WALTER REED NATIONAL MILITARY MEDICAL CENTER

CONSENT TO PARTICIPATE IN RESEARCH

Title: Pre-neuromusculoskeletal injury Risk factor Evaluation and Post-neuromusculoskeletal injury Assessment for Return-to-duty/activity Enhancement (PREPARE)

Principal Investigator: Courtney M. Butowicz, PhD

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 identify the physical and psychological factors that increase musculoskeletal injury (an injury that affects a bone, ligament, muscle, or tendon) risk. If you volunteer to participate in this study you will be asked to actively participate for up to 12 months. There will be up to 3 clinical assessments (approximately 30 minutes each) and a monthly questionnaire that asks about how you are feeling both physically and mentally (less than 10 minutes each). Throughout the course of the study, you retain the right to stop your participation in the study or refuse to complete any study procedure. The only study specific "intervention" (aka "treatment") is the clinical assessment that will allow the study team to provide information regarding how you move and how flexible you are back to your healthcare provider. Thus, the greatest risks to participating in the study are: 1) sustaining a musculoskeletal injury during the movement assessments, or 2) a breach of confidentiality.

Your decision to participate or not participate in this study will not affect your future medical care, or your future career as an active duty Service Member. 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, 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 cleared for physical activity or you recently sought treatment for a musculoskeletal injury that affects either your spine (back) or lower extremity (legs). The purpose of this research study is to learn about the physical and

psychological factors that affect musculoskeletal injury risk. It is also important for us to understand the physical and psychological factors that increase musculoskeletal injury risks, so that we can work to prevent them. Conversely, it is known that musculoskeletal injuries increase future musculoskeletal injury risks in military Service Members. However, the underlying mechanisms that increase musculoskeletal injury risk following the original injury have not yet been identified. Thus, it is important for us to better understand the physical and psychological changes that occur following a musculoskeletal injury so that we can efficiently screen for these factors and provide healthcare providers with important information to better customize rehabilitation strategies. We anticipate that the total time you will be completing study specific activities will be approximately 3.5 hours, over the course of the study (up to 1 year). 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 a called a multi-site clinical trial because participants from Fort Liberty and Walter Reed National Military Medical Center (WRNMMC) will participate in this study and you will receive a study specific intervention (aka "treatment"), in the form of the clinical assessments described below. Approximately 2690 people will take part in this study, over a period of 2.5 years.

Throughout the research study, the information collected from you during the clinical assessments will be shared with your healthcare provider (e.g., physical therapist), if you sustain a musculoskeletal injury during the study follow-up period or if you are currently seeking care for a musculoskeletal injury. This will allow him/her to better customize your rehabilitation protocol. Additionally, a summary of aggregated results (i.e., no individual participants will be identified) will be available to the public on http://www.clinicaltrials.gov.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can complete the study procedures we must obtain historical information about you, regarding your recent musculoskeletal injury and any previous musculoskeletal injuries or surgeries you may have sustained. This is called the "Screening Process", and it will be completed immediately following the completion of this form, if you choose to provide your consent to participate in this study. This is to ensure that you meet the inclusion criteria for the study.

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

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

You will complete clinical assessments (movement, joint range of motion) and self-reported questionnaires (during the clinical assessment appointments and monthly throughout the study). Specifically, you will be asked to complete the following study procedures:

1) Clinical Assessment (30 minutes each) – You will be asked to complete a variety of clinical movement and joint range of motion assessments that assess how you move and how flexible you are.
    a. Movement Assessments – You will complete all movement assessments while data are recorded with a Microsoft Azure based markerless motion capture system and an instrumented walkway. Prior to each movement assessment, the assessment will be described to you and you will have the opportunity to practice the assessment at least 2 times. Each movement assessment trial will start with a study team member saying "get set"; at this point you will assume a comfortable "athletic posture" (whatever body position you would normally take prior to making a dynamic

movement). Then within 5 seconds, the study team member will say "go ahead", you can initiate the movement assessment any time after you receive the "go ahead".

