EIRB Protocol Template (Version 1.6)

1.0 General Information

***Please enter the full title of your study:**

EVALUATING THE FUNCTIONALITY OF A NOVEL LAYPERSON TOURNIQUET: A DOPPLER STUDY

***Please enter the Protocol Number you would like to use to reference the protocol:**

TTW Doppler
* This field allows you to enter an abbreviated version of the Protocol Title to quickly identify this protocol.

Is this a multi-site study (i.e. Each site has their own Principal Investigator)?

No

Does this protocol involve the use of animals?

○ Yes ◉ No

2.0 Add Site(s)

2.1 List sites associated with this study:

Primary Dept?	Department Name
◆	**P and R** - Uniformed Services University of the Health Sciences (USUHS)

3.0 Assign project personnel access to the project

3.1 *Please add a Principal Investigator for the study:

Goolsby, Craig A, MD, MEd

Select if applicable

☐ Student ☐ Site Chair
☐ Resident ☐ Fellow

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Schuler, Keke, PHD
Associate Investigator

B) Research Support Staff

Dacuyan-Faucher, Nicole M
Team Member

3.3 *Please add a Protocol Contact:

Goolsby, Craig A, MD, MEd
Schuler, Keke, PHD

The Protocol Contact(s) will receive all important system notifications along with the Principal Investigator. (i.e. The protocol contact(s) are typically either the Protocol Coordinator or the Principal Investigator themselves).

3.4 If applicable, please select the Designated Site Approval(s):

Add the name of the individual authorized to approve and sign off on this protocol from your Site (e.g. the Site Chair).

4.0 Project Information

4.1 * Has another IRB/HRPP reviewed this study or will another IRB/HRPP be reviewing this study? If Yes, answer the questions according to the IRB/HRPP Determination.

○ Yes ◉ No

IRB Name	Review Date	Determination
No records have been added		

4.2 * Is this a research study or a Compassionate Use/Emergency Use/HUD project?

◉ Yes ○ No

4.3 What type of research is this?

- ☑ Biomedical Research
- ☐ Clinical trial (FDA regulated)
- ☐ Behavioral Research
- ☐ Educational Research
- ☐ Psychosocial Research
- ☐ Oral History
- ☐ Other

4.4 Are you conducting this project in pursuit of a personal degree?

○ Yes ◉ No

4.6 * Is this human subjects research? (As defined by 32 CFR 219) Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

(•) Yes ( ) No

4.7 * Do you believe this human subjects research is exempt from IRB review?

( ) Yes (•) No

5.0 Personnel Details

5.1 List any Research Team members without EIRB access that are not previously entered in the protocol:

No records have been added

5.2 Will you have a Research Monitor for this study?

( ) Yes
(•) No
( ) N/A

6.0 Data/Specimens

6.1 Does the study involve the use of existing data or specimens only (no interaction with human subjects)?

( ) Yes (•) No

7.0 Funding and Disclosures

7.1 Source of Funding:

Funding Source	Funding Type	Amount
: Other Defense Health Agency, USU TTW Program	: Research Development Testing and Evaluation (RDT&E) funds	1999990

Total amount of funding:

1999990

7.2 Do you or any other Investigator(s) have a disclosure of a personal interest or financial nature

significant with sponsor(s), product(s), instrument(s) and/or company(ies) involved in this study?

○ Yes ◉ No

If Yes, complete and attach Conflict of Interest forms for all key personnel

8.0 Study Locations

8.1 Is this a collaborative or multi-site study? (e.g., are there any other institutions involved?)

○ Yes ◉ No

8.2 Study Facilities and Locations:

Institution	Site Name	Site Role	FWA or DoD Assurance Number	Assurance Expiration Date	Is there an agreement?	IRB Reviewing for Site
P&R	USU	Performance site	P60001			

Other:

Other Institution Site	Site Role	FWA or DoD Assurance Number	FWA or DoD Expiration Date	Is there an agreement?	IRB Reviewing for Site
No records have been added					

8.3 Are there international sites?

Attach international approval documents, if applicable, when prompted. Note: Ensure local research context has been considered

○ Yes ◉ No

8.4 Is this an OCONUS (Outside Continental United States) study?

○ Yes ◉ No

Select the area of responsibility:

Have you obtained permission from that area of responsibility? (This is a requirement prior to study approval)

○ Yes ○ No

9.0 Study Details

9.1 Key Words:

Provide up to 5 key words that identify the broad topic(s) of your study

Tourniquet Development, Education, Doppler, Tourniquet Function

9.2 Background and Significance:

Include a literature review that describes in detail the rationale for conducting the study. Include descriptions of any preliminary studies and findings that led to the development of the protocol. The background section should clearly support the choice of study variables and explain the basis for the research questions and/or study hypotheses. This section establishes the relevance of the study and explains the applicability of its findings

Trauma is the leading cause of death in the United States for people ages 1 to 44; uncontrolled bleeding is a leading cause of those deaths.1 Immediate hemorrhage control, even prior to the arrival of emergency medical services, can save lives during these emergencies. Since the launch of the Stop the Bleed (STB) campaign in 2015, the public has been empowered to stop life-threatening hemorrhage.2 One of STB's five objectives is to equip every bleeding control kit with audio and visual instructions; this has not yet been achieved. Commonly used tourniquets, such as the Combat Application Tourniquet (CAT) or Special Operations Forces Tourniquet (SOF-T), do not provide audio instructions and are not designed to provide feedback to facilitate tourniquet application. A device that could facilitate application and provide real-time instructions and feedback could be immensely beneficial to both the public and the DoD, especially to minimally or untrained people such as DoD civilians, contractors, and dependents on military installations. To achieve the above mentioned STB's objective, the research team at the National Center for Disaster Medicine and Public Health is devoted to develop a layperson tourniquet with audio-visual instructions and performance feedback.

In January 2020, the research team conducted a pilot study to evaluate this novel layperson tourniquet in a community lay public sample recruited from at the NBC Health Expo in Washington, DC. Findings of this pilot study were promising. One highlight of the results was that the proportion of participants who applied the tourniquet correctly using the layperson tourniquet was significantly higher than that using the CAT (93.3% versus 6.3%). Moreover, for when asked about their favoritism toward the tourniquet, 93.3% favored the novel layperson tourniquet, whereas 68.8% favored the CAT.

