Date: Monday, October 14, 2024 7:31:02 PM Print Close

HP-00112058 Introduction Page_V2

Introduction Page

1 * Abbreviated Title:
TIC- WTA

2 * Full Title:
A Multi-Center Study on Early Trauma-Induced Coagulopathy: Defining Clinical and Biochemical Profiles

3

* Select Type of Submission:

- (●) **IRB Application**
- ( ) Humanitarian Use Device (for FDA approved Indication & non-research purposes ONLY)
- ( ) Single Patient Expanded Access (pre-use)
- ( ) Single Patient Emergency Use (post-use)
- ( ) Unsure if this proposal requires IRB review (Not Human Subject Research)

Note: The Type of Submission cannot be changed after this application has been submitted for review.

4 Original Version #:

ID: VIEW4DF8709A33C00
Name: v2_Introduction Page

HP-00112058

Research Team Information_V2

Research Team Information

1 * Principal Investigator - Who is the PI for this study (person must have faculty status)? ***Faculty status is defined as being a full-time (>51% effort) faculty member holding one of the following titles at UM: Professor; Associate Professor; Assistant Professor.***
Rosemary Kozar

CITI Training: ID00007671

1.1 * Does the Principal Investigator have a potential conflict of interest, financial or otherwise, related to this research?
◯ Yes ● **No**

2 Point of Contact - Who is the alternative point of contact for the PI? This person can be a study coordinator or any other study team member. In case the IRB cannot contact the PI, this person is a secondary person to contact:
William Teeter

CITI Training: ID00012931

2.1 Does the Point of Contact have a potential conflict of interest, financial or otherwise, related to this research?
◯ Yes ● **No**

3 Other Team Members - list all additional members of the research team for this study. DO NOT include the PI or POC in this list:

	Name	Edit Submission	cc on Email	Research Role	Has SFI?	CITI Training
View	Seeta Kallam	yes	yes	Other	no	ID00000744
View	Leslie Sult	yes	yes	Research Team Member	no	ID00002755
View	Mark Scarboro	no	no	Other	no	ID00006452
View	Chavi Rehani	no	yes	Research Team Member	no	ID00019937

IMPORTANT NOTE: All research team members (including PI) must have current CITI and HIPAA training completed.

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

HP-00112058 Resources_V2

Resources

If this study is a collaborative UM/VA study, please clarify which resources are being used at each institution.

1 * Describe the time that the Principal Investigator will devote to conducting and completing the research:
The PI devotes approximately 1% of her time to this study.

2 * Describe the facilities where research procedures are conducted:
University of Maryland Medical Center, Shock Trauma Center.

3 * Describe the availability of medical and/or psychological resources that subjects might need as a result of anticipated consequences of the human research:
All study procedures including screening and enrollment are conducted by qualified research staff at the Shock Trauma Center. The number of staff members is adequate. Both the PI and the research staff have adequate time to conduct, oversee, and complete the research. All staff members receive thorough training on the study protocol and are supervised by the PI and by study coordinators. The research procedures are unlikely to result in consequences that require medical resources but, because the procedures are carried out in the hospital setting, there would be adequate medical resources if the need were to arise.

4 * Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions:
A detailed training session including written training materials is provided to all research staff before they begin working on the study. Every participant research folder is checked by a study coordinator to ensure that all procedures are properly completed. To prevent future errors, the coordinator provides feedback to the staff member when a discrepancy is discovered.

ID: VIEW4DF83CB976400
Name: v2_Resources

Sites Where Research Activities Will Be Conducted

1 * Is this study a:

- (●) **Multi-Site**
- ( ) Single Site

2 * Are you relying on an external IRB (not UM) to be the IRB of Record for this study?

( ) Yes (●) **No**

3 * Are any other institutions/organizations relying on UM to be the IRB of Record for this study?

( ) Yes (●) **No**

3.1 Attach the applicable regulatory documents here (i.e., IRB Authorization Agreement (IAA), FWA, local ethics approval, other IRB approvals, etc.). Final UM approval will be contingent upon final execution of all required regulatory approvals:

Name	Created	Modified Date

There are no items to display

4 * Is UM the Coordinating Center for this study? (Applicable for multi-site studies. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.)

(●) **Yes** ( ) No

5 Is VA the Coordinating Center for this study? (Applicable for Collaborative studies between the VA, UM and other sites. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project)

( ) Yes (●) **No**

6 * Institution(s) where the research activities will be performed:

- [x] **University of Maryland, Baltimore**
- [ ] University of Maryland, Upper Chesapeake Kaufman Cancer Center
- [ ] VAMHCS
- [ ] UMB School of Medicine
- [ ] Marlene and Stewart Greenebaum Cancer Center
- [ ] University Physicians Inc.
- [x] **Shock Trauma Center**
- [ ] General Clinical Research Center (GCRC)
- [ ] Maryland Psychiatric Research Center (MPRC)
- [ ] Johns Hopkins
- [ ] International Sites
- [ ] UMB Dental Clinics
- [ ] Center for Vaccine Development
- [ ] Community Mental Health Centers
- [ ] Private Practice in the State of Maryland
- [ ] Institute of Human Virology (IHV) Clinical Research Unit
- [ ] Joslin Center
- [ ] UMB Student Classrooms
- [ ] National Institute of Drug Abuse (NIDA)
- [ ] National Study Center for Trauma and EMS

- [ ] Univ of MD Cardiology Physicians at Westminster
- [ ] Nursing Homes in Maryland
- [ ] University of Maryland Biotechnology Institute
- [ ] Maryland Department of Health
- [ ] Maryland Proton Treatment Center
- [ ] Mount Washington Pediatric Hospital
- [ ] Institute of Marine and Environmental Technology (IMET)
- [ ] Other Sites
- [x] **University of Maryland Medical System (Select below)**

* UMMS Sites:

