

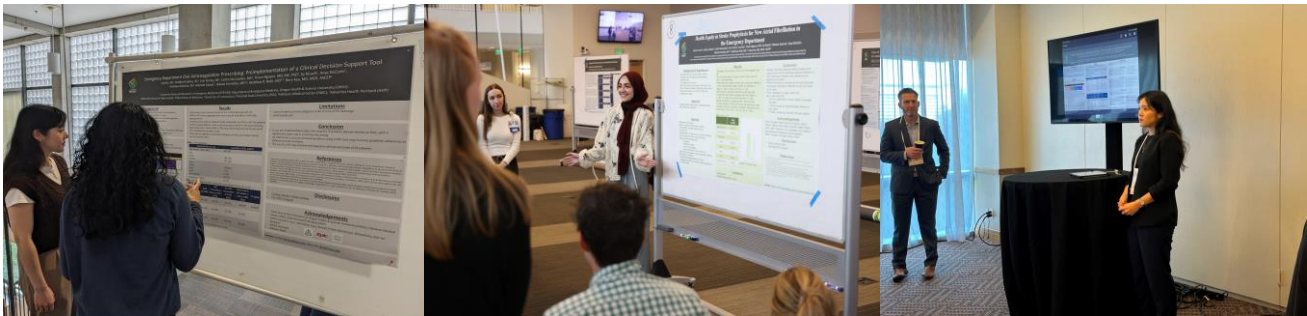
August 2023 Clinical Trials Newsletter

To those new to OHSU, welcome to our Emergency Department. As part of OHSU's triple mission, our ED team is leading research studies on multiple fronts, from studying the impacts of fentanyl, MPox, targeted temperature management in cardiac arrest patients, ultrasound in cardiac arrest, to self-care coaching for patients with heart failure. The list of topics is impressive, and I encourage you to read further and engage with the study teams to learn more. Some of our research students and staff had the opportunity to present at the National Conference for the Society of Academic Emergency Medicine in May 2023 (pictured below). We're excited that research is increasing at OHSU, Hillsboro Medical Center, and Adventist Hospital Portland, and appreciate all your support to make these studies successful. Enjoy the sunshine!

-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>



- DOTS
- Tropsensor
- PediDOSE
- P-ICECAP
- GUIDED-HF

- STRATIFY
- AF CDS
- FAST Exam
- REASON3
- Compartment Syndrome

- PACT
- KCENTRA
- Fentanyl (ToxIC)
- ICECAP
- BOOST-3

ACTIVE STUDIES

Examining the Prevalence, Clinical Characteristics, and Treatment of Mpox in U.S. Emergency Departments Participating in EMERGENCY ID NET

The CDC Sponsored Emergency ID Network has collaborated with the investigators at CDC to deploy a 6 month national emergency department surveillance project for mPOX. The study is looking to describe Mpox prevalence in the ED population. The CRISP Team will assist in identification of potential study patients.

Launched: June 2023

- **PI:** Jonathan Jui, MD; **Coordinator:** Mastura Wahedi
- **Inclusion:** Patients (≥ 3 months old years) with a rash of interest. (Essentially it is similar to a herpes zoster or varicella rash).
- **Status:** Active.
- **Contact:** Mastura Wahedi, wahedi@ohsu.edu

Drug Overdose Toxicology-Surveillance (DOTS)

DOTS is a multi-center project looking to identify illicit drugs in our community (as well as nationwide) and learn more about patterns of drug use. Illicit drugs will be identified in blood and the subject will answer questions about drug use in a structured interview.

Launched: April 2023

Study Duration: 5 years

Sites: 17 sites around the US

- **PI:** Rob Hendrickson, MD; **Coordinator:** Jeff Smith
- **Inclusion:** Subjects with toxicity from opioids, stimulants, or unknown illicit drugs who are older than 12 years.
- **Exclusion:** if symptoms are more likely due to a non-drug toxicity.
- **Status:** Enrolling; **Enrolled: 16; All site total: 88**
- **Contact:** Rob Hendrickson, hendriro@ohsu.edu; Jeff Smith, smitjeff@ohsu.edu

TropSensor - Measuring proteins in traditional and novel methods

TropSensor is a multi-site study of a novel device measuring Troponin transdermally – a needleless transdermal sensor. This device would provide a non-invasive alternative to standard of care measurements, meaning we may be able to measure Troponin levels without the use of a blood draw in the near future!



