COMIRB Application for Protocol Review

Section A: Submission Details

Date of Initial Submission: Oct 16, 2017 Version Date: Mar 29, 2018

Section B: Protocol Information

Protocol Number: **17-1818** PI: **Campion, Eric**

Do not enter PI name here it will be added automatically when selected in Section C below

Project Title:

A Western Trauma Association Multi-center study: Comparing End Title CO2 to Blood Gases in Operating Room

Section C: Key Study Personnel

Remove	Last Name	First Name and MI	Dept/Division	Best Contact Phone #	VA Employee	Role
PI	Campion	Eric	Denver Health - Surgery	303-602-1359	☐	Principal Investigator
X	Robinson	Caitlin	Denver Health - Surgery	303-602-1863	☐	Primary Contact

Add Another Investigator

Add 1 Investigator with the role of PI (and if PI is a student, 1 Investigator with Role of Faculty Mentor). Also add 1 Investigator with the role of Primary Contact. (Maximum of 3 investigators listed in this table). **All** Study Personnel, including any listed above, must be added on the electronic ***Personnel Form*** when the protocol is submitted to COMIRB through eRA(InfoEd).

Contact Information:

1. Is the PI a student or trainee (including resident/fellow), or doing this research to fulfill an educational requirement? ○ Yes ◉ No

2. Best contact for scientific questions?

2a. Name: Caitlin Robinson

2b. Phone (10 digit #): (303) 602-1863

Section D: Type of Review being Requested

See guidance on choosing the appropriate review type

1. Type of Review being requested:

- ☐ **Full Board**
- ☑ **Expedited** [adds Attachment F]
- ☐ **Exempt or Non-Human Subject Research (including QA/QI/Program Evaluation)**

Attachment F has been added (JUMP)

Section E: Funding

1. Do you have funding for this study? ○ Yes ◉ No ○ Pending (submitted)

Section F: Performance Sites

1. Are any of the investigators funding/directing research procedures conducted outside of the USA, or traveling outside of the USA to collect data? [adds Attachment B] ○ Yes ◉ No

Section F(a): Affiliate Performance Sites

Definition of Affiliate ⓘ

2. Indicate VA involvement in this study (must select one) **Note: 'Multi-site' means more than one local UCD-affiliated site**

☐ VA only study (if yes to any one of these criteria)	☐ Multi-site involving VA (if yes to any one, **and** no VA-only criteria met)	☑ Non-VA study
* Funding solely from the VA **OR** * All procedures performed on VA property, recruiting only at the VA, or using only VA equipment/ resources **OR** * All investigators and study personnel working solely on VA time	* Both VA and non-VA funding **OR** * Some procedures performed on VA property, some recruitment at the VA , or using some VA equipment/ resources **OR** * Some investigators and study personnel working on VA time	* No VA funding **AND** * No procedures/recruitment performed on VA property, and not using VA equipment/ resources **AND** * No investigators or study personnel working on VA time

3. Will any of the following Affiliates be utilized as sites for this research (includes data locations and investigator appointments)? ⓘ

Note: at least one of these affiliate institution must be checked 'yes.' UCD should usually be checked 'yes' due to the investigator's faculty appointment.

a. UCD (Downtown Denver Campus) ○ Yes ◉ No

b. UCD (Anschutz Medical Campus) ◉ Yes ○ No

c. University of Colorado Hospital (including the Adult CTRC or an off-campus site) ○ Yes ◉ No

d. Veteran's Administration Hospital (ECHCS) ○ Yes ◉ No

i) Are any study personnel employed/paid by the VA? ○ Yes ◉ No

e. Denver Health and Hospitals ◉ Yes ○ No

Include with this submission the SPARO Clearance Letter

f. Children's Hospital Colorado (including the Pediatric CTRC or an off-campus site) ○ Yes ◉ No

g. Colorado School of Mines ○ Yes ◉ No

Section F(b): Non-Affiliate Performance Sites

Definition of Non-Affiliate ⓘ

4. Does this study involve other Non-Affiliated Sites? ◉ Yes ○ No

This should be answered 'yes' if the study will involve any other locations other than those indicated in section F(a) above. The other sites may or may not actually be engaged in conducting the research; engagement can be clarified on Attachment A. [adds Attachment A]

