



JOHNS HOPKINS

INSTITUTE *for* CLINICAL &  
TRANSLATIONAL RESEARCH

## ICTR COVID-19 Clinical Research Center Town Hall

Wednesday October 14, 2020

# Town Hall Agenda

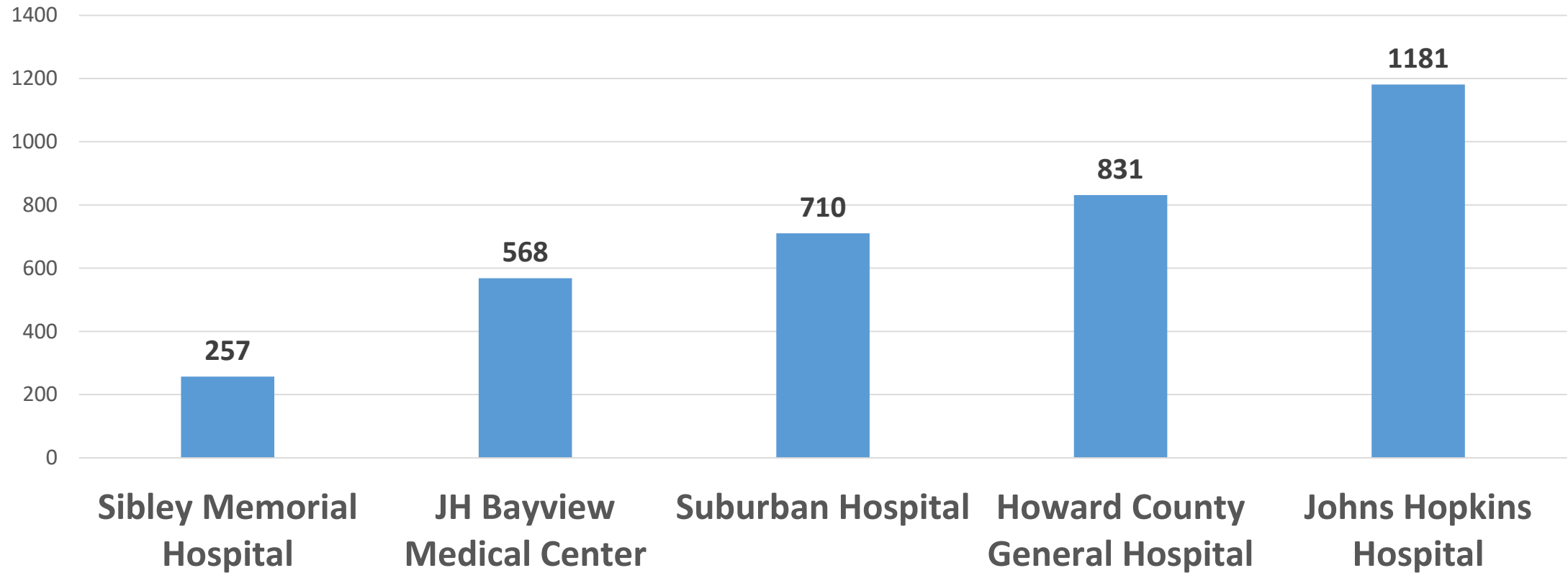


- **Introduction to the COVID-19 Clinical Research Center**  
Mark Sulkowski, MD
- **Outpatient Clinical Research Units**  
Kim Kafka, BSN
- **Clinical Research Coordinating Committee**  
Lauren Sauer, MS
- **COVID-19 And Data Research Evaluation (CADRE)**  
Stuart Ray, MD
- **Biospecimen Repository Committee**  
Andrea Cox, MD, PhD
- **Recruitment Innovations Unit**  
Cassie Lewis-Land, MS, CCRP
- **Capital Region Research (CAPRES)**  
Jackie Lobien, BSN, CCRP-CP
- **How to work with us**

# JHHS Hospitalized Patients with COVID-19

## October 13, 2020

Number of hospitalized patients (2020)



