Informed Consent Document Cover Page

Official Title of the Study: Trial of Neurostimulation and Blood Flow Restriction for PFPS in Active Duty (BFR)

NCT Number: NCT04086615

Date of Document: June 9, 2020

**BLANCHFIELD ARMY COMMUNITY HOSPITAL**
**CONSENT TO PARTICIPATE IN RESEARCH**
**Title:** *Trial of Neurostimulation and Blood Flow Restriction for PFPS in Active Duty*
**Principal Investigators:** Dr. Laura Talbot; MAJ (Dr.) John Morrison

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:

You are being asked to take part in this research study conducted at Blanchfield Army Community Hospital because you have knee pain with activities such as running, stair climbing, hopping/jumping, prolonged sitting, and repetitive movements such as kneeling or squatting. This is sometimes referred to as patellofemoral pain syndrome (PFPS). Participation in this study is voluntary.

With PFPS, it is important to carefully resume activity and get your muscles working in order to speed recovery. One approach is limiting blood flow to an exercising limb during neuromuscular electrical stimulation (NMES) with exercise. We are conducting a study to examine the effectiveness of two specific therapies for PFPS: (1) NMES with exercise supplemented with *high* blood flow restriction (BFR) and (2) NMES with exercise supplemented with *low* blood flow restriction over 9 weeks.

All participants will be asked to come to LaPointe clinic for testing and twice a week clinic visits over 9 weeks. Additionally, a 20 minutes home strengthening program will be performed by you on days not receiving the clinic NMES-BFR session. You will also receive weekly contact for the 9 weeks of the study via text, email or phone call from the study staff. The risks of participating in the study is short-term muscle soreness and fatigue from the strength testing and training. With BFR, there may be some discomfort with cuff compression on the leg. The potential benefits are improved muscle strength, function, and a reduction in knee pain. Still there may be no direct benefit to you. Alternative approaches include primary care management, physical therapy or a combination of both.

Your decision will not affect your future care at Blanchfield Army Community Hospital. 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?

The purpose of the study is to see if these two therapies improve: 1) lower extremity muscle strength, 2) physical activity level, 3) mobility/physical function, 4) knee symptoms/pain, and 5) quality of life. The duration of participation is 9 weeks with study visits lasting from 30 minutes to 1.5 hours based on type of visit.

Other studies have shown that each approach (NMES and BFR) is helpful. There have been no studies to see if these therapies combined with high or low blood flow restriction provide a benefit for soldiers with knee pain. A total of 84 active duty service members are expected to take part in this study, over a period of 2 years. At the end of this research study the clinical results will be provided at https://clinicaltrials.gov/ (NCT NCT04086615).

You are being asked to take part in this research study because you have knee pain with activities such as running, stair climbing, hopping/jumping, prolonged sitting, and repetitive movements such as kneeling or squatting. This is sometimes referred to as patellofemoral pain syndrome.

## 3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to provide some information so that the Investigators can confirm that you qualify for the study. This is called the "Screening Process". This information will be collected as a part of your initial visit. At the initial visit (week 0), we will verify that you meet the study conditions. The conditions are a diagnosis of knee pain with activities or PFPS, active duty military at the time of injury, age range of 18 to 44 years upon entry into the study and ability to provide informed consent. We will also determine if you have a medical condition that would pose a health or safety threat and/or impair your ability to participate in the study.

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

If you agree to be in this study, you have a chance of being in one of two different training groups which are 9 weeks long. Each training approach will be evaluated to see if the BFR-NMES with exercise approach increases lower leg muscle strength, improves your physical performance, and decreases knee pain and symptoms. There are some questionnaires, performance tests, and leg muscle strength testing that will be performed in addition to your training as part of these appointments.

You will be asked to come to the LaPointe clinic. During the initial visit and weeks 3, 6, and 9, we will measure your leg muscle strength, functional mobility and knee symptoms including pain level. The initial or first visit will take about 100 minutes plus an additional 20 minutes for

instructions on the home program. The number of in-clinic visits required is 19, including one initial visit with NMES-BFR training, 17 visits for NMES-BFR training and strength adjustments, and testing (weeks 3 and 6) and one 9-week post-test assessment visit for a total of 19 visits. Each NMES-BFR in-clinic session will take 30 minutes and each assessment (initial testing 1 hour and 50 minutes; weeks 3, 6, 9 about 1 hour and 10 minutes); the total in-clinic time will be approximately 13 hours and 45 minutes spaced over a 9-week period (table below). At each 3- and 6-week assessment, NMES-BFR training will be performed to minimize the number of visits for the participants. Most of these visits will be scheduled, to the best of our ability, with your regular primary care or physical therapy visits. The time commitment for the home training will be an additional 20 minutes per day and performed on days when not receiving the NMES-BFR training at the clinic.