In addition to research results, feedback provided by the participants in this pilot study allowed the research team and the manufacturing partner to make adjustments and improvements to the testing device. Now we have completed a pilot study evaluating overall user experience of the novel layperson tourniquet, our next step is to conduct a functionality study examining the function of this novel layperson tourniquet and to see if it performs on par with the CAT.

9.3 Objectives/Specific Aims/Research Questions:

Describe the purpose and objective(s) of the study, specific aims, and/or research questions /hypotheses

The objective of the study is to determine if the novel layperson tourniquet (SMART TQ)'s ability to occlude arterial blood flow is non-inferior to a Combat Application Tourniquet (CAT).

9.4 Study Design:

Describe study design in one to two sentences (e.g., prospective, use of existing records/data /specimens, observational, cross-sectional, interventional, randomized, placebo-controlled, cohort, etc.). Specify the phase – Phase I, II, III, or IV – for FDA-regulated investigational drug research

This study will be a single blinded, randomized clinical trial.

9.5 Target Population:

Describe the population to whom the study findings will be generalized

The study will benefit the general public.

9.6 Benefit to the DoD:

State how this study will impact or be of benefit to the Department of Defense

Research findings and information collected from this research study would help ongoing efforts of developing a layperson tourniquet.

10.0 Study Procedures, Data Management, and Privacy

10.1 Study Procedures:

Describe step-by-step how the study will be conducted from beginning to end

This study will be a single blinded, randomized clinical trial. The study will be conducted in a room at USU's Multidisciplinary Laboratories.

The study has two arms: SMART TQ is the experimental arm and CAT is the control arm..

The study will consist of three groups of individuals:

- **Medical professionals who apply the tourniquet (we will call this group, medical professionals in this protocol). Each medical profession will be assigned to a study arm and switch to the other study arm halfway to reduce practice effects and minimize biases. They will be identified via the research team's professional network.**
- **Volunteers who offer their legs for tourniquet application (we will call this group of individuals study participants).**
- **Blinded observers who will use a doppler to check and monitor pulse. Absence of the dorsalis pedis pulse will be used to indicate occlusion of blood flow. The pulse monitored by the blinded observers will be used as an outcome for this research study.** *The only person blinded in the study will be the person checking for a successful application by measuring the doppler pulse – that is the blinded observers. There will be a bedsheet, or similar screen, placed between the portion of the participant's leg that has the tourniquet applied and the participant's foot where the doppler pulse will be*

measured. In addition, the research team will provide blinded observers noise-canceling headphones to minimize the influence of audio instructions provided by the SMART TQ.

We will recruit two medical professionals and two blinded observers and consent volunteers (i.e., participants). The detailed information for the informed consent process is summarized in the later section.

Training Session

Two medical professionals will attend a training session prior to the study. The session will allow the study team to verify that medical professionals can apply both types of tourniquets successfully. We anticipate this training session lasting no more than one hour and will recruit one participant for the training session.

Study Session

Upon the completion of the informed consent, participants will be assigned study ID numbers and then randomly assigned to a study arm: SMART TQ or CAT. The study steps are below:

- **A study participant enters the study room, completing a demographic information sheet and taking blood pressure, and then lies down with the face and torso facing up.**
- **To capture the baseline dorsalis pedis (DP) pulse: A blinded observer uses a doppler ultrasound to check DP pulse, the artery pulse on the surface of the foot. Doppler ultrasound is a small medical ultrasound machine that uses high-frequency sound waves to measure the amount of blood flow through the arteries and veins. The doppler ultrasound probe will be placed on the exposed foot, a pulse detected, and the location where the pulse is detected on that foot will be marked with an "X" using a surgical marker, and the doppler probed removed. This marked location will be where the doppler probe is placed later to determine whether there is a pulse.**
- **The research team member will measure the circumference of the leg at the area of tourniquet application. To keep the application location consistent across all the participants, we will mark where on the leg the tourniquet should be placed for each application.**
- **A medical professional records which leg will be used for tourniquet application (left leg or right leg)**
- **The medical professional applies the tourniquet. This is the first application of the tourniquet. *For tourniquet application, in order to signal medical professional stops tourniquet application (i.e., stops tightening the tourniquet), the doppler signals will be audible to medical professionals. Once the doppler signals stop, the medical professionals will stop applying/tightening the tourniquet.***
- **Upon the completion of the tourniquet application, the blinded observer records the presence or absence of a dopplerable pulse. A blinded observer again uses a doppler ultrasound probe to check the dorsalis pedis (DP) pulse, the artery pulse on the surface of the foot, at the previously marked "X" location on the foot.**
- **The medical professional removes the tourniquet and the study participant takes a break.**
- **The medical professional places a blood pressure cuff first and then places a tourniquet over the blood pressure cuff. This is the second application of the tourniquet. The blood pressure cuff will be attached to a fluid (e.g., water)**

pressure sensor to measure surface pressure under the tourniquet. The medical professional will tighten the tourniquet until the doppler pulse is eliminated. The medical professional will then read and record the pressure readings.

- **The medical professional removes the tourniquet.**

The procedures will then be repeated to a participant's other leg for the other arm. For example, if a participant is initially assigned to the CAT and uses the right leg for tourniquet application. The participant will then be in the SMART TQ arm for the left leg.

Termination Procedures

For the first tourniquet application on each leg, the observer will use doppler ultrasound to assess the participant's foot for a present or absent dorsalis pedis pulse. The observer will make the assessment at the location previously marked with a surgical marker. As soon as the pulse is determined to be present or absent, the observer will verbally tell the medical professional, "remove the tourniquet now."

For the second tourniquet application on each leg, the medical professional will tighten the tourniquet on top of the neonatal blood pressure cuff as described. The study team member will record the pressure. As soon as the pressure is noted, the study team member will tell the medical professional, "remove the tourniquet now."

