Official Study Title: Post-Concussion Neuromuscular Function and Musculoskeletal Injury Risk

NCT: NCT05122728

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WALTER REED NATIONAL MILITARY MEDICAL CENTER

CONSENT TO PARTICIPATE IN RESEARCH

Title: Post-Concussion Neuromuscular Function and Musculoskeletal Injury Risk

Principal Investigator: Bradford D. Hendershot, PhD

Other Study Sites: University of Georgia (UGA)

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 changes that occur following a mild traumatic brain injury (mTBI, aka "concussion"), which may increase your chance of sustaining a future musculoskeletal injury (an injury that affects a bone, ligament, muscle, or tendon). If you volunteer to participate in this study you will be asked to actively participate for up to 12 months. There will be 3 laboratory based movement assessments (approximately 2 hours each) and a monthly questionnaire that asks about how you are feeling both physically and mentally (less than 15 minutes each). Additionally, we will ask that you complete a symptom checklist daily from the time you enroll in the study until you no longer have concussion related symptoms (e.g., headache), as a means to determine when you are able to complete the rest of the study related procedures. Throughout the course of the study, you retain the right to stop your participation in the study or refuse to complete any study procedure. There are no study specific interventions (aka "treatments"), so 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 in this study, or not to participate, will not affect your future medical care, your future career as an active duty Service member (if applicable), or your status as a member of the University of Georgia (UGA, if applicable). If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

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

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

You are being asked to take part in this research study because you recently sustained a mild traumatic brain injury (mTBI, aka "concussion") *or* you have been identified as a "match" (aka "non-concussed") to an individual with a recent mTBI. The purpose of this research study is to learn about the physical and psychological changes that occur after you sustain an mTBI. It is known that mTBIs increase musculoskeletal injury risks in military Service members and physically active civilians. However, the underlying mechanisms that increase musculoskeletal injury risk following mTBI have not yet been identified. Thus, it is important for us to better understand the physical and psychological changes that occur following an mTBI so that we can develop better rehabilitation programs to reduce the musculoskeletal injury risks following an mTBI. We anticipate that the total time you will be completing study specific activities will be approximately 9 hours, over the course of the study (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.

This study is a called a multi-site observational study because participants from Walter Reed National Military Medical Center (WRNMMC) and the University of Georgia (UGA) will participate in this study and you will not receive any intervention (aka "treatment") specifically related to this study, the study team will only collect observations about you. Approximately 124 people will take part in this study overall, with approximately 62 participants to be enrolled at WRNMMC and UGA, over a period of 2 years.

At the end of this research study the clinical results, including research results about you will only be shared with you if they are relevant to your clinical care, and only at the discretion of your treating medical provider (for example, physical therapist, primary care physician, or athletic trainer). However, a summary of results 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 mTBI (if applicable), relevant medical history, 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. If you are a potential "healthy matched control" we will ensure that you are matched to a participant with an mTBI based on the following criteria: 1) sex; 2) age (±2 years); 3) occupation/physical activity participation; 4) height (±5%); and 5) weight (±5%).

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 self-reported questionnaires (initial visit and monthly throughout the study) and laboratory based movement assessments. Specifically, you will be asked to complete the following study procedures:

1) Participant Completed Questionnaires (15 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. Birthdate
    iii. Sex
    iv. Traumatic brain injury history
    v. Musculoskeletal injury history
b. Symptom Checklist
    i. Presence and Severity of Symptoms
    ii. Pre-Injury Proxy Symptoms
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 experience any depressive symptoms over the past 7 days
    iv. Anxiety – A questionnaire that assess your level of anxiousness over the past 7 days.
d. The Brief Resilience Scale – A questionnaire that asks about how well you "bounce back" from difficult life experiences.
e. Tampa Scale of Kinesiophobia – A questionnaire that asks about pain-related fear of movement and re-injury.

