

*Evans Army Community Hospital, Ft Carson*  
**CONSENT TO PARTICIPATE IN RESEARCH**

**PROTOCOL TITLE:**

**Towards Comparative Effectiveness in Military Vestibular Rehabilitation**

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. 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 these researchers if you are taking part in another research study.

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.

Your decision will not affect your future care at Warrior Recovery Center, Evans Army Community Hospital (EACH), Ft Carson.

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

You are being asked to take part in this research study because you are an Active Duty Service Member between the ages of 18-49 referred to the Warrior Recovery Center's (WRC) Vestibular Rehabilitation program for persistent vestibular symptoms (dizziness, imbalance) following a mild-moderate traumatic brain injury (TBI). The purpose of this research study is to learn about the environment, resources and tools required to compare two different treatment approaches.

The duration of participation per visit is 1 hours for the today's visit, 2 hours for the Pre-Treatment Research Visit, and 2.5 hours for the Post-Treatment Research Visit. All other visits will be part of your standard of care and may include either eight 45 min Treatment Visits or three 30 min Treatment Visits depending on the treatment modality you are assigned to.

There will be up to 100 people taking part in the study at the Warrior Recovery Center (WRC) and Outcomes Assessment Center (OAC) at EACH, over a period of 26 months.

During the study, you will have 3 research visits including today's visit with the Research Assistant or the Research Nurse Coordinator. You will need to present to the Outcomes Assessment Center (660 Southpointe Ct, St 110, Colorado Springs, CO 80906 - 4 miles north of Ft Carson) twice within the next 3 months.

This study is looking at Individualized (one-on-one) and Generalized (in a group setting) Vestibular Rehabilitation Treatments. Both treatments are available to patients at the Warrior Recovery Center as standard of care.



## **2. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY**

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

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

You will be asked a series of questions about your injury, the symptoms you are experiencing and any medications you are taking. You will be asked about your military life, and about your personal and family medical history. You will be asked for permission for the study team to review your medical records for information pertinent to the study and you will be asked to complete some questionnaires about the symptoms you are experiencing.

You will be tested in two different devices; in a Computerized Dynamic Posturography (CDP) device and a Neuro-Otologic Testing System (NOTC). Your tolerance to the tests performed in these devices will determine your eligibility for continuing participation.

The CPD is a tests to assess how well you can maintain your balance under different conditions. We will stand on a platform inside a small booth. The platform and background will move in order to mimic different conditions you encounter in everyday life. During some of these tests, we will place a monitor on top of your head, instruct you to move your head and/or close your eyes. You will be securely strapped into a harness to prevent falling. You may request a break at any time. Qualified research staff will be monitoring you throughout this testing. This test will take approximately 45 min.

The NOTC is a test to assess your eye movements. You will be asked to sit in a chair in a small dark room and wear a pair goggles that have cameras pointing towards your eyes. You will be secured against the chair and a headset will be placed for you to speak with staff during the entire test. The research staff will be able to see you with a video camera during the entire test. Some of the tests performed in this device involve following a light with your eyes while the chair is still and some will involve rotation of the chair. Qualified research staff will be monitoring you throughout this testing. This test will take approximately 45 min.

Once your eligibility is confirmed, you will be randomized to one of two treatment modalities. Randomization is a selection process similar to flipping a coin, in which you have equal chance of being assigned to either of the groups. Both treatments modalities are offered indistinctly as standard of care to patients with vestibular issues at the WRC. The treatment visits are not research activities, only the randomization processes is considered a research activity.

The treatment modalities offered at the clinic are:

- **Individualized Vestibular Rehabilitation Treatment (IVRT):** These visits are scheduled depending on your needs and PT availability. These visits require one-on-one time with a PT. Individuals are commonly seen by the PT 3 times at two week intervals. These visits last 30 minutes and are designed to instruct you on exercises to perform on your own and evaluate your progress.
- **Generalized Vestibular Rehabilitation Treatment (GVRT):** These visits are available between 2 and 3 times per week and each visit lasts 45 minutes. In this modality, you can



choose how often you attend to complete 8 visits within a period between 4 and 8 weeks. The maximum number of patients in each class is 8.