Participant Post-study Assessment

Following the application of two tourniquets to both legs, the study team will ask the participant to rest while lying on the table for five minutes. After five minutes, the study team member will ask the participant the following questions:

- Do you have any persistent pain beyond mild aching at the application site?
- Do you have numbness, tingling, or other abnormal sensations?
- Does your leg feel weak?

If the answer is yes to any question, the team member will ask the participant to rest for five more minutes and re-ask the questions. If the answer to any question is still yes, the study team member will recommend that the participant seek medical care at an emergency department or with the participant's physician. If the study team member or participant is concerned that they are experiencing a medical emergency, they will call 9-1-1 and alert any of the medical professionals assisting with the study for assistance.

If the answer to the questions is no, the study team member will ask the participant to walk up and down the hall in the MDL. The study team member will observe the participant ambulating. If the person feels normal while walking, they can be discharged from the study.

The study team member will be advised to follow-up with their physician or emergency department for medical care if either leg develops worsening pain, swelling, redness, coldness, or bluish or pale color, or if they have shortness of breath or chest pain. The study team member will advise the participant that some mild local bruising or redness in the area of the tourniquet application may occur and that it does not require medical evaluation.

In addition, given the SMART TQ is an abbreviated investigational device, we will follow the abbreviation requirements specified by the FDA. Please see the "Devices" section for detailed information.

10.2 Data Collection:

Describe all the data variables, information to be collected, the source of the data, and how the data will be operationally measured.

The outcome variables in the study are: 1. the participants' resting blood pressure, 2. the presence or absence of dorsalis pedis pulse after tourniquet application, and 3. the surface pressure reading when the tourniquet is tightened. At the beginning of the study, participants will be asked to complete a demographic information sheet. On this sheet, they will fill out their age, gender, race, and ethnicity. The demographic information sheet is attached to this protocol.

10.3 At any point in the study, will you request, use, or access health information in any form, including verbal, hard copy and electronic?

○ Yes ◉ No

11.0 Statistical/Data Analysis Plan

11.1 Statistical Considerations:

List the statistical methods to be used to address the primary and secondary objectives, specific aims, and/or research hypotheses. Explain how missing data and outliers will be handled in the analysis. The analysis plan should be consistent with the study objectives. Include any sub-group analyses (e.g., gender or age group). Specify statistical methods and variables for each analysis. Describe how confounding variables will be controlled in the data analysis

The primary outcome variable for this research study binary (successfully stop the pulse: yes/no) and we conducted a power analysis for a parallel group non-inferiority trial. Assuming the two arms have the same high successful rate, with 80% power, and define the non-inferiority limit as 10% (so that a difference bigger than this would matter in practice), we estimated sample size required for each group is 13 applications (at least), so a total sample size of 26 applications (at least). Given the potential missing data and to ensure we will have enough statistical power for the final analyses, we will set the total sample size of 40 applications for this study. Since the tourniquet will be applied to participants' both legs (not at the same time), each leg will be one application and one participant will be able to fulfill two applications. As such, we will recruit no more than 20 participants for the study session and one additional participant for the training session.

11.2 Sample Size:

A total of 21 participants will be recruited. We will recruit no more than 20 participants that allow us to complete 40 applications, with 20 applications in each arm. We will recruit one additional participant for the training session.

11.3 Total number of subjects requested (including records and specimens):

21

11.4 If you are recruiting by study arm, please identify the arms of the study and how many subjects will be enrolled in each arm

We will recruit no more than 10 participants (20 applications) for each study arm.

11.5 Please provide a justification for your sample size

The primary outcome variable for this research study binary (successfully stop the pulse: yes/no) and we conducted a power analysis for a parallel group non-inferiority trial. Assuming the two arms have the same high successful rate, with 80% power, and define the non-inferiority limit as 10% (so that a difference bigger than this would matter in practice), we estimated sample size required for each group is 13 applications (at least), so a total sample size of 26 applications (at least). Given the potential missing data and to ensure we will have enough statistical power for the final analyses, we will set the total sample size of 40 applications for this study. Since the tourniquet will be applied to participants' both legs (not at the same time), each leg will be one application and one participant will be able to fulfill two applications. As such, we will recruit no more than 20 participants for the study session and one additional participant for the training session.

11.6 Data Analysis Plan: Complete description: Background, Objectives, Design, Step by Step how the project is going to be done, Data analysis plan:

Given that the primary study outcome variable is binary, we will use a chi-square test for the analysis. Descriptive statistics will be used to describe other study variables, including participants' demographic information.

12.0 Participant Information

12.1 Subject Population:

The study population includes individuals with access to the USU campus and prior tourniquet experience (an individual has received tourniquet training previously or has used tourniquet before so that they would understand the discomfort when a tourniquet is applied).

12.2 Age Range:

Check all the boxes that apply. if the age range of potential subjects (specimens, records) does not match the range(s) selected, please specify in the text box.

- [ ] 0-17
- [x] 18-24
- [x] 25-34
- [x] 35-44
- [x] 45-54
- [x] 55-64
- [ ] 65-74
- [ ] 75+

12.3 Gender:

- [x] Male
- [x] Female
- [x] Other

12.4 Special categories, check all that apply

- [ ] Minors /Children
- [x] Students
- [x] Employees - Civilian
- [ ] Employees - Contractor
- [x] Resident/trainee
- [ ] Cadets /Midshipmen
- [x] Active Duty Military Personnel
- [ ] Wounded Warriors
- [ ] Economically Disadvantaged Persons
- [ ] Educationally Disadvantaged Persons
- [ ] Physically Challenged (Physical challenges include visual and/or auditory impairment)
- [ ] Persons with Impaired Decisional Capacity
- [ ] Prisoners
- [ ] Pregnant Women, Fetuses, and Neonates
- [ ] Non-English Speakers
- [ ] International Research involving Foreign Nationals - Headquarters Review is necessary

You must also consider the requirements of DoDI 3216.02, paragraph 7.e.

You must also consider the requirements of DoDI 3216.02, Enclosure 3, paragraph 7.e.

