



## CONSENT TO PARTICIPATE IN RESEARCH

**Title:** "Development of Military Occupation-Specific Physical Employment Standards"  
H13-07-1

**Principal Investigator:**

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Military Performance Division  
U.S. Army Research Institute of Environmental Medicine  
Natick, MA 01760

### Introduction

You are being asked to participate in this research study because you are a healthy male Soldier assigned to an 11 series (11B or 11C) Military Occupational Specialty (MOS) or a healthy female Soldier assigned to an MOS with similar physical demands who can safely perform strenuous exercise. The purpose of the study is to establish physical performance standards that the Army can use to determine optimal levels of fitness for Soldiers.

This study is being conducted by researchers from the U.S. Army Research Institute of Environmental Medicine in Natick, MA. The study will take place at a previously designated training area. Approximately 20-30 Soldiers from each of seven combat MOSs and 10 women from related MOSs with similar physical demands will take part in the study. You can expect to be in the study for approximately five days.

### Eligibility

You may take part in this research study if all of the following applies to you:

- You are a man less than 45 years old or woman less than 55 years old.
- You are at low risk for experiencing an injury or developing a cardiac event while exercising (we will ask you to complete a form to assess your risk).
- You are willing to avoid taking any dietary supplements within 24 hours of exercise testing.

You cannot participate in this study if any of the following applies to you:

- You are on a medical profile preventing you from performing strenuous exercise.
- You have a chronic or recent injury or illness that limits exercise (for instance, low back pain, a knee injury, or the flu).
- You are a pregnant woman.

### Explanation of Procedures

If you agree to be in this study, you will be asked to:

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- 1) Fill-out a "participant screening form" to identify any risk factors that you might have (previous smoking history, high blood pressure, etc). This information will be used to determine if you are eligible to participate in the study.
- 2) Allow us to measure your height and weight, and tell us what your most recent 2 mile run time was.
- 3) Allow us to measure your heart rate and oxygen consumption while performing certain occupation related tasks. Heart rate will be monitored using a heart rate monitor consisting of a chest strap transmitter and a watch. To measure oxygen consumption, you will be asked to wear a mouthpiece connected by a flexible hose to a metabolic measuring system or facemask connected to a portable metabolic measuring device, which will monitor your oxygen uptake. Upon completion of each occupation related task, you will be asked to rate how hard you worked during the task.
- 4) Perform selected tasks related to your MOS that may include:

#	Occupational Tasks	Measure	MOS
1	<i>Conduct a Tactical Movement</i>	HR, VO <sub>2</sub> , RPE	11B, 11C
3	<i>Prepare a Fighting Position (Fill and Emplace Sandbags)</i>	HR, VO <sub>2</sub> , RPE	11B, 11C
4a	<i>Drag a Casualty to Immediate Safety (Dismounted)</i>	HR, RPE	11B, 11C
4b	<i>Remove a Casualty from a Wheeled Vehicle (Mounted)</i>	HR, RPE	11B,
5	<i>Lift, Carry, and Install the Barrel of a 25mm gun on the Bradley Fighting Vehicle</i>	RPE	11B
6	<i>Remove the Feeder Assembly of a 25mm gun on the Bradley Fighting Vehicle</i>	RPE	11B
7	<i>Load 25mm H-EIT Tracer Ammunition Cans onto the Bradley Fighting Vehicle</i>	HR, VO <sub>2</sub> , RPE	11B
8	<i>Load TOW Missile Launcher on Bradley Fighting Vehicle</i>	RPE	11B
9	<i>Move Over, Through, or Around Obstacles</i>	RPE	11B, 11C
10	<i>Move Under Direct Fire (3-5 second rushes)</i>	HR, RPE	11B, 11C
11	<i>Prepare Dismounted TOW Firing Position</i>	RPE	11B
12	<i>Lift and Carry M2 .50 Caliber Machine Gun</i>	RPE	11B
13	<i>Lift and Emplace Base Plate for 120mm Mortar</i>	RPE	11C
14	<i>Lift Emplace Cannon for 120mm Mortar</i>	RPE	11C
16	<i>Fire a Mortar (Lift and Hold Round, Place in Tube)</i>	RPE	11C

