COMIRB Application for Protocol Review

Exempt/Non-Human Subject Research

Section A: Submission Details

Date of Initial Submission: Sep 5, 2017 Version Date: Sep 5, 2017

Section B: Protocol Information

Protocol Number: **17-1714** PI: **Burlew, Clay C**

Do not enter PI name here it will be added automatically when selected in Section C below

Project Title:

Visceral Artery Injury in the Setting of Blunt Abdominal Trauma; a Case Series.

Section C: Key Study Personnel

Remove	Last Name	First Name and MI	Dept/Division	Best Contact Phone #	VA Employee	Role
PI	Burlew	Clay C	Trauma Surgery/ GITES	303-436-6000	☐	Principal Investigator
X	Halpern	Alison L	GME/ General Surgery Residency	910-620-3287	☐	Primary Contact
X					☐	

Add Another Investigator

Add 1 Investigator with the role of PI (and if PI is a student, 1 Investigator with Role of Faculty Mentor). Also add 1 Investigator with the role of Primary Contact. (Maximum of 3 investigators listed in this table). **All** Study Personnel, including any listed above, must be added on the electronic ***Personnel Form*** when the protocol is submitted to COMIRB through eRA(InfoEd).

Contact Information:

1. Is the PI a student or trainee (including resident/fellow), or doing this research to fulfill an educational requirement? ○ Yes ◉ No

2. Best contact for scientific questions?

2a. Name: Alison Halpern

2b. Phone (10 digit #): (910) 620-3287

Section D: Type of Review being Requested

See guidance on choosing the appropriate review type

1. Type of Review being requested:

☐ **Full Board**

☐ **Expedited** [adds Attachment F]

☑ **Exempt or Non-Human Subject Research (including QA/QI/Program Evaluation)**

Section E: Funding

1. Do you have funding for this study? ○ Yes ◉ No ○ Pending (submitted)

Section F: Performance Sites

1. Are any of the investigators funding/directing research procedures conducted outside of the USA, or traveling outside of the USA to collect data? [adds Attachment B] ○ Yes ◉ No

Section F(a): Affiliate Performance Sites

Definition of Affiliate ⓘ

2. Indicate VA involvement in this study (must select one) **Note: 'Multi-site' means more than one local UCD-affiliated site**

☐ VA only study (if yes to any one of these criteria)	☐ Multi-site involving VA (if yes to any one, **and** no VA-only criteria met)	☑ Non-VA study
* Funding solely from the VA **OR** * All procedures performed on VA property, recruiting only at the VA, or using only VA equipment/ resources **OR** * All investigators and study personnel working solely on VA time	* Both VA and non-VA funding **OR** * Some procedures performed on VA property, some recruitment at the VA , or using some VA equipment/ resources **OR** * Some investigators and study personnel working on VA time	* No VA funding **AND** * No procedures/recruitment performed on VA property, and not using VA equipment/ resources **AND** * No investigators or study personnel working on VA time

3. Will any of the following Affiliates be utilized as sites for this research (includes data locations and investigator appointments)? ⓘ

Note: at least one of these affiliate institution must be checked 'yes.' UCD should usually be checked 'yes' due to the investigator's faculty appointment.

a. UCD (Downtown Denver Campus) ○ Yes ◉ No

b. UCD (Anschutz Medical Campus) ○ Yes ◉ No

c. University of Colorado Hospital (including the Adult CTRC or an off-campus site) ○ Yes ◉ No

d. Veteran's Administration Hospital (ECHCS) ○ Yes ◉ No

i) Are any study personnel employed/paid by the VA? ○ Yes ◉ No

e. Denver Health and Hospitals ◉ Yes ○ No

Include with this submission the SPARO Clearance Letter

f. Children's Hospital Colorado (including the Pediatric CTRC or an off-campus site) ○ Yes ◉ No

g. Colorado School of Mines ○ Yes ◉ No

Section F(b): Non-Affiliate Performance Sites

Definition of Non-Affiliate ⓘ

4. Does this study involve other Non-Affiliated Sites? ○ Yes ◉ No

This should be answered 'yes' if the study will involve any other locations other than those indicated in section F(a) above. The other sites may or may not actually be engaged in conducting the research; engagement can be clarified on Attachment A. [adds Attachment A]