- [x] **University of Maryland Medical Center**
- [ ] UMMC Midtown Campus (formerly Maryland General Hospital)
- [ ] UM St. Joseph Medical Center
- [ ] UM Baltimore Washington Medical Center
- [ ] UM Capitol Region Health
- [ ] UM Charles Regional Medical Center
- [ ] UM Shore Medical Center at Easton
- [ ] UM Shore Medical Center at Chestertown
- [ ] UM Shore Medical Center at Dorchester
- [ ] UM Shore Emergency Center at Queenstown
- [ ] UM Shore Regional Health
- [ ] University of Maryland Rehabilitation & Orthopaedic Institute (formerly Kernan Hospital)
- [ ] UM Upper Chesapeake Health
- [ ] UM Upper Chesapeake Medical Center
- [ ] UM Harford Memorial Hospital
- [ ] University of Maryland Community Medical Group

ID: VIEW4DF870DF2C000
Name: v2_Sites Where Research Activities Will Be Conducted

HP-00112058

UM Coordinating Center_V2

UM Coordinating Center

You indicated that UM is the Coordinating Center for this multi-site study.

2.1 *Describe the processes to ensure communication among sites.

Things to consider including in the communication plan:

- all sites have the most current version of the protocol, consent document, etc.
- all required approvals have been obtained at each site (including approval by the site's IRB of record).
- all modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.
- all engaged participating sites will safeguard data as required by local information security policies.
- all local site investigators conduct the study appropriately.
- all non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

The Principal Investigator and Research Coordinator will ensure that all participating sites have received their IRB approval and local site Investigators conduct the study appropriately. Any modifications to the protocol will be communicated to all participating sites. The PI and Research Coordinator will assure that each site obtains approval for, and implements, the modifications. Any non-compliance will be reported in accordance with local policy.

2.2 *Describe the method for communicating to engaged participating sites including:

- reportable new information.
- problems.
- interim results.
- the closure of a study.

Conference calls between all sites and written reports distributed via email will be utilized to disseminate information about reportable new information, interim results, and closure of the study to all participating sites.

ID: VIEW4DF737D4C2800
Name: v2_UM Coordinating Center

HP-00112058

Funding Information_V2

Funding Information

1 * Indicate who is funding the study:

- [ ] Federal
- [ ] Industry
- [x] **Department / Division / Internal**
- [ ] Foundation
- [ ] Private
- [ ] State Agency

2 * What portion of the research is being funded? (Choose all that apply)

- [ ] Drug
- [ ] Device
- [x] **Staff**
- [ ] Participant Compensation
- [ ] Procedures
- [ ] Other

3 Please discuss any additional information regarding funding below:

ID: VIEW4DF85DF452400
Name: v2_Funding Information

HP-00112058

Research Protocol_V2

Research Protocol

1 * Do you have a research protocol to upload?

- ○ Yes
- ● **No, I do not have a research protocol and will use the CICERO application to enter my study information**

2 If Yes, upload the research protocol:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E00563F8D000
Name: v2_Research Protocol

HP-00112058

Risk Level_V2

Risk Level

What is the risk level of your study? (Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.)

* Choose One:

- (●) **Minimal - The probability & magnitude of harm/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/tests.**
- ( ) Greater Than Minimal - Does not meet the definition of Minimal Risk.

ID: VIEW4E02805225800
Name: v2_Risk Level

HP-00112058

Exempt Categories_Fed

Exempt Categories

You indicated on the "Risk Level" page that this study is Minimal Risk.

1 * Please review the following categories to determine if your research may be Exempt from IRB oversight. If you believe that your study qualifies as Exempt, select the Category under which it qualifies. If your research does not qualify as Exempt, select **"The research does not qualify as Exempt".**

☐ **Category 1**: Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ **Category 2**: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

☐ **Category 3**: Research involving benign behavioral interventions (brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and not offensive or embarrassing) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

☑ **Category 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:**

i. The identifiable private information or identifiable biospecimens are publicly available.
ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.
iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E [HIPAA], for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).
iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

☐ **Category 5**: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

☐ **Category 6**: Taste and food quality evaluation and consumer acceptance studies:

i. If wholesome foods without additives are consumed, or
ii. 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 contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S.D.A.

☐ **The research does not qualify as Exempt.**

ID: VIEW8D50FF499486A05
Name: v2_Exempt Categories

HP-00112058

Exempt Category 4_Fed

Exempt Category 4

You indicated on the "Exempt Categories" page that this study qualifies as Exempt under Category 4.

1 * Will the identifiable private information or identifiable biospecimens be secondary in nature?
● **Yes** ○ No

1.1 * Provide justification for the response selected above:
This is a data collection study and data collected will be from medical records which include data from standard of care.

2 * Will the identifiable private information or identifiable biospecimens are publicly available?
○ Yes ● **No**

3 * Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.
○ Yes ● **No**

4 * The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA, for the purposes of "health care operations", "research", or "public health activities and purposes".
● **Yes** ○ No

4.1 * Please clarify which of the above purposes the research falls under and provide justification:
This is a research study collecting data from standard of care to better define the clinical profile of coagulopathy using large datasets to include prehospital and in-hospital data and to define the causes of mortality.

5 * The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
○ Yes ● **No**

ID: VIEW8D50FF499486B26
Name: v2_Exempt Category 4

HP-00112058 Lay Summary_V2

Lay Summary

1 * Provide a summary of the background and purpose of the study in language that can be understood by a person without a medical degree.

Uncontrolled hemorrhage remains a significant cause of potentially preventable deaths in individuals suffering from traumatic injuries in both civilian and military settings. Over the last 20 years, there have been significant advances in the fundamental understanding of early trauma-induced coagulopathy (eTIC) which has led to the institution of therapeutic interventions to reverse eTIC immediately upon arrival to trauma centers and, more recently, in the prehospital setting. This raises the important question of why coagulopathy may be associated with mortality in trauma patients who are not in hemorrhagic shock. Typically, PT, PTT, and other laboratory definitions of coagulopathy correlate poorly with clinical signs of coagulopathy and the need for transfusion. Therefore, we are proposing a multicenter prospective observational study to better define the clinical profile of eTIC using large datasets to include prehospital and in-hospital data and to define the causes of mortality.

