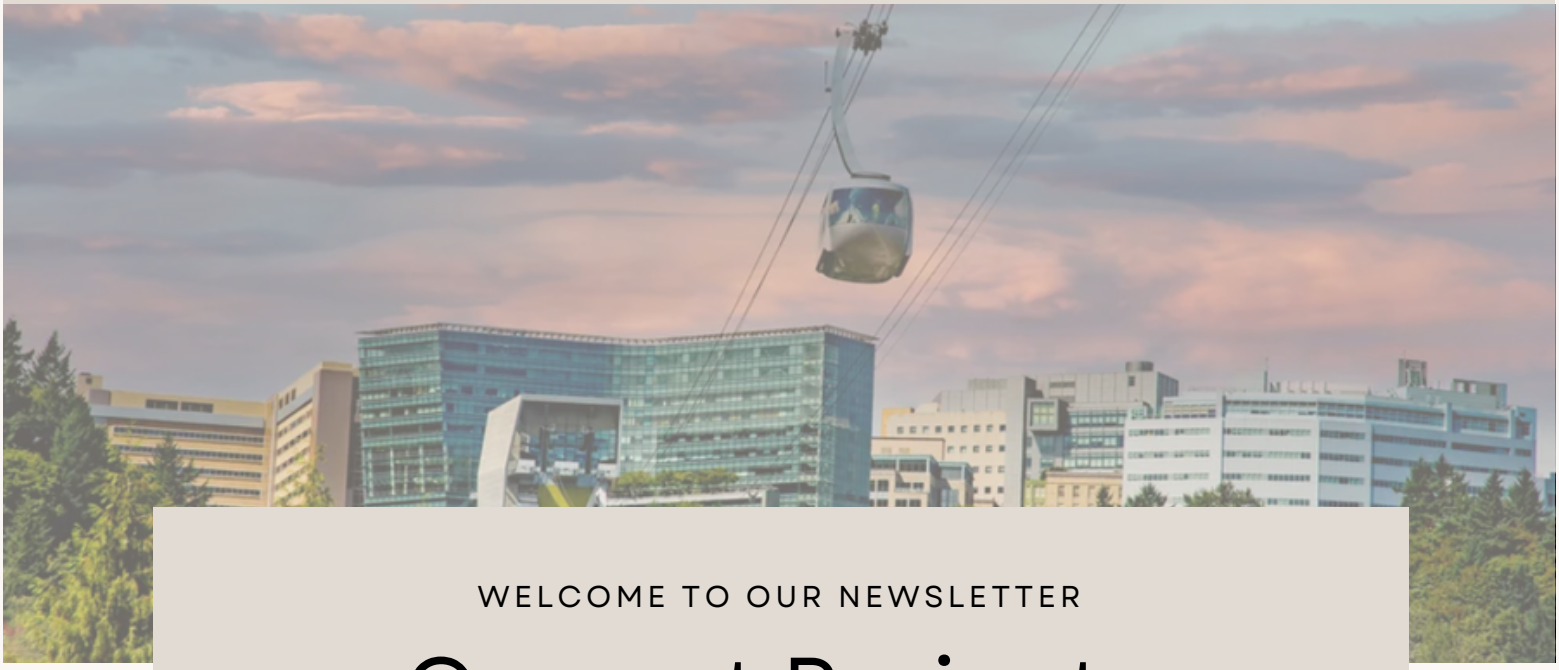
OHSU: EMERGENCY MEDICINE

MAR 2024



WELCOME TO OUR NEWSLETTER

Current Projects

- TAP
- BONE MARROW STUDY
- COMBO1
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- EMERGENCY ID NET
- DOTS
- RESPIRATIO
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- AIMS
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- PEDIDOSE
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- STRATIFY
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- FAST EXAM
- REASON3
- COMPARTMENT SYNDROME
- PACT
- KCENTRA
- FENTALOG (TOXIC)
- ICECAP
- BOOST-3
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ACTIVE STUDIES

Trauma and PCC Study (TAP)

The primary objective of the TAP study is to assess the efficacy of a single IV infusion of Kcentra on all-cause mortality at 6hrs after randomization (IP vs. Placebo) in subjects who have traumatic injury with no known anticoagulation treatment, and with confirmed or suspected acute major bleeding and/or predicted to receive a large volume blood product transfusion.

