Application for Protocol Review

Front Page

Wait...does this research involve the VA?

Yes ☐ No ☑ *Is this study funded, in whole or in part, by the VA?

Yes ☐ No ☑ *Are any research procedures performed on VA property, with VA patients, or using VA equipment/resources?

Yes ☐ No ☑ *Will any study personnel be working on VA time for this study?

A. Review Dates

*Date of Initial Submission: 15-Jan-2013

*Version Date: 15-Jan-2013

B. Project Information

Protocol Number: 13-0077

Project Title:

Enteral Nutrition in the Open Abdomen

Disease/Condition/Topic studied: Open abdomen outcomes in trauma patients

If you are completing this form to request the use of an HUD or Treatment IND throughout this form answer the questions as if the word "research" is replaced by "Use of Device or Drug".

C. Personnel / Contact Information

Personnel - Review (Add Personnel - Review)

Burlew, Clay Cothren

1) List Personnel

Name

Burlew, Clay Cothren

Primary Investigator	Start Date	End Date	Role
☑	15-Jan-2013		PI

Certifications

Certification	Begin	End
CITI Human Subjects Protection	26-Oct-2011	26-Oct-2014
HIPAA Research Course	04-May-2004	31-Dec-2030
CITI Human Subjects Protection	31-Mar-2005	30-Mar-2008
CITI Human Subjects Protection	01-Jan-2008	31-Dec-2011

Leave End Date Blank

Instructions for Completing this page

Faculty Mentor

*2) Are you a student or trainee, or are you doing this research to complete an educational requirement? ☐ Yes ☑ No

Contact Information

Providing accessible contact numbers can help expedite your review in case of questions.

*3) PI Office Phone: 303-436-6558

4) PI Cell Phone/Pager _____

*5) Primary Contact Phone: 303-436-6558 *Name: Clay Cothren Burlew

6) Best contact for scientific questions:

a. Phone: _____

b. Name: _____

D. Type of Review being Requested

*Type of review being requested: Expedited

*Complete (F) -- Attachment F: Expedited Research Complete

E. Funding

*1) Do you have any funding for this study? ☐ Yes ☑ No

F. Perfomance Sites

*1) Is this a multi-site study? ☑ Yes ☐ No

*Complete (A) -- Attachment A: Multi Site Studies Complete

*2) Is the PI responsible for any data, samples or research procedures collected or conducted outside of the USA? ☐ Yes ☑ No

Section F(a): Affiliate Performance Sites

3) Will any of the following Affiliates be utilized as sites for this research?

Yes ☐ No ☑ *a. University of Colorado Hospital

Yes ☐ No ☑ b. Veteran's Administration Hospital (ECHCS)

Yes ☐ No ☑ *c. Is any Investigator employed by the VA?

Yes ☑ No ☐ *d. Denver Health and Hospitals

Yes ☑ No ☐ *e. Is any Investigator employed by Denver Health and Hospitals?

Yes ☐ No ☑ *f. Children's Hospital Colorado

Yes ☐ No ☑ *g. Anschutz Medical Campus

Yes ☐ No ☑ *h. Downtown Denver Campus

Yes ☐ No ☑ *i. Colorado Prevention Center

Definition of Affiliate

Section F(b): Non-Affiliated Performance Sites

*Does this study involve other Non-Affiliated sites? ☑ Yes ☐ No

Make sure you have indicated that this is a multi-site study in F#1 above and submit Attachment A.

Definition of Non-Affiliate

Section F(c): COMIRB Requested Attachments

For the billing forms below, click on the Form Link to download the form and click SAVE to save the document to your local computer. Complete the form and then attach the completed form to this application. Both of these forms may also be found on the COMIRB Website

Billing Information Form 

Fee Waiver Request 

Include a copy of the Protocol with this Submission by clicking the link:
'Add Institution Forms/Supporting Documents' on the

Components for Initial Application page.

Contact Phone Number

Instructions for Completing this page

PI Office Phone: _____

PI Cell Phone: _____

Primarcy Contact Phone: _____

Faculty Advisor/Mentor (if applicable) Phone: _____

G. Description of Study

*1) Summary in lay terms: Provide a brief statement describing the research project in 8th Grade Language. This section should include the study aims and rationale, and a brief overview of how you will answer the research questions. (Approx. 1 paragraph)

The purpose of this study is to determine if EN in patients with a traumatic bowel injury requiring an open abdomen impacts outcomes. Patients who receive EN will be compared to those who remain nil-per-os (NPO). Additionally, an internal study control will be performed by analyzing concurrent injured patients requiring an open abdomen who did not have a bowel injury.

Specific aims:
Hypothesis 1: EN in patients with a traumatic bowel injury requiring an open abdomen improves fascial closure rate compared to patients who remain NPO.

Hypothesis 2: EN in patients with a traumatic bowel injury requiring an open abdomen reduces infectious complications compared to patients who remain NPO.

Hypothesis 3: EN in patients with a traumatic bowel injury requiring an open abdomen have a lower mortality rate compared to patients who remain NPO.

