WOMACK ARMY MEDICAL CENTER

CONSENT TO PARTICIPATE IN RESEARCH

Research Title: Neurocognitive Ankle Training for Instability to Optimize Neuromusculoskeletal outcomes (NATION)

Principal Investigator: Megan H. Roach, PhD, ATC

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 that you have. You may also wish to talk to others (for example, your friends, family, or your personal doctor) about your potential participation in this research study. Participation is voluntary. You do not have to take part in this research. It is your decision. You can also choose to stop participating at any time during the study. Your decision will not affect your current or future care within the Military Health System (MHS), including Womack Army Medical Center. 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.

1) **KEY INFORMATION:** This section provides a one-page summary of the information outlined in this consent form. More information will be provided to you on the following pages.

Purpose	The purpose of this study is to examine the effectiveness of a novel treatment plan to improve function and overall health in patients with chronic ankle instability.
Duration	You will be asked to actively participate for up to 6 months. There will be three (3) clinical assessments, approximately 60 minutes each. If assigned to a treatment plan (i.e., study intervention) you will complete a 6-week training intervention. Each week you will complete two (2) in-person sessions (approximately 50 minutes each) and three (3) at home sessions (approximately 15 minutes each). Thus, the intervention will consist of twelve (12) in-person sessions and 18 at home sessions over the course of 6-weeks or approximately 14.5 hours (i.e., 2.4 hours per week).
Procedures	Upon enrollment into the study, you will be randomly assigned to one of three study groups. You may be assigned to the novel intervention (NATION), a standard evidence-based treatment plan, or control group. Depending on which study group you are assigned to, you may be asked to complete a 6-week treatment

	plan that includes twelve (12) supervised sessions with a study team member (less than 50 minutes each) and 18 unsupervised home sessions (less than 15 minutes each). Regardless of study group, you will be asked to complete three study-related visits (i.e., baseline, 6-week, and 6-month follow-up). During study visits, you will complete self-reported questionnaires, sensory, range of motion, strength, balance, and hopping assessments.
Why might you want to participate in this research (benefits)?	We cannot guarantee that you will directly benefit from participating in this research study; however, the intervention may restore your ankle joint stability, reduce pain and recurrent episodes of instability, without the need for surgical intervention.
Why might you choose not to participate in this research (risk)?	There is a risk of sustaining a musculoskeletal injury during the assessment or treatment. Although efforts are made to protect your research study records, there is always a risk that someone could get access to personal information researchers have stored about you.
What are the alternatives to participating?	Your alternative is not to participate in this research.
What is the compensation for participating?	Active-Duty Service members who participate will only be eligible to receive compensation when participating off-duty. A payment will be made for completing the baseline ($50), 6-week ($50), and 6-month ($50) study visits. Thus, you will be eligible to obtain up to $150 for the estimated 3-hours of visits for clinical assessments ($50/visit).

2) WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of this research study is to determine the effectiveness of a novel non-surgical treatment plan for chronic ankle instability. Ankle sprains are common in Service members and civilians and often lead to chronic ankle instability. Chronic ankle instability is described as a history of one significant ankle sprain with subsequent recurrent ankle sprains, episodes of the ankle feeling unstable, and persistent symptoms such as pain, swelling, and weakness. The best treatment strategies for chronic ankle instability have not yet been identified. Treatment strategies currently consist of non-surgical (i.e., rehabilitation exercises) and surgical approaches. Thus, it is important for us to better understand the effectiveness of non-surgical treatment strategies for chronic ankle instability so that we can efficiently treat the condition without surgery. We anticipate the total time you will be completing study specific activities will be approximately 17.5 hours, over the course of the study (up to 6-months). If assigned to a treatment plan, more than 80% (14.5 hours) of the time will be spent performing rehabilitation exercises. Please see Section 4, “What will happen if you decide to be in this research?” for additional information on the time commitments involved with this study.

