] In addition to potential exposure to infected patients, a critical shortage of personal protective equipment and respirators put healthcare professionals at even greater risk. [4]

### 1.2 Objectives

1. Create a virtual community of adult HCWs in the United States
2. Identify HCWs interested in engaging in upcoming research studies, including those related to COVID-19
3. Create a dataset of health-related measurements, risk factors, and outcomes for future analysis

## 2. Study Design

### 2.1 Study Population

The HERO Registry will include HCWs currently working across the United States. For the purposes of this registry, a "healthcare worker" is defined as an individual who currently works in a setting where individuals receive healthcare. (*Note: individuals do not have to work directly with patients, but may have any role within a setting where individuals receive healthcare, such as housekeeping, food service, etc.*)

### 2.2 Study Eligibility Criteria

Volunteers will be eligible to participate in the HERO Registry if they meet the criteria listed below. See [Section 3. Registry Schedule](#) for additional information on the registration process and study schedule.

#### *Inclusion Criteria:*

- Individual currently works in a setting where individuals receive healthcare ("healthcare worker") (including emergency medical services)
- Age  $\geq$  18
- Able to speak and read English or Spanish

*Exclusion Criteria:* There are no specific exclusion criteria for this registry. Participants must meet inclusion criteria.

## **2.3 Participant Engagement**

Participants will be engaged in all stages of the HERO registry – design, planning, protocol development, start-up, implementation, and dissemination. Participant engagement may include:

- creating a study-wide Healthcare Worker Advisory Group;
- authentic engagement of participants, community groups, and clinicians;
- developing participant-centered approaches that recognize the needs and preferences of healthcare workers;
- multifaceted approaches that combine engagement tools and leverage the participant portal; and
- testing recruitment methods to advance methods for healthcare worker recruitment.

## **3. Registry Schedule**

### **3.1 Recruitment**

Participants will be recruited through a variety of methods such as IRB-approved advertisements, media, care provider recommendation, and peer recommendation.

#### **3.1.1 Consent Process**

Participants will be consented using an electronic consent form. All consent forms will be IRB-approved before they are provided to the potential participant.

#### **3.1.2 HERO Registry Profile**

Participants will create a Registry Profile by providing contact information, demographic information, healthcare worker status, a brief medical history (including COVID-19 risk factors), hydroxychloroquine tolerance, and their interest in participating in a future studies. An unlimited number of participants may create a Registry Profile.

#### **3.1.3 Research Study Referral**

Registry leadership will periodically review the list of registry participants to identify potential participants for ongoing research studies. Participants who appear to be eligible based on demographics (including geographic region) and clinical characteristics will be contacted via their preferred contact mechanism (email, call or text) regarding their interest in participation in studies for which they qualify. Ongoing research studies may include randomized clinical trials, surveys, behavioral studies, or other projects relevant to the community of HCW participating in the registry. Each ancillary study will have independent inclusion and exclusion criteria, and will require a separate consent process. There is no obligation for Registry participants to enroll in ancillary studies.

## **3.2 Data Collection**

Through the course of registry participation, participants may be asked to complete online questionnaires in an online portal or mobile app (“Digital Platform”). The Digital Platform may offer a variety of engagement opportunities such as allowing participants to provide regular updates on their health through self-reported information of existing test results. After the baseline survey, reports are optional.

Throughout their participation in the HERO Registry, participants may be asked to complete optional

questionnaires related to health status or sense of well-being; symptoms consistent with COVID-19 infection; COVID-19 testing and results, and medical encounters (e.g., clinic, urgent care, emergency department visits or hospitalizations); environmental/occupational risk factors; and other health-related information. Some questionnaires may be validated, whereas others will be new and experimental. Questionnaires include, but are not limited to, the PROMIS Emotional Distress – Anxiety – Short Form (8 items), a single-item burnout measure, and the Patient Health Questionnaire. Questionnaires will be prioritized based on feedback from the HERO Steering Committee and the Healthcare Worker Advisory panel.

Information collected in the Digital Platform is intended to create a comprehensive picture of the participant's health, and factors that may impact it over time. This includes but is not limited to environmental or occupational risk factors, medical history, exposures, social distancing practices, and presence of COVID-19 risk factors.

Participants may be requested to provide data via brief optional questionnaires up to once per day. Participants also may be asked to provide data if they experience a significant health event.

Collection of additional data elements will be reviewed and approved by the HERO Steering Committee. All questionnaires or data collection surveys will be approved by the IRB before they are sent to the participants.

## **4. Participant Retention and Withdrawal**

### **4.1 Strategies for Retention**

Over the course of the study, a diverse set of approaches for participant engagement and retention will be employed, which may include, but are not limited to:

- Newsletters with opportunities to be featured or contribute content
- Videos
- Links to expert content on COVID-19
- Feedback surveys so participants can voice their opinions
- Study-related goals and progress tracking

The main goal of this registry is to gather information on COVID-19 risk factors and interest in participation in future clinical trials related to COVID-19 or other research studies. This registry will collect the minimum information required via the HERO Registry Profile to pre-screen participants for other clinical trials and research studies. Participant retention will contribute to a robust longitudinal data source on HCWs at risk for COVID-19 infection.