**COVID-19  
Steering  
Committee**

**ICTR COVID-19 Clinical Research Center**

<https://ictr.johnshopkins.edu/covid-research-center>

Capital Region  
Research @  
Sibley, Suburban,  
and HCGH

Recruitment  
Innovation Unit

Research  
Coordinator  
Support Service

**COVID-19  
Outpatient  
Clinical Research  
Units**

**COVID-19  
Clinical Research  
Coordinating  
Committee**

**COVID-19 And Data  
Research Evaluation  
Committee (CADRE)**

**COVID-19  
Biospecimen  
Repository  
Committee**

# COVID-19 Steering Committee

<b>Chair: William Nelson, MD PhD</b>	<b>Director, Sidney Kimmel Comprehensive Cancer Center; Professor of Oncology</b>
Antony Rosen, MBBS, MS	Vice Dean for Research; Professor of Medicine
Daniel Ford, MD, MPH	Vice Dean for Clinical Investigation; Director, Institute for Clinical and Translational Research; Professor of Medicine
Andrea Cox, MD, PhD	Professor of Medicine, Infectious Diseases/Immunology
Elizabeth Jaffee, MD	Deputy Director, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins; Professor of Oncology
Sumati Murli, PhD	ICTR Director of Clinical Research Projects
Richard Rothman, MD, PhD	Vice Chair of Research, Department of Emergency Medicine Professor of Emergency Medicine
Lauren Sauer, MS	Director of Operations, Johns Hopkins Office of Critical Event Preparedness and Response (CEPAR); Assistant Professor of Emergency Medicine
Megan Singleton, JD, MBE, CIP	Associate Dean for Human Research Protection and Director of the Human Research Protection Program
Jeremy Sugarman, MD, MPH, MA	Deputy Director for Medicine, Johns Hopkins Berman Institute of Bioethics; Harvey M. Meyerhoff Professor of Bioethics and Medicine
Mark Sulkowski, MD	Professor of Medicine, Infectious Diseases; Associate Dean for CAPRES
David Thomas, MD MPH	Professor of Medicine, Chief Division of Infectious Diseases

# COVID-19 Clinical Research Center

## Overview

- Mission: *To facilitate COVID-19 clinical research at Johns Hopkins Medicine by supporting investigators and their study team members, establishing infrastructure for outpatient COVID-19 clinical studies, and providing a centralized location for access to University resources.*
- Website: <https://ictr.johnshopkins.edu/covid-research-center>
- Leadership
  - Mark Sulkowski, MD, Director
  - TBN, Deputy Directors for Outpatient and Inpatient Research
  - Kim Kafka, RN, BSN, Program Manager
  - Stephanie Swords, MA, CCRP, Research Operations

# Research Activity: March to October 2020

<p>JHSOM Institutional Review Boards</p>		<p>Total # of COVID-related submissions Approved/Acknowledged by the IRB= 316</p> <p>Total # of CIRs to modify an existing study to add a COVID-related component: 22</p> <p>Total number of COVID-related studies approved/acknowledged by the IRB = 338</p>
<p>Clinical Research Coordinating Committee</p>	<p>Prioritize human subjects research including clinical trials</p>	<p>283 Protocol Reviews: 23 Inpatient Trials; 5 Outpatient Trials; 1 Expanded Access</p>
<p>CADRE Review Committee</p>	<p>Research involving data only</p>	<p>159 projects involving COVID-19 related clinical data in research submitted</p> <p>135 projects discussed by CADRE Review committee: 50+ meetings</p> <ul style="list-style-type: none"> <li>• 96 approved; others determined not to require formal review</li> <li>• 4 linked to other projects as new collaborations</li> <li>• 24 pending return for re-review</li> </ul>
<p>Biospecimen Repository</p>	<p>Research involving previously collected specimens ± Data</p>	<p>37 protocols have been reviewed</p> <p>29 protocols have been approved for specimen/waste</p>

