Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Study Title and Key Personnel

All items marked with a red asterisk (*) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.

1.0 ***Full Title of the Submission:**
Introducing a layperson first responder program in Cameroon

1.1 **Protocol Version Date and/or Number:**

2.0 ***Working or Lay Title:**
LFR cameroon

3.0 **Principal Investigator:**

3.1 ***Name:** Ariane Christie
If the Principal Investigator requires a PI letter of exception, you are required to obtain one. More information can be found under UCLA Policy 900.
Degree(s): If degrees are not shown here, please add them to the next section, Section 1.1a/Item 1.0, which will then update the Principal Investigator's webIRB account information.
MD

3.2 **UCLA Title:**

3.3 ***Will the Principal Investigator conduct the informed consent process with potential study participants?**

- ○ Yes
- ◉ **No**
- ○ Not Applicable

3.4 ***Is the Principal Investigator an undergraduate student, graduate student, post-doctoral fellow, or resident physician?**

○ Yes ◉ **No**

3.4.1 **If you answered "yes" to the above question, indicate the Faculty Sponsor for this study.**

The Faculty Sponsor must meet the requirements of UCLA Policy 900.

4.0 **Study Contact Person: Indicate the person, in addition to the Principal Investigator, who should receive all of the study correspondence.**
Isaac Obeng-Gyasi

5.0 **List the key personnel and study staff below.**

Note: All personnel listed below are required to complete CITI training courses (except for Fund Managers and Regulatory Coordinators). Please verify CITI training completion for all personnel prior to submitting a New Study application or Amendment application to add personnel. Verify using the Training Log tab in the application workspace (accessible by clicking the Exit button at the bottom of this page). HIPAA training is also required if personnel will be accessing protected health information.
Please make sure to have all personnel update their webIRB profile and contact information. Instructions on how to update the webIRB profile are available here.

	Name	Department	Role	Other Role (if applicable)	Will Obtain Consent?	Manage device accountability?	Access to personally identifiable info?	Access to code key?
View	Ami Hayashi	SURGERY-CHAIRMAN	Co-Investigator		no	Not Applicable	Yes	Yes
View	MULUN HUANG	OFFICE OF RESIDENTIAL LIFE (AVC)	Co-Investigator		no	Not Applicable	Yes	Yes
View	Catherine Juillard	SURGERY-GENERAL	Co-Investigator		no	Not Applicable	Yes	Yes
View	Isaac Obeng-Gyasi	SURGERY-GENERAL	Study Coordinator		no	Not Applicable	Yes	Yes
View	Rasheedat Oke	SURGERY-GENERAL	Study Coordinator		no	Not Applicable	Yes	Yes

ID: IRB#23-000420 View: NEW 1.1a - Other Personnel

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Other Personnel

All items marked with a red asterisk (*) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.

1.0 Principal Investigator

1.1 **Name:** Ariane Christie
***Please type the Degree(s):** MD

1.2 **Principal Investigator's UCLA Department:** SURGERY-GENERAL

1.3 ***Protocol's UCLA Home Department:** SURGERY-GENERAL

This response defaults to the PI's payroll department. If you wish to affiliate this protocol with another department, please select the department from the list above.

For tips on effective search, please see guidance to the right.

2.0 If there will be other types of personnel working directly under the PI's supervision on aspects of the study, provide their name, title and institution, indicate their

responsibilities, training and qualifications and complete Item 2.1.

Please also indicate, if applicable, whether that person will obtain consent, manage device accountability, have access to personally identifiable information and/or have access to the code key.

Please use a new entry to add each individual unless describing a class of individuals who rotate through the study team (see guidance area to the right).

Note: If there will not be other types of personnel go to Item 3.0.

	Name, title, institution	Study role(s): e.g., conduct interviews/surveys, recruit participants, obtain consent, review records, etc.
View	Alain Chichom-Mefore, MD, University of Buea	Professor of Surgery and main contact for University of Buea. data analysis, manuscript preparation; Will have access to personal identifiable information, obtain consent and have access to code keys.
View	Kathleen O'Connor, Co-Investigator, University of Pittsburgh	Medical student, data analysis, manuscript preparation; Will not have access to personal identifiable information and will not have access to the code key. Participating in the study with affiliation to the UCLA PASE Program.
View	Matt Driban, Co-Investigator, University of Pittsburgh	Medical student, data analysis, manuscript preparation; Will not have access to personal identifiable information and will not have access to the code key. Participating in the study with affiliation to the UCLA PASE Program.
View	PASE fellows	These are a group of individuals who are research trainees with PASE and have other institutions besides UCLA Health as their home institutions. They conduct research activities with PASE and are constantly changing. They will have access to identifiable data and may obtain consent or recruit patients.
View	Peter Delaney, Co-Investigator, University of Michigan	Medical student, data analysis, manuscript preparation; Will not have access to personal identifiable information and will not have access to the code key.
View	Zachary Eisner, Co-Investigator, University of Michigan	Medical student, data analysis, manuscript preparation; Will not have access to personal identifiable information and will not have access to the code key.

For existing protocols: Item 2.0 has been modified and this item cannot be edited. When submitting an amendment please use the information found in the text box below to complete Item 2.0 above.
Briefly describe the other study personnel.

2.1 **Indicate the human subjects research training these personnel have or will receive. If training is required in a language other than English or if research is occurring in a location where research personnel do not have access to the internet (e.g., rural community without internet capability), please describe how human subjects training requirements will be fulfilled.**

Check all that apply:

- [x] **CITI Training**
- [x] **UC HIPAA Training**
- [ ] Other

2.2 **If you indicated "Other" to item 2.1, describe:**

2.3 ***Will this study use the UCLA Health Sciences Volunteer Program to assist with the conduct of the research study?**

○ Yes ◉ **No**

3.0 ***Will any of the study procedures or analyses be contracted to a consultant or an organization?**

○ Yes ◉ **No**

3.1 **If yes, specify the consultant(s) and/or organization(s) and the work that they will do for the study.**

ID: IRB#23-000420 View: NEW 1.1b - Type of Study Review

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Type of Study Review

1.0 ***Indicate the level of risk involved with this study.**

(if there are multiple groups or phases associated with this study, select the highest level of risk.)

- (●) **Minimal risk or no known risks - Click here for the OHRPP tip sheet on minimal risk.**
- ( ) Greater than minimal risk

2.0 ***Indicate the type of review that you are requesting for this study.**

- (●) **IRB Review: Expedited or Full Board**
- ( ) Certification of Exemption from IRB Review

2.1 **If you indicated "IRB Review: Expedited or Full Board" as the type of review in item 2.0, select the IRB that you think best matches your research.**

	Name	Description
( )	Medical Institutional Review Board 1	MIRB1 reviews general and internal medicine, infectious diseases and ophthalmologic research.
( )	Medical Institutional Review Board 2	MIRB2 reviews oncology and hematology research.
( )	Medical Institutional Review Board 3	MIRB3 reviews neuroscience, neurology, psychiatric, drug abuse and dental research.
( )	North General Institutional Review Board	NGIRB reviews research from the College of Letters & Science and the Professional Schools.
(●)	**South General Institutional Review Board**	SGIRB reviews social-behavioral research from the Schools of Public Health, Nursing, and Medicine.

***Please note**: The above requests are for initial routing purposes only. The final decision as to committee assignment and type of review, rests with OHRPP and/or the IRBs.*

3.0 *Is this a COVID-19 research proposal that falls under the following scope:

a. Access to the suspected and confirmed UCLA Health COVID-19 patients.
b. Access to the electronic medical record chart or data of those patients.
c. Access to the remnant or research biospecimen collection of those patients.
d. Planning any clinical research interventional trial (drug/device) for those patients.
e. COVID Population-based studies that overlap the UCLA Health population or UCLA healthcare workers.

○ Yes
◉ No

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Conflict of Interest Information

1.0 * Does the Principal Investigator, any of the key personnel, or their spouses, registered domestic partners, or dependent children, have a financial interest in the sponsor (profit, non-for-profit) of the research?

○ Yes ◉ No

1.1 If yes, attach a completed copy of the Financial Interests Form for each person who indicates a financial or related interest:

Document Name	Document Version #
There are no items to display	

2.0 * Does the Principal Investigator, any of the key personnel, or their spouses, registered domestic partners, or dependent children, have any financial interests related to the research sponsored by a government agency?

○ Yes ◉ No

2.1 If yes, attach a completed copy of the Financial Interests Form:

Document Name	Document Version #
There are no items to display	

3.0 * Indicate whether any of these financial interests have been submitted to or reviewed by the UCLA campus Conflict of Interest Review Committee (CIRC):

○ Yes ◉ No

3.1 If you have received a response from CIRC, attach it here:

Document Name	Document Version #
There are no items to display	

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Study Locations

1.0 ***Indicate the locations where any research activities will be performed by the UCLA research team with participants and/or private information obtained.**

Check all that apply:

- [ ] a. UCLA Sites or UCLA Health System Sites (Does not include Harbor-UCLA Medical Center, Olive View-UCLA Medical Center, or Orthopaedic Institute for Children)
- [ ] b. Off Campus (in California)
- [ ] c. Outside California (in the U.S.)
- [x] **d. Outside the United States** ***See note at right**
- [ ] e. Internet

1.1 **If you selected b, c or d above, please provide your assurance that documentation of each site's permission to conduct the research at the site(s) will be obtained and maintained by the UCLA PI as applicable:**

Agree [x]

2.0 ***Is this a multi-institutional study (i.e., a collaborative project with other sites that have their own IRBs or principal investigators)?**
(Includes but not limited to UC MOU and CTSI MOU collaborations where UCLA IRB review is requested.)

(●) **Yes** ( ) No

If no, please skip directly to the next page, do not complete the questions below.
If yes, please answer items 2.1-2.3:

2.1 **Will UCLA be responsible for the overall direction of the study at the other institutions?**

(●) **Yes** ( ) No

2.1.1 **Indicate the measures that will be taken to assure regulatory compliance at each site and that the following types of information will be communicated to the other sites: study procedures; modifications to the protocol and related documents; and safety updates, interim results and other information that may impact risks to study participants.**

Check all that apply:

- [x] **Conference calls or meetings with minutes distributed to each site**
- [x] **Timely e-mail communications**
- [x] **Postings on the study website**
- [ ] Other

2.1.1.1 **If you chose "other", describe.**

2.1.2 **If you answered "yes" to item 2.1 above, please provide your assurance that the current IRB approval for each site(s) will be obtained and maintained by the UCLA PI as applicable:**

Agree [x]

2.2 **Will the UCLA principal investigator specified on this application be responsible for the data coordinating center?**
No/Not Applicable

2.3 **Indicate the anticipated total number of study participants that will be enrolled across all of the institutions.**
1175

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Other Sites and/or Collaborators – Multi-Institutional Research

Use Section 1.5/item 1.0 to list off-campus locations where research activities will be performed by the UCLA research team. If UCLA is the lead institution or responsible for the oversight of the collaborators, please also list these collaborators below.

1.0 ***List the research sites or collaborating institutions (including UC/CTSI institutions).**

	Name of Site	Site(s) Information
View	University of Buea	

Name or description of the site or collaborating institution:	University of Buea
Name of contact person and address or general location of the site or collaborating institution, as applicable:	Dr. Alain Chichom-Mefire, Buea, Cameroon
Country	Camaroon
If the research procedures at this site are greater than minimal risk, indicate the resources applicable to handle research-related emergencies.	This item is not applicable to this study
If you indicated "Other", describe:	*No Value Entered*
Indicate the activities that will be conducted by employees of this institution/entity	☑ (a)Obtain informed consent ☑ (b)Perform research procedures, or obtain identifiable information or specimens for other than commercial purposes. ☐ (c)None of the above or not applicable to this study.
If you checked (a) or (b) in response to item above, check the applicable item:	The site takes responsibility for any necessary review. The PI will maintain related documentation in the research records (e.g., IRB approval).
Please upload site-specific materials, e.g., site information sheet.	

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Project Identification Information

1.0 ***Type of Submission (Select one)**

- (●) **Research Study**
- ( ) Application for Approval of "Research Participant Pool" or recruitment database only

2.0 ***Type of Submission (Select one)**
For Amendments, do not undo the response below. Undoing the response may remove sections of the original application.

- (●) **New Submission**
- ( ) Transfer of Ongoing Research from Another Site from Investigator moving to UCLA. Please complete Item 2.1.