You will also receive weekly contact for the 9 weeks of the study in addition to the twice a week clinic visit. This contact will be in the form of a telephone call, text message, or email depending on your preference and on the type or amount of information to be shared. The follow-up calls or texts will ask how well you are following the program and if you are having any safety issues. You will also be asked to rate your knee pain. The telephone call, email, or text will end with a reminder of follow-up visits**.** The contact will typically last less than 5 minutes. Total telephonic contact time for the study is expected to be no greater than 45 minutes (5 minutes each week X 9 weeks); with email and text the time is less.

If you agree to be in this study, you will be asked to read and sign this consent form. During this visit, we will measure your height, weight, and calculate a key index for relating weight to height (body mass index (BMI)). We will also measure your blood pressure and heart rate, leg strength, and functional mobility. We will measure your upper legs by using a tape measure and calipers (an instrument consisting of two curved hinged legs, used to measure thickness). We will assess your functional mobility in 4 ways: (1) stair climb, (2) chair rise test, (3) Step down test, and 6-minute walk. Stair Climb: While timed, you will be asked to ascend four stairs to the top platform, turn around, then descend the stairs as quickly as possible. Chair Rise Test: You will be asked to come to a full stand and then sit as many times as possible in 30 seconds. Step Down Test: While standing on an 8-inch platform, you will be asked to step forward and down from a single-leg stance as many times as possible for 30 seconds. 6-minute Timed Walk: On a marked path, you will walk as quickly as you can for 6-minutes. The distance walked will be measured and recorded. Your knee pain will be assessed after each test using the Visual Analog Scale (VAS), which asks to rate your knee pain on a scale of 0 (no pain) to 10 (worst possible pain). We will repeat these measures at weeks 3, 6 and 9.

During the initial visit (week 0) you will also be asked to complete some questionnaires. The questionnaires ask you about your general well-being, knee function, current pain level, and mood. The Kujala Anterior Knee Pain scale is a 13-item screening survey that to assesses patellofemoral pain. The IKDC subjective knee form asks you about your pain and knee function over the last 4 weeks. You may skip any questions that you do not want to answer. These questionnaires will take about 15-20 minutes to complete. If any scores are outside our expected range, we will notify your health care provider.

You will not know your group assignment until after the initial testing. After completing all

initial tests, you will be randomly assigned (like the flip of a coin) to one of two groups. The two groups are: 1) NMES with exercise supplemented with high blood flow restriction, and 2) NMES with exercise supplemented with low blood flow restriction. Your chances of being assigned to either training group are equal.

The *high* blood flow restriction constricts 80% of the arterial pressure to the leg. The *low* blood flow restriction will minimally constrict the arterial and venous pressure, which will have a minimal physiological reduction in blood flow. You will know your group assignment after initial screening and testing.

Regardless of group assignment, you will receive a battery powered portable KneeHAB® XP with a knee garment for your home and clinic use over the course of this study. The KneeHAB® XP with the knee garment is used for NMES. It is a small device about the size of a credit card. You will use a thigh garment that has four electrodes inside the garment that will be placed on your thigh. A small electrical charge will come from the device through the electrodes which will cause your muscles to contract. The device is adjustable so that it can cause your muscle to contract in different amounts. You will start at a very low level and progress up slowly over weeks as adjusted by the researcher on this study. When the device is being used, you may feel a tingling or buzzing sensation. This device has been used in other studies and has been found to help with pain. There may be an odd sensation as your muscle contracts as a result of the device, but this contraction is not caused by you. In other words, the muscle will contract involuntarily.