12.5 Inclusion Criteria:

Order Number	Criteria
1	**Participants – Individuals with access to the USU campus and prior tourniquet experience**

12.6 Exclusion Criteria:

Order Number	Criteria
1	**Individuals younger than 18 years old or older than 65 years old**
2	**Individuals with the following conditions or history will be excluded from participation:** **hypertension, prior vascular surgery, peripheral vascular disease, diabetes, prior lower extremity vascular surgery, active lower extremity infection, any hypercoagulable condition (such as Factor V Leiden, or Protein C and S deficiency), pregnancy, or any condition in which the participant is concerned they may suffer harm from brief tourniquet application.**
3	*Individuals with any history of deep venous thrombosis or pulmonary embolism.*

13.0 Recruitment and Consent

13.1 Please describe the recruitment process, including how subjects will be identified and selected for the study.

We will recruit 21 study participants, with 20 being study participants and one additional being the participant in the training session, from USU. We will obtain appropriate approvals to recruit participants. Recruitment will be conducted via passive methods, such as class announcements.

Individuals who are interested in this study can contact a member of the research team and the research team member will ask if the individual is able to complete the screening questions. Upon the completion of the screening questions, if eligible, participants' consent will be conducted in a private room or via private virtual method.

13.2 Compensation for Participation:

No compensation for participating in this research study.

13.3 Please describe the pre-screening process. If no pre-screening, enter Not Applicable in the text editor

The screening will be conducted virtually via a phone call. Once an individual expresses interest in this research study, the research team will proceed with the screening by calling the individual and asking the screening questions. We added this information to the revised protocol.

Screening Questions

1. How many times have you applied a tourniquet before?
2. Do you have any of the following conditions or history:

   hypertension, prior vascular surgery, peripheral vascular disease, diabetes, prior lower extremity vascular surgery, active lower extremity infection, any hypercoagulable condition (such as Factor V Leiden, or Protein C and S deficiency), pregnancy, *deep venous thrombosis, and pulmonary embolism*, or any condition you would want us to know.

13.4 Consent Process: Revised Common Rule, Section 219.116: General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens.

Are you requesting a waiver or alteration of informed consent?

○ Yes ◉ No

Please explain the consent process:

Study participants will receive informed consent. All informed consents will be conducted in person or via private virtual method. Participants will be provided with informed consent documents, explaining the study procedure, their ability to withdraw at any time, and compensation. The informed consent document for study participants will also explain the potential risks and discomfort they may experience during the

tourniquet application. Additionally, participants will be informed that one of the tourniquets used in this research study is an investigational device and it is for the present research use only.

Participants consent will be conducted in a private room or via a private virtual method.

Withdrawal from Study Participation:

Participation in this research study is completely voluntary. Participants may terminate their participation at any time. They can inform their decision to withdraw to the Principal Investigator, Dr. Craig Goolsby, verbally or in writing. In cases where participants withdraw verbally, the PI will document the decision in a timely manner.

13.5 DoDI 3216.02 requires an ombudsman to be present during recruitment briefings when research involves greater than minimal risk and recruitment of Service members occurs in a group setting. If applicable, you may nominate an individual to serve as the ombudsman.

- (•) N/A
- ( ) Propose ombudsman

13.6 Withdrawal from Study Participation:

Explain the process for withdrawal and specify whether or not the subjects will be given the opportunity to withdraw their data their data/specimens in the event they wish to withdraw from the study

Participation in this research study is completely voluntary. Participants may terminate their participation at any time. They can inform their decision to withdraw to the Principal Investigator, Dr. Craig Goolsby, verbally or in writing. In cases where participants withdraw verbally, the PI will document the decision in a timely manner.

14.0 Risks and Benefits

14.1 Risks of Harm:

Identify all research-related risks of harm to which the subject will be exposed for each research procedure or intervention as a result of participation in this study. Consider the risks of breach of confidentiality, psychological, legal, social, and economic risks as well as physical risks. Do not describe risks from standard care procedures; only describe risks from procedures done for research purposes

The study will not collect any PHI and pose no significant risk to medical professionals who will apply the tourniquet and blinded observers. However, the study participants may experience minor pain or discomfort when a tourniquet is applied. Previous work has demonstrated temporary and minor pain with tourniquet use.[3]

14.2 Measures to Minimize Risks of Harm (Precautions, safeguards):

For each research procedure or intervention, describe all measures to minimize and/or eliminate risk of harms to subjects and study personnel

Given that medical professionals will be the ones who apply the tourniquet and on site, any discomfort or pain mentioned by study participants will be addressed immediately. Tourniquet application is anticipated to cause temporary pain when tightened (similar to a blood pressure cuff). If a participant expresses a desire to stop, the medical professional will stop immediately and remove the tourniquet, and recommend follow up if the pain does not quickly subside. The tourniquets will be applied for a very brief period of time - likely less than 60 seconds for each application. This brief application is very unlikely to cause vascular, nerve, or other tissue damage. Anyone with symptoms following tourniquet application will be instructed to follow-up with an emergency department or their physician as appropriate.

14.3 Confidentiality Protections (for research records, data and/or specimens):

Describe in detail the plan to maintain confidentiality of the research data, specimens, and records throughout the study and at its conclusion (e.g., destruction, long term storage, or banking). Explain the plan for securing the data (e.g., use of passwords, encryption, secure servers, firewalls, and other appropriate methods). If data will be shared electronically with other team members/collaborators outside the institution, describe the method of transmission and safeguards to maintain confidentiality. Explain whether this study may collect information that State or Federal law requires to be reported to other officials or ethically requires action, e. g., child or spouse abuse

Each participant will be assigned a study ID number and data collected from this research study will be stored on a USU network computer and backed up on Google Drive. Only study personnel will have access to the study information and data /records.

14.4 Potential Benefits:

Describe any real and potential benefits of the research to the subject and any potential benefits to a specific community or society

If the individuals in the research are considered experimental subjects (per 10 USC 980), and they cannot provide their own consent, the protocol must describe the intent to directly benefit all subjects

There is no anticipated direct benefit to participants from participation in the study. However, information collected from this research study would help ongoing efforts of developing a layperson tourniquet.

14.5 Privacy for Subjects:

Describe the measures to protect subject's privacy during recruitment, the consent process, and all research activities, etc.