Section G: Description of Study

1. Summary in lay terms: Provide a brief statement describing the project in 8th Grade Language. This section should include what you are doing, why you are doing it, whether you think this is human subject research or not, and a brief overview of how you will achieve your goals (Approximately 1 paragraph)

This study is a retrospective review of patients who sustained blunt trauma, were patients of Denver Health Medical Center, and were identified to have sustained a visceral arterial dissection or pseudoaneurysm (celiac artery, superior mesenteric artery, inferior mesenteric artery) as a result of their trauma, as found by their post-trauma imaging. This is an incredibly rare, and infrequently discussed condition. We plan to identify patients who suffered this injury and plan to study risk factors that predisposed persons to this condition such as injury mechanism, patient demographics, and pre-existing medical conditions. We would also like to determine if there were any interventions required as a result of suffering this injury and their management in terms of anticoagulation following the injury if any was prescribed. Achieving these goals will be simple. Patients who sustained a visceral artery injury will be identified

by a review of patient charts who were patients of Denver Health Medical Center and presented as trauma activations or alerts. We will review their medical records to identify patients who suffered injury of their CA, SMA or IMA. Additional review once these patients are identified will include imaging, review of pre-existing risk factors and the medical management the patients required in their hospital stays. We plan to publish this as a case series to further the knowledge of clinicians diagnosing and treating this rare injury.

2. Are there special review considerations?

a. Would you like this study reviewed by the Social/Behavioral panel (consider for Downtown Denver Campus protocols, social research, and non-treatment behavioral research)? ○ Yes ◉ No

b. Is this an Oncology or Cancer Center project? ○ Yes ◉ No

c. Are drugs or biologics that involve **human gene transfer**, or deliver recombinant DNA to subjects, included in this research? ○ Yes ◉ No

d. Does the protocol involve administration of radioactive substances to subjects (including PET scans, radiolabeled tracers, radioactive drugs, etc.)? ○ Yes ◉ No

e. Does the protocol involve research on newborn blood spot? ○ Yes ◉ No

f. Is there any research being done on fetal or embryonic tissue? ○ Yes ◉ No

Section H: Protocol Information

1. Issue to be studied: Risk factors for visceral artery injury after blunt trauma and outcomes (interventions required, 30 and 90 day mortality)

2. Describe the project including questions, purpose and methodology (how will the study aim[s] be achieved):

This study is a retrospective review of patients who sustained blunt trauma, were patients of Denver Health Medical Center, and were identified to have sustained a visceral arterial dissection or pseudoaneurysm (celiac artery, superior mesenteric artery, inferior mesenteric artery) as a result of their trauma, as found by their post-trauma imaging. This is an incredibly rare, and infrequently discussed condition. We will identify a set of patients who suffered this injury and plan to study risk factors that predisposed persons to this condition such as injury mechanism, patient demographics, and pre-existing medical conditions. We would also like to determine if there were any interventions required as a result of suffering this injury.

Patients who sustained a visceral artery injury will be identified by reviewing the records of any patients who presented to Denver Health Medical Center as a Trauma Alert or Activation since 1/2016. Once patients are identified, we will review their medical records including imaging and will thus be able to describe pre-existing risk factors and the medical management the patients required in their hospital stays. We will enter the medical record of each of these patients and determine/record their age, gender, mechanism of trauma, initial imaging modality, the presence or absence of prior existence of comorbidities including peripheral vascular disease, CAD, diabetes, and renal disease, transfusion requirement, requirement of intervention (Surgery), requirement of intervention (Interventional Radiology procedure or other), 30 day mortality if available from the data in the medical record, 90 day mortality if available from the data in the medical record through follow up appointments. We will also view their imaging studies (CTA or angiogram) which diagnosed the injury. A spreadsheet with those categories will be recorded. It will be stored on a VPN protected server. The data stored will be de-identified (name and MRN removed). We will then compare the cases of visceral artery injury after blunt trauma.

We know based on our clinician-patient relationships (as a resident and faculty surgeon) that we have treated patients with this condition within the past year, so there are patients to be found in this chart review. While our case series will likely have a low N and will not give us data powered to draw statistically significant results, just describing anecdotally the characteristics of the patients, their presentations, their clinical course, and their outcomes will be helpful for clinicians who may see this injury in their practice. We plan to publish this as a case series.