i. *Gait* – You will complete over-ground gait (walking) trials at a self-selected pace. You will continuously walk along an oval shaped path. The instrumented walkway will be positioned within the pathway so that you walk across the length of the walkway down the long side of the oval. You will complete as many trials as possible during a six minute period.

ii. *Double Leg Squat* – You will stand with your feet shoulder-width apart, feet (toes) pointed forward, heels on the floor, and arms extended overhead. You will squat in a controlled manner, to a comfortable depth. You will complete 3 sets of 3 consecutive squats.

iii. *Single Leg Squat* – You will stand on the test limb, with the test limb foot (toes) pointed forward, heel on the floor, hands on your hips, and head facing forward. The non-test limb will be flexed to 90˚ of hip flexion and 90˚ of knee flexion. You will squat in a controlled manner, to a comfortable depth, and so that you are able to maintain your balance. You will complete 3 sets of 3 consecutive squats on each limb.

iv. *Jump-Landing* – You will stand on a 30cm (~1 foot) tall box, set at a distance that is equal to 50% of your height behind a target area. You will jump forward, and not vertically, to reach the target area. Both of your feet will leave the box at the same time. Upon landing on the ground you will immediately jump vertically for maximal height. You will complete 3 jump-landings.

v. *Single Leg Triple Hop* – You will stand at the end of the instrumented walkway with your heel on the edge of the walkway. You will perform three consecutive maximal forward hops on the same limb. On the last hop, you will be asked to "stick the landing" by maintaining your balance on the test limb upon landing. You will complete 3 trials on each limb.

vi. *Closed Kinetic Chain Upper Extremity Stability Test* – You will assume a standard push-up position with each hand placed on a marking on the floor. As quickly as possible, you 1) remove one of your hands from the floor and touch the opposite floor marking, 2) replace the original hand on the original floor marking, 3) repeat this process on the opposite hand, then 4) continue to alternate hands in this fashion for 15 seconds. You will complete 3 trials.

vii. *Functional Movement Screen Shoulder Clearing Test* – You will place one of your hand on the opposite shoulder and attempt to point your elbow upward. You will complete 1 trial on each limb.

viii. *Prone Plank Assessment* – You will lie flat on your stomach, so that your elbows and hands are in contact with the ground. You will be asked to lift your hips and chest off of the ground and to support yourself on your elbows, hands, and toes. You will hold this position for as long as possible. Testing will stop when you voluntarily state that you can no longer hold the testing position or the study team member determines that you can no longer hold the required position, after encouraging you to maintain the testing position. You will complete 1 trial.

ix. *Active Hip Abduction* – You will lie on your side with your hips perpendicular to the table and your legs straight, in line with your trunk. You will lift the leg that is on top up towards the ceiling. You will complete 1 trial on each side.

It is important to note that the equipment utilized to record how you move includes full-body videos that will include your face and other identifying characteristics about you. This information will not be stored in the aggregated study dataset, but these videos will be stored until the completion of the study and then they will be destroyed, as described below. Please initial below indicating that you understand that your image will be recorded during the clinical movement assessments.

_____ I understand that my image will be recorded during the clinical movement assessments and that this information will be stored until the end of the study.