This study is called a multi-site clinical trial because participants from Fort Liberty and the University of Kentucky (UK) will participate in this study, and you will receive a study specific intervention (aka “treatment”). Approximately 180 people will take part in this

study, over a period of 2.5 years. Participants in this study will receive a study specific intervention (aka "treatment"), in the form of the treatment plans as described below.

Throughout the research study, the information collected from you during the clinical assessments or treatment, if assigned to a treatment group, will be accessible to study team members. Access to the study data will be controlled by requiring access through a password protected computer and appropriate access credentials. Additionally, upon completion of the study, a summary of overall results (i.e., no individual participants will be identified) will be available to the public on http://www.clinicaltrials.gov.

3) WHY ARE YOU BEING ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you have self-reported or are suspected to have chronic ankle instability.

4) HOW LONG IS THE RESEARCH STUDY?

There will be about 180 people taking part in this study overall, with about 120 participants enrolled at WAMC/Fort Liberty and 60 participants at the University of Kentucky, over a period of 2.5 years. We anticipate the total time you will be completing study specific activities will be approximately 17.5 hours if assigned to a treatment group and 3 hours if assigned to the control group, over the course of the study (up to 6-months). For the treatment groups, more than 80% (14.5 hours) of the time will be spent performing rehabilitation exercises. Please see Section 4, "What will happen if you decide to be in this research?" for additional information on the time commitments involved with this study.

5) WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

You will be randomly assigned to one of 3 groups. Randomization is a process like flipping a coin and means you will have a chance of being assigned to one of the groups.

Treatment groups include the novel treatment plan (i.e., NATION) or standard evidence-based treatment plan. The third group will serve as a control in which no treatment will be prescribed. However, the home-based exercise portion will be offered to these individuals at the end of the study. You have a 33.3% chance of being assigned to any plan.

The novel treatment plan we are testing in this research is called Neurocognitive Ankle Training for Instability to Optimize Neuromusculoskeletal outcomes (NATION). If randomly assigned to NATION, you will complete standard rehabilitation exercises (lunges, balance on one leg) while carrying out a thinking task (counting backwards by seven, memorizing patterns). You will complete 12 supervised sessions (2 sessions per week, <50-minutes each) in-clinic with a study team member and 18 unsupervised home sessions (3 sessions per week, <15-minutes each) over the course of 6-weeks.

Some participants will be randomly assigned to a standard evidence-based treatment plan. If assigned to the evidence-based treatment plan you will complete the same exercises as the

NATION program (lunges, balance on one leg) without the thinking tasks. Identical to the NATION intervention, you will complete 12 supervised sessions (2 sessions per week, <50-minutes each) in-clinic with a study team member and 18 unsupervised home sessions (3 sessions per week, <15-minutes each) over the course of 6-weeks.

If randomly assigned to the control group, no treatment plan will be prescribed. However, the program for home-based exercises will be offered upon completion of the study.

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

You will complete an intake form including demographic information, clinical assessments (joint range of motion, strength, balance) and self-reported questionnaires. The self-reported questionnaires can be administered in-person or emailed to you to complete electronically if you cannot physically attend a follow-up visit. Specifically, you will be asked to complete the following study procedures:

1) Intake Form and Demographics (5 minutes) – Intake and demographic information will be collected from you during the baseline visit as outlined below. These questionnaires will be collected electronically and stored within the Research Electronic Data Capture (REDCap) System at the University of Kentucky (a non-authorized DoD system); all data will be stored in a coded fashion so that it is not directly linked to your personal information.
    a. *Ankle Instability Instrument* – A questionnaire that asks about your ankle instability history.
    b. *Balance History Questionnaire* – A questionnaire that asks about health conditions/current injuries that may influence your ability to balance.
    c. *Cumberland Ankle Instability Tool* – A questionnaire that asks about your ankle function.
    d. *NASA Physical Activity Scale* – A questionnaire that asks you about your physical activity level.
    e. *Demographic Information* – Routine demographic information (e.g., gender, ethnicity, race) will be documented.