# COVID-19 Outpatient Clinical Research Units

Kim Kafka, BSN



# COVID-19 Outpatient Clinical Research Units

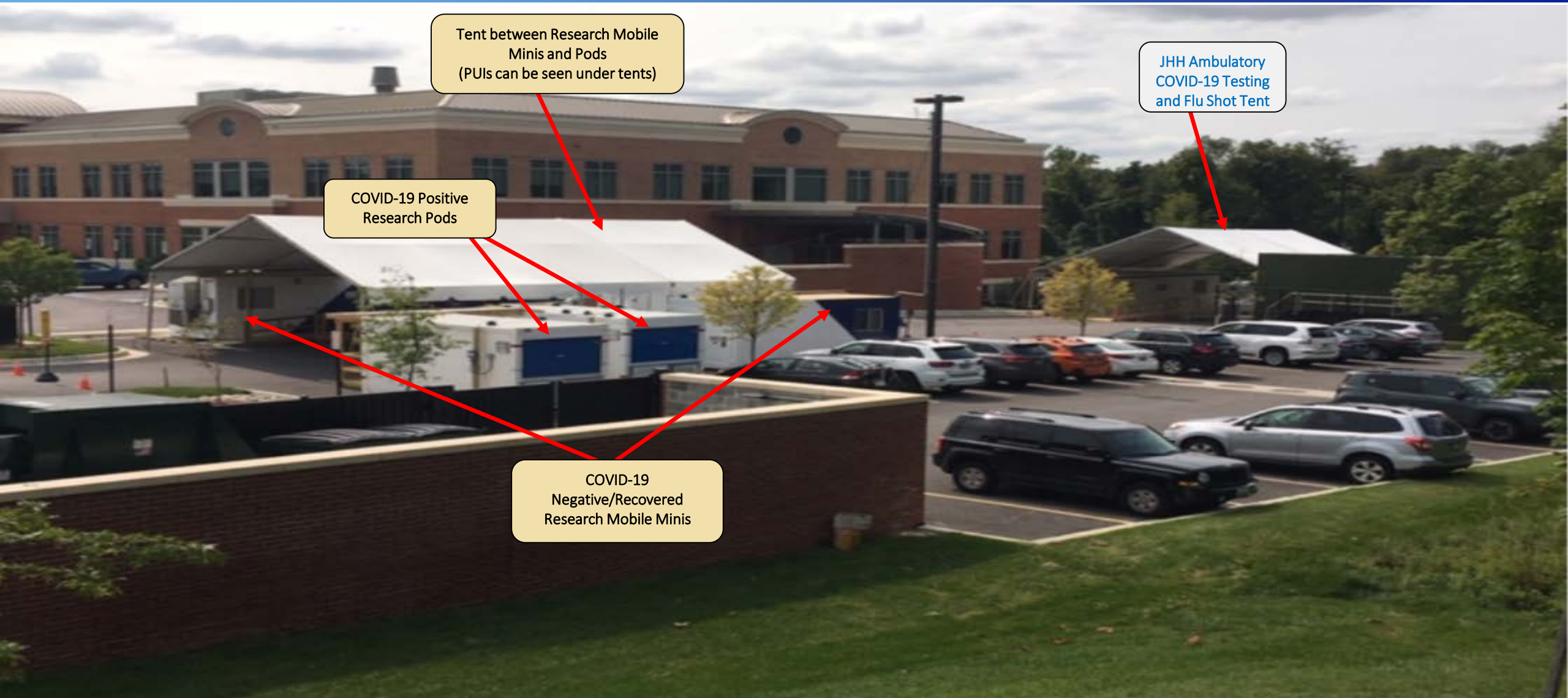
## Overview

- Part of ICTR CRUs
- Medical isolation units (PODS) allow for visits with participants with active SARS-CoV-2 infection



- Co-located with Johns Hopkins testing locations at Greenspring Station and Johns Hopkins Bayview Medical Center
- Program manager: Kim Kafka, RN BSN
  - <https://ictr.johnshopkins.edu/cru-online/>
  - For more information: [COVID19ResearchCtr@jhmi.edu](mailto:COVID19ResearchCtr@jhmi.edu)

# COVID-19 Outpatient Clinical Research Unit Greenspring Station, Pavilion 3



# COVID-19 Outpatient Clinical Research Unit

## Johns Hopkins Bayview



COVID CRU

# COVID-19 Clinical Research Coordinating Committee

Lauren Sauer, MS

# Clinical Research Coordinating Committee (CRCC) Overview



- Chairs: Drs. David Thomas and Richard Rothman
- Review Committee Administration: Lauren Sauer, Stephanie Swords and Dr. Mark Sulkowski

<https://ictr.johnshopkins.edu/coronaviruses/covid-johns-hopkins-clinical-research-coordinating-committee/>

# CRCC Goals and Who Needs to Apply

## While the CRCC has many goals, main priorities are:

- Enhance research participation across our health system
- Not overwhelm our patients with multiple requests regarding research participation
- Be sensitive to rapidly emerging data
- Limits to the number of treatment trials we can support
- Prioritize supplies such as PPE and reagent or specimen collection and transfer materials
- Minimize risks to patients, study participants, and staff

