

Dr. Michelle McNutt
UT-H - MS - Surgery

NOTICE OF APPROVAL TO BEGIN RESEARCH

April 02, 2018

HSC-MS-18-0227 - Blunt bowel and mesenteric injury: A WTA Multicenter Prospective Observational Study

Number of Subjects Approved: Target: 350 / Screen: 350

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: 03/30/2018

APPROVAL DATE: 04/02/2018

EXPIRATION DATE: 02/28/2019

CHAIRPERSON: L. Maximilian Buja, MD

L. Maximilian Buja

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

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

HEALTH INSURANCE PORTABILITY and ACCOUNTABILITY ACT (HIPAA):

Waiver for Retrospective Chart Review granted:

Information to be accessed: Date of Birth, Date of Death, Date of Discharge, Date of Service/Treatment/Admission, Medical Record #

Information to be retained: Date of Death, Date of Discharge, Date of Service/Treatment/Admission, Medical Record #

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.