ID: VIEW4E02805CF7000
Name: v2_Lay Summary

Justification, Objective, & Research Design

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the purpose, specific aims, or objectives of this research. State the hypothesis to be tested:
The objective of this prospective study is to better define the clinical profile of eTIC using large datasets to include prehospital and in-hospital data and to define the causes of mortality.

2 * 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 is a multi center prospective chart review study.

3 * Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data:
Uncontrolled hemorrhage remains a significant cause of potentially preventable deaths in individuals suffering from traumatic injuries in both civilian and military settings. Over the last 20 years, there have been significant advances in the fundamental understanding of eTIC which has led to the institution of therapeutic interventions to reverse eTIC immediately upon arrival to trauma centers and, more recently, in the prehospital setting. Modern day prehosptial interventions include minimizing crystalloids, prevention of hypothermia, and the use of prehospital blood products and tranexamic acid.

The presence of eTIC conferred a higher risk of death across all disease severities and was independently associated with a greater risk of death. Biomarkers of coagulopathy associated with eTIC remain strongly predictive of poor outcome despite advances
in trauma care.

4 * Provide the scientific or scholarly background, rationale, and significance of the research and how it will add to existing knowledge:
One of our large retrospective study demonstrated that despite these advances in trauma care, the incidence of eTIC has not improved and remains an important risk factor for mortality even when adjusted for potentially confounding risk factors, especially in patients with low injury severity scores (ISS). While our cohort had a measurable reduction in mortality compared to the cohorts studied 20 years earlier, the degree of reduction was low and the prevalence of eTIC remained approximately 30% of patients. Importantly, our study was limited by the lack of data on prehospital interventions. Moreover, most of the patients in our cohort were not in hemorrhagic shock, suggesting that shock is not a prerequisite for trauma-induced coagulopathy.

This raises the important question of why coagulopathy may be associated with mortality in trauma patients who are not in hemorrhagic shock. Typically, PT, PTT, and other laboratory definitions of coagulopathy correlate poorly with clinical signs of coagulopathy and the need for transfusion.7 This is especially true in patients with low ISS and those without active hemorrhage. Yet, eTIC, as defined by abnormal PT and PTT, remains significantly associated with mortality in our recent study. It is possible that eTIC represents a biomarker for mortality by a yet-to-be-defined mechanism rather than a threshold for treatment.

Therefore, we are proposing a multicenter prospective observational study to address the limitations of our retrospective study.

ID: VIEW4E02805EA0C00
Name: v2_Justification, Objective, & Research Design

HP-00112058 Supporting Literature_V2

Supporting Literature

1 * Provide a summary of current literature related to the research: ***If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.***

References

1. Kalkwarf KJ, Drake SA, Yang Y, et al. Bleeding to death in a big city: An analysis of all trauma deaths from hemorrhage in a metropolitan area during 1 year. J Trauma Acute Care Surg 2020;89(4):716-722. DOI: 10.1097/TA.0000000000002833.
2. Eastridge BJ, Mabry RL, Seguin P, et al. Death on the battlefield (2001-2011): implications for the future of combat casualty care. J Trauma Acute Care Surg 2012;73(6 Suppl 5):S431-7. DOI: 10.1097/TA.0b013e3182755dcc.
3. Kashuk JL, Moore EE, Millikan JS, Moore JB. Major abdominal vascular trauma--a unified approach. The Journal of trauma 1982;22(8):672-9. DOI: 10.1097/00005373-198208000-00004.
4. MacLeod JB, Lynn M, McKenney MG, Cohn SM, Murtha M. Early coagulopathy predicts mortality in trauma. The Journal of trauma 2003;55(1):39-44. DOI: 10.1097/01.TA.0000075338.21177.EF.
5. Brohi K, Singh J, Heron M, Coats T. Acute traumatic coagulopathy. The Journal of trauma 2003;54(6):1127-30. DOI: 10.1097/01.TA.0000069184.82147.06.
6. Teeter W, Neal MD, Brown JB, MacLeod JBA, Vesselinov R, Kozar RA. Trauma-Induced Coagulopathy: Prevalence and Association with Mortality Persist Twenty Years Later. Shock. 2024 Jun 24. doi: 10.1097/SHK.0000000000002416.
7. Moore HB, Neal MD, Bertolet M, et al. Proteomics of Coagulopathy Following Injury Reveals Limitations of Using Laboratory Assessment to Define Trauma-Induced Coagulopathy to Predict Massive Transfusion. Ann Surg Open 2022;3(2). DOI: 10.1097/as9.0000000000000167.

2 If available, upload your applicable literature search:

Name	Created	Modified Date

There are no items to display

ID: VIEW4E02805A7E400
Name: v2_Supporting Literature

Study Procedures

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below. (If this study is a collaborative UM/VA study please list each procedure that is being conducted and the locations where it is being conducted.)

1 * Describe all procedures being performed for research purposes only (these procedures would not be done if individuals were not in the study) and when they are performed, including procedures being performed to monitor subjects for safety or to minimize risks:

This is a multi center chart review study. The trauma registry and medical records will be reviewed for all patients in an effort to answer the question of why coagulopathy may be associated with mortality in trauma patients who are not in hemorrhagic shock. Data will be collected regarding demographics, pre-hospital comorbidities, admission physiology, mechanism of injury, admission labs, operative variables, outcomes, and complications. This data will be analyzed according to the best practices as suggested by the completeness and complexity of the data obtained.

2 * Describe all procedures already being performed for diagnostic or treatment purposes (if not applicable to the study, enter "N/A"):

N/A. This is a chart review study. All data will be collected from medical records.

