UTHealth Houston

Committee for the Protection of Human Subjects

7000 Fannin Street, Suite 1870
Houston, Texas 77030

Dr. Natalie Drucker
UT-H - MS - SURG - General Surgery (ACGME)

NOTICE OF APPROVAL TO BEGIN RESEARCH **October 18, 2023**

HSC-MS-23-0789 - Pediatric Prospective Observational Vascular Injury Trial Registry

Number of Subjects Approved: Target: 500

PROVISIONS: This approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered by the Committee for the Protection of Human Subjects, e.g. study documents, informed consent, etc.

APPROVED: By Expedited Review and Approval

REVIEW DATE: 10/17/2023

APPROVAL DATE: 10/18/2023

L. Maximilian Buja

CHAIRPERSON: L. Maximilian Buja, MD

Subject to any provisions noted above, you may now begin this research.

PLEASE NOTE: Due to revisions to the common rule that went into effect July 19, 2018, this study that was approved under expedited approval no longer needs to submit for continuing review. Changes to the study, adverse events, protocol deviations, personnel changes, and all other types of reporting must still be submitted to CPHS for review and approval. When this study is complete, the PI must submit a study closure report to CPHS.

CHANGES: The principal investigator (PI) must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. **ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.**

INFORMED CONSENT DETERMINATION:

Waiver of Consent Granted

INFORMED CONSENT: When Informed consent is required, it must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. Please note that only copies of the stamped approved informed consent form can be used when obtaining consent.

HEALTH INSURANCE PORTABILITY and ACCOUNTABILITY ACT (HIPAA):

Waiver for Retrospective Chart Review granted:
Information to be accessed: Complete Medical Record
Information to be retained: MRN

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.
RECORDS: The PI will maintain adequate records, including signed consent and HIPAA documents if required, in a manner that ensures subject confidentiality.