### **4.2 Discontinuation of Participants**

#### **4.2.1 Stopping Study Procedures or Withdrawal**

Participation in this study is voluntary and participants may withdraw at any time. In the event the participant chooses to withdraw, he/she will be instructed to contact the HERO Registry Team immediately. If a participant decides not to participate, or if they choose to drop out after the registry has started, he/she may withdraw at any time without jeopardy or penalty.

During the study, participants may decide that they would like to stop some or all of the registry

assessments. All surveys are optional. In the event a participant requests to stop his/her involvement in the study, the participant may immediately stop all activities. Participants will be asked to submit withdrawal requests via the contact information provided in the consent form.

A participant in the HERO Registry Study may participate in one or more ancillary studies. After completing the registry-specific activities for an ancillary study, the participant remains enrolled in the HERO Registry Study until they request to end their participation.

## **5. Statistical Considerations**

All analysis of the HERO Registry will be exploratory in nature. Analysis may include descriptive statistics of the cohort, statistical associations between variables of interest, and predictive modeling for health outcomes and behaviors. Analyses may be conducted on all participants in the HERO Registry or may be conducted on sub-populations defined based on clinical, demographic or other factors.

Analyses may include but are not limited to:

- Number and percent of participants who enroll in the HERO Registry by geographic region, age, COVID-19 risk factors, and past COVID-19 diagnosis
- Distribution of COVID-19 risk factors by participant characteristics
- Proportion of participants undergoing changes in health status (e.g. new diagnosis of COVID-19, ER visits, hospitalization)
- Proportion of all participants enrolled in the HERO Registry who participate in an ancillary research study
- Proportion of participants who continue to supply information about their health to the HERO Registry at various time points after their enrollment

Ancillary studies may include specific statistical analysis plans and sample size justification as appropriate for the stated study objectives.

## **6. Assessment of Safety**

### **6.1 Potential Risks and Benefits**

There is no direct benefit to the participants for their participation in this study, but the information obtained will be used in scientific research and may be helpful to the participant or others in the future. Participants may experience indirect benefits such as learning about their own health, access to health data, and opportunities to participate in future research.

The subtext that follows describes risks that are anticipated among procedures that may be offered to HERO Registry participants. There may also be other risks that are not known at this time.

#### **6.1.1 Privacy**

All information collected by the registry will be stored on a secure third party system with many layers of protection. However, there is a risk that someone could obtain unauthorized access to the data. Taking part in the HERO Registry may require the use of one or more external study websites, mobile applications, messaging, devices, email, or digital platforms. Because some of these systems are developed and

managed externally, there is no guarantee that they are free of risk.

## **6.2 Event Definitions and Reporting**

We do not anticipate any adverse events or severe adverse events will occur related to study procedures since procedures are limited to electronic data collection and reporting of health information. No additional physical exposure to the healthcare setting beyond that of the participant's work setting (for example, study-specific visits) is required for registry participation. Participants may be asked to report significant health events not related to their study participation throughout the duration of the HERO Registry.

## **7. Data Management**

### **7.1 Data Sources**

Data will be captured using multiple systems and approaches. All data collected in the context of this study will be stored and evaluated per applicable regulatory requirements and guidance for electronic records. Data will be stored and evaluated in a manner that protects patient confidentiality in accordance with the legal stipulations applying to confidentiality of data.

### **7.2 Data Aggregation**

Data collected from the HERO Registry will be available for analysis alone or in combination with other data sources for broad analysis of diverse endpoints. Data may include but is not limited to clinical, self-reported, behavioral, psychological, environmental, and other health-related measurements. Participant name, street address, phone number and email address will be removed from all datasets prior to analysis.

### **7.3 Data Access**

It is envisioned that the HERO Registry data may be available to qualified researchers for exploratory analysis in the future. These researchers may include academic, biopharma, medical device, patient advocacy, and other healthcare and life sciences groups or entities.

### **7.4 Record Retention**

All records will be retained for at least 6 years after study completion, per Duke policy.

## **8. Ethical Considerations**

In addition to the usual considerations of consent that apply to all studies, the four principal ethical considerations that guide operations are:

- Privacy: It is necessary to minimize the possibility that an unauthorized person will be able to identify the participant associated with any research data.
- Disclosure: The HERO Registry database must have rules for deciding whether and under what circumstances the results of analyses will be disclosed to a participant, a researcher, a clinician, or the participant's family.
- Protection from harm: The participant must be protected from harm resulting from effects on insurability or other adverse discrimination, and psychological harms or family disruption.
- Commercial potential: The possibility that there may be commercial value must be explicitly considered.