Please note: A separate protocol document must be submitted in addition to this Application form. See the COMIRB protocol template on the COMIRB website for the suggested format. Please upload your protocol separately.

2) Are there special review considerations?

Yes ☐ No ☑ *a. Will this project need CTRC Review (Clinical Translational Research Center)?

Yes ☐ No ☑ *b. Is this an Oncology or Cancer Center Project? (Protocol Review & Monitoring Committee)

Yes ☐ No ☑ *c. Would you like this study reviewed by the Social/Behavioral panel?

Yes ☐ No ☑ *d. Does the composition of the drug involve human gene transfer or recombinant DNA?

Yes ☐ No ☑ *e. Does the protocol involve the use of radioactive drugs or materials not under an IND (including PET scans, VQ scans, etc.) for research purposes only?

Yes ☐ No ☑ *f. Does the protocol invovle the administration of therapeutic radiation doses, using sealed sources, for research purposes only?

H. Human Subjects

Instructions for Completing this page

1) Age Range of subjects to be enrolled:

*(lower limit) 18 99 *(upper limit) Both upper & lower age limits are required

*2) Total Number of Subjects For All Sites: Up to 100

*3) Total Number of Local Subjects: Up to 100

Local enrollment number reflects the maximum number of subjects to be consented by the local investigators. If a chart review, local enrollment number should reflect the maximum number of charts to be reviewed by local investigators, regardless of where they originate. For single-site studies, total and local enrollment numbers should be the same.

*4) Is the enrollment limited on the basis of gender, race or ethnicity? ☐ Yes ☑ No

*5) Inclusion Criteria:

Define the characterists of the population to be included in the study (must match protocol)

All patients requiring an open abdomen following trauma will be prospectively followed.

*6) Exclusion Criteria:

Define the characterists of the Population(s) to be excluded. Include age < 18, prisoners, pregnant women, and decisionally challenged subjects, unless you check "yes" for the appropriate population in the Vulnerable Populations section below.

Patients to be excluded from analysis include age < 18, prisoners, pregnant women, decisionally challenged subjects, deaths within 24 hours, identification of injury > 24 hours, and those transferred from an outside hospital > 24 hours following initial injury.

Vulnerable Populations

Instructions for Completing this page

7) Inclusion of Vulnerable Populations: (check all that apply)

These vunerable populations cannot be enrolled into a study without prior IRB approval. Will any of these populations be enrolled into the study?

Yes ☐ No ☑ *a. Children (under age 18)?

Yes ☐ No ☑ *b. Wards of the state?

Yes ☐ No ☑ *c. Neonates (Birth to 30 days)?

Yes ☐ No ☑ *d. Prisoners or those on probation/alternative sentencing?

Yes ☐ No ☑ *e. Pregant Women / Fetuses?

Yes ☐ No ☑ *f. Decisionally challenged?
(Cognitively impaired, incompetent to consent, proxy, consenting in life threatening situations)

Attachment J must also be completed if the study intends to follow women who become pregnant during the study.

TARGETED Recruitment

8) Are any of the following populations being TARGETED for recruitment?

Yes ☐ No ☑ *a. Poor/uninsured

Yes ☐ No ☑ *b. Nursing home residents

Yes ☐ No ☑ *c. Students of PI or study staff

Yes ☐ No ☑ *d. Students to be recruited in their educational setting

Yes ☐ No ☑ *e. Employees directly under the supervision of PI or co-investigator

Yes ☐ No ☑ *f. People engaged in illegal activites and/or illegal immigrants

Yes ☐ No ☑ *g. People with Post Traumatic Stress Disorder (PTSD)

Yes ☐ No ☑ *h. People with Traumatic Brain Injury (TBI)

Yes ☐ No ☑ *i. Terminally Ill Patients

Yes ☐ No ☑ *j. People with mental illness or learning disabilities

Yes ☐ No ☑ *k. Others vulnerable to coercion

I. Procedures

Instructions for Completing this page

*1) Duration of study procedures for each subject: length of hopsital stay

*2) Are all study procedures for local site(s) accurately described in the protocol?
☑ Yes ☐ No

*3) Does this research involve the delivery of health care? ☑ Yes ☐ No

*Describe usual treatment for this condition in this population (local standard of care):

Local standard of care will be applied; this is an observational study of individual patient care.

*4) Is the local standard of care different from the nationally accepted standard?
☐ Yes ☑ No

*5) List which procedures are done only as a part of this study, and describe how the research procedures differ from standard care:

There is no intervention in this study.

*6) Are any additional materials used with subjects (questionnaires, interview guides, informational, diaries)?
No

Special Procedures

7) Indicate if any of these procedures are relevant to the study:

Yes ☐ No ☑ *a. Are any Drugs, Biologics or Supplements being prescribed to subjects as part of the research study? (i.e. will the risks of these items be listed in the Consent?)

Yes ☐ No ☑ *b. Are any Devices being used for research only procedures? (i.e. will the risks of the device be listed in the Consent?)

Yes ☐ No ☑ *c. Will the internet be used to collect research data? (e.g. Tests, Surveys, Chat Room, etc.)