You will be given a complete description of how to apply and use this piece of equipment and associated garment when it is given to you, including the accompanying exercises. For the KneeHAB® XP, you will be asked to apply and use this device on your own at home and record this use in a paper or electronic log. It will also be used at your study visits, so bring the device and garment with you. The garment electrodes are re-useable, so they can be used numerous times. You will receive a Fitbit Charge to monitor your activity throughout the day. You will be asked to wear the Fitbit everyday while awake as long as you are in the study. You will need to charge it periodically at night and sync it daily either by a phone App, computer or during in-clinic visits. You will be given an instruction booklet with information about the how to perform home exercises while wearing the KneeHAB XP device and use of the Fitbit.

You may experience some discomfort removing the electrodes initially if it sticks to the hair on your leg. However, since the electrodes will be placed in the same spot each time, this discomfort will get less with repeated use. You may also have some skin discomfort with use of the adhesive electrode pads. The position of the electrodes can be moved slightly if this is a problem. This will be explained in detail when you are given a demonstration of the device.

During the twice a week in-clinic visits, the BFR cuff will be placed on your injured leg at the same time as the KneeHAB® XP garment. You will feel pressure as the cuff inflates. You will perform the same home exercises with both the KneeHAP XP and the BFR cuff in place.

After the initial visit, you will be asked to come in for follow-up visits at weeks 3, 6, and 9 for testing, as noted above. During the follow-up visits, all groups will have their lower extremity strength, functional mobility and knee symptoms assessed. You will be trained to use the NMES

device with garment and exercises at home. You will alternate using the NMES with exercise and exercise alone every other day for 20-30 minutes a day, 7 days a week for 9 weeks (one day NMES training, next day exercise alone). Days that NMES-BFR is performed at the clinic, it will replace the home NMES training. The table below gives an overview on the estimated time for each of the study visits.

| | **Measurement with Time Requirements at Each Visit** | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| ***Variable*** | ***Instrument*** | ***Estimate time*** | ***Entry*** | ***Daily*** | ***2X week*** | ***3-wk testing*** | ***6-wk testing*** | ***9-wk testing*** |
| | Inclusion/Exclusion Criteria | 10 | X | | | | | |
| | Consent Form | 20 | X | | | | | |
| | NMES-Blood flow restriction | 30 | | | X | | | |
| Muscle Strength | Knee strength during flexion and extension (Nm) | 10 | X | | | X | X | X |
| Physical Activity | Steps walked | - | X | X | | X | X | X |
| | Energy (kcal) expenditure | - | X | X | | X | X | X |
| Functional Mobility | Stair climb | 5 | X | | | X | X | X |
| | Chair rise test | 5 | X | | | X | X | X |
| | Step Down Test | 5 | X | | | X | X | X |
| | 6-minute timed walk | 10 | X | | | X | X | X |
| Knee Symptoms | Kujala Anterior Knee Pain Scale (AKPS) | 5 | X | | | X | X | X |
| | Visual Analog Scale | 5 | X | | | X | X | X |
| | IKDC subjective knee form | 5 | X | | | X | X | X |
| Quality of Life | SF-12v2 Health Survey | 5 | X | | | X | X | X |
| Clinical Factors | Clinical demographic form | 5 | X | | | | | |
| Body Composition | Height, weight (BMI), BP, HR, Thigh Skinfold, Waist circumference | 15 | X | | | X | X | X |
| Adherence | Logs | 5 | | X | | | | |
| **Weekly Totals (minutes)** | | | **100** | **5** | **60** | **60** | **60** | **60** |
| **Study Visit Total over 9 weeks** | | | **approximate 14 hours** | | | | | |

The exercises, NMES and Blood Flow Restriction used in this study are procedures that are part of the usual care that you might receive at the physical therapy department, Ft. Campbell. Blood Flow Restriction with exercise is only performed in-clinic and typically prescribed for two times a week for a specified length of time.

The combination of NMES, BFR and exercise performed together in-clinic is for research purposes. The use of the Fitbit Charge for activity monitoring is for research purposes. The questionnaires (SF-12, Daily Exercise Logs, Kujala Anterior Knee Pain Scale, IKDC subjective knee form) and functional mobility tests (Stair Climb, chair rise test Step Down Test and 6-minute walk) are for research purposes. Strength testing is for research purposes. We plan to combine the in-clinic therapy with research testing for one session and during weeks 3,6, and 9.