Attachment A has been added (JUMP)

Section 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 question (Approximately 1 paragraph)

This will be a retrospective, multi-site study evaluating end-title CO2 in the operating room and comparing it to blood gas to determine if end-title CO2 (EtCO2) underestimates the actual plasma CO2 in patients who are severely bleeding. EtCO2 reflects the amount of CO2 in the arteries. It is important to regulate the amount of CO2 in the blood as increased or decreased concentrations can lead to additional complications and injury.
Our hypothesis is that EtCO2 readings, which are common vital signs taken during a trauma patient's hospital course, underestimate the actual plasma CO2 concentration. Therefore, it is possible that we are basing treatment practices on unreliable numbers.
Our second hypothesis is that EtCO2 readings will accurately represent blood CO2 concentration up until a critical amount of blood products have been given. We aim to determine this threshold and gradient of difference between EtCO2 and blood CO2 and number

of units of blood increases.
We will examine this hypothesis by comparing EtCO2 values to Blood Gas values (a small amount of arterial blood taken and evaluated for blood gas concentrations such as CO2, O2, pH etc) which is also routinely collected during a trauma patient's hospital course.
This is human subject research as we will be utilizing medical records to test this hypothesis. We will not be doing any interventions with these patients - only collecting data from medical records (prospecitvely) that is already being collected for treatment purposes.

2. Are there special review considerations?

a. Would you like this study reviewed by the Social/Behavioral panel (consider for Downtown Denver Campus protocols, social research, and non-treatment behavioral research)? ○ Yes ◉ No

b. Is this an Oncology or Cancer Center project? ○ Yes ◉ No

c. Are drugs or biologics that involve **human gene transfer**, or deliver recombinant DNA to subjects, included in this research? ○ Yes ◉ No

d. Does the protocol involve administration of radioactive substances to subjects (including PET scans, radiolabeled tracers, radioactive drugs, etc.)? ○ Yes ◉ No

e. Does the protocol involve research on newborn blood spot? ○ Yes ◉ No

f. Is there any research being done on fetal or embryonic tissue? ○ Yes ◉ No

Section H: Human Subjects

1. Age Range of Subjects to be enrolled: Lower Limit: **18** **Years** (inclusive) Upper Limit: **115** **Years** (inclusive)

Enrollment Numbers **Note: the number of subjects needed in #2 and #3 below should be justified in the Data Analysis section of the protocol included with your submission.**

2. Maximum number of subjects the study needs to **consent** at **all** sites (local + non-affiliated sites): **Up to** 4,000

3. a. Maximum number of **local** subjects (i.e., those enrolled at sites under COMIRB purview) that will be **consented**, including screen failures and withdrawals: **Up to** 300

b. Number of **local** subjects (i.e., those enrolled at sites under COMIRB purview) necessary to collect sufficient data to answer the research question: 300

Note: this number will typically be smaller than the number in #3a.

4. Is the enrollment limited on the basis of gender, race, or ethnicity? ○ Yes ◉ No

5. Inclusion Criteria: (Define the characteristics of the population to be included in the study - Must match protocol)

Trauma patients admitted to Denver Health & Hospital Authority who under an exploratory laparatomy (ex-lap) as a result of their trauma from 01/01/2017 - 06/31/2017.
Patients must be greater than or equal to 18 years old.

6. Exclusion Criteria: (Define the characteristics of the population(s) to be excluded, such as age < 18, Prisoners, Pregnant women, or decisionally challenged)

Patients less than 18 years old
Pregnant females
Prisoners (give that this is a retrospective study it might be difficult to determine prisoner status. We will do our best during chart review to determine if patients were prisoners at the time of the ex-lap.

