INDIANA UNIVERSITY

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

Office of Research Compliance

NOTICE OF EXPEDITED APPROVAL - AMENDMENT

DATE:	March 25, 2020
TO:	Jennifer Hartwell, Principal Investigator GENERAL SURGERY
FROM:	Turik, Michael A Chair - IRB-04
RE:	Protocol #: 1709064972A009 Protocol Type: Expedited Protocol Title: A Review of Blunt and Penetrating AAST Grade IV and V Liver Injuries Funding Source: None

The Indiana University Institutional Review Board (IRB) IRB 00000219 | IRB-04 recently reviewed and approved the above-reference protocol. Approval of this protocol is based on your agreement to abide by the policies and procedures of the Indiana University Human Research Protection Program (HRPP) and does not replace any other approvals that may be required. Relevant HRPP policies and procedures governing Human Subject Research can be found at: https://research.iu.edu/compliance/human-subjects/guidance/index.html.

Submission and Review Information:

Type of Submission:	Amendment
Level of Review:	Expedited
Expedited Category(ies), if applicable:	Category 5: 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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
Approval Date of Submission:	March 25, 2020
Expiration Date:	
Authorized IRB Signature	 Kanti Crain

Regulatory Determinations:

- Study continues to meet the criteria for approval defined by the HRPP Policy on IRB Review Process.

Documents Approved with this Submission (for Amendments and Renewals, documents appearing in bold were either added or replaced with the submission):

Attachment Type - Document Version #
Protocol - Protocol, 03/24/20 Data Collection Instrument - Data Variables, 10/10/18 Data Collection Instrument - Additional Variables for KC-IRB Questionnaire K; ID #23650

NOTE: If you submitted and/or are required to provide subjects with an informed consent document, please ensure you are using the most recent version of the document to consent subjects.

The following key personnel are approved to participate in the above titled research activities:

Investigator Name	Role	Training
Jennifer Hartwell	Principal Investigator	Yes
Meghan Wooster	Key Personnel	Yes

Organizations:

Organization
IU Health Methodist Hospital
IU HEALTH
ESKENAZI HEALTH
Indiana University

You should retain a copy of this letter and all associated approved study documents for your records. Please refer to the assigned study number and exact study title in future correspondence with our office. Additional information is available on our website at https://research.iu.edu/compliance/human-subjects/guidance/index.html.

If you have any questions or require further information, please contact the HSO via email at irb@iu.edu or via phone at (317)274-8289.