At the end of your study participation you will be asked to complete survey about your experience participating in the study.

During this study we will send text messages and/or e-mail messages, in addition to phone calls, depending on your preference to assist with scheduling your research visits.

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

If you choose to take part in this study, you may develop or experience a temporary increase in your dizziness during the CDP and NOTC. Depending on the level of discomfort, we may have you moving to less demanding tasks, taking a break or suspending the test. While this only happen to approximately 10% of the normal population, we expect that more than 50% of people participating in this study will present increased dizziness during the evaluations. Increased dizziness may make you develop nausea and/or anxiety. Anxiety can also result from standing on a moving platform in a small booth (CPD) and/or from sitting in a small, dark room (NOTC). We will ask you to let us know if the symptom appears so we can stop the test before it progresses. Both dizziness, nausea and anxiety can persist beyond the testing period.

There is a chance (30 – 50%) you may experience headache, fatigue and/or tinnitus (*ringing in your ears*) during and/or after the CDP and NOTC evaluations. The symptoms should go back to your baseline within hours, if the symptoms persist, you will be asked to contact your primary care provider.

There is a small (5 - 10%) chance for you to develop temporary musculoskeletal (*muscle or bone*) discomfort during the CDP and NOTC evaluations. If this happen, we will try to modify your posture or the way you are attached to the devices to see if the discomfort disappear. If it doesn't and the discomfort becomes unbearable to you, we will suspend the evaluation.

There is a small chance (5 - 10%) you may develop headache and/or fatigue while completing the study questionnaires. You may also encounter questions that you may prefer not to answer, if this occur, you can make a line over the question move to the next one.

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

There may also be other risks of taking part in this study that we do not yet know about. If any new risks are discovered during this study, you will be informed by being asked to review and sign a new consent.

**5. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?:**

The treatment/intervention is part of your standard of care / regular medical care. Benefits received from the treatment/intervention are not benefits related to the study.

There are no direct benefits to you for taking part in the study. The likelihood for tests and evaluations performed as part of this study to identify any health issues not already recognized by your medical provider is minimal. However, the results of this study will be useful to the healthcare and scientific communities addressing the health and well-being of military personnel.



We expect that the project as a whole will not only provide evidence about the most appropriate approaches to treat post-traumatic dizziness in military populations but to also to provide standardization of treatment and evaluation.

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

You can choose not to take part in this research study. You will be eligible to receive vestibular rehabilitation treatment or any other treatment you are entitled to receive independent of your participation in this study.

**7. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?**

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

**8. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?**

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

**9. WHO IS CONDUCTING THIS RESEARCH?**

The Defense and Veterans Brain Injury Center (DVBIC) in collaboration with the Warrior Recovery Center (WRC) at Evans Army Community Hospital (EACH), Fort Carson, CO.

**10. STUDY SPONSOR**

Defense and Veterans Brain Injury Center (DVBIC) as part of the Defense Health Agency and the Department of Defense

**SOURCE OF FUNDING:**

Defense and Veterans Brain Injury Center (DVBIC) will supply the research staff and supplies for the research portions of this study.

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

Alicia Souvignier, DPT  
Captain, United States Public Health Service  
Officer in Charge, Warrior Recovery Center Rehabilitation  
Site Director, Defense and Veterans Brain Injury Center

**12. LOCATION OF THE RESEARCH:**

Warrior Recovery Center (WRC), Bldgs 7488/89 Sutherland Circle, Ft Carson, CO 80913

In addition to today's consent visit, your standard of care clinic visits will take place at the WRC including your Vestibular Rehabilitation Physical Therapist, GVRT or IVRT appointments. These appointments will be made with clinic staff (719-526-7453).