Vulnerable Populations:

7. Inclusion of Vulnerable Populations (check all that apply):
These vulnerable populations **cannot** be enrolled into a study without prior IRB approval. Will any of these populations be enrolled into the study?

a. Children (under age 18)? [adds Attachment H] ○ Yes ◉ No

b. Wards of the State (children in custody of the state)? ○ Yes ◉ No

c. Neonates (Birth to 30 days)? [adds Attachment I] ○ Yes ◉ No

d. Pregnant Women or Fetuses? [adds Attachment J] ○ Yes ◉ No

i. Does this study exclude pregnant women from enrollment, **and** counsel women on avoiding pregnancy during the trial, but intend to retain or follow-up women who incidentally become pregnant during the trial? ○ Yes ◉ No

e. Prisoners or those on probation or alternative sentencing? ⓘ ○ Yes ◉ No
[adds Attachment K]

f. Decisionally Challenged (adults only)? Check yes also if populations with a high likelihood of decisional impairment will be screened for the study. [adds Attachment L] ○ Yes ◉ No

i. Cognitively impaired
ii. Incompetent to consent
iii. Proxy consent
iv. Consenting in life threatening situations

Check 'no' for #7(f) if this study involves **only** use of existing data (i.e., retrospective chart review), even if some of the subjects were decisionally challenged when the data were generated.

TARGETED Recruitment

8. Check any of the following populations that are being TARGETED for recruitment:

☐ a. Indigent/Uninsured?
☐ b. Nursing Home Residents?
☐ c. Students of PI or study staff?
☐ d. Students to be recruited in their educational setting?
☐ e. Employees directly under supervision of the PI or a Co-I?
☐ f. People engaged in illegal activities and/or illegal immigrants?
☐ g. People with Post Traumatic Stress Disorder (PTSD)?
☐ h. People with Traumatic Brain Injury (TBI)?
☐ i. Terminally Ill Patients (life expectancy < 6 mos)?
☐ j. People with mental illness or learning disabilities?
☐ k. Others vulnerable to coercion?

Section I: Procedures

1. Duration of study procedures for each subject: N/A Retrospective review

2. Anticipated time to complete all study enrollment: N/A Retrospective review

3. Are all study procedures for local site(s) accurately described in the protocol? ○ Yes ◉ No

Describe how the procedures done at local site(s) differ from those described in the protocol:

Given this projects status as a multi-center retrospective study we did not write a protocol. Additionally, the methods for identifying cases and completing chart review will differ between sites. We have included a data dictionary to ensure that the data collected is consistent across sites.

4. Does this research involve the delivery of health care, or treatment-oriented procedures? ○ Yes ◉ No

a. Is there a "usual practice" for what you are studying (e.g., educational techniques, behavioral modification)? ○ Yes ◉ No

5. Are any additional materials used with subjects (questionnaires, interview guides, informational, diaries)? **Not Applicable**

6. Indicate if any of these procedures are relevant to this study:

a. Is the administration of any drugs, biologics, supplements, or isotopes dictated by the protocol? [adds Attachment C] ○ Yes ◉ No

b. Devices (Including Mobile Medical Applications) [adds Attachment D]
   1. Does this study collect **any** data about **any** devices, **or**
   2. Use a diagnostic assay to determine eligibility? ○ Yes ◉ No

c. Will the internet be used to collect research data? (i.e. Test, Surveys, Chat Rooms, etc.) [adds Attachment G] ○ Yes ◉ No

d. Will you create a database for future recruitment? [adds Attachment P] ○ Yes ◉ No

e. Will Genetic Testing be involved with this study? [adds Attachment Q] ○ Yes ◉ No

f. Will Biological samples such as urine, sputum, or blood be collected for use in **this** study? [adds Attachment R] ○ Yes ◉ No

g. Will data and/or biological samples be stored (banked) for future unspecified research questions? [adds Attachment S] ○ Yes ◉ No

h. Are public schools/universities being used as a setting for this research? [adds Attachment T] ○ Yes ◉ No

Section J: Potentials Risks for Subjects

1. Do you view the risk of this study as minimal ? **(Note: The Committee may disagree)** ◉ Yes ○ No

a. Justify this determination:

We will not be contacting or working with these patients in any way - only their medical records since this is a retrospective review. There is no risk to the subject other than the potential risk for privacy break.

