



## Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

**Protocol Number:** H-58125  
**Status:** Approved  
**Initial Submit Date:** 9/4/2025  
**Approval Period:** 10/6/2025 - 10/6/2030

### Section Aa: Title & PI

#### A1. Main Title

MULTICENTER EVALUATION OF CT ACCURACY AND RESOURCE USE IN ANTERIOR ABDOMINAL PENETRATING TRAUMA

#### A2. Principal Investigator

Name:	RYAN DUMAS	Phone:	
Id:	257749	Fax:	
Department:	SURGERY: HCHD DIVISION	Email:	u257749@bcm.edu
Center:		Mail Stn:	

#### A3. Administrative Contact

Name:	CHELLUH MCGILL	Phone:	7137984749
Id:	259421	Fax:	
		Email:	u259421@bcm.edu
		Mail Stn:	

#### A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

### Section Ab: General Information

#### A4. Co-Investigators

Name:	DAVID WYNNE	Phone:	7137984417
Id:	155782	Fax:	713 7988050
Department:	RADIOLOGY	Email:	wynne@bcm.edu
Center:		Mail Stn:	BCM360
Name:	JAMES TUDOR	Phone:	
Id:	235370	Fax:	
Department:	RADIOLOGY	Email:	u235370@bcm.edu
Center:		Mail Stn:	
Name:	EMMA BURKE	Phone:	
Id:	244086	Fax:	
Department:	SURGERY: HCHD DIVISION	Email:	u244086@bcm.edu
Center:		Mail Stn:	

**A5. Funding Source:**

Baylor College of Medicine (Internal Funding Only)

**A6a. Institution(s) where work will be performed:**

BCM: Baylor College of Medicine

**A6b. Research conducted outside of the United States:**

Country:

Facility/Institution:

Contact/Investigator:

Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

**A7. Research Category:****A8. Therapeutic Intent**

Does this trial have therapeutic intent?

No

**A9. ClinicalTrials.gov Registration**

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?

No, this clinical is not a clinical trial, or does not meet the definition of an Applicable Clinical Trial, or does not need to be registered under the terms and conditions of an award, or is not a clinical trial with results intended to be reported in a journal belonging to the ICMJE. Registration is not required.

**Section B: Exempt Request****B. Exempt From IRB Review**

Not Applicable

**Section C: Background Information**

Anterior abdominal penetrating trauma (AAPT) presents a diagnostic and management challenge. Hemodynamically stable patients without peritonitis, evisceration, or evidence of gastrointestinal bleeding are eligible for a variety of management pathways: observation with serial examinations, computed tomography (CT) imaging, local wound exploration, or diagnostic laparoscopy<sup>1,2</sup>. Each of these management strategies imposes different burdens on patients and trauma systems. Most data on CT utility in this patient population are over a decade old and based on small cohorts<sup>2,3</sup>. Advances in image resolution, reconstruction algorithms, and deployment of photon-counting detectors have dramatically improved axial imaging capabilities. A contemporary, multicenter study is necessary to determine if CT can reliably exclude clinically relevant injuries, thereby identifying patients appropriate for discharge and reducing unnecessary admissions and interventions. References Martin, Matthew J. MD; Brown, Carlos V.R. MD; Shatz, David V. MD; Alam, Hasan B. MD; Brasel, Karen J. MD; Hauser, Carl J. MD; de Moya, Marc MD; Moore, Ernest E. MD; Rowell, Susan E. MD; Vercruysse, Gary A. MD; Baron, Bonny J. MD; Inaba, Kenji MD. Evaluation and management of abdominal stab wounds: A Western Trauma Association critical decisions algorithm. *Journal of Trauma and Acute Care Surgery* 85(5):p 1007-1015, November 2018. | DOI: 10.1097/TA.0000000000001930 Como, John J. MD; Bokhari, Faran MD; Chiu, William C. MD; Duane, Therese M. MD; Holeyvar, Michele R. MD; Tandoh, Margaret A. MD; Ivatury, Rao R. MD; Scalea, Thomas M. MD. Practice Management Guidelines for Selective Nonoperative Management of Penetrating Abdominal Trauma. *The Journal of Trauma: Injury, Infection, and Critical Care* 68(3):p 721-733, March 2010. | DOI: 10.1097/TA.0b013e3181cf7d07 Gachabayov, Mahir MD, PhD; Gogna, Shekhar MD; Samson, David MPH; Latifi, Rifat MD, FACS, FICS. Does computed tomography scan add any diagnostic value to the evaluation of stab wounds of the anterior abdominal wall? A systematic review and meta-analysis. *Journal of Trauma and Acute Care Surgery* 88(4):p 572-576, April 2020. | DOI: 10.1097/TA.0000000000002587