Launched: November 19, 2023

- **PI:** Martin Schreiber, MD; **Coordinators:** Echo Meyers and Austin Lerwick
- **Inclusion:** Patients (≥ 15 years old) with a traumatic injury with confirmed or suspected acute major bleeding.
- **Status:** Active.
- **Contact:** Coordinators @trauma pager 11502

Direct Biologics stem cell: Bone Marrow Mesenchymal Stem Cell Derived Extracellular Vesicles for Hospitalized Patients with Moderate-to-Severe ARDS: A Phase III Clinical Trial

The objective of this study is to evaluate the safety and efficacy of IV administration of bone marrow mesenchymal stem cell derived from extracellular vesicles, ExoFlo, versus placebo for the treatment of hospitalized patients with moderate-to-severe ARDS

Launched: November 2023
Study Duration: Ongoing

- **PI:** Akram Khan, MD; **Coordinator:** PRISM Research Team
- **Inclusion:** Meets the established Berlin criteria of moderate-to-severe ARDS (chest imaging with bilateral opacities, PaO2/FiO2 <= 200mmHg)
- **Exclusion:** ALT or AST >8x ULN, history of cirrhosis, DNR order, Moribund
- **Status:** Enrolling; **Enrolled: 0**
- **Contact:** Akram Khan, khana@ohsu.edu (page 15351); Jose Pena, penaj@ohsu.edu (page 11912); vocera “MICU RESEARCH”

COMBO1: Combination therapy with Baloxavir and Oseltamivir 1 for hospitalized patients with influenza- the pragmatic COMBO1 trial

To test the hypothesis that combination therapy with oseltamivir and single dose baloxavir will result in shorter time to clearance of viral shedding by virus titer using qCulture from nasal swabs in hospitalized pts with influenza in comparison with standard oseltamivir monotherapy in a pragmatic clinically relevant trial population.

Launched: November 2023
Study Duration: June 2024

- **PI:** Akram Khan, MD; **Coordinators:** PRISM Research Team
- **Inclusion:** laboratory confirmed influenza A or B during the 2021-2024 influenza seasons.
- **Exclusion:** end stage renal disease not undergoing dialysis, severe hepatic insufficiency, nausea/vomiting or aspiration risk precluding oral medications.
- **Status:** Active, **Enrolled: 2**
- **Contact:** Akram Khan, khana@ohsu.edu (page 15351); Edvinas Pocius, pocius@ohsu.edu (page 11912); vocera “MICU RESEARCH”

IVY-6: Influenza and Other Viruses in the Acutely Ill

Assessing the clinical validity of SARS-CoV-2 RT-PCR results and vaccine effectiveness.

Launched: September 2023
Study Duration: Ongoing
Sites: OHSU & Vanderbilt University Medical Center

- **PI:** Akram Khan, MD; **Coordinators:** PRISM Research Team
- **Inclusion:** Acute symptom onset within 14 days of admission; positive or negative SARS-CoV-2, influenza, or RSV test after onset of symptoms; COVID positive for cohort 1, COVID negative for cohort 2.
- **Exclusion:** test > 14 days of onset of symptoms, previously enrolled in surveillance program.
- **Status:** Active, **Enrolled: 63**
- **Contact:** Akram Khan, khana@ohsu.edu (page 15351); Edvinas Pocius, pocius@ohsu.edu (page 11912); vocera “MICU RESEARCH”

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) 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 Toxico-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: 42; All site total: 510**
- **Contact:** Rob Hendrickson, hendriro@ohsu.edu; Jeff Smith, smitjeff@ohsu.edu

Assessment of Implementation of Methods in Sepsis and Respiratory Failure (AIMS)

The Assessment of Implementation of Methods in Sepsis and Respiratory Failure (AIMS) study seeks to determine the safest and most effective approach to sepsis intervention using the evidence-based Surviving Sepsis Campaign guidelines. The goal of the AIMS study is to determine whether the Hour-1 or 3-Hour Bundle is most effective when implemented in emergency departments.

