AWARD NUMBER: W81XWH-15-1-0025

TITLE: Clinical Study of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Severe Pelvic Fracture and Intra-abdominal Hemorrhagic Shock using Continuous Vital Signs

PRINCIPAL INVESTIGATOR: Dr. Megan Brenner

CONTRACTING ORGANIZATION: University of Maryland, Baltimore
Baltimore, MD 21201

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**4. Title and Subtitle**

Clinical Study of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Severe Pelvic Fracture and Intra-abdominal Hemorrhagic Shock using Continuous Vital Signs

**6. Author(s)**

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**7. Performing Organization Name(s) and Address(es)**

University of Maryland, Baltimore
Baltimore, MD 21201

**14. Abstract**

Resuscitative balloon occlusion of the aorta (REBOA) has been clinically demonstrated to stop bleeding below the diaphragm. It has the potential to significantly decrease blood loss thereby decreasing blood-product resuscitation requirements, improve physiologic parameters, and ultimately lead to increased survival in patients in hemorrhagic shock from severe torso injury. This is a simple endovascular technique which can be taught to forward deployed physicians and has over the past decade vastly improved the survival of ruptured abdominal aortic aneurysm patients. Although the technique is still in its infancy for trauma patients, we predict that the use of intra-aortic balloon occlusion will improve the survival of trauma patients and reduce morbidity. We have undertaken a 2 phase study to evaluate simulation-based REBOA training and the effectiveness of REBOA stabilization of severe intra-abdominal hemorrhagic shock and/or pelvic fracture patients. In phase 1, a simulator based REBOA training curriculum was developed to train STC clinicians, and its efficacy will be evaluated. Phase 2 is a single center, prospective observational study in which patients with severe hemorrhagic shock and/or pelvic fracture admitted to the Trauma Resuscitation Unit of our level 1 trauma center are stabilized with REBOA. Our main objective was to assess the impact on mortality and morbidity after REBOA. We hypothesized that use of REBOA in cases of NCTH will decrease morbidity and mortality.
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1. **INTRODUCTION:**

Resuscitative balloon occlusion of the aorta (REBOA) has been clinically demonstrated to stop bleeding below the diaphragm. It has the potential to significantly decrease blood loss thereby decreasing blood-product resuscitation requirements, improve physiologic parameters, and ultimately lead to increased survival in patients in hemorrhagic shock from severe torso injury. This is a simple endovascular technique which can be taught to forward deployed physicians and has over the past decade vastly improved the survival of ruptured abdominal aortic aneurysm patients. Although the technique is still in its infancy for trauma patients, we predict that the use of intra-aortic balloon occlusion will improve the survival of trauma patients and reduce morbidity. We have undertaken a 2 phase study to evaluate simulation-based REBOA training and the effectiveness of REBOA stabilization of severe intra-abdominal hemorrhagic shock and/or pelvic fracture patients. In phase I, a simulator based REBOA training curriculum was developed to train STC clinicians, and its efficacy will be evaluated. Phase 2 is a single center, prospective observational study in which patients with severe hemorrhagic shock and/or pelvic fracture admitted to the Trauma Resuscitation Unit of our level 1 trauma center are stabilized with REBOA. Our main objective was to assess the impact on mortality and morbidity after REBOA. We hypothesized that use of REBOA in cases of NCTH will decrease morbidity and mortality.
2. **KEYWORDS:**

| Trauma; Hemorrhage; Junctional Hemorrhage; Non-Compressible Torso Hemorrhage (NCTH); Combat Casualty Care; Aortic Occlusion; REBOA; Resuscitative Endovascular Occlusion of the Aorta; Thoracotomy; Aortic cross-clamp; Simulation; Virtual reality simulation; Endovascular |
3. **ACCOMPLISHMENTS:**

**What were the major goals of the project?**

Hypothesis 1: A simulator based learning platform is effective to train physicians who are already skilled in vascular access procedures, to place REBOA.

Specific Aim: Design and evaluate a comprehensive simulator based training program to train attending trauma surgeons, critical care faculty, trauma fellows, and chief residents to perform REBOA.

Hypothesis 2: Use of resuscitative endovascular balloon occlusion of the aorta (REBOA) in cases of non-compressible torso hemorrhage (NCTH) of the abdomen and pelvis will decrease the morbidity and mortality associated with this often fatal pattern of injury with improved physiological parameters, outcomes, and recovery periods and will allow time for vascular repair.

Specific Aim: Evaluate the ability of REBOA to improve survival and functional outcomes in patients with NCTH. Analysis of continuously recorded vital sign data will show that the use of REBOA will improve physiologic parameters in patients with NCTH.

**What was accomplished under these goals?**

Hypothesis 1: This objective is 95% complete and ongoing. After FDA approval of a new novel REBOA catheter (ER-REBOA™ (Prytime Medical, Boerne, TX)) in October 2015, we incorporated this catheter into our practice in February 2016. Our REBOA training course (Basic Endovascular Skills in Trauma (BEST) course) and standard operating procedure was updated to incorporate this new catheter. The BEST course continues to be held and training of new trauma surgery fellows and new staff occurs. A modified BEST course was also held at the American College of Surgeons Clinical Congress (October 16–20, 2016, Washington, DC) and at the 30th Eastern Association for the Surgery of Trauma (EAST) Annual Scientific Assembly (January 10-14, 2017, in Hollywood, FL). See appendix A for the latest description and analysis of the BEST course. See #6 Products for a full listing of associated conference abstracts related to the training course.

Hypothesis 2: This objective is 85% complete and ongoing. Multiple abstracts have been presented at various conferences (see #6 Products for a full listing of associated abstracts presented at conferences). We continue to enroll patients into the prospective observational trial and continue to process and analyze data for scientific review. In this past annual year (3/1/2016 to 2/28/2017) we enrolled 29 new subjects, and within the last quarter (12/1/2016 to 2/28/2017) we enrolled 6 new subjects. See appendix B for the latest in depth clinical description and analysis.
**What opportunities for training and professional development has the project provided?**

There have been multiple participants who work on this project who have been able to present different works as abstracts at various conferences (see #6 Products for a full listing). Participants have also had an opportunity to attend the various lectures and educational opportunities that are associated with each of these conferences.

