



Date: May 30, 2013 11:46:44 AM EDT

View: Introduction Page

Print Close



Introduction Page

- 1 *** Abbreviated Title:**
AORTA Study
- 2 *** Full Title:**
Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA): A prospective observational study of the Endovascular Skills in Trauma and Resuscitative Surgery (ESTARS) Working Group
- 3 *** Select Type of Submission :**
New IRB Application
- 4 **Original Version #:**

View: Type of Application

ID: VIEW439861A002800
Name: Introduction Page



Type of Application

- 1 *** Select the most appropriate answer:**
 I have an existing external sponsor's protocol.
 I do not have an existing external sponsor's protocol.

View: NIH Sponsored Study

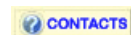
ID: VIEW4572037F13C00
Name: Type of Application

NIH Sponsored Study

- 1 *** Is this a National Institutes of Health (NIH) sponsored study?**
 Yes No

View: Research Team Information

ID: VIEW45869AB314800
Name: NIH Sponsored Study



Research Team Information

- 1 *** Principal Investigator** - Who is the PI for this study (person must have faculty PI status)?
Megan Brenner
- 2 **Point of Contact** - Who is the alternative point of contact for the PI? (If **not** Principal Investigator). This person can be a study coordinator or any other study team member. In case the IRB can not contact the PI, this person is a secondary person to contact:
Megan Brenner

- 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 |
|----------------|-----------------|-------------|----------------------|
| Melanie Hoehn | yes | yes | Sub-Investigator |
| Seeta Kallam | yes | yes | Research Team Member |
| Lisa Gettings | no | yes | Other |
| Joseph DuBose | yes | yes | Sub-Investigator |
| Christine Wade | yes | yes | Research Team Member |
| Deborah Stein | yes | yes | Sub-Investigator |

IMPORTANT NOTE: All Research Team Members must log into CICERO and complete the Conflict of Interest Statement in the **Submit COI Statement** activity. All research team members' COI statements MUST BE COMPLETED before the application can be submitted.

View: Sites Where Research Activities Will Be Conducted

Sites Where Research Activities Will Be Conducted

- 1 * Is this study a:
 - Single Site
 - Multi-Site

- 2 * Is UMB the Coordinating Center for this study?
 - Yes No

- 3 * Institution(s) where the research activities will be performed:
 - University of Maryland Medical Center
 - Shock Trauma Center

View: Initiating Research

Initiating Research

- 1 * Indicate who is initiating this research:
 - PI

View: Funding Information

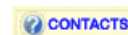
Funding Information

- 1 * Indicate who is funding the study
 - No Funding

- 2 * What portion of the research is being funded?
 - Other

- 3 Please discuss any additional information regarding funding below:
 - There is no funding for this study.

View: Organization Review Requirements



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:
 - Trauma Rsrch-CORE**
 - If this information is incorrect, please notify the HRPO office.

- 2 **RSC Review Criteria** - select 'Yes' if the answer is true for any of the following questions. Review by the Radiation Safety Committee may be required. See "Help" for definitions, examples and additional information:
 - * 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 true for any of the following questions. Review by the Institutional Biosafety Committee may be required. See "Help" for definitions, examples, and other information:
 - * 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

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: a) the exposure of human subjects to pathogenic microorganisms, or b) the potential exposure of UMB research staff to infectious materials through the sampling or processing of materials from patients with known infectious disease or from environmental surfaces?

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 completely or partially in VA facilities or at VA approved off-site locations/facilities (including VA-leased space) or otherwise utilizes VA resources? Yes No
 * 6.2 -Will the research be conducted by researchers with VA appointments while on official VA duty (including those with WOC status)? Yes No
 * 6.3 - Will the VAMHCS or its satellites will be recruitment sites for this research project? Yes No
 * 6.4 - Is the research VA-funded? Yes No
 * 6.5 - Does the research involve VA medical records or VA databases, or otherwise derives data from intervention or interaction with VAMHCS subjects or tissues? Yes No

7 **Conflict of Interest (COI)** - IRB policies require that each and every member of the study team must declare any conflicts of interest for this Application submission. This means that each member of the study team must independently log into this site and execute the "Submit COI Statement" activity. The study team members and the status of their COI declaration for this submission appears below:

| Researcher | COI Statement Submitted | Date Submitted | CISC Review Date |
|----------------|-------------------------|----------------|----------------------|
| Megan Brenner | Yes | 3/25/2013 | Not Reviewed by CISC |
| Seeta Kallam | Yes | 3/25/2013 | Not Reviewed by CISC |
| Deborah Stein | Yes | 3/25/2013 | Not Reviewed by CISC |
| Melanie Hoehn | Yes | 5/6/2013 | Not Reviewed by CISC |
| Christine Wade | Yes | 3/25/2013 | Not Reviewed by CISC |
| Lisa Gettings | Yes | 4/1/2013 | Not Reviewed by CISC |
| Joseph DuBose | Yes | 5/6/2013 | Not Reviewed by CISC |

