University of Maryland, Baltimore
Institutional Review Board (IRB)
Phone: (410) 706-5037
Fax: (410) 706-4189
Email: hrpo@umaryland.edu

# APPROVAL OF RESEARCH NOTIFICATION

**OF NOTE: The Principal Investigator should review the University of Maryland Baltimore criteria for performing research during the current COVID-19 pandemic emergency. Understand that IRB approval of this research does not suggest that performance of this research under current guidelines is allowed. Failure to comply with the UMB President's directives would be considered non-compliance. The UMB Research directives can be found at https://www.umaryland.edu/coronavirus/ . If you need clarification or guidance please call the Human Research Protections Office at 410-706-5037.**

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Date: December 16, 2021

To: Jonathan Morrison
RE: HCR-HP-00055545-9
Type of Submission: Continuing Review
Type of IRB Review: Expedited

**Approval for this project is valid from 12/16/2021 to 12/15/2022**

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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, "*Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA): Observational study of the Endovascular Skills in Trauma and Resuscitative Surgery (ESTARS) Working Group*".

The IRB has determined that this protocol qualifies for expedited review pursuant to Federal regulations 45 CFR 46.110, 21 CFR 56.110, & 38 CRF 16.110 category(ies):
(5) - 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.

This study is approved to enroll 700 local participants.

This study is approved to enroll 3000 worldwide participants.

Below is a list of the documents attached to your application that have been approved:
AAST AORTA JSR manuscript_2020.pdf
Eligibility Checklist for HP-00055545_2 v9-25-2013-1380108078905

AORTA study proposal - Draft 28 Februar 2013 DuBose.doc
Study Schedule.docx
UMB-WellSpan IRB Agreement.pdf
Avaro article.pdf
Sesma article.pdf
White article.pdf
REBOA article.pdf
AORTA study proposal - Draft 28 Februar 2013 DuBose.doc
Proposed revision 3 August 2020 AORTA Data collection tool final.docx
10-10-15 AAST AORTA data collection tool Revised.docx

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(4)(iii)). The PI must also inform the IRB of any new and significant information that may impact a research participant's 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 12/15/2022.** 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 **12/15/2022**. 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 410-605-7000 ext. 6568 for assistance.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.

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.