**Section D: Purpose and Objectives**

We propose a multicenter, pragmatic, prospective observational study to evaluate the management practices of anterior abdominal penetrating trauma in patients without indication for urgent or emergent intervention. Centers participating in the trial would enroll all patients meeting inclusion criteria and record variables of interest from a review of the medical record. Through this multicenter study, we aim to: Determine the negative predictive value of modern CT scans in excluding clinically significant injuries in hemodynamically stable, nonperitonitic patients with anterior abdominal penetrating trauma (AAPT). We hypothesize that patients without injuries identified on CT may be safely discharged without need for hospital admission or diagnostic laparoscopy. Describe institutional variation in the management of hemodynamically stable, nonperitonitic patients with AAPT. We hypothesize that practice patterns vary widely between institutions, with very few groups using local wound exploration. Compare hospital length of stay and resource utilization across management strategies for hemodynamically stable, nonperitonitic patients with AAPT. We hypothesize that hospital length of stay and resource utilization will vary significantly across management strategies, with CT-based discharge associated with the lowest burden.

We anticipate that the results of this study will provide contemporary, multicenter data on how trauma centers manage stable AAPT patients and the role of CT imaging in their care. There is a lack of data on the sensitivity and specificity of modern-day CT scans to identify clinically significant injuries in hemodynamically stable, nonperitonitic patients with AAPT. A better understanding of how this tool can be used in triaging patients for intervention, observation, or discharge is necessary to inform future guideline development, optimization of patient outcomes, and systems resource allocation.

## Section E: Protocol Risks/Subjects

### E1. Risk Category

Category 1: Research not involving greater than minimum risk.

### E2. Subjects

Gender:

Both

Age:

Adult (18-64 yrs), Geriatric (65+ yrs)

Ethnicity:

All Ethnicities

Primary Language:

English, Spanish

Groups to be recruited will include:

Patients

Which if any of the following vulnerable populations will be recruited as subjects?

Emergency room patients, Homeless

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

Although emergency room, prisoners, and homeless patients will be included in this analysis, this study is not designed to specifically intervene on any of these populations.

### E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

### E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

### E5. Children

Will children be enrolled in the research?

No

## Section F: Design/Procedure

### F1. Design

Select one category that most adequately describes your research:

a) Chart/scan/record review

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

This study will be prospective, observational study. There is no intervention planned as part of the study; all patients are managed at the discretion of the trauma team at their respective institution. Therefore, no group assignments will be used and there will not be any control subjects. Participating centers will identify eligible patients based upon their institutional trauma registry. Data will be collected from the medical record according to a data collection tool provided by the coordinating center, Baylor College of Medicine. We intend to collect prospective data for 18 months. This was determined by a query of our institutional registry and a power analysis to determine subject enrollment.

Inclusion Criteria:

The study population includes all patients  $\geq 18$  years of age presenting to a participating trauma center with isolated penetrating trauma (e.g. stab, gunshot wound) to the anterior abdomen that do not have an indication for immediate operative exploration. We define the anterior abdomen as inferior to the costal margins, superior to the inguinal ligaments and pubis, and medial to the anterior axillary lines. Trauma centers would be eligible to participate in this study if they have a designation as a level I or II trauma center, a 64-detector or greater CT scan available for their trauma patients, a minimum slice thickness of 2mm for source images and reformats, and 24-hour in-house radiology coverage.

Exclusion Criteria:

Exclusion criteria include patients  $< 18$  years of age, traumatic brain injury, pregnancy, hemodynamic instability or hemorrhagic shock upon presentation, peritonitis or evisceration on exam, and penetrating injuries outside of the defined borders of the anterior abdomen. Patients presenting to non-participating centers and transfer patients will not be eligible for inclusion. Trauma centers will be ineligible for participation in the study group if they do not meet the minimum criteria of a 64-detector CT scanner, 2mm slice thickness for source images and reformats, and 24-hour in-house radiology coverage. Centers who do not have level I or II trauma designation will also not be eligible to participate.

## F2. Procedure

This study is a pragmatic, prospective chart review. Therefore, all patient care activities will occur according to the standard clinical care at each participating center. There is no investigational procedure in this study. There will be no contact with subjects nor will there be any additional requirements of the subject as part of participation in this study. If a center expresses interest in being included in this study, they will first be sent a survey to determine eligibility and collect basic institutional information about resources, trauma designation, and imaging technology. Centers meeting inclusion criteria will then be allowed to begin data collection.

Standardized, prospective data will be collected from each eligible patient. The patient enrollment period will last for 24 months. Variables of interest are listed on the data collection sheet, which is attached in Section S. Local data will be entered into a REDCap by each participating site. Participating centers will only have access to their center's data via individual center data usage groups. Only the research team at BCM will have access to the complete data set from all participating centers. Once data collection is complete, the BCM PI and PI's staff will perform the statistical analysis outlined in Section G.

Medical record EMR to be accessed: Cerner and Epic

All variables to be obtained are detailed and upload Section S.

Data will be stored securely on redcap. Enrolled institutions will contribute prospective data to this secure redcap database.

All data will be FULLY de-identified.