Yes ☐ No ☑ *d. Will you create a database for future recruitment?

Yes ☐ No ☑ *e. Will Genetic Testing be involved with this study?

Yes ☐ No ☑ *f. Will Biological samples such as urine, sputum, or blood be collected for use in this study?

Yes ☐ No ☑ *g. Will data and/or biological specimens be stored (banked) for future unspecified research questions?

Yes ☐ No ☑ *h. Are daycares to grade 12 schools being used as a setting for the research?

J. Potential Risks to subjects

*1) Do you view the risk of this study as minimal? ☑ Yes ☐ No

Note: the committee may disagree

*a. Justify this determination:

Data will be abstracted from the medical records of patients concurrent with their hospital care (the data abstraction form is attached). The data will be de-identified, and entered into a database by the PI without patient identifiers. A coded identity will be assigned that reflects the order in which a subject was entered into the database; it will not be based on subject information. The database will be kept on a password-protected computer in a locked office. Data abstraction forms will be kept in a locked office. The database code will be noted on the data abstraction form in the event that a patient will need to be re-identified. These forms will be destroyed once all analyses have been completed and the project concluded. We believe this observational study poses no more than minimal risk for breaches of confidentiality of personal data.

*2) Describe the anticipated risks of the research:

[list risks in order of likelihood and magnitude (very common, common, uncommon, rare but serious)]

This observational study involves the analysis of existing patient records, and therefore poses no more than minimal risk to the subject. For subjects, the primary risk is protecting personal privacy and the confidentiality of information, and is considered an unlikely and minimal risk.

*3) Describe the plan to minimize risk:

(use procedures that are standard of care where possible)

All data collected will be stored in password protected files. The PI is the only member of the research team who will have access to these files. Responsibility and accountability for security and confidentiality will lie with the PI. Information will not be published that could possibly be used to identify an individual subject.

*4) Is it possible that the research team may be made aware of certain incidents/diseases that are reportable to state authorities?

Yes ☐ No ☑

5) Describe the Potential Benefits

*Describe the potential benefits of the study:

This study evaluates the outcomes related to enteral nutrition in the open abdomen. This could impact future clinical management of these patients and would significantly add to the literature in this regard. There is no direct benefit to subjects by their includion in this study.

Risk/Benefit Analysis:

Instructions for Completing this page

6) Describe why the risk to subjects are reasonable in relation to the anticipated benefits to participants and/or society, and in relation to the importance of the knowledge that may reasonably be expected to result, thereby falling in favor of performing the study:

*a. To Participant:

There is a less than minimal risk to a breach of confidentiality for study subjects and a potential benefit of providing information that could lead to improvements in the treatment of post-injury open abdomen patients.

*b. To Society:

The potential benefit is a better understanding of the impact of enteral nutrition in post-injury patients including a potential reduction in mortality.

*c. Justify the importance of the knowledge gained:

Recent studies indicate improved outcomes and decreased mortality in patients receiving enteral nutrition in the open abdomen, but questionable impact in those with bowel injuries. Clarification of outcomes in this patient population will potentially improve our future care of this patient population.

K. Recruitment Methods---

*1) Will subjects be recruited for this study? Yes

Subject identification/advertising

Instructions for Completing this page

2) How will potential subjects be identified? (Select All that apply)

Yes ☐ No ☑ *a. You have an existing *Research Relationship* with potential subjects?

Yes ☑ No ☐ *b. You have or have had a *Clinical or Professional* Relationship with potential subjects?

Yes ☐ No ☑ *c. Will you use a *Recruitment Database* to identify potential subjects?

Yes ☐ No ☑ *d. Will you use ResearchMatch (complimentary recruitment service)

Yes ☐ No ☑ *e. Will you use *HIPAA A Authorization* to obtain permission to recruit patients?

Yes ☐ No ☑ *f. Will you use *Advertising* to recruit subjects?

*3) Provide a detailed description of how recruiment will take place:

All post-injury patients with an open abdomen will be screened for inclusion in this observational study.

4) Indicate the methods of recruitment to be used in this study (check all that apply):

Yes ☐ No ☑ *a. In-person or face-to-face

Yes ☐ No ☑ *b. Written correspondence (letters/postcards, etc.)

Yes ☐ No ☑ *c. Electronic correspondence (emails)

Yes ☐ No ☑ *d. Telephone

Yes ☐ No ☑ *e. Advertisements

Yes ☐ No ☑ *f. Other Methods

Recruitment Incentives/Reimbursement

Instructions for Completing this page

*5) Will participants be paid for their time, reimbursed for travel or meal expenses, or receive any sort of "gift" for participating in this study? ☐ Yes ☑ No

*6) Are any other materials being given to subjects?
(Such as Pens, Mugs, Calendars, T-Shirts) ☐ Yes ☑ No

L. Informed Consent

*1) Will subjects be screened prior to consent (e.g., phone screening)? Not Applicable

*2) Will subjects provide information about other identifiable persons such as relatives or friends (secondary subjects)? No

*3) Are you using any level of Deception? No

*4) Will a signed and dated copy of the consent form be provided to the subject?
☐ Yes ☑ No

*a. If NO, please explain:
We are asking for waiver of consent.