3 * Describe the duration of an individual participant's participation in the study:

N/A. This is a chart review study.

4 * Describe the amount of time it will take to complete the entire study:

Around 5 yrs.

5 * Describe any additional participant requirements:

None

ID: VIEW4E0280585B400
Name: v2_Study Procedures

HP-00112058

Sample Size and Data Analysis_V2

Sample Size and Data Analysis

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Provide the rationale and sample size calculations for the proposed target population:
This is a chart review study looking at patients in coagulopathy.

2 * Provide the plan for data analysis. Include in the description the types of comparisons that are planned (e.g., comparison of means, comparison of proportions, regressions, analysis of variance, etc.), which is the primary comparison/analysis, and how the analyses proposed will relate to the primary purposes of the study:
a. Descriptive Analysis
• Patient Characteristics: Summarize baseline characteristics using mean ± standard deviation for continuous variables and frequencies/percentages for categorical variables.
• Incidence of ETIC: Calculate the incidence of ETIC across institutions and overall.
b. Comparative Analysis
• Comparison of ETIC vs. Non-ETIC Groups:
o Use chi-square tests for categorical variables.
o Use t-tests or Mann-Whitney U tests for continuous variables depending on the normality of distribution.
o Stratify analyses by key variables like age, sex, ISS, and institution type.
c. Multivariable Analysis
• Logistic Regression: To identify independent risk factors associated with the development of ETIC. Adjust for potential confounders like age, sex, ISS, and mechanism of injury.
• Cox Proportional Hazards Model: To assess the impact of ETIC on time-to-event outcomes such as mortality, adjusting for confounders.
d. Subgroup Analysis
• Perform subgroup analyses based on:
o Injury severity (ISS categories).
o Mechanism of injury (blunt vs. penetrating).
o Geographic region or institution type.
e. Advanced Analyses (depending on data quality)
o Machine Learning Techniques: Supervised learning algorithms to develop predictive models for eTIC.
o Case Matching: Various matching methods (e.g. propensity score, full exact, mahalanobis matching) to create comparable groups for robust analysis.

ID: VIEW4E02806052800
Name: v2_Sample Size and Data Analysis

HP-00112058 Sharing of Results_V2

Sharing of Results

1 * Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared:

Any study results derived from data will be submitted for peer-review in manuscript form and if accepted will be made publicly available in a clinical journal.

ID: VIEW4E02808CBD800
Name: v2_Sharing of Results

HP-00112058 Participant Selection_V2

Participant Selection

1 * How many local potential participants (or specimens/charts) do you anticipate will be screened for this study? ***Screening includes determining potential participants' initial eligibility for and/or interest in a study.***
15000

2 * How many participants (or specimens, or charts) will be enrolled/used for this study? ***A local prospective participant is considered enrolled in the study when a UM-approved Informed Consent Document (not including separate screening consent forms) is signed.***

Local - the number being enrolled at this site:
7000

Worldwide - the number being enrolled total at all sites (including local enrollment):
30000

3 * Gender:

- [x] **Male**
- [x] **Female**

4 * Age(s):

- [ ] 0 to 27 days (newborn infants)
- [ ] 28 days to 12 months (Infant)
- [ ] 13 months to 23 months (Toddler)
- [ ] 2 to 5 years (Preschool)
- [ ] 6 to 11 years (Child)
- [ ] 12 to 17 (Adolescents)
- [x] **18 to 88 years (Adult)**
- [ ] 89 years and older

5 * Race/Ethnicity:

- [x] **All Races Included**
- [ ] American Indian or Alaskan Native
- [ ] Asian/Other Asian
- [ ] Asian/Vietnamese
- [ ] Black or African American
- [ ] Hispanic or Latino
- [ ] Mixed Race or Ethnicity
- [ ] Native Hawaiian or Pacific Islander
- [ ] White or Caucasian

6

* Language(s):

- [x] **English**
- [ ] Chinese
- [ ] French
- [ ] Italian
- [ ] Japanese
- [ ] Korean
- [ ] Local Dialect
- [ ] Spanish

- [ ] Vietnamese
- [ ] Other

6.1 Specify Other:

7

* Are you excluding a specific population, sub-group, or class?

○ Yes ● **No**

7.1

If Yes, indicate your justification for excluding a specific population, sub-group, class, etc.:

ID: VIEW4E0E519C1D000
Name: v2_Participant Selection

HP-00112058

Vulnerable Populations_V2

Vulnerable Populations

1 * Will you be targeting ANY of the following Vulnerable Populations for enrollment? (Select all that apply)

- [ ] Employees or Lab Personnel
- [ ] Children (Minors)
- [ ] Cognitively Impaired/ Impaired Decision Making Capacity
- [ ] Pregnant Women/Fetuses
- [ ] Wards of the State
- [ ] Students
- [ ] Prisoners
- [ ] Nonviable Neonates or Neonates of Uncertain Viability
- [ ] Economically/Educationally Disadvantaged
- [x] **None of the above**

Only select populations which you will be targeting for enrollment. Do not include populations that may be enrolled incidentally. Enrollment of a vulnerable population is considered to be "targeted" if the study team will be aware that a subject is from a vulnerable group as a result of interaction with the subject or collection of specific information about the subject, and the research team does not wish to exclude them. "Incidental" enrollment is limited to situations where a study team is unaware that a subject is from a vulnerable group.

ID: VIEW4E0E519917800
Name: v2_Vulnerable Populations

HP-00112058 Eligibility_V2

Eligibility

1 * Do you have an existing Eligibility checklist(s) for this study?

◯ Yes ● **No**

1.1 If Yes, upload here. If you need a template, you can download it by clicking **HERE**. The checklists you upload will also be available under the Documents tab of this application.