2. Describe the anticipated risk of the research: (list risks in order of likelihood and magnitude (very common, common, rare but serious))

The only potential risk is that or a break in privacy due to our review of their medical records, this would be a very unlikely event.

3. Describe the plan to minimize risk: (use procedures that are standard of care where possible)

Patient's protected health information will be stored in a separate, locked excel document on Denver Health Servers which are behind many firewalls. The only PHI that will be included in our data base is dates (of injury, procedures etc). The inclusions of dates is necessary as our hypothesis is based on the differences in numbers between EtCO2 and Blood gas readings. Timing is essential here.

4. Is it possible that the research team may uncover certain incidents (e.g., child abuse) or diseases (e.g., tuberculosis) that are reportable to state authorities through interventions/testing required by this protocol? ○ Yes ◉ No

5. Describe the Potential Benefits of this Study:

Determining if there is a significant difference between EtCO2 readings and blood gas readings will be essential in helping to enhance patient care in trauma settings. Additionally, if we establish that a gradient exists whereby EtCO2 is an accurate indicator of blood gas readings based on the amount of blood products a patient is given, it will help with resuscitation efforts in major trauma cases. Since patients are treated based off EtCO2 readings is will be essential to establish a correction between EtCO2 and blood CO2 to make sure we are not treating the patients off of false numbers. If so, then we will attempt to calculate by how much EtCO2 needs to be adjusted such that it accurately represents blood CO2. This way, our patients will be treated according to what is physiologically true.

6. Describe why the risks 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 this study:

a. To Participant:

None

b. To Society:

For trauma patients, accurate treatment of major physiological imbalances.

c. Justify the importance of the knowledge gained:

Understanding the extent to which EtCO2 can be an accurate indicator of Blood CO2 will be very important in that it will enhance our knowledge of how to best treat traumatically injured patients. Since treatment (including ventilator settings, administration of medication etc) is often based of EtCO2 values, it will be very important to determine to what extent we can base treatment off of these readings.

Section K: Recruitment Methods

1. Will subjects be recruited to this study? **No (Secondary data or sample use only)**

a. Describe how you will find the data, records, or samples of your subjects:

We will utilize our trauma registry to identify all patients that have presented to DHHA for ex-lap following trauma during 01/01/2017 -06/31/2017

Section L: Informed Consent

I. Consent Process / Consent Documentation

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 (1), answer "No" **only** if you are requesting a Full Waiver of Consent for the entire study. Otherwise, answer "Yes" and provide details of the consent process used in this study in the subsequent questions.

1. Does this study have a consent process? ○ Yes ◉ No
2. Is a Waiver of Consent or a Waiver of Documentation of Consent being Requested? ◉ Yes ○ No
   [adds Attachment M]

Consent cannot be waived if doing research on Newborn Blood Spots

a. Describe which group or portion(s) of the study the waiver pertains to:

Entire study.

Based on your your answers to above, waiver of consent and/or waiver of documentation of consent is needed. Please complete Attachment M.

Attachment M has been added (JUMP)

Section M: Privacy and Confidentiality during Study Procedures

Privacy - refers to subjects' ability to control others' access to information about 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 - refers to the investigator protecting others' access to subject information

3. Check if any of the following Personal Information attributes are being collected/stored for ***research purposes***?

- ☐ Name/Initials
- ☐ Address
- ☐ E-Mail Address
- ☐ Telephone/Fax Number
- ☐ Social Security Number (unless **only** being used for reimbursement or hospital processing)
- ☐ 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 data about an individual, group or institution be considered sensitive? ○ Yes ◉ No

Section N: HIPAA (Health Information Portability and Accessibility Act)

Learn more about HIPAA

1. Do HIPAA regulations apply to this research (i.e. covered entity accessing, using or disclosing identifiable health information [PHI])? ◉ Yes ○ No

