



JOHNS HOPKINS

INSTITUTE *for* CLINICAL &  
TRANSLATIONAL RESEARCH

## ICTR COVID-19 Clinical Research Center Town Hall

Wednesday November 11, 2020

# Town Hall Agenda



- Introduction of Deputy Directors
  - Kelly Dooley, MD PhD
  - David Hager, MD PhD
- Overview of current clinical research
  - Mark Sulkowski, MD
- Navigating COVID-19 human subjects research at Johns Hopkins
  - Stephanie Swords, MA, CCRP
  - Lauren Sauer, MS
  - Kim Kafka, BSN
- How to work with us

# 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
  - Kelly Dooley, MD, MPH PhD and David Hager, MD, PhD, Deputy Directors for Outpatient and Inpatient Research
  - Lauren Sauer, PhD, Director of Operations, Office of Critical Event Preparedness and Response (CEPAR)
  - Kim Kafka, RN, BSN, Program Manager
  - Stephanie Swords, MA, CCRP, Research Operations

# ICTR COVID-19 Clinical Research Center

## Deputy Directors

- Dr. Dooley is an Associate Professor of Medicine & Pharmacology with appointments in Clinical Pharmacology and Infectious Diseases. She obtained her MD from Duke University and PhD from JHSPH. She is the JHU site leader for the outpatient COVID-19 research network, ACTIV-2. Her research focuses on tuberculosis therapeutics with an emphasis on clinical trials of TB drugs and HIV/TB co-treatment.
- Dr. Hager is an Associate Professor of Medicine. He obtained his MD from Cornell University and his PHD from the JHSPH. Dr. Hager is the Medical Director of the inpatient COVID-19 ICU and serves as Associate Director for the MICU. His research interests include sepsis, intermediate care, and mechanical ventilation strategies for acute lung injury.
- *They will oversee outpatient and inpatient clinical research operations and will be responsible for establishing and implementing best practices for the ICTR COVID-19 Clinical Research Center*

**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**

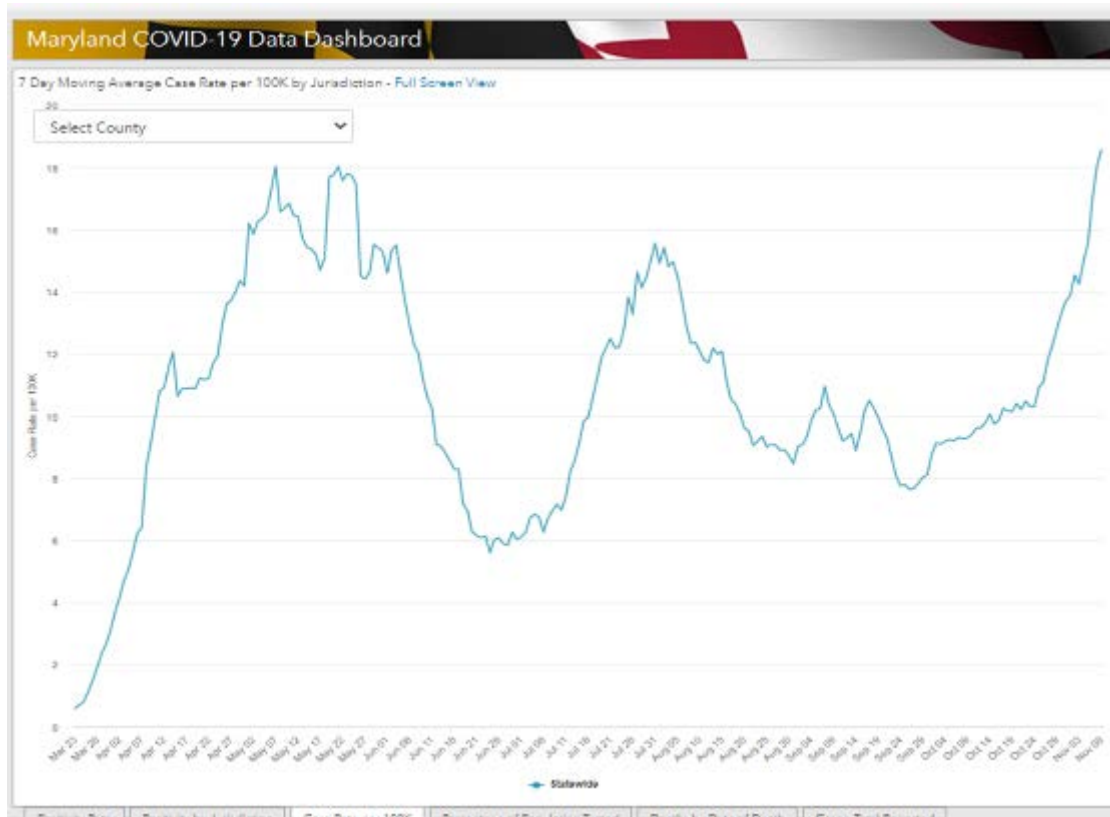
**COVID-19 And Data  
Research Evaluation  
Committee (CADRE)**

