

Certificate of Exemption

04-Dec-2024

Title:	Care patterns and outcomes of patients with substance use disorders in the UCHHealth system
COMIRB#:	24-2127
Investigator:	Eden Bernstein
Subject:	Amendment
Funding Source(s):	No Sponsor~
Panel:	UCD Panel D
Effective Date:	04-Dec-2024
Exemption Category:	4
Submission ID:	PAM001-1

REQUESTED CHANGES:

Documents Changed: Application and Protocol

Description of Changes Made: Broadened date range to 2019 - present. Included justification for including patients age 12 and older. Included explicit mention that we will collect data on costs.

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

REVIEW DETAILS:

This protocol continues to meet the criteria for exemption under category 4.

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