

Consent (Permission) to Participate in a Research Study

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Title of Study: Body-Worn Sensors for Risk of Injury Prediction during Military Training

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Sponsor: Department of Defense

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READ THE FOLLOWING CAREFULLY

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 document carefully.

You are being asked to participate in a research study. Before you give your consent to be part of this study, please read the following and ask as many questions as necessary to be sure that you understand what your participation will involve. If you have any questions that remain unanswered, please ask the study doctor or one of his/her research study personnel before signing this form. The following is a short summary of this study. It will help you decide whether to take part.

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.

Should you decide to participate, you may need to obtain permission by your supervisor.

PURPOSE

You are being asked to take part in a research study because you are a Service Member in the Special Warfare Center and School or in the 82nd Airborne Division at Fort Bragg, North Carolina. Taking part in this study is voluntary. The purpose of this study is to test whether measures of balance and agility can help predict if a Service Member may be at risk for an injury to their legs before beginning their school and training. This study involves an investigational device that has not been approved by the U.S. Food and Drug Administration (FDA), but the device has been determined to have no significant risk by an Institutional Review Board, which has reviewed the safety of this study.

To participate in this study, you must be a male or female Service Member between 18 and 55 years of age who is currently in the Special Warfare Center and School or 82nd Airborne Division. You may not be able to participate in the study if you have had an injury to your low back or legs that limits your physical activity, have been told by your doctor that you should not exercise, or are taking a medicine that may affect your balance, coordination, or agility. Pregnant females will not be able to participate in the study.

NUMBER OF STUDY PARTICIPANTS

If you decide to participate in this study, you will be one of 8,300 people who will be in this research study.

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DURATION OF THE STUDY

You will be enrolled in this study for the duration of your training in the Special Warfare Center and School or 82nd Airborne Division. The first study visit should take a total of 20 minutes of your time. Subsequent study visits for individuals sustaining a lower extremity injury should take a maximum of 10 minutes of your time.

PROCEDURES

During this study visit and subsequent visits, you will be asked to complete several surveys on an iPad. You will be asked to fill out a survey providing information about your age, gender, military rank, current assignment, military occupational specialty, past medical history and injury history to your legs, and current medical issues that you are dealing with now in your legs which include pain, soreness, tightness, or recent injuries. You may be asked to fill out a survey that is specific to having a past injury to your hip(s), knee(s), or ankles. You will be asked about your height and weight.

During this research visit, we will test your ability to balance on each leg and your ability to move side to side quickly. You will be asked to perform these tests while wearing a knee sleeve on each leg that has a small sensor above and below your knee. You will be asked to dress in shorts, T-shirt, and athletic footwear. Test instructors will describe, demonstrate, and record all of the tests for you. You will be asked to put on the knee sleeves and wear them for all the activities. First, you will be asked to walk for up to 13 seconds. You will then be asked to stand on each leg for up to 30 seconds. You will be asked to do this for each leg at least once and up to two times per leg. Next, you will also be asked to perform an agility test that measures how quickly you move side to side. You will be asked to do this at least two times and up to three times. You will be given between a 30 second and 1 minute rest period between each of these tests. The research team will be on hand to watch you do the tests. You will be given additional time to rest, if needed, throughout all of the activities.

In the future, if you happen to have an injury to one or both legs while attending Special Warfare Center and School or when in the 82nd Airborne Division training that require medical attention by medical staff, you will be asked by the medical personnel about the injury (type of injury, parts injured, how the injury was treated, if you missed time in school, etc.), and this information will be entered in the iPad. Study visits for individuals sustaining a leg injury should take a maximum of 10 minutes of your time.

Instead of being in this research study, you may choose to decline to take part. If at any point you feel that you do not want to continue with the testing, you can withdraw from the study. If you decide not to participate, this will in no way affect the care you will receive from the Military staff assigned to your unit or your participation in either Special Warfare Center and School or when in the 82nd Airborne Division. **The information collected on the iPad will be sent to the secure data server that meets Department of Defense guidelines housed at the University of Miami.**

You may be asked if you would be willing to have photographs, film, video or tape recordings for the purpose of teaching, research, scientific meetings and scientific publications, including professional journals or medical books. If you agree, you will be asked to sign an "Authorization for Audio/Video/Photography Recording in a Research Study" informed consent form.

