WALTER REED NATIONAL MILITARY MEDICAL CENTER

CONSENT TO PARTICIPATE IN RESEARCH

Title: Comparison of Non-Surgical Treatment Options for Chronic Exertional Compartment Syndrome (CECS)

Principal Investigator: Jeffrey C. Leggit, MD, CAQSM

Other Study Sites: Carl R. Darnall Army Medical Center (CRDAMC), Fort Belvoir Community Hospital (FBCH), Madigan Army Medical Center (MAMC), Uniformed Services University (USU), and Womack Army Medical Center (WAMC)

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

Please take time to review this information carefully. 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 participation in this 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:

You are being asked to consent to participate in a voluntary research study. The purpose of this study is to see if the use of botulinum toxin-A (BoNT-A, Trade names: BOTOX® or Xeomin®) injection and gait retraining will improve the recovery for patients with chronic exertional compartment syndrome (CECS). Participants who volunteer for this study may be asked to participate for up to 36 months. Participants will be randomized to one of four groups: 1) Saline injection with home-based gait retraining program, 2) Saline injection with supervised gait retraining program, 3) BoNT-A injection with home-based gait retraining program, or 4) BoNT-A with supervised gait retraining program. Participants assigned to the home gait retraining program will have their gait analyzed by a medical professional in clinic and then will be given strategies to use to work on improving their gait at home. They will also receive weekly calls or texts (for the first 6 weeks) from a study team member to remind them to complete their home exercises. Participants assigned to the supervised gait retraining program will have their gait analyzed by a medical professional and attend 8 physical therapy sessions to work on their gait in the clinic. All participants will be given lower extremity strengthening and stretching exercises. All groups will return to the clinic for follow up research visits at 6 weeks, 3 months, 6 months, and 12 months post-injection. Participants will also complete questionnaires via telephone, mail, or email at 24 months post-injection. At the end of the 3-month follow up visit, you may choose to have a different study treatment if you are not satisfied with your results to date. Typically, surgery using a fasciotomy is the current definitive treatment for your condition. Fasciotomy is a surgical procedure where the fascia of the muscle is cut to relieve pressure in your leg compartment(s). Fasciotomy has been known to be partially effective with pain

and symptoms and has an average delay of about 13 weeks for return to full active duty. Your participation in this study is completely voluntary. If you do not decide to participate in the study, you and your doctor will decide on the treatment you get, including physical therapy and/or surgical fasciotomy, as opposed to having the study decide on the treatment you receive.

Possible risks/discomforts include: pain, bleeding, swelling, and infection at the injection site. There are rare potential risks of BoNT-A injections that may include muscle weakness, muscle fatigue, flu-like symptoms, and an even rarer risks of transient breathing and swallowing which has the potential to cause death if not appropriately treated. Other risks and discomforts include musculoskeletal injury from overuse or a fall from the gait retraining, gait analysis, balance testing, and exercise program, as well as a breach of confidentiality.

Possible benefits include: The possible benefits to you as a research participant in this research study are relief of pain and symptoms in your leg(s), avoidance of surgical fasciotomy, and return to full active duty status. However, there is no guarantee that you will benefit from being in this research.

Your decision will not affect your future care at Walter Reed National Military Medical Center (WRNMMC). 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 an active duty service member between the ages of 18 and 50 (inclusive) and have chronic leg pain and symptoms in either one or both of your legs that increases when you run. The purpose of this research study is to help determine the best treatment for your condition. The goal of this treatment is to get you back to your normal higher level of function so that you are able to perform your required work duties, return to full duty, and complete your service-specific physical fitness tasks. If you choose to participate, you will be followed for up to 24 months. The duration of participation per visit varies based on the activities scheduled. Please see Section 4, “What will happen if you decide to be in this research?” for additional information on the time commitments involved.

Typically, surgery using a fasciotomy is the definitive treatment for your condition. Fasciotomy is a surgical procedure where the fascia of the muscle is cut to relieve pressure in your leg compartment(s). Fasciotomy has been known to be partially effective with pain and symptoms and has an average delay of about 13 weeks for return to full active duty.

This study is designed to use a non-surgical treatment approach to determine if BoNT-A and/or gait retraining will help relieve your pain and symptoms of your leg(s) and improve recovery with a condition like yours. If pain and/or symptoms remain persistent in your leg(s), after study treatment, surgery may still be an option for you.

