

## **Amendment Approval**

23-Jul-2024

**Title:** In Hospital Extended-Release Naltrexone for Alcohol Use Disorder: A Mixed Methods Study  
**COMIRB#:** 22-0961  
**Investigator:** Susan Calcaterra  
**Subject:** Amendment  
**Funding Source(s):** None~  
**Panel:** UCD Panel A  
**Approval Date:** 23-Jul-2024  
**Expedited Category:** 5, 6, 7

**Submission ID:** PAM002-1

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### **REQUESTED CHANGES:**

#### Documents Changed:

- 1) "Application for Protocol Review v7.16.24" for COMIRB #22-0961
- 2) Study personnel form v7.12.24
- 3) Study Protocol v7.16.24
- 4) Study Protocol TC v.7.16.24
- 5) Word doc description of changes
- 6) SPARO letter

#### Description of Changes:

1. Changes made to the "Application for Protocol Review.v.7.16.24" for COMIRB #22-0961
  - a. Change primary contact to Susan Calcaterra, Section C. Key Study Personnel
  - b. Added Denver Health as a study site with attached SPARO letter -- see Section F.3.e. for change in Application for Protocol Review.
  - c. SPARO clearance letter attached
  - d. Section H. Human Subjects. 2, 3a, 3b. Increased the enrollment numbers with adding a new site (Denver Health).
  - e. Section Q. 2. Added "facilities associated with Denver Health"
  - f. Section A. Waiver or Alteration of Consent. Added "(Aim 1 and 2).
  - g. Attachment O. HIPAA Waiver. PHI Access and Use. Added this sentence: "The data will be obtained both from Health Data Compass and from an existing operational dashboard designed to support the Addiction Medicine Service at the University of Colorado Hospital. The dashboard is maintained by the Division of Hospital Medicine Data and Analytics team and is populated from the Epic Data Warehouse."
  - h. Attachment O. HIPAA Waiver 3. Checked "account numbers".
  - i. Attachment O. HIPPA Waiver 2. Checked "any other unique identifying number, characteristic, or code"
  - j. Attachment O. HIPAA Waiver 4. Added "ICD codes associated with encounters, pharmacy data, encounter data, i.e., outpatient medical visits, race, gender, age."
2. Changes made to the "Study Personnel Form.v.7.12.24"
  - a. Added Dr. Dale Terasaki, MD, MPH as the Denver Health study PI
  - b. Added Dr. Paul Christine, MD as a Denver Health study personnel
  - c. Added Dr. Jarratt Pytell, MD as a Denver Health study personnel
  - d. Added Ryan Loh, MS as a Denver Health study personnel (data analyst)
3. Changes made to the "Study Protocol v.7.12.24"
  - a. Page 3. Under V. Research Methods. Edited to say: "Data will also be obtained from Denver Health (and a data use agreement will be completed between Denver Health and University of Colorado). Claims data will be obtained from Colorado

All Payer Claims data.”

b. Page 3. In Study Outcomes Measures Table, last column under Data Source added: “Health Data Compass at University of Colorado; Denver Health; All Payer Claims Data via CIVHC”

c. Page 4. Under B. Description of Population Being Studied, edited to remove “No patients will be enrolled” for SA 1 to SA 3.

d. Page 4. Under C. Study Design and Research Methods. Study Site. Added “and Denver Health”.

e. Page 4. Under C. Study Design and Research Methods. Study Team Members. Added “and the Denver Health Site PI, Dr. Dale Terasaki.

f. Page 4. Under Recruitment and Consent. Removed “and is available in Health Data Compass”.

g. Page 5. Under Measures / Data Collection. Added: “at University of Colorado and the Denver Health Data Warehouse at Denver Health. Data will...”

h. Page 5. Under Measures / Data Collection. Removed this section. “or the use of CORHIO Patient Care 360, a health information exchange which requires a secure login and password (<https://www.corhio.org/>).”

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## REVIEW DETAILS-

This submission was reviewed under Expedited procedures and the following determinations were made:

### APPROVED

The following documents have been reviewed as part of this approval:

1. Application v 7.16.24
2. Application [Compare Report] 2.2.23 v 7.16.24
3. Change Form v 7.16.24
4. Description of Changes v 7.16.24
5. Personnel eForm
6. Protocol v 7.16.24\_CL
7. Protocol v 7.16.24\_TC
8. SPARO letter v 7.11.24

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