The periodic performance of the BEST course also provides an opportunity for participants to continually practice their professional skillset as educators.

**How were the results disseminated to communities of interest?**

Information regarding scientific findings were disseminated at conferences. A full listing of abstracts and conferences can be found in the Products section (#6).

**What do you plan to do during the next reporting period to accomplish the goals?**

In the next reporting period we plan to continue to enroll patients in the prospective observational trial. We also will continue to obtain continuous vital sign data and process it as previously described in appendix A.
4. **IMPACT:**

**What was the impact on the development of the principal discipline(s) of the project?**

This study has helped our institution with evidence based guidelines for the use of REBOA. This data is in various stages of presentation, or manuscript in preparation format.

**What was the impact on other disciplines?**

Nothing to report.

**What was the impact on technology transfer?**

Nothing to report.

**What was the impact on society beyond science and technology?**

Nothing to report.
5. **CHANGES/PROBLEMS:**

1. On November 9\textsuperscript{th}, 2015, the University of Maryland transitioned their clinical electronic medical record to a new software package. This transition was anticipated, but our new electronic data tool had IT compatibility issues with the new software and was non-functional. Our backup procedures for paper documentation were re-initiated and continue currently.

2. The new electronic medical record, which necessitated a redesign of our electronic data tool. This is now complete and being used to enter and store study data.

3. Our CORE staff had unforeseen staffing issues on Thanksgiving Day 2015 and as a result, approximately 24 hours of prospective data collection time were lost. This did not affect our study as no patients matched screening criteria during this time.

4. Due to the riots during spring 2015, the city was closed to travel by all non-essential personnel. Our research staff was unable to report for work, resulting in a gap of 48 hours of prospective data collection. The clinical staff present in the Trauma Center assumed the responsibility of noting any REBOA placements. No placement occurred during this time and no data was lost.

5. On February 1, 2016, a newly FDA-approved device compatible with a smaller 7Fr sheath was available for clinical use. The SOP and data tool were updated in anticipation of these devices becoming available and were updated immediately.

6. Continuing IRB approval was obtained on May 4, 2016 (see letter below), extending approval for the project to May 3, 2017. There have been no other new changes or problems during this reporting period.

---

**Actual or anticipated problems or delays and actions or plans to resolve them**

Nothing to report.

**Changes that had a significant impact on expenditures**

Nothing to report.

**Significant changes in use or care of human subjects**

Nothing to report.
Significant changes in use or care of vertebrate animals

Nothing to report.

Significant changes in use of biohazards and/or select agents

Nothing to report.
6. **PRODUCTS:**

- **Publications, conference papers, and presentations**

  **Journal publications.**

  1. Accepted for Publication in the Journal: Journal of Special Operations Medicine
     Title: Resuscitative Balloon Occlusion of the Aorta: Pushing care forward
     Authorship: W Teeter MD, A Romagnoli MD, J Glaser MD, A Fisher PA, J Pasley DO, B Scheele DO, M Hoehn MD, M Brenner MD

  **Books or other non-periodical, one-time publications.**

  Nothing to Report

  **Other publications, conference papers and presentations.**

  **1th Annual Academic Surgical Congress Abstract Submission - February 2-4, 2016 in Jacksonville, FL**

  1. Virtual Reality Simulation for Residents: A Trainee Experience in Damage Control Endovascular Skills
     Authorship: William A. Teeter, MD, MS; Megan Brenner, MD, MS; Melanie Hoehn, MD; Deborah Stein, MD, MPH; Thomas Scalea, MD

  **39th Annual CONFERENCE ON SHOCK – June 11-14th, Austin, TX**

  2. REBOA IMPROVES MEAN BLOOD PRESSURE (MBP) AND SHOCK INDEX (SI) AS MEASURED BY CONTINUOUS VITAL SIGNS (CVS) EVEN IN PATIENTS ARRIVING IN ARREST
     Authorship: W Teeter MD, M Brenner MD, M Hoehn MD, P Hu PhD, S Yang PhD

  **24th Annual Military Health System Research Symposium Aug. 15-18, 2016, Kissimmee, FL**

  3. Resuscitative Balloon Occlusion of the Aorta: Pushing care forward
     Authorship: W Teeter MD, A Romagnoli MD, J Glaser MD, A Fisher PA, J Pasley DO, B Scheele DO, M Hoehn MD, M Brenner MD

  **75th Annual Meeting of AAST and Clinical Congress of Acute Care Surgery - September 14-17, 2016, Waikoloa, HI**

  4. Time to aortic occlusion: It’s all about access
     Authorship: A Romagnoli MD, W Teeter MD, J Pasley DO, P Hu PhD, G Hagegeorge, D Stein MD, T Scalea MD, M Brenner MD

  5. Age is just a number: REBOA can be performed in older patients at high risk for atherosclerotic vascular disease
     Authorship: M Ghneim MD, W Teeter MD, A Romagnoli MD, M Hoehn MD, P Hu PhD T Scalea MD M Brenner MD
6. Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) Can Be Deployed Rapidly and Safely by Acute Care Surgeons
Authorship: D HAMPTON MD, W TEETER MD, G HAGEGEORGE, M HOEHN MD, D STEIN MD, T SCALEA MD, M BRENNER MD

7. Paradigm shift in hemorrhagic traumatic arrest: REBOA is at least as effective as RTACC
Authorship: W Teeter MD, A Romagnoli MD, H Li PhD, S Yang PhD, P Hu PhD, D Stein MD, T Scalea MD, M Brenner MD

American College of Emergency Physicians Annual Meeting 2016, October 15-20th, 2016, Las Vegas, NV

8. REBOA improves quality of resuscitation versus thoracotomy in patients in traumatic arrest.
Authorship: William Teeter, MD MS, Anna Romagnoli, MD, Melanie Hoehn, MD, Jay Menaker, MD, Deborah Stein, MD MPH, Thomas Scalea MD, Megan Brenner MD MS.