HR = heart rate

VO<sub>2</sub> = Oxygen consumption

RPE = Rated Perceived Exertion

### 1. Conduct a Tactical Movement

The tactical movement will require you to walk, while carrying about 102 lbs of equipment (basic Soldier uniform (12.4 lbs), personal protective equipment (about 70.4 lbs), and 24 hour sustainment load (19.0 lbs)). To obtain an estimate of energy expenditure during the task, you will walk on a treadmill for a total time of 40 min at 3-4 km/hr (2-2.5 mph). Prior to walking you will be fitted with a heart rate monitor and instructed to complete a light warm up. Then you will walk on a treadmill at 3-4 km/hr (2-2.5 mph) for 30 minutes wearing the full 102 lbs load. After 30 minutes, you will be stopped and quickly outfitted with an oxygen measuring device. You will walk for 10 more minutes at 2-2.5 mph. At the end of 10 min, you will be asked to rate how hard you worked during the task.

### 3. Prepare a Fighting Position -Fill and Emplace Sandbags

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While wearing a fighting load (82 lbs) and a heart rate monitor, you will use an entrenchment tool to fill 26 sandbags to 55-60% full (30-40 lbs of sand). Then you will carry 26 sandbags a distance of 10 meters where you will build a fighting position within 26 minutes. After filling the first 13 sandbags, you will be stopped and quickly outfitted with the portable oxygen measuring device for the rest of the digging and carrying portions of the task. After filling the sandbags and again after building the fighting position, you will be asked to rate how hard you worked during the task.

*4a. Drag a Casualty to Immediate Safety (Dismounted)*

Upon a signal, you will drag a casualty (approximately 270 lbs) a distance of 15 meters as quickly as possible while wearing a fighting load (82 lbs). During this task, you will be equipped with a heart rate monitor. Upon completion of the task, you will be asked to rate how hard you worked during the task.

*4b. Remove a Casualty from a Wheeled Vehicle (Mounted)*

As part of a two Soldier team and while wearing a fighting load minus the weapon (77 lbs), you and a partner will remove a casualty (approximately 227 lbs) from the commander's seat of a wheel mounted vehicle as quickly as possible. During this task, you will be equipped with a heart rate monitor. Upon completion of the task, you will be asked to rate how hard you worked during the task.

*5. Lift, Carry, and Install the Barrel of a 25mm gun on the Bradley Fighting Vehicle (BFV)*

As part of a two Soldier team and while wearing a fighting load (82 lbs), you will lift and carry the barrel of a M242 25 mm gun (107 lbs; prorated 53.5lbs/Soldier) a distance of 25 meters and insert the barrel into the receiver. Upon completion of the task, you will be asked to rate how hard you worked during the task.

*6. Remove the Feeder Assembly of a 25mm gun on the Bradley Fighting Vehicle*

While wearing 39 lbs of specific personal protective equipment and seated in the BFV, you will remove the M242 feeder assembly (59 lbs) from the gun and place it on the floor in the rear of the vehicle. Upon completion of the task you will be asked to rate how hard you worked during the task.

*7. Load 25mm H-EIT Tracer Ammunition Cans onto the Bradley Fighting Vehicle*

While wearing a fighting load minus a weapon (77 lbs), you will lift 30 cans of 25 mm ammunition (45 lbs), carry them 15 meters, and place them onto the tailgate of a BFV. You will be outfitted with a heart rate monitor and the portable oxygen measuring device for the duration of the task. When the task is complete, you will be asked to rate how hard you worked during the task.

*8. Load TOW Missile Launcher on Bradley Fighting Vehicle*

While wearing a fighting load minus a weapon (77 lbs), you will load (and unload) two TOW-2B Aero Missiles (65 lbs) into the BFV Mounted TOW Weapon System. Upon completion of the task, you will be asked to rate how hard you worked during the task.

*9. Move Over, Through, or Around Obstacles*

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While wearing a fighting load (82 lbs), you will scale/climb a 2 meter obstacle with assistance. Upon completion of the task, you will be asked to rate how hard you worked during the task.

*10. Move Under Direct Fire (3-5 Second Combat Rushes)*

While wearing a fighting load (82 lbs) and a heart rate monitor, you will rise from a prone, kneeling, or crouched position, sprint 3 to 5 meters and return to a prone, kneeling, or crouched position. Combat rushes will be repeated as directed over a distance of 100 meters. Upon completion of the task, you will be asked to rate how hard you worked during the task.