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

- a. Treatment Relationship (i.e. for clinical purposes) ☑
- b. HIPAA (A) Authorization ☐
- c. HIPAA Waiver [adds Attachment O] ☑ Attachment O has been added (JUMP)
- d. Data Use Agreement ☐
- e. Business Associate Agreement ☐
- f. HIPAA not needed to access to health information in this study ☐

3. Will PHI be disclosed outside the covered entity? ○ Yes ◉ No
Note: study monitors reviewing study records at our study site is considered a disclosure

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

- ☐ HIPAA (B) Authorization
- ☑ Requesting HIPAA Waiver [adds Attachment O]
- ☐ Data Use Agreement (for disclosure of a limited data set only)
- ☐ Business Associate Agreement (full PHI)

Attachment O has been added (JUMP)

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

- ○ Yes; studying is using a stand-alone HIPAA B form
- ○ **N/A: Combined Consent/HIPAA Document used (*preferred method)**
- ○ No: Waiver of Consent (or Waiver of Documentation of Consent) precludes HIPAA Authorization
- ◉ No: Requesting HIPAA Waiver

Make sure that you have requested a HIPAA Waiver (#2c or #4) above

6. The HIPAA rule makes transfer of data within a study complicated. If there will be more than one transfer step of data in this study, you are strongly encouraged to include a flow diagram of the data movements in this research. Click here for a sample flow diagram.
☐ Check here if you are including a flow diagram of data movement with your submission

Section 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 storage, and management of data (e.g. MS Access, Electronic CRF, Red Cap, etc.):

Data will be stored in a locked excel spreadsheet on DHHA servers behind multiple firewalls. Patients name and MRN will be kept in a separate excel file.

   b. Describe where the primary data set will be located:

      i. Secure Server (●) Yes ( ) No

         A. Describe Server

DHHA servers, behind multiple firewalls within our PHI folder - Department of Surgery Research folder which is protected and only accessible by those within the Department of Surgery Research.

      ii. Local Hard Drive ( ) Yes (●) No

      iii. REDCap Data Storage ( ) Yes (●) No

      iv. Data are transmitted directly to sponsor/funding entity site: ( ) Yes (●) No

   c. How will these data be protected?

      i. Encrypted (●) Yes ( ) No

      ii. Restricted Access (●) Yes ( ) No

         A. If Restricted Access, who will have access to the data?

Only those listed on the COMIRB application will have access to this data.

   d. Is removal of identifiable data from the department restricted? (●) Yes ( ) No

   e. Will **identifiable** data be stored on a mobile device? ( ) Yes (●) No

   f. Will additional copies of identifiable data be created? ( ) Yes (●) No

   g. Will the system/application be accessible via the internet? ( ) Yes (●) No
   (Please check "no" for REDCap data storage and e-CRF transmission to Sponsor)

Audio/Digital Audio Recordings

2. Will any audio or visual data be collected? ( ) Yes (●) No

Paper Data

3. Will data be stored in Paper Format (**This includes Consent and HIPAA documents**)? ( ) Yes (●) No

Data Destruction Plan

4. Is there a plan to destroy study data? (if yes, select one of the subsequent choices) (●) Yes ( ) No

   a. HIPAA Regulations: 7 years after IRB acknowledgement of study closure (●) Yes ( ) No

   b. NIH Regulations: >3 years from the date the Financial Status Report is submitted ( ) Yes (●) No

   c. FDA Regulations involving **Drugs**: 2 years following the data 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: Destruction of VA research data will follow the VA ORD Records Control Schedule (RCS) 10-1, Section 7.6 , Research Investigator files, approved July 2015. ○ Yes ◉ No

f. Children's Hospital Colorado Policy: see CHCO Research Data-Ownership, Use, and Retention Policy ○ Yes ◉ No

g. Other Agency Criteria ○ Yes ◉ No

Section P: Data and Safety Monitoring Plan

Unanticipated Problems (UAP's) require monitoring and reporting

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

Click here and see #14 for UAP policy

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

Research coordinator Caitlin Robinson will monitor for UPAs.