9. Virtual Reality Simulation can help prepare Emergency Medicine physicians for REBOA
Authorship: W. Teeter MD, A Romagnoli MD, M Hoehn MD, J Menaker MD, D Stein MD, T Scalea MD, M Brenner MD

Maryland Committee on Trauma Paper Competition November 4, 2016, Baltimore, MD

10. Life Over Limb: Lower Extremity Ischemia in the Setting of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)
Authorship: Philip J. Wasicek MD, William Teeter MD MS, Shiming Yang PhD, Peter Hu PhD, Melanie Hoehn MD, Deborah Stein MD MPH, Thomas Scalea MD, Megan Brenner MD MS

12th Annual Academic Surgical Congress February 7-9, 2017, Las Vegas, NV

11. Virtual Reality Simulation for Endovascular Skills for Trauma: Final Results of a Trainee Experience

88th Annual Meeting Pacific Coast Surgical Association February 17-20, 2017, Indian Wells, CA

12. Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a feasible option for proximal aortic control in severe hemorrhage and arrest.

13. Virtual Reality Simulation (VRS): Bringing Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) Closer to the Point of Injury

14. Life Over Limb: Lower Extremity Ischemia in the Setting of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)
   Authorship: Philip J. Wasicek MD, William Teeter MD MS, Shiming Yang PhD, Peter Hu PhD, Melanie Hoehn MD, Deborah Stein MD MPH, Thomas Scalea MD, Megan Brenner MD MS

15. REBOA is feasible in patients at risk for age-related vascular disease
   Authorship: Bryan Gamble MD, Mira Ghneim MD, William Teeter MD, Deborah Stein MD MPH, Thomas Scalea MD, Megan Brenner MD MS

16. Too much of a good thing? Prolonged aortic occlusion is associated with decreased survival.
   Authorship: M Hoehn MD, D Stein MD, P Wasicek MD, W Teeter MD, A Romagnoli MD, P Hu PhD, T Scalea MD, M Brenner MD

Website(s) or other Internet site(s)

Nothing to report.

Technologies or techniques

Nothing to report.

Inventions, patent applications, and/or licenses

Nothing to report.

Other Products

Nothing to report.
PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Organization: University of Maryland, Baltimore – Shock Trauma & Anesthesiology Research Organized Research Center (STA-ORC)

Name: Megan Brenner  
Project Role: PI  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: 0.18  
Contribution to Project: Supervise and contribute to study design, manuscript revision, and data analysis.

Name: Thomas Scalea  
Project Role: PI  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: .01994  
Contribution to Project: Dr. Scalea met with all other PIs and Co-Investigators to discussed clinical research logistics, data management and results.

Name: Fu M. Hu  
Project Role: Co-In  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: .294  
Contribution to Project: Integrating the data collection system for this study. He also works in the development and analysis of the continuous VS and in working with Dr. Brenner to design the join prediction models.

Name: Hegang Chen  
Project Role: Statistician  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: 0.05  
Contribution to Project: The design, analysis and interpretation of the data.

Name: Jennifer Kidd  
Project Role: Epidemiological Assistant I  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: .55  
Contribution to Project: Assist the project coordinator with patient identification, data abstraction, audit and collection, follow up and reporting.

Name: Raymond Fang  
Project Role: Co-In  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: .15  
Contribution to Project: Provides experience as health care providers for military severe pelvic fracture and intra-abdominal hemorrhagic shock victims to maximize the military relevance of the results and their interpretation.

Name: Catriona Miller  
Project Role: Co-In  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: .15  
Contribution to Project: Assists with the study design, study coordination and reporting, data collection, data storage, and data analysis.
<table>
<thead>
<tr>
<th>Name</th>
<th>Project Role</th>
<th>Researcher Identifier (e.g. ORCID ID)</th>
<th>Nearest person month worked</th>
<th>Contribution to Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melanie Hoehn</td>
<td>Co-Investigator</td>
<td></td>
<td>0.037</td>
<td>Supervise and contribute to study design, manuscript revision, and data analysis.</td>
</tr>
<tr>
<td>Christine Wade *</td>
<td>Manager, Clinical Research</td>
<td></td>
<td>0.50</td>
<td>She is responsible for overseeing the 24/7 coverage for the CORE Research Group.</td>
</tr>
<tr>
<td>Eric Lund</td>
<td>It Appt Int Engineer</td>
<td></td>
<td>0.05</td>
<td>He was responsible for overseeing the 24/7 basis obtain pre-hospital and admit data on every admit to the STC.</td>
</tr>
<tr>
<td>Shiming Yang</td>
<td>Research Associate</td>
<td></td>
<td>0.60</td>
<td>Working Dr. Hu in the acquisition, integrating, testing, and maintaining the trauma training center VS data collection system.</td>
</tr>
<tr>
<td>Hsiao-Chi Li</td>
<td>Graduate Research Assistant</td>
<td></td>
<td>1.0</td>
<td>Assisting Dr. Hu with development and analysis of the continuous VS and other project data analysis.</td>
</tr>
<tr>
<td>Umang Shah</td>
<td>General Associate</td>
<td></td>
<td>0.15</td>
<td>Research assistant who screens and obtains pre-hospital and admit data on admissions in STC.</td>
</tr>
<tr>
<td>George Hagegeorge</td>
<td>IT Support Associate</td>
<td></td>
<td>0.60</td>
<td>Assisting in the acquisition, integrating, testing and maintaining the trauma training center VS and video data.</td>
</tr>
</tbody>
</table>
Name: Keven Barnes *
Project Role: Assistant
Contribution to Project: Assist the project coordinator with patient identification, data collection, follow up and reporting.

Name: Diandra Browne
Project Role: Research coordinator
Contribution to Project: IRB task management, IT design and assist with reporting.

Name: Ryne C. Jenkins
Project Role: Assistant
Contribution to Project: Assist the project coordinator with patient identification, data collection, follow up and reporting.

Name: Rajan Patel
Project Role: Graduate Research Assistant
Contribution to Project: To matching the patient vital signs with the REBOA procedure time and duration based on the video review. Assist in calculating the VS features for the study.

Name: Ashley Hargrove *
Project Role: Res Asst, Clinical
Contribution to Project: Assist the project coordinator with patient identification, data collection, follow up and reporting.

