

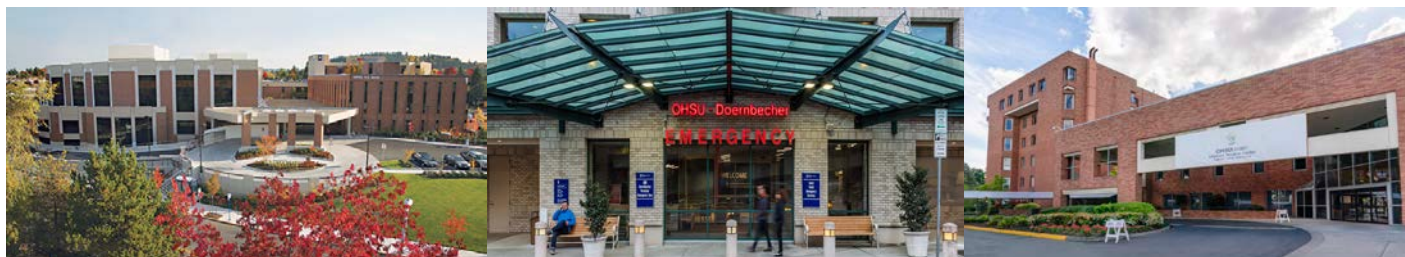
October 2020 Updates on ED Clinical Trials

2020 has seemed like the longest year ever and a lifetime ago since we last saw each other's smiles. And yet, your support of one another, resiliency in the face of crises, and continued efforts to ensure humanism in medicine, makes me proud to be a part of our the ED team. We're in this together. Stay strong. Thank you to every member of our healthcare team.

–Bory Kea, MD, MCR, Director of Clinical Trials

For the interested reader, more details on the below research studies can be found at:

<http://www.ohsu.edu/cprem>



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COVID-19 STUDIES



C3PO- Clinical Trial of COVID-19 Convalescent Plasma of Outpatients – a SIREN Network Trial

The Clinical Trial of COVID-19 Convalescent Plasma in Outpatients (C3PO) is a multi-center randomized, single-blind, two-arm, placebo-controlled phase III trial with blinded outcome assessment to establish the safety and efficacy of a single dose of convalescent plasma (CP) for preventing the progression from mild to severe COVID-19 illness. This trial will be conducted in the OHSU Emergency Department.

Rapid tests are available for research purposes only.

Any healthcare provider (RN, NP, PA, MD, or PharmD): PAGE #11502 to screen for C3PO!

- **PI:** Bory Kea; **Coordinator:** Jenny Cook
- **Status:** Launched 8/19/20; **Enrolled:** 6

- **Order a Rapid COVID-19 test IF:**
 - ≥1 COVID-like sx for ≤7days
 - ≥18yo
 - ≥1 risk factor (age≥50y; HTN; diabetes; CAD; chronic lung disease; chronic kidney disease; immunosuppression; sickle cell disease, or obesity (body mass index [BMI]>30)
 - Likely to be d/c'd home
- **INCLUSION CRITERIA:**
 - One or more symptoms of COVID-19 illness and laboratory-confirmed SARS-CoV-2 infection
 - Has at least one study defined risk factor for severe COVID-19 illness
 - ED team deems stable for outpatient management without new supplemental oxygen requirement
 - Informed consent from subject
 - ABO-compatible CP available at the site at the time of enrollment
 - Duration of symptoms ≤ 7 days at ED presentation
- **EXCLUSION CRITERIA**
 - Age < 18 years
 - Prisoner or ward of the state.
 - Presumed unable to complete follow-up assessments
 - Prior adverse reaction(s) from blood product transfusion
 - Religious, social or other contraindications to receiving blood products
 - Receipt of any blood product within the past 120 days
 - Inability to tolerate up to 250 ml of intravenous fluid
 - Enrollment in another interventional trial for COVID-19 illness
- Registered with ClinicalTrials.gov: [NCT04355767](https://clinicaltrials.gov/ct2/show/study/NCT04355767)
- **Contact:** Study coordinators: Jenny Cook cookjen@ohsu.edu, James Magas magas@ohsu.edu; PI: Bory Kea kea@ohsu.edu

Clinical Evaluation of the BinaxNOW® COVID-19 Antigen (Ag) Card

Objective: To estimate the clinical sensitivity and specificity of the BinaxNOW® COVID-19 Ag card against the reference method, Abbott RealTime SARS-CoV-2, in patients suspected of COVID-19 infection by *any* healthcare provider (RN, NP, PA, or MD) using nasal swabs. Staff will collect 2 nasal swabs from each subject. Swabs will be shipped to the Sponsor's central laboratory for reference testing.

If ANY clinical staff suspects a patient of COVID-19 and ≤7 days symptoms, please page Trauma Research Group (TRG) at 11502.