8 **Department of Health and Mental Hygiene (DHMH)** - Answer the following questions to determine whether or not DHMH review is needed:
 * 8.1 DHMH will rely on UMB IRB for review of this protocol? Yes No
 * 8.2 This protocol will need DHMH IRB review? Yes No

ID: VIEW44034C719B400
 Name: Organization Review Requirements

View: Summary of Required Reviews

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 |
|-----------------------|---------------|
| Trauma Rsrch-CORE | Complete |
| SOM Program in Trauma | Complete |

ID: VIEW440367DB65800
Name: Summary of Required Reviews

View: Risk Level



Risk

* 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: VIEW43BD8D9C46C00
Name: Risk Level

View: Exempt_Determination

Exempt Determination

1 Choose ONE or MORE Exempt Categories from the list below. If your study meets NONE of the below listed criteria, leave the answers BLANK, and click the Continue button:

- 45 CFR 46.101(1)** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 45 CFR 46.101(2)** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- 45 CFR 46.101(3)** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 45 CFR 46.101(4)** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. PLEASE NOTE: According to the Office for Human Research Protections (OHRP), to qualify for this exemption the data, documents, records, or specimens must be in existence before the project begins. The principle behind this policy is that the rights of individuals should be respected; subjects must consent to participation in research.
- 45 CFR 46.101(5)** Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- 45 CFR 46.101(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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

ID: VIEW48675960F0C01
Name: Exempt_Determination

View: Expedited_Determination

Expedited Determination

1 Choose ONE ore MORE Expedited Category from the list below. If your study meets NONE of the below listed criteria, leave the answers BLANK, and click the Continue button:

- 45 CFR 46.110 (1)(a)** Clinical studies of drugs and medical devices when research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
- 45 CFR 46.110 (1)(b)** Clinical studies of drugs and medical devices when research on medical devices for which (i) an investigational

- device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- 45 CFR 46.110 (2)(a)** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.
- 45 CFR 46.110 (2)(b)** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- 45 CFR 46.110 (3)** Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
- 45 CFR 46.110 (4)** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- 45 CFR 46.110 (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)**
- 45 CFR 46.110 (6)** Collection of data from voice, video, digital, or image recordings made for research purposes.
- 45 CFR 46.110 (7)** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
- 45 CFR 46.110 (8)(a)** Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects.
- 45 CFR 46.110 (8)(b)** Continuing review of research previously approved by the convened IRB as follows: (b) where no subjects have been enrolled and no additional risks have been identified.
- 45 CFR 46.110 (8)(c)** Continuing review of research previously approved by the convened IRB as follows: (c) where the remaining research activities are limited to data analysis.
- 45 CFR 46.110 (9)** Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

ID: VIEW48675A98D4000
Name: Expedited_Determination

View: Qualifies As Expedited

Based on the information you have provided, your study may qualify for EXPEDITED REVIEW. Click on the CONTINUE button below to complete the rest of the submission.

ID: VIEW43CBE29BE1800
Name: Qualifies As Expedited

View: Waiver of Consent

View: Waiver of Consent

Waiver of Consent

- 1 * Will this research require a waiver of consent?

Yes No

ID: VIEW43B3982218000
Name: Waiver of Consent

View: Waiver of Consent (Cont.)

Waiver of Consent (cont.)

- 1.1 * Explain why the research could not be practicably conducted without the waiver:

This is a prospective observational study, designed to prospectively record data on patients who are managed according to institutional patient management protocols. Thus, waiver of informed consent is requested. Data will be recorded on a data sheet and as soon as the patient is discharged, all data will be logged anonymously utilizing the American Association for the Surgery of Trauma-Multi-Institutional Trials (AAST MIT) online data entry system .

The study design is based on physiologic data collected on regular basis for this type of injuries. Patients will be managed according to standard of care by the clinical team. No clinical decisions will be made by the researchers or as a result of this study being conducted. Consent for this study may delay appropriate intervention by the trauma team members

- 1.2 * Explain why the waiver will not adversely affect the rights and welfare of the subjects:

The waiver would not adversely affect the rights and welfare of the subjects as their confidentiality will be maintained at all times. The information to be obtained has already been collected for standard of care purposes. Patients will be managed according to standard of care by the clinical team. No clinical decisions will be made by the researchers or as a result of this study being conducted therefore posing no more than minimal risk to patient.