Name: Brandon Bonds *
Project Role: Post-doc Fellow
Contribution to Project: Assisting in the integration, testing, and maintaining the trauma training center VS data collection system.

Name: Hannah Huber*
Project Role: Res Asst, Clinical
Contribution to Project: The coordination of activities between patient identification, data collection, follow up and reporting.
Name: Seeta Kallam
Project Role: Res Project Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: .025
Contribution to Project: IRB preparation, submission, maintenance, and compliance.

Name: Anthony Herrera *
Project Role: Res Acct, Clinical
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: .025
Contribution to Project: Assist the project coordinator with patient identification, data collection, follow up and reporting.

Organization: University of Maryland Medical Center
Name: William Teeter
Project Role: Research Resident
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 2.25
Contribution to Project: Data management and QA review related to simulator training and clinical performance of REBOA.

Organization: University of Maryland Medical Center
Name: Philip Wasicek
Project Role: Research Resident
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 2.25
Contribution to Project: Data management and QA review related to simulator training and clinical performance of REBOA.

* indicates team member were involved outside of the current year.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

What other organizations were involved as partners?

Nothing to Report
SPECIAL REPORTING REQUIREMENTS

Timeline and Cost

Activities

CY   16    17

Estimated Budget (projected)

Cost Efficiency

Revised

Ella

10

15

12

$544,232

$485,709

$593,250

$495,000

Budget Expenditure to Date $228,877

$209,476

$220,416

$209,476

Full Expenditure

$299,995

$300,000

$299,995

Budget Expenditure

$236,000

$236,000

$236,000

$250,000

50 Percent of Budget

$147,500

$147,500

$147,500

$150,000

30 Percent of Projected

$178,290

$178,290

$178,290

$180,000

30 Percent of Actual

$89,010

$79,010

$79,010

$80,000

15 Percent of Actual

$49,506

$49,506

$49,506

$50,000

Updated:

Megan Bloomer Award Amount: 999,999

University of Maryland Baltimore

Log NO: 13057166

REBOA for Severe Pelvic Fracture and Intra-abdominal Hemorrhagic Shock

8. SPECIAL REPORTING REQUIREMENTS
Appendix A: Review of Educational Course and Simulator Based Learning Platform to Educate Physicians to Placed REBOA

Hypothesis 1:

A simulator based learning platform is effective to train physicians who are already skilled in vascular access procedures, to place REBOA.

Technical Objectives and Associated Specific Aims:

Standardized REBOA technique.

A standardized protocol for REBOA placement was established. The common femoral artery is accessed either directly via open cut-down or percutaneously using external landmarks only or using ultrasound guided placement. Once accessed, dilators are then utilized to upsize to the appropriate sized sheath (12 Fr sheath if using CODA® catheter (Cook Medical, Bloomington, IN), and 7 Fr sheath if using ER-REBOA™ (Prytime Medical, Boerne, TX)). Catheter insertion distance is then approximated using external morphometric landmarks. The catheter system (including wire for CODA® catheter) is then inserted to the appropriate distance. Radiographic confirmation of catheter placement is suggested prior to balloon inflation (although blind balloon inflation has been performed without complication during this study). The balloon should then be inflated and additional radiographic confirmation should be obtained. Standardized clinical performance of REBOA on the VIST Mentice simulator, as well as formal clinical standard operating procedure was created (see figure 1).

Development and Analysis of VIST Simulator Training Program by Knowledge Acquisition related to the REBOA Procedure and Performance on the VIST Simulator.

A VIST simulator training program with powerpoint lectures and hands-on training was established. A description of the indications for REBOA is given, as well as a detailed description of step-by-step method of performing REBOA. After the lecture, participants were then trained and allowed to practice the individual steps of performing REBOA on a VIST Mentice simulator (Mentice, Gothenberg, Sweden). A preliminary analysis of physician knowledge related to REBOA before and after didactic and simulator sessions was performed. 43 physicians participated in the pre- and post-test analysis. Physicians had a mean improvement of 2.7±1.6 questions (19±11%) correct in the post-test course (out of 14 questions). As seen in Figure 2-4, Most physicians had an improvement with the post-test score, and none had a decrease in their score (as seen in Figures 1 and 2, demonstrated distribution of differences in pre-and post-tests and their paired profiles. No physicians changed their answers from a correct answer on the pre-test to an incorrect answer on the post-test as seen in by an analysis of agreement between tests in Figure 4.
Figure 1: Clinical Standard Operating Procedure

Hypotensive (SBP < 90) partial or non-responder

Access common femoral artery for a-line or REBOA

No REBOA

CXR: possible aortic injury?

Position REBOA in ZONE I, inflate and proceed to Emergent Laparotomy

Position REBOA in ZONE II and inflate

FAST: positive?

Pelvic x-ray fracture?

No

Yes

Yes

Position REBOA in ZONE III and inflate

Aortic Zone I

Aortic Zone II

Aortic Zone III

Zone I = Origin of left subclavian artery to the celiac artery

Zone III = Lowest renal artery to aortic bifurcation
Figure 2: Improvement in Knowledge by Pre- and Post-Test Analysis, Distribution of Difference between Post-Test and Pre-Test

Distribution of Difference: Posttest - Pretest
With 95% Confidence Interval for Mean

- Normal
- Kernel

Percent

Difference

-2  0  2  4  6  8
Figure 3: Paired Profiles of Post-Test and Pre-Test Performance and Improvement in Knowledge

![Paired Profiles for (Posttest, Pretest)](image)

Figure 4: Analysis of Agreement of Pre-test and Post-test Answers

![Agreement of Pretest and Posttest](image)
Using a VIST-Mentice® (Mentice, Gothenberg, Sweden) endovascular simulator, physicians were asked to perform REBOA. This simulator consists of a personal computer-based software coupled with a haptics unit through which devices are inserted and manipulated. Of note, this virtual reality simulator has vital sign monitoring that is responsive to complete aortic occlusion, as well as simulation of radiographic imaging. The simulator also provides tactile feedback with balloon inflation by simulating the pressure required to inflate the balloon. The procedure involved starting with arterial access already obtained with a 5 French arterial line in place and required the participants to upsize arterial access to the appropriately sized 12 French arterial sheath. Next, a wire is positioned at the appropriate distance using external morphometric landmarks of the simulator. Radiologic confirmation is obtained between each step. A CODA catheter is then inserted and the balloon inflated to achieve aortic occlusion. During the procedure, evaluators did not provide assistance for tool selection, suggesting steps for task progression, or assisting with procedural tasks. Each physician performed this task six times. Participants improved the time to perform the task from the first attempt to the sixth attempt a mean of 120±36 seconds. The distribution of improvement can be seen in Figure 5. An examination of paired profiles (Figure 6), agreement (Figure 7), and q-q plot (Figure 8) demonstrate that all participants improved their times from the first attempt to the last (sixth) attempt.