2.1 **If you selected "Transfer of Ongoing Research" in Item 2.0 indicate the current status of the study and a brief summary of the work to date.**

3.0 ***Who developed this study?**

Check all that apply:

- [x] **UCLA investigator**
- [x] **Investigator from another institution**
- [ ] Industry/Pharmaceutical Company
- [ ] Cooperative Group (e.g., Children's Oncology Group, AIDS Clinical Trial Group)
- [ ] Other

3.1 **If other, specify.**

4.0 **Review For and Reliance Upon External IRBs.**

***Indicate if one of the following applies to this study. (Select one)**

- (●) **None of the options apply.**
- ( ) UCLA IRB to serve as IRB of record for another institution.

5.0 ***Is this study cancer related,** including the recruitment of individuals with cancer, collection of cancer human biological samples, specimens or data, or the recruitment of individuals because they are cancer survivors or at risk of developing cancer?

( ) Yes (●) **No**

Note: If you answered "Yes", you must submit an application to the Jonsson Comprehensive Cancer Center (JCCC) Internal Scientific Peer Review Committee (ISPRC). Click here for instructions for submitting to the ISPRC. The ISPRC approval notice or letter of exemption should be attached in Section 2.1/Item 7.2 of the webIRB application.

6.0 ***Nurse Involvement:** Does this study involve any nursing time, effort, and/or resources at UCLA Health System sites, including as subjects, investigators, clinical care providers or data or specimen collectors?

○ Yes ◉ **No**

Note: If you answer "Yes", please submit an application to the Research and Innovation Council (RIC). For more information about nursing review and how to apply, click here. ***IRB approval is not contingent on RIC approval and you do not need to upload documentation of approval from the RIC into webIRB.***

7.0 ***Federal regulations (45 CFR 46.111) require scientific review before an IRB approves a study. For the majority of studies being reviewed and approved by the UCLA IRB, the IRB performs this review.**
See http://ora.research.ucla.edu/OHRPP/Documents/Policy/4/Scientific_Review.pdf for additional details.

Do you want the IRB to consider external scientific or scholarly review?
○ Yes ◉ **No**

7.1 **If yes, indicate the source of scientific or scholarly review for the study.**

Check all that apply.

- ☐ National Institutes of Health (NIH)
- ☐ The funding agency (other than NIH)
- ☐ Faculty Sponsor
- ☐ JCCC – Internal Scientific Peer Review Committee (ISPRC)
- ☐ Clinical Translational Research Center (CTRC)
- ☐ UCLA Department
- ☐ Other

7.1.1 **If you checked "other", describe.**

7.2 **Attach a copy of the scientific or scholarly review, if applicable.**

Document Name	Document Version #
There are no items to display	

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Lay Summary and Keywords

Please provide the following information about your study.

1.0 ***Provide a brief lay summary describing this study. (limit 500 words).**
Why is this project important?

- Providing medical care or first aid to injured individuals before they arrive at the hospital has been linked to reduced deaths due to injury.

- In other African countries, people who are not trained medical professionals have learned first aid skills to become "layperson first responders" (LFR)

- The purpose of a LFR is to provide basic first aid and safe transport of an injured person to the nearest hospital

- We are training LFRs in Cameroon because we think that they can provide lifesaving care to victims of injury

that they may encounter in their everyday life.

Summary of the project:

Part I

1. Researchers will conduct surveys and interviews to see what commercial drivers (taxis and mototaxis) think about LFR programs. We will ask potential first responders about their feelings about providing first aid to injured persons. The purpose of these interviews is to make sure that people are interested in the project and agree with the structure of the training.

a. People can sign up to participate in a survey or interview in multiple places. They may be contacted by the union leaders if they belong to a union to see if they want to participate. Researchers will also hold a dinner to tell drivers about the training program and to sign them up to participate in interviews. Researchers may also visit taxi stands to ask drivers if they would like to participate.

2. Healthcare providers will also be interviewed to see how they feel about victims of injury receiving care before coming to the hospital

a. Providers can sign up to participate in these surveys and/or interviews through the hospital administration where they work.

Part II

3. Drivers can sign up to be trained through their union leaders, during the introduction dinner, or at their driver stand

4. Each training is about five hours long.

a. Trainers will lead each group of drivers through a series of presentation slides and practical demonstrations of skills

b. The training covers basic first aid, including the core principles of airway, breathing, circulation, and disposition management

c. Drivers participating in the training will take a 23-question exam before the training begins and after it ends to test their comprehension

d. At training completion, drivers will receive a certificate, badge of completion, and first aid kit to keep

Part III

5. Six months after they participate in the training, first responders will be contacted to take a follow-up exam (same 23 questions) to see what information they remember

6. LFRs may also be contacted for an interview or survey to discuss their feelings about providing first aid now that they have been trained. They might also be asked whether their salary has changed since becoming a first responder

7. Healthcare professionals will also be contacted again about one year after trainings have started to see if their feelings about first aid before the hospital has changed.

2.0 ***List three to five keywords describing this study (separate the words with commas). The keywords may be used for identifying certain types of studies.**
layperson first responder training, training program evaluation, stakeholder assessment

3.0 ***Is this study conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Control and Prevention, etc.)?**

○ Yes ◉ **No**

4.0 ***Is this study regulated by the Food and Drug Administration (FDA)?**

○ Yes ◉ **No**

4.1 **If yes, check all that apply:**

- [ ] Human Drugs
- [ ] Medical Devices
- [ ] Biological Products
- [ ] Mobile Medical Applications
- [ ] Food Additives
- [ ] Color Additives
- [ ] Other

ID: IRB#23-000420 View: NEW 2.3 - Methods/Procedures - Descriptors

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Methods/Procedures - Descriptors

Note: The items listed below are not an inclusive list of methods and procedures that may be used in research studies. The list only includes items that will trigger additional questions related to the research or are needed for the review process

1.0 ***Indicate all that apply to this study.**

- [x] **Audio, Visual or Digital Recordings**
- [ ] Certificate of Confidentiality for research not supported by NIH (please see Quick Guide and Tip Sheet)
- [ ] Clinical Trial of a Drug, Biologic, Device or a Behavioral Intervention (complete item 3.0 below INSTEAD of checking this box in 1.0)
- [x] **Community Based Research**
- [ ] Controlled Substances (Schedule I or II)
- [ ] Deception or Partial Disclosure
- [ ] Devices/Diagnostics (Note: Submit all HUDs in BruinIRB)
- [ ] Drugs/Biologics/Dietary Supplements
- [ ] Genetic Analyses/Genotyping
- [ ] Human Embryonic Stem Cells and/or Induced Pluripotent Stem Cells
- [ ] Human Gene Transfer/ Recombinant DNA
- [ ] Infectious Agents
- [ ] Non-FDA approved medical equipment used with UCLA hospital patients or research participants that operate under the UCLA Hospital License.
- [ ] Radiation (Standard of Care or Investigational Use of radioactive materials, radiation producing machines or ionizing radiation)
- [ ] Substance Abuse Research (with Medication)
- [ ] Treatment in an Emergency Setting (with request to waive consent)
- [ ] **None of the above**

2.0 ***Will the study require services or resources owned/rented/operated or provided by the UCLA Health System (e.g. clinic and/or hospital visit(s), CTRC, professional medical services, clinical treatment, diagnostics, labs, medical supplies, etc.)?**

Please direct any questions about this to The Financial Coverage & Activation Team at coverageanalysis@mednet.ucla.edu.

○ Yes ◉ **No**

3.0 ***Criteria to meet the NIH definition of a Clinical Trial (check all that apply):**

- ☑ **Does the study involve human participants research?**
- ☐ Are participants prospectively assigned to an intervention? NIH defines an "intervention" as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.
- ☑ **Is the study designed to evaluate the effect of the intervention on the participants?**
- ☐ Is the effect being evaluated a health-related biomedical or behavioral outcome? NIH defines a "health-related biomedical or behavioral outcome" as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life.
- ☐ None of the above

ID: IRB#23-000420 View: NEW 6.1 - Funding and Other Study Characteristics

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Funding and Other Study Characteristics

1.0 ***Indicate the funding status for this study.**

- ◉ **Funded**
- ○ Application for funding is pending
- ○ Departmental funding / Self funding / No funding

2.0 ***Check all that apply**:

- [ ] The research will be conducted through the UCLA Clinical and Translational Research Center (CTRC)
- [ ] The study will be supported by or conducted in collaboration with the U.S. Department of Defense (DOD)
- [ ] The study will be supported by or conducted in collaboration with the U.S. Department of Energy (DOE)
- [ ] The study will be supported by or conducted in collaboration with the U.S. Department of Justice (DOJ)
- [ ] The study will be supported by or conducted in collaboration with the U.S. Department of Education (ED)
- [ ] The study will be supported by or conducted in collaboration with the U.S. Environmental Protection Agency (EPA)
- [x] **None of the above**

2.1 **If you selected DOD, DOE, DOJ, ED, and/or EPA support/collaboration, please provide your assurances that you will review the additional requirements for research supported by the relevant federal agency.**

Agree ☐

Note: Please refer to the Federally-Supported Research section of the OHRPP guidance document: Funding Considerations for Federally-Funded and Industry-Sponsored Human Research.

ID: IRB#23-000420 View: NEW 6.2 - Funding - Description

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Funding - Description

Based on the response to section 6.1/item1, this study is or will be funded. Please provide the following information.

The Office of Contract and Grant Administration (OCGA) provides the list of funding sources used by webIRB in this section. Please check your OCGA paperwork to find the correct name of the funding source(s) for this study. Identifying the right funding source is important because:

▪ webIRB will auto-populate the designated funding source name on the approval letter for the study. Many funding sources require an accurate identification of their name on the IRB approval letter before they will release funding;
▪ The Office of Research Administration uses data from webIRB to generate funding reports.

Click here for tips on how to find the funding source name in webIRB.

1.0 **Identify the funding source(s).**
If a specific funding source has ended, do not delete it, instead please click Update next to the funding entry and **revise item 1.9**.

	Funding Source	Funding Source Information
View	NIH - MISCELLANEOUS AGENCIES AND DEPARTMENTS	

Name of the Funding Source	NIH - MISCELLANEOUS AGENCIES AND DEPARTMENTS
If other, specify	*No Value Entered*
UCLA PI named on the grant, contract, subcontract or gift:	Ariane Christie
Indicate the type of award:	Grant
If other award, specify	*No Value Entered*
Indicate the Grant Title:	Implementation of a data-driven pre-hospital lay first responder program in Cameroon
Indicate the Award Number assigned by the	1K01TW012689-01

Funding Source	Funding Source Information
funding source:	
Indicate the description that applies to the source of funding named in the above item. If this is a subcontract, indicate the original source of funding:	Federal
If Other, specify	*No Value Entered*
Attach a copy of the funding proposal, subcontract, or scope of work.	**Document Name**: LFR proposal **Document Version #**: 0.01
Does the content of this IRB application differ from the activities described in the attached funding proposal, subcontract, or scope of work?	No
If yes, describe:	*No Value Entered*
Check this box to indicate that this specific funding has ended	No

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Study Design

1.0 ***Check all that apply to the study design.**

- [x] **Direct subject contact ONLY – The research activities involve direct contact with study participants (e.g., collection of data or specimens in person or via internet, phone, mail, etc.)**
- [ ] **No direct subject contact** – None of the research activities involve direct contact with study participants and include only analyses of data, records and/or human biological specimens (e.g., medical record or other record review, study of specimens left over from clinical procedures).
- [ ] **BOTH Direct subject contact AND No direct subject contact** – Some of the research activities involve direct contact with study participants and some of the research activities involve analyses of data, records and/or human specimens obtained without contact with participants.

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Audio, Visual or Digital Recordings

You indicated that this study includes recordings (audio or visual) (section 2.3/item 1.0). Please provide the following information.

1.0 ***Who will transcribe the research tapes/recordings?**

Check as many as apply:

- [x] **Members of the research team**
- [ ] Persons outside the research team

2.0 ***Is the use of recordings an optional part of the research?**

(●) **Yes** ( ) No

3.0 ***** **Will individual study participants be able to review, edit, and erase the tapes/recordings of their research participation?**

(●) **Yes** ( ) No

3.1 **If no, provide an ethical and scientific justification for NOT allowing study participants to review, edit, and erase the tapes of their research participation.**

4.0 Transcription of Research Tapes/Recordings

4.1 ***** **Type of media (Check as many as apply):**

- [ ] CD ROM
- [ ] DVD
- [x] **Digital Files**
- [ ] VHS tape
- [ ] Cassette or microcassette
- [ ] Handwritten files
- [ ] Other

4.2 ***** **Method of transmission (Check as many as apply):**

- [ ] Courier or mail with delivery confirmation
- [x] **Posted to a secure website**
- [ ] Email
- [ ] Other
- [ ] **Not Applicable**

4.3 ***** **Transcription Service (Check as many as apply):**

- [ ] Transcription service secures tapes in a secure locked area
- [ ] Transcription(s) sign confidentiality agreements
- [ ] Transmission of voice files and text files is encrypted and password protected
- [ ] Other
- [x] **Not Applicable**

4.3.1 **If you selected "other" for any/all of the above items, describe.**

Information about Study Data

This information is needed to determine how you will best protect the confidentiality of data.