- 1.3 If appropriate, describe plans for providing subjects with additional pertinent information after participation:

Since this is a full waiver of consent study, the subject and/or LAR will not be approached. There will be no communication of the study with the participant.

- 2 * Will your study still require a Consent Form?

Yes No

ID: VIEW4655DB2704000
Name: Waiver of Consent (Cont.)

View: Type of Research

Type of Research

- 1 * Indicate the type of research this study involves (Choose all applicable):

- Device
 One or more drugs or biologics
 Genetics testing
 None of the above
 Psychological / Sociological

ID: VIEW4514342955C00
Name: Type of Research

View: Lay Summary

Lay Summary

- 1 * Provide a summary of the background and purpose of the study in **lay terms**. This summary will be used during the IRB review and should include layman's terms and language that can be understood by a person without a medical degree.

Aortic occlusion (AO) to facilitate the acute resuscitation of trauma and acute care surgery patients in shock remains a controversial topic. It is held that the early utilization of AO preserves cerebral perfusion and coronary filling in the setting of life-threatening hypotension and hypovolemia due to hemorrhage. Recent basic science data supports these contentions, suggesting that the AO utilization in the setting of physiologic depletion due to hemorrhage may result in increased central aortic pressure, carotid flow and partial pressure brain tissue oximetry. The majority of data on the clinical utilization of AO has, however, been retrospective and limited in nature. The largest collated description of this experience was a landmark study, but was limited by the absence of consistent definitions and the variability of employed practices between published series. To date, no large multicenter prospective study of the clinical utilization of AO in trauma and acute care surgery has been attempted.

The purpose of the present study is to examine, in a prospective observational fashion, the modern utilization of AO in the acute resuscitation of trauma and acute care surgery patients in shock.

ID: VIEW475E142D4E000
Name: Lay Summary

View: Justification, Objective, & Research Design

Justification, Objective, & Research Design

1 * Provide context, justification, and scientific/scholarly rationale for the study:

Aortic occlusion (AO) to facilitate the acute resuscitation of trauma and acute care surgery patients in shock remains a controversial topic. It is held that the early utilization of AO preserves cerebral perfusion and coronary filling in the setting of life-threatening hypotension and hypovolemia due to hemorrhage. Recent basic science data supports these contentions, suggesting that the AO utilization in the setting of physiologic depletion due to hemorrhage may result in increased central aortic pressure, carotid flow and partial pressure brain tissue oximetry. The majority of data on the clinical utilization of AO has, however, been retrospective and limited in nature. The largest collated description of this experience was a landmark study, but was limited by the absence of consistent definitions and the variability of employed practices between published series. To date, no large multicenter prospective study of the clinical utilization of AO in trauma and acute care surgery has been attempted.

AO for trauma has traditionally been accomplished by supra-diaphragmatic clamping of the descending thoracic aorta via emergent thoracotomy or as an initial step during laparotomy. This approach has been employed in a variety of settings, with variable results due to unclear indications and alterations in practice. An evolution in endovascular technologies, however, has provided additional means by which to achieve AO. Expanding experience with the utilization of balloon occlusion in the setting of abdominal aortic rupture due to chronic vascular disease has demonstrated the potential of these new technologies. Discussion of the employment of endovascular aortic occlusion in the realm of trauma has led to the description of this approach and the demonstration of its effectiveness in animal models of severe hemorrhage. To date, however, no comparison of the clinical employment of endovascular AO to traditional open means has been conducted.

2 * What is the purpose/objective of this study?

The purpose of the present study is to prospectively examine, the modern utilization of AO in the acute resuscitation of trauma and acute care surgery patients in shock. It is our hypothesis that this observational collection will provide meaningful data on the effectiveness of AO via both open and endovascular means. This data can then be utilized to develop and refine protocols that will optimize resource utilization and patient outcomes for patients with shock.

3 * 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 Prospective multi-center observational study of the utilization of aortic occlusion in the acute resuscitation of trauma and acute care surgery patients. Data and endpoints will be observational and involve no prescribed therapeutic interventions or alterations in patient care. Institutions and providers will conduct normal diagnosis, management and surveillance procedures without interference of this study.