Collaborations with external sites: Each will enroll in the trial, obtain individual IRB approval and provide a letters of support to BCM. Subsequently sites will enroll patients and upload de-identified data to redcap.

## Section G: Sample Size/Data Analysis

### G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 1200      Worldwide: 1200

Please indicate why you chose the sample size proposed:

This sample size is an estimate based on internal data for patients presenting to Ben Taub hospital with injuries that would meet inclusion criteria. We anticipate our study will enroll approximately 30 centers; it is reasonable to expect each center to see approximately 40 patients during the study period with injuries that fit this pattern.

### G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

The primary outcome in this study is the negative predictive value of CT scan in hemodynamically stable, nonperitonitic patients with anterior abdominal penetrating trauma. To achieve this, we need to collect data on the number of identified and missed intraabdominal injuries to calculate true negatives and false negatives in the patient population of interest. Our secondary and tertiary aims are to describe national practice patterns in management of AAPT and resource allocation associated with each management strategy. Therefore, we will collect data on initial management strategy and complications for each enrolled patient. All variables to be collected are listed in the data collection sheet that is attached in Section S. Normally distributed, continuous data will be reported as mean  $\pm$  standard deviation or median [interquartile range] for non-parametric data. Frequencies will be reported for categorical variables. Categorical variables will be compared using chi-squared tests while student's t-test and/or Mann Whitney tests will be used to compare continuous variables.

## Section H: Potential Risks/Discomforts

### H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

The risks associated with participation in this study are very low as all patient care will continue according to local protocols at each participating center. The main risk is loss of patient confidentiality due to data breach. To minimize this risk, only necessary patient information will be entered into the data collection tool. Each patient will be assigned a study-specific, unique ID number to further reduce the risk of confidentiality breach. Participating centers will be responsible for local chart review and input of data into a password-protected individual center data usage group in REDCap. The complete dataset will only be available to the research team at the coordinating center, Baylor College of Medicine. Upon conclusion of the study, the PI and Co-PI at the primary site will download the data onto institutional, password-protected computers. Data sharing will adhere to the protocol outlined in the primary institution's (BCM) Data Use Agreement. All communications related to the study will be sent via HIPAA compliant emails.

### H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

### H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

Yes

Is BCM the COORDINATING CENTER for this multi-site research?

Yes

If the answer to EITHER of the questions above is "Yes", please complete the following questions:

If this is a multicenter study and the BCM PI is an INVESTIGATOR with responsibilities of SPONSOR or if BCM is the COORDINATING CENTER, describe the management of information among the sites related to participant protections. Your description should include reporting of unanticipated problems, protocol modifications, IRB and/or institutional approvals, and interim results among the sites.

Participating centers will be responsible for identifying and performing chart reviews of eligible patients from their centers. Variables identified in the data collection sheet (attached in Section S) will be entered into REDCap for collection. Because this is a chart review, there will be no problems related to drug administration or device use. The only potential issue would be a breach of confidentiality. To prevent this, all data will only be accessible to necessary research personnel and will be stored on a password-protected platform (REDCap). Participating centers will only have access to their center's data via individual center data usage groups. The BCM PI and PI's staff will be responsible for all data analysis and will be the only site with access to the complete dataset in REDCap. We do not anticipate any modifications to this protocol because there is no intervention planned as part of this study. Each participating site will be responsible for obtaining their own IRB approval or exemption, depending on the protocol at their local institution. Results will only be shared upon conclusion of the study as this is a chart review.

When research is conducted in collaboration with outside entities or organizations, the PI must obtain the necessary approvals from those entities. The BCM IRB may request documentation that such approvals have been obtained. Please list and describe the planned sites for this multi-site research for which the BCM PI is either Sponsor-Investigator and/or Coordinating Center. Sites that do not meet the requirements for inclusion in section A6a of the protocol summary and BCM informed consent documents should be listed here.

All data analysis will be performed at Baylor College of Medicine. We anticipate enrolling approximately 30 trauma centers from across the United States. This section and sections A4 and A6a will be updated as centers enroll and obtain local IRB

approval/institutional permissions.

## Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

There are no direct benefits to the individuals who participate in this study. However, we do anticipate improvement in the care of trauma patients because of this study. Participants could potentially benefit from these improvements.

Describe potential benefit(s) to society of the planned work.

The findings of this study may contribute significantly to understanding the risk and benefits of different management strategies for penetrating abdominal trauma. A better understanding of the resource utilization associated with the different management strategies is also important to better anticipate the needs of trauma centers. If we are able to support our hypothesis that discharge can be a safe option for these patients after a negative CT scan, it can reduce the burden penetrating abdominal trauma places on patients and our hospital systems.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

The potential of this project to improve care of penetrating trauma patients outweighs the minimal risk to subjects. There is no intervention associated with participation in this study, all patients are managed according to local practice guidelines. Therefore, all care should proceed in a typical fashion. The only risk associated with participation in this study is loss of confidentiality. However, data will be collected in a de-identified fashion to minimize this risk.