*11. Prepare Dismounted TOW Firing Position*

While wearing a fighting load minus the weapon (77 lbs), you will lift, carry (15 meters), and load one TOW-2B Aero Missile (65 lbs) into a Ground Mounted TOW Weapon System. Upon completion of the task, you will be asked to rate how hard you worked during the task.

*12. Lift and Carry the M2 .50 Caliber Machine Gun*

As part of a 2 Soldier team and while wearing a fighting load (82 lbs), you will lift and carry the M2 HB Machine Gun with tripod (153 lbs; prorated 76.5lbs/Soldier) a distance of 10 meters. Upon completion of the task, you will be asked to rate how hard you worked during the task.

*13. Emplace Base Plate for 120mm Mortar*

As part of a 2 Soldier team and while wearing a fighting load (82 lbs), you will lift, carry (25 meters), and emplace the 120mm mortar base plate (136 lbs; prorated 68lbs/Soldier). Upon completion of the task you will be asked to rate how hard you worked during the task.

*14. Emplace Cannon for 120mm Mortar*

As part of a 2 Soldier team and while wearing a fighting load (82 lbs), you will lift, carry (25 meters), and emplace the 120mm mortar cannon tube (110 lbs; prorated 55lbs/Soldier). Upon completion of the task, you will be asked to rate how hard you worked during the task.

*16. Prepare to Fire a Mortar (Lift and Hold Round, Place in Tube)*

While wearing a task specific uniform weighing 46 lbs, you will lift a total of five 120mm HE rounds (29 lbs) to approximately 2 meters in height. You will be expected to hold the first round up over the tube for 10 seconds, before placing it in the tube. The remaining four rounds must be loaded, but do not have to be held. Upon completion of the task, you will be asked to rate how hard you worked during the task.

During this study, we would like to take pictures and videos of Soldiers performing the tests. These pictures and videos will be used for education or illustration purposes only. You will be asked to review and sign a visual image release form indicating whether or not you allow us to take pictures/videos. You may still participate in the study even if you do not allow us to take pictures/videos.

## **Risks and Discomforts**

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During any of these tests, you might strain or pull a muscle, sprain a joint, or fall and hurt yourself. Whenever you exercise in ways you are not used to, muscle soreness may occur and might last for 2-5 days or more. To reduce the likelihood of injury, technicians will train you to perform all the tests and will help you warm up. You will be fitted for equipment and provided with safety equipment, as needed. You will be supervised and spotted during testing. We will remind you to pay attention and watch your step to reduce falls. You should prepare yourself daily by getting enough sleep the night before, drinking enough water, eating enough food, and warming up prior to testing. This will ensure you are well rested, hydrated, have enough energy, and are physically prepared to do your best during testing.

You might get blisters on your feet from walking with a backpack during the Tactical Road March. The risk of getting blisters can be minimized by wearing clean, dry socks. You might experience skin irritation from wearing the backpack or weighted vest. These skin irritations are usually temporary and will dissipate over the course of a few days. If you are required to lift heavy objects, you might drop the object on a body part. You might also experience back pain or strain during the Tactical Road March test or when lifting heavy objects. To minimize this risk, you will warm up and be instructed in proper technique prior to testing.

If at anytime during testing you experience pain, unexpected discomfort, extreme soreness, headache, loss of concentration, dizziness, unusual fatigue, or difficulty breathing, you should immediately inform a researcher, who will call a medic or doctor. You may also call a doctor on your own.

There is a possibility you may be hurt, possibly sustaining sprains or fractures, if you fall while performing the tests or while lifting and carrying heavy objects. You should be careful to maintain your balance and stay away from any obstacles that you are not instructed to climb over. Heavy exercise can uncover or worsen pre-existing heart problems such as impaired blood flow and damage to the heart muscle and irregular rhythms, causing serious medical problems and even death. Since you are young and have minimal preexisting risk factors prior to participation, your risk during these tests should be low. Foot blisters, skin chafing, muscle cramps, injuries due to falling, or low blood pressure following exercise may occur. Every attempt will be made to eliminate such risks through the use of screening and experienced personnel.

### **Benefits**

You will receive no direct benefits for participating in this study. The results of this study can be used to help establish physical performance standards to ensure that future Soldiers are capable of competently and safely performing their duties.

