Office of Human Subjects Research
Institutional Review Boards

1620 McElderry Street, Reed Hall, Suite B-130
Baltimore, Maryland 21205-1911
410-955-3008
410-955-4367 Fax
e-mail: jhmeirb@jhmi.edu

Date: January 14, 2021

APPLICATION APPROVAL

Review Type:	Expedited
Principal Investigator:	Elliott Haut
Number:	IRB00265294
Title:	Implementing Best-Practice, Patient-Centered Venous Thromboembolism (VTE) Prevention in Trauma Center
Committee Chair:	Susan Bassett
IRB Committee:	IRB-X

Date of Approval: December 23, 2020

Date of Expiration: December 22, 2021

The JHM IRB approved the above-referenced Application.

To keep the JHM IRB application current we are assigning an Expiration Date as noted above. Prior to the expiration date, you will receive an email notification indicating that some action is required. If the Board has determined that a Continuing Review or Progress Report is required, you will need to submit Continuing Review or Progress Report prior to the expiration date. If the Board has determined that No Progress Report is required, you may run the administrative extend approval function.

IRB review included the following:

45 CFR 46.116: A waiver of consent was granted based on the following criteria: 1) the research involves no more than minimal risk to subjects; 2) the waiver will not adversely affect the rights and welfare of the subjects; 3) the research could not be practicably carried out without the waiver; and 4) the IRB will advise you if it is appropriate for participants to be provided with additional pertinent information after participation.

Progress Report Required:

The Board determined that this research meets the criteria for submission of a Progress Report as an alternative to a Continuing Review Application. The Progress Report must be submitted using a Further Study Action and selecting progress report at least 6 weeks prior to the expiration date. Please note, the Progress Report **must** be submitted prior to the expiration date shown on this notice. If the Progress Report is not submitted prior to the expiration date all activity must stop. Before any research activity can resume, you must submit the progress report.

45CFR46.404 and/or 21 CFR 50.51: This study has been approved for the inclusion of children as 'research not involving greater than minimal risk'. The permission of parents/guardians is waived.

Assent is waived for all children.

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).

Changes in Research: All proposed changes to the research must be submitted using a Change in Research application. The changes must be approved by the JHM IRB prior to implementation, with the following exception: changes made to eliminate apparent immediate hazards to participants may be made immediately, and promptly reported to the JHM IRB.

Unanticipated Problems: All unanticipated problems must be submitted using a Protocol Event Report.

If this research has a commercial sponsor, the research may not start until the sponsor and JHU have signed a contract.

Study documents:

Additional Supplemental Study Documents:
Patient education sheet
Data security approval
Confirmation Questions for coordinating center IRB00265294.docx
IT Risk approval email for IRB.pdf

Protocol:
eformR Haut clean version 10-22-2020 revised #1 CLEAN 12-9-2020.docx

Johns Hopkins Study Team Members:

Oluwafemi Owodunni, Joseph Canner, Brandyn Lau, Peggy Kraus, Mujan Varasteh Kia, Michael Streiff