# IRB Application (Version 1.0)

## 1.0 General Information

* Please enter the full title of your study:

Blunt bowel and mesenteric injury: A WTA Multicenter Prospective Observational Study

* Please enter the Study Alias you would like to use to reference the study:

WTA BIPS Study

* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Is this Study using Subject Management?

○ Yes ◉ No

## 2.0 Add Department(s)

### 2.1 List departments associated with this study

| Primary Dept? | Department Name |
|---|---|
| ◉ | UT-H - MS - Ctr for Translat Injury Rsch |

## 3.0 Assign key study personnel(KSP) access to the study

### 3.1 * Please add a Principal Investigator for the study:

Michelle McNutt

Select if applicable

☐ Student ☐ Department Chair

If the Principal Investigator is a Student, Resident, or Fellow, the name of the Faculty Advisor must be supplied below.

### 3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Charles Wade, PhD

Co-Investigator

B) Research Support Staff

Jeanette Podbielski, R.N.

IRB - Study Coordinator

### 3.3 Please add a Study Contact:

Michelle McNutt

Jeanette Podbielski, R.N.

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) can typically be someone other than the Principal Investigator themselves).

### 3.4 For applicable Human Subjects Research, please add a Faculty Advisor:

3.5 For applicable Human Subjects Research, please select the Designated Department Approval(s):

Add the name of the individual authorized to approve and sign off on this protocol from your Department (e.g. the Department Chair or Dean).

3.6 If applicable, please select the Administrative Assistant(s)

Administrative Assistants have READ-ONLY access to submissions in iRIS.

## 4.0 Contact Information and Additional Study Personnel

4.1 Form Version 10 - published 8/10/15

4.2 The primary mechanism for CPHS communication with you will be through iRIS Correspondence, however, we may need to call you for clarification. Please provide names and contact numbers as outlined below. Please make sure these individuals have a good knowledge of the protocol. For most studies the Principal Investigator and study coordinator are listed as the primary and secondary contacts.

| | Name | Office Phone | Pager/Cell Phone |
|---|---|---|---|
| * Primary Contact | Jeanette Podbielski | 713-500-6407 | |
| Secondary Contact | Michell McNutt | 713-500-7244 | |

4.3 List Study Personnel who are not listed in the UT White Pages Directory (not UT employees or guests) and specify their roles on this study.

**Key study personnel are defined as personnel responsible for the design, conduct, or reporting of the proposed research or other educational activities.**

*** NOTE: Human subjects training certification and research conflict of interest forms are required for Key Study Personnel. Only Human subjects training certification is required for Non-key Study Personnel.**

| Name | Affiliation | E-mail address | Role in this study | Comments - describe role on study |
|---|---|---|---|---|
| No records have been added. | | | | |

## 5.0 Locations

5.1 * Is the research being conducted at the Clinical Research Unit (CRU) or are other CRU services being requested? NOTE: If YES, you will be required to complete some additional questions within this application and your application will be routed automatically to the CRU for review.

○ Yes ◉ No

5.2 * Is the research being conducted at a Memorial Hermann Healthcare System facility? Please note: If the research will be conducted at a Memorial Hermann Healthcare System facility, remember to complete and attach the Memorial Hermann Application Form which you can find under the Review Board Forms section when you are putting together the submission packet.

◉ Yes ○ No

5.3 Please identify other locations or facilities not listed above where the research is being conducted.

Select all that apply:

- ☐ BBS - Behavioral and Biomedical Sciences Building
- ☐ Ben Taub General Hospital (Harris Health)
- ☐ HCPC - Harris County Psychiatric Center
- ☐ Hermann Medical Plaza (UT Clinics)

- [ ] HISD - Houston Independent School District
- [ ] Houston Medical Center Building
- [ ] IMM - Institute of Molecular Medicine
- [ ] LBJ Hospital (Harris Health)
- [ ] M. D. Anderson
- [ ] Methodist Hospital
- [ ] St. Luke's Episcopal Hospital
- [ ] Texas Childrens' Hospital
- [ ] Texas Heart Institute
- [ ] Thomas Street Clinic (Harris Health)
- [ ] UT - School of Dentistry
- [ ] UT Professional Building
- [ ] UT - School of Nursing
- [ ] UT - School of Public Health
- [ ] Valley Baptist Medical Center - Brownsville (VBMC)
- [ ] Veterans Affairs Medical Center
- [ ] OTHER

**Please identify additional locations or facilities not listed above:**

***Please be reminded that if you are conducting research at facilities other that UT, MHH, THI and HCHD, you must ensure you have all the necessary approvals required by that facility including review and approval by their IRB.***

## 6.0 Memorial Hermann Hospital Locations

### 6.1 Select all locations that apply:

*Please note: If conducting research at any of the Memorial Hospital Healthcare locations, the Memorial Hermann Healthcare Research Application must also be completed and attached to your submission packet along with the Memorial Hermann Ancillary List.*

