

Certificate of Exemption

09-Jan-2025

Title:	Operative and nonoperative management of splenic injury with concomitant traumatic brain injury
COMIRB#:	24-0230
Investigator:	Thomas Schroepfel
Subject:	Amendment
Funding Source(s):	No Sponsor~
Panel:	UCD Panel A
Effective Date:	09-Jan-2025
Exemption Category:	4
Submission ID:	PAM002-2

REQUESTED CHANGES:

Adding Leslie Rivas-Quijano as research staff.

This study is transitioning from a multi-center retrospective secondary research study involving only UCHHealth institutions to a multi-center retrospective study involving non-UCHHealth institutions.

UCHHealth Memorial Hospital Central will coordinate data collection for this multi-center retrospective study. We will utilize an existing data set from our institution that was abstracted under this previously approved exempt study-COMIRB 24-0230. Other participating institutions will execute a data use agreement with UCHHealth and provide their data to our site through a secure REDCap database. Each institution will retrospectively identify patients through an institutional trauma registry. The EMR will be reviewed for patients >15 years of age who meet inclusion criteria for this protocol and were treated at each respective institution between 1/1/2017 and 1/1/2024. Data from each institution will be submitted securely through a REDCap database. Each institution will assign subjects a unique study ID and the linking document will be stored on a secure password protected drive accessible only by research staff assigned to the protocol at each institution. No additional PHI will be collected, but we will continue to collect PHI in the form of dates (admission date/date of injury).

Your COMIRB Amendment submission PAM002-2 has been determined to be EXEMPT from IRB review. There is no requirement for continuing review and your study has not been given an expiration date.

For the duration of your protocol, any change to the Principal Investigator, or any changes that may affect the exemption determination must be submitted to COMIRB before implementation of the changes. Information on how to submit changes (amendments) and reports of unanticipated problems for your study to COMIRB can be found on the COMIRB website <http://www.ucdenver.edu/research/comirb/submissions/>.

When your research is complete, please notify COMIRB by e-mail at COMIRB@ucdenver.edu

REVIEW DETAILS:

It was verified this research is still eligible for exemption.

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