2) Health Outcomes (10 minutes) – Self-reported questionnaires will be collected from you during the baseline, 6-week, and 6-month study visits that ask the following information outlined below. These questionnaires will be collected electronically and stored within the REDCap System at the University of Kentucky (a non-authorized DoD system); all data will be stored in a coded fashion so that it is not directly linked to your personal information.
    a. *Cumberland Ankle Instability Tool* – A questionnaire that asks about your ankle function.
    b. *Defense and Veterans Pain Rating Scale* – A questionnaire that asks you to rate your current pain level.
    c. *Fear-Avoidance Beliefs Questionnaire* – A questionnaire that asks about your fear of movement and re-injury as it relates to your ankle instability.

d. *Modified Disablement in the Physically Active Scale* – A questionnaire that asks you about your physical and mental well-being over the last 24 hours.
e. *NASA Physical Activity Scale* – A questionnaire that asks you about your physical activity level.
f. *Quick-Foot and Ankle Ability Measure* – A questionnaire that asks about your foot and ankle function related to activities of daily living and sport.
g. *Musculoskeletal Injury Questionnaire* – A questionnaire that asks you to self-report your history of ankle sprains and any other musculoskeletal injuries or musculoskeletal-related surgeries.

3) Clinical Outcomes (45 minutes) – You will be asked to complete 7 clinical assessments to understand quantify your joint range of motion, ankle strength, balance, foot sensation, and reaction time. The clinical outcomes will be collected from you during the baseline, 6-week, and 6-month study visits.
    a. *Ankle Range of Motion*: You will stand on a tape measure secured to the floor and face a wall. With your foot firmly planted on the floor you will bend your knee until your knee contacts the wall. You will repeat this process until the study team member determines the furthest distance you can move away from the wall and still maintain contact with the wall without your heel lifting off the ground. One practice trial and three test trials will be performed on the involved ankle.
    b. *Ankle Strength*: You will sit on a table and push or pull into a small hand-held dynamometer for 3- to 5-seconds while a study team member provides resistance. You will complete one practice trial and three test trials for each ankle motion. Motions include pushing your foot down, pulling your foot up, pushing your foot in, and pushing your foot out.
    c. *Star Excursion Balance Test*: You will stand on one leg in the center of a Y made out of tape measures. While maintaining your balance you will reach as far as you can along the tape measure with the non-stance leg, briefly touch the tape measure, and return to the start position. You will perform four practice trials and three test trials in each reach direction of the Y.
    d. *Single-Limb Balance on a Force Plate*: You will stand on one leg on a force plate and try to remain as still as possible. The force plate will record how much you move while balancing. You will complete one practice trial, two 10-second trials with your eyes open, and two 10-second trials with an upper extremity reaction task (i.e., extinguish the Fitlights®).
    e. *Foot Sensation*: You will lay on your stomach on a table while wearing noise-cancelling headphones and be asked to remain as still as possible. A study team member will touch the bottom of your foot with thin nylon fibers of varying sizes. You will verbally indicate when you feel the fiber. The study team member will increase or decrease the size of the fiber depending on your response. This process will continue until the study team member determines the smallest fiber you can consistently feel.
    f. *Choice Reaction Lateral Hop-to-Stabilization Task*: A Fitlight® will be placed at eye-level and a hurdle will be placed halfway between the start position and target landing area. When prompted by the light, you will hop over the hurdle as quickly as possible with the objective of landing and stabilizing for a minimum of three

seconds. You will start in a double-leg stance with a hurdle placed on each side of you and be instructed to wait for the FitLight® prompt. The light will indicate which side you should hop towards, green indicating left and red indicating right. You will complete three practice trials and three successful trials on each leg. Unsuccessful trials (land outside of target area, land with incorrect leg or on the wrong side, pivot during landing, fail to clear the hurdle) will be repeated.

g. *Lower Extremity Reaction Time Task*: Five FitLight® targets will be arranged in a semi-circle around your foot. You will be instructed to stand on one leg and deactivate the illuminated lights as quickly as possible with the non-stance foot. You will complete one 30-second practice trial followed by three 60-second test trials on both legs. The research team will wrap a small sensor around your low back to track your motion during the task.