RISKS AND DISCOMFORTS

Taking part in the study involves little risk. You may find that some of the survey questions are personal and request information that you may not want to disclose. The risks of physical injury in this study are the same as that you would experience with exercise, playing sports, or military training.

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Subjects may become tired while performing the tests. We will give you multiple rest periods between the tests. There may be a risk for falling when doing the balance and agility activities. You have the right to ask any questions about any hazards of this study at any time. You will be asked to tell the study investigator about any possible side effects you might have at any time during the study.

BENEFITS

No direct benefit can be promised to you for being in this study. However, others may benefit in the future from the information learned during this study. We hope that this study will allow us to develop a way to screen Service Members for potential risk to future leg injuries and provide a Service Member with an exercise and rehabilitation program designed to help prevent the injury from occurring.

INCENTIVES/PAYMENTS TO PARTICIPATION

You will not be paid for taking part in this study.

COMPENSATION FOR STUDY-RELATED INJURY

Although risks are unlikely, if injury should occur, treatment will be available through your Unit's Medical Command. 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 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.

CONFLICT OF INTEREST

The University of Miami has an interest related to the study. Drs. Kim, Gailey, Bennett and Gaunaord have disclosed that they have a personal interest related to this study. The mobile sensor system used in this study was developed at the University of Miami. You may ask any questions necessary to assure that this relationship has not overly influenced the conduct of this research study. If you require further information, please contact Dr. Gailey with questions and concerns. If you have any questions regarding disclosure review and the conflict management process at the University of Miami, please call the Office of Disclosures & Relationship Management (DRM) at 305-243-0877.

USE OF RESEARCH RESULTS

As we mentioned above, your research data will be stored on a secure database server that meets Department of Defense guidelines housed at the University of Miami. You will be assigned your own secure identifiable number which will be used to identify you throughout the study. Access to the secure database server is password protected. Your name and other personal identifiable information will not be released to other parties not mentioned here unless you give us specific written permission to do so. Your name and specified personal information will be shared with Nelson Hager, MD, MS, Vice Chair, Department of Physical Medicine and Rehabilitation, Uniformed Services University for the Health Sciences, 4301 Jones Bridge Road, Bethesda, MD 20814. You will be told in writing any new information that might affect your decision to be in the study. Your de-identified research results will be used for analysis to determine the benefits and shortcomings of this study. The de-identified results can be disseminated in scientific conference, journal manuscript, and federal guidelines. This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

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CONFIDENTIAL STATEMENT

Records identifying you may be inspected by the sponsor of this study (Department of Defense), the study investigator and his personnel, or by one or more Federal governmental agencies for regulatory purposes. In addition, University of Miami Institutional Review Board (IRB), which approved this research, may have access to this informed consent document as well as to your records for auditing purposes. The purpose of these audits is to help ensure that the research is being conducted in an appropriate manner and is in the public interest. Your name and other information identifying you will be protected to the fullest extent possible. Any information shared with the sponsor may no longer be protected under federal law.

PARTICIPATION AND WITHDRAWAL FROM THE STUDY

You may ask any questions you want about the study and we will answer them. You can refuse to be in the study or withdraw from the study at any time. If you choose to withdraw from the study, please contact the Principal Investigator, Robert Gailey, at 305-284-4535 or email at rgailey@miami.edu. Your research data will remain in the Secure Server at the University of Miami. If you do refuse or withdraw, the care you are entitled to at Fort Bragg will not be affected in any way. Whatever you decide, you will not be penalized or lose 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 affect your willingness to continue participation.

SPECIAL CIRCUMSTANCES

The Principal Investigator can take you out of the study if for any reason he feels it is in your best interest to do so or if the study must be stopped for administrative reasons.

You will receive a copy of this document for your information. You may, if you want, show this document to family members, physicians or friends and ask their advice.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team and Dr. Gaunard at: 305-284-4535/305-206-2441 (24-hour contact)

This research has been reviewed and approved by the University of Miami Institutional Review Board ("IRB"). The Human Subject Research Office (HSRO) provides administrative support to the University of Miami's IRBs. Please call the HSRO at 305-243-3195 if you are a participant in any research being conducted by UM, and have any questions.

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PARTICIPANT'S STATEMENT/SIGNATURE

- *I have read this form and the research study has been explained to me.*
- *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
- *I agree to be in the research study described above.*
- *I will receive a copy of this consent form after I sign it.*

Printed Name of Participant

Signature of Participant

Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date