2. **PI confirms that all unanticipated problems will be reported to COMIRB within five (5) days (this box must be checked)** ☑

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

N/A (study does not involve physical/psychological harms)

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

a. Sponsor ○ Yes ◉ No

b. Coordinator Center/Lead Site ○ Yes ◉ No

c. FDA ○ Yes ◉ No

d. None ○ Yes ◉ No

e. Other ◉ Yes ○ No

i. Describe other entity:

COMIRB

5. Will periodic global review of safety/adverse events (SAE's and AE's) occur? ⓘ ○ Yes ○ No ◉ N/A

6. Will any formal interim analyses be performed? ○ Yes ◉ No

7. Are there defined **participant** discontinuation criteria? ⓘ ○ Yes ◉ No

8. Are there any **overall protocol/study** stopping rules? ⓘ ○ Yes ◉ No

Section Q: Resources for Conducting Research

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

1. Are there any factors that limit the feasibility of this study? (e.g. limited population, competing resources, other studies, etc.) ○ Yes ◉ No

2. Describe the facilities available for the research:

For this retrospective study Denver Health has the facilities to conduct this chart review.

3. Describe the resources available to conduct the research (e.g. Support Staff, Time, Funding, etc.)

Denver Health as adequate research support staff in addition to computers in private areas suitable for chart review.

4. What resources are available at performance sites to treat emergencies resulting from study-related procedures (check all that apply)?

- [x] a. Not Applicable
- [ ] b. Basic Life Support (BLS) trained personnel
- [ ] c. Advanced Cardiac Life Support (ACLS) trained personnel and crash cart
- [ ] d. Emergency supplies to stabilize subject until emergency personnel arrive
- [ ] e. Emergency response team within facility
- [ ] f. Call 9-1-1
- [ ] g. Other

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

All persons assisting with this research will be adequately trained with COMIRB and Denver Health required trainings. Additionally, all staff will read this Application for Protocol Review and Data Dictionary Prior to starting any Data Collection.

6. Will other medical or psychological resources be required as a consequence of the research?
(Include referral plans for newly identified diagnosis, suicidal ideation or problem behaviors [e.g., EtOH abuse]. Think about possible incidental findings on any imaging studies done for research purposes only.) ○ Yes ◉ No

Section R: 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? ◉ Yes ○ No
This applies to affiliate investigators even if they have submitted a COI declaration in accordance with their home institutional policy.

2. Are there any Conflict of Interest issues to be disclosed for the investigators or key personnel **that relate to this study**? ○ Yes ◉ No

Section S: Clinical Trials Compliance

1. Clinical Trials (standard definition)

A research study in which one or more human subjects are prospectively assigned *[individually or in clusters]* to one or more interventions *[including behavioral interventions, placebo or other control]*, to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

a) Does this study meet the above definition of a clinical trial? ○ Yes ◉ No

This study is not a clinical trial and therefore does not require posting on clinicaltrials.gov. However, you may wish to optionally post this study on ct.gov. **YOU SHOULD KNOW** that many journals are now requiring that studies be registered on clinicaltrials.gov **before enrolling the first subject**, in order to be accepted for publication (see the International Committee of Medical Journal Editors notice: http://www.icmje.org/publishing_10register.html). With voluntary posting on ct.gov, be aware that:

- The FDA mandatory language about ct.gov posting should **not** appear in the consent form
- Only study methodology needs to be posted; do not post study results (very onerous process)
- Contact the Clinical Research Support Center (303.724.1111) for assistance, training, and guidance on ct.gov issues

Complete attached Fee Billing Form

A Attachment A: Multi-Site Studies

Jump Back

What is this Attachment for? ☐ show/hide

1. Sites

a. Will research procedures be performed at one or more unaffiliated sites external to the UCD System)? ◉ Yes ○ No

b. Is UCD or one of its Affiliates the lead/central site for this multi-center project? ○ Yes ◉ No

c. How many external, unaffiliated sites? 12

d. List external, unaffiliated sites that will be involved in this study [Note: if UCD is **not** the lead site and this is a large, multicenter trial (>10 sites), please enter 'Large Multi-site Protocol.'