This study is called a multi-site study because participants from several military treatment facilities (MTFs) across the country will be in the study. Participating MTFs include Carl R. Darnall Army Medical Center (CRDAMC), Fort Belvoir Community Hospital (FBCH), Madigan Army Medical Center (MAMC), the Uniformed Services University (USU), Walter Reed National Military Medical Center (WRNMMC), and Womack Army Medical Center (WAMC).

There will be about 620 people taking part in this study overall with about 125 of those participants to be enrolled here at WRNMMC. Enrollment for the study will occur over a period of 2 years. The study time frame from the participant receiving an injection to completion of the study is 24 months.

This study involves a drug called BoNT-A which will be injected into your leg compartment(s) with the intentions of reducing your pain and symptoms. Although BoNT-A has been approved by the Food and Drug Administration (FDA) for injection into limb (i.e. arm) musculature to treat spasticity (i.e. severe muscle contraction and stiffness), it has not been well-studied, except for case studies, for the specific treatment of chronic exertional compartment syndrome.

At the end of this research study the clinical results, including research results about you will not be directly shared with you.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to have some tests and provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process". These tests may have already been done, or this information already collected, as a part of your regular medical care.

The clinical screening tests included in this study are:

- Magnetic Resonance Imaging (MRI) to rule out other causes of your leg pain/symptoms
- A self-paced treadmill test to reproduce your leg pain/symptoms and an intramuscular compartment pressure test using needles to confirm your diagnosis of chronic exertional compartment syndrome.
- An Ankle Brachial Index (ABI) using a blood pressure cuff and a doppler instrument to look at the blood pressures in your legs and arms and then compare these pressures to get an index.
- For biological females only: Urine hCG test for pregnancy

The researchers will also ask both you and your provider questions to ensure you qualify. These include questions regarding your age, current condition, medical history, and medical care eligibility.

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

Many of the activities in this study are performed regularly as part of standard of care for patients being seen for lower extremity CECS.

If you agree to participate in this research study, the following research activities will take place outside standard of care:

Contact Information

As soon as possible following consent, you will be asked to complete a questionnaire collecting your contact information. The local study team will use the information you provide on this form to contact you regarding study-related procedures and appointments. This questionnaire will take approximately 5 minutes to complete.

Screening & Baseline Data Collection:

As part of the screening and baseline research activities, the following things will happen before you receive your study injection:

- Magnetic Resonance Imaging (MRI) of your legs.
- Intramuscular compartment pressure test with a self-paced jog on the treadmill.
- For females only – urine hCG test for pregnancy.
- Ankle brachial index (ABI).
- Gait analysis on a treadmill.
- Muscle strength of both your lower extremities will be measured.
- Ankle range of motion of both your ankles will be measured.
- Height and weight will be collected.
- Balance test will be completed.
- Foot structure will be observed.
- Leg length will be measured.
- You will be asked to complete questionnaires about your ability to run and your current level of function.
- You will be asked about your footwear and use of orthosis.
- A study team member will ask you a series of questions about your military active duty status, medical history, running history, and the current pain and symptoms you are experiencing in your leg(s) when you run.
- A member of the research team will conduct a medical record review of clinical notes and results related to your leg pain/symptoms.

The screening and baseline study activities will take place across multiple in-person visits to WRNMMC. Overall, the total time to complete all screening and baseline activities will be a maximum of 5.5 hours.

If you had any of the required screening/baseline clinical tests performed as part of your regular clinical care within the 6 months prior to consenting to participate in this research study, they will not be repeated. If applicable, a member of the research team will collect the relevant clinical information about your previous MRI, intramuscular pressure test, etc. from your medical record.

Randomization:

Once the study team confirms that you are eligible for this research study (via the screening MRI, intramuscular pressure test, ABI blood pressures, and urine hCG test for pregnancy), you will be

randomly assigned to one of four groups. Randomization is a process like flipping a coin and means you will have a chance of being assigned to any of the groups.

The four study groups are: 1) Saline injection with a home-based gait retraining program, 2) Saline injection with a supervised gait retraining program, 3) BoNT-A injection with a home-based gait retraining program, or 4) BoNT-A injection with a supervised gait retraining program.