## Section J: Consent Procedures

### J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

Yes

Please describe the portion of the research for which a waiver is required. (Example: chart review to determine subject eligibility)

We are requesting a waiver of consent for the entirety of this chart review. It would be infeasible to conduct this chart review without a waiver due to the large, anticipated sample size. It would be impossible for the research team to contact and obtain consent from all eligible subjects. There is no study intervention or contact with patients as a result of participation in this study.

Explain why the research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals.

This is an observational study without randomization of subjects to treatment or intervention groups. Research staff will collect necessary data through review patient charts including documented vital signs, labs, radiographs, and operative notes. All data will be de-identified and presented in aggregate to protect patient privacy. Only necessary research personnel will have access to the secure drive containing study data. Only study team members at the coordinating institution (BCM) will have access to the entire dataset. Each individual participating institution will only be able to access their institution's data in the REDCap system.

Explain why the waiver will not adversely affect the privacy rights and the welfare of the research subjects.

This study is observational; there is no intervention or group assignments that would impact patient welfare. All information will be stored on a secure drive shared only with necessary research personnel.

Explain why the research could not practicably be conducted without the waiver and could not practicably be conducted without access to and use of the protected health information.

The large, anticipated sample size for this study would require an immense number of resources to obtain consent from all subjects, exceeding reasonable expectations of any research team. This study is observational in nature and will rely on patient chart reviews for all data collection. Patient care will not be impacted by participation in this study. De-identified patient information is required to determine eligibility and answer the research questions posed by this study.

Describe how the research could not practicably be carried out without using the collected identifiable biospecimens in an identifiable format.

Not applicable

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure.

Data will be de-identified and presented in aggregate to protect patient confidentiality. All study documents will be maintained at the site for at least two years following study completion to allow for analysis and publication. All research records will be stored on a secure drive.

Describe how an adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

At the end of the required record retention, data will be destroyed based on BCM policies.

Describe how adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

Only Baylor College of Medicine PI & PI's staff will have access to the complete dataset related to this project. Study data will be stored on a secured drive shared between members of the study team. Data from outside institutions will be sent to BCM for analysis; data will not be sent from BCM to other institutions. Participating centers will have individual center data usage groups in REDCap, allowing them to only view their center's data.

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

No

Specific information concerning drug abuse:

No

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

No

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:

No

Partial Social Security # (Last four digits):

No

Billing or financial records:

No

Photographs, videotapes, and/or audiotapes of you:

No

Other:

No

Will additional pertinent information be provided to subjects after participation?

No

If No, explain why providing subjects additional pertinent information after participation is not appropriate.

No additional information would impact care

### **J1a. Waiver of requirement for written documentation of Consent**

Will this research require a waiver of the requirement for written documentation of informed consent?

No

### **J2. Consent Procedures**

Who will recruit subjects for this study?

PI

PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Research populations will be identified through the local trauma registry at each institution. Patients meeting eligibility criteria will undergo chart review to collect the necessary data. There will be no direct contact between research staff and the study participants.

Are foreign language consent forms required for this protocol?

No

### **J3. Privacy and Intrusiveness**

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

### **J4. Children**

Will children be enrolled in the research?

No

### **J5. Neonates**

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

### **J6. Consent Capacity - Adults who lack capacity**

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

No

### **J7. Prisoners**

Will Prisoners be enrolled in the research?

No

## **Section K: Research Related Health Information and Confidentiality**

Will research data include identifiable subject information?

Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

No

Specific information concerning drug abuse:

No

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

No

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:

No

Partial Social Security # (Last four digits):

No

Billing or financial records:

No

Photographs, videotapes, and/or audiotapes of you:

No

Identifiable biospecimens

No

Will identifiable biospecimens be stored for future research?

NA

If yes, is the storage of biospecimens optional for subjects?

NA

Will identifiable private information be stored for future research?

Yes

If yes, is the storage of information optional for subjects?

No

Questionnaire, Survey, and/or subject diary

No

Other:

No

At what institution will the physical research data be kept?

N/A, there is no physical research data.

How will such physical research data be secured?

N/A

At what institution will the electronic research data be kept?

Baylor College of medicine

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):

Yes

Such electronic research data will be secured via Other:

No

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

No

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

Research data from outside institutions will be shared with the BCM research team through entry into REDCap. Each participating institution will input data into an individual center data usage group, which allows access only to their local data. Only the BCM PI and PI's staff will have access to the complete dataset. No data will be sent from BCM to outside institutions; only summative reports of findings will be shared. A DUA/DTA will be provided by BCM to institutions participating in this study.

Will you obtain a Certificate of Confidentiality (COC) for this study?

No

Please further discuss any potential confidentiality issues related to this study.

N/A

## Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

0 dollars

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

0

Distribution Plan:

0 dollars

## Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

## Section N: Sample Collection

None

## Section O: Drug Studies

Does the research involve the use of ANY drug\* or biologic? (\*A drug is defined as any substance(other than food) that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

### O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug?

No

## Section P: Device Studies

Does this research study involve the use of ANY device?