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

If you choose to take part in this study, there are possible risks from being in this research study. These include: The calipers used to assess thigh fat may bruise sensitive skin. For the physical performance tests, there is a risk that you may fall during the testing; however, most of the tests are self-paced and are no more risk than daily activities. Finally, you may experience muscle soreness from the strength tests. However, this is only short-term and should disappear within 30 minutes after testing is done. Increased physical activity or strength exercise training may cause post-exercise discomfort such as sore knees, fatigue and sore muscles. With NMES, there is a small risk that the electrical muscle stimulation might produce some discomfort with muscle contractions. The skin pads for NMES garment may cause a reddened area on sensitive skin. If the pads become dry, there is a risk of a burn. With exercise and increased physical activity, post-exercise discomfort such as fatigue, muscle soreness and muscle stiffness may occur with changes in activity level. There is also a possibility of falling. There is a risk of experiencing chest pain and/or a heart attack. With blood flow restriction training, there may be a slight discomfort with cuff compression on the leg, muscle soreness and infrequently transient numbness. With strength testing, there is the possibility of dizziness, lightheadedness or fainting with maximal effort.

A limited amount of study information will be entered into your medical record and this information will become part of your medical record. This information could be used for evaluations of military fitness for duty, medical evaluation, boards, and other personnel actions. The information is limited to this consent form with a note stating you are taking part in a research study, the name of the study, group assignment and some interventions performed. This consent form outlines the study assessments, procedures and interventions based on group assignment. At every study visit the study staff will document that you came to the study visit, completed study assessments, and the study intervention was reinforced (based on group assignment).

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

**PREGNANCY PRECAUTIONS:** If you are a FEMALE ABLE TO BECOME PREGNANT and you want to take part in this study, it is not known whether neuromuscular electrical stimulation (NMES) and blood flow restriction (BFR) can cause birth defects or other problems in an unborn child. If you are pregnant, you cannot take part in this study. Women of childbearing age must take a urine pregnancy test before enrolling in the study. If the test is positive, you cannot take part in this study. Pregnancy during the time you are receiving neuromuscular electrical stimulation and blood flow restriction may be a risk for the pregnancy and to an unborn baby. 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. Detailed testing using the KneeHAB® XP device and Delfi Personal

Tourniquet System (BFR) has not been done on pregnant women. The maker states that "Safety of NMES and BFR for use during pregnancy has not been established."

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

**Please initial below:**

_____ I have read the above precaution and understand it is unknown whether neuromuscular electrical stimulation (NMES) and blood flow restriction (BFR) adversely affect pregnancy and/or the developing child.

## 6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

The benefits of this study are unknown; however, other studies not involving knee pain with activities have shown NMES and exercise improves muscle strength, function, and knee pain. The information we attain may help us learn about strengthening leg muscles and pain relief in people with PFPS. However, there is no guarantee you will benefit from being in this research.

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

Alternative approaches which could be considered in your case include primary care management, physical therapy, or a combination of both, as determined by your physician. Your doctor can provide detailed information about the various rehabilitation alternatives available to you based on your current medical condition. Not participating in this study is the alternative to participating in this study.

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

You must be in off-duty status to receive compensation. If in off-duty status, you will receive a $30 AAFES gift card at week 3, 6, 9 visits for a total of $90. This card can be used at any AAFES gas stations or AAFES exchange. We can schedule appointments before, after duty, or at lunch.

When you complete the study, you may keep your *used* Fitbit Charge activity monitor. If the Fitbit is lost or broken, we will provide a replacement. Once enrolled in the study if you are unable to complete the 9 weeks, you may keep the Fitbit. You must be in off-duty status to receive these items.

## 9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

There are no costs to you for taking part in this research study.

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

Dr. Laura Talbot, RN, PhD is the Overall Principal Investigator of this study. Dr. Laura Talbot is at the University of Tennessee Health Science Center located in Memphis, TN. She is in the College of Medicine, Department of Neurology. Her phone number is 901-448-3630.

MAJ (Dr.) John Morrison, DPT is the On-Site Principal Investigator of this study. MAJ. Morrison is at BACH LaPointe Health Clinic, Department of Physical Therapy. His phone number is 270-412-8686.

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

This research is being conducted by the University of Tennessee Health Science Center and Blanchfield Army Community Hospital.

**12. SOURCE OF FUNDING:**

This study is funded by the TRISERVICE NURSING RESEARCH PROGRAM, A DEPARTMENT OF DEFENSE PROGRAM.

**13. LOCATION OF THE RESEARCH:**

Blanchfield Army Community Hospital at Fort Campbell, Kentucky.