**Figure 5: Distribution of Difference Between First and Sixth Attempt**
Figure 6: Paired Analyses of Improvement Between First and Sixth Attempt

Figure 7: Agreement Plot of Improvement from First to Sixth Attempt
Figure 8: Q-Q Plot of Difference between First and Sixth Attempt

Q-Q Plot of Difference: $T_6\_time - T_1\_time$
A validated REBOA placement training program.

Finalization of hypothesis 1 is ongoing. An abstract of the findings was written and presented at the Annual Meeting of American College of Surgeons, October 16-20, 2016, and will be presented at the World Congress of Trauma in Basil, Switzerland in 8/2017. A manuscript is currently in process.

RESUSCITATIVE ENDOVASCULAR BALLOON OCCLUSION OF THE AORTA (REBOA) CAN BE DEPLOYED RAPIDLY AND SAFELY BY ACUTE CARE SURGEONS DAVID HAMPTON MD, MENG, WILLIAM TEETER MD, GEORGE HAGEGEORGE, MELANIE HOEHN MD, DEBORAH STEIN MD, MPH, THOMAS SCALEA MD, MEGAN BRENNER MD, MS

Introduction: REBOA is an emergent procedure requiring endovascular skills. We hypothesized there was no difference in REBOA deployment times or complications between acute care surgeons (ACS) trained in endovascular procedures during residency (ACS-EP) and those who did not (ACS-NEP), and ACS virtual reality simulation (VRS) and clinical procedural times did not differ.

Methods: Patient demographics, vital signs, and trauma statistics were obtained. ACS professional training and surgical case history were documented. All ACS completed a 1-day REBOA VRS course. The procedural time was defined as the interval from common femoral arterial access to balloon inflation. Published VRS results were compared to clinical performance. Intra-group ACS and patient comparisons were made using chi squared and student t-tests. Significance was p < 0.05.

Results: Twenty-eight REBOAs were performed: ACS-EP (n=11) vs. ACS-NEP (n=17). There was no difference in admission SBP, HR, ISS, or BMI between patients treated by either group. There was no difference in intra-group procedure times (ACS-EP: 303 seconds (SD:±100) and ACS-NEP: 315 seconds (SD:±105), p=0.46). There was no difference in ACS REBOA procedure times as compared to VRS training (ACS: 310 seconds (SD:±102) versus VRS: 277 seconds (SD:±55), p=0.18). There were no REBOA-related complications. Sixty-eight percent of patients arrived in arrest, and 30-day survival was 11%.

Conclusion: There was no difference in REBOA deployment times or complications between the two groups. ACS-NEPs can perform REBOA rapidly and safely after completion of a 1-day VRS course. This is the first study to validate transfer of skills from VRS to clinical performance of REBOA.
Appendix B: Brief Clinical Summary and Review of Data Capture Process: Continuous Vital Signs (VS) and Videography

Hypothesis 2:

Use of resuscitative endovascular balloon occlusion of the aorta (REBOA) in cases of non-compressible torso hemorrhage (NCTH) of the abdomen and pelvis will decrease the morbidity and mortality associated with this often fatal pattern of injury with improved physiological parameters, outcomes, and recovery periods and will allow time for vascular repair.

Technical Objectives and Associated Specific Aims:

1.) Evaluate the ability of REBOA to improve survival and functional outcomes in patients with NCTH. Analysis of continuously recorded vital sign data will show that the use of REBOA will improve physiologic parameters in patients with NCTH.

Descriptive Characteristics of Population (as of 2/28/2017)

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Patients</td>
<td>79</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
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</tr>
<tr>
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<tr>
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<tr>
<td>ISS</td>
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<td>39 ± 15</td>
</tr>
<tr>
<td>GCS</td>
<td></td>
<td>6 ± 5</td>
</tr>
<tr>
<td>SBP on Admission</td>
<td></td>
<td>113 ± 34</td>
</tr>
<tr>
<td>HR on Admission</td>
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<td>110 ± 32</td>
</tr>
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</table>
### Mortality (%) for Different CPR Conditions

<table>
<thead>
<tr>
<th>Patients with</th>
<th>n</th>
<th>Mortality (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No CPR</td>
<td>27</td>
<td>37%</td>
</tr>
<tr>
<td>CPR before AO only</td>
<td>12</td>
<td>75%</td>
</tr>
<tr>
<td>CPR at time of AO</td>
<td>6</td>
<td>83%</td>
</tr>
<tr>
<td>CPR including after AO</td>
<td>13</td>
<td>92%</td>
</tr>
<tr>
<td>CPR without ROSC</td>
<td>21</td>
<td>100%</td>
</tr>
</tbody>
</table>

### Brief Clinical Summary

During the initial first two years of the study period, 79 patients had REBOA for severe non-compressible hemorrhage and traumatic arrest. Mean age was 40±18 years. Mean admission GCS was 6±5 and median ISS 39±15. Mean admission SBP and HR was 113±34 and 110±32, respectively for those patients with vital signs. The distal thoracic aorta (Zone 1) was occluded in 78.5% of patients and 21.5% had distal abdominal aortic occlusion (Zone 3). Mean time to aortic occlusion (including cannulation) was 8.7±4.5mins and femoral artery cannulation was 4.2±3.2mins. Percutaneous access was used in 44%, and groin cutdown used in 56%, including 73% of those in arrest. Overall mortality was 72%, which included 37% for hemorrhage patients, 75% in patients who had cardiac arrest and CPR performed before aortic occlusion (AO), 83% in patients who had cardiac arrest and CPR at time of AO (and may have had CPR before AO), 92% in patients who were in cardiac arrest and CPR performed after AO (and may have had CPR before and/or at time of AO), and 100% in patients who were in cardiac arrest and never had return of spontaneous circulation (ROSC). Of the patients in cardiac arrest, 46% were resuscitated and went to the operating room. Four patients had femoral arterial shunts placed three with 12 Fr sheath, one with 7 Fr sheath) with one patient surviving to definitive repair (requiring femoral bifurcation reconstruction). Two femoral arteries required repair with patch angioplasty (both with 12 Fr sheaths). Three balloon ruptures occurred without sequelae after REBOA use. One patient developed mesenteric ischemia that was directly attributed to prolonged aortic occlusion time (209 minutes). No aortoiliac injury occurred from REBOA use.