Name	Created	Modified Date
There are no items to display		

1.2 If No, create an eligibility checklist below:

List inclusion criteria (List each Inclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Age between 18-88 years of age
View	2	Sustain a traumatic injury
View	3	Hospital length of stay ≥ 24 hours or death any time after hospital arrival
View	4	Coagulation studies performed within 6 hours after admission

List exclusion criteria (List each Exclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Isolated hanging or drowning
View	2	Age < 18 or > 88 years of age
View	3	Hospital length of stay < 24 hours

After entering the inclusion and exclusion criteria above, click the Save link. CICERO will automatically generate a printable Eligibility Checklist for you to use in your research. To review the checklist, click on the resulting link below. This checklist is also available under the Documents tab of this application.

Eligibility Checklist for HP-00112058 v8-26-2024-1724703572652(0.01)

ID: VIEW4E0E5185F9000
Name: v2_Eligibility

HP-00112058

Recruitment_V2

Recruitment

1 * Describe plans for recruitment, including the identification of potential participants (or acquisition of charts/records/samples) and initial interactions with them: (If this study involves the VA please list all sites at which recruitment will take place.):
The PI or research staff will review trauma registry data to identify patients. Patients who meet inclusion criteria and no exclusion criteria will be included in the study. The eligible subject list will be generated using hospital medical record numbers. No interventions are expected as a result of the study being done. Decision making will be made solely by the treating physicians. No patient will be approached directly.

2 * Describe measures that will be implemented to avoid participant coercion or undue influence (if not applicable to the study, enter "N/A"):
This is a chart review study. There will be no interactions with the patient or patient's family.

3 * Who will recruit participants (or acquire charts/records/samples) for this study? (Check all that apply)

- [x] **PI**
- [x] **Study Staff**
- [ ] Third Party

3.1 If you are using a third party, specify Third Party Recruiters:

4 Upload any recruitment tools such as screening/telephone scripts and introductory letters (do not upload advertisements here):

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E0BCAA0A6C00
Name: v2_Recruitment

HP-00112058 Advertising_V2

Advertising

1 * Will you be using advertisements to recruit potential participants?

◯ Yes ● **No**

ID: VIEW4E0BCCF811000
Name: v2_Advertising

HP-00112058

Research Related Risk_V2

Research Related Risks

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.

1 * Individually list each research-related risk, using a separate line for each. Next to each risk, delineate the likelihood/seriousness of the risk, and the provisions for minimizing the risk:

There is a slight risk that a breach of confidentiality would occur. This is very unlikely, since all hardcopy data will be stored in a designated locked office, within a secured, locked, storage cabinet. Electronic data will be stored in a password protected computer. Only designated members of the research team have access to the study office and data storage equipment. All members of the research team are trained in maintaining confidentiality. All patient data will be de-identified and assigned a study number prior to storage. Patient confidentiality will be maintained to the extent provided by law.

ID: VIEW4E1B52509F000
Name: v2_Research Related Risks

Potential Benefits and Alternatives

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the potential direct benefit(s) to participants:
There will be no direct benefits from this research for the subjects involved in the study. The protocol des not modify the patient's care in any way.

2 * Describe the importance of the knowledge expected to result from the study:
Although there are no immediate benefits to patients from this study, a possible future benefit would occur. The results of this study may lead to better management of coagulopathy.

3 * Describe how the potential risks to participants are reasonable in relationship to the potential benefits:
Since the risks of the proposed study are minimal and the benefit to society is potentially great, the anticipated benefits outweigh the potential risks.

4 * Describe the alternatives to participation in this study. If there are no alternatives, state that participation is voluntary and the alternative is not to participate. For intervention studies, describe appropriate alternative clinical procedures or courses of treatment available to subjects.
N/A. This is a chart review study.

ID: VIEW4E1B5251B0400
Name: v2_Potential Benefits and Alternatives

HP-00112058

Withdrawal of Participants_V2

Withdrawal of Participants

If the questions below are not applicable to the research (i.e., chart review), enter "N/A".

1 * Describe anticipated circumstances under which subjects will be withdrawn from the research without their agreement:
N/A. This is a chart review study.

2 * Describe procedures for orderly termination:
N/A. This is a chart review study.

3 * Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection:
N/A. This is a chart review study.

ID: VIEW4E1B52531F800
Name: v2_Withdrawal of Participants

HP-00112058

Privacy of Participants_V2

Privacy of Participants

If the study does not involve interaction with participants, answer "N/A" to the questions below.

1 * Describe how you will ensure the privacy of potential participants throughout the study ***(privacy refers to persons and their interest in controlling access to themselves):***
N/A. This is a chart review study and there will be no interaction with the participants.

2 * Describe the location where potential participants will receive research information and detail the specific actions the study team will take to ensure adequate privacy areas:
N/A. This is a chart review study and there will be no interaction with the participants.

3 * Describe potential environmental stressors that may be associated with the research:
There are no potential environmental stressors that may be associated with research because this is a chart review study

4 * Will this study have a site based in the European Union?
◯ Yes ● **No**

5 * Will the study have planned recruitment or data collection from participants while they are located in the European Union?
◯ Yes ● **No**

Access link below for information about the EU General Data Protection Regulations to assist in answering these questions.
https://www.umaryland.edu/oac/general-data-protection-regulation/

ID: VIEW4E1B525B87C00
Name: v2_Privacy of Participants

HP-00112058

Confidentiality of Data_V2

Confidentiality of Data

1 * Will stored research data contain identifiers or be able to be linked to and identify individual participants (either directly or through a code/research ID)?

- (●) **Yes**
- ( ) No, the data will be stored de-identified/anonymous (stripped of all identifiers, no way to identify individual participants)

2 * Where will research data be kept (address electronic and paper data as applicable)? (If this is a VA study please list specific sites that data will be kept.)

