Office of Human Subjects Research
Institutional Review Boards

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Date: February 16, 2021

APPLICATION APPROVAL

Review Type:	Expedited
Principal Investigator:	Elliott Haut
Number:	IRB00275884
Title:	Surveying Nurses about their Perspective on Venous Thromboembolism Patient-Centered Education Bundle: CLOTT III
Committee Chair:	Susan Bassett
IRB Committee:	IRB-X

Date of Approval: February 16, 2021

Date of Expiration: February 16, 2023

The JHM IRB approved the above-referenced Application.

Issue:Issue:Issue:

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.

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.

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:

Recruitment Materials:
FINAL_Haut_IRB00275884_SurveyRecruitmentDocument_021621.docx

Additional Supplemental Study Documents:
Survey Qualtrics IRB00275884.pdf

Protocol:
eformE IRB00275884.docx

Johns Hopkins Study Team Members:

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