- **PI:** Bory Kea; **Coordinator:** Nancy Le
- **Inclusion:** Subject is suspected of COVID-19 infection by a healthcare provider.
- **Exclusion:** Subjects with active nose bleeds or acute facial injuries/trauma, currently enrolled in a study to evaluate an investigational drug, already participated in this study, unable/unwilling to provide informed consent, vulnerable populations (prisoners and pregnant woman).
- **Enrolled:** 67
- **Status:** RESTART on Friday, October 9, 2020 @7:00
- **Contact:** Nancy Le, Clinical Research Coordinator: lena@ohsu.edu

ED COVID-19 Registry Subject Follow up Study

This prospective cohort study will follow subjects up to 30 days post their ED visit for any COVID-like illness and be asked to consent to a weekly follow-up symptom survey for the 4 weeks following their ED visit. The purpose of this study is to learn more about the clinical course and outcomes of similar patients, and to help guide health systems and emergency departments during the current pandemic.

Sites: OHSU adult and peds EDs, and Tuality ED.

- **Co-PI's:** Craig Newgard, Esther Choo; **Coordinator:** Jenny Cook

- **Status:** Enrolling; **Launched:** April 17, 2020
- # of subjects consented: **381**

Leronlimab for severe COVID-19 infection

Purpose: To examine the impact of leronlimab on progression during mild COVID-19 infection.

- **PI:** Marcel Curlin, MD
- **Inclusion:** Age 18 and above, severe illness due to COVID-19 infection
- **Exclusion:** DNR status, requiring vasopressors for >24 hours, severe liver disease, end stage renal disease requiring chronic dialysis, other investigational treatment for COVID-19.
- Enrolled: **391**
- **Contact:** Amber Gordon (OCTRI) gordoamb@ohsu.edu

TJ003234 (Anti-GM-CSF Monoclonal Antibody) for moderate to severe COVID-19 infection

Purpose: To examine the impact of TJ 003234 on progression during severe COVID-19 infection.

- **PI:** Marcel Curlin, MD
- **Inclusion:** Age 18 and above, moderate to severe illness due to COVID-19 infection
- **Exclusion:** Severe CAD, Severe preexisting pulmonary disease, severe renal impairment, severe hepatic disease, HIV/HBV/HCV/TB, immunomodulatory drugs, ECMO, pregnancy, recent live vaccination
- Enrolled: **24**
- **Contact:** Amber Gordon (OCTRI) gordoamb@ohsu.edu

ACTIVE STUDIES



ICECAP- Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients (a SIREN Network study)

This study will enroll comatose adult survivors of out of hospital cardiac arrest that have already been rapidly cooled using a definitive temperature control method. Additionally, OHSU is anticipating that 5-6 of its network partners will also participate in ICECAP. Sites: OHSU - Portland Adventist ED

- **ICECAP PI:** Daya, **ICECAP Co-I:** Julia Durrant (OHSU), Miko Enomoto (OHSU), Josh Lupton (OHSU & Portland Adventist), Marwan Mouammar (Portland Adventist), Matthew Neth (Portland Adventist), William Spurlock (Portland Adventist), **Coordinator:** Nancy Le
- Registered with ClinicalTrials.gov: NCT 04217551
- FDA IDE: William Meurer, G160072
- **Status:** Enrolling; **Launched:** September 2020
- **Enrolled: 3; All site total: 14**

For more information: <https://siren.network/clinical-trials/icecap>



BOOST- 3 Brain Oxygen Optimization in Severe TBI Phase-3 Trial (a SIREN Network study)

BOOST 3 is a trial run through the nationwide SIREN Network. This study is comparing two strategies currently used for monitoring and treating patients with severe traumatic brain injury in the ICU. BOOST 3 allows for EFIC (Exception from Informed Consent) if an LAR is not present (within 6 hours).

- **BOOST-3 PI:** David Zonies, **SIREN PI:** Daya, **Coordinators:** Keeley McConnell (TRG), Jenny Cook EM Coordinator

- Registered with ClinicalTrials.gov: NCT03754114
- **Status:** Enrolling; **Launched:** March 16, 2020
- Study has received approval to continue during Research Level 2 operations
- Enrolled: **OHSU: 5 All site total: 77**

For more information: <https://www.ohsu.edu/school-of-medicine/emergency/boost-3-study>

CLOTT2 - The Pathogenesis of Post traumatic Pulmonary Embolism

Investigation into the significance of incidentally discovered venous thromboembolism following trauma and the role of fibrinogen break down in the development of post-traumatic VTE.

- **PI:** Kiraly, Laszlo; **Coordinator:** Dylan Payton
- **Inclusion:** >18 yo and ≥ 40 yo with ICU admission expected for ≥ 3 days and has at least on risk factor
- **Exclusion:** Outside of age range, direct admit to ward, and/or minor injuries
- **Status:** Enrolling; **Launched:** May 2018
- **Contact:** Dylan Payton, paytond@ohsu.edu

SWAT - Shock, Whole blood and assessment of TBI

Evaluate outcomes associated with early whole blood resuscitation practice as compared to component resuscitation in poly trauma patients with hemorrhagic shock and further characterize outcome benefits in those with TBI.

