

US Army Research Institute of Environmental Medicine (USARIEM)

CONSENT TO PARTICIPATE IN RESEARCH
[National Capital Region]

Title of Protocol: Body composition of US Marine Corps officers in The Basic School (TBS), Quantico

Principal Investigator: Adam W. Potter, USARIEM

Introduction: You are asked to participate in a research study conducted at The Basic School, US Marine Corps (TBS, USMC) by Dr. Adam Potter, USARIEM. You are asked to participate in this research because you are a healthy, 18 years or older adult Marine in the national capital region.

The table below summarizes some **key** points to think about. After reading this summary, if you think you might be interested in participating, read the rest of the consent form for more details about the study.

RESEARCH SUMMARY	
Informed Consent	It is important that you understand what will be required of you so that you can make an informed decision. This process is called informed consent. <ul style="list-style-type: none">• Please ask questions about anything you do not understand.• Feel free to talk with your family, friends, or others before you decide.• After your questions have been answered, you will be asked if you want to participate. If you agree, you will sign this consent form.• You will be given a copy of this form to keep.
Voluntary Participation	You do not have to take part in this research. It is your choice. You can also choose to stop participating at any time during the study.
Purpose	Characterize the body composition and physical performance foundation of the USMC population by assessing Marines from the national capital region (NCR).
Duration	Study participation would include 1 total visit expected to take about 35 minutes.
Procedures	You will be asked to: <ol style="list-style-type: none">1) complete a background questionnaire2) have baseline measurements of your height and weight as well as tape measurements of your body composition3) have a three-dimensional body surface scan using a 3D scanner4) Determine your body composition using a dual-energy x-ray absorptivity (DXA) scanner5) have measures of your total body water using a non-invasive bioelectrical impedance (BIA) device6) measure how high you can jump as a measure of physical performance

Risks	<p>The main risks from being in this study are:</p> <ul style="list-style-type: none"> • Small amount of exposure to radiation from the DXA • Small risk of muscle strain or sprain from the jump test • Steps to lessen the risks are described later in this consent form. <p>You should NOT participate in this study if:</p> <ul style="list-style-type: none"> • You have a physical profile or injuries that limit your ability to jump. • Have metal in your body. • Are pregnant. • Are not immunized against COVID-19
Benefits	There are no direct benefits to you.
Payment	You <u>will not</u> be paid for your participation in this study.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to characterize the body composition (what the body is made of: fat, protein, minerals and body water), using standing height and physical performance measures of the USMC population by assessing Marines in the national capital region.

This study seeks to provide critical insight into the unique physical and performance qualifications of Marines.

WHAT WILL HAPPEN DURING THIS RESEARCH?

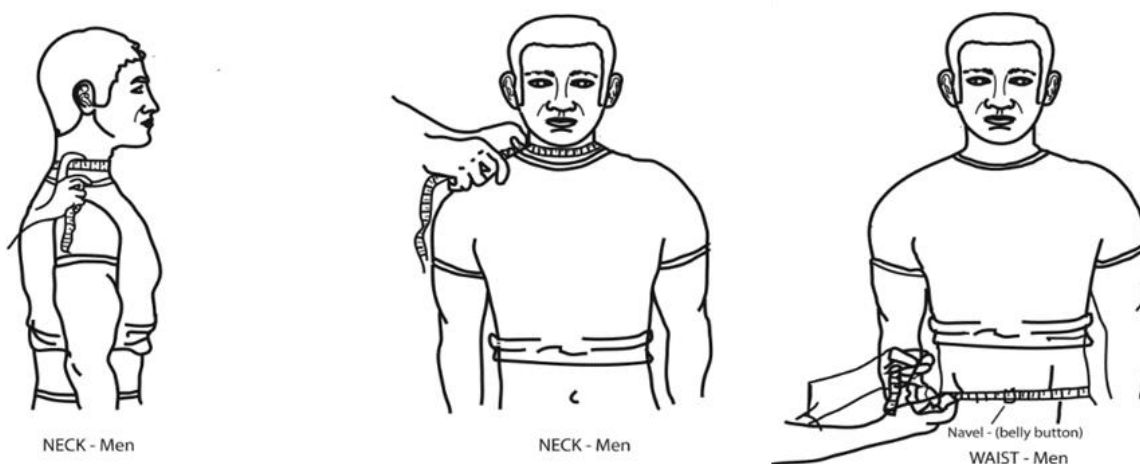
If you agree to participate in this research, you will be asked to participate in 1 study related visit that is expected to take about 35 minutes. You will wear standard physical training attire (e.g., shorts, t-shirt, socks, running shoes/boots) for the visit.

Procedure	Time of Procedure	Visit 1
Demographics Questionnaire	3 min	<input checked="" type="checkbox"/>
Anthropometrics (height, weight, circumferential tape measures)	5 min	<input checked="" type="checkbox"/>
3D Body Surface Scan	5 min	<input checked="" type="checkbox"/>
Dual-energy X-ray Absorptiometry (DXA)	12 min	<input checked="" type="checkbox"/>
Bioelectrical Impedance Analysis (BIA)	5 min	<input checked="" type="checkbox"/>
Counter Movement Jump (CMJ)	5 min	<input checked="" type="checkbox"/>
Total	35 min	

Anthropometrics (height, weight, circumferential tape measures)