*5) Will consent be obtained prior to any research procedures being done? ☐ Yes ☑ No

*a. If NO, please explain:
We are asking for waiver of consent.

Based on your answers above, Waiver of Consent, or Waiver of Documentation of Consent, MUST be requested for these activities (see next section).

Waiver of Consent / Waiver of Documentation of Consent

Instructions for Completing this page

*6) Is a Waiver of Consent or a Waiver of Documentation of Consent being requested?

☑ Yes ☐ No

*If YES, describe which group or portion of study:

Entire study population.

*Complete (M) -- Attachment M: Waiver of Consent Request Complete

Consent Process

All studies must either have a consent process or waive consent completely. Note that studies using deception or a waiver of documentation of consent still have a consent process of some kind. For the next question, answer no only if you are requesting a full waiver of consent. Otherwise, answer yes and provide details of the consent process used in this study in the subsequent questions.

*7) Does this study have a consent process? ☐ Yes ☑ No

M. Privacy and Confidentiality during Study Procedures

Instructions for Completing this page

Privacy - refers to persons and their interest in controlling the access of others to themselves.

*1) Will the PI/research team interact with subjects to collect information?

☐ Yes ☑ No

*2) Could association with the research be considered stigmatizing or damaging to the subjects financial standing, employability, or reputation?
(e.g. STD/HIV clinic, Substance abuse rehabilitation center)

☐ Yes ☑ No

Confidentiality

*3) Is any of the following personal information is collected as research data? ☐ Yes ☑ No

- Name/Initials
- Address
- Telephone/Fax Number
- E-Mail Address
- Social Security #
- Medical Record/Health Plan/Ascension Number

*4) Will personal information elements be stored separately from other research data? ☑ Yes ☐ No

*5) Will personal information be available to anyone other than research personnel?

☐ Yes ☑ No

*6) Will any study data about an individual, group, or institution be considered sensitive?

☐ Yes ☑ No

N. HIPAA

*1) Do HIPAA regulations apply to this research?
(i.e. covered entity accessing, using or disclosing PHI) ☑ Yes ☐ No

Access/Disclosure

Instructions for Completing this page

2) How are you accessing PHI under HIPAA regulations (i.e. what authorizations are in place)?

Yes ☑ No ☐ *a. Treatment relationship (i.e. for clinical purposes)
Yes ☐ No ☑ *b. HIPAA authorization
Yes ☑ No ☐ *c. HIPAA Waiver *Complete (O): Attachment O: HIPAA Waiver Complete
Yes ☐ No ☑ *d. Data Use Agreement
Yes ☐ No ☑ *e. Business Associate Agreement
Yes ☐ No ☑ *f. Other

*3) Will PHI be disclosed outside the covered entity? ☐ Yes ☑ No

4) What authorization(s) is (are) in place for the use and disclosure of the PHI collected?

Yes ☐ No ☑ *HIPAA B Authorization
Yes ☑ No ☐ *N/A - HIPAA waiver requested
Yes ☐ No ☑ *Data Use Agreement
Yes ☐ No ☑ *Business Associate Agreement

5) Will a signed and dated copy of the HIPAA B form be provided to the subject?

Yes ☐ No ☑ *a. Yes
Yes ☐ No ☑ *b. N/A - combined consent/HIPAA document used
Yes ☐ No ☑ *c. No - waiver of consent (or waiver of documentation of consent) precludes HIPAA authorization
Yes ☑ No ☐ *d. No - requesting HIPAA waiver

O. Data Management and Security Plan

Electronic Data

*1) Will data be stored in ELECTRONIC format? ☑ Yes ☐ No

*a. Describe the system/application(s) used for the collection, storage, and management of data:
(e.g. Access, electronic CRF, Red Cap)

Deidentified data will be stored on the PI's computer that is password protected.

2) Describe where the primary data set will be located:

Yes ☐ No ☑ *a. Secure server:
Yes ☑ No ☐ *b. Local Hard Drive:

*i. If YES, this is only allowed if the computer is encrypted. Describe protections:

Standard Denver Health work-based computer with associated isntitutional protections.

Yes ☐ No ☑ *c. Data are transmitted directly to sponsor/funder site:
Yes ☐ No ☑ *d. REDCap data storage

3) How will this data be protected?

Yes ☐ No ☑ *a. Encrypted
Yes ☐ No ☑ *b. Part 11 (FDA) compliant Note: No UCD servers are Part 11 compliant
Yes ☑ No ☐ *c. Restricted Access

*i. If restricted access, who will have access to the data?

Only the PI.