1.0 ***Indicate all that apply to the study data.**

Check all that apply:

- [ ] Obtained from a medical or clinical record
- [ ] Created or collected as part of health or mental health care
- [ ] Used to make healthcare or mental healthcare decisions and/or provided to other healthcare professionals
- [ ] Research data will be entered into the participants' medical or clinical record
- [x] **None of the above**

2.0 ***Is it reasonably foreseeable that the study will collect information that State or Federal law requires to be reported to other officials (e.g., child or elder abuse), ethically requires action (e.g., suicidal ideation), or is a reportable disease?**

- ( ) Yes
- (•) **No**

2.1 **If yes, explain below and include a discussion of the reporting requirements in the consent document:**

3.0 ***Indicate if any of the following are being obtained and used without any direct contact with study participants.**

- [ ] Records (Not medical)
- [ ] Human biological specimens
- [x] **None of the Above**

4.0 *Indicate all identifiers that may be **accessed or included in the research records** for the study**:**

- [x] **Names**
- [ ] Dates
- [x] **Age (if over 89 years)**
- [ ] Postal Address
- [x] **Phone Numbers**
- [ ] Fax Numbers
- [ ] E-Mail Address
- [ ] Social Security Number
- [ ] Medical Record Number
- [ ] Health Plan Numbers
- [ ] Account Numbers
- [ ] License/Certificate Numbers
- [ ] Vehicle ID Numbers
- [ ] Device Identifiers/Serial Numbers
- [ ] Web URLS
- [ ] IP Address Numbers
- [ ] Biometric Identifiers (including finger and voice prints)
- [ ] Facial Photos/Images
- [ ] Any Other Unique Identifier (this does not include the code assigned by the investigator to identify the data)
- [ ] **None of the above**

4.1 **If social security numbers will be collected explain why they are necessary, how they will be used, how they will be protected and how long they will be retained.**

5.0 ***Select all that apply:**

- [ ] The data and/or specimens will be directly labeled with personal identifying information when acquired by the investigator for this research
- [x] **The data and/or specimens will be labeled with a code that the research team can link to personal identifying information when acquired by the investigator for this research**
- [ ] The data and/or specimens will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information when acquired by the investigator for this research
- [ ] The data are restricted use data (A term used in Social-Behavioral research. See guidance on the right.)

5.1 **Indicate how the data will be used when this study is completed.**

Check all that apply:

- [x] **Use for this study**
- [x] **Use for possible future research**
- [ ] Use to create a bank or repository at UCLA
- [ ] Add to existing repository
- [ ] Other

5.1.1 **If Other, specify:**

ID: IRB#23-000420 View: NEW 9.2a - Privacy and Confidentiality

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Privacy and Confidentiality

Important Notes:

- **Privacy is about people.** Privacy refers to a person's wish to control the access of others to themselves.
- **Confidentiality is about data.** Confidentiality refers to the researcher's plan to handle, manage, and disseminate the participant's identifiable private information.

See OHRPP Quick Guide: Protecting Privacy and Maintaining Confidentiality

1.0 ***Privacy: How will the investigator maintain privacy in the research setting(s)? (e.g., interviewing participant in a room or area where conversations cannot be overheard by others, or conducting medical procedures in an examination room, or behind a curtain in an emergency room).**

Interviews and verbally-administered surveys will be conducted in a space where conversations cannot be overheard by others.

2.0 ***Confidentiality: If the protocol will collect and maintain identifiable data, explain how the planned safeguards to maintain confidentiality of identifiable data and data security are appropriate to the degree of risk from disclosure.**

Note: Other sections of the application (e.g., Sections 9.3, 9.3a, 9.4, 9.5, and 15.3) will request specifications such as identification of persons who will have access to code keys or measures to comply with HIPAA requirements.

Paper forms and consent will be stored at the University of Buea. Deidentified data collected on digital spreadsheets will be password-protected and held on a secure server.

CTR Data
No personal identifying information from the Cameroon Trauma Registry (CTR) will be shared with the Lay First Responders(LFR) research team. Data will de-identified by the CTR research team before sharing with the LFR research team for analysis.

ID: IRB#23-000420 View: NEW 9.3 - Data Security

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Data Security

You indicated that the study team will have access to personally identifiable or coded information (Section 9.2/item 5). Please complete the following items.

1.0 ***Do you agree to follow the OHRPP Data Security in Research guidance and procedures?**

- (●) **Yes**
- ( ) I have an alternate equally effective plan (*Note: The plan must be attached to item #2.1*)

2.0 ***Do you have a data security plan for this study?** *(Note: a plan is not required for all studies; it may be recommended in some instance).*

( ) Yes (●) **No**

2.1 **If yes, attach it here:**

Document Name	Document Version #
There are no items to display	

3.0 ***Indicate all that apply to personally identifiable information or codes during conduct of the study:**

- [x] **The data and/or specimens will be coded**
- [x] **The personal identifying information will be removed and destroyed**
- [ ] Personally identifying information will be maintained with the data and/or specimens

3.1 **If you indicated that the personal identifying information will be removed or destroyed or that the data/specimens will be coded, provide the following information:**

- **The process for removing and destroying the personal identifying information or for coding the information, and**
- **Indicate who will perform the task**

During conduct of the study, Identifying sheets and audio recording will be securely kept in a locked cabinet with limited access by the principal investigator, co investigators and the study coordinator to ensure confidentiality until data is transcribed and coded. the co-investigators for the Lay first responders project will code the data and destroy identifying information by shredding all surveys and destroying all audio recording from the

participants.

CTR Data
No personal identifying information from the Cameroon Trauma Registry (CTR) will be shared with the Lay First Responders(LFR) research team. Data will de-identified by the CTR research team before sharing with the LFR research team for analysis.

4.0 ***Will coded or personally identifiable data be collected, transmitted or stored via the internet?**

(●) **Yes** ( ) No

4.1 **If yes, indicate all that apply:**

- [ ] A mechanism such as Survey Monkey, Zoomerang, or an e-mail anonymizing service will be used to strip off the IP addresses for data submitted via e-mail.
- [ ] The data will be encrypted.
- [x] **A firewall will be used to protect the research computer from unauthorized access.**
- [ ] Controlled access privileges will be used on the hardware storing the data.
- [ ] Other.

4.1.1 **If you indicated "Other", describe:**

5.0 ***Provide your assurances that if there is a data security breach for this study, the PI will notify the IRB and your department's IT Compliance Coordinator.**

Agree [x]

ID: IRB#23-000420 View: NEW 9.4 - Data Security Plan - During the Study

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Data Security Plan - During the Study

You indicated that data and/or specimens for this study will be coded (Section 9.3/item 3). Please complete the following information.

1.0 During the study indicate **how data will be stored and secured** including paper records, electronic files, audio/video tapes, specimens. Specify how the **code key** will be securely maintained, as applicable.

Check all that apply:

1.1 ***Electronic Data**

- [ ] Encryption or password protection software will be used
- [x] **Secure network server will be used to store data**
- [ ] Stand alone desktop computer will be used to store data (not connected to server/internet)
- [ ] A contracted outside vendor will store the code key. The vendor will have a business associate agreement with UCLA.
- [ ] Other
- [ ] **Not Applicable**

1.2

*Hardcopy Data, Recordings and Specimens

- [x] **Locked file cabinet or locked room with limited access by authorized personnel**
- [ ] Locked lab/refrigerator/freezer with limited access by authorized personnel
- [ ] The code key will be kept in a locked file in a locked room
- [ ] The coded data and/or specimens will be maintained in a different room
- [ ] Other
- [ ] **Not Applicable**

1.3 **If you indicated "Other" in item 1.1 or 1.2 above, describe here.**

2.0 ***By checking this box, I provide my assurance that all the person(s) who will have access to the code key have been identified in section 1.1 or section 1.1a.**

Agree [x]

ID: IRB#23-000420 View: NEW 9.5 - Data Security Plan

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Data Security Plan

You indicated that the study will have access to personally identifiable or coded information (Section 9.2/item 5). Please complete the following items:

1.0 ***After the study is completed**, indicate how the data codes and/or personal identifying information will be handled.

Check all that apply:

- [x] **All data files will be stripped of personal identifiers and/or the key to the code destroyed.**
- [ ] All specimens will be stripped of personal identifiers and/or the key to the code destroyed.
- [ ] Personal identifiers and/or codes linking the data and/or specimens to personal identifiers will be maintained for future research.
- [x] **Audio or Video recordings will be transcribed and then destroyed or modified to eliminate the possibility that study participants could be identified.**
- [ ] Photos or Images will be modified to eliminate the possibility that study participants could be identified.
- [ ] Restricted use data will be destroyed or returned to the source.

1.1 **If you indicated that personal identifiers will be maintained for future research, provide the following information:**
a) How the information will be securely handled and stored
b) assure confidentiality, and
c) who will have access to the identifiers and/or codes.

2.0 **Describe any additional steps, if any, to be taken to assure that the subjects' identities and any personal identifying information are kept confidential.**

ID: IRB#23-000420 View: NEW 9.8 - Data and/or Specimens for Possible Future Use

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Data and/or Specimens for Possible Future Use

You indicated that prospectively collected data and/or specimens would be stored for future use (Section 9.2/item 5.1). Please provide the following information.

1.0 ***Specify what information directly or indirectly linked to the subject will be provided with data and/or specimens to other investigators.**

Check all that apply:

- [ ] No subject identifiers (The data/specimens are anonymous; no one including the investigator could identify the person from whom the materials were gathered.)
- [x] **The data will be coded (A code links the data/specimens to the study participants. A key to the code exists.)**
- [ ] Personal Identifying Information
- [ ] **Not applicable, the data will not be shared outside the study team.**

2.0 **Distribution Rules: Describe the criteria used to determine the adequacy of requests to obtain data and/or specimens (e.g., the type of researchers that will be eligible to receive data):**

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Study Summary - Research Study

1.0 **Study Materials: As applicable to this study, attach the following:**

- **Protocol, Dissertation Proposal or Study Plan**
- **Preliminary Data**
- **Surveys, Questionnaires or other instruments to be used with study participants**
- **References**

Document Name	Document Version #
Cameroon Trauma Registry (CTR)	0.02
Data collection measures for all parts of the study	0.01
Drivers Survey & Focus Group Protocol	0.01
LFR training material	0.01
Provider Survey & Focus Group Protocol	0.01

2.0 ***Specific Aims: Indicate the purpose of the research, specifying the problems and/or hypotheses to be addressed.**

The study will be the implementation and evaluation of a Layperson First Responder (LFR) training amongst our current target trainees: taxi and mototaxi drivers in Limbe, Cameroon. The aims of each of the study phases are as follows:

1. stakeholder acceptability assessment with 113 Cameroonian taxi and mototaxi drivers and 50 healthcare workers : our aim is to test the hypothesis that Cameroonian taxi and mototaxi drivers, as well as healthcare providers, will rate LFR training as an acceptable intervention to improve trauma outcomes in Cameroon.

2. pilot training phase with 20 Cameroonian taxi and mototaxi drivers: our aim is to identify facilitators and barriers to implementing the LFR training at scale, and incorporate this knowledge in the full-scale LFR training phase for taxi and mototaxi drivers in Limbe, Cameroon.

3. Full-scale LFR training: we aim to train 1105 taxi and mototaxi drivers, and test the hypothesis that Cameroonian taxi and mototaxi drivers will achieve increased preparedness and motivation to care for a victim of road traffic injury immediately after the training, as compared to before the training.

4. 6 months follow up phase with Cameroonian taxi and mototaxi drivers who completed LFR training: our aim is to test the hypothesis that after 6 months, Cameroonian taxi and mototaxi drivers will still have retained increased preparedness and motivation to care for a victim of road traffic injury as compared to before the training; and to identify number of drivers who have in the 6 months interval provided first-aid care for a victim of road traffic injury.

3.0 *Background and Significance: Provide a summary of the background for this study and explain how it will contribute to existing knowledge.

For greater than minimal risk biomedical studies, include preliminary data. If necessary, attach in Item 1.0 graphs or tables used to convey information. If there no preliminary data are available, briefly indicate why this proposed study is a reasonable starting point.