All hardcopy data will be stored in a designated locked office and stored in a secured, locked storage file by the PI and research staff at University of Maryland Baltimore and University of Maryland Medical Center. Electronic data will be stored in a password protected computer. Only designated members of the research team will have access to the study office and data storage equipment.

3 * How will such data be secured?

Research data collected by the PI and research staff will be kept strictly confidential and will be used for research purposes only. All hardcopy data will be stored in a designated locked office and stored in a secured, locked storage file by the PI and research staff at University of Maryland Baltimore and University of Maryland Medical Center. Electronic data will be stored in a password protected computer. Only designated members of the research team will have access to the study office and data storage equipment.

4 * Who will have access to research data?

Investigators and research staff approved on the protocol.

5 * Will study data or test results be recorded in the participant's medical records?

- ( ) Yes
- (●) **No**

6 * Will any data be destroyed? ***(Please note that data for FDA regulated research cannot be deleted however, VA data must be destroyed according to the VHA Records Control Schedule (RCS) 10-1)***

- ( ) Yes
- (●) **No**

6.1 If Yes, what data (e.g., all data, some recordings, interview notes), when and how?

7 Do you plan to obtain a Certificate of Confidentiality?

- ( ) Yes
- (●) **No**

7.1 If Yes, upload your Certificate of Confidentiality. If you have not yet obtained the Certificate, please note that once it is obtained, you will need to submit an amendment to attach the document, make any needed changes to the submission and make needed changes to the Informed Consent Document.

Name	Created	Modified Date

There are no items to display

8 * Discuss any other potential confidentiality issues related to this study:

None

ID: VIEW4E1B5265E0400
Name: v2_Confidentiality of Data

HP-00112058

Monitoring Plan Selection_V2

Monitoring Plan Selection

1 * Type of data safety monitoring plan for the study:

- ○ Will use/defer to the external sponsor's Data Safety Monitoring Plan
- ○ Data Safety Monitoring by a Committee
- ○ Data Safety Monitoring by an Individual
- ● **There is no data safety monitoring plan in place**

ID: VIEW4E1B00E30D400
Name: v2_Monitoring Plan Selection

HP-00112058 No Monitoring Plan_V2

No Monitoring Plan

You indicated that there is no data safety monitoring plan in place for the study.

1 * Provide the rationale for why a data safety monitoring plan is not necessary for this study:
This is a minimal risk protocol. Any breaches of confidentiality will be reported as a RNI immediately through CICERO.

ID: VIEW4E1B07B5A2400
Name: v2_No Monitoring Plan

HP-00112058

Research Related Costs_V2

Research-Related Costs

1 * Is the study's financial supporter (e.g., commercial sponsor, federal or state grant or contract, private foundation, physician-sponsor) covering any research-related costs?

- ○ No
- ● **Yes**

1.1 If Yes, check all that apply:

- ☑ **Research-Related Services (personnel costs, tests, supplies, exams, x-rays, or consultations required in the study)**
- ☐ Investigational or Study Device
- ☐ Investigational or Study Drug
- ☐ Investigational Procedure(s)

1.2 If No, who is responsible for payment?

2 * Who is responsible for the uncovered research-related costs?

- ☐ Participant
- ☐ Sponsor
- ☐ UM
- ☐ Other
- ☑ **There will be no uncovered research-related costs**

2.1 If Other, specify:

3 If the participant is responsible for any research-related costs, identify and estimate the dollar amount:

ID: VIEW4E1B5D9641800
Name: v2_Research Related Costs

HP-00112058 Compensation for Research Related Injury_V2

Compensation for Research-Related Injury

1 * Is this study under a master agreement that includes a provision requiring the sponsor to provide compensation to participants for research-related injury?

◯ Yes ● **No**

1.1 If Yes, please provide the date and title of the agreement and upload the portion of the contract language relevant to compensation for research-related injury:

Name	Created	Modified Date
There are no items to display		

1.2 If No (the study is not under a master agreement), is there proposed contract language concerning payment to participants for treatment in the event of a research-related injury?

◯ Yes ● **No**

1.2.1 If Yes, indicate the status of the contract review/approval with the ORD and upload the proposed language relevant to compensation for research-related injury:

1.2.2

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E1B629EEC000
Name: v2_Compensation for Research-Related Injury

HP-00112058

Payment to Participants_V2

Payment/Reimbursement to Participants

1 * Will participants receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research?

◯ Yes ● **No**

ID: VIEW4E1C52A5D7800
Name: v2_Payment to Participants

HP-00112058 HIPAA_V2

HIPAA (Health Insurance Portability and Accountability Act)

1 * Are you affiliated with, or will you be accessing data from a HIPAA-covered entity? A covered entity might be a hospital, a physician practice, or any other provider who transmits health information in electronic form.

• At UMB, this includes UMB schools designated as covered entities (School of Medicine and School of Dentistry) and entities under the University of Maryland Medical System (UMMS). The Baltimore VA Medical Center is also a covered entity.

• If you are a researcher from any school that is not a covered entity but is accessing electronic medical records from a covered entity (such as UMMC), HIPAA would be applicable. Please see a list of covered entities included under UMMS here: *executed-ace-designation-042018.pdf*

● **Yes** ○ No

2 * If Yes, will the study view, access, share, collect, use, or analyze health information that is individually identifiable under HIPAA?

● **Yes** ○ No

ID: VIEW4E1B0A2114400
Name: v2_HIPAA

HP-00112058

Protected Health Information_V2

Protected Health Information (PHI)

You indicated that HIPAA applies and the study will view, access, share, collect, use, or analyze health information that is individually identifiable.