3. Recruitment - Describe from where and how subjects, records, or specimens will be identified:

All patients who presented to Denver Health Medical Center since 1/2016 will be reviewed. We will review the admission CT scans and Trauma H&Ps to determine if patients suffered a visceral artery injury (celiac, SMA or IMA). Those who sustained a visceral artery blunt traumatic dissection or aneurysm and their data will be used. We will use the patient's Denver Health Medical record to search for their demographic data, imaging data, comorbidities, and outcomes including interventions required (op note and procedure notes), 30 and 90 day mortality (by reviewing progress notes, follow up visit notes).

4. Subject Population - Describe the target population:

Patient's aged 18-89 who presented to Denver Health Medical Center after sustaining a blunt trauma induced visceral artery injury.

5. Data Analysis - Describe how data will be analyzed to achieve aims:

Once patients are identified, we will use the patient's Denver Health Medical record to search for the above patients' demographic data, imaging data, comorbidities, and outcomes including interventions required (op note and procedure notes), 30 and 90 day mortality (by reviewing progress notes, follow up visit notes). This is a very rare injury and thus our study will not be powered to show significant differences between the three patients in the variables above. However, just reporting the patient's mechanism of injury, basic demographics, presentation, clinical course, and radiology findings in valuable to the field of trauma. There have been fewer than 20 of these cases reported in the literature. We plan to publish this as a case series describing the clinical presentations and courses of these three patients.

6. Privacy and Confidentiality - Describe what information will be accessed, how collected, recorded, and protected:

Patient names will not be used. Data obtained from the review will be stored on password protected computers and the dataset will be kept in a VPN password protected file. Personal information elements be stored separately from other research data. Only the members of this IRB will have access.

Section I: QA/QI or Program Evaluation Project

1. Is this project (must check one): [you may wish to view COMIRB's QA /QI /PE tool]

- ☐ Quality Assurance / Quality Improvement
- ☐ Program Evaluation
- ☑ Not QA/QI or PE (continue for Exempt or other Non-human subject research determination request)

Section J: Other Non-Human Subject Research Determination

1. Are you requesting a formal determination of **Not Human Subject Research**? ○ Yes ◉ No

Answer "No" if you are requesting a determination of Exempt research. The project will still be reviewed for both Exempt and Not Human Subject research qualifications

Section K: Exempt Human Subject Research

Definition of Minimal Risk:
That the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

1. Describe how this study meets the regulatory definition of **Minimal Risk**:

There is very minimal if any risk to the patient in this retrospective review. There is a very rare risk of the patient's information being identified. There is no physical harm anticipated as there are no physical exams, no psychological tests, no procedures being done on the patient. Their medical care will not be affected by retrospectively reviewing their previous care. The study of their condition may lead providers to better recognize and treat visceral artery blunt traumatic dissection or aneurysm. Also, the study of others with this condition may lead to knowledge to treat any further problems that the patient may sustain as a result of their visceral artery blunt traumatic dissection or pseudoaneurysm.

Section L: Special Populations

1. Prisoners ⓘ ○ Yes ◉ No
2. Decisionally Challenged ⓘ ○ Yes ◉ No
3. Children ○ Yes ◉ No

Section M: Number or Subjects/Specimens

1. Number or Subjects, Records, or Specimens to be studied? 10
2. Number of Subjects, Records, or Specimens is not Applicable to this study: ☐

Section N: Age Range

1. Not Applicable to this Study ☐
2. Age Range of Subjects to be enrolled: Lower Limit: **18** **Years** (inclusive) Upper Limit: **89** **Years** (non-inclusive)

Unless you can justify why age range is not applicable to this study, COMIRB requires both a lower and upper limit age range be specified. If you are arguing that data will be unidentifiable, and you are including subjects greater than 89 years old, state how you will protect these subjects' identity (e.g., all ages > 89 will be recorded as 89).

3. Are you stating that recorded data will be unidentifiable? ◉ Yes ○ No

a. How will you protect the identify of subjects > 89 years old?

There are no subjects >89 years old to be included in this study.