Low- and middle-income countries (LMIC) bear 90% of the world's mortality burden due to injury. Prehospital care is a critical component of the survival chain following injury, but access is extremely limited in LMICs. For patients with traumatic injury, basic life support measures such as external hemorrhage control and spinal protection may be equally effective as advanced interventions in the prehospital setting.

The World Health Organization recommends that prehospital infrastructure development begin with Lay First Responder (LFR) programs. LFR programs train non-medical professionals with high exposure to injury in basic principles of trauma scene care. Such trainee populations have included mototaxi drivers, taxi drivers, police officers, and firefighters. Implementation of LFR programs may reduce 45% of all-cause mortality across LMIC.

LFR programs have been piloted in Sierra Leone, Chad, Uganda, Tanzania, Guatemala, among others. In general, these countries and other LMIC lack prospective data registries for trauma and have no infrastructure within healthcare systems for tracking prehospital care. Without clinical data to follow patient outcomes following prehospital LFR care, capacity to build a data-driven LFR curriculum is limited.

Within the existing LFR programs, the primary outcomes are improved post-training knowledge retention scores and increased customer regard for LFR-trained drivers. To estimate access to prehospital care following the implementation of a LFR program in the absence of a trauma database, researchers in Sierra Leone administered a Prehospital Emergency Trauma Care Assessment Tool (PETCAT). The PETCAT is a survey administered to trauma care providers at nearby hospitals to trainee catchment areas. It asks such providers to estimate general frequency of basic life support interventions among trauma patients at their institution. Implementation of this tool in Sierra Leone indicated an increase in prehospital care access in areas with LFR trainees.

The Cameroon Trauma Registry (CTR) is a prospective, ongoing, multisite trauma registry. Since 2015, it has collected data on over 30,000 patients across four medical centers: Laquintinie Hospital, Regional Hospital of Limbe, Catholic Hospital of Pouma, and Regional Hospital of Edea. The registry collects clinical data including demographics, injury characteristics, prehospital care, injury severity, vital signs, and clinical eventual outcomes. Like other nations in the region, Cameroon currently has extremely limited prehospital infrastructure. Analysis of CTR data from 2020 indicates that 76% of patients do not receive prehospital care. Prehospital care providers are untrained in 98% of cases and commercial vehicles constitute 67% of transports to the hospital. Recipients of prehospital care have higher severity of injury but ultimately have reduced emergency department mortality than the cohort without prehospital care. Such data indicates that layperson first responder training will increase access to prehospital care and improve outcomes such as mortality among injured patients.

The objective of this study is the implementation and evaluation of a Layperson First Responder (LFR) training amongst our current target trainees: taxi and mototaxi drivers in Limbe, Cameroon. Limbe is a long-standing CTR site with a mixed urban and rural catchment providing diverse contexts for recruiting participants and evaluating the training program. The proposed study will leverage a longstanding partnership between the University of California Los Angeles and the University of Buea in Cameroon, with curricular support from LFR international, a non-profit organization that has worked with resource-limited communities in LMIC to train first aid providers .

4.0 *Research Design and Methods: Describe in detail the design and methodology of the study.

Methodology
This study will develop and validate an LFR program for the Cameroonian context. In the development phase (Aim 1), mixed-methods data from the Cameroon Trauma Registry (CTR) and stakeholder interviews will be used to adapt an existing LFR curriculum to address Cameroonian injury patterns and care priorities. In the validation phase (Aims 2 and 3), we will use an interrupted time series design to measure rates of prehospital care, physiologic parameters and clinical outcomes of patients enrolled in the CTR before and after training commercial drivers in first aid and safe transport. We will use these data to evaluate the feasibility (Aim 2) and effectiveness (Aim 3) of LFR implementation in increasing access to quality prehospital care for trauma patients in Cameroon.

The CTR gathers prospective data on patient demographics, injury characteristics, receipt of prehospital care, clinical findings and management, disposition and outcomes on patients admitted for injuries at ten trauma hospitals in Cameroon. Each hospital has a full-time research assistant overseen by a field supervisor. Patients are followed from presentation through hospital discharge. Since July 2015, the CTR has captured information on over 25,000 patients; in 2022, data was collected on 604 patients at Limbé Regional Hospital. The purpose of the CTR is to provide the research infrastructure to support trauma process improvement, including rigorous evaluation of new program implementation. (Copy of the CTR with data elements is attached above 10.1/1.0) No personal identifying information from the Cameroon Trauma Registry (CTR) will be shared with the Lay First Responders(LFR) research team. Data will de-identified by the CTR research team before sharing with the LFR research team for analysis.

Study site: Limbé is a city in in the Southwest region of Cameroon. It was selected as the site for LFR pilot implementation testing because it has a medium population size (estimated 112,500 persons), mixed urban/rural catchment served by both motataxis and taxis in a relatively geographically isolated region and the longstanding inclusion of Limbé Regional Hospital (LHR) as a CTR site dating back to 2015.

Aim 1: Develop a Cameroon-adapted LFR program using a two-stage, mixed-methods approach We hypothesize that registry analysis and stakeholder interviews will identify targets for LFR curriculum adaptation. Our approach will be to use 1) pre-study CTR data to explore site-specific injury and care patterns and 2) semi-structured interviews to understand acceptability, perceived barriers and facilitators of the proposed intervention among commercial drivers. Summary findings will be used to adapt existing curricula to focus on local injury priorities and to develop an LFR implementation protocol tailored to the Cameroonian context. LFR adaptation is a prerequisite for assessment of feasibility and effectiveness in Aims 2 and 3. A secondary rationale for Aim 1 is to generate a reproducible adaptation protocol for scaling and export.

1a Adapt an LFR curriculum using quantitative analysis of prospective trauma registry data
To be feasible for commercial drivers, the LFR curriculum should prioritize high yield material. Specifically, it should emphasize topics which 1) affect many injured persons and 2) are likely to improve outcomes through early stabilization. To identify the appropriate training priorities for the context, we will extract injury data on all patients enrolled at the LRH site of the CTR in the 18 months immediately preceding the start of the funding period. Data extracted will include demographics, injury characteristics and severity, receipt of prehospital care, physiologic parameters including vital signs and laboratory data, physical exam findings, treatments provided, deficits in treatment, clinical outcomes and disposition through discharge. Patients who received bystander prehospital care will be identified and physiologic patterns and clinical outcomes will be compared to patients who did not receive prehospital care. Patterns of injury will be summarized and used to identify priorities for LFR curriculum adaptation.

1b Adapt an LFR program using qualitative semi-structured interviews of target stakeholders
Multiple prior LMIC have successfully utilized commercial drivers as LFR trainees24-26. However, LMIC contexts vary and nothing is known regarding Cameroonian drivers' perspectives on participation in injury response. LFR depends on trainee buy-in making it essential to understand the priorities of this target group. We will recruit 10% of the targeted driver cohort to participate in semi-structured interviews regarding LFR training. We will host five informational dinners for drivers. To maximize attendance, dinners will be held at staggered times of day within sight of commercial public pick-up and drop-off points throughout the municipality of Limbé. At each dinner, drivers will receive a 10- minute presentation on the proposed LFR pilot. Presentations will focus on recruitment, training, follow-up and the experience of driver cohorts in other LMIC24-27, 35. For understandability, presentations will be conducted by Cameroonian research assistants in English and French. Following presentation, selected drivers will be asked to participate in on-site focus groups of 10 participants (at least 2 focus groups per dinner). Interview recruitment will target maximal driver difference for variables including age, sex, vehicle type (taxi versus mototaxi), prior injury experience and baseline perception of LFR. Participating drivers will be verbally consented and receive semi-structured interviews to elicit perceived acceptability, barriers and facilitators of participating in LFR. Focus groups will take approximately 30 minutes to complete. Notably, drivers interested in participating in LFR will be asked to provide contact information for future training. Interviews will be transcribed and coded using a grounded theory approach. Critical themes will be identified and used to

develop an LFR implementation protocol for the Cameroonian context.

LFR Curriculum pre-testing: A 5.5 hour LFR training curriculum developed by LFR international 24-27 will be adapted for the Cameroonian context based on the trauma priorities identified in Aim 1a. The adapted curriculum will then be pre-tested on a cohort of 20 drivers. Verbally administered pre- and post- test knowledge and skill evaluations and Likert based acceptability surveys will be used to gauge appropriateness for the implementation pilot. Iterative cycles of modification and testing with groups of 20 drivers will be undertaken until 1) >80% of drivers achieve baseline post-test knowledge metrics and 2) median Likert scores suggesting an acceptable curriculum are achieved (median overall acceptability>3).

Aim 1 Sample Size
Aim 1a: Based on 2022 CTR enrollment at Limbé Regional Hospital, we expect to analyze baseline prehospital and injury patterns on approximately 906 hospitalized patients. Aim 1b: To maximize inclusion of variable opinions, we will target 10% of the pilot implementation driver training cohort of 1125 drivers for a total of 113 drivers to participate in focus groups.

Aim 1 Statistical Analysis plan
Aim 1a: No personal identifying information from the Cameroon Trauma Registry (CTR) will be shared with the Lay First Responders(LFR) research team. Data will de-identified by the CTR research team before sharing with the LFR research team for analysis.
Quantitative analysis of CTR data will be summarized using means and standard deviations for normally distributed variables and by medians and interquartile ranges for nonparametric variables. Patients who did and did not receive bystander prehospital care will be compared using Chi squared or Fisher's exact test (for small subgroups) for categorical variables and Kruskal-Wallis analysis for numerical variables. Associations between bystander prehospital care and patient outcomes will be tested using bivariate and multiple logistic aggression. For all analysis, alpha level of 0.05 will designate significance. Statistical analysis will be conducted in Stata1733.
Aim 1b: Qualitative interviews will be recorded, transcribed, translated into English and back translated for accuracy. Two independent members of the research team (including the PI) will perform two stage open and axial coding using a grounded theory technique using Dedoose34. As needed, thematic disagreement between coders will be reviewed and adjudicated by Dr. Dissak-Delon (qualitative mentor).

Aim 2: Evaluate feasibility of LFR program implementation in the Cameroonian context
We hypothesize that training commercial drivers as LFR providers will increase the proportion of hospitalized Cameroonian trauma patients who receive prehospital care. Our approach will be to compare the percentage of CTR patients at Limbé Regional Hospital receiving prehospital care before and after LFR implementation. Increasing prehospital care is the mechanism by which we expect to achieve our overall objective of improving timely access to trauma care in Cameroon.

Interrupted time series evaluation of an LFR intervention Using the existing CTR, we will collect prospective observational data on baseline prehospital care rates (Aim 2), physiologic parameters and key trauma outcomes (Aim 3) over an 18- month pre-intervention period. Following curriculum pre-testing, over the course of 3 months 1125 commercial drivers will undergo LFR training. Provider competence will be evaluated with skill and knowledge assessments during and six months after training. Following this 6-month training and transition period, we will collect 18 months of prospective post-intervention period data from the CTR. Data evaluated will include prehospital care rates (Aim 2), physiologic data and trauma outcomes (Aim 3)

LFR Intervention Using the pre-tested curriculum developed in Aim 1, Cameroonian senior medical students from the University of Buea will administer LFR training to a cohort of 1125 commercial drivers. All commercial taxi and mototaxi drivers working in the Limbé municipality will be eligible for LFR training. To maintain class sizes less than 30, approximately 45 trainings will be held over the course of three months. Trainees will be recruited from individuals who attended informational dinners, fliers posted at union headquarters and taxi stands, social media, text listserv announcements and communications from taxi union leaders. Verbal consent will be administered using a standard oral consent script. The training will be approximately 5.5 hours and consist of didactic lectures and hands-on simulations adapted for individuals of variable literacy levels24-27. Trainees will be evaluated by verbally administered pre- and post-knowledge assessments, practical skills assessment and a course feedback survey. Drivers not achieving minimum post-training competency will be offered supplemental training. Basic demographic and contact data will be collected for all participants. To improve attendance and optimize learning, participants will receive a meal during training. Additionally, each trainee will be provided with an LFR Identification badge, certificate of completion and LFR first aid kit containing gauze, gloves, towels, splinting materials and a tourniquet 23. Training kit materials will be locally sourced and tailored to fit the trauma priorities identified in Aim 1a. Six months after completing training, drivers will be contacted by text to take a 25-question knowledge test and a utilization survey. Meals and LFR kit restocking will be provided at follow-up.