Participants will be assigned a study ID number upon the completion of informed consents. All study procedures will be conducted in a private room at USU's Multidisciplinary Laboratories.

14.6 Incidental or Unexpected Findings:

Describe the plan to address incidental findings and unexpected findings about individuals from screening to the end of the subject's participation in the research. In cases where the subject could possibly benefit medically or otherwise from the information, state whether or not the results of screening, research participation, research tests, etc., will be shared with subjects or their primary care provider. State whether the researcher is obligated or mandated to report results to appropriate military or civilian authorities and explain the potential impact on the subject

Not Applicabile

15.0 Study Monitoring

15.1 Your study requires either Data and Safety Monitoring Plan (DSMP) or a Data and Safety Monitoring Board (DSMB).

- (•) DSMP
- ( ) DSMB
- ( ) Both
- ( ) Not Applicable

A DSMP should describe the plan to monitor the data to verify that the data are collected and analyzed as specified in the protocol. Include who will conduct the monitoring, what will be monitored, and the frequency of monitoring. It should also include the plan to ensure the safety of subjects

Data confidentiality and security will be maintained at all-time regarding participants' information (i.e., consent documents) and all collected information. The PI will review data for timeliness of submission, completeness, and adherence to the study protocol. Data monitoring will start at the time of participant registration and throughout until completion of the study. Study progress, adherence to protocol, and timeline of data entry, will be tracked closely throughout the study. Research personnel will maintain a clear record and documentation of all collected information, and ensure the accuracy of the record and documentation.

16.0 Reportable Events

16.1 Reportable Events: Consult with the research office at your institution to ensure requirements are met. Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event.

Consult with the research office at your institution to ensure requirements are met

• Describe plans for reporting expected adverse events. Identify what the expected adverse events will be for this study, describe the likelihood (frequency, severity, reversibility, short-term management and any long-term implications of each expected event)

• Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the research protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event

Because all study procedures will be conducted in person and medical professionals will apply tourniquets, any adverse events related to this study will be observed and addressed immediately.

Anticipated but not serious adverse events, such as minor discomfort or pain, will be reported on the Progress Report, which is generally performed on a 12-month cycle. More frequent Progress Reports may be required at the discretion of the IRB.

Serious adverse events are unlikely. Tourniquets left in place for prolonged periods of time (typically greater than 2 hours) have an increased risk of serious complications such as limb loss (amputation), compartment syndrome (muscle and nerve damage requiring surgery), and permanent nerve damage (weakness, numbness, pain in leg). We anticipate a very brief tourniquet application (no more than one minute) which will mitigate this risk.

Unanticipated adverse events will be identified by either medical professionals if a participant sees their physician or an emergency department, or research staff on-site if there is an immediate problem. Examples of less serious unanticipated adverse events include severe pain, extensive bruising, or temporary nerve injury (numbness, burning, pins-and-needles sensations).

All serious adverse events that are related to or may be related to study procedures will be reported by the PI within 24 hours by submitting an adverse event report to the IRB and a written follow-up report within 5 business days.

17.0 Equipment/non-FDA Regulated Devices

17.1 Does the study involve the use of any unique non-medical devices/equipment?

(•) Yes ( ) No

Please describe:

We are listing all the requirements by the FDA for the abbreviated IDE and addressing each requirement specifically. Please see each requirement for details. We do not have any FDA correspondence regarding this device at this point.

1. **Labels the device in accordance with 812.5;**

The novel layperson tourniquet, SMART TQ, will be labeled with the name and place of business of the manufacturer, the quantity of contents, and the statement: "CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use."

2. **Obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval;**

Why this device is not a significant risk device: This device is not a significant risk device because this device is not invasive, does not present serious risk to individuals' health, safety, and welfare.

The research team is seeking IRB approval and will maintain all communications and determinations from IRB.

3. **Ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, informed consent under part 50 and documents it, unless documentation is waived by an IRB under 56.109(c).**

All study participants will be asked to sign informed consent documents and they will keep one copy for their records. The research team will keep the other copy. All informed consent documents will be stored securely in a locked office.

4. **Complies with the requirements of 812.46 with respect to monitoring investigations;**

The study PI and study team will closely monitor the study procedures, data collection, and records throughout the entire investigation period.

5. **Maintains the records required under 812.140(b) (4) and (5) and makes the reports required under 812.150(b) (1) through (3) and (5) through (10);**

We will obtain all necessary regulatory approvals and maintain all relevant records. We understand that the level of pain may be experienced differently by different people, and therefore, some participants may express higher levels of pain than we anticipated. In this case, the tourniquet will be removed immediately and medical professionals are available to address any concerns.

6. **Ensures that participating investigators maintain the records required by 812.140(a)(3)(i) and make the reports required under 812.150(a) (1), (2), (5), and (7);**

We will maintain all study-related documents and make reports if necessary.

7. **Complies with the prohibitions in 812.7 against promotion and other practices.**

The device is for investigational use only and it will not be used for promotion or any other practices.

18.0 FDA-Regulated Products

18.1 Will any drugs, dietary supplements, biologics, or devices be utilized in this study?

- [ ] Drugs
- [ ] Dietary Supplements
- [ ] Biologics
- [x] Devices
- [ ] N/A

18.3 Device Details:

- [ ] Are device(s) in this research being used in accordance to the approved labeling?
- [ ] Are device(s) in this research being used in a manner other than its approved labeling?

When adding a device indicate in the details section of the device if the use is either used in accordance to the approved labeling or in a manner other than it's approved labeling

View Details	Device Name
No devices have been added to this Protocol	

18.4 Reporting Requirements for FDA-regulated research under IND and IDE:

Describe the process for complying with FDA regulatory requirements for adverse event reporting and adverse device effects reporting to the sponsor

18.5 Sponsor (organization/institution/company):

☐ N/A

If applicable, provide sponsor contact information:

Defense Health Agency, Uniformed Services University of the Health Sciences, TTW program

19.0 Research Registration Requirements

19.1 ClinicalTrials.gov Registration:

- ○ Registration is not required
- ◉ Registration pending
- ○ Registration complete

19.2 Defense Technical Information Center Registration (Optional):

- ◉ Registration is not required
- ○ Registration pending
- ○ Registration complete

20.0 References and Glossary

20.1 References:

1. Levy MJ, Jacobs LM. A Call to Action to Develop Programs for Bystanders to Control Severe Bleeding. JAMA Surg. 2016;151(12):1103-1104.