*4) Is removal of identifiable data from the department restricted? ☑ Yes ☐ No

*5) Will identifiable data be stored on a mobile device? ☐ Yes ☑ No

*6) Will additional copies of identifiable data be created? ☐ Yes ☑ No

*7) Will data be backed up? ☐ Yes ☑ No

*8) Will media used for backup be stored off-site? ☐ Yes ☑ No

*9) Will the system/application be accessible via the internet? (other than e-CRF transmission to Sponsor) ☐ Yes ☑ No

Audio Recordings, Video Tapes, Digital Videos, and Photographs

Audio Recordings

Instructions for Completing this page

*10) Will data be collected as Audio Recordings or Digital Audio? ☐ Yes ☑ No

Video Recordings

*11) Will data be collected as Video Tape or Digital Video? ☐ Yes ☑ No

Photograghs

*12) Will data be collected as Photographs or Digital Photo? ☐ Yes ☑ No

Paper Data

Instructions for Completing this page

*13) Will data be stored in paper format?

[Remember this includes consent and HIPAA documents] ☐ Yes ☑ No

Data Destruction Plan

*14) Is there a plan to destroy study data? ☑ Yes ☐ No

Yes ☑ No ☐ *a. HIPAA regulations: 7 years after IRB acknowledgement of study closure.

Yes ☐ No ☑ *b. NIH regulations: >3 years from the date the Final Financial Status Report is submitted.

Yes ☐ No ☑ *c. FDA regulations involving drugs: 2 years following the date a marketing application is approved (or per sponsor requirements which may be longer)

Yes ☐ No ☑ *d. FDA regulations involving devices: 2 years following the approval for marketing (or per sponsor requirements which may be longer)

Yes ☐ No ☑ *e. VA regulations: Cannot destroy records following closure of the study

Yes ☐ No ☑ *f. Other Agency Criteria

P. Data and Safety Monitoring Plan

Unanticipated Problems (UAPs), required monitoring and reporting

All studies have potential unanticipated problems (at minimum, breach of confidentiality is a reportable UAP). This includes any "unanticipated event" or any "unexpected adverse event that is at least probably related to the research." All UAPs must be reported in accordance with current COMIRB policy using the electronic forms available on protocol manager.

*1) Describe who will monitor for unanticipated problems of local subjects:

The PI will monitor for any breach of patient confidentiality.

*2) Confirm that all unanticipated problems will be reported to COMIRB within 5 days: ☑

Safety Monitoring

Instructions for Completing this page

3) Will the PI be responsible for ongoing review of local adverse events and serious adverse events (physical or psychological harms to subjects)?

Yes

4) To what external entities will local adverse events be reported?

Yes ☐ No ☑ *a. Sponsor

Yes ☐ No ☑ *b. Coordinating Center/Lead Site

Yes ☐ No ☑ *c. FDA

Yes ☐ No ☑ *d. None

Yes ☐ No ☑ *e. Other

*5) Will periodic review of safety and adverse events (SAE's and AE's) across all sites occur?

Yes ☑ No ☐

Click to view policy

a. If Yes, check all that apply

Yes ☑ No ☐ *i. Principal Investigator

Yes ☐ No ☑ *ii. Safety /Medical Officer

Yes ☐ No ☑ *iii. DMC (Internal Monitoring Group)

*iv. DSMB/DSMC

[A DSMB or DSMC is an external independent monitoring group compromised of at least 3 individuals who are not related to the study and have the appropriate expertise]

Yes ☐ No ☑

Yes ☐ No ☑ *v. Other

b. For Each box Checked 'Yes' above, answer the following:

*Describe Expertise:	*Review Frequency:	*Written reports:	*Report Frequency:
PI experience > 10 years.	Quarterly	☐ Yes ☑ No	

Additional Protections

*6) Will an Interim Analysis be performed? ☐ Yes ☑ No

*7) Are there any protocol/study stopping rules? ☐ Yes ☑ No

*8) Are there defined participant discontinuation criteria? ☐ Yes ☑ No

Q. Resources for Conducting the Research

COMIRB wants to ensure that the PI has the resources to conduct a safe and compliant study.

Instructions for Completing this page

*1) Are there any factors that limit the feasibility of this study? (e.g. limited populations, competing resources, other studies, etc.)

☐ Yes ☑ No

*2) Describe the facilities available for the research:

Current office and clinical facilities of Denver Health.

*3) Describe resources available to conduct the research (e.g. support staff, time, funding, etc.):

The is an unfunded, investigator initiated study.

4) What resources are available at performance sites to treat emergencies resulting from study-related procedures? (Check All that Apply)

Yes ☐ No ☑ *a. Not Applicable

Yes ☐ No ☐ *b. Basic Life Support (BLS) trained personnel

Yes ☐ No ☐ *c. Advanced Cardiac Life Support (ACLS) trained personnel and crash cart

Yes ☐ No ☐ *d. Emergency drugs/supplies to stabilize subject until emergency personnel arrive

Yes ☐ No ☐ *e. Emergency response team within facility

Yes ☐ No ☐ *f. Call 911

Yes ☐ No ☐ *g. Other:

*5) Describe process to ensure that all persons assisting with the research are adequately informed about the protocol and their related duties and functions:

The PI will coordinate any necessary education in data collection.