- [x] Memorial Hermann - Texas Medical Center, Houston, TX
- [ ] Children's Memorial Hermann Hospital, Houston, TX
- [ ] Memorial Hermann Sugar Land, Sugar Land, TX
- [ ] Memorial Hermann Memorial City Medical Center, Houston, TX
- [ ] Memorial Hermann Southeast, Houston, TX
- [ ] Memorial Hermann The Woodlands, The Woodlands, TX
- [ ] Memorial Hermann Katy, Katy, TX
- [ ] Memorial Hermann Southwest, Houston, TX
- [ ] Memorial Hermann Northwest, Houston, TX
- [ ] Memorial Hermann Northeast, Houston, TX
- [ ] TIRR Memorial Hermann, Houston, TX
- [ ] Memorial Hermann Corporate Office
- [ ] Physicians at Sugar Creek - Family Practice Medicine, Sugar Land, TX
- [ ] University Place Retirement Community and Nursing Center, Houston, TX
- [ ] Memorial Hermann Prevention and Recovery Center (PaRC), Houston, TX
- [ ] Memorial Hermann Rehabilitation Hospital - Katy, Katy, TX
- [ ] CRU use outside Memorial Hermann Hospital System facilities and services
- [ ] Hermann Medical Plaza (non-UT Clinics)
- [ ] Other

If "other", provide additional information:

## 7.0 Funding Source

7.1 * Have you applied for or have you already received funding or support for this research proposal?

○ Yes ◉ No

7.2 Please identify how this study is funded or supported. If the agency/sponsor is not listed, please call the iRIS Support line at 713-500-3470 for assistance. You can select more than one agency.

| | Sponsor | Funding |
|---|---|---|
| Federal - NIH | | |
| Private - Non-profit | | |
| Academic Health Center | | |
| Other | | |
| Federal | | |
| Internal - UTHSC-H | | |
| Pharmaceutical or Device Manufacturer | | |
| State Agency | | |

7.3 If this is an industry sponsored clinical trial, provide contact information for the sponsor for IRB fee billing purposes.

| Contact Name | Contact Phone Number | Contact E-mail address | Additional information (if necessary) |
|---|---|---|---|

7.4 Status of funding:

Please select one:

○ Applied/Pending
○ Approved
◉ Not Applicable

7.5 If this is investigator initiated research for which you have applied/received monetary or in-kind support from industry sponsors, please describe in detail. Include details on kind of support, who has oversight over the research project and who has ownership of the data.

## 8.0 Study Summary

8.1 * Summarize the proposed research using non-technical language. Limit to about 250 words. This summary will be used as a reference throughout the course of the study by reviewers and will appear in the "Study Summary" section in iRIS. Please include the following in your summary: the purpose research design procedures to be used risks and potential benefits and importance of knowledge that may reasonably be expected to result

Purpose: The purpose of this study is to prospectively identify high mechanism blunt abdominal trauma patients and validate the retrospectively designed BIPS as a method of identifying patients who may require surgical intervention for bowel injury.

Research Design: This is a multi-center, prospective, observational study. UTHealth will be the lead site with Dr. Michelle McNutt serving as the overall PI. Members of the Western Trauma Association (WTA) will have the opportunity to participate in this study. Currently there are approximatley 15 to 20 centers interested in participating.

Procedures: Potential subjects will be identified by reviewing the trauma surgery morning reports and data will be abstracted from the medical records and trauma registry to complete the data entry for this study. There will be interaction with the patient. The study will not involve any experimental medication, device or procedure.

Risks and potential benefits. The only possible risk is breach of confidentiality and all measures will be taken to ensure the patient's privacy is maintained. Each subject will be identified by a study specific number. Hard copies of data will be kept in a secure, locked area and electronic data will be stored on password-

protected computers. There is no benefit to the subjects participating in this study.
Importance of knowledge gained: The information obtained from this observational study will assist the trauma physicians to determine if the BIPS (Bowel Injury Predivtive Score) is an effective method of identifying patients who require surgical intervention for bowel injury.

## 9.0 Determining Review Type

9.1 * The purpose of this panel is to allow iRIS to branch to simpler versions of the application for certain types of proposals (e.g. when you are uncertain whether the activity you are conducting needs to be reviewed and approved by the IRB). Please select the appropriate option:

NOTE: MEDICAL SCHOOL ONLY: Studies that do not qualify for the exempt or expedited review process will require a Departmental Research Review form to be attached to the submission. The exempt criteria are listed in the next panel and the expedited criteria are listed in the bubble to the right. If you do not believe that your protocol qualifies for either category, a Departmental Research Review form will need to be uploaded in the Study Documents section of the submission packet. For more information can be found on the Departmental Research Review information page.

Your submission will be returned to you if this form is not included.