## Apply to the CRCC?

- Who: Investigators who intend to conduct research related to COVID-19 involving human subjects
- When: Before submission to the IRB and ORA
- How: Application Form is here: <https://ictr.johnshopkins.edu/coronavirus/clinical-research-coordinating-committee/>
- Uncertain: Ask via [COVID19ResearchCtr@jhmi.edu](mailto:COVID19ResearchCtr@jhmi.edu)

# Clinical Research Coordinating Committee

## Guiding principles for prioritization

- **Research Imperative**
- **Scientifically and Ethically Sound Research**
- **Potential to Be Informative**
- **Responsible Stewardship**
- **Balanced Portfolio**
- **Collaboration**
- **Equity**
- **Changing Priorities**
- **Fair Allocation**
- **Transparency.**

## Priority Guidance for Enrolling Hospitalized Patients in COVID-19 Clinical Trials

### OVERVIEW

- **This priority guidance applies *only* when patients are eligible for multiple protocols, in instances where neither the attending nor the patient have a predetermined preference.**
- **Patient and attending preference for a specific trial supersedes this priority guidance**
- Clinical trials above are IRB-approved studies actively recruiting and enrolling hospitalized patients and are categorized by the inclusion of patients on mechanical ventilation. Clinical trials that permit the enrollment of patients with or without mechanical ventilation were prioritized in both categories.
- This priority ranking will be updated by the COVID-19 Clinical Research Coordinating Committee as new information becomes available regarding COVID treatments, study progress, changes in eligibility requirements, and whether protocols are temporarily placed on pause. Investigators should contact the CRCC when new information pertinent to their trial is available.



# COVID-19 And Data Research Evaluation Committee (CADRE)

Stuart Ray, MD

# COVID-19 And Data Research Evaluation Committee (CADRE)

## Overview



The CADRE Committee guides investigators to the most efficient path for accessing data. The committee's default position will be for investigators to receive data from existing registries whenever possible

- Chairs: Drs. Daniel Ford and Christopher Chute
- Review Committee: Dr. Stuart Ray, Diana Gumas

<https://ictr.johnshopkins.edu/coronavirus/cadre/>

# CADRE: Data Repositories

## **JH-CROWN: The COVID-19 PMAP Registry**

**PI: Brian Garibaldi**

The goal for the use of this PMAP registry/repository is to maintain a curated database of clinical information for patients evaluated at Johns Hopkins Medical Institutions for suspected or confirmed COVID-19. It will be used to support IRB-approved research projects, recruitment efforts into clinical trials, quality improvement projects, and pilot projects. The applications for this data include studying the natural history of COVID-19, defining clinical biomarkers that predict trajectory and outcome, as well as determining the clinical effectiveness of various interventions and healthcare services provided to such patients.

## **Data Analyses for COVID-19 Resource**

**PI: Christopher Chute**

This study will create a PMAP registry of SARS-CoV-2 tested persons in the State of Maryland and Washington DC, regardless of result. The goal is to use EHR data from the Chesapeake Regional Information System for our Patients (CRISP) to first identify predictors of various stages of COVID-19 severity and then utilize that information for clinical mitigation, risk profiling, and disease and resource modeling.



# COVID-19 Biospecimen Repository Committee

Andrea Cox, MD PhD

# COVID-19 Biospecimen Repository Committee

## Overview



The COVID-19 Biospecimen Committee evaluates requests from researchers for accessing serum, plasma, respiratory specimens, or urine from COVID-19 patients. Where analysis can be made using remnant serum stored at 4°C for a few days, premade specimen collections of serum for pilot studies are provided. Requests for custom made collections and prospective specimens are considered after pilot studies are completed or if cold stored specimens are not suitable for the specific analysis.

- Chairs: Drs. Andrea Cox and Antony Rosen

<https://ictr.johnshopkins.edu/coronavirus/biospecimencommittee/>

# COVID-19 Biospecimen Repository Committee

## Specimen Repositories

### **Clinical Characterization Protocol for Severe Infectious Diseases (CCPSEI)**

**Overall PIs: Lauren Sauer/Paul Blair**

**Outpatient PI: Yuka Manabe**

**Pediatric PI: Deborah Persaud**

This enables the prospective collection of data and biological samples from participants infected with SARS CoV-2 virus. Information gathered from COVID-19 patients participating in this study will be invaluable in helping to understand the clinical features of patients with COVID-19 and in the analysis of downstream research questions specific to the clinical course of COVID-19, the development of medical countermeasures and diagnostic tests, and, basic biology questions associated with SARS-CoV-2. Adults and children may be enrolled in this study.