Outcomes Assessment Center (OAC), 660 Southpointe Ct, St 110, Colorado Springs, CO 80906 (4 miles north of Ft Carson). Your research study visits including the Pre- and Post-Treatment Research Evaluation Visits will take place at the OAC. Free parking will be available. These appointments will be made with research staff (719-251-0696).

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

Study personnel have no conflicts of interest to disclose.



**14. 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/efoms/dd2005.pdf>.

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

Secure storage of personal identifying information (PII) (ex: name, date of birth, phone number, etc) in locked cabinets behind locked doors and/or in password protected files/folders within the DoD network.

Research record deidentification through removal of PII and record coding.

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

If you are randomized to GVRT (group setting), we also ask that you respect the privacy of everyone in the group and not share or repeat what is said in any way that could identify anyone. However, since someone in the group may not obey instructions to keep all comments confidential, we recommend that you avoid saying anything that you don't want to be repeated outside the group. We ask your cooperation in protecting the privacy of the comments made within this group by not saying anything that would identify you or others as study participants.

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

By signing this document, you give your permission for information gained from your participation in this research study to be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; 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.

- Approved personnel from the Defense and Veterans Brain Injury Center (DVBIC), Warrior Recovery Center (WRC), and Evans Army Community Hospital (EACH) at Fort Carson
- Representatives from Regional Health Command – Atlantic (RHC-A) Institutional Review Board (IRB), US Army Human Protections Office (AHRPO), Defense Health Agency (DHA) Human Research Protections Program (HRPP), US Army Medical Command (MEDCOM) Headquarters HRPP
- State and Federal Government representatives, when required by law



- As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

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.

### **15. 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 (719) 526-3257.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., 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 DoD healthcare 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 DoD healthcare beneficiary, you are authorized space-available medical care for your injury at a DoD hospital or an DoD clinic; medical care charges for care at a DoD hospital or a DoD clinic will be waived for your research-related injury. If you obtain care for research-related injuries outside of a DoD or DoD hospital or clinic, you will not be reimbursed for those medical expenses.

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

### **16. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?**

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, you must immediately inform the research staff of your decision. If you decide to withdraw from the research study, we recommend for you to follow up with your provider regarding your treatment. Since the treatment is part of your standard of care, withdrawing from the study will not affect your ability to continue receiving the treatment.

If you are unable to complete the study, we will offer you the opportunity to voluntarily complete a satisfaction survey and if you have completed at least 50% of your treatment program, we will offer you the opportunity to voluntarily complete research activities listed in the Post-Treatment Research Evaluation Visit.

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 she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

**17. VOLUNTARY PARTICIPATION:**

The decision to take part in this research study is completely voluntary on your part. 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.

**18. INCIDENTAL FINDINGS**

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

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

You do not have an option to decline receiving information about an incidental finding. A qualified person will talk to you if there is an incidental finding.

We will also give information about this incidental finding to your Vestibular Rehabilitation Physical Therapist 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.

**19. CONTACT INFORMATION:**

**Principal Investigator (PI)**

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

Principal Investigator: CAPT Alicia Souvignier, DPT

Phone: (719) 526-3257

Mailing Address: Warrior Recovery Center, Bldg 7488, Sutherland Circle, Ft Carson, CO 80913

**Institutional Review Board (IRB) Office**

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at:

Regional Health Command - Atlantic (RHC-A) Institutional Review Board (IRB),

9275 Doerr Road, Fort Belvoir, Virginia 22060-2204

Email: usarmy.belvoir.medcom-rhc-a.mbx.irb-office@mail.mil, (706) 787-8053/(910) 907-8351



**US Army Medical Command (MEDCOM) Human Research Protection Program (HRPP)**

Acting MEDCOM Headquarters Human Protection Administrator (HPA): Jeffrey Rollins  
Phone: (703) 681-0647

Mailing Address: 7700 Arlington BLVD, 2SW428B, Falls Church, VA 22042

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**

\_\_\_\_\_  
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