ID: VIEW43B257658E400
Name: Justification, Objective, & Research Design

View: Summary & Supporting Literature

Summary & Supporting Literature

1 * Provide a summary of current literature:

AO for trauma has traditionally been accomplished by supra-diaphragmatic clamping of the descending thoracic aorta via emergent thoracotomy or as an initial step during laparotomy. This approach has been employed in a variety of settings, with variable results due to unclear indications and alterations in practice. An evolution in endovascular technologies, however, has provided additional means by which to achieve AO. Expanding experience with the utilization of balloon occlusion in the setting of abdominal aortic rupture due to chronic vascular disease has demonstrated the potential of these new technologies. Discussion of the employment of endovascular aortic occlusion in the realm of trauma has led to the description of this approach and the demonstration of its effectiveness in animal models of severe hemorrhage

References:

- 1.Mollberg NM, Glenn C, John J, Wise SR, Sullivan R, Vafa A, Snow NJ, Massad MG. Appropriate use of emergency department thoracotomy: implications for the thoracic surgeon. *Ann Thorac Surg.* 2011 Aug;92(2):455-61.
- 2.Khorsandi M, Skouras C, Shah R. Is there any role for resuscitative emergency department thoracotomy in blunt trauma? *Interact Cardiovasc Thorac Surg.* 2012 Dec 28. [Epub ahead of print].
- 3.Mollberg NM, Wise SR. Appropriate use of emergency department thoracotomy. *J Am Coll Surg.* 2012 May;214(5):870-1.
- 4.Seamon MJ, Chovanes J, Fox N, Green R, Manis G, Tsiotsias G, Warta M, Ross SE. The use of emergency department thoracotomy for traumatic cardiopulmonary arrest. *Injury.* 2012 Sep;43(9):1355-61.
- 5.Passos EM, Engels PT, Doyle JD, Beckett A, Nascimento B Jr, Rizoli SB, Tien HC. Societal costs of inappropriate emergency department thoracotomy. *J Am Coll Surg.* 2012 Jan;214(1):18-25.
- 6.Rhee PM, Acosta J, Bridgeman A, Wang D, Jordan M, Rich N. Survival after emergency department thoracotomy: review of published data from the last 25 year. *J Am Coll Surg.* 200 Mar;190(3):288-98.
- 7.Morrison JJ, Poon H, Rasmussen TE, Khan MA, Midwinter MJ, Blackbourne LH, Garner JP. Resuscitative thoracotomy following wartime injury. *J Trauma Acute Care Surg.* 2013 Mar;74(3):825-9.
- 8.Robertson AT, Bulstrode CJ. Emergency department thoracotomies: is it time we took them to the field? *J Trauma Acute Care Surg.* 2012 Nov;73(5):1070-2.
- 9.Ashrafian H, Athanasiou T. Emergency prehospital on-scene thoracotomy: a novel method. *Coll Antropol.* 2010 Dec;34(4):1449-52.
10. Suliburk JW. Complications of emergency center thoracotomy. *Tex Heart Inst J.* 2012;39(6):876-7.
- 11.Berland TL, Veith FJ, Cayne NS, Mehta M, Mayer D, Lachat M. Technique of supra-celiac balloon control of the aorta during endovascular repair of ruptured abdominal aortic aneurysms. *J Vasc Surg.* 2013 Jan;57(1):272-5.
- 12.Mehta M, Paty PS, Bynre J, Roddy SP, Taggart JB, Sternbach Y, Ozsvath KJ, Darling III RC. Hemodynamic status impacts outcomes of endovascular abdominal aortic aneurysm repair for rupture. *J Vasc Surg.* 2013 Feb 3. [Epub ahead of print]
- 13.Stannard A, Eliason JL, Rasmussen TE. Resuscitative endovascular balloon occlusion of the aorta (REBOA) as an adjunct for hemorrhagic shock. *J Trauma.* 2011 Dec;71(6):1869-72.
- 14.Morrison JJ, Percival TJ, Markov NP, Villamaria C, Scott DJ, Saches KA, Spencer RA, Rasmussen TE. Aortic balloon occlusion is effective in controlling pelvic hemorrhage. *J Surg Res.* 2012 Oct;177(2):341-7.