Launched: January 2023
Study Duration: Ongoing

- **PI:** Terri Hough, MD
- **Inclusion:** All suspected sepsis patients
- **Status:** Active
- **Contact:** Scott Sherry, sherrys@ohsu.edu; Caitlyn Hickey, hickeyc@ohsu.edu

Roche PK study: A multicenter, single-dose, uncontrolled, open-label, one group study to investigate the pharmacokinetics of RO7223280 in critically ill patients with bacterial infections.

To investigate the plasma PK following IV administration of a single dose of 600mg RO7223280 in critically ill pts with bacterial infections.

Launched: January 2023
Study Duration: June 2024

- **PI:** Akram Khan, MD; **Coordinators:** PRISM Research Team
- **Inclusion:** ongoing clinical syndrome meeting at least one of the follow criteria- hospital acquired (or nosocomial) bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), and bacteremia.
- **Exclusion:** ongoing documented catheter-related bacteremia, major surgery within 48hr prior to dosing, known Child-Pugh class C.
- **Status:** Active, **Enrolled: 6**
- **Contact:** Akram Khan, khana@ohsu.edu (page 15351); Jose Pena penaj@ohsu.edu (page 11912); vocera “MICU RESEARCH”

DOMPE REP0122 ARDS: Phase 2. Proof-of-concept, randomized, double-blinded, placebo-controlled, multicenter study to asses efficacy and safety of reparixin as add-on therapy to standard of care in adult patients with Acute Respiratory Distress Syndrome (RESPIRATIO).

To characterize the efficacy of reparixin in ameliorating lung injury and systemic inflammation and expediting clinical recovery and liberation from mechanical ventilation in adult patients with moderate to severe ARDS, and to characterize the pharmacokinetics (PK) of reparixin in the same population of acutely ill pts enrolled in the study.

Launched: March 2023
Study Duration: Ongoing

- **PI:** Akram Khan, MD; **Coordinators:** PRISM Research Team
- **Inclusion:** mechanically ventilated pts with PaO2/FiO2 RATIO ≤200 in the presence of PEEP of ≥ 5cm H20, ≤ 48hrs of fulfilling ARDS criteria, ≤ 7 days from hospital admission.
- **Exclusion:** eGFR < 30mL/min or hepatic, discharged.
- **Status:** Active, **Enrolled: 4**
- **Contact:** Akram Khan, khana@ohsu.edu (page 15351); Genesis Briceno, parra@ohsu.edu (page 11912); vocera “MICU RESEARCH”

DOMPE REP0321 CAP: Reparixin 1200mg three times a day as add-on therapy to standard of care to limit disease progression in hospitalized adult patients with COVID-19 and other community-acquired pneumonia. A multinational, multicenter, randomized, double-blinded, placebo-controlled, parallel-group phase III trial.

To evaluate the efficacy of oral reparixin vs standard care alone in limiting disease progression in adult patients hospitalized for infectious pneumonia acquired in the community (CAP), including COVID-19

Launched: March 2023
Study Duration: Ongoing

- **PI:** Akram Khan, MD; **Coordinators:** PRISM Research Team
- **Inclusion:** clinically suspected CAP within 48hr from hospital admission, need for non-invasive supplemental o2, SpO2 <92%.
- **Exclusion:** eGFR <50mL/min or hepatic, in IMV/ECMO, discharged.
- **Status:** Active; **Enrolled: 20**
- **Contact:** Akram Khan, khana@ohsu.edu (page 15351); Genesis Briceno, parra@ohsu.edu(page 11912); vocera “MICU RESEARCH”

Solace: Wearable Technology to Detect Physiologic Parameters in Suicidal Adolescents.