**COVID-19  
Biospecimen  
Repository  
Committee**

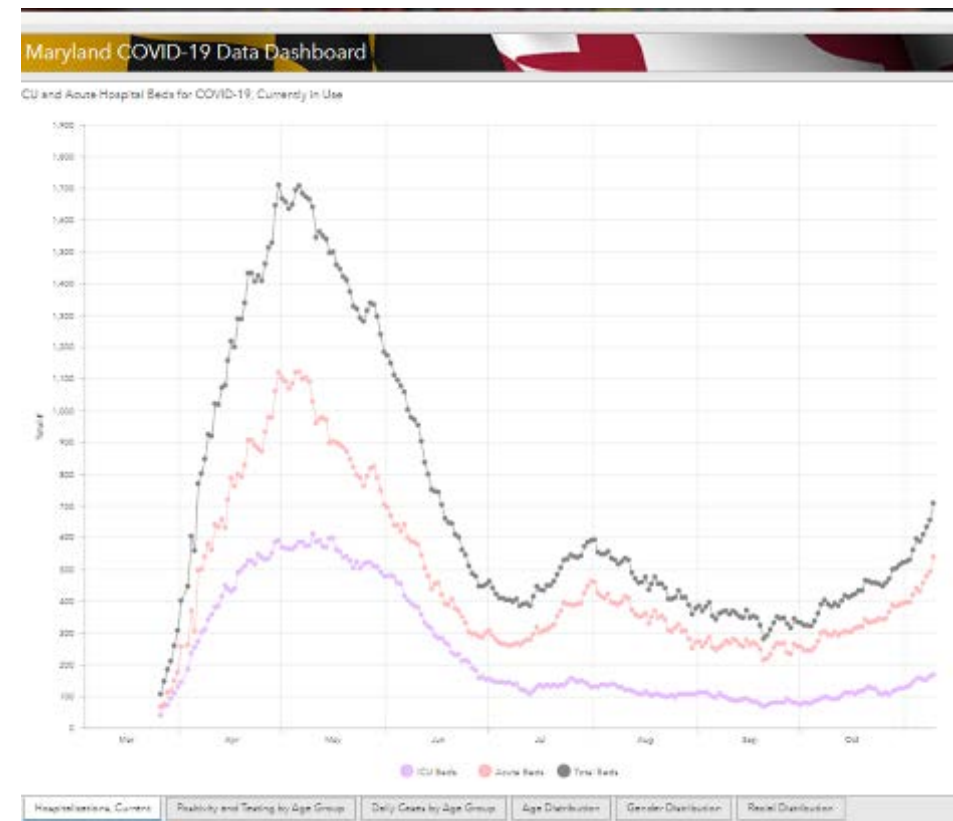
# Overview of Current Therapeutic Clinical Research at Johns Hopkins