4) Service Member Outcome (1 minute) – If you are an active-duty Service member, you will be asked to complete one questionnaire. The single-item questionnaire will be collected from you during the baseline, 6-week, and 6-month study visits that ask the following information outlined below.
    a. *Confidence to Deploy*: Active-Duty participants will be asked to rank their confidence in their ability to travel to/within a combat zone, carry/wear/use all required equipment and/or weapon, and perform required military duties for the duration of a six-month deployment on a scale of 0% to 100%.

5) Participant Workload (2 minutes) – If assigned to a treatment group, you will be asked to complete a participant workload questionnaire. The questionnaire will be collected from you at the completion of each supervised rehabilitation session.
    a. *NASA Task Load Index:* A questionnaire that asks you to assess workload in the following domains: mental, physical, temporal, performance, effort, and frustration.

6) Participant Satisfaction (2 minutes) – If assigned to a treatment group (NATION or Evidence-Based), you will be asked to complete a participant satisfaction questionnaire upon completion of your treatment (i.e., ~6-weeks).

6) WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH STUDY?

If you choose to take part in this study, there are risks associated with the study activities:

1) *Musculoskeletal injury during movement tasks or the clinical assessment.* The risk of sustaining a musculoskeletal injury, feeling unstable or losing your balance when performing clinical assessments or treatments during this study is no greater than the risks you face daily as a physically active individual. The study team has significant experience utilizing the data collection methods included in this study and they will implement appropriate safeguards to minimize your risk of injury.

2) *A breach of confidentiality*. 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 study records or other information researchers have stored about you. As described below, your research data will be identified by a unique study number rather than your name and all measures allowed by law to protect your confidentiality will be taken by the research staff.

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. All available precautions will be taken to minimize these risks. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

7) ARE THERE BENEFITS TO TAKING PART IN THIS RESEARCH STUDY?

There may or may not be a direct benefit to you by taking part in this research study. There is no guarantee that you will benefit from being in this research. However, the rehabilitation protocol may restore your ankle joint stability, reducing pain and recurrent episodes of instability, without the need for surgical intervention. Additionally, others may benefit in the future from the information learned during this study. The possible benefits to others are improved non-surgical treatment approaches for chronic ankle instability. These benefits may advance the care and management of patients with chronic ankle instability and reduce surgical rates, recurrent ankle sprains, and subsequent musculoskeletal injuries.

8) WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH STUDY?

Your alternative is not to take part in this research study. Regardless of your decision to participate in this study or not, your decision will not affect the medical care that you receive at WAMC or your status as an active-duty military Service member.

9) WILL YOU GET PAID FOR TAKING PART IN THIS RESEARCH STUDY?

Yes. You will be compensated for your time/participation in this research study. You will receive $50 after every study-related visit completed. There are three study-related visits scheduled to occur during the 6-month study period. Study-related visits include the baseline, 6-week, and 6-month follow-ups. Thus, you can potentially earn up to $150. If you are a Service member, you can only receive compensation if your study visit occurs while *off duty* (you are not scheduled to perform any work that may arise during the time period).

Compensation will be distributed in the form of a loadable gift card. Full name, date of birth, social security number, and mailing address must be collected for gift card payment tracking purposes via Greenphire, Inc. Greenphire is a third-party payer that the Henry Jackson Foundation utilizes for the Clincard payment system. If you do not want to supply this information, then you will not be compensated. If you decline payment or do not want to supply this information, then no information will be shared with Greenphire, Inc. In some

instances, you may also be required to supply this information on a W-9 form for tax purposes.