## **8.1 Consent**

Participants creating a HERO Registry profile will sign an e-consent to cover the exchange of data through the profile. For participants signing a consent, the date and time the participant signed the form, the version signed, and a copy of the template will be made available to the participant.

Informed consent procedures to the HERO Registry will comply with 45 CFR Part 46 and 21 CFR Part 50, as applicable. Signed consent and appropriate authorizations will be obtained from each participant in data collection associated with the HERO Registry, as necessary.

## **8.2 Institutional Review Board (IRB)**

The HERO Registry will not begin without documented approval by an IRB. Over the course of the study, the HERO Registry Team will ensure:

- Protocol and consents are reviewed and approved by the IRB prior to study initiation
- All existing amendments to the protocol and ICFs are reviewed and approved by the IRB prior to implementation, except where necessary to eliminate apparent immediate hazards to participants
- Copies are maintained of communications from the IRB indicating approval of the protocol and ICFs and any amendments
- Annual IRB renewal is obtained for the duration of the study
- A final report is submitted to the IRB after completion or termination of the study

## **8.3 Return of Research Results**

Participants may be kept engaged by sharing information learned by conducting the study.

## **8.4 Privacy**

### **8.4.1 General Considerations**

There are a number of general operating principles to safeguard research participants' privacy, including physical and operational security control measures.

### **8.4.2 Policies Around Access to Data**

Below is a list of policies and minimum requirements around access to data:

- Each user must have an authenticated and approved reason for obtaining access to those resources
- Access to the data is logged to an immutable log
- An account is issued to an individual and is not to be shared with any other individual or group

### **8.4.3 Study-Specific Considerations**

In addition to these general principles, participants' privacy will be protected by controlling access to sources of information that might potentially be used to identify the individual participants.

## **8.5 Compensation**

Participants in the HERO Registry will not be compensated.

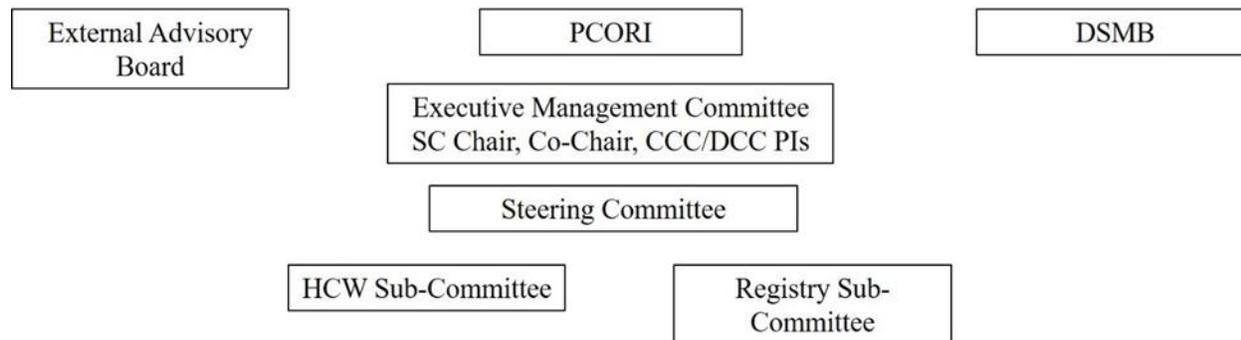
## 9. Study Governance

### 9.1 Steering Committee

The HERO Steering Committee will oversee overall study operations with a subcommittee dedicated to the registry. After reviewing scientific and operational data, the Steering Committee will propose amendments to the protocol and may make recommendations to the Sponsor regarding ancillary studies.

The Executive Committee is a subset of the Steering Committee, and consists of the Principal Investigators of the Clinical Coordinating Center (CCC), the DCC (Data Coordinating Center), and the Steering Committee Co-Chair. The Executive Committee is charged with overseeing the day-to-day operations of the study as an extension of the Steering Committee, to ensure efficient and high-quality performance.

The Coordinating Center is composed of a CCC and a DCC, each overseen by principal investigator(s). The CCC is responsible for study coordination, communication, and financial administration. The DCC is responsible for receipt and processing of data, quality control programs, and statistical analysis and reporting.



**Figure 1: Operational Structure Diagram for HERO studies**

### 9.2 Publications

The HERO Registry will adhere to authorship standards described in the International Committee of Medical Journal Editors' Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. [5] Authorship credit should be based on:

- Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
- Drafting the article or revising it critically for important intellectual content
- Final approval of the version to be published
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Additional authorship requirements imposed by individual journals will also be met. Authorship credit will be assigned in an equitable fashion and will be commensurate with participation and effort on the individual manuscript. Committee members will appear as authors on manuscripts based solely on actual contributions to the writing of the manuscript.

## 10. References

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