

University of Colorado Hospital  
Denver Health Medical Center  
Veteran's Administration Medical Center  
The Children's Hospital  
University of Colorado Denver  
Colorado Prevention Center

## Certificate of Approval

07-May-2013

**Investigator:** Clay Burlew  
**Sponsor(s):**  
**Subject:** COMIRB Protocol 13-0077 Initial Application  
**Effective Date:** 02-May-2013  
**Expiration Date:** 14-Mar-2014  
**Expedited Category:** 5  
**Title:** Enteral Nutrition in the Open Abdomen

Description:

APP001-3: Response to Minor Modifications. HIP001-2 submitted concurrently.

All COMIRB Approved Investigators must comply with the following:

- | For the duration of your protocol, any change in the experimental design/consent and/or assent form must be approved by the COMIRB before implementation of the changes.
- | Use only a copy of the COMIRB signed and dated Consent and/or Assent Form. The investigator bears the responsibility for obtaining from all subjects "Informed Consent" as approved by the COMIRB. The COMIRB REQUIRES that the subject be given a copy of the consent and/or assent form. Consent and/or assent forms must include the name and telephone number of the investigator.
- | Provide non-English speaking subjects with a certified translation of the approved Consent and/or Assent Form in the subject's first language.
- | The investigator also bears the responsibility for informing the COMIRB immediately of any Unanticipated Problems that are unexpected and related to the study in accordance with COMIRB Policy and Procedures.
- | Obtain COMIRB approval for all advertisements, questionnaires and surveys before use.
- | Federal regulations require a Continuing Review to renew approval of this project within a 12-month period from the last approval date unless otherwise indicated in the review cycle listed below. If you have a restricted/high risk protocol, specific details will be outlined in this letter. Non-compliance with Continuing Review will result in the termination of this study.

You will be sent a Continuing Review reminder 75 days prior to the expiration date. Any questions regarding this COMIRB action can be referred to the Coordinator at 303-724-1055 or UCHSC Box F-490.

### Review Comments:

APP001-3: APPROVED. Minor Modifications addressed. At next change or Continuing Review, change section O of the Application to clearly state that data is on a secure server rather than a hard drive.

Approved Documents:

1. Application for Protocol Review and Attachments A, L, M and O, Version Date: April 11, 2013.

2. Protocol: Enteral Nutrition in the Open Abdomen, Version Date: April 11, 2013.

3. Data Collection Sheet: WTA Multi Institutional Study: Enteral Nutrition in the Open Abdomen, Version Date: April 11, 2013.

Noted Document:

1. Denver Health SPARO letter, signed January 23, 2013.

Please note that COMIRB will no longer be E-mailing approved documents. Stamped, approved documents can be retrieved in the eRA (InfoEd) system. [Please click here](#) to access instructions on finding these uploaded documents. Documents will be available within the next 48 hours.

Sincerely,

UCD Panel A

Please provide Feedback on [Your Experience with the COMIRB Process](#)