No

## Section Q. Consent Form(s)

None

## Section R: Advertisements

None

October 6, 2025



RYAN DUMAS  
BAYLOR COLLEGE OF MEDICINE  
SURGERY: HCHD DIVISION

Baylor College of Medicine  
Office of Research  
One Baylor Plaza, 600D  
Houston, Texas 77030  
Phone: (713) 798-6970  
Fax: (713) 798-6990  
Email: irb@bcm.edu

**H-58125 - MULTICENTER EVALUATION OF CT ACCURACY AND RESOURCE USE IN ANTERIOR ABDOMINAL PENETRATING TRAUMA**

**APPROVAL VALID FROM 10/6/2025 TO 10/6/2030**

Dear Dr. DUMAS

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol named above was reviewed and approved by Expedited procedures on 10/6/2025 by Board 5.

The study **does not require continuing review** but will require a 5 year renewal check in with the IRB Office. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must be submitted to the IRB as an amendment for review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

Research that has been approved by the BCM IRB may be subject to further appropriate review and approval or disapproval by officials of the institution(s) where the research will be conducted. However, those institutional officials may not approve the research if it has not yet been approved by the IRB.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,

A handwritten signature in cursive script that reads "Craig Jensen".

CRAIG JENSEN, M.D., B.A.

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals





Eastern Association for the Surgery of Trauma  
Advancing Science, Fostering Relationships, and Building Careers

### EAST MULTICENTER STUDY DATA COLLECTION TOOL

*EAST PRECISE- AAPT: PRagmatic Evaluation of CT In Stable Anterior Abdominal Penetrating Trauma*

**Baseline Institutional Data:** *To be completed once by each participating center at the beginning of study enrollment.*

Enrolling Center: \_\_\_\_\_  
Enrolling Co-investigator: \_\_\_\_\_  
ACS Trauma Center Verification Level: \_\_\_\_\_  
Computed Tomography (CT) scanner detector count: \_\_\_\_\_  
CT slice thickness: \_\_\_\_\_  
Contrast phases obtained for trauma imaging protocol: \_\_\_\_\_  
Do you have a dedicated trauma radiologist? \_\_\_\_\_  
Does your institution have a protocol for serial abdominal exams? \_\_\_\_\_  
If yes, please describe (include exam frequency, personnel involved, and duration of serial exams):  
\_\_\_\_\_

**Patient Demographics:**

Site Specific ID: \_\_\_\_\_ Age (years): \_\_\_\_\_ Gender: \_\_\_\_\_  
Weight (kg): \_\_\_\_\_ Height (m): \_\_\_\_\_ BMI (kg/m<sup>2</sup>): \_\_\_\_\_

**Injury:**

Mechanism of penetrating injury:  
\_\_\_\_\_ Gunshot  
\_\_\_\_\_ Stab  
\_\_\_\_\_ Other – please specify: \_\_\_\_\_

ISS: \_\_\_\_\_ AIS Abdomen: \_\_\_\_\_

**Medical History:**

\_\_\_\_\_ Prior abdominal surgery  
\_\_\_\_\_ Active use of anticoagulant (vitamin K antagonist, direct thrombin inhibitor, factor Xa inhibitor)  
\_\_\_\_\_ Active use of antiplatelet medication (aspirin, clopidogrel, or related medication)  
\_\_\_\_\_ Chronic kidney disease (pre-admission GFR < 90mL/min/1.73m<sup>2</sup> or prior diagnosis of CKD)  
\_\_\_\_\_ Known intravenous contrast allergy  
\_\_\_\_\_ Known metallic implants – please specify: \_\_\_\_\_

**Initial ED Vital Signs:** *First recorded values from ED, leave blank if not obtained*

Heart Rate: \_\_\_\_\_ Blood Pressure: \_\_\_\_\_ Glasgow Coma Scale score: \_\_\_\_\_  
Respiratory Rate: \_\_\_\_\_ O2 Saturation: \_\_\_\_\_ End Tidal CO2: \_\_\_\_\_ Temperature: \_\_\_\_\_

**Trauma Bay Imaging:**

Select all studies done in the trauma bay:

- Chest X-Ray
- Abdominal X-Ray (KUB)
- Pelvic X-Ray
- Focused assessment with sonography for trauma (FAST)
- Other – please specify: \_\_\_\_\_

Trauma bay imaging major findings:

- Chest X-Ray: \_\_\_\_\_
- Abdominal X-Ray: \_\_\_\_\_
- Pelvic X-Ray: \_\_\_\_\_
- Focused assessment with sonography for trauma (FAST): \_\_\_\_\_
- Other: \_\_\_\_\_

**Initial Management Strategy:**

Select the option that best describes the initial management strategy for this patient:

- Diagnostic laparoscopy
- Local wound exploration
- Observation with serial abdominal exams
- CT scan
- Other – please specify: \_\_\_\_\_

**Diagnostic Laparoscopy:** *Questions will only appear if diagnostic laparoscopy is selected for 'Initial Management Strategy'*

Please select the option that best describes the diagnostic laparoscopy:

- Therapeutic (injury identified and required intervention)
- Non-therapeutic (injury identified but did not require intervention)
- Negative (no injury identified)

*If therapeutic selected:*

- List the injuries identified in the operative report: \_\_\_\_\_
- List the procedures performed to repair the identified injuries: \_\_\_\_\_

*If non-therapeutic selected:*

- List the injuries identified in the operative report: \_\_\_\_\_

What was the patient's disposition after diagnostic laparoscopy?