**NOTE:** The above table represents the total experience of the study as of the date of submission of the annual report. Totals may not be additive to 100% given ongoing data collection, partial data collection, and submission of abstracts/publications at various time points.
Real-time Continuous Vital Signs and video recording and archiving system

The need to adequately interpret vitals trends and subsequently respond rapidly to patient physiology and resuscitative needs is particularly paramount following trauma. Large quantities of real-time patient monitoring data are now available through hospital vital signs monitoring systems, yet vital signs are typically recorded manually periodically by clinical staff. Non-invasive continuous vital signs monitoring provides accurate real-time displays of continuous hemodynamic and perfusion data and trends that might provide for early detection of circulatory deficits that can contribute to both significant organ dysfunction and death. Continuous monitoring may both allow early recognition of pathologic processes which require intervention and may give clinicians feedback on the pathophysiological processes present in the patient before and after intervention.

Our goal is to apply this sophisticated data collection tool in order to provide real time data regarding the physiologic consequences of REBOA. By capturing heart rate, heart rate variability, pulse oximetry, temperature, end tidal CO2, respiratory rate, and systolic blood pressure and MAP (if arterial line present) on REBOA patients, we will be able to quantify the physiologic changes associated with REBOA in a linear fashion as they relate to time and length of balloon occlusion rate, and systolic blood pressure and MAP (if arterial line present).

Theoretically, the continuous monitoring of patient vital signs during balloon inflation should allow for assessment of time to hemodynamic stability, the degree of stability, and what happens to the patient physiologically when the balloon is deflated. Such detailed data will allow us to fine tune and perfect our technique. In addition to the real time, time stamped continuous vital signs data, all trauma bays and operating rooms at STC are recorded by video cameras from multiple angles, which gives us the ability to thoroughly document the exact time course of resuscitation efforts.

Continuous vital signs collection:

Real-time patient VS data feed is collected (Bed Master) every 2 seconds and recorded for future analysis. Raw real-time VS waveforms, trends, and alarms are compressed more than 90%, transferred to a centralized VSDR server through the secure hospital intranet, and stored securely for linkage with demographic, injury-specific clinical, imaging, and general laboratory data for subsequent analysis. VSDR collects over 80 VS variables from conventional vital signs and physiologic parameters—SpO2, etc., shock index (systolic blood pressure divided by heart rate), continuous electrocardiogram, oxygen saturation, and end-tidal carbon dioxide waveforms at 240 Hz. The numerical values of heart rate, blood pressure, intracranial pressure, cerebral perfusion pressure, respiratory rate, and temperature, are recorded every 2 seconds. Data rates after
compression averaged 76.4 KB/h for numerical and 12.3MB/h for waveforms. The VSDR server is interfaced with the Shock Trauma Research Registry, which provides patient demographic, admission assessment, laboratory, and outcome data. Custom processing and viewing programs, previously developed by our team, are used for real-time patient data abstraction, artifact removal, 5- to 60-minute time-window averaging, VS variability, and summary data output to both computer automatic processing and human reviewing.

The use of continuous data collection allows linear, episodic data to be converted to 2-dimensional analysis. Our goal is to apply this sophisticated data collection tool in order to provide data regarding the physiologic consequences of REBOA. By capturing heart rate, heart rate variability, pulse oximetry, temperature, end tidal CO2, respiratory rate, and systolic blood pressure and MAP (if arterial line present) on REBOA patients, we will be able to quantify the physiologic changes associated with REBOA in a linear fashion as they relate to time and length of balloon occlusion. The work proposed here will be based on mean and standard deviations of the every-6-second raw data over the course of the balloon inflation. We will calculate the dose of time spent above and below certain vital sign thresholds or cut offs and record the minimum and maximal values. Vital signs before, during, and after REBOA placement will be assessed and compared. The stability of vital signs readings during REBOA placement will be compared to patient outcomes.

**Triple redundant VS collection system and real-time Monitor of monitors for ensuring reliable data collection**

In order to capture all the unscheduled and emergency REBOA cases, it is critical to develop a real-time patient vital signs collection network which will **capture all patient VS at anytime, anywhere** (13 TRU and 10 ORs).

STC has implemented a single VS collection server-based VSDR system in the past 10 years. The effective real-time data collection rate is between 60% to 80% for all 13 TRU and 10 ORs. The missing VS data collection was mainly due to hardware and software failure and no real-time notification of collection failure and user errors.

To ensure anytime, anywhere reliability (>99% collection rate) of real-time VS data collection, we designed and implemented a **triple redundant VS collection system and real-time Monitor of monitors (MoMs)** for live VS collection status notification.
Fig. 9 illustrates the triple redundant VSDR and MoMs system architecture.

BM1, 2, 3 are the VS trend data collection server and BMA,B,C are the waveform (240Hz) and alarm status collection server. All triple-redundant data servers including 3 vital signs trend data collectors (blue dots in Fig 9) and 3 waveform collectors (green dots in Fig 9), send the latest data with timestamps to the MoMs Sever. Fig. 10 shows a snippet of the MoMs system. Each data server is represented by a large block (Fig 10). Each bed unit collected by such server is represented by a colored small box. If a bed unit is online in the last 5 minutes, the box shows in green, with the admission status (admitted or discharged) and the last heart rate value. If a bed unit is offline for longer than 5 minutes, the box is colored as yellow. It turns red, if the bed unit has been offline longer than 6 hours.