- ○ Humanitarian Use Device - NOT as part of a research study
- ○ Request for permission to rely on IRB approval from an IRB with whom UT Houston has signed a reliance agreement (all UT System Component IRBs, NICHD Federated IRB , Baylor College of Medicine, Chesapeake IRB, BRANY IRB, Quorum IRB, WIRB/WCG IRB, IRBshare, etc.)
- ○ Requesting assistance in whether or not formal IRB review is appropriate. See HELP bubble.
- ◉ None of the above - Requesting review by UTHealth's IRB

## 10.0 Subject Contact Question

10.1 * Does this study involve contact with subjects?

- ◉ My study does not involve contact with subjects.
- ○ My study involves contact with subjects (including "in-person", e-mail, phone, anonymous or online surveys, etc.).

**If the study involves contact with subjects, select an option below:**

- ○ My study ONLY involves normal education practices, educational tests, surveys, interviews, or observations of public behavior.
- ○ My study involves interventions, drugs or devices, clinical observations, or other study procedures.

## 11.0 Exempt Categories 4a or 4b

11.1 * What is the source of the records/biological specimen? (Choose all applicable options. For example, if you are planning to collect biological specimens and medical records information, choose both options).

- ☐ Data - Publicly available data
- ☐ Data - Historical dataset from previous research
- ☑ Data - Medical Records
- ☐ Biological specimen - Tissue repository or bank
- ☐ Biological specimen - Historical dataset from previous research
- ☐ Biological specimen - Pathology Department (See note below.)
- ☐ Other

*** Provide a detailed description of the source. (For example - UT Houston Pathology , AllScripts, Care4, or CCTS Biobank.)**

Care 4, MH trauma registry

11.2 * Provide a description of the records/ samples that will be analyzed in this research. (For example – prostate cancer from blocks).

Bowel injury information, emergency department and in-patients records, abdominal radiology reports, injury information, hospital/ICU/ventilator days, discharge status including mortality information.

11.3 * Provide How and where will you obtain your list of eligible records/samples for the study?

Patients will be identified by reviewing the daily trauma surgery morning report.

11.4 * Is the data that will be collected for the research and/or the samples that will be analyzed already existing at the time of this application? (If data/samples are existing at this time, the research may qualify for exemption).

○ Yes ◉ No

11.5 * State the "start date" and "end date" of creation of data or collection of samples used in this research. For example, data collected will include information that was recorded between Jan 1, 2013 through Dec 31, 2013 or skin biopsies collected from Jan 1, 2013 to Dec 31, 2013.)

5/1/18 to 4/30/2019

11.6 How many records/samples are you expecting to use?

100 for UT (anticipate up to 350 for all sites)

11.7 * Select the most appropriate statement. If you will be recording identifiers (second option), you must attach your proposed linking log and data collection form for review.

○ Investigator has access to identifiers, but the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

◉ Investigator will record identifiers. (Please note that identifiers should not be included in data collection forms. Subjects should be assigned codes and the logs linking the codes and identifiers should be maintained separately from the data.)

○ The identifiers are maintained at the source only. The investigator receives de-identified data/samples.

11.8 * How long will the data/samples be stored?

6 years

11.9 * Where will the research data/leftover sample be stored and how long will it be protected? Address paper and electronic data separately.

The de-identified data will be kept in REDCap. The research data will be kept in a secure locked office area and electronic data will be stored on password-protected computers accessible to only those research personnel working on the project.

11.10 * Outline the plan to destroy the data following study completion? (Include plan for destroying codes, links, master list and/or PHI that has not been de-identified.)

Hard copies will be shredded and electronic data will be destroyed per UT IT guidelines.

12.0 Waiver of Consent and Waiver of Authorization for Retrospective Chart Reviews

12.1 CPHS may waive the requirement to obtain informed consent and waiver of authorization of Protected Health

Information (PHI) if the study is a retrospective chart review. Please provide protocol specific information to answer each of the following questions. * Justify why the study poses no more than minimal risk to the subjects.

This is an observational study there if poses no more than minimal risks.

12.2 * Explain why the waiver of informed consent and authorization will not adversely affect the rights and welfare of the subjects.

This is observational therefore there is no interaction with the patient and there be no experimental medications, devices, or interventions involved in this study. There will be no change in the care that the patient receives. All data entered into the REDCap database will be de-identified.

12.3 * Explain why the study cannot be practically conducted without the waiver of informed consent or waiver of HIPAA authorization.

Trauma surgery patients are often unable to provide a true informed consent at time of admission to the hospital. The intervention to treat the bowel injury often occurs before the LAR/family member can provide consent and/or the patient is coherent and able to consent.

12.4 * Whenever appropriate, will the subjects be provided with additional pertinent information after participation?

No

12.5 * Do you have any additional comments supporting the waiver of informed consent and authorization of HIPAA?

No

13.0 Statement of Investigator

13.1 * "I have discussed the protocol with all of my collaborators. The research is NOT underway and WILL NOT BEGIN until approved by the CPHS."

(•) Agree ( ) Disagree