2) Laboratory Movement Assessment (2 hours each) – You will be asked to complete a variety of laboratory based assessments that assess how well you move and how well your muscles work.
    a. Movement Assessments – You will complete all movement assessments while you are outfitted with reflective markers that are tracked by video cameras. Motion tracking cameras will only capture and track these reflective markers; no identifying information (e.g., face, clothing, body marks) will be recorded or captured from you. These markers are adhered to your skin via double sided tape. 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). The exception to this is the gait (walking) trials, for which you will maintain a relaxed, comfortable posture. Then within 5 seconds, the study team member will provide you with a visual stimulus (green light). You will complete the movement as quickly as possible after seeing the green light.
        i. *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 set of force platforms. You will jump forward, and not vertically, to reach the force platforms. 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 5 jump-landings.
        ii. *Single Leg Hop* – You will stand on a 30cm (~1 foot) tall box, set at a distance that is equal to 50% of your height behind a set of force platforms. You will jump forward, and not vertically, to reach the force platforms; you will keep your hands on your hips throughout the entire movement. Both of your feet will leave the box at the same time. You will land on one foot (the study team will tell you which foot to land on). Once you land on the ground you will attempt to come to a stable position as quickly as possible upon landing. You will perform 5 single leg hop trials on each leg (10 total trials).
        iii. *Anticipated Cut* – You will stand on a 30cm (~1 foot) tall box, set at a distance that is

equal to 50% of your height behind a set of force platforms. You will jump forward, and not vertically, to reach the force platforms. Both of your feet will leave the box at the same time. You will land on one foot (the study team will tell you which foot to land on). Immediately upon landing, you will make a "cut" at a 45° angle (marked with tape on floor) in the direction provided by the study team prior to the trial. You will complete 5 trials cutting in each direction (10 total trials).

iv. *Gait* – You will complete over-ground gait (walking) trials at a self-selected pace. You will start 3m in front of the force platforms so that you are at a steady walking speed by the time you reach the force platforms. You will complete 5 gait trials so that each foot makes contact with the force platform (10 total trials).

1. You will also complete gait tasks under a "dual-task condition". During dual-task conditions you will be asked to count backwards from a randomly generated number between 80 and 120 at a predetermined denomination (example, count backwards from 100 by 7s; 100…93…86…79). You will complete 5 gait trials so that each foot makes contact with the force platform (10 total trials).

b. Muscular Function Assessments

i. We will test the strength of your quadriceps (the muscles on the front of your thigh) and your calf muscles. You will be seated in a machine called a dynamometer that tests muscular strength. Adhesive electrodes will be placed on your skin over the aforementioned muscles and over your shin bone (the areas will be shaved and cleansed with alcohol prior to electrode placement). These electrodes are controlled by an electrical stimulator that will provide a small amount of electricity to your muscles. You will push as hard as you can against the dynamometer, but the machine will not move (maximal voluntary isometric contraction).

1. *Interpolated Twitch Technique* – Initially, the muscle stimulating electricity will be slowly increased to determine the maximum amount of force your muscle can produce. You will then perform a second maximal voluntary isometric contraction. During the maximal voluntary isometric contraction, you will receive a small electrical muscle stimulating current. This stimulating current will be followed by two more small electrical muscle stimulating currents during relaxation following the maximal voluntary isometric contraction. You will complete 6 trials for each muscle group (24 total trials [12 each limb]).
2. *Muscular Ramp Contraction* – You will perform six maximal voluntary isometric contractions to determine the maximum amount of force you can have your muscle produce. You will then be provided with visual feedback (i.e., graph on a computer screen) that shows your muscle force; the graph will show your muscle force from 20 – 100% of your maximal voluntary isometric contraction and you will be asked to match the theoretical maximal voluntary contraction ramp with actual maximal voluntary contraction ramp. You will complete 6 trials for each muscle group (24 total trials [12 each limb]).

c. Sensory Assessments

i. We will examine your sensation of joint movement and light touch.

1. *Closed Chain Proprioception*: You will complete this assessment while you are outfitted with reflective markers that are tracked by video cameras. Motion tracking cameras will only capture and track these reflective markers; no identifying information (e.g., face, clothing, body marks) will be recorded or captured from you. These markers are adhered to your skin via double sided tape. You will stand with feet shoulder-width apart, feet (toes) pointed anteriorly, heels on the floor, and arms extended overhead. You will be asked to squat in a deep,

slow, and controlled manner, to what you believe is 60-degrees of knee flexion and asked to hold that position for 5 seconds. You will then return to a full, upright position, march in place 10 times (5 each leg), and regain the original starting position. You will then be asked to replicate the same knee joint angle as you did in your initial trial. You will perform 3 trials following the initial trial (4 total trials).