You will have a one in two (50%) chance of being placed in a placebo control group that receives a saline injection. This saline injection is an inactive, harmless substance that looks like the research study medication, but contains no medication.

You have a one in two (50%) chance of being placed in a research study group that receives the BoNT-A injection.

This research study is a single blind study, which means that you will not know whether you are receiving the research study medication (i.e. BoNT-A injection) or a placebo (i.e. saline injection). After 3 months of being in the study, you will be unblinded and will have the opportunity to receive a different study treatment if you did not receive the BoNT-A injection or the supervised gait retraining sessions and you are not satisfied with your results.

Study Treatments:

After the study team confirms that you are eligible to participate in this research study and you are randomized to a study arm, you will be able to schedule the research appointment for your study injection(s). The injection procedure will be completed by a trained physician and will take place 1-2 weeks after your intramuscular compartment pressure test. This appointment will take approximately 1 hour.

Regardless of the study group you are assigned to, you will undergo a gait analysis by a medical professional at WRNMMC and will be given a standard set of lower extremity (e.g. legs and feet) exercises. These exercises include strengthening and stretching of your hip, leg, ankle and foot muscles. These exercises are typically recommended to patients with injuries like yours. Depending on your group assignment, your exercises will be documented through a home exercise log or a clinic exercise log.

If you are assigned to the home gait retraining program, you will be given strategies to work on improving your gait at home. A member of the research team will call or text you weekly (until your 6 week follow up visit) to remind you to complete your exercises.

If you are randomized to the supervised gait retraining program, you will attend 8 physical therapy sessions at WRNMMC to work on your gait with a medical professional. These visits will last approximately 30-45 minutes each.

Follow Up Visits:

Regardless of the study group you are assigned to, you will be asked to return to WRNMMC for study follow up visits at 6 weeks, 3 months, 6 months, and 12 months after your study injection.

During the 6 week, 3 month, 6 month, and 12 month follow up visits at WRNMMC, the following things will happen:

- Ankle brachial index (ABI).
- Gait analysis on a treadmill.
- Muscle strength of both your lower extremities will be measured.
- Ankle range of motion of both your ankles will be measured.
- Balance test will be completed.
- Foot structure will be observed.
- You will be asked to complete questionnaires about your ability to run and your current level of function.
- You will be asked about your footwear and use of orthosis.
- A study team member will ask you a series of questions about your satisfaction with your treatment, military active duty status, running history, the current pain and symptoms you are experiencing in your leg(s) when you run, and whether you have undergone fasciotomy surgery for your compartments or received any other relevant medical treatments or diagnostics related to your leg pain/symptoms.
- A member of the research team will conduct a medical record review of clinical notes and results related to your leg pain/symptoms.

At the 6 month follow up visit, in addition to the procedures listed above, intramuscular compartment pressure testing will be repeated with a self-paced treadmill test. The 6 week, 3 month, 6 month, and 12 month follow up visits at WRNMMC will each take approximately 2.5 hours to complete.

At 24 months (2 years) after your study injection, you will be asked to complete questionnaires about your ability to run and your current level of function. A study team member will also ask you questions about your satisfaction with your treatment, military active duty status, running history, the current pain and symptoms you are experiencing in your leg(s) when you run, and whether you have undergone fasciotomy surgery for your compartments or received any other relevant medical treatments or diagnostics related to your leg pain/symptoms. A member of the research team will conduct a medical record review of clinical notes and results related to your leg pain/symptoms.

The 24 months (2 year) follow up can be conducted in person, over the phone, or via mail (based on your preference) and should take approximately 30 minutes to complete.

Your study participation will end after the 24 months (2 year) follow up.

<u>Study Participation Timeline Handout:</u>

The Participation Timeline Handout describes in detail the possible time commitments involved if you chose to participate in this research study. Your time commitment will vary depending on which of the four study groups you could be randomized into. A study team member will review this handout with you in detail.

Your initials here indicate that you received the timeline handout, understand the possible time commitments required if you chose to participant in this research study, and all of your questions regarding the potential time commitments have been answered:

Participant initials: _____

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

If you choose to take part in this study, there are risks associated with study treatments.