1 * Which PHI elements will be used or disclosed in this study? (Check all that apply)

- [x] **Name**
- [ ] Address (if more specific than Zip Code)
- [x] **Dates**
- [ ] Ages over age 89
- [ ] Telephone numbers
- [ ] Fax numbers
- [ ] Email addresses
- [ ] Social Security numbers
- [x] **Medical record numbers**
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Device identifiers and serial numbers
- [ ] Web universal resource locators (URLs)
- [ ] Internet protocol (IP) address numbers
- [ ] Biometric identifiers, including fingerprints and voiceprints
- [ ] Full-face photographic images and any comparable images
- [ ] Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification
- [ ] None

2 * Why is the PHI necessary for this research?
If SSNs are going to be used, describe the specific use and type of SSN to be used (real, scrambled, last 4 digits).
The PHI will need to be accessed prior to enrollment for patient's demographics, date of birth, past medical history, etc. to screen and determine patient eligibility.

3 * What is the source(s) of the PHI?
PHI is obtained from the patient's medical records.

4 * Provide written assurance that Protected Health Information will not be reused. (Note: this refers to re-use on another study or for a purpose which has not been approved, not to the re-use of screening data during the current study).
PHI for this study will not be re-used in another study or for any purpose that has not been approved.

5 * How will permission to allow the use/disclosure of the individual's protected health information (PHI) be obtained? (Choose all that apply:)

- [ ] Obtain written authorization *(upload authorization form at the end of the application under "Consent and HIPAA Authorization Forms")*
- [x] **Requesting waiver/alteration of authorization (includes waiver of authorization for recruitment only)**
- [ ] Qualifies as a limited data set (LDS)

5.1 If you are using a limited data set (LDS), please attach the Data Use Agreement (DUA):

Name	Created	Modified Date

There are no items to display

ID: VIEW4E1B0A24AA400
Name: v2_Protected Health Information

Waiver/Alteration of Authorization

You indicated that a waiver/alteration of authorization is requested.

1 * Provide rationale for how the research presents no more than minimal risk to the privacy of individuals:
The research data being collected is from standard of care. No additional information is being collected as part of research. Therefore, this study does not increase the privacy risk to participants.

2 * Describe the plan to ensure the protection of PHI collected during this study from improper use and disclosure:
Once enrolled, the subject's MRN will be used to follow the subject and collect data while enrolled in the study. Once data collection is complete, including outcomes, all PHIs will be removed from the datasets. Each subject will be assigned a unique identification number (UIN) upon completion of data collection, prior to analysis. The completely de-identified datasets will then be used for data analysis. No identifying information (MRN, DOB, etc.) will be connected with the UIN on any of the datasets. For example, demographic information (e.g. gender, age, etc) collected will be linked to the subjects UIN only.

3 * Describe the plan to destroy the PHI collected during this study at the earliest opportunity consistent with the conduct of the research. If there is a need to retain PHI, provide a justification:
The PHIs which will need to be accessed prior to determining eligibility includes any information contained in the patient's medical record or information that the PI or research staff have uncovered about the patient's clinical course. This information will be used to determine eligibility according to the inclusion / exclusion criteria. PHI will be destroyed at the earliest time possible but not prior to completion of study at all sties, data analysis and study publication.

4 * Why could the research not practicably be done without access to and use of this PHI?
Access to PHI is needed in order to determine whether individuals qualify for inclusion in this study. Without access to PHI, eligibility could not be determined.

5 * Why could the research not practicably be done without the waiver or alteration?
Thousands of individuals are admitted to the trauma center each year. It is not feasible to contact each person to obtain an authorization to determine eligibility for inclusion.

6 * Will the subjects' PHI be disclosed to (or shared with) any individuals or entities outside of UM?
○ Yes ● **No**

6.1 If Yes, describe the individuals or entities outside of UM to whom PHI will be disclosed.

ID: VIEW4E1B0A2896400
Name: v2_Waiver/Alteration of Authorization

HP-00112058

Informed Consent Process_V2

Informed Consent Process

If the study does not involve interaction with participants or a waiver of consent is being requested , answer "N/A" to the questions below.

1 * Indicate the type(s) of consent that will be involved in this study: (check all that apply)

- [x] **Not applicable (study may qualify as exempt)**
- [ ] Request to Waive Consent/Parental Permission (Consent is not being obtained)
- [ ] Request to Alter Consent (Some Elements of Consent Waived)
- [ ] Request to Waive Documentation of Consent (Verbal/Oral Consent)
- [ ] Written Consent Form
- [ ] Electronic Consent

2 * Describe the Informed Consent process in detail:
N/A. This is a chart review study.

3 * Confirm that the consent process will explain the following:

- The activities involve research.
- The procedures to be performed.
- That participation is voluntary.
- The name and contact information for the investigator.

○ Yes ● **No**

4 * Describe who will obtain Informed Consent:
N/A. This is a chart review study.

5 * If obtaining consent from a legally authorized representative (LAR), describe how you will confirm that the individual is the LAR and can provide legally effective informed consent. *(Answer "N/A" if not obtaining consent from LARs)*
N/A. This is a chart review study.

6 * Describe the setting for consent:
N/A. This is a chart review study.

7 * Describe the provisions for assessing participant understanding:
N/A. This is a chart review study.

8 * Describe the consideration for ongoing consent:
N/A. This is a chart review study.

ID: VIEW4E1C661D0AC00
Name: v2_Informed Consent Process

HP-00112058

Consent Forms - Draft_V2

Consent and HIPAA Authorization Forms - Draft

1 Upload all of your Consent Forms for approval. Use only Microsoft Word.

Name	Created	Modified Date
No Consent Forms Uploaded		

IMPORTANT NOTE: the above list of consent forms (if any) are DRAFT versions. Under no circumstances should copies of these be distributed to patients/study subjects. If/when this research submission is approved by the IRB, approved consent forms will be available for download and use from the "Documents" tab of the Submission's workspace (click Exit and then look for the Documents tab - approved submissions only)

1A Archived Consent Forms:

Name	Created	Modified Date
There are no items to display		

2 Upload any HIPAA authorization forms here:

There are no items to display

Please refer to HRPO's website for specific instructions for preparing informed consent documents and to access current templates:
http://hrpo.umaryland.edu/researchers/consents.html

ID: VIEW4E1C7712D3000
Name: v2_Consent Forms - Draft

Organization Review Requirements (other than IRB)

Answer the following questions to determine additional organizational review requirements:

1 **Department/Division Review** - All research submissions are required to undergo department/division/institutional review prior to IRB review. The following entity is listed as the required department/division/institutional review:

SOM Program in Trauma

If this information is incorrect, please notify the HRPO office.