b. Joint Range of Motion – Range of motion assessments will be measured with either a goniometer or digital inclinometer, tools commonly used to measure joint range of motion within the clinic. Your joint will be moved through its range of motion to the point of first resistance or until you vocalize discomfort. Prior to each range of motion assessment, the assessment will be described to you and you will have the opportunity to practice the assessment at least 1 time. Three trials of each assessment will be recorded for each leg.
    i. *Knee Extension* – You will lie flat on your back so the test limb is flexed to 90˚ of hip and knee flexion (supported by your hands). The non-test limb will be extended on the testing table. The study team member will passively extend (straighten) your knee and measure your maximum range of motion with an inclinometer placed along your shin bone.
    ii. *Hip Abduction* – You will lie flat on your back with the test limb and non-test limb fully extended on the testing table. The study team member will passively abduct (move outward) your limb and measure your maximum range of motion with a goniometer placed across your hip bones and down the length of your thigh.
    iii. *Hip Internal Rotation* – You will lie flat on your stomach so the test limb is flexed to 90˚ of knee flexion. The non-test limb will be extended on the testing table. The study team member will passively internally rotate your limb and measure your maximum range of motion with an inclinometer placed along the outside of your lower leg.
    iv. *Hip External Rotation* – You will lie flat on your stomach so the test limb is flexed to 90˚ of knee flexion. The non-test limb will be extended on the testing table. The study team member will passively externally rotate your limb and measure your maximum range of motion with an inclinometer placed along the outside of your lower leg.
    v. *Ankle Dorsiflexion* – You will stand facing a wall so the test limb foot is perpendicular to the wall, with your second toe and heel aligned on a piece of tape placed on the floor. Your non-test limb foot will be placed behind the test limb in a comfortable position. You will actively lunge forward, trying to touch your knee to the wall. You will stop lunging just prior to when your test limb heel lifts off of the floor. The study team member will measure your maximum range of motion with an inclinometer placed along your shin bone. If your test limb knee touches the wall prior to your test limb heel lifting off of the floor, the study team member will move your foot back and the trial will be repeated.

2) Participant Completed Questionnaires (10 minutes each) – Self-reported questionnaires that ask the information outlined below will be collected from you. These questionnaires will be collected electronically and stored within the Uniformed Services University of the Health Sciences Research Electronic Data Capture (REDCap) system; all data will be stored in a coded fashion so that it is not directly linked to your personal information.
    a. Participant Demographics
        i. Name
        ii. Sex

iii. Musculoskeletal injury and surgery history
iv. Traumatic brain injury history

b. Service Specific Physical Fitness Readiness Assessment Scores
c. Patient Reported Outcomes Measurement Information System:
   i. Physical Function – A questionnaire that asks about the types of physical activity you can currently complete.
   ii. Pain Interference – A questionnaire that asks about how any pain you are experiencing is interfering with your daily activities.
   iii. Depression – A questionnaire that assesses if you have experienced any depressive symptoms over the past 7 days
   iv. Anxiety – A questionnaire that assess your level of anxiousness over the past 7 days.
d. Tampa Scale of Kinesiophobia – A questionnaire that asks about your fear of movement and re-injury as it relates to your musculoskeletal injury.

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 the study activities:

1) *Musculoskeletal injury during the movement assessment.* The risk of sustaining a musculoskeletal injury 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 have not yet observed any musculoskeletal injuries resulting from any of the testing procedures.

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.

All available precautions will be taken to minimize these risks.

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

We cannot guarantee that you will directly benefit from participating in this research study. However, you may benefit from this study if information collected from you during the clinical assessments and self-reported questionnaires aids your healthcare provider in more either reducing your musculoskeletal injury risk or personalizing the rehabilitation plan for your musculoskeletal injury. Additionally, others may benefit in the future from the information learned during this study. The possible benefits to others are improved musculoskeletal injury risk mitigation strategies and musculoskeletal injury treatment approaches that may reduce the risk of future musculoskeletal injuries.

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

You do not have to participate in this research study. Choosing not to participate in this study is your alternative to participating in the study. Regardless of your decision to participate in this study or not, your decision will not affect the medical care that you receive at a military treatment facility or your status as an active duty

military Service Member.

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

No, you will not be compensated for your time/participation in this research 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 responsible for the scientific and technical direction of the study):

Principal Investigator: Courtney M. Butowicz, PhD
DoD-VA Extremity Trauma and Amputation Center of Excellence
Walter Reed National Military Medical Center
America Building (Bldg. 19), Room B312
8901 Wisconsin Avenue
Bethesda, MD 20889

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

The Defense Health Program 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 Department of Defense Instruction (DoDI) 3216.02.

12. SOURCE OF FUNDING:

Research funding is provided by the Defense Health Program Military Operational Medicine Research Program.

These funds are managed, in part, by the Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF).

13. LOCATION OF THE RESEARCH:

Walter Reed National Military Medical Center (WRNMMC).