Feasibility evaluation: We will compare CTR prehospital care rates and patterns pre- and post- implementation of LFR training. Knowledge and skill assessment scores will be evaluated to track curriculum efficacy and

knowledge retention for iterative protocol optimization and future scaling.

Aim 2 Sample Size: The World Health Organization (WHO) recommends that initial LFR programs train 0.5 to 1% of the overall catchment population22. Limbé is a mixed- urban rural settlement divided into three municipalities with a collective pool of commercial drivers that serve all three municipalities. Collaborators at the MOPH in Cameroon currently utilize a local population estimate of 112,500 persons for the included region. As the objective of the proposed research is to understand the feasibility and effectiveness of LFR training on increasing prehospital care in Cameroon, it is critical not to undertrain providers and we will target 1% of the projected 112,500 population for a total of 1125 drivers. Results from this pilot will be used to refine the recruitment target for the Cameroonian context and inform power calculations for a multi-site clinical implementation trial.

Aim 2 Statistical Analysis The primary metric of program feasibility will be percent change in the proportion of trauma patients receiving prehospital care in the post-intervention cohort compared to pre-intervention phase controls. CTR data from non-study site partner hospitals will be used to estimate time series adjustments for secular changes during the study period. Additional feasibility metrics will include: the percent change in the proportion of trauma patients who received prehospital care from commercial drivers; and the distribution of patients receiving specific prehospital interventions (including bleeding control, tourniquet placement, cervical immobilization and splinting). Comparisons between groups will be made using Chi2 or Fisher's exact test (for subgroups <10% of total n) for categorical variables and Kruskal-Wallis for numerical variables. For all statistical comparisons an alpha level of 0.05 will be considered significant. Pre- and post- training knowledge scores and six- month scores will be compared using Wilcoxon- signed rank tests.

Aim 3: Evaluate effectiveness of LFR program implementation in the Cameroonian context
We hypothesize that LFR program implementation will be associated with improved physiologic parameters on presentation and improved clinical outcomes including trauma mortality. Our approach will be to compare clinical physiologic parameters and clinical outcomes in pre-and post-implementation cohorts. This will generate a preliminary evidence base to support a future multi-site clinical implementation trial.

We will compare changes in clinical outcomes between the pre-intervention and post- intervention cohorts. Prospective observational data on clinical care outcomes will be collected during the pre-implementation and post-implementation periods using the existing CTR. Physiologic parameters will include: vital signs, primary survey exam findings and laboratory data at the time of presentation. Although in-hospital clinical care will contribute substantially to the patients' course, we will also explore associations between LFR implementation and clinical outcomes. Proportions of 24-hour and hospital mortality, complications, operations and blood transfusions will be compared between pre-implementation and post-implementation cohorts.

*Aim 3 Sample Size: Based on 2022 CTR data trends, we project 906 trauma patients will be enrolled in the 18-month pre-implementation period and 906 patients will be enrolled in the 18- month post implementation data collection period.

*Aim 3 Statistical Analysis: The primary outcome for this aim will be injury severity-stratified percentage change in the proportion of CTR patients presenting with normal vital signs in the post-intervention cohort compared to the pre- intervention cohort. Normal vital signs will be defined as heartrate between 60 and 100 beats per minute, systolic blood pressure over 100 mm Hg and respiratory rate greater than 8 and less than 20 breaths per minute. Additional physiologic measurements of interest will include overall and injury severity-stratified presentation heartrate, systolic and diastolic blood pressure, mean arterial pressure, Glasgow Coma Scale scores, percentage of patients with primary survey abnormalities and hemoglobin. Clinical outcomes of interest will include overall and injury severity-stratified percentages of 24-hour and hospital mortality, complications and care utilization including operations and blood transfusions. Highest estimated abbreviated injury scores will be used to stratify patients by injury severity. Categorical variables will be reported as percentages. Numeric variables will be reported as mean and standard deviation for normally distributed variables or median and interquartile range for non-parametric variables. Comparisons between groups will be made using Chi2 or Fisher's exact test (for subgroups <10% of total n) for categorical variables and Kruskal Wallis for numeric variables. Clinical outcomes will be adjusted for secular trends based on non-pilot CTR hospitals. Associations between LFR implementation and clinical outcomes will be explored using univariate and multiple adjusted logistic regression modeling.

Enrollment
DRIVER -- Places where an individual can sign up:
At mototaxi or taxi stand
At the introduction dinner
Through their union president
Test dates and times will be determined later with data from acceptability studies

HEALTHCARE PROFESSIONALS – Enrollment will be done by research assistants prior to administration of the acceptability survey or PETCAT. Research assistants will read each survey prompt to the provider

Driver Acceptability Surveys
Commercial taxi union leaders will be contacted first to obtain their permission to engage their drivers with this study. Union leaders and research assistants will collaborate to set up an introduction dinner to the project. At the introduction dinner, drivers will be approached by research assistants to take a survey about becoming a first responder and their thoughts about training. This survey is a Likert scale. Participants do not need to give demographic information or sign up for the trainings later in order to take the survey.

Pilot LFR Training
Full five-hour curriculum with 20 trainees to test language, flow, and comprehension
Slides adapted with permission from LFR International
Focus group afterwards with voluntary participation; research assistant asks participants about what they liked and disliked about the training. They will also be invited to propose ideas to improve the training.
Administration of Likert survey regarding attitudes towards layperson first responder training of commercial drivers and training effectiveness. These surveys will be read aloud to participants and research assistants will record responses.

Prehospital Emergency Trauma Care Assessment Tool (PETCAT)
This is a survey of healthcare professionals who provide trauma care used by LFR International to evaluate prevalence of prehospital care before and after LFR training. We will be able to track specific rates of prehospital care through the Cameroon Trauma Registry; however, other lay first-responder programs do not have similar data registries. Thus, administration of the PETCAT to healthcare providers at Laquintinie Hospital, Regional Hospital of Limbe, Catholic Hospital of Pouma, and Regional Hospital of Edea will allow later validation of the PETCAT.

Healthcare professional acceptability survey
Short Likert-scale survey designed to assess provider perceptions of layperson first responders; administered by research assistants to trauma care providers at Laquintinie Hospital, Regional Hospital of Limbe, Catholic Hospital of Pouma, and Regional Hospital of Edea.

Full LFR Training
Individuals who sign up for specific class dates will receive a call or WhatsApp message (or other acceptable mode of communication) from a research assistant the night before the training to confirm their attendance.
Curriculum may be adjusted slightly based on feedback from the pilot training, but overall, the training will still be about five hours with hands-on and didactic components.
Demographics information that will be collected include Name, Best way to contact, Age, Gender, Educational attainment, Occupation, Years of experience, Income
, religion and Marital status.
Pre-test – 23 multiple-choice questions, read aloud to those who request it in a separate room
Post-test – same 23-question test; after the five-hour training but before drivers receive certificate and first aid kit
Likert satisfaction survey as they are leaving

Follow-Up
Training participants will be contacted to return to the training site (union center or otherwise) at six months after their original training. Those who arrive to take the retention test will receive a restock of their first aid kit.
Depending on acceptability studies, retention exams may be administered virtually. This will still occur six months after initial training.
The retention test is the same questions as the previous examinations
Likert survey about training utilization and feelings about being a first responder
Healthcare providers – second PETCAT one year after training of initial trainee cohort to see if prevalence of prehospital care has changed.

Research Procedures with Minors:
The study will involve training school children in selected schools across Buea and Tiko Health Districts. The objective is to equip minors with basic life-saving skills, focusing on staying safe, seeking help, and managing life-threatening bleeding situations.

Recruitment and Consent Process:

Training Sessions:

Schedule: Training will occur on Wednesday afternoons in designated classrooms provided by each school. The sessions will be held once every four weeks to minimize disruptions to the school's regular activities. This scheduling allows the training to integrate seamlessly into the school's routine without imposing additional time or financial burdens

on the schools or participants.

Structure of Training: The program is designed to include three modules, each lasting two hours, for a total of six hours of training per school. The modules are as follows:

- **Module 1: First Aid Basics** – Introduction to basic first aid concepts and a pretest to assess initial knowledge.
- **Module 2: Safety and Emergency Response** – Training on how to stay safe and the steps to call for help during an emergency.
- **Module 3: Life-Threatening Bleeding Management** – Instruction on identifying life-threatening bleeds, stopping bleeding, and knowing when and how to refer a case to appropriate medical personnel.

Training Methodology: The sessions will be interactive, involving demonstrations, role-playing exercises, and supervised practice to ensure students comprehend and can apply the skills taught.

Post-Evaluation and Follow-Up:

- **Immediate Post-Training Assessment:** A post-test will be conducted at the end of Module 3 to evaluate each participant's understanding and retention of the material.

- **Three-Month Post-Training Evaluation:** A follow-up assessment will occur approximately three months after the final training session, aligning with the beginning of the school's second term. This evaluation will take place within the school premises and will measure the usability, effectiveness, and potential challenges encountered by the students in applying their skills. Additionally, short interviews and surveys will be conducted with teachers, school administrators, and community leaders to gauge the program's impact on both the students and the broader school community.

Setting and Location of Research Activities:

The research activities will be conducted within the premises of four selected schools in the Buea and Tiko Health Districts: GHS Bokwango, GHS Bueatown, BGS Molyko, and GTHS Molyko. Each school has agreed to provide a classroom space for the training sessions. The locations were chosen for their accessibility to the researchers, teachers, and community leaders involved, as well as the willingness of the school administration to facilitate the program.

Research Personnel:

The training and evaluation sessions will be conducted by trained facilitators who have expertise in first aid education and experience working with minors. These facilitators will be responsible for leading each module, ensuring safety during practical exercises, and conducting the pre- and post-training assessments. Additionally, research personnel will include:

- **Research Assistants:** They will support data collection activities, assist with organizing materials, and record observations during training sessions.

- **Community Leaders and School Staff:** Local community leaders and school teachers/administrators will be engaged in coordinating the schedule and logistics and may participate in focus group discussions to provide insights into the program's community impact.

Studying the willingness of community members to intervene as first responders to road traffic injuries (RTIs) in the communities along National Road 3 (N3) in Cameroon.

Research Setting/Location

The study will take place along National Road 3 (N3), a major thoroughfare connecting urban and rural areas in Cameroon. N3 is a critical transportation corridor known for a high frequency of road traffic crashes due to factors such as increasing vehicle density, poor road conditions, and lack of adequate traffic regulation. The communities selected for this study include several small towns and rural villages situated adjacent to the N3, each with distinct socioeconomic characteristics.

Health Districts Involved:

The Communities involved are located along the stretch of the N3 passing through the following health districts : Limbe, Tiko, Dibombari, Bonasama, Deido,Japoma, Edea, Pouma, Ngog-Mapubi, Mbankomo, Efoulan and Biyem-Assi .Each selected community is approached based on its proximity to areas with reported high traffic accident rates, ensuring a focus on communities significantly affected by road traffic injuries(RTI's).

Research Procedures

Overview of Research Activities
The study will employ a mixed-methods approach, integrating both quantitative and qualitative methodologies to provide a comprehensive understanding of community members' willingness to report and intervene in RTIs.

Procedures for Conducting Research Activities:

Community Engagement and Recruitment:
Community Meetings: Initial meetings will be organized in each community to introduce the research team, explain the study's purpose, and build rapport with community leaders and residents. This will also help in establishing trust and gaining community buy-in.

Informational Sessions: Informational sessions will be held to explain the importance of the study, addressing concerns and misconceptions about participation. Visual aids and translated materials will be used to enhance understanding, particularly for less literate populations.

Participant Selection:
Inclusion Criteria: Adult community members (ages 18 and above) residing in the study areas will be eligible to participate. Efforts will be made to ensure diversity in demographics, including gender, age, and socioeconomic status.

Sampling Method: A stratified random sampling method will be employed to select participants, ensuring representation across different subgroups within the communities. This will involve random selection from lists of residents compiled during community meetings.

Data Collection Procedures:
Quantitative Data Collection:
Structured Questionnaires: Trained research assistants will administer structured questionnaires to participants. These questionnaires will assess demographics, knowledge of first aid, willingness to (report road traffic crashes) RTCs, and previous experiences with emergencies.

Administration Setting: Data collection will occur in familiar settings such as community centers, schools, or health clinics, ensuring participants feel comfortable and secure.

Duration: Each questionnaire session will last approximately 20-30 minutes, allowing ample time for participants to respond thoughtfully.

Qualitative Data Collection:

In-Depth Interviews: Semi-structured interviews will be conducted with selected community leaders, healthcare workers, and active members of local organizations to gather insights into community perceptions and barriers to intervention in RTCs.