Section O: Expected Completion Date

1. What is the expected completion date of this research? **1/1/2017**

Section P: Recruitment and Subject Material Used

1. Indicate which of the following materials will be used in this study (Check all that apply):

- ☐ Advertisements
- ☐ Flyer
- ☐ Telephone Script
- ☐ Recruitment Letter
- ☐ Invitation to Participate
- ☐ Questionnaire/Survey (including verbally administered)
- ☐ Informational/Educational Materials
- ☐ Diaries
- ☐ Interview/Focus Group guides
- ☑ Other

a. List Other Materials:

Patient Medical Records

Include copies of all recruitment and research materials with this submission. For all materials, please include on the document COMIRB Protocol Number, PI Name, Study Title, and Version #

Section Q: Educational Setting

1. Will research be conducted in a classroom or similar educational setting? ○ Yes ◉ No

Section R: Use of Samples/Specimens

1. Will biological specimens be used in this project? ○ Yes ◉ No

Section S: Use of Data, Documents, or Records

1. Will data, documents, or records (not associated with samples) be used? ◉ Yes ○ No
2. Are the data publicly available (can be accessed by anyone, regardless of reason)? ⓘ ○ Yes ◉ No
3. Will the data, documents, or records already be **in existence** at the time of this application? ◉ Yes ○ No
   'Existing' is defined as data that have been collected and are on the shelf at the time of this application. **To qualify for Exempt status, data used in the research must already be in existence at the time of this application**.

   a. What was the time period for source data collection? From: 1/1/2016 To: 9/1/2017

   b. State the purpose for the initial data collection and who collected it:

The patients in this study were admitted to Denver Health Medical Center Following blunt trauma and received care at this facility. The data is thus in form of imaging, laboratory values, and notes from clinicians in the medical record regarding their hospitalization. It is stored on the DHMC medical record.

4. Did individuals provide consent for these data to be used in research? ○ Yes ◉ No
5. Are the data provided to the investigators in such a manner that subject **cannot** be identified by the investigators? ○ Yes ◉ No
6. Is information provided to the investigators, or accessed by the investigators, in a manner where subject identifiers are seen, but identifiers are **not** being recorded in the data set (e.g., chart review)? ◉ Yes ○ No

   i. Is a master list or spreadsheet used to identify records of interest or to track which records have been extracted (separate from data)? ◉ Yes ○ No

   ii. Describe how record tracking will occur:

Data will be kept on a secure server- VPN protected GITES Server within the Surgery Department. Patient identifiers (Name and MRN) will be removed from the data prior to storing.

If data are recorded with any unique identifiers or any links to subjects' identities at any time, the protocol does not qualify for exemption under category #4 below. It is possible that it could qualify for Exemption under a different category (e.g., educational research, category #1). You might want to contact COMIRB at (303) 724-1055 to discuss this issue.

Please submit a copy of the data collection tool (spreadsheet, database fields) you will use to record data.

Section T: Surveys/Interviews/Tests for this Project

1. Will Surveys/Interviews/Tests be used to collect research data? ○ Yes ◉ No

Section U: Identifiers used in Research

1. Check the box next to each identifier you will be **recording** as part of the research data set:

- ☐ Name/Initials
- ☐ Address
- ☐ City
- ☐ County
- ☐ Precinct
- ☐ Zip Code
- ☐ Telephone Number
- ☐ Fax Number
- ☐ E-Mail Address
- ☐ Unique ID Numbers: Student ID, Health Plan Beneficiary Number, Medical Record Number, Etc.
- ☐ Certificate/License Number
- ☐ Vehicle Identifiers
- ☐ Device Identifiers
- ☐ Web Universal Resource Locator (URL)
- ☐ Internet Protocol Address Numbers
- ☐ Biometric Identifiers (including Finger or Voice Prints)
- ☐ Full Face Photographs and Comparable Images
- ☐ Any Other Unique Identifying Number, Characteristic or Code
- ☐ All Dates (except birth year, unless >89 yo) that are directly related to an individual (e.g. Birth, Graduation, Admission/Discharge)*
- ☒ **None of the above**

***For all subjects over 89 years, birth year alone is indicative of a subject's age and is considered a direct identifier**

Section V: Protected Health Information (HIPAA)

Protected Health Information is identifiable health information. De-identified data is NOT considered to be PHI. If the research involves looking at medical records, this is considered "accessing" PHI, regardless of whether this information is being recorded

1. Do the HIPAA Regulations apply to this study (*Health Information Portability and Accountability Act*)? ◉ Yes ○ No
   This question should be answered 'no' if:
   - The research is performed at a **non-covered entity** (e.g., DDC, School of Public Health)
   - The **only** PHI viewed/collected is for patient pre-screening, the investigators have a treatment relationship with subjects, and the VA is not a study site
2. Is Protected Health Information (PHI) being accessed, collected or recorded for this project? ◉ Yes ○ No
3. Will HIPAA Authorization be obtained from subjects? ○ Yes ◉ No

Attachment O has been added to this application

Section W: Conflict of Interest

1. Have all investigators and coordinators listed on this application completed and submitted a UCD COI disclosure form to the **UCD** COI office? ◉ Yes ○ No
   This applies to affiliate investigators even if they have submitted a COI declaration in accordance with their home institutional policy.