*6) Will other medical or psychological resources be required as a consequence of the research? (include referral plans for newly identified diagnoses, suicidal ideation, or problem behaviors [e.g., EtOH abuse])

☐ Yes ☑ No

R. Conflict of Interest

The following is based on the UCD Definition of Conflict of Interest:

*1) Have all investigators and coordinators listed on this application completed and submitted a UCD COI disclosure form to the UCD COI office?
This applies to affiliate investigators even if they have submitted a COI declaration in accordance with their institutional policy.
[The requisite form for UCD can be found at:
http://www.ucdenver.edu/academics/research/AboutUs/regcomp/Pages/Regulatory-Compliance.aspx] ☑ Yes ☐ No

*2) Are there any Conflicts of Interest issues to be disclosed for the investigators? ☐ Yes ☑ No

UCD Definition of Conflict of Interest
Conflict of Interest Management

Attachment F: Request Expedited Review

Protocol

Protocol

Protocol #: 13-0077

Burlew, Clay Cothren

PI: Full Name Burlew, Clay Cothren

Project Title:

Enteral Nutrition in the Open Abdomen

*Version Date: 15-Jan-2013

Minimal Risk:

Definition of Minimal Risk

To Qualify for expedited review, the research Must Be No More Than Minimal Risk.

Does the study involve any of the following:

*1. Research Involving Prisoners as subjects..... ☐ Yes ☑ No

*2. Research that includes genetic testing with direct or indirect identifiers..... ☐ Yes ☑ No

*3. Research involving major deception (see Attachment N: Deception)..... ☐ Yes ☑ No

Major Deception: Mislead subjects about their health status, the researchers, or the research purpose.

Minor Deception: Incomplete disclosure of some purpose of the study to avoid biasing the results.

*4. Research involving consent via proxy..... ☐ Yes ☑ No

*5. Research involving emergency waiver of consent..... ☐ Yes ☑ No

*6. Classified research involving research subjects..... ☐ Yes ☑ No

*7. Requests for non-significant risk determination for devices..... ☐ Yes ☑ No

*8, Prospectively validating greater than minimal risk medical care..... ☐ Yes ☑ No

*9. Do any of the investigators have any Conflict of Interests to be disclosed? ☐ Yes ☑ No

*10. Identification of subjects or their reponses will reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing..... ☐ Yes ☑ No

Expedited Research Categories

Instructions:

If the research does not fit any of the categories below, it must be reviewed at full board review even if it is minimal risk.

Ckeck all of the following categories that apply to this research. More than one category may be checked.

Category 1

☐ Clinical studies of drugs and medical devices only when conditions (a) OR (b) is met:

a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risk associated with the use of the product is not eligible for expedited review.)
b. Research of medical devices for which
   i. an investigational device exemption application (21 CFR Part 812) is not required; OR
   ii. the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2

☐ Collection of blood samples by finger stick, heel stick, ear stick, or venipucture as follows:

a. from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; OR
b. from other adults and children considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount may not exceed the LESSER of 50 ml or 3ml per kilogram in an 8 week period and collection may not occur more frequently than 2 times per week.

Category 3

☐ Prospective collection of biological specimens for research purposes by noninvasive means.

Examples:

a. hair and nail clippings in a nondisfiguring manner.
b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction.
c. permanent teeth if routine patient care indicates a need for extraction.
d. excreta and external secretions (including sweat).
e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or applying a dilute citric solution to the tongue.
f. placenta removed at delivery.
g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor.
h. supra- and subgingival dental plaque and calculus provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings.
j. sputum collected after saline mist nebulization.

Category 4

☐ Collection of data through noninvasive procedures (not involving general anestesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy
b. weighing or testing sensory acuity.
c. magnetic resonance imaging.
d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category 5

☑ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from HHS Regulations for the protections of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Category 6

☐ Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 7

☐ Research on individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Attachment A: Multi Site Studies

Protocol

General Information

Protocol #: 13-0077

PI: Clay Cothren Burlew, MD

Project Title:

Enteral Nutrition in the Open Abdomen

*Version Date: 15-Jan-2013

1) Sites

*a. Is this a multi-site study (one or more sites external to UCD system)? Yes

*b. How many total sites (count all UCD-affiliated sites as just one site)? 5

*c. What other external sites will be involved in this study?

Unclear how many additional sites will elect to join this prospective observational study. It is being proposed through the Western Trauma Association multi-center trials group.

2) IRB Oversight

*a. Will each non-affiliated site obtain separate IRB approval from an appropriate IRB? Yes

4) COMIRB Ceding to Another IRB

a. Is COMIRB being asked to cede to another IRB? ☐ Yes ☑ No

5) Coordinating Center

*Is UCD or one of the Affiliates acting as the coordinating center for a multi-center project? Yes

Copies of all external site IRB approvals must be submitted to COMIRB when available.

PI must maintain records of current IRB approvals from all sites.

6) Multicenter Oversight

Describe the plan for managing this multi-site study by answering the following:

*a) Who will be responsible for ensuring all IRB approvals are obtained?

Current PI

*b) What training and education plan is in place to ensure consistency across sites?

PI will individually discuss with the other institution's lead investigator.

*c) How will protocol modifications be managed across sites?

No modification in this observational study.