# COVID-19 in Maryland, November 9, 2020

## 7-day moving average cases/100,000 persons



## Hospital bed occupancy: ICU, Acute, Total



# NIH COVID-19 Treatment Guidelines Panel: Recommendation for Pharmacologic Management

Disease Severity	Panel's Recommendation
Prevention and prophylaxis of infection	<ul style="list-style-type: none"> <li>• <b>Do not use any agent except in a clinical trial</b></li> </ul>
Non-hospitalized	<ul style="list-style-type: none"> <li>• <b>No specific therapy recommended except in a clinical trial [11/9 EUA for investigational monoclonal antibody therapy]</b></li> </ul>
Hospitalized and require supplemental oxygen	<ul style="list-style-type: none"> <li>• <b>Remdesivir (5 days, option for 10 days) (AI); or</b></li> <li>• <b>Remdesivir plus dexamethasone (10 days)(BIII)</b></li> </ul>
Hospitalized and require oxygen high-flow device or non-invasive ventilation	<ul style="list-style-type: none"> <li>• <b>Dexamethasone plus Remdesivir (AIII); or</b></li> <li>• <b>Dexamethasone (AI)</b></li> </ul>
Hospitalized and require invasive mechanical ventilation or extracorporeal membrane oxygenation	<ul style="list-style-type: none"> <li>• <b>Dexamethasone (AI); or</b></li> <li>• <b>Dexamethasone plus Remdesivir (CIII)</b></li> </ul>

Strength of recommendation: A, Strong; B, Moderate; C, Optional

Quality of Evidence: I, One or more randomized trials with clinical outcomes and/or validated lab endpoints; II, One or more well-designed, nonrandomized trials or observational cohort studies; III, Expert opinion



# Clinical trials for prevention of SARS-CoV-2 infection

- COVID-19 vaccines
  - Center for Immunization Research
  - Enroll: 410-955-7283 or Email [JHSPH.ProjectSAVE@jhu.edu](mailto:JHSPH.ProjectSAVE@jhu.edu)
  - COVID-19 Investigational Vaccine Study (CIR 339) Astra Zeneca
  - Pfizer (fully enrolled)
    - PIs Anna Durbin MD and Kawsar Talaat MD
- Biomedical prevention for household contacts (and health care workers)
  - Convalescent plasma
    - Enroll: 888-506-1199 or visit [www.covidplasmatrial.org](http://www.covidplasmatrial.org)
    - PI Shmuel Shoham, MD
  - Lambda interferon:
    - Enroll: 410-314-1142 or Email [PROTECT-study@jhmi.edu](mailto:PROTECT-study@jhmi.edu)
    - PI Mark Sulkowski
  - REGN-COV2 monoclonal antibodies (opening soon)
    - PI Chloe Thio

# Therapeutic trials for ambulatory patients with SARS-CoV-2 infection

- Convalescent plasma
  - Enroll: 888-506-1199 or visit [www.covidplasmatrial.org](http://www.covidplasmatrial.org)
  - PI David Sullivan, MD
- ACTIV-2
  - Adaptive study design
  - Current drug: Bamlanivimab versus placebo (monoclonal antibody)
  - Enroll 410-955-2898 or visit [www.riseabovecovid.org/](http://www.riseabovecovid.org/)
  - PI Kelly Dooley, MD PhD
- COMBO Trial (Camostat and bicalutamide) (opening soon)
  - PI Cathy Handy Marshal, MD

# Therapeutic trials for hospitalized patients with mild to moderate COVID-19

- **END-COVID:** Molnupiravir (EIDD-2801), oral antiviral for 5 days
  - JHH, JHBMC, Howard County General Hospital, Suburban Hospital
  - PI Ashwin Balagopal
- **CRITICAL:** Crizanlizumab, monoclonal antibody targeting P-selectin
  - JHH, JHBMC, HCGH
  - PI Charlie Lowenstein, MD
- **Adaptive COVID-19 Treatment Trial (soon ACTT-4)**
  - ACTT-1 Remdesivir versus Placebo
  - ACTT-2 Remdesivir + Baricitinib versus Remdesivir + Placebo
  - ACTT-3 Interferon beta-1a + Remdesivir versus Remdesivir + Placebo
  - JHH
  - PI Noreen Hynes, MD MPH
- **Prone positioning**
  - JHH and JHBMC
  - PI Mahendra Damarla, MD