2. *Passive Joint Repositioning:* You will be seated in a machine called a dynamometer. You will be secured to the dynamometer while blindfolded and listening to static noise through headphones. The dynamometer will be positioned so both the dynamometer and your knee joint are aligned and the dynamometer movement arm will be fixed to your ankle. Your lower leg will be passively moved from a starting position to a target position where the dynamometer will lock in place for 10 seconds; you will be asked to remember this joint angle. The dynamometer will then be returned to the starting position, and the assessment will be initiated. The dynamometer will slowly move your lower leg and you will be asked to press a trigger when you believe your leg is at the target position. Three combinations of starting and target positions (105° to 70°, 30° to 60°, and 90° to 45°) will be completed for three trials each (9 total trials per timepoint). Two practice trials will be conducted prior to testing.
3. *Light Touch Sensation* – This will assess your ability to sense various pressures on the sole (bottom) of your foot. You will lie prone (on your stomach) and barefoot, so that your feet hang off the end of the table. A study team member will lightly press a small thin filament, (similar in size to pencil lead, but flexible, not rigid) against the sole of your foot; you will inform the study team member when you sense the pressure on your foot. At that time the study team member will apply a different filament to the same area of your foot; depending on your response to the initial filament (yes you can feel the filament or no you cannot) will determine if the subsequent filament is more or less rigid than the previous filament. This process will continue until your lowest level of sensation is determined.

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.* There could be a low risk of musculoskeletal injury (sprain, strain) or a low risk of falling when participating in the research activities that include jumping, landing, and changing direction.

2) *Pain or discomfort during the muscular function assessments.* It is likely that you will experience some level of pain or discomfort when completing the muscular function assessments. This pain is the result of the electrical shock and it is typically not the result of damage/injury to the muscle itself. The study team will continually monitor your level of pain throughout the assessments. You can stop the electrical stimulation at any point if you choose. There is the rare risk that electrical stimulation can cause skin irritation or burn with the use of electrical stimulation.

3) *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, others may benefit in the future from the information learned during this study. The possible benefits to others are improved treatment approaches for patients with mTBI that may reduce future musculoskeletal injury risks.

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 WRNMMC or UGA or your status at either WRNMMC or UGA.

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

Active Duty Service members and all other participants who are eligible to receive medical care within the Military Health System are not eligible for compensation for participating in this study. Participants who are not eligible to receive medical care within the Military Health System will be compensated up to $200. The payment schedule is outlined below; you must complete all components of the study to receive the entire $200. All payments will be made following the conclusion of your time enrolled within the study.

Movement Assessment	**Initial**	**6-weeks Post-Initial**	**12-weeks Post-Initial**	**Completion Bonus (only received if all functional assessments are completed)**		
	$50	$25	$25	$25		
Participant Questionnaires	**Initial**	**1-month Post-Initial**	**3-months Post-Initial**	**6-months Post-Initial**	**9-months Post-Initial**	**12-months Post-Initial**
	$25	$10	$10	$10	$10	$10

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

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

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

Principal Investigator: Bradford D. Hendershot, PhD
DoD-VA Extremity Trauma and Amputation Center of Excellence
Walter Reed National Military Medical Center
America Building (Bldg. 19), Room B320
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 from the Military Performance Optimization Research Award.

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) and the University of Georgia (UGA).

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. Additionally, aggregated data from this study will be sent to our study team located at Womack Army Medical Center (WAMC) for data analysis. All necessary safety and security procedures will be followed at both WRNMMC and WAMC. All data records may be looked at by local research staff, study team members from WAMC, staff from the WRNMMC and WAMC Human Research Protections Program Office (HRPPO) and local Institutional Review Board (IRB), the WRNMMC Department of Research Programs (DRP), WAMC Department of Clinical Investigation, and the Department of Defense (DoD) Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Moreover, the Henry M Jackson Foundation for the Advancement of Military Medicine (HJF) and authorized research staff employed by HJF will have access to research records. 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. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

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

Generally, only people on the local research team will know that you are in this research study. You and your research data will be identified only by a unique coded study number and not by your name, social security number, DoD ID, or other protected identifier. The unique coded study number cannot be linked to your name except at the facility where you complete study related 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.