>10 Sites 'Large Multi-center Protocol'

2. IRB Oversight

a. Will each non-affiliated site referenced in #1d obtain IRB approval from their own IRB? ◉ Yes ○ No

F Attachment F: Request for Expedited Review

Jump Back

To **Qualify** for expedited review, the research **Must be No More Than Minimal Risk:**

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is not greater than the risk of doing so as part of routine physical examination.

1. Does this project meet the definition of minimal risk? ◉ Yes ○ No

Justify this assessment:

We will not be contacting or working with these patients in any way - only their medical records since this is a retrospective review. There is no risk to the subject other than the potential risk for privacy break.

2. Does this study involve any of the following:

a. Research Involving Prisoners as subjects: ○ Yes ◉ No

b. Research that includes genetics testing with direct or indirect Identifiers: ○ Yes ◉ No

c. Research involving Major 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 results

d. Research involving consent via proxy: ○ Yes ◉ No

e. Research involving emergency waiver of consent: ○ Yes ◉ No

f. Classified Research involving human subjects: ○ Yes ◉ No

g. Requests for non-significant risk determination for devices: ○ Yes ◉ No

h. Prospectively validating greater than minimal risk health care: ○ Yes ◉ No

i. Identification of subjects or their responses will reasonably place them at risk of criminal or civil liability or be damaging to the financial standing, employability, insurability, reputation, or be stigmatizing: ○ Yes ◉ No

This Project Qualifies for Expedited Review.

Attachment F: Expedited Research Categories

Instructions:

If the research does not fit any of the categories below, it **must** be reviewed at Full Board **even** if it is minimal risk.

Check all of the following categories that apply to his 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 venipuncture 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.

a. Hair and nails clippings in a non disfiguring manner
b. deciduous teeth at time of exfoliation or if routine patient care indicates need for extraction
c. permanent teeth if routine patient care indicates need for extraction
d. excreta and external secretions (including sweat)
e. uncannulated saliva collection either in an unstimulated fashion or stimulated by chewing gumbase ow 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 anesthesia 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 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 are an invasion of the subject's privacy.
b. weighing or testing sensory acuity.
c. magnetic resonance imaging.
d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, ultrasound, electroretinography, diagnostic infrared imaging, doppler blood flow, and echocardiography.
e. moderate exercise, muscular strength testing, body composition assessement, 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 the category may be exempt from HHS Regulations for the protection 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 behavioral) 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)

☐ **§ 46.118** Protocols submitted for review under 45 CFR 46.118 (infrastructure protocols). Research protocols lacking definite plans for involvement of human subjects.

M Attachment M: Waiver of Consent Request

Jump Back

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. Consent waiver is not an option if the study is subject to FDA Regulations, except for under very select circumstances (contact COMIRB). Consent waiver is not an option if the study is performing research on newborn blood spots.

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 an alteration of consent, justify such in accordance with the criteria below established under 45 CFR 46.116(d)(1-4) [**waiver of consent**] or 45 CRF 46.117(c)(1 or 2) [**waiver of documentation of consent**].

For all waivers, the research (or procedures for which the waiver is sought) 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.

Notes on study pre-screening:

1) If you are interacting with potential subjects (phone or in person) to screen for eligibility, COMIRB does not consider verifying eligibility criteria listed on the study advertisement to be a research procedure; no waivers are required for such verification. Questioning that goes beyond such verification requires a consent process prior to questioning. Please submit the **pre-screening script** to read to potential subjects and request a waiver of *documentation of consent* using this Attachment. Please see **COMIRB's Guidance on Pre-screening**.

2) For VA research: Using the medical record to pre-screen potential subjects requires full waiver of consent (and waiver of HIPAA).