- ICU admission
- Stepdown or floor unit admission
- Discharge
- Other – please specify: \_\_\_\_\_

**Local Wound Exploration:** *Questions will only appear if local wound exploration is selected for 'Initial Management Strategy'*

Was the anterior fascia penetrated?

- Yes
- No

*If yes: Which management strategy was selected:*

- CT scan
- Admission with serial abdominal exams
- Diagnostic laparoscopy
- Other – please specify: \_\_\_\_\_

*If CT scan selected:*

Provide the CT abdomen/pelvis major findings: \_\_\_\_\_

*If admission with serial exams selected:*

Where was the patient admitted to?

- \_\_\_\_\_ ICU
- \_\_\_\_\_ Stepdown or floor unit
- \_\_\_\_\_ Other – please specify: \_\_\_\_\_

*If diagnostic laparoscopy selected:*

Please select the option that best describes the diagnostic laparoscopy:

- \_\_\_\_\_ Therapeutic (injury identified and required intervention)
- \_\_\_\_\_ Non-therapeutic (injury identified but did not require intervention)
- \_\_\_\_\_ Negative (no injury identified)

*If therapeutic selected:*

List the injuries identified in the operative report: \_\_\_\_\_

List the procedures performed to repair the identified injuries: \_\_\_\_\_

*If non-therapeutic selected:*

List the injuries identified in the operative report: \_\_\_\_\_

What was the patient's disposition after diagnostic laparoscopy?

- \_\_\_\_\_ ICU
- \_\_\_\_\_ Stepdown or floor unit
- \_\_\_\_\_ Discharge
- \_\_\_\_\_ Other – please specify: \_\_\_\_\_

*If no: What was the patient's disposition?*

- \_\_\_\_\_ ICU admission for other injury or condition
- \_\_\_\_\_ Stepdown or floor unit admission for other injury or condition
- \_\_\_\_\_ Discharge
- \_\_\_\_\_ Other – please specify: \_\_\_\_\_

**Observation with Serial Abdominal Exams:** Questions will only appear if observation with serial abdominal exams is selected for 'Initial Management Strategy'

Did the patient develop peritonitis or hemodynamic instability?

- \_\_\_\_\_ Yes
- \_\_\_\_\_ No

*If yes:*

Indicate which procedure was performed:

- \_\_\_\_\_ Laparoscopy
- \_\_\_\_\_ Laparotomy
- \_\_\_\_\_ Laparoscopy converted to laparotomy
- \_\_\_\_\_ Other – please specify: \_\_\_\_\_

Please select the option that best describes the procedure:

- \_\_\_\_\_ Therapeutic (injury identified and required intervention)
- \_\_\_\_\_ Non-therapeutic (injury identified but did not require intervention)
- \_\_\_\_\_ Negative

*If therapeutic selected:*

List the injuries identified in the operative report: \_\_\_\_\_

List the procedures performed to repair the identified injuries: \_\_\_\_\_

*If non-therapeutic selected:*

List the injuries identified in the operative report: \_\_\_\_\_

What was the patient's disposition after the procedure?

\_\_\_\_\_ ICU

\_\_\_\_\_ Stepdown or floor unit

\_\_\_\_\_ Discharge

\_\_\_\_\_ Other – please specify: \_\_\_\_\_

Did the patient develop active bleeding?

\_\_\_\_\_ Yes

\_\_\_\_\_ No

*If yes:*

Was additional CT imaging obtained?

\_\_\_\_\_ Yes

\_\_\_\_\_ No

*If yes:*

Provide the CT abdomen/pelvis radiology major findings: \_\_\_\_\_

Did the patient require operative or interventional radiology procedures?

\_\_\_\_\_ Yes

\_\_\_\_\_ No

*If yes:*

List the procedures: \_\_\_\_\_

List the identified injuries: \_\_\_\_\_

Did the patient require ongoing admission for non-abdominal injuries or illnesses?

\_\_\_\_\_ Yes

\_\_\_\_\_ No

*If yes:*

What was the total duration of serial clinical exams in hours? \_\_\_\_\_

**CT Scan:** Questions will only appear if CT scan is selected for 'Initial Management Strategy'

Provide the CT abdomen/pelvis radiology major findings: \_\_\_\_\_

Did the patient require operative intervention or an interventional radiology procedure based on imaging results?

