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)

- Sibley Memorial Hospital: 257
- JH Bayview Medical Center: 568
- Suburban Hospital: 710
- Howard County General Hospital: 831
- Johns Hopkins Hospital: 1181
# COVID-19 Steering Committee

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

### JHSOM Institutional Review Boards

| Total # of COVID-related submissions Approved/Acknowledged by the IRB | 316 |
| Total # of CIRs to modify an existing study to add a COVID-related component: | 22 |
| Total number of COVID-related studies approved/acknowledged by the IRB = | 338 |

### Clinical Research Coordinating Committee

| Prioritize human subjects research including clinical trials | 283 Protocol Reviews: 23 Inpatient Trials; 5 Outpatient Trials; 1 Expanded Access |

### CADRE Review Committee

| Research involving data only | 159 projects involving COVID-19 related clinical data in research submitted 135 projects discussed by CADRE Review committee: 50+ meetings  
- 96 approved; others determined not to require formal review  
- 4 linked to other projects as new collaborations  
- 24 pending return for re-review |

### Biospecimen Repository

| Research involving previously collected specimens ± Data | 37 protocols have been reviewed 29 protocols have been approved for specimen/waste |
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
COVID-19 Outpatient Clinical Research Unit
Greenspring Station, Pavilion 3

Tent between Research Mobile Minis and Pods
(PUIs can be seen under tents)

COVID-19 Positive Research Pods

COVID-19 Negative/Recovered Research Mobile Minis

JHH Ambulatory COVID-19 Testing and Flu Shot Tent
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/coronavirus/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
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/
<table>
<thead>
<tr>
<th>Project</th>
<th>Description</th>
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<tr>
<td>JH-CROWN: The COVID-19 PMAP Registry</td>
<td>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.</td>
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<tr>
<td>Data Analyses for COVID-19 Resource</td>
<td>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.</td>
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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/
<table>
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<tr>
<th>COVID-19 Biospecimen Repository Committee</th>
<th>Specimen Repositories</th>
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<tbody>
<tr>
<td><strong>Clinical Characterization Protocol for Severe Infectious Diseases (CCPSEI)</strong></td>
<td>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.</td>
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<tr>
<td>Overall PIs: Lauren Sauer/Paul Blair</td>
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<td>Outpatient PI: Yuka Manabe</td>
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<td>Pediatric PI: Deborah Persaud</td>
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<tr>
<td><strong>The Johns Hopkins COVID-19 Remnant Specimen Repository</strong></td>
<td>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.</td>
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<tr>
<td>PIs: Lauren Sauer/Andrea Cox/William Clarke</td>
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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.

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

**Participant completes the HOPE Registry survey on REDCap**

**Participant is provided opportunity to select studies they are interested in**

**Study team determines the participant’s eligibility and recruits participant if applicable**

**We recruit participants via social media, online advertisements, phone calls, MyChart, emails and text messages**

**The survey uses branching logic to determine which studies the participant may be eligible for**

**Participant selection triggers email notification to appropriate study team**
Recruitment Innovations Unit
HOPE Registry Enrollment

HOPE Registry Dashboard
Total Participants: 4117

How participants Heard About the Registry:
- MyChart Message: 76%
- Phone Call: 1%
- Email: 7%
- Text Message: 3%
- Social Media/Website: 6%
- Postcard from Testing Site: 1%
- Sway Advertisement: 6%

*Some participants may have been contacted via multiple methods

Response Rates:
- MyChart: 6.81%
- Email: 14.85%
- Text Message: 6.96%
- Phone Call: 34.72%

COVID-19 + Mean Age: 53.4

Demographics:
- White: 80.1%
- Black or African American: 9.1%
- Asian: 4.7%
- Native Hawaiian or Pacific Islander: 0.1%
- American Indian or Native Alaskan: 0.3%
- Other: 5.6%
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

<table>
<thead>
<tr>
<th>Study Name</th>
<th>SH</th>
<th>SMH</th>
<th>HCGH</th>
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<tbody>
<tr>
<td>HERO</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Expanded Access for Convalescent Plasma</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Qualification of donation for Convalescent Plasma collection</td>
<td>X</td>
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<tr>
<td>RECOVER</td>
<td>X</td>
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<tr>
<td>Prazosin</td>
<td>X</td>
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<td>CRITICAL</td>
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<td>X</td>
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<tr>
<td>IL-6 Inhibitor</td>
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<td>X</td>
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<tr>
<td>CCPSEI Outpatient</td>
<td>X</td>
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COVID-19 Clinical Research Center
How to work with us

• Ask questions early and often
  —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

COVID-19 Clinical Research Center