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 Human Research Protections Program Office (HRPPO) and local Institutional Review Board (IRB), the WRNMMC Department of Research Programs (DRP), the Henry M. Jackson Foundation for the Advancement of Military Medicine, and the Department of Defense (DoD) Higher Level Review as part of their duties. These duties include making sure that research participants are protected. Those listed above will have access to your records and agree to safeguard your protected health information (PHI) by using and disclosing it only as permitted by you in this consent or as directed by state and federal law. 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 and the healthcare provider that you identify as the primary individual who is providing care for your musculoskeletal injury will know that 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 you complete visits. 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. This intake form will be kept in a locked cabinet inside of a locked room and stored separately from your coded research records. The only times that your identity will be connected to your research related data are when a post-clinical assessment report is provided back to your healthcare provider. This report will include information that may help your healthcare provider in better customizing your clinical care.

All data collected from your study visits will be labeled with your unique coded study number. Coded data from VALD HumanTrak motion capture system will be stored on the local system off-network cloud. Coded data from the gait assessment will be stored on the local system off-network computer. Coded data will be used in the USU REDCap system and stored on an off-network server. Your protected health information regarding musculoskeletal injury history will be extracted from the DHA MHSDR, stored on the WRNMMC-DHA owned network, and then aggregated with the coded data set from VALD HumanTrak motion capture, gait assessment, and USU REDCap on the WRNMMC-DHA owned network. No data will be added to your medical record. Your coded study data will be entered into a secure, access controlled, and password protected electronic database or within the Uniformed Services University of the Health Sciences' Research Electronic Data Capture (REDCap) system (self-reported information only). Once your coded data is entered in the database it will only be accessible by authorized members of the local study team, the study team at WRNMMC and the WRNMMC DRP and IRB. The aggregate dataset and master linking list will remain on the WRNMMC secure network for up to 5 years following study completion at which point both the dataset and master list will be destroyed via DoD compliant 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 members of the research team who have access to your records 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.

A description of this clinical trial will be available on http://www.clinicaltrials.gov as required by US 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.

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.

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.

16. LONG TERM USE OF DATA

The investigators have requested to save selected data collected from your participation in this research study for possible use in future research.

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

Your de-identified research data, meaning that all of your personal identifiers will be removed, will be securely stored in the aforementioned electronic database. These 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 Health Insurance Portability and Accountability (HIPAA) authorization for 6 years following study closure. They will keep your coded paper research forms for 5 years following study closure. The aggregate dataset and master linking list will remain on the WRNMMC secure network for up to 5 years following study completion at which point both the dataset and master list will be destroyed via DoD compliant digital data sanitation methods.

If you consent to participate in this research study, your de-identified data collected as part of this research may be kept for use in future research studies or given to other researchers for use in future approved research studies. This future research may be in the same area as the original study or it may be for a different kind of study.

If you agree below, your identifiable data may also be kept for use in future research studies or given to other researchers for use in future research studies. If you agree below, you may also be contacted to participate in a future research study. You have the opportunity below to choose whether you wish to allow the study team to keep your identifiable data for use in future research and whether you wish to be contacted for future research.

Please select your responses in Section 23. Authorizations for Future Research found below.

17. USE OF INFORMATION AND SPECIMENS

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

18. INCIDENTAL FINDINGS

There is a possibility that while reviewing your study 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 may let you know if we observe such an incidental finding. Depending on the type of incidental finding, we will follow our local regulatory requirements for reporting any incidental findings (for example, contacting a healthcare professional).

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 Military Health System (MHS) 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. 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. If you decide to no longer participate in this research study, no additional data will be collected from you. You may request to have your data withdrawn at any time before your identifiers (coded identification number) have been removed. Once your data have been de-identified (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:

Courtney M. Butowicz, PhD
DoD-VA Extremity Trauma and Amputation Center of Excellence
Walter Reed National Military Medical Center
America Building (Bldg. 19), Room B312
8901 Wisconsin Avenue
Bethesda, MD 20889
courtney.m.butowicz.civ@health.mil
301-295-8506

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment (clinical movement assessments completed as part of this study). Contact your personal healthcare provider 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 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 canceled.

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 Investigator immediately at 301-295-8506.

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

For MHS beneficiaries, transportation to and from hospitals or clinics will not be provided or paid 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.