\_\_\_\_\_ Yes

\_\_\_\_\_ No

*If yes:*

List the procedures: \_\_\_\_\_

List the identified injuries: \_\_\_\_\_

*If no:*

Was the patient discharged or admitted for observation after CT scan?

- Admitted for serial abdominal exams
- Admitted for a non-abdominal injury or unrelated illness
- Discharged
- Other – please explain \_\_\_\_\_

*If admitted:*

Did the patient fail non-operative management?

- Yes, required an operation or interventional radiology procedure
- No

*If yes:*

List the procedures: \_\_\_\_\_

List the identified injuries: \_\_\_\_\_

**Emergency Department (ED) Length of Stay (LOS):** *Please list the total time in hours from patient arrival to determination of final disposition (e.g. discharge, admission, OR, IR). Each partial or full hour counts as 1 hour.*

ED LOS: \_\_\_\_\_

**Complications:**

Please select all complications the patient experienced during admission.

- Acute kidney injury
- Hospital-acquired pneumonia
- Urinary tract infection
- Deep vein thrombosis or pulmonary embolism
- Intra-abdominal abscess
- Sepsis or septic shock
- Iatrogenic intra-operative injury
- Superficial surgical site infection
- Deep surgical site infection
- Organ space surgical site infection
- Other – please specify: \_\_\_\_\_

**Length of Stay (LOS):** *If not discharged from the ED, please list the total hospital and ICU LOS for the patient. Each partial or full day will count as 1 calendar day. Enter '0' if patient did not require admission to the hospital or ICU.*

Total Hospital LOS (days): \_\_\_\_\_ Total ICU LOS (days): \_\_\_\_\_

**Discharge Location:**

Select the patient's final disposition from the index admission.

- Home
- Skilled nursing facility
- Inpatient rehabilitation facility
- Hospice
- Expired
- Other – please specify: \_\_\_\_\_

**Readmission:**

Was the patient readmitted to the hospital for any reason within 30 days of injury?

- Yes – please specify reason: \_\_\_\_\_
- No

*If yes:*

During readmission, did they require operative intervention or another procedure related to their abdominal trauma?

Yes

No

*If yes:*

List the procedures: \_\_\_\_\_

List the identified injuries: \_\_\_\_\_

**Follow-Up:**

Did this patient follow up in the outpatient clinic? \_\_\_\_\_

*If yes:*

Did they experience a complication from their injuries? \_\_\_\_\_



Eastern Association for the Surgery of Trauma  
Advancing Science, Fostering Relationships, and Building Careers

## EAST MULTICENTER STUDY DATA DICTIONARY

*EAST PRECISE- AAPT: PRagmatic Evaluation of CT In Stable Anterior Abdominal Penetrating Trauma*

Data Entry Points and appropriate definitions / clarifications:

Entry Space	Definition / Instructions
<b>Baseline Institutional Data – Completed once by each enrolling center at the beginning of study enrollment.</b>	
ACS Trauma Center Verification Level	Level of trauma center verification as defined by the American College of Surgeons. <i>Options:</i> Level I, Level II, Level III
Computed Tomography (CT) Scanner detector count	Number of detector rows in the typical CT scanner utilized in the emergency department (ED) by trauma patients
CT slice thickness	Width of cross-sectional image layer for CT scans on institutional trauma panscan (whole body) CT protocol
Contrast phases obtained in local trauma imaging protocol	Stages of contrast enhancement following infusion of pressure-injected intravenous (IV) contrast captured on institutional trauma panscan (whole body) CT protocol. <i>Options:</i> Early arterial, late arterial, portal venous, nephrogenic
Dedicated trauma radiologist	Presence of radiology-trained MD, DO, or MBBS dedicated to reviewing all trauma imaging during a shift.
Protocol for serial abdominal exams	Institutional guideline outlining process for serial abdominal exam frequency, personnel performing exam, and duration of exams.
<b>Demographics</b>	
Site Specific ID	Free text entry for unique site-specific identifier (e.g. BCM1)
Age	Age of patient enrolled in years
Gender	Gender of patient enrolled
Weight	Weight of patient enrolled in kilograms
Height	Height of patient enrolled in meters
BMI	Body mass index of patient enrolled in kg/m <sup>2</sup>
<b>Injury</b>	
Mechanism of injury	Single choice for best description of penetrating mechanism. <i>Options:</i> gunshot, stab, other. If 'other' is selected, a text box will appear for clarification.
ISS	Numerical value for calculated Injury Severity Score (ISS)

AIS Abdomen Numerical value for Abbreviated Injury Score (AIS) abdomen

**Medical History**

Prior abdominal surgery Any prior open, laparoscopic, or robotic surgery the patient has undergone prior to presentation

Active use of anticoagulant Any use of vitamin K antagonists, direct thrombin inhibitors, factor Xa inhibitors or other pharmacologic anticoagulants immediately preceding presentation

Active use of antiplatelet medication Any use of aspirin, clopidogrel, or related antiplatelet agents immediately preceding presentation

Chronic kidney disease Prior diagnosis of chronic kidney disease (CKD) or pre-admission GFR < 90mL/min/1.73m<sup>2</sup>

Known intravenous contrast allergy Previously reported or documented allergic reaction to intravenous contrast

Known metallic implants History of metallic implant prior to presentation. If 'yes' is selected, a text box will appear for clarification of metallic implant history.