2 If available, upload your supporting literature here: (Uploading Help)

| | | |
|-------------------|------------------|------------------|
| White article.pdf | 5/7/2013 9:35 AM | 5/7/2013 9:35 AM |
| Sesma article.pdf | 5/7/2013 9:35 AM | 5/7/2013 9:35 AM |
| REBOA article.pdf | 5/7/2013 9:35 AM | 5/7/2013 9:35 AM |
| Aura article.pdf | 5/7/2013 9:35 AM | 5/7/2013 9:35 AM |

Avatar article.pdf

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- 3 * Provide a list of 3 keywords or search terms (1 per line) relevant to your research that would help potential participants find your study using search engines:

* Keyword 1: Aortic occlusion

* Keyword 2: Thoracotomy

* Keyword 3: Acute care surgery

ID: VIEW4427429624400
Name: Summary & Supporting Literature

View: Study Design

Study Design

- 1 * What is your study design?
- Drug, Approved
 - Group Discussion
 - Neuropsychological or psychophysiological testing
 - Drug, Phase III
 - Chart/record Review, Retrospective
 - Other
 - Device
 - Pilot
 - Survey/questionnaire
 - Audio or video recording/photographing
 - Intervention-Psychosocial or Behavioral
 - Laboratory/specimen collection
 - Use of existing banked specimens
 - Chart/record Review, Prospective**
 - Interview
 - Drug, Phase IV
 - Deception
 - Drug, Phase I
 - Other Psychosocial or behavioral procedures
 - Drug, Phase I/II
 - Specimen banking
 - Drug, Phase II

ID: VIEW45627CDF92400
Name: Study Design

View: Study Procedures

Study Procedures

- 1 * Describe all research procedures:
This is a multicenter, prospective chart review study. The date of the chart review will start from the 1st July 2013 through 31st December 2020.
- After identifying an eligible subject , a study ID number will be assigned. The study ID number will be linked and coded so that the patient can be identified.
- Data capture will begin immediately after admission. Standardized data will be collected for each patient. Please see the attached data collection tool in Additional documents.
- 2 * Describe all procedures already being performed for diagnostic or treatment purposes:
N/A. This is a chart review study.
- 3 * Describe participants' duration of participation:
N/A. There will be no study participants. This is a chart review study

- 4 * Describe the duration of the entire study:
N/A This is a chart review study .
- 5 * Describe any additional participant requirements:
none

ID: VIEW4540FA8938400
Name: Study Procedures

View: Research Related Risks

Research Related Risks

- 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:
Confidentiality - 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 and stored in secured, locked storage cabinets. 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 provide by law.

As soon as the patient is discharged, all data will be logged anonymously utilizing the American Association for the Surgery of Trauma-Multi-Institutional Trials (AAST MIT) online data entry system and identifiers that are kept for the purpose of in-hospital follow up will be immediately destroyed.

ID: VIEW43B3485673400
Name: Research Related Risks

View: Potential Benefits

Potential Benefits

- 1 * Describe the potential benefit(s) to participants:
There will be no direct benefits from this research for the subjects involved in the study. The protocol does 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.

Outcomes following the utilization of aortic occlusion have not been well defined. If the optimal selection and timing for intervention can be identified, then there is significant potential for benefit in terms of resource utilization, morbidity and mortality.
- 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

ID: VIEW43B34A7DE3400
Name: Potential Benefits

View: Privacy

Privacy

- 1 * Describe how you will ensure the privacy of potential participants:
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:
N/A. We are requesting a full waiver of consent for this study; therefore potential participants will not receive research information.
- 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 prospective chart review study.
- 4 * Describe how privacy will be protected through each phase of the study and detail the specific actions the study team will take to ensure adequate privacy areas:
N/A

ID: VIEW43B24BD857800
Name: Privacy

View: Confidentiality

Confidentiality

- 1 * Will research data be linked to individual participants (identifiable)?
 Yes No
- 2 * Will research data be de-identified (no links or codes maintained)?
 Yes No

3 * Where will research data be kept?

All hardcopy data will be stored in a designated locked office and stored in secured, locked storage files by the PI and research staff at the 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 * 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 secured, locked storage files by the PI and research staff at the 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. The subject's name will never be directly connected with data (data sheets) that is collected from his/her or their medical records. The research data collected will not identify the patient directly. However, the study ID number will be linked and coded which could identify the patient. The research data that is collected from the subject and his/her medical records will be grouped together with other participants' information for any reporting of the study findings.

As soon as the patient is discharged, all data will be logged anonymously utilizing the American Association for the Surgery of Trauma-Multi-Institutional Trials (AAST MIT) online data entry system and identifiers that are kept for the purpose of in-hospital follow up will be immediately destroyed.

5 * Who will have access to research data?

Board for the protection of human subjects and the investigators associated with AAST-MIT will have access to the research data and medical records. Identifying information would be seen if one of the above-mentioned agencies reviewed the subject's medical record at the Shock Trauma Center and University of Maryland Baltimore, but confidentiality would be protected.