*d) What is the plan to disseminate information on unanticipated problems involving risks to participants or others?

Minimal risk in this observational study. If risk identified, PI will personally contact the investigators.

*e) If applicable, who will be responsible for ensuring all applicable adverse events are reported to the FDA?

N

☑ Unless Not Applicable

*f) Where will central data be stored?

De-identified data will be stored in the PI's password protected computer in her locked office.

*g) Who is centrally responsible for managing the data?

Clay Cothren Burlew, MD

*h) Will data monitoring of external sites occur? No

*i) Will biological samples from external sites be stored locally? N/A

Attachment M: Waiver of Consent Request

Protocol

COMIRB #: 13-0077

Principal Investigator:

Protocol Title:

Enteral Nutrition in the Open Abdomen

*Version Date: 15-Jan-2013

Except as provided below, written documentation of informed consent that embodies all the required elements of informed consent, as described in 45 CFR 46.116 is required for all research subjects.

A Full Waiver is not an option if the study is subject to FDA Regulations unless the study meets the exemption criteria as defined by the FDA.

With sufficient justification, the IRB may approve a consent process that does not include or alters some or all of the elements of informed consent, provided that it finds and documents specific requirements. If requesting a waver of consent, justify such in accordance with the following four criteria established under 45 CFR 46.116(d) (1-4) or 45 CFR 46.117(c) (1 or 2).

The research must involve no more than minimal risk to the subjects.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

If Subject to HIPAA regulations and requesting a full or partial waiver, you will need to complete Attachment O - Waiver or HIPAA Authorization

Type of Waiver being Requested

Select the type of waiver being requested (more than 1 may be chosen):

Yes ☑ No ☐ *Full Waiver

Yes ☐ No ☑ *Partial Waiver (screening/recruitment purposes or for deception)

Yes ☐ No ☑ *Waiver of Written Documentation (i.e., verbal consent)

A. Full or Partial Waiver:

If requesting a waiver or alteration from the requirements for obtaining informed consent, justify such in accordance with all of the criteria established under 45 CFR 46.116(d) (1-4). This is not an option if the study is subject to FDA regulation.

1. Explain why the proposed waiver poses minimal risk to the subjects:

This study involves data collection from an existing medical record. This is data collection only (observational study). There will be no patient contact, treatment, or intervention. Therefore this poses no more than minimal risk to the research subject.

2. Explain why the waiver or alteration will not adversely affect the rights and welfare of the subjects:

Personal health information will be kept in password protected files and will be separate from clinical data to ensure patient privacy is protected.

3. Explain why the research could not practicably be carried out without the waiver or alteration *(note: a survey can still provide subjects with elements of consent in writing; see postcard consent template on the COMIRB website)*:

Without this waiver the study could be compromised because of an inability to collect data on every eligible patient. This could lead to misinterpretation of the results.

4. Once subjects have completed the study, will an information sheet be given to, or other debriefing be done with, the subject?

Explain:

There will be no patient contact during or after the study.

Attachment O: HIPAA Waiver

Protocol

COMIRB #: 13-0077

Pricipal Investigator: Burlew, Clay Cothren

Protocol Title:

Enteral Nutrition in the Open Abdomen

*Version Date: 15-Jan-2013

*This request is for: Full Waiver

1) Check the protected health information (PHI) that will be collected or accessed* for this project:

*If the research includes looking at medical records or some other form of PHI, this is considered to be accessing PHI, regardless of whether this information is being recorded.

- [x] Names/Initials
- [ ] Telephone numbers
- [ ] Fax numbers
- [ ] Electronic mail addresses
- [x] All dates (except year) that are directly related to an individual (Date of birth, discharge date)*
- [ ] Social security numbers
- [x] Medical record numbers
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] URLs (http://...)
- [ ] Vehicle identifiers and serial numbers
- [ ] Certificate/license numbers
- [ ] Device identifiers and serial numbers
- [ ] Biometric identifiers (including finger and voice prints)
- [ ] Full face photographic images and any comparable images
- [ ] IP address numbers
- [ ] Geographic subdivisions smaller than a state
- [ ] Any other unique identifying number, characteristic or code

*For all subjects over 89 years, all elements of dates including year that are indicative of their age cannot be used

*2) Describe what health information will be recorded under this waiver:

Name and medical record will be recorded to creaste the patient list, and stored in a separate file from clinical data. Dates will be collected to allow for calculation of ages and post-injury date analysis.

3) Criteria to justify HIPAA waiver:

*a. Is it possible or likely that the PHI collected under this waiver will contain information that puts the subject at risk for civil or criminal liability, or that could be damaging to a subjects financial standing, employability, or reputation?

☐ Yes ☑ No

*b. Is there a plan to destroy the identifiers as soon as possible? ☑ Yes ☐ No

*i. If YES, describe:

Identifiers will be stored separately from clinical data, not used in data analysis, and destroyed following completion of analysis.