All data collected from your study visits will be labeled with your unique coded study number. Your coded study data will be entered into a secure, access controlled, and password protected electronic database housed on a DoD server. 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, the study team at WAMC, the WRNMMC DRP and IRB, and the WAMC Human Research Protections Program Office (HRPPO),

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

If applicable, a description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the study 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 participants 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 for six years following study closure. They will keep your coded paper research forms for 5 years following study closure.

If you consent to participate in this research study, your de-identified data collected as part of this research may be kept for 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 see 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). This includes if your responses on the National Institutes of Health Patient-Reported Outcomes Measurement Information System (PROMIS) Depression measure indicate you are depressed. This information will be passed on to your referring healthcare provider (if relevant/available) or a behavioral health specialist, as is required by local policies. The healthcare provider will then follow local requirements to address patients who report depressive symptoms

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

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

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

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

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 and/or specimens 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:

Bradford D. Hendershot, PhD
DoD-VA Extremity Trauma and Amputation Center of Excellence
Walter Reed National Military Medical Center
America Building (Bldg. 19), Room B320
8901 Wisconsin Avenue
Bethesda, MD 20889
bradford.d.hendershot2.civ@mail.mil
301- 400-3477

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 lose you status a Military Health System beneficiary or member of the UGA community, 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 the Principal Investigator immediately at 301-400-3477.

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

If you are injured because of your participation in this research and you are not a Military Health System beneficiary, you will work with the local study team to obtain the necessary immediate care for your injury.

You will not be reimbursed for medical expenses related to the care your study related injury.

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

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:

Bradford D. Hendershot, PhD
DoD-VA Extremity Trauma and Amputation Center of Excellence
Walter Reed National Military Medical Center
America Building (Bldg. 19), Room B320
8901 Wisconsin Avenue
Bethesda, MD 20889
bradford.d.hendershot2.civ@mail.mil
301-400-3477

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
Program (HRPP) Office
Phone: 301-295-8239

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

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

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

Principal Investigator (PI) Name and Rank: Bradford D. Hendershot, PhD

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

Title of Research Study: Post-Concussion Neuromuscular Function and Musculoskeletal Injury Risk

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 changes that occur following a mild traumatic brain injury (mTBI, aka "concussion"), which may increase your chance of sustaining a future musculoskeletal injury (an injury that affects a bone, ligament, muscle, or tendon). This information may help healthcare providers in reducing post-concussion musculoskeletal injury risks.

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

The local research team may 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, electronic email address, 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 research team will have access to your health information in order to monitor your health status, and/or analyze the research data. Additionally, your PHI may be made available to groups such as the WRNMMC Department of Research programs and the WRNMMC Institutional Review Board.

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, 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:

The investigator has requested to save data collected from your participation in this research study for possible use in future research. The stored data will not have any identifying links, so you will not be contacted requesting your permission to use this data in another study. This future research may be in the same area as the original study or it may be for a different kind of study.

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?

To maintain the integrity of this research study, you will not have access to your personal health information related to this research until the study is complete. At the conclusion of the research and at your request, you will have access to your health information that the MHS maintains in a designated record set. A designated record set means a set of data that includes health information or billing records used in whole or in part by your health care providers at the MHS to make decisions about you. If it is necessary for your care, your health information will be provided to you or your health care providers.

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 as necessary to maintain the integrity or reliability of this research.
- If you revoke this Authorization, you may no longer be allowed to participate in this research study.

- If you want to revoke your Authorization, you must write to:

  Bradford D. Hendershot, PhD
  Department of Physical Medicine and Rehabilitation
  Walter Reed National Military Medical Center
  8901 Wisconsin Ave. Bethesda, MD, 20889
  301-400-3477
  Bradford.d.hendershot2.civ@mail.mil.

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.

Signature of Research Participant or Personal Representative:

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

_____
Participant Printed Name