- BoNT-A injections: There are rare minor side effects of bleeding, pain, infection, and temporary general muscle weakness, muscular atrophy, and flu-like symptoms. Even rarer is a side effect of temporary breathing and swallowing difficulties which has the potential to cause death if not appropriately treated. To minimize risks, injection procedures will be completed by trained physicians using standard universal precautions.

- Saline injections: There are very rare side effects associated with saline injections that include pain, bleeding, and infection. To minimize risks, injection procedures will be completed by trained physicians using standard universal precautions.

- Intramuscular compartment pressure testing: Needle insertion for this test may cause pain, minor local bleeding to the area, and in rare incidents, infection. To minimize the risks, this procedure will use local topical anesthesia to reduce pain and will be completed by trained physicians using standard universal precautions.

- Gait analysis, gait retraining, ankle brachial index pressure testing, balance testing, self-paced treadmill testing, lower extremity strengthening and stretching exercises: There is a potential risk for physical discomfort (increased pain and reduced activity level), an overuse musculoskeletal injury, or a fall during the physical performance-based tests and gait retraining. To minimize the risks, physical tests and gait training will be completed by trained medical personnel. If you are randomized to the home based gait retraining group, you will have one session with a trained medical personnel to review your gait retraining and home exercise program before completing the rest of the program on your own.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

If you are a FEMALE ABLE TO BECOME PREGNANT and you want to take part in this study, you should know that BoNT-A might be harmful to (1) an unborn child if you are pregnant; or (2) an infant if you are breast-feeding. You will take a pregnancy test before you can participate in this study. You should not get pregnant or breastfeed while in this study. The only completely reliable methods of birth control are not having sex or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm killing products are not totally effective in preventing pregnancy.

If you become pregnant or feel you might be pregnant, contact your personal physician and the principal investigator of this study listed in the Contact Information section at the end of this document.

There may also be other risks of taking part in this study that we do not yet know about.

All available precautions will be taken to minimize these risks.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

We do not know which non-surgical treatment approach works better for chronic exertional compartment syndrome, so you may or may not benefit from this study. The possible benefits to you as a research participant in this research study are relief of pain and symptoms in your leg(s), avoidance of surgical fasciotomy, and return to full active duty status. However, there is no guarantee that you will benefit from being in this research.

Additionally, others may benefit in the future from the information learned during this study. The possible benefits to others are improving future rehabilitation care for musculoskeletal injuries in the military population for positive impact on force readiness.

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

There may be other options for treating your condition. Alternative treatments and/or procedures that may be available to you include: surgical fasciotomy or other non-surgical treatments. You should talk with your personal physician about these options.

Choosing not to take part in this research study is also an option.

There may be other research studies involving experimental treatments that could be helpful to your condition.

The medication involved in this research study may also be available through your personal physician without taking part in this study.

If you do not join, your medical care will not be affected.

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

No, you will not receive any compensation for participating in this study.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

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

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

Principal Investigator at WRNMMC: Jeffrey C. Leggit, MD, CAQSM
Department of Family Medicine
Uniformed Services University
4301 Jones Bridge Road
Bethesda, MD 20814
(301) 295-9460

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

Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation at the Uniformed Services University (USU), is overseeing this research study. As such, authorized staff from MIRROR and the USU will have access to your coded research data.

The Department of Defense (DoD) Defense Health Agency (DHA) is providing funding for this study. As a sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

12. SOURCE OF FUNDING:

Research funding is provided from the Department of Defense (DoD) Defense Health Agency (DHA) through the Uniformed Services University (USU).

13. LOCATION OF THE RESEARCH:

Walter Reed National Military Medical Center (WRNMMC), Carl R. Darnall Army Medical Center (CRDAMC), Fort Belvoir Community Hospital (FBCH), Madigan Army Medical Center (MAMC), the Uniformed Services University (USU), and Womack Army Medical Center (WAMC).

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

The study team does not have any conflict of interests related to financial sponsors.

15. 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 local research team will keep your research records. Your research records will be stored in a locked cabinet inside a locked room accessible only by authorized local research staff. These records may be looked at by local research staff, staff from the WRNMMC Department of Research Programs (DRP) and Institutional Review Board (IRB), the local DoD research office, the FDA, and the Department of Defense (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:

Generally, only people on the local research team will know that you are in this research study. You and your research data will be identified only by a unique coded study number and not by your name, social security number, DoD ID, or other protected identifier. The unique coded study number cannot be linked to your name except at the clinic where you complete visits. The WRNMMC research team will maintain a separate confidential electronic enrollment log which matches the unique coded study numbers with participants' names and their DoD ID number. This enrollment log will be stored separately from all other electronic research data in a secure, password-protected database on a DoD computer and network that requires CAC access. The WRNMMC research team will also maintain an intake form that collects your preferred contact information. This intake form will be kept in a locked cabinet inside of a locked room and stored separately from your coded research records.