**Initial ED Vital Signs**

Heart rate First recorded heart rate (HR) in beats per minute captured in the emergency room

Blood pressure First blood pressure in mmHg captured in the emergency room. Enter value as SDP/DBP.

Glasgow Coma Scale score First total Glasgow Coma Scale score captured in the emergency room.

Respiratory rate First respiratory rate in breaths per minute captured in the emergency room.

O2 saturation First oxygen saturation in percent captured in the emergency room.

End Tidal CO2 First ET/CO2 in mmHg captured in the emergency room.

Temperature First temperature taken after arrival in the emergency room. Enter value in Celsius.

**Trauma Bay Imaging**

Select all studies done in the trauma bay Select all imaging completed in the trauma bay. *Options* – Chest X-ray, Abdominal X-ray, Pelvic X-Ray, Focused assessment with sonography for trauma (FAST), Other. If 'other' is selected, a text box will appear for clarification.

Trauma bay imaging findings For each previously selected imaging study, a free text box will appear. Copy and paste the radiology report into the appropriate box. For FAST exam, the description of findings from the trauma team note is acceptable.

**Initial Management**

Select the initial management strategy Initial management strategy for the enrolled patient. *Options* – Diagnostic laparoscopy, local wound exploration, observation with

serial examinations, CT scan, Other. If 'Other' is selected, a text box will appear for clarification.

### **Diagnostic Laparoscopy**

Therapeutic

An injury is identified with diagnostic laparoscopy and is repaired.

Non-therapeutic

An injury is identified with diagnostic laparoscopy but did not require intervention.

Negative

No injury is identified with diagnostic laparoscopy.

Disposition after diagnostic laparoscopy

Select the option that best describes the patient's disposition after completion of diagnostic laparoscopy. *Options* – ICU admission, stepdown or floor unit admission, discharge, Other. If 'other' is selected, a text box will appear for clarification.

### **Local Wound Exploration**

Which management strategy was selected?

This question will appear if 'yes' is selected for the question 'Was the anterior fascia penetrated?'. Select the next step that was taken to further assess the patient's injury. *Options* – CT scan, admission with serial abdominal exams, diagnostic laparoscopy, Other. If 'other' is selected, a text box will appear for clarification.

Therapeutic

An injury is identified with diagnostic laparoscopy and is repaired.

Non-therapeutic

An injury is identified with diagnostic laparoscopy but did not require intervention.

Negative

No injury is identified with diagnostic laparoscopy.

### **Observation with Serial Abdominal Exams**

Therapeutic

An injury is identified intraoperatively and is repaired.

Non-therapeutic

An injury is identified intraoperatively but did not require intervention.

Negative

No injury is identified intraoperatively.

### **CT Scan**

CT abdomen/pelvis radiology major findings

Critical findings on CT imaging related to the patient's anterior abdominal penetrating injury. This will be a free text box.

### **ED LOS**

ED LOS

Please list the total time in hours from patient arrival to determination of final disposition (e.g. discharge, admission, OR, IR). Each partial or full hour counts as 1 hour.

### **Complications**

Please select all complications the patient experienced during admission.

*Options* – acute kidney injury, hospital-acquired pneumonia, urinary tract infection, deep vein thrombosis or pulmonary embolism, intra-abdominal abscess, sepsis or septic shock, iatrogenic intra-operative injury, superficial surgical site infection, deep surgical site infection, organ space surgical site infection, other. If 'other' is selected, a text box will appear for clarification.

**Length of Stay**

Total hospital LOS

If not discharged from the ED, please list the total hospital LOS for the patient. Each partial or full day will count as 1 calendar day. Enter '0' if patient did not require admission to the hospital.

Total ICU LOS

If not discharged from the ED, please list the total ICU LOS for the patient. Each partial or full day will count as 1 calendar day. Enter '0' if patient did not require admission to the ICU.

**Discharge Location**

Select the patient's final disposition from the index admission

*Options* – home, skilled nursing facility, inpatient rehabilitation facility, hospice, expired, other. If 'other' is selected, a text box will appear for clarification.

**Readmission**

Was the patient readmitted for any reason within 30 days of injury?

*Options* - yes, no. If 'yes' is selected, a text box will appear for clarification.

During readmission, did they require operative intervention or another procedure related to their abdominal trauma?

This question will appear if 'yes' is selected for readmission. If 'yes' is selected for this question, a question will appear asking to list the procedures and identified injuries.

**Follow-Up**

Did the patient follow up in the outpatient clinic?

*Options* – yes, no. If 'yes' is selected, a question will appear asking if the patient experienced a complication from their injuries.