2 **RSC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Radiation Safety Committee may be required.

* 2.1 Does the research involve the use of ionizing radiation? ○ Yes ● **No**

2.2 Does the research involve the sampling of radioactive human materials for subsequent use or analysis in a laboratory?

3 **IBC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Institutional Biosafety Committee may be required.

* 3.1 Does the research involve human gene transfer? ○ Yes ● **No**
-OR-
Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.

3.2 Does the research involve the exposure of human subjects to pathogenic microorganisms, or the exposure of research staff to human subjects or samples known or reasonably expected to carry infectious disease(s)?

3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard?

4 **Cancer Center Criteria** - Answer the following to determine if review by the Cancer Center (Hematology-Oncology) may be required.

* Does the protocol involve in any way studies related to the prevention, treatment, diagnosis, or imaging of neoplastic diseases? ○ Yes ● **No**

5 **General Clinical Research Center Review Criteria** - the GCRC offers free and/or cost shared resources for patient-oriented research. Click Here for more information.

Answer the following to determine if review by the GCRC may be required.

* Will the General Clinical Research Center (GCRC) facility or resources be used to conduct this activity? ○ Yes ● **No**

6 **VA Review Criteria** - Answer the following questions to determine if review by the VAMHCS R&D Committee may be required.

* 6.1 - Will the research be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments)? ○ Yes ● **No**
* 6.2 - Will the research utilize VA resources (e.g., equipment, funds, medical records, databases, tissues, etc.)? ○ Yes ● **No**
* 6.3 - Will the research be conducted on VA property, including space leased to and used by VA? ○ Yes ● **No**

PLEASE NOTE that the research may be funded by VA, by other sponsors, or may be unfunded.

ID: VIEW4E1AF91AB2400
Name: v2_Organization Review Requirements (other than IRB)

HP-00112058

Summary of Required Reviews_V2

Summary of Required Reviews (other than IRB)

1 **Additional Committee Reviews** - Based on your responses to the previous questions, you have identified the following additional reviews. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's webpage.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

2 **Required Department and Specialty Reviews** - Based on the PI's organization (department, division, etc.) affiliation and answers to previous questions (use of Cancer Center, etc.), the organizations listed below are required to review this application. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	**Review Status**
SOM Program in Trauma	Complete

ID: VIEW4E1C8D9AE4000
Name: v2_Summary of Required Reviews (other than IRB)

HP-00112058

Additional Documents_V2

Additional Documents

1

Upload all additional documents here:

Name	Created	Modified Date
Published manuscript that proposed study is based on(0.01)	9/4/2024 9:43 AM	9/4/2024 9:43 AM
Data Collection sheet(0.01)	9/4/2024 9:42 AM	9/4/2024 9:42 AM

ID: VIEW4E0962513A000
Name: v2_Additional Documents

HP-00112058

Final Page of Application_V2

Final Page of Application

You have reached the final page of this application. It is recommended that you click on the "Hide/Show Errors" link on the upper or lower breadcrumb row of this page. The "Hide/Show Errors" will do a search of your application, and highlight areas that are required or need to be completed prior to submitting.

By submitting this application, you are electronically routing the protocol for departmental scientific review and all other necessary reviews. According to information you have provided, this application will be routed to the following Departments for review prior to being forwarded to the IRB for review. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	**Review Status**
SOM Program in Trauma	Complete

Required Safety Committee Reviews - In addition to the IRB, the following committees must review this submission. Each additional committee has a separate online form that the study team will be required to fill out. All committee applications (IRB plus those listed here) must be completed properly before the 'package' of applications can be submitted. The team may complete these additional forms in any order or at any time prior to submission of the IRB Application. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's Workspace.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

You may check the progress of your application at any time by returning to the Workspace of this submission. A detailed history, including notes, dates, and times of events, is provided to you for this purpose.

If a reviewer returns the application to you, you must address their concerns and resubmit the protocol for review to all designated departments. After all departments have reviewed the application, it will automatically be sent to the IRB for review. Changes made to the submission after its approval must be submitted as modifications.

Investigator Attestation
By submitting this application, I, the Principal Investigator (PI), certify that the information provided in this application is complete and correct. Research will be conducted according to the submission as described, only by the approved principal investigator and study team members.

In addition, I agree to the responsibilities of a PI, including:

- Obtaining informed consent (if applicable) from all subjects as outlined in the submission.
- Reporting new information to the IRB per the requirements of the Investigator Manual.
- If Required, obtaining renewal of the protocol prior to the expiration of the approval period or halt all study activities upon study expiration.
- Accepting ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.
- Ensuring performance of all research activities by qualified personnel according to the IRB approved submission.
- Ensuring that research personnel have or will receive appropriate training.
- Ensuring no changes will be made in the research until approved by the IRB (except when necessary to eliminate apparent immediate hazards to subjects).

Click the "Finish" button and then click "Submit Application" in the submission Workspace.

ID: VIEW4E1B10C500000
Name: v2_Final Page of Application

HP-00112058

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Seeta Kallam

2 Research Role:
Other

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
● **Yes** ○ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Works on IRB submissions

HP-00112058

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Leslie Sult

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
● **Yes** ○ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Manages all research activities

HP-00112058

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Mark Scarboro

2 Research Role:
Other

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Director of research.

HP-00112058

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Chavi Rehani

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
● **Yes** ○ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Performs all research activities under the supervision of Investigators.