**14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS**:

There are no financial interests to disclose.

**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.

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. Procedures to protect the confidentiality of the data in this study include but are not limited to coded data, removal of personal information, computer password protection, creation of firewalls around the data, locking of drawers and offices.

The research team will keep your research records. These records may be looked at by staff from: the Blanchfield Army Community Hospital, the Department of Defense (DoD), University of Tennessee Health Science Center at Memphis, Triservice Nursing Research Program (who is funding this study), Walter Reed National Military Medical Center (WRNMMC) Institutional Review Board and other government agencies as part of their duties. The WRNMMC Institutional Review Board (IRB) and the Defense Health Agency will provide ethical and regulatory oversight of the protection of human research volunteers for this study. These duties include making sure that the research participants are protected.

As described in section 5 above, this consent form will be placed, and progress notes will be written in your medical record indicating that you are taking part in a research study and some interventions will be performed as part of the research protocol. The initial note will document the name of the study, reference to the consent process & form, and group assignment. Your study data from the measurements described in the table above will *not* be placed in the medical records. At every study visit the study staff will document that you came to the study visit, completed study assessments, and the study intervention was performed (based on group assignment). If you agree to participant in this study the limited information described above will be entered into your medical record and this information will become a permanent part of that record. This information could be used for evaluations of military fitness for duty, medical evaluation boards, and other personnel actions.

**Please initial the sentences that reflects your choice:**
____ I agree to have this limited amount of study related information entered into my medical record.
____ I do not agree to have this study related information entered into my medical record (You will not be able to participate in this study).

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. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed. All records will be kept in a confidential form. Otherwise, only the researchers conducting this study will have access to the records from this study. Information gained from this study may be used as part of a scientific publication, but you will in no way be personally identified. Your name will not appear in any published paper or presentation related to this study. If you do not complete the full 9 weeks of the study, researchers may still use the information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

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.

By signing this document, you give your permission for information gained from your participation in this research study to 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 be presented de-identified.

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.

## 16. LONG TERM USE OF DATA

The information that we obtain from you for this study might be used for future studies. We will remove anything that might identify you from the information. If we do so, that information may then be used for future research studies indefinitely with no limitations or parameters. There is a possibility that the information may be given to another institution or investigator without getting additional permission from you. This will be through a Data Sharing Agreement and the researchers must provide a reasonable plan to be considered.

## 17. USE OF INFORMATION AND SPECIMENS

The information in this study will be used only for research purposes and in ways that will not reveal who you are. You will not be identified in any publication from this study. Specimens are not a part of this study.

## 18. 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. You will be advised to see your primary care provider for further evaluation.

You do not have an option to decline receiving information about an incidental finding.
A qualified person (usually a member of the research team) will talk to you if there is an incidental finding.

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.

## 19. 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.

## 20. 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 notify the principal investigators (either Dr. Talbot or MAJ Morrison in writing (via text or email) and return the KneeHAB® XP system. Already collected data will be retained and analyzed, even if you choose to withdraw from the research. If you are receiving an intervention as part of this research study, you will no longer be eligible for such research-related rehabilitation. 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 the principal investigators as discussed in the HIPAA Authorization Form.

The principal investigators of this research study may terminate your participation in this research study at any time if she 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.

## 21. 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 Investigators immediately using the contact information in the section below.

If you are injured because of your participation in this research 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.

Transportation to and from hospitals and 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.

## 22. CONTACT INFORMATION:

**Principal Investigators (PI)**

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

Principal Investigator: Dr. Laura Talbot
Phone: 901-448-3630
Mailing Address:
University of Tennessee Health Science Center
Department of Neurology, College of Medicine
855 Monroe Ave., room 415
Memphis, TN 38163
ltalbot@uthsc.edu

On-Site Principal Investigator: MAJ John Morrison
Phone: 270-412-8686
Mailing Address:
LaPointe Health Clinic
Physical Therapy Department
5979 Desert Storm Avenue
Fort Campbell, KY 42223
john.e.morrison.mil@mail.mil

**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 Institutional Review Board or the Human Protections Administrator at the WRNMMC Department of Research Programs at:
Phone: (301) 295-8239.
Mailing Address: 8901 Wisconsin Ave, Building 17B, Floor: 3, Suite: 3C, Bethesda, MD, 20889

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 Time

**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 Time