10) ARE THERE COSTS FOR TAKING PART IN THIS RESEARCH STUDY?

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

11) WHO IS THE STUDY SPONSOR?

The study sponsor is the organization or people who oversee the study. They may also be responsible for analyzing any research study information. The Military Operational Medicine Research Program (MOMRP) is providing funding for this study. As a sponsor of this research, the Department of Defense may also have access to your research data in accordance with DoDI 3216.02.

12) IS THERE A SOURCE OF FUNDING?

Research funding is provided from the Military Operational Medicine Research Program (MOMRP). These funds are managed, in part, by the Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF).

13) WHAT IS THE LOCATION OF THE RESEARCH STUDY?

Womack Army Medical Center (WAMC), the University of Kentucky (UK).

14) ARE THERE ANY DISCLOSURES OF FINANCIAL INTERESTS OR OTHER COMMERCIAL RELATIONSHIPS?

The research study team has no financial interests or commercial relationships related to this research study.

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

Your records related to this research study may only be shared 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. You can locate and read the form online (https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf), or a copy of the form can be given to you upon request.

The local research team will keep your research records. These records may be looked at by staff from the WAMC Human Research Protections Program Office (HRPPO), the Defense Health Agency, and the DoD. The committee responsible for protecting research participants, called the Institutional Review Board (IRB), may also look at your records 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 you are in this research study. Your research data will be stored with 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 military treatment facility where the research team is based out of. The local research team will maintain a separate confidential electronic enrollment log which matches the unique coded study numbers with participants' names, contact information, and DoD ID number. This enrollment log will be stored separately from all other electronic research data in a secure, password-protected database on a secured computer and network. The local research team will also maintain an intake form that collects your preferred contact information. Your contact information will be stored separately from your coded research records.

All data collected from your study visits will be labeled with your unique coded study number and shared with the study team at the University of Kentucky, except for your protected health information (e.g., musculoskeletal injuries, ankle surgeries) obtained from DHA-owned systems, that will only be stored on the Womack Army Medical Center-DHA owned network. Coded data will be entered in the University of Kentucky's REDCap (a non-authorized DoD system) and stored on an off-network server. Coded data from the balance and reaction time outcomes will be stored on the local system off-network computer/iPad and shared with the University of Kentucky via DoD compliant procedures. Your coded study data will be entered into the University of Kentucky's REDCap, a secure, access controlled, and password protected electronic database. Your data will only be accessible by authorized members of the local study team, the study team at the University of Kentucky, the Womack Army Medical Center HRPPO, and the Naval Medical Center Portsmouth IRB. Your protected health information (e.g., musculoskeletal injuries, surgeries) obtained from DHA-owned systems will be extracted from the Military Health System Data Repository or MHS Genesis, stored on the Womack Army Medical Center-DHA owned network, and then aggregated with the coded data set from REDCap. No data will be added to your medical record. The aggregate dataset and master list will remain on the DHA secure network for up to 5 years following study completion at which point they will be destroyed via DoD complaint digital data sanitation methods.

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

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.

A description of this clinical trial will be available online at http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of results. You can search this website 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.

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; all information will be presented as anonymous data.

16) WHAT KIND OF SPECIMENS WILL YOU PROVIDE AND HOW WILL THEY BE USED?

We will not be collecting any biological samples/specimens (for example, blood) from you during this research study.

17) WILL YOUR INFORMATION OR SPECIMENS BE USED IN THE FUTURE?

The investigator has requested to save information collected from your participation in this research study for possible use in future research. Identifiers will be removed, and de-identified information may be used or shared for future research. You have several 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 participating in research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

18) WHAT HAPPENS IF THE RESEARCHERS SEE AN INCIDENTAL FINDING?