Vital signs data of each one minute median are submitted to three independent MoMs servers (red dots). The MoMs server processes the data and provides the patient VS data collection status in real-time to any remote MoM viewer inside the hospital intranet (for security purposes).

With the implementations of the above system we have been able to improve our data collection rate to >99% for all patient beds.

Fig. 9 Illustration of VSDR and MoMs system architecture
Vital Signs data abstraction software.

The Vital Signs data abstraction software was developed to accurately match the vital signs for feature abstraction and statistical analysis. Based on the REBOA patient admission and insertion time (abstracted from videography), we are able to match vital signs data to REBOA performance metrics and aortic occlusion time with high accuracy.
REBOA Vital Signs Viewer

The REBOA Vital Signs Viewer was developed to provide the detailed evaluation of the physiological changes pre and post REBOA procedure (Figure 12).
Vital Signs Data Processing

During analysis and interpretation of hemodynamic data, it was noted that there was raw data abstracted from continuous vital sign recording that did not represent physiologic data from the patient. An example of this included recording and continued data capture of arterial line tracing while the arterial line was disconnected from the patient and was being upsized for sheath insertion prior to REBOA deployment (this is represented by the black box in Figure 12 around time of AO-aortic occlusion). An additional example of inaccurate data included artifact/interference created by cardio-pulmonary resuscitation and chest compressions on heart rate recording. Cases were reviewed by a clinician and data was compared to the medical record and available videography. A clinician then determined and annotated what data should be excluded, when CPR was being performed, and which form of blood pressure measurement (non-invasive cuff or arterial line) should be used at specific time points for data analysis. This data processing by a clinician remains ongoing and the data analyzed and presented represents only partially clinician-processed data.

VS feature abstraction and statistical analysis.

A total 51 cases are included in the current analysis out of 79 enrolled. Patients who arrived to the hospital in cardiac arrest and never had return of spontaneous circulation were excluded (21 cases). Seven cases had insufficient recorded continuous vital signs (CVS). For the sake of data quality, our research group determined that they should be excluded from this portion of the analysis. Continuous vital signs with 0.5 Hz sample rate were collected for REBOA cases. Given recorded and videography-verified aortic occlusion time, the mean of the systolic blood pressure
and heart rate for 10 minute blocks were taken before (up to 30 minutes pre-AO), and after (up to 120 minutes after AO). Blood pressure measurements during CPR were excluded. Based on the location of REBOA inflation (Zone 1 is at the diaphragm and Zone 3 just proximal to the iliac bifurcation [See illustration below]) and presence vs absence of pulse on arrival to the TRU, the study cases are grouped into eight categories:

1. Group 1 are patients with REBOA performed in Zone 1 without CPR (N=13).
2. Group 2 are patients with REBOA performed in Zone 1 with CPR before AO (N=10).
3. Group 3 are patients with REBOA performed in Zone 1 with CPR around the time of AO. (N=5).
4. Group 4 are patients with REBOA performed in Zone 1 with CPR after AO (N=10).
5. Group 5 are patients with REBOA performed in Zone 3 without CPR (N=8).
6. Group 6 are patients with REBOA performed in Zone 3 with CPR before AO (N=1).
7. Group 7 are patients with REBOA performed in Zone 3 with CPR around the time of AO. (N=1).
8. Group 8 are patients with REBOA performed in Zone 3 with CPR after AO (N=3).

We used the mean systolic blood pressure and heart rate values of 10 minute blocks up to 30 minutes prior to aortic occlusion and throughout aortic occlusion. We then aggregated these values for each time point and reported them as a box plot (with mean, IQR, and 2nd and 98th
percentiles) as a composite of the entire group. Data was not available for all cases within each
time point, so the number of cases analyzed is reported underneath each box plot. In addition,
aortic occlusion times varied, so the number of cases available to analyze decreased with
increasing time after aortic occlusion. Within group 1, the mean aggregated blood pressure
increased after aortic occlusion for up to 30 minutes after aortic occlusion, and then slowly
decreased, but did not reach pre-AO levels by 120 minutes post-aortic occlusion (Figure 13). In
addition, heart rate initially decreased, but then gradually increased (Figure 14). Within group 2,
the mean blood pressure increased after aortic occlusion (Figure 15), and the heart rate stayed
relatively elevated immediately after aortic occlusion before decreasing at 20-40 minutes after
AO (Figure 16). Group 3 (Figure 17 and 18) and group 4 (Figure 19 and 20) displayed similar
trends, with an increase in blood pressure after aortic occlusion and an increase initially in heart
rate after aortic occlusion. Within group 5, the mean aggregated blood pressure increased after
aortic occlusion and then stays relatively stable, without a large amount of variation (Figure 21).
Similarly, heart rate decreases after aortic occlusion and remains relatively stable (Figure 22).
Groups 6 and 7 (Figures 23 and 24, and Figures 25 and 26, respectively) contained only 1 patient
each, so the individual case was presented, instead of an aggregate of patients. The case in group
6 shows a gradual decline in heart rate, and an increase in systolic blood pressure immediately
after aortic occlusion. The case in group 7 shows a decline in heart rate; and after return of
spontaneous circulation after AO, the patient was severely hypotensive for the majority of time.
Group 8 also represents a limited number of patients (3), but shows decrease in systolic blood
pressure (Figure 27). However, this is may not be demonstrating the entire clinical picture as
CPR is in progress for significant portions before and after AO. In addition, Figure 28 shows an
increase in heart rate after AO.

