

## **Certificate of Exemption**

01-Jul-2024

**Title:** A multicenter analysis of chest tube practices in trauma.  
**COMIRB#:** 22-1710  
**Investigator:** Thomas Schroepfel  
**Subject:** Amendment  
**Funding Source(s):** No Sponsor~  
**Panel:** UCD Panel D  
**Effective Date:** 01-Jul-2024  
**Exemption Category:** 4  
**Submission ID:** PAM001-1

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### **REQUESTED CHANGES:**

In addition to adding research staff above, the study is transitioning to a multi-center retrospective secondary research study. The study title will be changed to: A multicenter analysis of chest tube practices in trauma.

UCHealth Memorial Hospital Central will coordinate data collection for a multi-institution retrospective study. We will utilize an existing data set from our institution that was abstracted under this previously approved exempt study-COMIRB 22-1710. Other participating institutions will execute a data use agreement with UCHealth 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 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. Additional data points for chest x-ray have been added to the data tool. No additional PHI will be collected, but we will continue to collect PHI in the form of dates (admission date/date of injury).

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**Your COMIRB Amendment submission PAM001-1 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](mailto:COMIRB@ucdenver.edu)**

### **REVIEW DETAILS:**

It was verified this research is still eligible for exemption.

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