In order to understand the results of the study, PI and research staff and the Institutional Review Board for the protection of human subjects will be grouped together with other participants' information for any reporting of the study findings.

Information that does not disclose the subject's name and data collected from the subject and other study participants will be discussed with both doctors and non-medical personnel. This information may be summarized at scientific meetings or published in medical journals.

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

Yes No

7.1 * Will results of specific tests be revealed to the research participant or his/her doctor?

Yes No

7.2 * Will results of the overall study be revealed to the research participant or his/her doctor?

Yes No

7.3 * Explain why or why not:

Patients will be managed by the clinical team according to standard of care. No clinical decisions will be made by the researchers or as a result of this study being conducted.

8 * Do you plan to obtain a Certificate of Confidentiality?

Yes No

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

The PI, co-investigators, and research staff will keep the patients' information as private as possible. They will do their best to see that it is shared only when required by state or federal law or in terms of this protocol as reviewed and approved by the IRB.

ID: VIEW43B49CBDC800
Name: Confidentiality

View: HIPAA Waivers

HIPAA

1 * Select one:

- This research will require a HIPAA privacy waiver (for entire study)
 This research will require a partial HIPAA privacy waiver (for recruitment)
 Neither of the above

2 If your study requires a HIPAA Authorization Form, upload that document here: [\(Uploading Help\)](#)

There are no items to display

ID: VIEW453FC2F168C00
Name: HIPAA Waivers

View: HIPAA - Privacy Waiver Requested

HIPAA - Privacy Waiver Requested

1 * Provide a brief description of the Protected Health Information (PHI) for which use or access is necessary (including sources of the PHI):

MDN

- Demographics
- Date and Time of Admission
- Injury Characteristics
- Trauma Bay Presentation and Diagnostic Measures
- Injury Management: Acute Damage Control and Definitive
- Perioperative and In-hospital follow-up
- Outcome

1a. If SSNs are going to be used, describe the specific use, the type of SSN to be used (real, scrambled, last 4 digits) and the security measures in place for protecting them.

- 2** * Provide a plan to protect the identifiers from improper use and disclosure and to destroy the identifiers at the earliest opportunity consistent with the conduct of the research (or provide a health or research justification for retaining the identifiers):

The PHIs which will need to be accessed prior to determine 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 for study according to the inclusion/exclusion criteria.

Once identified as a eligible subject, the subject's MRN will be used to follow the subject and collect data while in the study. Each identified subject will be assigned a unique identifier 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, 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 subject's UIN only.

- 3** Why could the research not practicably be done without the waiver or alteration?

The study is to collect data from patient's medical records. No intervention will be performed and no change in patient management will occur as a result of this study being conducted. Consent for this study may delay appropriate intervention by the trauma team members. Sensitivity and specificity of criteria that are expected to be applied universally to allevaluable trauma patients, should be based on evaluation of all patients without exclusion of those who may not consent.

ID: VIEW43D6633AD5000
Name: HIPAA - Privacy Waiver Requested

- 4** Why could the research not practicably be done without access to and use of this PHI?

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.

ID: VIEW43D6633AD5000
Name: HIPAA - Privacy Waiver Requested

View: Recruitment

Recruitment

- 1** * Describe plans for recruitment, including the identification of potential participants and initial interactions with them:

This is a multicenter, prospective, observational study.

Patients will be identified by the PI or research staff. 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. Information regarding clinical examination and imaging results will be recorded. Patients will be managed according to standard of care by the clinical team. No clinical decisions will be made by the researchers or as a result of this study being conducted. Decision making will be made solely by the treating physician. No patients will be approached directly.

- 2** * Describe measures that will be implemented to avoid participant coercion or undue influence:

This is a prospective, observational study of data generated by standard of care. A full waiver of consent is being sought for this study; there will be no interactions with the patient or patient's family.

- 3** * Who will recruit participants for this study?

- PI & Staff
- PI
- Third Party

ID: VIEW449A0764FBC00
Name: Recruitment

View: Advertising

Advertising

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

Yes No

ID: VIEW4517F2C65B000
Name: Advertising

View: Research Related Costs

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?

N/A

1.1 If Yes, check all that apply:

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

1.2 If No, who is responsible for payment?

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

- Participant
- Sponsor
- Other
- UMB
- 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: VIEW43CA73E7CC800
Name: Research Related Costs

View: Participant Selection

Participant Selection

1 * How many local potential participants (or specimens, or charts) do you anticipate will be screened for this study?