2. Are there any Conflict of Interest issues to be disclosed for the investigators or key personnel **that relate to this study**? ○ Yes ◉ No

Section X: Exempt Categories

Categories for Exemption (More than one may be selected)

Category 1

☐ Research is conducted in established or commonly accepted educational settings involving normal educational practices, such as: research on regular or special education instructional strategies; **OR** research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2 (there are limitations on enrollment of Children in this category)

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless** information obtained is recorded in such a manner that subjects can be identified directly or through identifiers linked to the subjects; **AND** any disclosures of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Category 3

☐ Research involving the use of educational tests (cognitive, diagnostic aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not Exempt under Category 2 above, if the subjects are elected or appointed officials or candidates for public office; **OR** Federal statutes require without exception that the confidentiality of the personal identifiable information will be maintained throughout the research and thereafter.

Category 4 (data recorded with linked codes or identifiers at any time is not acceptable for this category)

☑ Research involving the collection of study or existing data, documents, records, pathological specimens, or diagnostic specimens ('Existing' is defined as data that has been collected and is on the shelf at this time of this application) where the source is publicly available; **OR** the information is recorded by the investigator is such a manner that subjects cannot be identified directly or through identifiers linked to the subject.

Category 5

☐ Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads which are designed to study, evaluate, or otherwise examine public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; **OR** possible changes in methods or levels of payment for benefits or services under those programs.

Category 6

☐ Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed; **OR** if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe; or agricultural chemical or environmental containment at or below the level found to be safe by the Food and Drug Administration; or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

M Attachment M: Waiver of Consent Request

Jump Back

Except as provided below, written documentation of informed consent that embodies all the required elements of informed consent, as described in 45 CFR 46.116 is required for all research subjects. Consent waiver is not an option if the study is subject to FDA Regulations, except for under very select circumstances (contact COMIRB). Consent waiver is not an option if the study is performing research on newborn blood spots.

With sufficient justification, the IRB may approve a consent process that does not include or alters some or all of the elements of informed consent, provided that it finds and documents specific requirements. If requesting an alteration of consent, justify such in accordance with the criteria below established under 45 CFR 46.116(d)(1-4) [**waiver of consent**] or 45 CRF 46.117(c)(1 or 2) [**waiver of documentation of consent**].

For all waivers, the research (or procedures for which the waiver is sought) must involve no more than minimal risk to the subjects.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Notes on study pre-screening:

1) If you are interacting with potential subjects (phone or in person) to screen for eligibility, COMIRB does not consider verifying eligibility criteria listed on the study advertisement to be a research procedure; no waivers are required for such verification. Questioning that goes beyond such verification requires a consent process prior to questioning. Please submit the **pre-screening script** to read to potential subjects and request a waiver of *documentation of consent* using this Attachment. Please see **COMIRB's Guidance on Pre-screening**.

2) For VA research: Using the medical record to pre-screen potential subjects requires full waiver of consent (and waiver of HIPAA).

Note on HIPAA: If this study is subject to HIPAA regulations, you are using the combined consent/HIPAA document, and you are requesting a waiver of consent or waiver of documentation of consent, you will also need to complete Attachment O (Waiver of HIPAA Authorization); Attachment O can be opened by selecting the appropriate box in section N, #5.

Type of Waiver being Requested

Select the type of waiver being requested (more than one may be chosen):

- [x] **Full Waiver of consent (no consent, or consent is altered to omit certain required elements)**
- [ ] **Waiver of Written Documentation (e.g., verbal Consent, information sheet)**

Section A: Waiver or Alteration of Consent

Describe the portion of the project for which consent waiver is requested (e.g., screening phase only, deception, entire study)

The waiver is requested for the entire study. We wish to retrospectively review patients who suffered a known blunt traumatic visceral artery dissection or aneurysm.

If requesting a waiver or alteration from the requirements for obtaining informed consent, justify such in accordance with all the criteria established under 45 CFR 46.116(d) (1-4). Waiver of consent is not an option if the study is subject to FDA regulation.