- **PI:** Bory Kea, **Coordinator:** Jordan Taboada
- **Status:** Enrolling; **Enrolled: 61; All site total: 741**
- **Contact:** Jordan Taboada, taboada@ohsu.edu

For more information: <https://rce.ai/european-heart-journal-digital-health/>

Pediatric Dose Optimization for Seizures in EMS (PediDOSE)

This study is a multi-center, stepped wedge trial of midazolam dosing for seizures in pediatric patients in the Emergency Medical Services (EMS) setting. It randomizes the timing of each of the participating EMS agencies at 20 different sites to switch from conventional, weight-based dosing to standardized, age-based dosing so that every EMS agency switches from conventional to standardized dosing over a 4-year enrollment period in this 5-year study. The primary outcome is seizing on ED arrival measured by the Ceribell Device. Federal exception from informed consent (EFIC) procedures will be used for enrollment.



Launched: November 2022

- **PI:** Matthew Hansen, **Coordinator:** Jordan Taboada
- **Inclusion:** Patient is Age ≥ 6 months to ≤ 13 years AND had a paramedic-witnessed seizure AND Require transport to any hospital; Ceribell Placement on patients age ≥ 2 years.
- **Exclusion:** Patient has a prior history of a benzodiazepine allergy; OR has known or presumed pregnancy; OR Has severe growth restriction based on the paramedic's assessment.
- **Status:** Enrolling; **Enrolled:** 52; **All site total:** 1,140
- **Contact:** cprem@ohsu.edu
- **24-hour line:** 503-494-1777



P-ICECAP

P-ICECAP – Pediatric Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients

This study is a multicenter, randomized, adaptive allocation clinical trial to identify the optimal duration of induced hypothermia for neuroprotection in comatose survivors of cardiac arrest.

Launched: October 2022 Site: [Doernbecher Children's Hospital](#)

- **PI:** Serena Kelly, **Co-I:** Aileen Kirby, Cydni Williams, Beech Burns, Mo Daya, Bory Kea
- **Coordinator:** Jeff Smith
- Registered with ClinicalTrials.gov: NCT05376267
- FDA IDE: William Meurer, G210126
- **Status:** Enrolling; **Enrolled:** 2; **All site total:** 72
- **Contact:** Jeff Smith, smitjeff@ohsu.edu

Implementation of a Self-Care Plan for Patients with Acute Heart Failure Discharged from the ED (GUIDED-HF)

GUIDED-HF is a multi-site project with implementation of a self-care plan for acute heart failure (HF) at OHSU and Hillsboro Medical Center. This project aims to provide self-care coaching (x3 virtual visits) for patients discharged from the Emergency Department (ED) with HF.

Launched: February 1, 2022

Sites: [OHSU & HMC](#)

- **PI:** Bory Kea; **Study Coordinator:** Joy Kim
- **Inclusion:** Diagnosed with HF and/or received loop diuretics in ED.
- **Status:** Enrolling; **Enrolled: 48**
- **Contact:** Joy Kim, kimjoy@ohsu.edu

Tailored Dissemination and Implementation of Emergency Care Clinical Decision Support to Improve Emergency Department Disposition (STRATIFY)

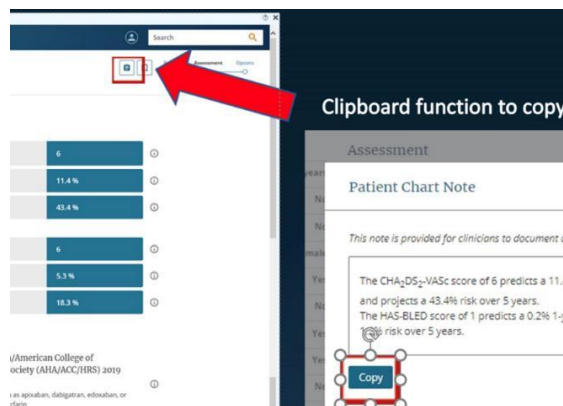
STRATIFY is a study on the development and dissemination/implementation of a clinical decision support tool for heart failure risk stratification and disposition. This project aims to examine ED workflow at OHSU and Hillsboro Medical Center (HMC) to determine how to best integrate it into a clinical decision support (CDS) tool for patient and provider shared-decision making, specifically for acute heart failure patients.