2. Lei R, Swartz MD, Harvin JA, et al. Stop the Bleed Training empowers learners to act to prevent unnecessary hemorrhagic death. Am J Surg. 2019;217(2):368-372.

3. Kragh JF, Jr., O'Neill ML, Walters TJ, et al. Minor morbidity with emergency tourniquet use to stop bleeding in severe limb trauma: research, history, and reconciling advocates and abolitionists. Mil Med. 2011;176(7):817-823.

20.2 Abbreviations and Acronyms:

Uniformed Services University of the Health Sciences
CONSENT TO PARTICIPATE IN RESEARCH
PARTICIPANTS
Title: *Evaluating the Functionality of a Novel Layperson Tourniquet: A Doppler Study*
Principal Investigator:
Craig Goolsby, MD, MEd, FACEP

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study.

Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

- This research study is carried out by the National Center for Disaster Medicine and Public Health (NCDMPH).
- The purpose of this research study is to learn about the functionality of a novel layperson tourniquet.
- We are asking for your consent to participate in this research study and participation is completely voluntary
- Duration of participation is no more than an hour.
- The research study will require you to have a tourniquet placed on each of your legs at different times.
- There is no direct benefit to you for participating in this research study. However, your participation will be valuable to the ongoing efforts of developing a novel layperson tourniquet.
- No compensation for participating in this study.
- You might experience pain or discomfort when a tourniquet is placed on your leg.

If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are individuals with access to the USU campus and have prior tourniquet experience.

(USUHS) IRB 1
IRB NUMBER: USUHS.2020-060
IRB APPROVAL DATE: 01/05/2021

The purpose of this research study is to learn about the functionality of a novel layperson tourniquet the research team at National Center for Disaster Medicine and Public Health (NCDMPH) is currently developing.

The duration of participation is no more than an hour.

3. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You will first be randomly assigned a study arm, either the arm using the Combat Application Tourniquet, also known as CAT, or the arm using the novel layperson tourniquet. Both of your legs will be used for tourniquet application in this study.

Once you are assigned a study arm, you will complete the following steps in this research study:

Step 1: You will be asked to complete a demographic information sheet and then to lie down with the face and torso facing up.

Step 2: To capture your baseline dorsalis pedis (DP) pulse: A blinded observer uses a doppler ultrasound to check your DP pulse, the artery pulse on the surface of your foot. Doppler ultrasound is a small medical ultrasound machine that uses high-frequency sound waves to measure the amount of blood flow through your arteries and veins. The doppler ultrasound probe will be placed on your exposed foot, a pulse detected, and the location where the pulse is detected on that foot will be marked with an “X”, and the doppler probed removed. This marked location will be where the doppler probe is placed later to determine whether there is a pulse.

Step 3: The research team member will measure the circumference of your leg at the area of tourniquet application.

Step 4: A medical professional records which leg will be used for tourniquet application (left leg or right leg)

Step 5: The medical professional applies the tourniquet. This is the first application of the tourniquet. A blinded observer again uses a doppler ultrasound probe to check your dorsalis pedis (DP) pulse, the artery pulse on the surface of the foot, at the previously marked “X” location on your foot.

Step 6: Tourniquet is removed by the medical professional and you will take a break.

Step 7: The medical professional places a blood pressure cuff and then places a tourniquet over the blood pressure cuff. This is the second application of the tourniquet.

Step 8: Tourniquet is removed by the medical professional

.

Steps 2 then 8 will then be repeated using a different tourniquet on your other leg.

4. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, you may experience pain or discomfort when a tourniquet is applied. The pain or discomfort should only be temporary.

The risk of a tourniquet application is similar to the risk from a blood pressure cuff applied to your arm in your doctor's office. There is a possible, but low risk, of skin bruising or injury, peripheral nerve injury (A

nerve injury can cause you to feel pain, burning, numbness, or other sensations in your leg. It could also cause weakness of your leg), muscle injury or blood vessel injury. The device will be applied for a short duration which further minimizes these risks.

5. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

There are no direct benefits to you for taking part in the study. However, others may benefit in the future from the information learned during this study. In addition, information collected from this research study would help ongoing efforts of developing a layperson tourniquet.

6. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Your alternative is not to participate in this research.

7. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No compensation for participating in this study.

8. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

9. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Craig Goolsby, MD, MEd, FACEP
Professor and Vice Chair
Department of Military & Emergency Medicine
Science Director
National Center for Disaster Medicine & Public Health
Uniformed Services University
Phone: 301.400.4215
Email: Craig.Goolsby@usuhs.edu

10. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

The study sponsor is Defense Health Agency, Uniformed Services University of the Health Sciences (TTW Program).

As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

11. SOURCE OF FUNDING:

The funding source of this research study is Defense Health Agency, Uniformed Services University of the Health Sciences (TTW Program).

12. LOCATION OF THE RESEARCH:

All study procedures will be conducted in a private room at USU's Multidisciplinary Laboratories.

13. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

The Principal Investigator of this research study, Dr. Craig Goolsby has a patent pending for tourniquet and method of use; patent controlled by Uniformed Services University of the Health Sciences – Henry M. Jackson Foundation Joint Office of Technology Transfer.

14. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at: http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

The research team will keep your research records. The study records will be available to the research team, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to:

- For the duration of this study, the research team will keep your study records secured. The informed consent forms will be kept securely behind locked doors in the NCDMPH.
- Only research staff will have access to the study records.
- A study ID number will be assigned to you.
- Your demographic data will be combined with data from other people taking part in this research study. We will present research reports about the combined data we have gathered. These research talks, presentations, and papers will not identify you.
- Your demographic data and the study ID number that is assigned to you will be entered into a scientific database. No identifying information will be entered in this database. This database will be stored in a Common Access Card protected secure USU computer.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

15. LONG TERM USE OF DATA

The investigator has requested to save selected data collected from your participation in this research study for possible use in future research. De-identified information and data may be used for internal

documentation in the event of an FDA audit of this tourniquet, and for scientific publication to demonstrate the device's effectiveness.
De-identified information and aggregated data collected from this research study will be used for future commercialization of this tourniquet. You may request the research team not to include your information or data for this purpose. Any profits from commercialization of this tourniquet will not be shared with you.

