Tulane University
Human Research Protection Program

Tulane Human Research Protection Office
Institutional Review Boards
Biomedical
Social Behavioral
FWA00002055

DATE:	November 17, 2021
TO:	Patrick Mcgrew
FROM:	Tulane University Biomedical IRB
STUDY TITLE:	Obstetric Trauma: A Review of the Incidence, Risk Factors, and Maternal-fetal Outcomes
REF #:	2021-1574
SUBMISSION TYPE:	Initial Submission
ACTION:	**APPROVED**

On November 12, 2021, the Tulane University Biomedical IRB provided an expedited review and approval determination for the initial submission of this minimal risk study. The review was provided in accordance with the appropriate research regulations.

The following items were submitted as part of the submission:

- CITI - Christofer Anderson.pdf (Training Certificate)
- CITI - Patrick McGrew.pdf (Training Certificate)
- CITI - Vidda Simpson.pdf (Training Certificate)
- OB Trauma Protocol.docx (Study Protocol)
- UMC RRC Conditional Approval (Other)
- Waiver of Parental Permission.docx (Parental Permission)

This study is approved for the local enrollment of 1000 subjects/charts.

This study is granted approval November 12, 2021. The first Annual Progress Report is due on November 11, 2022.

All research must be conducted in accordance with this approved submission.

Please submit any proposed changes to the research study, including enrollment of additional study participants, to the IRB for review and approval prior to implementation, unless a change is necessary to avoid immediate harm to subjects. If subject safety becomes an issue, please notify Tulane University Human Research Protection Office (HRPO) as soon as possible.

The informed consent process begins with a description of the study and assurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study

with dialogue between the Investigator and research participant. Federal regulations require each participant to receive a copy of their signed consent form unless the IRB waives this requirement.

Please submit any unanticipated problems involving risk to subjects or others, deviations from the approved research, non-compliance, and complaints to the IRB in accordance with Tulane University Human Research Protection Program (HRPP) Standard Operating Procedures (SOPs). Please contact the HRPO via irbmain@tulane.edu or (504) 988-2665 if you have questions and/or concerns regarding reporting events. In addition, please also submit any reports generated by the DSMB or oversight committee to the IRB, if required.

Pursuant to Tulane University HRPP SOPs, a study progress report will be required annually.

If your study is supported in whole or in part by a federal grant, please note that Federal regulations prohibit the use of Federal funds for human subject research that is not conducted under current IRB approval. Loss of IRB approval for this study due to lapse, suspension or termination will be communicated by the Tulane IRB to Tulane's Office of Grants and Contracts Accounting, which may result in an administrative hold being placed on the related grant(s). Therefore, to avoid an interruption in research activity, including use of coded, identifiable human data or biospecimens, and access to grant funds it is critical that IRB approval for the study be maintained.

Please notify the IRB within 30 days of completion of all study activities and data analysis by submitting a Study Closure Form.

The Principal Investigator is responsible for being familiar with and complying with Tulane University HRPP SOPs found at https://research.tulane.edu/hrpo. Please do not hesitate to contact our office with any questions or concerns.

We encourage investigators and research staff to provide feedback about the IRB review process, our website, and any other aspects of the HRPP that will help us to identify improvements we can make. You can complete this form in an anonymous manner at HRPO/IRB Feedback Survey.

Sincerely,

Tulane University Human Research Protection Office

Please note that the actual signature by the IRB Chair(s) is not required for this document to be effective. IRBManager generates this letter pursuant to the IRB Chair's electronic signature and approval. This process is consistent with Federal Regulations and Tulane Standard Operating Policies with respect to the IRB and Human Research Protection Office, which consider electronically generated documents as official notices to sponsors and others of approval, disapproval or other IRB decisions. Please refer to Tulane's Electronic Signatures and Records Policy by visiting the HRPO website at https://research.tulane.edu/hrpo.