- **PI:** Bory Kea; **Study Coordinator:** Joy Kim
- **Status:** Analyzing retrospective EHR data using the STRATIFY risk factors to understand and address data challenges in STRATIFY implementation
- **Contact:** Joy Kim, kimjoy@ohsu.edu

Atrial Fibrillation (AF) Clinical Decision Support (CDS) Tool

A stepped-wedge clinical trial of an electronic clinical decision support tool to improve stroke prevention in patients with atrial fibrillation. Patients and providers will be recruited for qualitative interviews at 3 sites (OHSU, AHP, HMC).

Please use the clipboard function to copy documentation from the tool:



Launched Step 1: OHSU – January 11, 2022; HMC – April 4, 2022

Launching Step 1: AHP – February, 2023

Launching Step 2 (Link + BPA): OHSU – March 2023

- **PI:** Bory Kea; **Study Coordinator:** Joy Kim
- **Inclusion:** : >18 years, OAC naïve
- **Status:** Enrolling; **Enrolled: Quantitative – 581; Qualitative – 7 patients, 10 providers**
- **Contact:** Joy Kim, kimjoy@ohsu.edu

Automated Ultrasound Image Analysis of the Abdominal FAST Exam

Purpose of this study is to attain a library positive and negative abdominal ultrasound images of the standard Focused Assessment with Sonography for Trauma (FAST) imaging protocol, which can be

subsequently annotated to train a machine learning algorithm.

Launched: October 13, 2021

Sites: OHSU, Medstar, Brook Army Medical Center, Tripler Army Medical Center, Womack Army Medical Center

- **PI:** Nikolai Schnittke; **Coordinators:** Samantha Underwood and Michael Fleming
- **Inclusion:** Adults ED trauma patients who either have a positive FAST exam performed and saved by the clinical team, or have a CT scan of the abdomen/pelvis performed as part of the trauma workup, with follow-up research FAST performed by the study team. Non-trauma patients with peritoneal fluid are also eligible for a research FAST exam performed by the study team.
- **Exclusion:** Skin disease and/or wounds that would preclude transducer placement, prisoners.
- **Status:** Enrolling; **Enrolled: 154; All site total: 257**
- **Contact:** Nikolai Schnittke, schnittk@ohsu.edu

For potential enrollment please call or page TRG: 4-5939 pager: 11502

REASON3: Bedside Cardiac Ultrasound in Cardiac Arrest

The objective is to measure survival rates associated with different presenting rhythms as assessed by ultrasound versus ECG strip in patients presenting in cardiac arrest.

Launched: August 17, 2021

- **PI:** Nikolai Schnittke
- **Inclusions:** Adult ED patients in nontraumatic cardiac arrest
- **Exclusions:** Resuscitation ended due to end-of-life decisions, ultrasound images or rhythm strip not saved.
- **Status:** Enrolled; **Enrolled: 16; All site total: 640**
- **Contact:** Nikolai Schnittke, schnittk@ohsu.edu

Observational Study of Extremity Compartment Syndrome Using SWE and MFI

An observational study to evaluate the utility of two ultrasound modes (shear wave elastography and microvascular flow imaging) in the diagnosis of compartment syndrome related to lower and/or upper extremity traumatic injury.