### **Cost of Participating**

You will be responsible for transportation to testing sites. There are no additional costs associated with participation in this study.

### **What Happens if You Get Hurt or Sick**

If you are hurt or get sick because of this research study and you are a DoD healthcare beneficiary you can get medical care within the DoD healthcare system, as long as you remain a

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DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at Army hospitals or clinics.

Whether or not you are a DoD healthcare beneficiary, the Army will not pay for your transportation to and from the hospital or clinic. No reimbursement is available from the Army if you incur medical expenses to treat research-related injuries. You will not receive any injury compensation (pain and suffering, or lost wages) for research-related injuries. You are not giving up your legal rights. You should discuss this issue thoroughly with the principal investigator before you agree to be in this study. If you think you have an injury related to this study or have any questions, please contact the principal investigator.

### **Keeping Things Private**

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We will take steps to help make sure that all the information we get about you is kept private. Your name will not be used wherever possible. We will use a code instead. Any information connecting your name to this code number will be stored separately from the data. All the study data that we get from you will be kept locked up or in password-protected computer files. The code will be locked up too. When the study is over and we have analyzed all of the data, the code list will be destroyed. If any reports and talks are given about this research, we will not use your name.

Sponsors, funders, inspectors from Army human research protections program offices, and other government regulatory agencies, and the USARIEM Human Use Review Committee may have to review the research records to make sure that this study is being done correctly and that your rights and welfare are being protected.

If we use photographs, videos, or audiotape recordings of you for education or illustration purposes, we will protect or disguise your identity by covering part of your face or will obtain your permission to use your images or voice.

Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Particularly to participants who are military personnel, information bearing on your health may be required to be reported to appropriate medical or command authorities.

### **Storage of Data**

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Records and data from this study will be stored in a locked office at the testing site. Once the study is completed the records will be shipped to the U.S. Army Research Institute of Environmental Medicine in Natick, MA for 3 years after the end of this research and then destroyed.

### **Voluntary Participation**

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- Taking part in this study is voluntary. You do not have to be in this study if you don't want to be. If you choose not to take part, it will not affect your current or future relations with this Institute, your superiors, or the US Army.
- If you decide to participate, you are free to leave the study at any time, for whatever reason. If you decide to withdraw from the study, we ask that you tell the researchers.

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- You do not have to answer any questions you do not want to answer.
- You will not be penalized or lose any benefits you are otherwise owed for not taking part or for deciding to stop taking part in the study.

### **Significant New Findings:**

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We will tell you in a timely manner of any significant new information that might affect your willingness to stay in this study.

### **Withdrawal**

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- We ask that you follow the directions to the best of your ability.
- If you are unable to do so, or the researchers feel it is best for you to leave the study, the researchers may end your participation in the study even though you might like to continue.
- The researchers may have to withdraw you from the study if you become ill or injured during the research.
- The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate. The investigator will make the decision and let you know if it is not possible for you to continue.

### **Contacts and Questions:**

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- The researchers conducting this study are listed below. You may contact them with questions or more information about this research.

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- If you believe you may have a research related injury or illness, please immediately contact the Principal Investigator at (b)(6) For local medical care, please contact your unit aid station, troop medical clinic, or emergency department.
- If you have any questions about your rights as a research participant or any complaint, you may contact (b)(6) Human Protections Administrator, USARIEM at (b)(6)

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### **Volunteer Registry Database**

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It is the policy of the U.S. Army Medical Research and Materiel Command (USAMRMC) that data sheets are to be completed on all volunteers participating in research for entry into the command Volunteer Registry Database. The information to be entered into this confidential database includes name, address, social security number, study name, and dates. The intent of the database is two-fold: first, to readily answer questions concerning an individual's participation in research sponsored by USAMRMC; and second, to ensure that the USAMRMC can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at USAMRMC for a minimum of 75 years.

You will be given a copy of this signed form to keep for your records and future reference.

### **Statement of Consent**

I have read the contents of this consent form and have listened to the verbal explanation given by the investigator. My questions have been answered to my satisfaction. I give my consent to take part in this study. Signing this consent document does not give up any of my legal rights nor does it release the investigators, institution or sponsors from their responsibilities.

\_\_\_\_\_  
Participant's Name (printed)

\_\_\_\_\_  
Date of Briefing

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date of Signing

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