# Therapeutic trials for hospitalized patients with severe COVID-19

- Novel arm restraint (COVID-19 and non-COVID-19 patients)
  - JHH, JHBMC
  - PI Dale Needham, MD PhD
- Clazakizumab, monoclonal antibody to IL-6
  - JHH, Howard County General Hospital
  - PI Nada Alachar MD
- Convalescent plasma
  - JHH, JHBMC
  - PI David Hager, MD PhD
- DART Trial: Decitabine (induce T regulatory cells)
  - JHH, JHBMC
  - PI Franco D'Alessio MD and Pali Shah, MD
- Cord Blood Derived T-Regulatory Cell Infusions
  - JHH
  - PI Doug Gladstone MD
- Acalabrutinib, Bruton's tyrosine kinase inhibitor
  - JHH
  - PI Brent Petty, MD
- OP-101 (dendrimer n-acetyl-cysteine)
  - JHH
  - PI Nauder Faraday MD MPH

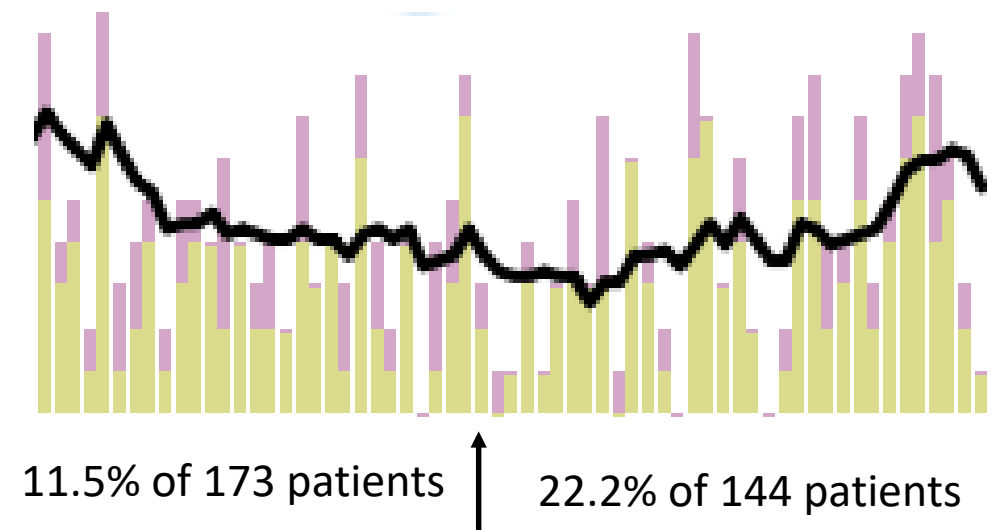
# Priority Guidance for Enrolling Hospitalized Patients in COVID-19 Clinical Trials

- Recruitment of hospitalized patients is guided by prioritization rank
- After IRB approval and before recruitment, study PIs/teams present their study and implementation plans to the Clinical Research Coordinating Committee
- Ranking by CRCC members is anonymous and updated with the initiation of new studies or the availability new information for ranked studies
- Patient/LAR and attending preference for a specific study supersedes the priority ranking
- Current priority guidance is online and shared on Microsoft Teams
  - [Study Prioritization for Participants](#) *updated 11/2/2020 Current recruitment priority ranking of active protocols*

# Impact of prioritization for patient recruitment

- Less imposition on patients and care teams
- More enrollment in therapeutic trials
- More coordination with non-interventional studies

Enrollment of hospitalized patients before and after prioritized recruitment



9/22/2020  
Prioritization

# Navigating COVID-19 Clinical Research at Johns Hopkins

# Planned clinical research

- Data resources only?
  - COVID-19 and Data Research Evaluation (CADRE) Committee
  - <https://ictr.johnshopkins.edu/coronavirus/cadre/>
- Biospecimens resources only?
  - COVID-19 Biospecimen Committee
  - <https://ictr.johnshopkins.edu/coronavirus/biospecimencommittee/>
- Involves direct interaction with participants and COVID-19?
  - COVID-19 Clinical Research Coordinating Committee
  - <https://ictr.johnshopkins.edu/coronavirus/covid-johns-hopkins-clinical-research-coordinating-committee/>