Focus Group Discussions (FGDs): FGDs will be organized with community members to facilitate discussions about perceptions of RTIs, first aid knowledge, and the community's role in response efforts. Each group will consist of 6-10 participants and will last approximately 60-90 minutes.

Recording and Transcription: All interviews and FGDs will be recorded (with participants' consent) and transcribed verbatim for analysis.

Training of Research Assistants:

Selection and Training: Local research assistants will be recruited from the communities where the study is conducted. They will undergo training that covers ethical research practices, community engagement strategies, data collection techniques, and first aid basics to ensure they can effectively communicate with participants and gather accurate data.

Cultural Competence: Training will also include sessions on cultural sensitivity and local customs to ensure respect for community values and practices.

Ethical Considerations:
Informed Consent: Participants will be provided with clear information about the study's aims and processes. Written informed consent will be obtained before participation, ensuring participants understand their rights and the voluntary nature of their involvement.

Confidentiality: Participants' data will be anonymized to protect their identities, and all collected information will be securely stored to maintain confidentiality.

Community Feedback: After data collection, the research team will organize feedback sessions to share preliminary findings with community members. This will not only validate the study results but also foster a sense of community ownership over the research outcomes.

Research Team

The research activities will be conducted by a multidisciplinary team comprising:

Principal Investigator (PI):Ariane Christie

Co-Investigators: Elvis Tanue
Research Assistants: Trained local community members who will facilitate data collection and serve as liaisons between the research team and participants.

*** Will you be providing results of any experimental tests that are performed for the study?**

- ◯ Yes - Complete Items 4.1.1 and 4.1.2
- ◯ No
- ◉ **Not Applicable**

4.1.1 **You indicated in Item 4.1 that the research involves experimental tests. Please describe the tests, provide a**

rationale for providing participants with the experimental test results and explain what, how and by whom participants and their health care provider will be told about the meaning, reliability, and applicability of the test results for health care decisions.

4.1.2 Will tests be performed by a Clinical Laboratory Improvement Amendments (CLIA) approved lab?

◯ Yes ◯ No

5.0 *Indicate how much time will be required of the subjects, per visit or contact, and in total for the study.

DRIVERS
Ten minutes for acceptability study
Thirty minutes for focus group interview if they choose to participate
Five hours of training (including demographic collection, pre- and post-training exams
Twenty minutes for follow-up test
Twenty minutes for follow-up interview
Total: 6 hr 20 min if also participating in a focus group interview, 5 hr 50 min otherwise

HEALTHCARE PROVIDERS
Ten minutes for PETCAT survey
Thirty minutes for focus group interview if they choose to participate
Total: 40 min if also participating in a focus group interview, 10 min otherwise

6.0 *Statistics and Data Analysis: Describe the proposed statistical procedures or descriptive analyses for the study. If applicable, indicate how the sample size was determined.

All survey results will be summarized using median Likert score and interquartile range for each question. Comparison of scores before and after the full-scale training will be analyzied usirng paired t-test. Statistical analysis will be performed in Stata16.

Interview transcripts from the focus groups will be independently coded by two qualitative researchers using the software Dedoose. Critical themes will be identified using a grounded theory approach and used to build a process map of LFR implementation barriers and facilitators.

Sample size determination: Limbe, Cameroon has an estimated population of 112,500 persons. The WHO recommends training approximately 0.5 - 1% of the total catchment population as LFR to establish adequate prehospital care coverage.14 Therefore, we plan to train 1125 drivers in our pilot LFR training program. In order to understand acceptability of pilot LFR training among our target population, we plan to survey 10% of the target trainee cohort (Approximately 113 taxi and motorcycle taxi drivers).

AIM 1
Sample size: Aim 1a: Based on 2022 CTR enrollment at Limbé Regional Hospital, we expect to analyze baseline prehospital and injury patterns on approximately 906 hospitalized patients. Aim 1b: To maximize inclusion of variable opinions, we will target 10% of the pilot implementation driver training cohort of 1125 drivers for a total of 113 drivers to participate in focus groups.

Statistical Analysis plan: Aim 1a: Quantitative analysis of CTR data will be summarized using means and standard deviations for normally distributed variables and by medians and interquartile ranges for nonparametric variables. Patients who did and did not receive bystander prehospital care will be compared using Chi squared or Fisher's exact test (for small subgroups) for categorical variables and Kruskal-Wallis analysis for numerical variables. Associations between bystander prehospital care and patient outcomes will be tested using bivariate and multiple logistic aggression. For all analysis, alpha level of 0.05 will designate significance. Statistical analysis will be conducted in Stata1733. Aim 1b: Qualitative interviews will be recorded, transcribed, translated

into English and back translated for accuracy. Two independent members of the research team (including the PI) will perform two stage open and axial coding using a grounded theory technique using Dedoose34. As needed, thematic disagreement between coders will be reviewed and adjudicated by Dr. Dissak-Delon (qualitative mentor).

AIM 2
Sample size: The World Health Organization (WHO) recommends that initial LFR programs train 0.5 to 1% of the overall catchment population22. Limbé is a mixed- urban rural settlement divided into three municipalities with a collective pool of commercial drivers that serve all three municipalities. Collaborators at the MOPH in Cameroon currently utilize a local population estimate of 112,500 persons for the included region. As the objective of the proposed research is to understand the feasibility and effectiveness of LFR training on increasing prehospital care in Cameroon, it is critical not to undertrain providers and we will target 1% of the projected 112,500 population for a total of 1125 drivers. Results from this pilot will be used to refine the recruitment target for the Cameroonian context and inform power calculations for a multi-site clinical implementation trial.

Statistical analysis: The primary metric of program feasibility will be percent change in the proportion of trauma patients receiving prehospital care in the post-intervention cohort compared to pre-intervention phase controls. CTR data from non-study site partner hospitals will be used to estimate time series adjustments for secular changes during the study period. Additional feasibility metrics will include: the percent change in the proportion of trauma patients who received prehospital care from commercial drivers; and the distribution of patients receiving specific prehospital interventions (including bleeding control, tourniquet placement, cervical immobilization and splinting). Comparisons between groups will be made using Chi2 or Fisher's exact test (for subgroups <10% of total n) for categorical variables and Kruskal-Wallis for numerical variables. For all statistical comparisons an alpha level of 0.05 will be considered significant. Pre- and post- training knowledge scores and six- month scores will be compared using Wilcoxon- signed rank tests.

AIM 3
Sample size: Based on 2022 CTR data trends, we project 906 trauma patients will be enrolled in the 18- month pre-implementation period and 906 patients will be enrolled in the 18- month post implementation data collection period.

Statistical analysis: The primary outcome for this aim will be injury severity-stratified percentage change in the proportion of CTR patients presenting with normal vital signs in the post-intervention cohort compared to the pre-intervention cohort. Normal vital signs will be defined as heartrate between 60 and 100 beats per minute, systolic blood pressure over 100 mm Hg and respiratory rate greater than 8 and less than 20 breaths per minute. Additional physiologic measurements of interest will include overall and injury severity-stratified presentation heartrate, systolic and diastolic blood pressure, mean arterial pressure, Glasgow Coma Scale scores, percentage of patients with primary survey abnormalities and hemoglobin. Clinical outcomes of interest will include overall and injury severity-stratified percentages of 24-hour and hospital mortality, complications and care utilization including operations and blood transfusions. Highest estimated abbreviated injury scores will be used to stratify patients by injury severity. Categorical variables will be reported as percentages. Numeric variables will be reported as mean and standard deviation for normally distributed variables or median and interquartile range for non-parametric variables. Comparisons between groups will be made using Chi2 or Fisher's exact test (for subgroups <10% of total n) for categorical variables and Kruskal Wallis for numeric variables. Clinical outcomes will be adjusted for secular trends based on non-pilot CTR hospitals. Associations between LFR implementation and clinical outcomes will be explored using univariate and multiple adjusted logistic regression modeling.

Characteristics of the Study Population

1.0 ***Is this an observational or ethnographic study for which the number of participants observed or interviewed cannot be determined in advance.**

Yes **No**

2.0 **If you answered "no" to item 1.0, indicate the maximum number of study participants you hope to enroll:**

1175

3.0 **How many participants do you expect you will need to recruit, consent and/or screen to meet the target number above?**

1250

4.0 ***Indicate the specific inclusion criteria for enrollment of each of the groups of research participants in this study.**
If there are any inclusion criteria based on *gender, pregnancy/childbearing potential, race, ethnicity or language spoken*, explain the nature of and scientific rationale for the inclusions.

Inclusion Criteria(Driver Cohort)
Over age of 18
Member of mototaxi or taxi union
English or pidgin-speaking

Inclusion Criteria (N3 Communities):
Individuals aged 18 and above
Residents who have lived in the communities for at least 6 months

Inclusion Criteria (School Children):
Form 1 students aged 10-14 years in four government schools in Tiko and Buea
Stakeholders, including principals, community leaders, and parents, involved with these four government schools in Tiko and Buea

5.0 ***Indicate the specific exclusion criteria for each of the groups of research participants in this study.**
If there are any exclusion criteria based on *gender, pregnancy/childbearing potential, race, ethnicity or language spoken*, explain the nature of and scientific rationale for the exclusions.

Exclusion Criteria (Driver Cohort)
under age of 18

Exclusion Criteria (N3 Communities)
Individuals unable to understand the questionnaire due to ill-health

Exclusion Criteria (School Children)
Any child who is not in forms 1 to 3 in the selected schools and who is not sampled.
Any child whose parents do not ascent for them to be part of the study.
All stakeholders who do not consent to the study.

6.0 ***How (chart review, additional tests/exams for study purposes, etc.), when and by whom will eligibility be determined?**

Eligibility will be determined at the time of participant recruitment with a brief verbal confirmation of their meeting of inclusion criteria.

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Characteristics of Study Population

1.0 ***Indicate the age range of the study participants.**

Check all that apply:

- [ ] 0 to 6 years
- [ ] 7 to 11 years
- [ ] 12 to 17 years
- [ ] 17 or younger **in California** who can consent for themselves - see note below
- [ ] 17 or younger **outside California** who can consent for themselves - see note below
- [x] **18 years or older**

NOTE:

- For additional information on minors **in California** who are permitted to consent for themselves please refer to the section "Legal Exceptions Permitting Certain Minors to Consent" in the OHRPP Guidance document, Child Assent and Permission by Parents or Guardians

- For additional information on minors **outside of California** who are permitted to consent for themselves please refer to the section "Exceptions Outside of California" in the OHRPP Guidance document, Child Assent and Permission by Parents or Guardians

2.0 ***Indicate if any of the following populations/specimens will be specifically recruited/obtained for the study.**

- [x] **Adults who are competent to give informed consent**
- [ ] Adults unable to give informed consent
- [ ] Adults with diminished capacity to consent
- [ ] Fetal Tissue
- [ ] Neonates
- [ ] Participants Unable to Read, Speak, or understand English
- [ ] Pregnant Women/Fetuses
- [ ] Prisoners
- [ ] UCLA Faculty/Staff
- [ ] UCLA Students
- [ ] Wards
- [ ] **Unknown/Not Applicable**

3.0 ***Is it possible that there may be non-English speakers enrolled in this study or children whose parents are non-English speaking?**

○ Yes ◉ **No**

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Risks & Benefits

Benefits

1.0 ***Are there any potential direct benefits (physical, psychological, social or other) to study participants?**

◉ **Yes** ○ No

1.1 **If yes, describe.**
Through the Layperson First Responder (LFR) program, participants will learn skills essential in providing first-aid to victims of road traffic accidents as well as other acute traumatic injuries. This skill could additionally help participants expand credentials as taxi and moto taxi drivers among their customers and their community.

2.0 ***Describe the potential benefits to society including the importance of the knowledge to be gained.**
We expect the successful completion of this project to have high potential of increasing rates of prehospital care for trauma patients and improving trauma outcomes in Cameroon.

Risks

3.0 ***Indicate the potential risks/discomforts, if any, associated with each intervention or research procedure.**

Additionally discuss any measures that will be taken to minimize risks. If data are available, estimate (a) the probability that a given harm may occur, (b) its severity, and (c) its potential reversibility. The information provided should be reflected in risks section of the informed consent documents.

If this is an exempt study and there are no risks, indicate N/A. Otherwise, please see the help text.

There is potential discomfort that is caused by a participant disclosing their personal information. To minimize such discomfort, verbally-administered surveys and interviews will take place in a private space. Additionally, detailed explanations will be given to participants about data confidentiality and participant's rights in the consent process.