Launched: May 5, 2021

- **PI:** Kenton Gregory
- **Inclusions:** Adult ED patients with suspected (clinical suspicion and/or high-risk injury requiring scheduled compartment checks) single or multiple acute compartment syndrome of the lower and/or upper extremity.
- **Exclusions:** Prior fasciotomy of affected extremity, Skin disease and/or wounds that would preclude transducer placement, Prisoners.
- **Status:** Enrolling; **Enrolled: 24; All Site total: 83**
- **Contact:** Nikolai Schnittke, schnittk@ohsu.edu ; Bryson Hicks, hicksbr@ohsu.edu

For potential enrollment please call or page TRG: 4-5939 pager: 11502

PACT- Prehospital Airway Control Trial

PACT is an open-label, multi-site, stepped wedge randomized trial comparing a standard strategy of airway management with a strategy of first attempt with supraglottic airway (SGA) for trauma patients in a prehospital setting. The primary outcome is 24-hour mortality. It is assessed 24 hours after hospital arrival.

Eight local agencies in the Clackamas and Washington counties are participating including AMR Clackamas, Clackamas County Fire District 1, Lake Oswego Fire, Molalla Fire, Canby Fire, Tualatin Valley Fire & Rescue, Hillsboro Fire & Rescue, and Metro West Ambulance.

Launched: April 1, 2021

- **PI:** Mo Daya, **Co-I:** Marty Schreiber **Coordinator:** Nancy Le, Sam Underwood
- **Inclusion:** Trauma requiring advanced airway management. Indicators of the need for advanced airway management include: a) GCS < 8, b) SpO2 < 90 despite supplemental oxygen, c) ETCO2 > 60 despite supplemental ventilation, or d) provider discretion. **Transport to LITES Trauma Center – OHSU ONLY.**
- **Exclusion:** <15 years of age, pregnant, prisoner, initial advanced airway attempted by a non-PACT agency, in cardiac arrest without ROSC at time of intervention, caustic substance ingestion, airway burns, objection to enrollment voiced by subject or family members at the scene.
- **Status:** Enrolling; **Enrolled: 1243**
- **Contact:** Nancy Le, lena@ohsu.edu

****OHSU Team- please remember to document: (1) Date & Time of Airway Exchange and (2) Reason for Airway Exchange (hypoxia, inadequate ventilation, etc).****

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).

Launched: March 2021 Sites: OHSU and sites at Houston (2) and Seattle (1)

- **PI:** Schreiber, **Coordinator:** Jerome Differding
- Registered with ClinicalTrials.gov: NCT04019015
- FDA IND: Martin Schreiber, 18153
- **Inclusion:** 18 years and older, SBP <70 or no palpable pulse, suspicion of hemorrhagic shock, transport to participating hospital
- **Status:** On Hold
- **Contact:** Jerome Differding, differdi@ohsu.edu

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

Purpose of this multi-center study is 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. 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.

Please use "poisoning by opioids" in your impression for all opioid overdoses.

Launched: November 2020

- **PI:** Adrienne Hughes; **Study Coordinator:** Jordan Taboada
- **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:** Enrolling (resumed Feb 2022); **Enrolled: 61**
- **Contact:** Jordan Taboada, taboada@ohsu.edu



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.

Launched: September 2020 Site: [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:** Keeley McConnell
- Registered with ClinicalTrials.gov: NCT 04217551
- FDA IDE: William Meurer, G160072
- **Status:** Enrolling; **Enrolled: 57; All site total: 747**
- **Contact:** Joy Kim, kimjoy@ohsu.edu

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).

Launched: March 16, 2020

- **BOOST-3 PI:** David Zonies, **SIREN PI:** Daya, **Coordinator:** Michael Seigneur (TRG)
- Registered with ClinicalTrials.gov: NCT03754114
- **Status:** Enrolling; **Enrolled: OHSU: 36; All site total: 491**
- **Contact:** Michael Seigneur, seigneum@ohsu.edu

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

CLOSED STUDIES

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.

Launched: October 15, 2020

- **PI:** Schreiber, **Coordinator:** Laura Nguyen
- **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:** Closed to Enrollment; **Enrolled: 2,654; All site total: 19,759**

- **Contact:** Laura Nguyen, nguyelau@ohsu.edu