# Clinical Research Coordinating Committee review is before submission to the COVID-19 IRB

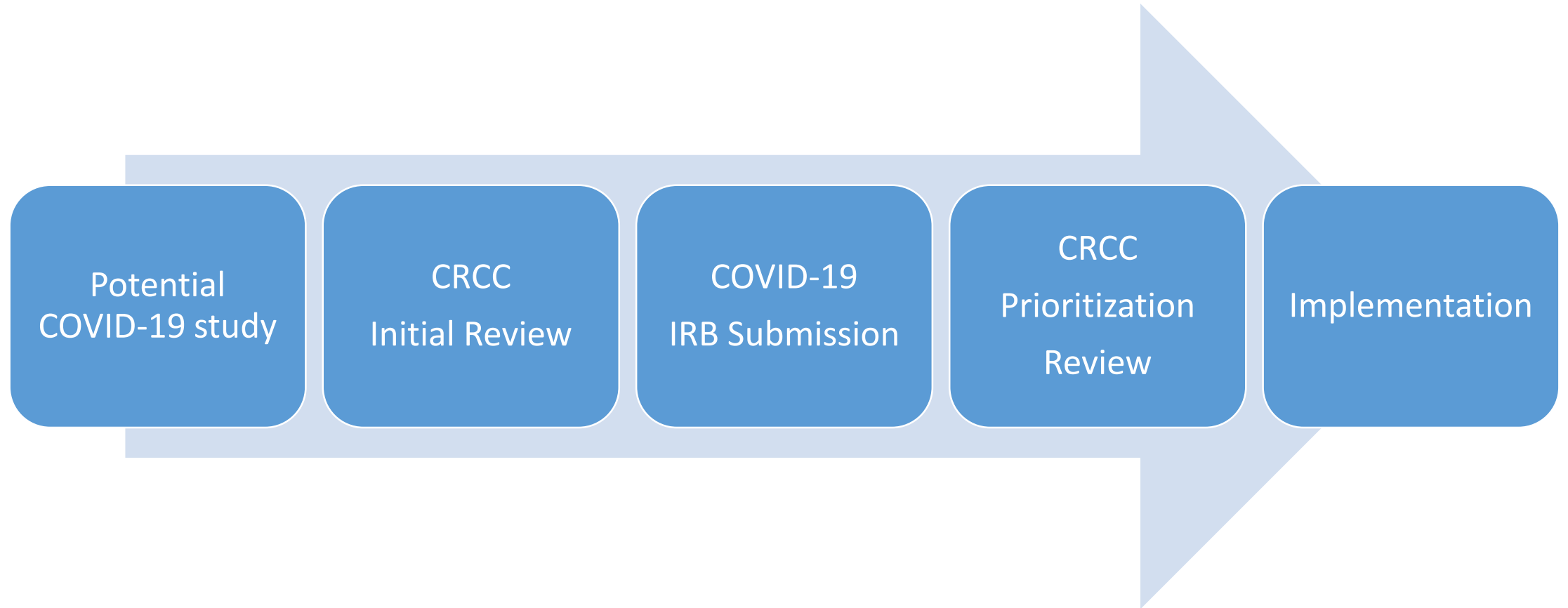
## **While the CRCC has many goals, main priorities are:**

- 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**

- When: Before submission to the IRB and ORA
- How: Application Form : <https://ictr.johnshopkins.edu/coronavirus/clinical-research-coordinating-committee/>
- Uncertain: [COVID19ResearchCtr@jhmi.edu](mailto:COVID19ResearchCtr@jhmi.edu)