There is a possibility that while reviewing your test results, the researchers may see something abnormal that they did not expect to see in this study. This is what is called an

"incidental finding." Generally, tests done for research purposes are not meant to provide clinical information.

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

The researchers will also give information about this incidental finding to your primary doctor or 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. ***Please initial below indicating that you understand that you cannot decline having the study team report incidental findings to an appropriate healthcare professional.***

_____ I understand the reporting of incidental findings to a healthcare professional is in my best interest, and I understand that I cannot decline having the study team report an incidental finding to a healthcare professional.

19) WHAT HAPPENS IF YOU WITHDRAW FROM THIS RESEARCH?

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. If you do not want to continue taking part in the research study, no additional data will be collected from you. You may to have your data withdrawn at any time before your identifiers (coded identification number) have been removed. Once your data have been deidentified (meaning that all personal identifiers have been removed), it will be impossible for the researchers to tell which data is yours. Furthermore, it may not be possible for researchers to avoid appropriate disclosures that have already been made (for example, presentations or publications prior to withdrawal that include your data.

Should you choose to withdraw, you must contact the Principal Investigator in writing via mail or email:

Megan H. Roach, PhD, ATC
Womack Army Medical Center
Extremity Trauma and Amputation Center of Excellence

Department of Clinical Investigations
2817 Rock Merritt Ave
Fort Liberty, NC 28310
megan.h.roach.civ@health.mil

Please note that taking back your consent to take part in this research does not take back your HIPAA Authorization to use or reveal your protected health information. To make that revocation, please send a letter to 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 she 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 the military mission requires it, or if the study is canceled.

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 as soon as possible using the contact information in the section below (section 21).

If you are injured because you took part in this research study and you are a DoD healthcare beneficiary, you are authorized space-available medical care for your injury within the DoD healthcare system if you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

For MHS Beneficiaries, transportation to and from hospitals or clinics will not be provided for by the DoD. Unless you are covered by TRICARE, no 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) WHO DO YOU CONTACT IF YOU HAVE QUESTIONS?

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

Megan H. Roach, PhD, ATC
910-907-1042
megan.h.roach.civ@health.mil
Extremity Trauma and Amputation Center of Excellence
Department of Clinical Investigations
2817 Rock Merritt Ave
Fort Liberty, NC 28310

Womack Army Medical Center Human Research Protection Program (HRPP) Office
The Human Research Protection Director (HPD) will be available to answer questions or discuss concerns you may have about this research study.

Caryn Duchesneau, CIP
301-639-0374
caryn.l.duchesneau.civ@health.mil
Human Research Protection Program Office
Womack Army Medical Center
2817 Rock Merritt Ave
Fort Liberty, NC 28310

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, you can contact the office of the committee responsible for ensuring research participant protection, the Institutional Review Board (IRB).

Naval Medical Center Portsmouth
620 John Paul Jones Circle
ATTN: CID
Portsmouth, VA 23708
(757) 953-5939
usn.hampton-roads.navhospporsva.list.nmcp-irboffice@health.mil

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.

22) HIPAA AUTHORIZATION

An Authorization is your signed permission to use or reveal your health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by the Department of Defense (DoD), permits the Military Health System (MHS) to use or reveal your health information with a valid Authorization. The MHS is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force. A valid Authorization must include the core elements and required statements as contained below.

The consent above describes the purposes of the requested use and disclosure of your health information. Please read the information below and ask questions about anything you do not understand before deciding to give permission for the use and disclosure of your health information. If you do not wish to give permission to use and disclose your health information, you may not be able to participate in the study.

a. What health information will be used or disclosed?

The local research team will review your electronic medical record to identify any musculoskeletal injury or ankle surgeries you sustain during the study period. The study team will also collect additional information about that injury, including your medical/treatment history related to that musculoskeletal injury and if you are precluded from participating in any physical activities as a result of your injury.