You have a number of options with regard to this request. If the stored data has an identifying link you can request to be contacted and sign a separate consent form to allow the use or available of this data in another study. You may also choose either to not allow any further use of your data, allow use of only de-identified data, or give consent now for the use of your identifiable data to be used in future studies. This future research may be in the same area as the original study or it may be for a different kind of study. You will be provided choices at the end of this consent form to allow or deny use in future research studies.

Any future research using your retained data will require a research protocol for the proposed study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

16. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

17. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must notify the Principal Investigator, Dr. Craig Goolsby, of this research study. You can withdraw from this research study by contacting the Principal Investigator by calling Dr. Goolsby at 301-295-9657 during business hours or send a letter or email using the following contact information:

Craig Goolsby, MD, MEd, FACEP
Professor and Vice Chair
Department of Military & Emergency Medicine
Science Director
National Center for Disaster Medicine & Public Health
Uniformed Services University
Phone: 301.400.4215
Email: Craig.Goolsby@usuhs.edu

If you decide to no longer participate in this research study, the researcher will *not* use your data that was part of this research study.

The principal investigator, Dr. Craig Goolsby, of this research study may terminate your participation in this research study at any time if he determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

18. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think you have a research-related injury, notify your healthcare provider or report to an emergency room immediately. Please also notify the Principal Investigator using the following contact information.

Craig Goolsby, MD, MEd, FACEP
Professor and Vice Chair
Department of Military & Emergency Medicine
Science Director
National Center for Disaster Medicine & Public Health
Uniformed Services University
Phone: 301.400.4215
Email: Craig.Goolsby@usuhs.edu

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military, dependent of active duty military, retiree), you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are authorized space-available medical care for your injury at a DoD hospital or an DoD clinic; medical care charges for care at a DoD hospital or a DoD clinic will be waived for your research-related injury. If you obtain care for research-related injuries outside of a DoD or DoD hospital or clinic, you will not be reimbursed for those medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

19. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator:
Craig Goolsby, MD, MEd, FACEP
Professor and Vice Chair
Department of Military & Emergency Medicine
Science Director
National Center for Disaster Medicine & Public Health
Uniformed Services University
Phone: 301.400.4215
Email: Craig.Goolsby@usuhs.edu

Institutional Review Board (IRB) Office

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at:

Uniformed Services University of the Health Sciences
4301 Jones Bridge Road
Room A2051
Bethesda, MD 20814
Phone: 301-319-4730 (direct); 301-295-3303 (main VPR office)

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

Future Research

Please initial the sentences that reflect your choices, and then sign below:

_____ (initials) I authorize the storage of data collected as a part of this study for future use in research studies and commercialization of the tourniquet.

_____ (initials) I do not authorize the storage of data collected as a part of this study for future use in research studies and commercialization of the tourniquet.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date

(USUHS) IRB 1
IRB NUMBER: USUHS.2020-060
IRB APPROVAL DATE: 01/05/2021

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND

January 05, 2021

MEMORANDUM FOR Lt Col CRAIG GOOLSBY, MD, MEd, MILITARY & EMERGENCY MEDICINE

SUBJECT: USU Institutional Review Board (IRB) (FWA 00001628; DoD Assurance P60001) Approval of Amendment ref# 933653 to Protocol USUHS.2020-060

The Amendment ref# 933653 for your Minimal Risk human subjects research protocol USUHS.2020-060, entitled "***EVALUATING THE FUNCTIONALITY OF A NOVEL LAYPERSON TOURNIQUET: A DOPPLER STUDY,***" was reviewed and approved for execution on January 05, 2021 by Edmund G. Howe, M.D., J.D., IRB Chair under the provision of 32CFR 219.110(b)(1)(ii). This approval will be reported to the USU IRB scheduled to meet on January 28, 2021.

The objective of this single blinded randomized trial is to determine whether the novel layperson tourniquet (SMART TQ) has a non-inferior ability to occlude arterial blood flow compared to a Combat Application Tourniquet (CAT).

This action approves the following changes to the protocol:

1. Addition of "Age, Sex, Height, Weight, Fat Measurement (e.g., caliper at the point of tourniquet application)" to the demographic information sheet as a part of data collection.
2. Revision to tourniquet application: in order to signal medical professional stops tourniquet application, the doppler signals will be audible to medical professionals. Once the doppler signals stop, the medical professionals will stop applying the tourniquet.
3. Changes to study steps: the second to last step will be changed to "The medical professional places a blood pressure cuff first and then places a tourniquet over the blood pressure cuff. This is the second application of the tourniquet. The blood pressure cuff will be attached to a fluid (e.g., water) pressure sensor to measure surface pressure under the tourniquet. The medical professional will tighten the tourniquet until the doppler pulse is eliminated. The medical professional will then read and record the pressure readings."

The following documents were revised/reviewed:

1. EIRB Modification Form - (Version 1.1)
2. EIRB Protocol Template - (Version 1.6)
3. Informed Consent - Participants (English) - (Version 1.6)
4. Demographic Information Sheet - (Version 1.1)

As a reminder, it is your responsibility to ensure all applicable protocol related approvals have been obtained prior to initiating study activities.

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4799

You are required to submit amendments to this protocol, changes to the informed consent document (if applicable), adverse event reports, and other information pertinent to human research for this project. No changes to this protocol may be implemented prior to IRB approval. If you have questions regarding this IRB action or questions of a more general nature concerning human participation in research, please contact Yaw Adomako-Ankomah, PhD at 301-295- 0428 or yaw.adomako-ankomah.ctr@usuhs.edu.