22. CONTACT INFORMATION:

Principal Investigator (PI)

The overall Principal Investigator or a member of the research staff will also be available to answer any questions throughout this study:

Courtney M. Butowicz, PhD
DoD-VA Extremity Trauma and Amputation Center of Excellence
Walter Reed National Military Medical Center
America Building (Bldg. 19), Room B312
8901 Wisconsin Avenue
Bethesda, MD 20889
courtney.m.butowicz.civ@health.mil
301-295-8506

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 WRNMMC IRB Office, the overall IRB of Record for this study at:

Walter Reed National Military Medical Center
Department of Research Programs, Building 17
4650 Taylor Road
Bethesda, MD 20889
301-295-8239

Human Research Protection Program (HRPP) Office

Human Protections Administrator. Contact number: 301-259-8239.

23. AUTHORIZATIONS FOR FUTURE RESEARCH:

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

_____ I do not authorize the storage of identifiable data collected as a part of this study for future use in research studies.

_____ I authorize the storage of identifiable data collected as a part of this study for future use in 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.

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)

AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Principal Investigator (PI) Name and Rank: Dr. Courtney M. Butowicz, PhD

Corps and Service/Organization: Walter Reed National Military Medical Center (WRNMMC)

Title of Research Study: Pre-neuromusculoskeletal injury Risk factor Evaluation and Post-neuromusculoskeletal injury Assessment for Return-to-duty/activity Enhancement (PREPARE)

I. Purpose of this Document

An Authorization is your signed permission to use or disclose 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 disclose 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 in this document.

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.

II. Authorization

The purpose of this study is to identify the physical and psychological factors that increase musculoskeletal injury (an injury that affects a bone, ligament, muscle, or tendon) risk. Along these lines, this study aims to develop comprehensive musculoskeletal clinical assessments that can identify these factors so important information regarding you can be shared back to healthcare providers who are working to reduce your musculoskeletal injury risk or who are caring for your musculoskeletal injury.

A. What health information will be used or disclosed about you?

The local research team will review your electronic medical record to identify any musculoskeletal injury and related 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), telephone number, telephone carrier, electronic email address, full face photograph (via video), 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, so that they may collect information related to your injury, 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 will have access to your health information.

However, your PHI may be made available to federal health oversight groups such as the local Institutional Review Board (IRB), the WRNMMC Department of Research Programs (DRP), the DoD Higher Level Review, the Uniformed Services University of Health Sciences, Henry M. Jackson Foundation for the Advancement of Military Medicine, 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 <u>future</u> research studies?

Yes, your health information *<u>is</u>* requested for future research studies as specified below:
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 musculoskeletal injuries (an injury that affects a bone, ligament, muscle, or tendon).

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

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

____ I *<u>do not</u>* give permission to use my health information for future research studies

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 revoke this Authorization?

- You may change your mind and revoke (take back) your Authorization at any time. However, if you revoke this Authorization, any person listed above may still use or disclose any already obtained health information that has been fully de-identified, as it will be impossible to remove your data at this point.
- If you revoke this Authorization, you will no longer be allowed to participate in this research study.
- If you want to revoke your Authorization, you must write to:

Courtney M. Butowicz, PhD
DoD-VA Extremity Trauma and Amputation Center of Excellence
Walter Reed National Military Medical Center
America Building (Bldg. 19), Room B312
8901 Wisconsin Avenue
Bethesda, MD 20889
courtney.m.butowicz.civ@health.mil
301-295-8506

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 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 disclosed 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.
- If you believe your privacy rights have been violated, you may file a written complaint with the WRNMMC Privacy Officer, located at 8901 Wisconsin Avenue, Bethesda, MD 20889, Telephone: 301-319-4775.

Signature of Research Participant:

Your signature acknowledges that:

- You authorize the MHS to use and disclose your health information for the research purposes stated above.
- You have read (or someone has read to you) the information in this Authorization.
- You have been given a chance to ask questions, and all of your questions have been answered to your satisfaction.

_____ _____

Participant Signature Date (Time)

_____

Participant Printed Name