As these plots represent the median of averages, and clinician data processing is still
ongoing/incomplete, we did not perform statistical analysis on these graphs. We plan to plot
individual cases with a similar box plot representation, and then compare vital sign parameters
immediately before AO with parameters immediately after AO and at other time points. We also
plan to attempt to quantify the amount of time continuous vital signs did not record certain vital
signs (e.g. blood pressure), and the reasons behind it (e.g. lack of arterial line, etc.).
Figure 13: Group 1 Systolic Blood Pressure Aggregate of Mean 10-Minute Intervals
Figure 14: Group 1 Heart Rate Aggregate of Mean 10-Minute Intervals
Figure 15: Group 2 Systolic Blood Pressure Aggregate of Mean 10-Minute Intervals
Figure 16: Group 2 Heart Rate Aggregate of Mean 10-Minute Intervals
Figure 17: Group 3 Systolic Blood Pressure Aggregate of Mean 10-Minute Intervals
Figure 18: Group 3 Heart Rate Aggregate of Mean 10-Minute Intervals
Figure 19: Group 4 Systolic Blood Pressure Aggregate of Mean 10-Minute Intervals
Figure 21: Group 5 Systolic Blood Pressure Aggregate of Mean 10-Minute Intervals
Figure 22: Group 5 Heart Rate Aggregate of Mean 10-Minute Intervals
Figure 23: Group 6 Systolic Blood Pressure Aggregate of Mean 10-Minute Intervals
Figure 24: Group 6 Heart Rate Aggregate of Mean 10-Minute Intervals
Figure 25: Group 7 Systolic Blood Pressure Aggregate of Mean 10-Minute Intervals
Figure 26: Group 7 Heart Rate Aggregate of Mean 10-Minute Intervals
Figure 27: Group 8 Systolic Blood Pressure Aggregate of Mean 10-Minute Intervals
Figure 28: Group 8 Heart Rate Aggregate of Mean 10-Minute Intervals
Realtime Video Recording System Infrastructure and Video Review:

The trauma bays in the STC TRU (trauma resuscitation unit) and the operating rooms have integrated audio-visual recording capability and are recorded continuously from multiple angles. This video capability will allow us to obtain exact timelines of REBOA placement and other resuscitation efforts during REBOA placement as necessary to ensure accuracy. Video is stored for 48 hours prior to being deleted without appropriate IRB approvals.

The TRU bays are video recorded by three cameras pointed toward the patient resuscitation area at each bay. The camera over the lower extremity of the patient is the Axis P5534 Pan/Tilt/Zoom IP camera. The camera behind the head area of the patient and also the camera located outside the bay are fixed position Axis P3344-6MM.

Capture of all video signals (including other patient care units) are distributed across five HP PowerEdge R310 servers, Intel Xeon 2.27GHz processors with 4 GB RAM running an embedded version of Windows. Videos are rendered via Vision Client 7.2.1 and output in AVI format utilizing H.264/MPEG-4 AVC video codec for playback on common media players.
Prospective REBOA Data Collection and Analysis

**Real-time VS data collection**

- Triple redundant VS collection system
- Monitor of Monitors (MoMs) real-time collection status notification

**VS & Video Data Processing**

- VS Case matching and REBOA VS Viewer
- VS Feature abstraction

**REBOA Case Analysis**

- Real-time patient status collection (STC-CORE)
- Shock Trauma Registry
  ISS, Age, GCS etc

- Statistic Analysis/Modeling and Report

**Video recording**

- 24X7 Video recording for 13 TRU and 10 OR

**Video Review**

- Video Review

**Timing of REBOA and Events**
Appendix C: IRB Approval Letter

APPROVAL OF RESEARCH NOTIFICATION

Date: May 4, 2016

To: Megan Brenner
RE: HCR-HP-0061192-1
Type of Submission: Continuing Review
Type of IRB Review: Expedited

Approval for this project is valid from 5/4/2016 to 5/3/2017

This is to certify that the University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) approved the continuing review report for the above referenced protocol entitled, "Clinical Study of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Severe Visceral Trauma and Intra-abdominal Hemorrhagic Shock using Continuous Vital Signs ".

The IRB has determined that this protocol qualifies for expedited review pursuant to Federal regulations 45 CFR 46.110, 21 CFR 56.110, & 38 CFR 16.110 category(ies):
(8) - Research involving materials (data, documents, records, or specimens) that have been collected for any purpose, or will be collected solely for non-research purposes.

The IRB made the following determinations regarding this submission:
- A waiver of consent has been approved per 45 CFR 46.116(d).
- A waiver of HIPAA authorization for release of the PHI identified in the CICERO application has been reviewed and approved for this research study.

Below is a list of the documents attached to your application that have been approved:
Eligibility Checklist for HP-0061192 v3-24-2015-1427219238785
bibliography
10-14-15 REBOA data collection tool Revised.docx
10-14-15 REBOA data collection tool Revised.docx
M. Scarbrough CITI Completion Certificate
10-14-15 REBOA data collection tool Revised.docx
K. Volpin CITI Completion Certificate
K. Fioretti HIPAA 201
R. Jenkins HIPAA 125
C. Feather HIPAA 201.pdf
A. Romagnoli HIPAA 125.pdf
J. Kidd HIPAA 125
A. Romagnoli HIPAA 201.pdf
R. Jenkins HIPAA 201
K. Fioretti HIPAA 125
C. Feather CITI Completion Certificate
In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL. Investigators are reminded that the IRB must be notified of any changes in the study. In addition, the PI is responsible for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(a)(iii)). The PI must also inform the IRB of any new and significant information that may impact a research participants' safety or willingness to continue in the study and any unanticipated problems involving risks to participants or others.

DHHS regulations at 45 CFR 46.109(e) require that continuing review of research be conducted by the IRB at intervals appropriate to the degree of risk and not less than once per year. The regulations make no provision for any grace period extending the conduct of the research beyond 5/3/2017. You will receive continuing review email reminder notices prior to this date, however, it is your responsibility to submit your continuing review report in a timely manner to allow adequate time for substantive and meaningful IRB review and assure that this study is not conducted beyond 5/3/2017. Investigators should submit continuing review reports in the electronic system at least six weeks prior to this date.

Research activity in which the VA Maryland Healthcare System (VAMHCS) is a recruitment site or in which VA resources (i.e., space, equipment, personnel, funding, data) are otherwise involved, must also be approved by the VAMHCS Research and Development Committee prior to initiation at the VAMHCS. Contact the VA Research Office at 410-605-6000 ext. 6568 for assistance.


If you have any questions about this review or questions, concerns, and/or suggestions regarding the Human Research Protection Program (HRPP), please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-5037 or HRPO@umaryland.edu.