1. Explain why the research (or procedures for which the waiver is sought) poses minimal risk to the subject:

The patients have already been fully treated for the above condition and this study will not change the care that they received. It does not influence their care at all. They are not subject to any interventions, tests, etc. The only risk is that of small break in PHI which is unlikely with the de-identified information.

2. Explain why the waiver or alteration will not adversely affect the rights and welfare of the subject:

The patients have already been fully treated for the above condition and this study will not change the care that they received.

3. Explain why the research could not practicably be carried out without the waiver or alteration *(note: a survey can still provide subjects with elements of consent in writing; see postcard consent template on the COMIRB website).*

Some of the patients affected by this condition may be deceased. We plan on conducting a restrospective review. They cannot give consent to review of their records. Even the patients who aren't deceased have been discharged and it would not be possible to obtain consent.

4. Once subjects have completed the study, will information be given to, or other debriefing be done with the subject? Explain:

No, but our de-identified results will be published and available to all.

O Attachment O: HIPAA Waiver

Jump Back

1. Describe the portion of the project for which HIPAA waiver is requested (e.g., screening, entire study)

Entire Study

PHI Access and Use

2. List what **health information*** will be **accessed*** under this waiver:

Patient's DOB, MRN, Age, Sex, Date of admission, Imaging including CT and XR, Operative records, procedural records, Progress notes, laboratory values.

*** Health information means any clinical data pertaining to health that you are recording for the research (e.g., lab results, mood diary, smoking status, procedure results)**

*** If the research includes looking at medical records or some other form of PHI, this is considered to be *accessing* PHI, regardless of whether this information is being recorded**

3. Check the identifiers that will be viewed with the above health information: **NONE** ☐

☒ Names/Initials	☐ URLs (http://...)
☐ Telephone Numbers	☐ Vehicle identifiers and serial numbers
☐ Fax Numbers	☐ Certificate / license numbers
☐ Electronic mail addresses	☐ Device identifiers and serial numbers
☐ All dates (except year alone*) that are directly related to an individual (date of birth, discharge date, etc.)	☐ Biometric identifiers (including finger and voice prints)
☐ Social Security Numbers	☐ Full Face photographic images and any comparable images
☒ Medical Record numbers	☐ IP address numbers
☐ Health plan beneficiary numbers	☐ Geographic subdivisions smaller than a state
☐ Account Numbers	☐ Any other unique identifying number, characteristic or code

*** For all subjects over 89 years, birth year alone is considered a direct identifier**

4. Which of the above **identifiers and health information** will be **recorded** for the research (OK to say 'all of the above,' or 'none'):

Age, Sex, Date of admission, Imaging including CT and XR, Operative records, procedural records, Progress notes, laboratory values.

PHI Disclosure

5. Will any of the above health information be **disclosed** with any of the identifiers in #3 above to parties outside of the research institution under this waiver (i.e., without obtaining the subjects' authorization)? ○ Yes ◉ No

HIPAA Waiver Justification

6. Is it possible or likely that the PHI collected under this waiver will contain information that puts the subject at risk for civil or criminal liability, or that could be damaging to a subject's financial standing, employability, or reputation? ○ Yes ◉ No

7. Will the PHI be used for any purposes other than those described in this protocol, this waiver request, or as required by law? ○ Yes ◉ No

8. Describe the plan to destroy the identifiers as soon as possible, consistent with the conduct of this research and local regulations:

All data with patient identifiers will be deleted following the initial obtaining of information. Only the data of age, sex, mechanism of injury, laboratory values, and treatment course will be kept on a secured file.

9. Will a signed informed consent document be obtained? ○ Yes ◉ No

10. Describe why this research could not be done without this HIPAA waiver:

We plan on conducting a restrospective review. To obtain the data regarding imaging, laboratory values and clinical course, we need the documentation from the medical record. We are unable to contact these patients, and thus this study could not be published.

Note: waiver of consent, or waiver of documentation of consent, when using the combined consent/HIPAA form is an acceptable justification.

11. Describe why this research could not be done without access to, and use of, the PHI listed above:

Without the PHI listed above, we would be unable to study what risk factors influence the rare condition of visceral arterial dissection and what outcomes are common with this injury. This injury has been rarely reported in the literature and any information regarding patients with this condition could help raise awareness of this injury in blunt trauma as well as educate clinicians on the treatment of this condition.