Note on HIPAA: If this study is subject to HIPAA regulations, you are using the combined consent/HIPAA document, and you are requesting a waiver of consent or waiver of documentation of consent, you will also need to complete Attachment O (Waiver of HIPAA Authorization); Attachment O can be opened by selecting the appropriate box in section N, #5.

Type of Waiver being Requested

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

- [x] **Full Waiver of consent (no consent, or consent is altered to omit certain required elements)**
- [ ] **Waiver of Written Documentation (e.g., verbal Consent, information sheet)**

Section A: Waiver or Alteration of Consent

Describe the portion of the project for which consent waiver is requested (e.g., screening phase only, deception, entire study)

Entire study.

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

1. Explain why the research (or procedures for which the waiver is sought) poses minimal risk to the subject:

We will not be contacting or working with these patients in any way - only their medical records since this is a retrospective review. There is no risk to the subject other than the potential risk for privacy break.

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

We are only collecting that has already been collected and documented as part of the patients routine care at DHHA following their trauma. Data will be kept de-identifed except in the case of dates. We will not contact the patients in any way and therefore will not adversely affect the rights & welfare of the subject - we are changing nothing, only looking at what has already been done.

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).*

Many patients have been discharged or have expired as a result of their injury. Attempt to gain informed consent from these participants would be extremely time consuming and involve the collection and storage of even more PHI (email addresses, phone numbers, next of kin information etc). It is unrealistic to get consent on these patients.

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

No - we are not working with these patients in any way, they will not be made aware that a piece of their hospital data is included in a study.

O Attachment O: HIPAA Waiver

Jump Back

1. Describe the portion of the project for which HIPAA waiver is requested (e.g., screening, entire study)

Entire study

PHI Access and Use

2. List what **health information*** will be **accessed*** under this waiver:

Age, trauma mechanism, vital signs, arterial blood gases, EtCO2 readings, fluid requirements, injuries, operations, outcomes.

*** Health information means any clinical data pertaining to health that you are recording for the research (e.g., lab results, mood diary, smoking status, procedure results)**

*** 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**

3. Check the identifiers that will be viewed with the above health information: **NONE** ☐

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

*** For all subjects over 89 years, birth year alone is considered a direct identifier**

4. Which of the above **identifiers and health information** will be **recorded** for the research (OK to say 'all of the above,' or 'none'):

Dates.
Only the above listed health information will be recorded: Dates, Age, trauma mechanism, vital signs, arterial blood gases, EtCO2 readings, fluid requirements, injuries, operations, outcomes.
It will be necessary to retain MRNs until the completion of the study in case we need to (with prior IRB approval) add a variable that will assist in the answering of this research question.

PHI Disclosure

5. Will any of the above health information be **disclosed** with any of the identifiers in #3 above to parties outside of the research institution under this waiver (i.e., without obtaining the subjects' authorization)? ○ Yes ◉ No

HIPAA Waiver Justification

6. 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 subject's financial standing, employability, or reputation? ○ Yes ◉ No

7. Will the PHI be used for any purposes other than those described in this protocol, this waiver request, or as required by law? ○ Yes ◉ No

8. Describe the plan to destroy the identifiers as soon as possible, consistent with the conduct of this research and local regulations:

All identifiable information will be destroyed upon completion of study except dates which will remain part of the dataset.

9. Will a signed informed consent document be obtained? ○ Yes ◉ No

10. Describe why this research could not be done without this HIPAA waiver:

This information will be collected from patients who have been discharged from the hospital or perhaps died as a result of their injuries. It is therefore not feasible to obtain informed consent from these patients. Additionally, it is necessary to view PHI in order to collect the necessary data (i.e. MRNs).
This entire study will be completed under waiver of consent.

Note: waiver of consent, or waiver of documentation of consent, when using the combined consent/HIPAA form is an acceptable justification.

11. Describe why this research could not be done without access to, and use of, the PHI listed above:

MRNs are necessary to identify the medical records for chart review.

IRB Review Fee Billing Form

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. Full COMIRB Fee Policy

Type of Review Requested:	**Expedited**
Funding Type:	**Unfunded**

No Payment is required