1000

2 How many participants (or specimens, or charts) will be enrolled/used for this study?

* Local - the number being enrolled at this site or will be consented using a UMB-approved Informed Consent Document:
700

* Worldwide - the number that will be enrolled total at all sites:
3000

3 Gender:

- Male
- Female

4 Age(s)

- Nonviable Neonates or Neonates of Uncertain Viability
- 0 to 27 days (Term 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)
- 18 to 44 years (Adult)
- 45 to 64 years (Middle Age)
- 65 plus years (Elderly)

5 Race/Ethnicity:

- 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

6 Language(s):

- English
- Chinese
- French
- Italian
- Japanese
- Korean
- Local Dialect
- Spanish
- Vietnamese
- Other

6.1 Specify Other:

Language will not be a qualifier, any language can be spoken by the participant.

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

- Yes No

ID: VIEW43B36EB5E8400
Name: Participant Selection

View: Vulnerable Populations

Vulnerable Populations

* Will you be recruiting ANY of the following Vulnerable Populations? (Select all that apply)

- 1
- Employees or Lab Personnel
 - Children
 - Women of Child-bearing Potential
 - Educationally Disadvantaged
 - Critically ill or Injured Patients**
 - Cognitively Impaired/ Impaired Decision Making Capacity
 - Pregnant Women
 - Wards of the State
 - Terminally ill Patients
 - Students
 - Prisoners
 - Emancipated Minors
 - Fetuses
 - Neonates
 - Homeless or Economically Disadvantaged
 - Emergency Room Patients**
 - Mentally ill
 - Post Traumatic Stress Disorder (PTSD) Participants
 - None of these applies.

ID: VIEW45627D2912400
Name: Vulnerable Populations

View: Vulnerable Populations - Critically Ill or Injured Patients

Vulnerable Populations - Critically Ill or Injured Patients

1 You chose "Critically Ill or Injured Patients" as a Vulnerable Population that you will be recruiting.

* Describe how will you obtain informed consent, protect subject confidentiality, and prevent undue coercion.

All of the patient population for this study is critically ill by the nature of the inclusion criteria. No procedures are being performed nor information obtained that is not already present as part of standard of care in the existing medical record.

This is a prospective observational study. The subject's care will not be affected in any way. No patient contact will occur

View: Vulnerable Populations - Emergency Room Patients

Vulnerable Populations - Emergency Room Patients

1 **You chose "Emergency Room Patients" as a Vulnerable Population that you will be recruiting.**

* Describe how will you obtain informed consent, protect subject confidentiality, and prevent undue coercion.

All of the patient population for this study is critically ill by the nature of the inclusion criteria. No procedures are being performed nor information obtained that is not already present as part of standard of care in the existing medical record.

This is a prospective observational study. The subject's care will not be affected in any way. No patient contact will occur

View: Eligibility

Eligibility

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

| Number | Criteria |
|--------|--|
| View 1 | All adult (Age ≥ 18) trauma and acute care surgery patients treated with resuscitative AO (via open or endovascular means) in the acute phases after injury |
| View 2 | Transient or refractory hypotension (SBP<90mmHg) with a positive abdominal FAST, severe pelvic fracture(s), or neither with persistent hypotension without obvious source. |
| View 3 | CXR without evidence of thoracic aortic injury |
| View 4 | Subject deemed by the attending surgeon to potentially benefit from an internal aortic cross-clamp. |

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

| Number | Criteria |
|--------|---|
| View 1 | Subject < 18years of age |
| View 2 | Prisoner |
| View 3 | Evidence of cardiac, thoracic aortic, or great vessel injury on primary survey, FAST and/or xrays |
| View 4 | Any open/exsanguinating upper extremity wound |

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-00055545 v5-7-2013-1367934298163(0.01)

If you created additional Eligibility checklists outside of CICERO, you may upload them 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 | | |

View: Sample Size / Data Analysis

Sample Size / Data Analysis

1 *** Provide your rationale and sample size calculations for the proposed target population:**

This is a prospective observational study so there is no sample size calculation. We will be gathering data on all patients admitted with vascular injury to establish an aggregate database of information on the presentation, diagnosis, management (acute and definitive), surveillance and outcomes following vascular trauma

2 *** Provide your plan for data analysis. Include in your description the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance, etc.), which is the primary comparison/analysis, and how will the analyses proposed relate to the primary purposes of your study:**

Standardized data will be collected for each patient (see data sheet, Appendix A). Risk factors for complications (both procedural and outcome-related) and mortality, complications and in-hospital outcomes will be assessed using univariate and multivariate analysis. Continuous variables will be compared using Student's t-test and the Mann Whitney U test. The Chi-squared tests or Fisher's exact test will be used to compare categorical variables. All variables with a p value <0.2 on univariate analysis will be entered into a multivariable logistic regression analysis to identify independent risk factors for ischemic complications, need for re-intervention and mortality. Data will be reported as adjusted odds ratios with 95 % confidence intervals. Statistical significance will be set at a p<0.05.