Risk/Benefit Analysis

4.0 ***RISKS/BENEFIT ANALYSIS: Indicate how the *risks to the participants are reasonable in relation to anticipated benefits*, if any, to participants and the importance of the knowledge that may reasonably be expected to result from the study:**

The discomfort that the study might cause participant is minimal and can be further minimized as mentioned above. Therefore, the risk of discomfort is outweighed by the benefits of the study in implementing a potentially life-saving program and expanding public health knowledge.

Alternatives

5.0 ***Indicate the alternatives to participating in this study.**

Check all that apply.

- [x] **All types of studies - Choose not to participate in the study**
- [ ] Clinical/Intervention Studies - Receive standard of care instead of participating in the study
- [ ] Clinical/Intervention Studies - Medication, device, or other treatment is available off study
- [ ] Item is Not Applicable (e.g., study of existing data)
- [ ] Other

5.1 **If "other" was selected, specify.**

5.2 **If this is a clinical/intervention study:**

Describe the standard of care or activities at UCLA (or study site) that are available to prospective participants who do not enroll in this study. If not applicable to your study, state not applicable (N/A).

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Data & Safety Monitoring Plan

1.0 ***Is a Data and Safety Monitoring Plan (DSMP) required by the funding agency or other entity?**

○ Yes ◉ **No**

ID: IRB#23-000420 View: NEW 16.1 - Payment, Costs, and Injury

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Payment, Costs, and Injury

1.0 ***Indicate what the participants will receive for their participation in the study.**

Check all that apply.

- ☑ **No payment will be provided**
- ☐ University check
- ☐ Course Credit
- ☐ Cash
- ☐ Gift Cards/Bruincard Deposit
- ☐ Non-Monetary Gifts or Services
- ☐ Other (including vouchers for parking)

1.1 **If you selected Non-Monetary Gifts or Services or Other, describe:**

1.2 **If you selected *Cash* and/or *Gift Cards/Bruincard Deposit* please specify the estimated total amount of money you will require to pay all participants during the length of the entire study. This information is required by UCLA Business and Finance Services (BFS), the office that will provide the cash/gift cards for payment.**

2.0 **If study participants will receive financial or other payment for their participation in the study, please provide the following information:**

- If applicable, the amount each participant will receive and the payment schedule to be followed including whether partial payment will be provided when the participant does not complete the study.
- If there are different plans for different populations or sub-studies, specify the groups and describe the plans.
- If families or children will be involved in the research, clarify how the payments, items or services will be apportioned.

3.0 ***Will subjects** incur **any financial obligations from participation in the study?**

○ Yes ◉ **No**

3.1 **If yes, describe:**

4.0 ***Indicate below that you are familiar with UCLA policy related to treatment and compensation for injury and that you will use in the consent form for this study the appropriate UC required statement describing "Treatment and Compensation for Injury." Click here to access the UCLA policy: Treatment and Compensation for Research Related Injury.**

Note: Select **Not Applicable** if study is minimal risk.

- (●) **Agree**
- ( ) Not Applicable

ID: IRB#23-000420 View: NEW 18.1 - Identification/Recruitment Methods

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Identification/Recruitment Methods

1.0 ***How will you identify and/or recruit participants for this study.**

Check all that apply:

- [x] **Advertisements/Flyers/Information Sheet/Internet Postings**
- [x] **Direct recruitment of potential study participants (e.g., physicians talking with their own or clinic patients about the study, contact between the study team and potential subjects in person, on the phone or on the internet, etc.)**
- [ ] Random or Other Probability Sampling
- [ ] Recruitment Letters/Emails
- [x] **Referrals (e.g., referrals from non-investigator healthcare providers, snowball sampling, participants referring other participants, etc.)**
- [ ] Review of medical records to identify potential research participants
- [ ] Review of publicly available records
- [ ] Review of other records
- [ ] Participant pool for which potential research participants have given permission for future contact
- [ ] Potential Study Participants are identified from another IRB approved study or IRB approved screening protocol
- [ ] Other

ID: IRB#23-000420 View: NEW 18.2 - Recruitment Methods

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Recruitment Methods

1.0 **Please upload copies of your recruitment materials below. This includes advertisements, flyers, internet postings, recruitment scripts and letters/emails.**

Document Name	Document Version #
flyer for drivers	0.01
flyer for healthcare providers	0.01
Information Sheet for N3 community members	
Information Notice for School Children and parents	

Ads/Flyers/Info Sheets/Internet Postings

2.0 If you have indicated that study participants will be recruited with advertisements/flyers (Section 18.1/Item 1.0), please indicate the type of media that will be used (e.g., newspaper, radio, internet, etc.) and/or where information will be posted or distributed.

flyers for healthcare providers will be directly distributed by research assistants that are employees of the Cameroon Trauma Registry to healthcare professionals in the hospitals they work in

flyers for drivers will be distributed by moto taxi and taxi union leaders, who we have partnered with, to moto taxi and taxi drivers. The flyers will also be posted at mototaxi stands and at union headquarters if applicable (with permission of partners at union).

Information Sheet for N3 Community members. This will be used to inform and educate the N3 community members of the program

Information Notice for School Children and parents. This will be used to inform and educate the school children and parents

Direct Recruitment

3.0 If you have indicated that participants will be recruited through direct contact (Section 18.1/Item 1.0), please provide the following information:

- A description of how, when, and where initial contact would be made (e.g. in a public setting, in a waiting room, via a phone call, via a letter, via the internet, etc.)
- If applicable to the study, indicate how the potential research participant's privacy will be maintained.
- Who will make the contact (e.g. the investigator, a patient's physician, etc.)

Direct contact will be for recruiting healthcare providers only:

Research assistants employed by our program and who work at different hospitals in Cameroon will contact hospital officials to set up an appropriate time to speak with any trauma care providers willing to participate. This includes doctors, nurses, and technicians who care for injured patients in the emergency room.
Providers will be contacted at four hospitals: Laquintinie Hospital, Regional Hospital of Limbe, Catholic Hospital of Pouma, and Regional Hospital of Edea

Recruitment for N3 communities
Community Engagement and Recruitment:
Community Meetings: Initial meetings will be organized in each community to introduce the research team, explain the study's purpose, and build rapport with community leaders and residents. This will also help in establishing trust and gaining community buy-in.

Informational Sessions: Informational sessions will be held to explain the importance of the study, addressing concerns and misconceptions about participation. Visual aids and translated materials will be used to enhance understanding, particularly for less literate populations.

Participant Selection:
Inclusion Criteria: Adult community members (ages 18 and above) residing in the study areas will be eligible to participate. Efforts will be made to ensure diversity in demographics, including gender, age, and socioeconomic status.

Sampling Method: A stratified random sampling method will be employed to select participants, ensuring representation across different subgroups within the communities. This will involve random selection from lists of residents compiled during community meetings

Recruitment of School children
School children will be recruited for the study by distributing assent and parental permission forms through the students. Each child will take home a form that parents or guardians can read and sign to indicate their consent for their child's participation. The signed permission forms will then be returned to the school the following day, ensuring that parents are well-informed about the study. The recruitment will involve three Health Areas (HAs) within Buea and Tiko Health Districts, with students selected from state secondary schools to ensure a diverse and representative sample. We aim to balance the total number of children in the

intervention and control groups, with each group comprising 70 students from various schools. Additionally, qualitative interviews will be conducted with selected individuals such as teachers and school administrators to gather insights on the training program's impact. This approach emphasizes parental involvement and consent while prioritizing the well-being of the children involved.

3.1 If you will be directly recruiting potential participants who are your patients, students, laboratory workers or any others with whom you have a relationship of authority or unequal power, describe what measures you will put in place to avoid those approached from feeling pressured or unduly influenced to participate in the study.

Recruitment Letters/Emails

4.0 If you have indicated that recruitment letters will be distributed to participants (Section 18.1/item 1.0), please indicate who will send out the recruitment letter (i.e. will it be the investigator or other persons who have authorized access to the information), how inquiries will be handled, and if there will be follow-up contacts.

Referrals

5.0 If you have indicated that study participants will be identified from referrals (Section 18.1/item 1.0), please indicate the source of the referral (e.g., friends, other participants, healthcare providers) and how the referral will be elicited.

We will work with taxi and mototaxi drivers unions, which are our established partners, to recruit participants through the Ministry of Territorial Administration. We will provide study information and eligibility criteria directly to leaders of the drivers unions, who will then report to us names and contacts of drivers interested in participating in the study. Included in the study information will be methods to contact the research team should potential participants have any questions.

Research Participant Pools/Recruitment Databases

6.0 If you have indicated that subjects will be identified and recruited from a subject pool(s) or recruitment database, (Section 18.1/item 1.0), please indicate the name of the Pool or Recruitment Database and UCLA

Department. If the Pool or Recruitment Database is not at UCLA, identify the location.

ID: IRB#23-000420 View: NEW 19.1 - Eligibility Screening

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Eligibility Screening

1.0 ***Will you be conducting a preliminary assessment with potential research participants to determine study eligibility during the recruitment process?**

(●) **Yes** ( ) No

You indicated that eligibility screening will be conducted during the recruitment process (Section 19.1/item 1.0). Please provide the following information.

2.0 ***Will private identifiable information be collected during the screening?**

( ) Yes (●) **No**

2.1 **If private identifiable information is collected during screening, are there plans to retain data from participants found to be ineligible for the study?**

( ) Yes ( ) No

2.2 **If private identifiable data will be collected during the screening, indicate your plans for retaining the data.**

- [ ] The data will be retained with identifiers
- [ ] The data will be retained without identifiers
- [ ] The data will be destroyed

2.2.1 **If you chose more than one response above, explain.**

3.0 **Describe how screening will be performed.**

Research assistants affiliated with the Cameroon trauma Registry will ask participants their age to confirm that they are over 18yr, and will be asked to provide identifications that they are a motor taxis driver.

4.0 **Attach screening script(s), if applicable.**

Document Name	Document Version #
There are no items to display	

ID: IRB#23-000420 View: NEW 20.1 - Informed Consent Process

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Informed Consent Process

You indicated that adults (and/or minors who are permitted to consent for themselves) are participating in the study (Section 11.2/item 1.0 or Section 12.2/item 1.0).

For additional information on minors who are permitted to consent for themselves please refer to the section "Legal Exceptions Permitting Certain Minors to Consent" in the OHRPP Guidance document, Child Assent and Permission by Parents or Guardians.

1.0 ***Indicate your plans for obtaining informed consent for this study.**

Check all that apply:

- [ ] **Signed consent** will be obtained from the research participant or Legally Authorized Representative.
  - Signed consent means research participants will be asked to **sign and date** a written consent form.
- [x] **A waiver of signed consent is requested for the entire study. One of the following procedures will be conducted:**
  - **A written information sheet will be used. Signed consent will not be obtained from research participants.**
  - **Oral consent will be obtained from the research participant or Legally Authorized Representative (LAR)**
  - **This option should be selected if the study involves consenting participants via the internet.**
- [ ] A **waiver of consent** is being requested.
  - Research participants will **not** be asked to sign a consent form or give oral consent
- [ ] Consent will be obtained by a collaborating institution.

1.1 **- If you checked more than one plan above, list the study groups and the plan that you will use for each.**
- If you checked "Consent will be obtained by a collaborating institution", explain the consent process and upload a copy of the most recent approved consent document in item 1.2.

A waiver of signed consent requested for Taxi Drivers and Moto Taxi drivers, Healthcare providers for the qualitative interviews and Lay First Responders training.

1.2 **If applicable, attach the consent document(s) from collaborating institution(s).**

Document Name	Document Version #
There are no items to display	

ID: IRB#23-000420 View: NEW 20.2 - Waiver of Signed Informed Consent (Consent Without a Signature)

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Waiver of Signed Informed Consent (Consent Without a Signature)

You indicated that you are obtaining oral consent for the study (Section 20.1/item 1). Please provide the following information.

1.0 ***Indicate the reason that you are requesting to conduct an oral consent process instead of obtaining signed consent.**

- (●) **The research is minimal risk and does not involve any procedures for which written consent is normally required outside the research setting (e.g., in everyday life written consent is not needed for minimal risk surveys, non-invasive health measurements, etc.) (45 CFR 46.117)**
- ( ) The only record linking the participants and the research would be the consent document, and the main risk of research would be a breach of confidentiality (45 CFR 46.117).

e.g., Participants could suffer from social stigma, embarrassment, or other harms if it became known that they participated in research that identified them as having issues including, but not limited to, risky sexual behaviors, HIV, or mental health problems.

○ If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms in not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

If you indicated that the **main risk is a breach of confidentiality**, answer 1.1, if apppropriate.