- **PI:** Schreiber, Martin; **Coordinator:** Sean Van Walchren
- **Inclusion:** blunt or penetrating trauma who meet 2 or more of the following criteria (SBP < 90mmhg, penetrating mechanism, + FAST and/or Tachycardia); and receives at least 1 unit of blood and goes to the OR with in 60minutes of arrival.
- **Exclusion:** <15, CPR > 5 consecutive minutes without ROSC, penetrating TBI with brain matter exposed, ED death, know pregnancy and/or prisoner
- **Status:** Enrolling; **Launched:** November 2018
- **Contact:** Sean Van Walchren, vanwalch@ohsu.edu

Digital Capillary Refill with HydraSense

Using a novel device (Hydrasense) to compare manual vs digital capillary refill: currently enrolling in patients 6mo-65yo.

- **PI:** Sheridan; **Coordinator:** Nancy Le
- Enrolled: **351**; Enrollment Goal: 600
- **Status:** Enrolling; **Launched:** September 12, 2018

This study requires NO work or input from RNs or MDs. The study team will work around staff with any patients they enroll to make sure and prioritize your time with them over the study.

HydraSense for Sepsis

A novel device for distal perfusion: currently enrolling in patients 6mo-65yo with fever, sepsis, and ESI 2-3.

- **PI:** Sheridan; **Coordinator:** Nancy Le
- Enrolled: **54**; Enrollment Goal: 100
- **Status:** Enrolling; **Launched:** June 24, 2019

Solace

Wearable technology for physiologic monitoring of adolescent suicidality: enrolls adolescents presenting with suicidality with goal of developing objective/physiologic markers that correlate with escalating suicidality.

- **PI:** Sheridan; **Coordinator:** Nancy Le
- Enrolled: **181**; Enrollment Goal: 200 across the pediatric ER and inpatient adolescent psychiatric unit at Unity
- **Status:** Enrolling with end date of December 2020; **Launched:** September 25, 2017

CLOVERS (Fluids vs. Vasopressors IRB 18184)

Goal is to find out if a liberal or restrictive fluid strategy is the more appropriate initial approach in patients with suspected infection and low blood pressure. Both arms are current standard of care with equipoise between the arms. Patients are enrolled in the ED.

Here is a [link to a 5 min patient video that further explains the study](#).



- **PI:** Akram Khan (khana@ohsu.edu)
- **Status:** Enrolling; **Launched:** July 2018
- **Contact:** Smartweb à Last Name à PRISM (#11912) (8am to 9pm)

SAVE-O2 - Strategy to Avoid Excessive Oxygen for Critically Ill Trauma Patients

SAVE-O2 will be a multicenter cluster randomized, stepped wedge implementation trial of a multimodal educational intervention to target normoxia in adult trauma patients admitted to the intensive care unit (ICU). The goal is to improve oxygenation to >90% of eligible patient-hours spent in the desired normoxia range, excluding time without supplemental oxygen or time on FiO2 100% and below the normoxia range. Launch Date: **October 15, 2020**

- **PI:** Schreiber, **Coordinator:** Samantha Underwood
- **Inclusion:** Patients who meet criteria for entry into the OHSU trauma registry
- **Exclusion:** Age <18 years, Prisoners, Known pregnancy, Transferred patients not admitted through the emergency department
- **Status:** Pre-study Preparation
- **Contact:** Samantha Underwood, underwos@ohsu.edu

UPCOMING STUDIES

Predicting medical consequences of novel fentanyl analog overdose using the Toxicology Investigators Consortium (ToxIC)

Purpose:

- Molecular identification and quantitation of fentanyl analogues (fentalogs) in a prospective cohort of 1000 Emergency Department (ED) patients with opioid overdose (OD) from the established ToxIC

hospital network. As this is a multi-center protocol, the number of subjects to be enrolled at each ToxIC site is approximately between 25-100.

- As an Exploratory Sub-Aim, we will characterize psychostimulant drug co-ingestions with fentalogs (e.g. synthetic cannabinoids, cocaine, cathinones, etc.) to provide confirmatory identification and quantitation.
 - To evaluate the medical consequences (sequelae, clinical management, and resource utilization) of fentalog OD.
 - Trend and geolocate confirmed fentalog OD and novel fentalog outbreaks across the ToxIC Network with periodic dissemination of findings to stakeholders.
 - Launch Date: **November 2020**
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- **PI:** Adrienne Hughes; **Study Coordinator:** Joy Kim
 - **Inclusion:** ED patient Opioid OD. Availability of waste blood or urine specimens for analysis.
 - **Exclusion:** Age < 18 years. Non-toxicological diagnosis. Prisoners. Trauma/Burns.
 - **Status:** Pre-study preparations. Anticipated launch November 2020. Study has received OHSU IRB approval.
 - **Contact:** Joy Kim, kimjoy@ohsu.edu

KCENTRA

A multicenter, pre-hospital pilot trial to determine the feasibility and safety of Kcentra administration for the early treatment of patients with traumatic shock, compared to placebo, in the field. This study will be conducted under EFIC (Exception from Informed Consent).

Launch Date: **December 2020**. Sites: OHSU and sites at Houston (2) and Seattle (1)

- **PI:** Schreiber, **Coordinators:** Samantha Underwood and Keeley McConnell
- Registered with ClinicalTrials.gov: NCT04019015
- FDA IND: Martin Schreiber, 18153
- **Status:** Pre-study Preparation