The objective of this study is to evaluate various physiologic biosignals that could be associated with suicidality in adolescent patients. Patients presenting to the ED aged 13-17 with acute suicidal thoughts or attempt are enrolled if they provide assent/consent. The study protocol involves wearing a smartwatch and undergoing Ecologic Momentary Assessment (EMA). The EMA pings them 4x a day with validated suicidal scores. Using machine learning the goal is to predict the validated suicidal metrics with physiologic signals.

Launched: January 2023

- **PI:** David Sheridan, MD, MCR; **Coordinators:** Dalton Wesemann and Nick Patrick
- **Status:** Ongoing in the OHSU ED and Unity Inpatient Adolescent Psychiatric Unit
- **Contact:** Dalton Wesemann, wesemann@ohsu.edu; Nick Patrick, patricni@ohsu.edu

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: 77; All site total: 2,130**
- **Contact:** cprem@ohsu.edu
- **24-hour line:** 503-494-1777

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: 3; All site total: 102**
- **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: 76**
- **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.

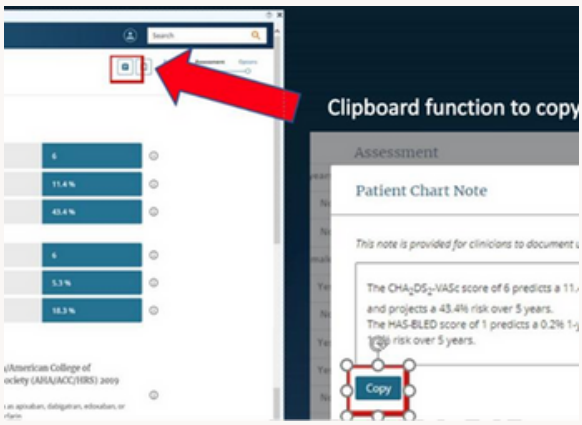
- **PI:** Bory Kea; **Study Coordinator:** Joy Kim
- **Status:** OHSU building Fast Healthcare Interoperability Resource (FHIR) application using the STRATIFY risk factors to launch the STRATIFY clinical decision support tool in March 2024
- **Contact:** Joy Kim, kimjoy@ohsu.edu

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).

➜ **Launched Step 1 (Link Out):** OHSU – January 11, 2022; HMC – April 4, 2022
➜ **Relaunched Step 1 after Epic transition:** AHP – April 20, 2023
➜ **Launched Step 2 (Link + BPA):** OHSU – March 1, 2023; HMC - August 1, 2023

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



- **PI:** Bory Kea; **Study Coordinator:** Joy Kim
- **Inclusion:** >18 years, OAC naïve
- **Status:** Enrolling; **Enrolled: Quantitative – 581; Qualitative – 9 patients, 11 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: 180; All site total: 296**
- **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: 18; All site total: 747**
- **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: 31; All Site total: 113**
- **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: 132; All Site total: 1350**
- **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, **Coordinators:** Austin Lerwick and Echo Meyers
- 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:** Austin Lerwick, lerwick@ohsu.edu ; Echo Meyers, meyersec@ohsu.edu

Predicting medical consequences of novel fentanyl analog overdose using the ToxicologyInvestigators 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
- **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; **Enrolled: 110**
- **Contact:** Adrienne Hughes, hughesad@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:** Joy Kim
- Registered with ClinicalTrials.gov: NCT 04217551
- FDA IDE: William Meurer, G160072
- **Status:** Enrolling; **Enrolled: 62; All site total: 885**
- **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: 43; All site total: 539**
- **Contact:** Michael Seigneur, seigneum@ohsu.edu

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