View: Participant's Payment

Participant's Payment

- 1 * Will participants receive payment (money, gift certificates, coupons, etc.) for their participation in this research?
- Yes No

ID: VIEW43B49CFF5F800
Name: Participant's Payment

View: Monitoring Plan Determination

Monitoring Plan Determination

- 1 * Will the investigator use/defer to the sponsor's Data Safety Monitoring Plan?
- Yes
- No
- N/A

ID: VIEW43C4161FB7C00
Name: Monitoring Plan Determination

View: Monitoring Plan Selection

Monitoring Plan Selection

- 1 * Will the monitoring be done by an Individual or by a Committee?
- Committee
- Individual

ID: VIEW457C5CEE6D000
Name: Monitoring Plan Selection

View: Monitoring Plan - Individual

Monitoring Plan - Individual

- 1 * Identify the individual who will be performing the safety monitoring:
Megan Brenner
- 2 * Describe this individual's role in relation to the protocol:
Principal Investigator
- 3 * What data will be reviewed?
- Patient Charts / Clinical Summaries
- Laboratory Tests
- Medical Compliance
- Outcomes (Primary, Secondary)
- Enrollment Numbers
- Procedure Reports
- Other
- Preliminary Analyses
- Raw Data
- Adverse Events
- 3.1 If Other, specify:
- 4 * What will be the frequency of the review?
- Annually
- Bi-Annually
- Other
- 4.1 If Other, specify:
The PI will primarily be responsible for monitoring checks for efficacy of data collection, enrollment numbers, as well as clarification of any questions. This will be done on an as needed basis throughout the study

▸ * Safety monitoring results will be reported to:

- GCRC
- Other
- Sponsor
- IRB

5.1 If Other, specify:

ID: VIEW4585999158C00
Name: Monitoring Plan - Individual

View: Study Schedule

Study Schedule

- 1 If you have a Study Schedule from the sponsor, upload the document below. You can also create the Study Schedule in Microsoft Excel or Microsoft Word, and upload the document (see HELP button on the right column for other formats): [\(Uploading Help\)](#)

| Name | Created | Modified Date |
|---------------------|-------------------|-------------------|
| Study Schedule.docx | 3/27/2013 9:41 AM | 3/27/2013 9:41 AM |

ID: VIEW43CA726D2F800
Name: Study Schedule

View: Sample Collection

Sample Collection

- 1 * Will samples (blood, tissue, urine, etc.) be collected as part of this study?

Yes No

ID: VIEW455990CB07800
Name: Sample Collection

View: Additional Documents

Additional Documents

- 1 Upload all additional documents here: [\(Uploading Help\)](#)

| Name | Created | Modified Date |
|---|--------------------|--------------------|
| AORTA study proposal - Draft 28 Februar 2013 DuBose.doc | 3/25/2013 10:45 AM | 3/25/2013 10:45 AM |
| AORTA data collection tool - final 8 March 2013.docx | 3/25/2013 10:45 AM | 3/25/2013 10:45 AM |

ID: VIEW43E9519AA4800
Name: Additional Documents

View: Final Page of IRB Protocol

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, the investigator attests to the fact that all research activity to be implemented in human subjects is completely and accurately described herein. 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 need signature(s) of the following Department Chairs before it can be sent to the Human Research Protections Office and 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 |
|-----------------------|---------------|
| Trauma Rsrch-CORE | Complete |
| 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 unsigned, you must address their concerns and resubmit the protocol for signature to all designated departments. After all signees have reviewed the application, it will automatically be sent to the Human Research Protections Office for placement on the next available IRB agenda. By submitting this application, you are certifying that this submission conforms with the OSHA/HHS guidelines for HIV/HBV occupational safety. Please know that once an application has been put on the IRB agenda, no further changes to the application can take place until after IRB review and approval. Changes made to the submission after its approval are

to be considered amendments.

Click the "Finish" button.

ID: VIEW43E6EA11B5400
Name: Final Page of IRB Protocol