### **The Johns Hopkins COVID-19 Remnant Specimen Repository**

**PIs: Lauren Sauer/Andrea Cox/William Clarke**

This resource maintains a curated repository of specimens collected for clinical purposes from adults as well as children evaluated at the Johns Hopkins Medical Institutions for identification of suspected or confirmed COVID-19, which are no longer needed for clinical care. These samples will be used to support IRB-approved research projects, recruitment efforts into clinical trials, quality improvement projects, and pilot projects. This repository will serve as a complement to other approved repositories for use of clinical data.

# Recruitment Innovations Unit and HOPE Registry

Cassie Lewis-Land, MS CCRP

# Recruitment Innovations Unit

## Overview



*The RIU offers investigators and research teams training, consultations and a toolkit of evidence-based, field-tested recruitment practices.*

- Program Manager: Cassie Lewis Land, MS, CCRP
- Program Director: Cheryl Dennison Himmelfarb, PhD, RN, ANP  
[Research\\_Recruitment@jhu.edu](mailto:Research_Recruitment@jhu.edu).

Hopkins Opportunities for Participant Engagement (HOPE):  
A centralized recruitment registry to match participants with research teams conducting various COVID-19 research studies.

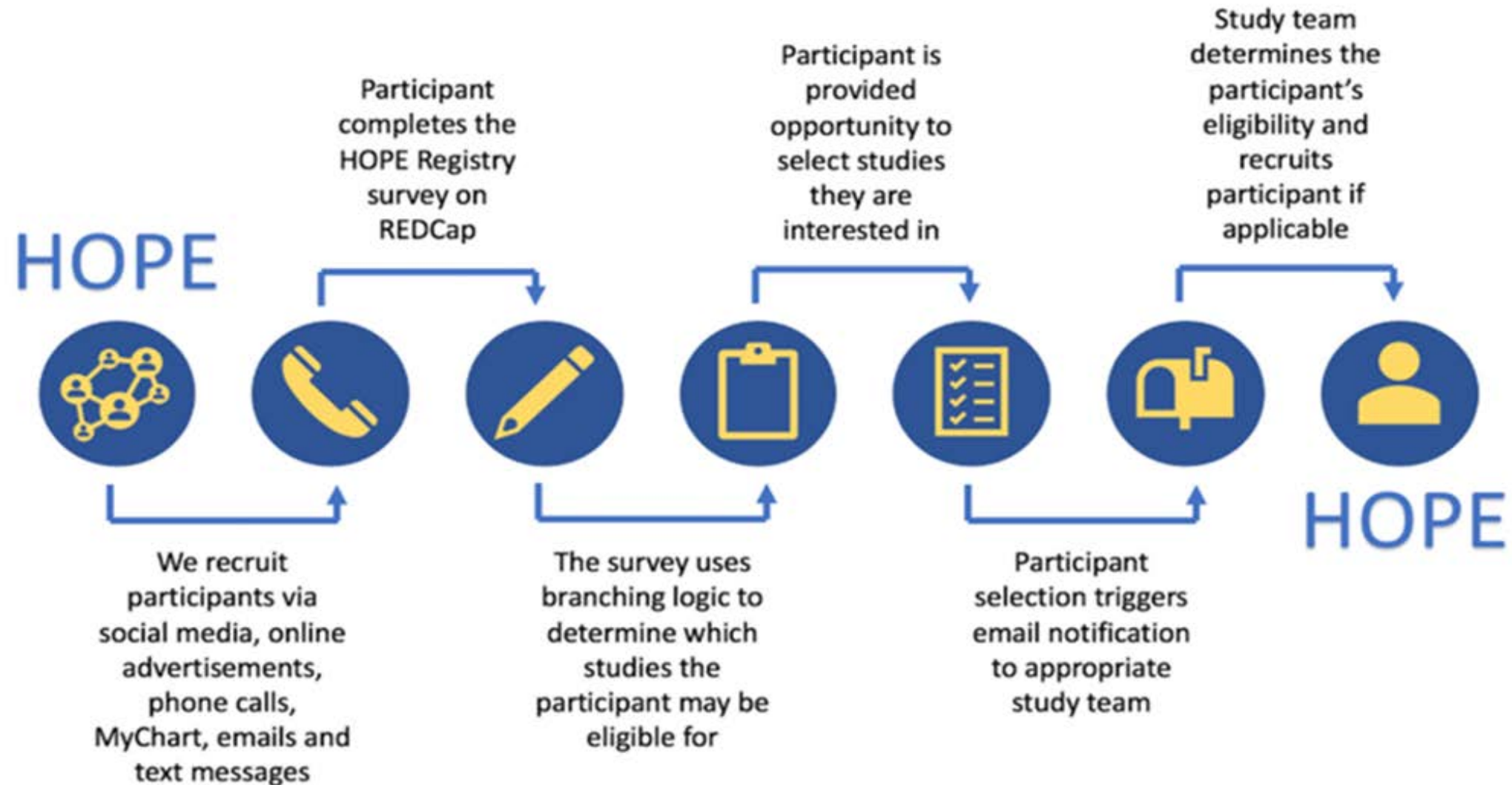
- Dr. Daniel Ford, PI  
<https://ictr.johnshopkins.edu/research-hope/>