# Navigating COVID-19 Human Subjects Research



# Guidance for the CRCC review

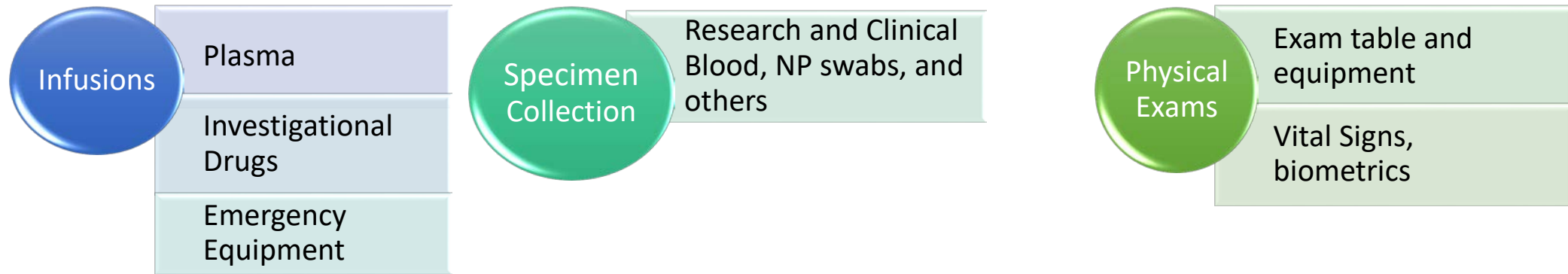
- Consult with the ICTR COVID-19 Clinical Research Center team
  - [COVID19ResearchCtr@jhmi.edu](mailto:COVID19ResearchCtr@jhmi.edu)
- Study team?
- Will the study recruit hospitalized patients?
  - Review current study priority guidance
    - [Study Prioritization for Participants](#)
  - Request approval for hospital nursing leadership
    - [https://www.hopkinsmedicine.org/institutional\\_review\\_board/forms/jhhs\\_nursing.pdf](https://www.hopkinsmedicine.org/institutional_review_board/forms/jhhs_nursing.pdf)

# Guidance for the CRCC review

- Will the study team interact with participants with active SAR-CoV-2 infection?
  - Review HEIC guidance
    - [https://intranet.insidehopkinsmedicine.org/heic/novel\\_coronavirus/so\\_re\\_sources.html](https://intranet.insidehopkinsmedicine.org/heic/novel_coronavirus/so_re_sources.html)
- Will your study team collect/handle biologic specimens from patients with COVID-19?
  - Review the need for Biosafety Approval
    - <https://www.hopkinsmedicine.org/hse/forms/PathogenToxinRegistration.pdf>

# Guidance for the CRCC review

- Will the study recruit ambulatory patients with active COVID-19?
  - 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
  - <https://ictr.johnshopkins.edu/covid-research-center/greenspring-covid-19-outpatient-cru/>
  - <https://ictr.johnshopkins.edu/covid-research-center/bayview-covid-19-outpatient-cru/>
- Program manager: Kim Kafka, RN BSN
  - <https://ictr.johnshopkins.edu/cru-online/>
  - For more information: [COVID19ResearchCtr@jhmi.edu](mailto:COVID19ResearchCtr@jhmi.edu)

# Guidance for the CRCC review

- Do you plan to recruit patients at Howard County General Hospital, Suburban Hospital or Sibley Memorial Hospital?
- Contact Johns Hopkins Capital Region Research (CAPRES)
  - <https://ictr.johnshopkins.edu/capital-region-research-capres/>
  - Program Director: Jackie Lobien, BSN, CCRP-CP
    - [jlobien1@jhmi.edu](mailto:jlobien1@jhmi.edu)
- Outside of JHM? Johns Hopkins Clinical Trials Network
  - <https://ictr.johnshopkins.edu/collaboration/collaborations/johns-hopkins-clinical-research-network-jhcrn/>
  - Director: Adrian S. Dobs, MD, MHS
  - [jhcrn@jhmi.edu](mailto:jhcrn@jhmi.edu)

# Guidance for after COVID-19 IRB approval

- Consult with the ICTR COVID-19 Clinical Research Center team
  - [COVID19ResearchCtr@jhmi.edu](mailto:COVID19ResearchCtr@jhmi.edu)
- Studies are reviewed by the Clinical Research Coordinating Committee for prioritization
- Recruitment resources
  - Microsoft Teams for JHH, JHBMC and HCGH
    - Stephanie Swords, MA, CCRP
  - HOPE registry
    - PI Dan Ford, MD MPH
    - Program Manager: Cassie Lewis-Land
    - Volunteers: <http://johnshopkinshope.org/>
    - Researchers: [https://ictr.johnshopkins.edu/programs\\_resources/programs\\_resources/research-participant-recruitment-and-retention-2/research-hope/](https://ictr.johnshopkins.edu/programs_resources/programs_resources/research-participant-recruitment-and-retention-2/research-hope/)



# 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