The following protected health information (PHI) will be collected: name, date of birth, DoD ID number (if applicable), and rank (if applicable) as well as the dates and results of clinic visits, diagnostic evaluations, and any other clinical tests related to your injury.

b. Who will be authorized to use or disclose (release) your health information?

Authorized members of the local research team will have access to your health information recorded in the electronic medical record if you experience a musculoskeletal injury or ankle surgery, so that they may collect information related to your injury/surgery, to monitor your treatment progress, and to collect and analyze relevant research data.

c. Who may receive your health information?

Only authorized researchers involved in this study at WAMC/Fort Liberty will have access to your identifiable health information.

However, your PHI may be made available to federal health oversight groups such as the local Institutional Review Board (IRB), the DoD Higher Level Review, and the Food and Drug Administration (FDA) as part of their duties. These duties include making sure that human research participants are protected.

Everyone using study information will work to keep your personal information confidential.

d. What if you decide not to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you will not be able to participate in this research study.

Receiving routine medical treatment is **not** conditioned (withheld or refused) as part of this study, whether you sign this Authorization or not.

e. Is your health information requested for future research studies?

Yes, your health information *is* requested for future research studies. If you agree below, your health information may be kept for use in future research studies or given to other researchers for use in future research studies. The specifics of these future research studies are unknown at this time, but these studies will frequently be in the area of chronic ankle instability.

f. Can you access your health information during the study?

You may have access to your health information at any time unless your identifiers are permanently removed from the data.

g. Can you take back this authorization?

- You may change your mind and take back your Authorization at any time. However, if you take back this Authorization, any person listed above may still use or share any already obtained health information as necessary to maintain the integrity or reliability of this research.
- If you take back this Authorization, you may no longer be allowed to take part in this research study.
- If you want to take back your Authorization, you must write to:
  Megan H. Roach, PhD, ATC
  Womack Army Medical Center
  Extremity Trauma and Amputation Center of Excellence
  Department of Clinical Investigations
  2817 Rock Merritt Ave.
  Fort Liberty, NC 28310
  megan.h.roach.civ@health.mil
  910-907-1042

h. Does this Authorization expire?

No, it does not expire.

i. What else may you want to consider?

- No publication or public presentation about the research described above will reveal your identity without another signed Authorization from you.
- If all the information that does or can identify you is removed from your health information, the remaining de-identified information will no longer be subject to this Authorization and may be used or shared for other purposes.
- In the event your health information is disclosed to an organization that is not covered by HIPAA, the privacy of your health information cannot be guaranteed.

23) FUTURE USE OF INFORMATION:

Based on your selections below, your health information collected as part of this research may be kept for future research studies or given to others for future approved research studies. You will be able to participate in the research study if you do not allow your identifiable information to be kept and used for future research.

Your health information will not be used for future research studies unless you give your permission by initialing your choice below:

_____ I *do not* give permission to use my health information for future research studies.

_____ I give permission to use my health information for future research studies.

With regard to future research studies done on stored data that has a link to my personal identity:

_____ I *do not* wish to be notified by investigators in the event of research findings of potential impact to my family members or myself.

_____ I wish to be notified by investigators in the event of research findings of potential impact to my family members or myself. I agree that the principal investigator may use any appropriate identifier to locate me in the future.

24) SIGNATURES

SIGNATURE OF PARTICIPANT

Your signature below indicates that:

- You authorize the Military Health System to use and reveal your health information for the research purposes stated above as described in the HIPAA Authorization.
- You have read (or someone has read to you) the information in this consent including the HIPAA Authorization.
- You agree that you have been provided time to read the information describing the research study in the consent form. The content and meaning of this information have been explained to you. You have been provided with the opportunity to ask questions.
- You voluntarily consent to take part in this research 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 (DDMMMYYYY)

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

_____
Printed Name of Administering Individual

_____ __ __ / __ __ __ / __ __ __ __
Signature of Administering Individual Date (DDMMMYYYY)