*c. Will the PHI be disclosed to parties outside of the research institution? ☐ Yes ☑ No

*4. Is there more than minimal risk to privacy? ☐ Yes ☑ No

*5. Will a signed informed consent document be obtained? ☐ Yes ☑ No

*6. Could this research be done without the HIPAA waiver? ☐ Yes ☑ No

Please explain:

Without this waiver the study could be compromised because of an inability to collect data on every eligible patient. This could lead to misinterpretation of the results.

Appendix 1

EForm Name:	Application for Protocol Review (FB/Exped)
Page:	Page 3
Section:	Section F(c): COMIRB Requested Attachments
Question:	Billing Information Form
File Name:	COMIRB-Billing-Form.docx

IRB Review Fee Billing Form

Protocol Number:_____

NOTE: Payment of the IRB Review Fee is due at time of Protocol Submission. You must complete the information below and submit one (1) IRB Review Fee Billing Form with each initial Expedited and Full Board protocol submission.

An IRB Review fee is charged for initial and annual continuing full board review and initial expedited review of non-federally sponsored research and for research awards administered by affiliated institutions. FOR THE FULL FEE POLICY AND FEE WAIVER APPLICATION, PLEASE SEE THE COMIRB WEBSITE AT http://www.ucdenver.edu/academics/research/AboutUs/comirb/Pages/COMIRBFees.aspx

1. Type of IRB Review I am Requesting (check only one):

   _____Full Board Initial Review __XX___Expedited Initial Review

   _____Full Board Continuing Review _____Expedited continuing Review, no fee.

2. Method of payment selected is based upon the Grantee Institution. YOU MUST DESIGNATE AND COMPLETE ONE OF THE FOLLOWING OPTIONS (check only one):
   - _____UCD, AMC/UCH: Provide Speed Type_____
   - _____CHC
   - _____DHHA
   - _____DVAMC
   - _____CPC and Others: Submit check payable to COMIRB with submission packet

OR, PAYMENT IS NOT INCLUDED BECAUSE:

- _____ This is a federally funded study granted to University of Colorado Denver, Anschutz Medical Center - (No Fee & No Fee Waiver Required)
- _____ Downtown Denver Campus (DDC) is the performance site – (No Fee & No Fee Waiver Required)
- __XX___ I am requesting waiver of the IRB review fee and have attached a completed COMIRB Fee Waiver/Reduction Application containing two (2) signatures for consideration for the following reason(s):
  - _____This is a Student Project Without Funding
  - ___XX__This is an investigator-initiated Study Without Funding
  - _____This is a Pilot Study Without Funding
  - _____This is a Foundation-funded study with limited funding of only $_____
  - Other_____

Note: If Billing Information is Incomplete, the Protocol Review Cannot Be Processed!

Appendix 2

EForm Name:	Application for Protocol Review (FB/Exped)
Page:	Page 3
Section:	Section F(c): COMIRB Requested Attachments
Question:	Fee Waiver Request
File Name:	fee waiver.pdf

COMIRB Fee Waiver/Reduction Application

To apply for waiver or reduction of COMIRB review charges, please submit only one copy of this form and place it in the top protocol submission packet, along with the Application for Protocol Review containing the Principal Investigator's original signature and the COMIRB Billing Information page.

Protocol Title: Enteral Nutrition in the Open Abdomen

Principal Investigator: Clay Cothren Burlew, MD COMIRB #: 13-0077

Department of origin: Denver Health, Department of Surgery

PI's Institution (choose only one): ☐ UCDA, ☐ VAMC, ☐ University Hospital, XX Denver Health Hospital, ☐ Children's Hospital Colorado, or ☐ Other _____

1. Is there a Federal Grant Application? No __XX___ or, Yes _____. If yes, complete the following:
   Grant Recipient: _____
   Grant Proposal and/or Project Number: _____
   Project period from _____ to _____
   Total Amount of Federal Grant Funding Received or Applied For or Received: _____
2. Has any Non-Federal Funding Been Applied For or Received? No __XX___ or, Yes _____. If yes, complete the following: $$Amount of Funding Applied For and/or Received: _____, Sponsor Name: _____

Brief narrative description of project (attach additional pages if needed): _____Evaluation of the impact of enteral nutrition on outcomes in trauma patients requiring an open abdomen after initial surgery.

Reason the review fee is unable to be paid and why I feel this protocol justifies fee waiver/reduction: ____This is an unfunded, investigator initiated study.

By signing below, I affirm that the information submitted for this application is complete and accurate **(2 SIGNATURES REQUIRED)**.

Principal Investigator's Signature: _____ Date: 1/17/13

Authorizing Official Signature*: _____ Date: 1/18/13

Authorizing Official Name (Printed) Arthur A. Gonzalez, Dr. P.H., FACHE
Chief Executive Officer

*Accepted Authorized signatures:

a. For SOM: Division Head
b. For SOM Department Chairs: John Moorhead, PhD, Associate Dean, Research Affairs
c. For Schools of Nursing, Pharmacy, and Dentistry: Dean's Signature
d. For Affiliate Institutions: The CEO

COMIRB Use Only:

☐Approved ☐Denied ☐ Reduced Fee to _____

Alison Lakin, AVC for Regulatory Compliance Date