1.1 **According to DHHS regulations at 45 CFR 46.117 when the main risk of the research would be a breach of confidentiality and an oral consent process is used, each subject should be asked whether he/she wants documentation linking the subject with the research and the subject's wishes will govern.**

Check here if you want the IRB to consider allowing a waiver of this regulation so that you do not need to ask each subject if he/she wishes documentation.

☐ Request to waive documentation linking the participant with the research

2.0 **If the oral consent process applies only to certain parts of the study (e.g., specific procedures or populations), explain.**
Oral consent will be obtained from eligible research participants for the qualitative interviews and Lay First Responders training aspects of the study.

Verbal consent will be administered using oral consent scripts (attached in 20.3)

ID: IRB#23-000420 View: NEW 20.3 - Description of the Consent Process

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Description of the Consent Process

1.0 ***Indicate the type of setting(s) in which the consent process will be conducted.**

Check all that apply.

- ☐ In a private home
- ☑ **In a private room**
- ☐ In a waiting room
- ☐ In a public setting
- ☐ In a group setting
- ☐ On the internet
- ☐ Over the telephone
- ☐ Other

1.1 **If you checked more than one response, or indicated other, describe.**

1.2

If the setting is not private, describe the measures to protect confidentiality or indicate "not applicable."

2.0 ***Indicate the measures that will be taken to provide prospective research participants with sufficient opportunity to consider whether or not to participate in the study.**

Check all that apply.

- [x] **Member(s) of the study staff will meet with the prospective participants/families to review the consent document(s) and/or provide an oral explanation of the study. Individuals will be given a chance to ask questions before making a considered decision about whether or not to participate in the study.**
- [x] **Prospective participants/families will have the opportunity to take the consent form(s) home and may discuss the documents with others prior to deciding whether or not to participate in the study.**
- [ ] Prospective participants will self-administer the consent and send it back if they decide to participate in the study.
- [ ] Other

2.1 **If you indicated other, describe.**

3.0 ***Indicate the length of time subjects are given to decide whether they wish to participate in the study.**
The first time that participants are explained of the consent, they will have 10 minutes to decide to participate in the study, to decline participation, or to take the consent home and decide later, in which case they could return at any time before conclusion of the full-scale LFR phase of the study in case they choose to participate in the study.

School Children will be given assent and parental permission forms that will be returned after a week.

4.0 ***How will you assess whether subjects understand the information conveyed during the consent process?**

Check all that apply.

- [ ] Use the Subject Comprehension Tool form for research
- [ ] **Investigator or study team member will evaluate during the consent process**
- [ ] Other
- [ ] Not Applicable

4.1 **If you indicated other, describe.**

5.0 ***Attach copies of the informed consent documents, information sheets, consent scripts as applicable to this study. Include copies of translated forms, if applicable.**

Document Name	Document Version #
DRIVER LFR Pilot Consent.docx	0.01
DRIVER LFR Stakeholder Consent.docx	0.01
HEALTHCARE LFR Stakeholder Consent.docx	0.01

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Cultural Considerations

The following items are designed to acquaint the IRB with cultural features of the population that you are studying that may require procedures to ensure truly informed consent.

1.0 ***Check all that apply to the population(s) with which this study will be conducted.**

- [ ] Participants may be illiterate or insufficiently literate to be able to comprehend a conventional written informed consent form.
- [ ] The participants may be reluctant or unwilling to sign a written informed consent form.
- [ ] The husbands make decisions for their wives.
- [ ] Elders make decisions for younger adult family members.
- [ ] Elders make decisions for their community.
- [ ] It is considered impolite to refuse a request.
- [ ] People are fearful of refusing requests that they regard as coming from authorities.
- [x] **None of the above are applicable to this study.**

1.1 **If any of the above items are applicable to this study, indicate the steps that you will take to ensure voluntary participation after providing the study information, and if applicable, any planned involvement with the community regarding the consent process.**

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Additional Information and/or Attachments

1.0 **Attach any other documents that have not been specifically requested in previous items, but are needed for IRB Review.**

Document Name	Document Version #
There are no items to display	

2.0 **If there is any additional information that you want to communicate about this study, include it in the area provided. Note: this section should not be used instead of the standard application items.**

Instructions for Study Submission

You have completed your application, **but it has *not yet been submitted*.**

FOLLOW THESE STEPS TO SUBMIT THE APPLICATION TO THE IRB FOR REVIEW:

1. Click the **Finish** button to return to exit the SmartForm and return to the study workspace.
2. Use the **View SmartForm Progress** function to make sure that the application is complete.
3. If you are the PI or PI Proxy, click **Submit Study** under **My Activities**. If you are a member of the study team, you can let the PI know that the study is ready to submit by clicking **Send Ready Notification.**
4. Once the study is submitted, the state indicator at the top of the page will no longer display **Pre-Submission.**

5. After submission of the study, the **PI Assurances** activity will immediately become available under **My Activities**. The PI should provide his/her assurances at that time. If the PI is not available, the study can be submitted by a PI Proxy and the assurances provided at a later time. The study will be reviewed by the IRB while the **PI Assurances** are pending; however, it will not be approved until the **PI assurances** are completed.
6. ***If there is a Faculty Sponsor for the study***: The study can not be submitted to the IRB until the Faculty Sponsor provides his/her assurances through **FS Assurances** activity.

ID: IRB#23-000420 View: Display - Method Description

Audio, Visual or Digital Recordings

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

Certificate of Confidentiality for research not supported by NIH (please see Quick Guide and Tip Sheet)

The Certificate of Confidentiality button in this section is only if your study is NOT supported or conducted by NIH but you will obtain a Certificate of Confidentiality (for example, for studies collecting information about illegal drug use).

If you previously checked this box for an NIH-supported study before the policy change, you do not need to change your response here.

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project. Certificates of Confidentiality are issued to institutions or universities where the research is conducted. They allow the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

Effective October 1, 2017, NIH has updated its policy for issuing Certificates of Confidentiality for NIH-funded and conducted research. For information about the policy change or about obtaining Certificates for research supported by other agencies, please see https://humansubjects.nih.gov/coc/index.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

Clinical Trial of a Drug, Biologic, Device or a Behavioral Intervention (complete item 3.0 below INSTEAD of checking this box in 1.0)

A clinical trial is a research study designed to answer specific questions about medical or behavioral treatments. The trial may be interventional or observational. Interventional studies are those in which the research participants are assigned by the investigator to a treatment or other intervention, and the outcomes measured. Observational studies are those in which individuals are observed and the outcomes are measured by the investigators.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

Community Based Research

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

Controlled Substances (Schedule I or II)

Check here only if you are using a Schedule I or II Controlled substance in this study. Research using Schedule I or Schedule II controlled Substances must be submitted to the Research Advisory Panel of California for review and approval prior to initiation. Research using Schedule III, IV, or V Controlled Substances as a study drug do not require review by the Research Advisory Panel. For further information see: http://ag.ca.gov/research/guide.php o Schedule I Controlled Substances are drugs or substances with a high potential for abuse, that have no currently accepted medical use in treatment in the United States. Examples of Schedule I Controlled Substances are: heroin, lysergic acid diethylamide (LSD), methylenedioxy-methamphetamine (MDMA), marijuana, and psilocybin. o Schedule II Controlled Substances are drugs or substances with a high potential for abuse, that have a currently accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions. Examples of Schedule II Controlled Substances are: fentanyl, methadone, methylphenidate, morphine, and oxycodone. For further information see: http://www.deadiversion.usdoj.gov/schedules/index.html

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

Deception or Partial Disclosure

Deception includes withholding information about the real purpose of the study or purposely giving subjects false information about some aspect of the research to prevent bias. Some professions, such as the American Psychological Association (APA) have ethical codes regarding the use of deception in research. (See sections 8.07 and 8.08 at http://www.apa.org/ethics/code/index.aspx#807) If deception is included in the study, you must also apply for approval of a waiver of the informed consent process (Section 20.1) in addition to selecting the other consent procedures planned for the study (e.g., written or oral consent).

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

Devices/Diagnostics (Note: Submit all HUDs in BruinIRB)

A medical device is defined, in part, as any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized. Medical devices include, among other things, surgical lasers, wheelchairs, sutures, pacemakers, vascular grafts, intraocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for in vitro diagnosis (IVD) of disease and other medical conditions such as pregnancy. For further information see: http://www.fda.gov/oc/ohrt/irbs/irbreview.pdf

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

Drugs/Biologics/Dietary Supplements

- Drug: The term "drug" means: articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals.
- Biologics vs. Drugs: Most drugs consist of pure chemical substances and their structures are known. Most biologics, however, are complex mixtures that are not easily identified or characterized. Biological products differ from conventional drugs in that they tend to be heat-sensitive and susceptible to microbial contamination. This requires sterile processes to be applied from initial manufacturing steps. For more information see: http://www.fda.gov/consumer/updates/biologics062608.html#drugs
- Dietary Supplements are products that are intended to supplement the diet and have one of the following ingredients:
    - □ A vitamin
    - □ A mineral
    - □ An herb or other botanical
    - □ An amino acid
    - □ A dietary substance for use by man to supplement the diet by increasing the total daily intake
    - □ A concentrate, metabolite, constituents, or an extract of combinations of these ingredients.

For additional information see: http://www.foodsafety.gov/~dms/supplmnt.html

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

Genetic Analyses/Genotyping

Genetic analyses/genotyping include, but are not limited to, studies of inheritable conditions or traits, gene markers or mutations, and pedigrees.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

Human Embryonic Stem Cells and/or Induced Pluripotent Stem Cells

Research with human embryonic stem cells (hESC) and related lines requires IRB review under the following conditions: o Clinical research in which human subjects are given hESCs or related products. o When the UCLA research team will have a research related direct interaction or intervention with the cell donors, including donation of blastocysts or gametes for the purpose of creating hESCs,. o Cells provided to the UCLA research team that have identifiers or codes that can be linked back to the donor. Research involving hESC requires review and approval by the ESCRO Committee. For further information see: http://www.stemcell.ucla.edu/research

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

Human Gene Transfer/ Recombinant DNA

Studies involving gene transfer and/or recombinant DNA require approval of the UCLA Institutional Biosafety Committee (IBC). Human gene transfer is an investigational method for correcting defective genes responsible for disease development through one of the following techniques: o A normal gene may be inserted into a nonspecific location within the genome to replace a nonfunctional gene. o An abnormal gene could be swapped for a normal gene. o The abnormal gene could be repaired through selective reverse mutation, which returns the gene to its normal function. o The regulation of a particular gene could be altered. Recombinant DNA molecules, according to the NIH Guidelines, are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

Infectious Agents

Studies involving the use of Risk Group 2 or 3 infectious agents (such as bacteria, fungi, parasites, prions, rickettsia, viruses, etc.) require approval of the UCLA Institutional Biosafety Committee (IBC).

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

Non-FDA approved medical equipment used with UCLA hospital patients or research participants that operate under the UCLA Hospital License.

Clinical Engineering is responsible for completing incoming inspections on investigational devices that are used to diagnose, treat or monitor a patient and that are used in the patient care area on site at UCLA, but *not* in other hospitals such as Cedars Sinai, CHLA, or Drew. If a device is FDA and/or testing - laboratory approved for the purpose it was designed, then evaluation is not required of the device. If you have a copy of an inspection report from Clinical Engineering, please attach here. As appropriate, please contact Clinical Engineering at 310-267-9000 to arrange an inspection.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

Radiation (Standard of Care or Investigational Use of radioactive materials, radiation producing machines or ionizing radiation)

Note: This includes CT-guided biopsy, fluoroscopy use, etc.; MRI is not included. The radiological procedures included in this study must be described in the SafetyNet system. Please create a new SafetyNet application after submitting this webIRB application to the IRB for review.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

Substance Abuse Research (with Medication)

Research for the treatment of controlled substance addiction or abuse that uses any drug (scheduled or not) as treatment, requires the review and approval of the Research Advisory Panel of California prior to initiation. For further information see: For further information see: http://ag.ca.gov/research/guide.php

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

Treatment in an Emergency Setting (with request to waive consent)

Federal regulations allow certain research activities to be conducted in emergency settings with waiver of informed consent - in the interest of facilitating potentially life-saving and life-enhancing research with protecting the rights and welfare of participants. For further information see: o OHRP Guidance: http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc97-01.htm o FDA Guidance: http://www.fda.gov/oc/ohrt/irbs/except.html

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#23-000420 View: Display - Method Description

None of the above

Click "OK" below to return to the SmartForm page where you can select the appropriate response.