All data collected from your study visits will be labeled with your unique coded study number. Paper case report forms that collect your study data will be stored in a locked cabinet inside of a locked room separately from the enrollment log that connects your identity with your unique coded study number and the intake form which collects your contact information. Your coded study data will be entered into Research Electronic Data Capture (REDCap), a secure, access controlled, and password protected electronic data capture and management system housed on a DoD server and maintained by the Uniformed Services University (USU) in Bethesda, MD. Once your coded data is entered in REDCap, it will only be accessible by authorized members of the local study team, the WRNMMC DRP and IRB, the local DoD research office, and authorized staff from Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation (PM&R) at USU, and is serving as the data coordinating center for this study.

Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

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

If applicable, a description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This web site will not include information that can identify you. At most, the Web site will include a summary of results. You can search this Web site at any time.

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.

16. 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. The data that will be stored and that may be used in future research will be de-identified, meaning that all of your personal identifiers will be removed. This future research may be in the same area as the original study or it may be for a different kind of study.

Any future research using your retained de-identified data will require a research protocol for the proposed study reviewed by an Exempt Determination Official (EDO) 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.

Your de-identified research data will be securely sent to Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR) and stored at the Uniformed Services University (USU) alongside other de-identified research data. This de-identified research data will be kept indefinitely, or as long as it is practical to maintain, and may be used in future research studies.

The local study team will keep this consent form and your signed HIPAA authorization for six (6) years following study closure. They will keep your coded paper research forms for five (5) years following study closure. The master code list which connects your identity with your unique study code will be destroyed as soon as all data collection is completed and analyzed, and no later than 1 year following study closure.

If you consent to participate in this research study, your de-identified data collected as part of this research may be kept for future research studies or given to others for future approved research

studies. If you would not like your de-identified data collected as part of this research to be kept for possible future research, you should not consent to participate in this research study.

17. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

We will also give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

You do not have an option to decline receiving information about an incidental finding.

18. 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.

19. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, you must contact the Principal Investigator in writing via mail or email at:

Jeffrey C. Leggit, MD, CAQSM
Uniformed Services University

Department of Family Medicine
4301 Jones Bridge Road
Bethesda, MD 20814
(301) 295-9460
jeff.leggit@usuhs.edu

If you decide to no longer participate in this research study, the researcher may keep and analyze all coded-de-identified data that was collected during your participation in this study. However, no additional data will be collected after the time of your withdrawal.

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your personal physician to discuss medical treatment for your condition.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to or email the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator 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, if you no longer meet eligibility criteria, if you are no longer eligible to receive medical care at a military hospital, if the military mission requires it, or if the study is cancelled.

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

If you think that you have a research-related injury, notify your Principal Investigator immediately at (301) 295-9460.

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.

21. CONTACT INFORMATION:

Principal Investigator (PI)

The Principal Investigator or a member of the research staff at Walter Reed National Military Medical Center (WRNMMC) will be available to answer any questions throughout this study:

Jeffrey C. Leggit, MD, CAQSM
Uniformed Services University
Department of Family Medicine
4301 Jones Bridge Road
Bethesda, MD 20814
(301) 295-9460
jeff.leggit@usuhs.edu

Human Research Protection Program (HRPP) Office

The WRNMMC Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Administrator/HRPP POC: Robert Roogow, MS
Phone: (301) 319-7736

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 WRNMMC IRB Office at:

Walter Reed National Military Medical Center
Department of Research Programs, Building 17B, 3rd Floor, Suite C
4650 Taylor Road
Bethesda, MD 20889
(301) 295-8239

If at any time you believe you have suffered an injury or illness as a result of participating in this research study, you should contact the Human Protections Administrator (HPA), Department of Research Programs (DRP) at Walter Reed National Military Medical Center (WRNMMC) at (301) 295-8239 or (301) 319-7736.

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.

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