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Yaw Adomako-Ankomah, PhD, CIP
IRB Analyst
USU Human Research Protection Program

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND

September 23, 2020

MEMORANDUM FOR Lt Col CRAIG GOOLSBY, MD, MEd, MILITARY & EMERGENCY MEDICINE

SUBJECT: USU Institutional Review Board (FWA 00001628; DoD Assurance P60001) Approval of Protocol USUHS.2020-060 for Human Subjects Participation

The Initial Review (ref# 928430) for your Minimal Risk human subjects research protocol USUHS.2020-060, entitled "***EVALUATING THE FUNCTIONALITY OF A NOVEL LAYPERSON TOURNIQUET: A DOPPLER STUDY***," was reviewed by the full Institutional Review Board (IRB) on September 10, 2020 and Approved pending revisions. These revisions have been reviewed and approved by Edmund G. Howe, M.D., J.D., IRB Chair. The date of this approval is September 21, 2020. This approval will be reported to the USU IRB scheduled to meet on September 24, 2020.

The objective of this single blinded randomized trial is to determine whether the novel layperson tourniquet (SMART TQ) has a non-inferior ability to occlude arterial blood flow compared to a Combat Application Tourniquet (CAT).

The following documents were reviewed:

1. EIRB Protocol Template - (Version 1.4)
2. Informed Consent - Participants (English) - (Version 1.5)
3. Medical Professional Information Sheet - (Version 1.0)
4. Scientific Review - (Version 1.0)
5. Screening Questionnaire - (Version 1.0)
6. Observer Checklist - (Version 1.0)
7. Demographic Information Sheet - (Version 1.0)
8. Class Announcement - (Version 1.0)

As a reminder, it is your responsibility to ensure all applicable protocol related approvals have been obtained prior to initiating study activities.

You are required to submit amendments to this protocol, changes to the informed consent document (if applicable), adverse event reports, and other information pertinent to human research for this project. No changes to this protocol may be implemented prior to IRB approval. If you have questions regarding this IRB action or questions of a more general nature concerning human participation in research, please contact Yaw Adomako-Ankomah, PhD at 301-295- 0428 or yaw.adomako-ankomah.ctr@usuhs.edu.

ADOMAKO-ANKOMAH.YAW.1541043442 Digitally signed by ADOMAKO-ANKOMAH.YAW.1541043442 Date: 2020.09.23 14:04:00 -04'00'

Yaw Adomako-Ankomah, PhD, CIP
IRB Analyst
USU Human Research Protection Program

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND

DATE: September 17, 2020

TO: MEMORANDUM FOR Lt Col CRAIG GOOLSBY, MD, MEd, MILITARY & EMERGENCY MEDICINE

FROM: USU IRB

STUDY TITLE: ***Evaluating the Functionality of a Novel Layperson Tourniquet: A Doppler Study***

IRB REFERENCE #: USUHS.2020-060
SUBMISSION TYPE: INITIAL REVIEW

ACTION: MODIFICATIONS REQUIRED
ACTION DATE: September 10, 2020
REVIEW TYPE: Full Committee Review

Thank you for your submission of revised INITIAL REVIEW materials for this research study. The USU IRB has completed the review of this protocol submission and has determined that the following MODIFICATIONS are REQUIRED in order to secure approval:

Stipulations:

1) ICD_ Section 3:
   a. Step 2: Add that you will mark on skin.
   b. Step 5: Add that "A blinded observer again uses a doppler ultrasound to check your dorsalis pedis (DP) pulse, the artery pulse on the surface of your foot.
   c. Step 7: The medical professional places a neonatal blood pressure cuff, a smaller sized blood pressure cuff, and then places a tourniquet over. Finish sentence "…over a …" (clarify that this is the second application of the tourniquet)

Research activities in accordance with this submission may not begin until the IRB has reviewed and approved responses to these stipulations.

If you have questions regarding this IRB action or questions of a more general nature concerning human participation in research, please contact Yaw Adomako-Ankomah, PhD at 301-295- 0428 or yaw.adomako-ankomah.ctr@usuhs.edu.

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Yaw Adomako-Ankomah, PhD, CIP
IRB Analyst
USU Human Research Protection Program

Learning to Care for Those in Harm's

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND

DATE: August 28, 2020

TO: MEMORANDUM FOR Lt Col CRAIG GOOLSBY, MD, MEd, MILITARY & EMERGENCY MEDICINE

FROM: USU IRB

STUDY TITLE: ***Evaluating the Functionality of a Novel Layperson Tourniquet: A Doppler Study***

IRB REFERENCE #: USUHS.2020-060
SUBMISSION TYPE: INITIAL REVIEW

ACTION: DEFERRED
ACTION DATE: August 27, 2020
REVIEW TYPE: Full Committee Review

Thank you for your submission of INITIAL REVIEW materials for this research study. The USU IRB has completed its review of this protocol submission with an action of DEFERRED. In order for the IRB to proceed with the final review and approval of this protocol, please address the following:

Comments to address in both protocol and ICD:

1) Update protocol to align with responses provided to reviewer comments (Note: the revised ICD submitted to address reviewer comments has been uploaded into the protocol as version 1.2).
2) Provide more detail about end-point for stopping device and how that will be communicated to medical professional and study team.
3) Provide plan for monitoring participants after tourniquet have been completed (check for numbness, tingling, and walking difficulty).
4) Provide more detail on blinding of observers for pulse measurements (how will blinding be achieved given that the smart tourniquet provides verbal instructions).
5) Add signature/check boxes for opting in/out of future use of data.

Recommendation:

1) Consider informing participants whether any profits from commercialization of this device will or will not be shared with the participants. Just a statement to that effect will be sufficient.

Please note that it is possible that there will be additional stipulations after thorough review of the recorded meeting proceedings. Any changes to these stipulations will be conveyed to the study team as soon as possible.

Research activities in accordance with this submission may not begin until the IRB has reviewed and approved responses to these stipulations.

If you have questions regarding this IRB action or questions of a more general nature concerning human participation in research, please contact Yaw Adomako-Ankomah, PhD at 301-295- 0428 or yaw.adomako-ankomah.ctr@usuhs.edu.

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Yaw Adomako-Ankomah, PhD, CIP
IRB Analyst
USU Human Research Protection Program