<http://johnshopkinshope.org/>



# Recruitment Innovations Unit

## HOPE Registry

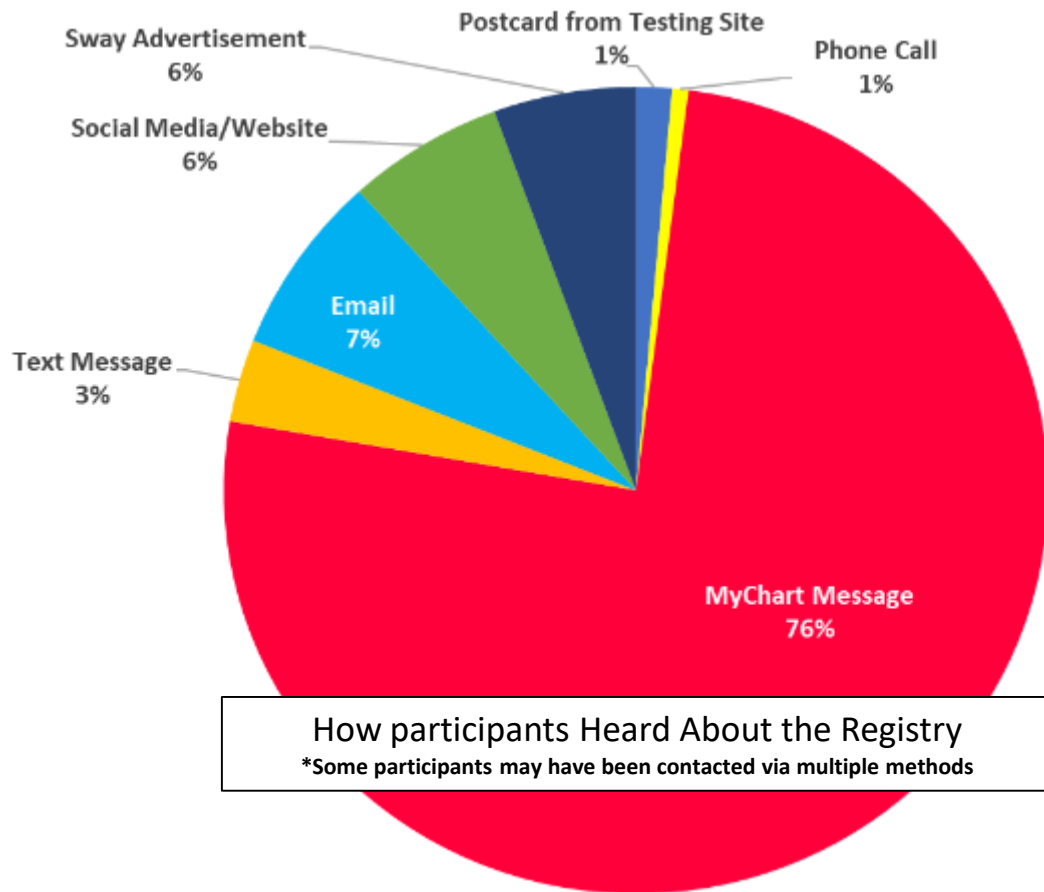


# Recruitment Innovations Unit

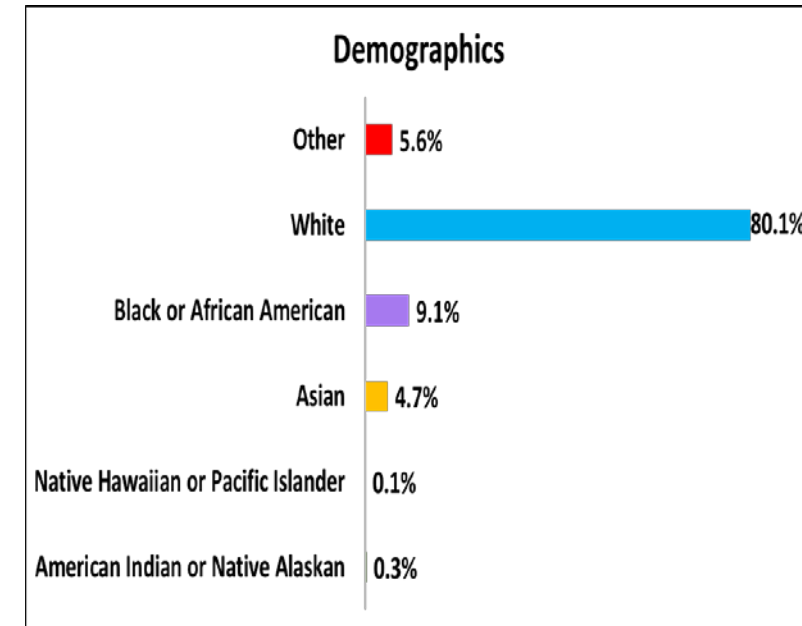
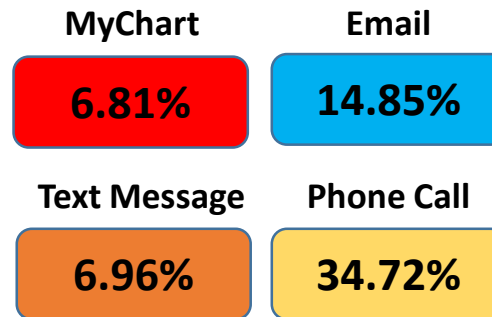
## HOPE Registry Enrollment

### HOPE Registry Dashboard

Total Participants **4117**



### Response Rates



Mean Age **53.4**

COVID-19 + **371**

# Capital Region Research (CAPRES)

Sibley Memorial, Suburban, and  
Howard County General Hospitals

Jackie Lobien, BSN, CCRP-CP

# Capital Region Research (CAPRES)

## Overview



CAPRES promotes and supports high quality research across multiple disciplines in our three community hospitals— Howard County General Hospital, Sibley Memorial Hospital, and Suburban Hospital.

- Program Director: Jackie Lobien, BSN, CCRP-CP
- Associate Dean: Mark Sulkowski, MD

<https://ictr.johnshopkins.edu/capital-region-research-capres/>

# Capital Region Research (CAPRES)

Sibley Memorial, Suburban Hospital, and Howard County General Hospitals

- CAPRES provides skilled research staff /IDS pharmacy at each location
- Uniform regulatory environment using the JHSOM IRB and ORA

## COVID-19 Research at the Community Hospitals

Study Name	SH	SMH	HCGH
HERO	X	X	X
Expanded Access for Convalescent Plasma	X	X	X
Qualification of donation for Convalescent Plasma collection	X		
RECOVER	X		
Prazosin	X		
CRITICAL			X
IL-6 Inhibitor			X
CCPSEI Outpatient	X		

# COVID-19 Clinical Research Center

## How to work with us

- Ask questions early and often
  - [COVID19ResearchCtr@jhmi.edu](mailto:COVID19ResearchCtr@jhmi.edu)
- Start at the ICTR COVID-19 CRC website
  - <https://ictr.johnshopkins.edu/covid-research-center>
  - Re-design underway to provide step-by-step guidance for human subjects and non-human subject research
- Join our monthly Town Hall Meetings



# Questions

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COVID-19 Clinical Research Center