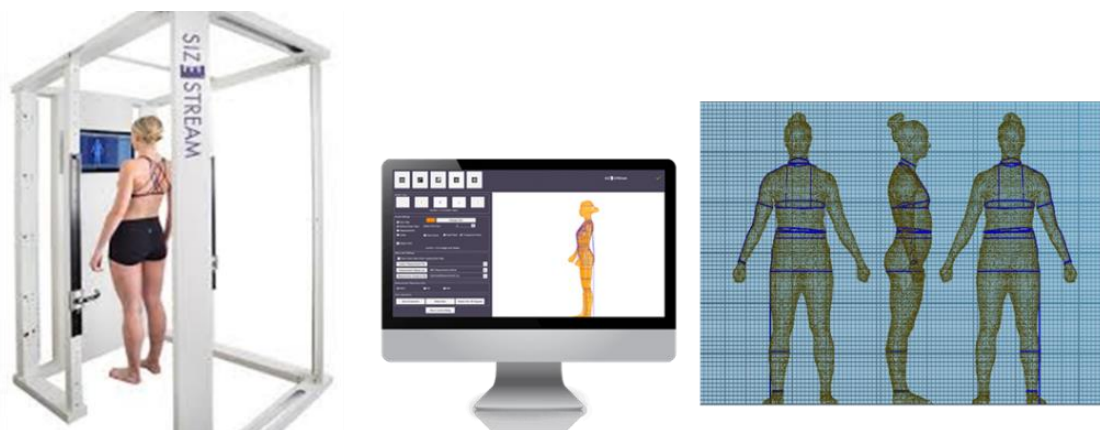
Anthropometric measurements (height, weight, circumferential measures) will be measured using standard equipment. Standing height will be measured in bare or stocking feet while standing on a flat surface, feet together, knees straight, and the head, shoulder blades, buttocks, and heels in contact with the stadiometer (height ruler device). Body weight will be measured using a calibrated electronic scale. Measurement of height and weight will take less

than 3 minutes to complete. Circumference measurements will be taken by a trained team member at the neck, waist and hips per US Army Regulation 600-9 (AR 600-9). Measurements will be made in triplicate using a tape measure and recorded (see image below).



3D Body Surface Scanner

This test uses a 3-D scanner (SS20 Scanner, SizeStream, Cary, NC) for automated, computerized measurements of body circumferences, lengths, surface area, and volume based on anatomical landmark locations (figure below). We will give you a swim cap and form-fitting compression shorts for the body scan measurements; if you are a woman, you will also wear your sports bra for the measurement. You will be asked to stand with arms straight, relaxed, and abducted from the body on the platform for the 3D body surface scan. The total scan time will last less than 5 minutes.



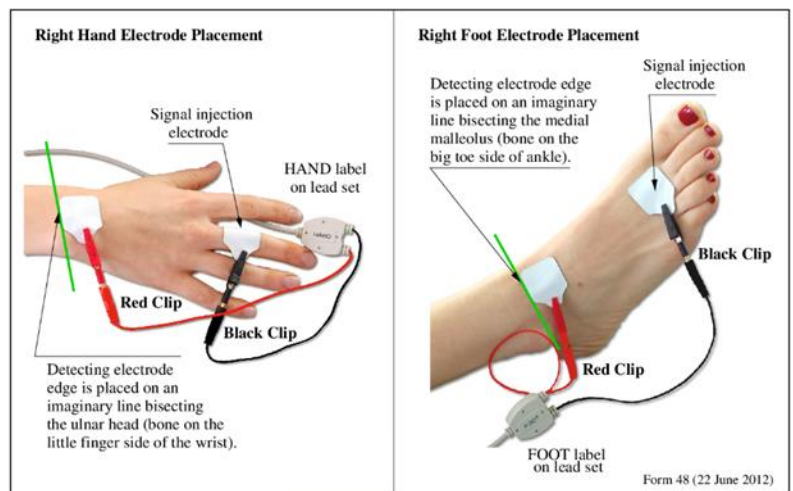
Dual-energy X-ray Absorptiometry (DXA)

Body composition will be assessed using Dual-energy X-ray Absorptiometry (DXA) (Prodigy Advance; General Electric Healthcare, Madison, WI). These data will be used to calculate lean body mass, fat mass and bone mineral density. A trained study staff member will conduct the DXA scan. You will be asked to lay motionless face-up on the DXA densitometer table for the ~10 min scan (image below). Females will be asked to take a pregnancy test $\leq 48h$ before the DXA scan, verifying they are not pregnant.



Bioelectrical Impedance Analysis (BIA)

Total body water (TBW) will be assessed using a Bioelectrical Impedance Analysis (BIA, 50 kHz) device. BIA is a non-invasive tool that will be administered by trained study staff. You will be asked to lay motionless face-up, with arms and legs spread apart at a 30° angle. Skin on your right hand and foot will be cleansed with alcohol and two electrocardiograph-like electrodes will be placed on the surfaces of the right hand and foot (figure below). Two additional electrodes will be applied at the right wrist and right ankle (figure below). BIA is expected to take less than 5 min to complete.



Counter movement jump (CMJ) on a force sensing plate

You will be asked to perform a counter-movement vertical jump (CMJ) on a dual force platform as a measure of performance. You will complete a standard warm-up prior to study procedures. The warm-up will consist of 10 body weight squats, 10 body weight walking lunges, five progressive body weight squat jumps, and three maximal body weight CMJs before data collection. You will be asked to step onto the force platform, place your hands on your hips and remain still for a period of 5 seconds. Then you will be asked to jump up (vertically) for maximal height and land with both feet striking the platform at the same time (figure below). You will be provided with a one-minute rest period after the warm-up and 15 seconds of rest between each of the three jumps.



HOW LONG WILL I BE IN THE STUDY?

You will be in the study for one study visit (35 minutes).

WHAT PRECAUTIONS DO I NEED TO TAKE?

For each visit you will be asked to:

- Not deviate from your normal eating and hydration habits.
- Females must not be pregnant or within one year of a pregnancy

HOW MANY PEOPLE WILL BE IN THE STUDY?

Up to 1,800 participants will be enrolled in this study (1,200 from the national capital region and 600 from TBS). Although you may consent and desire to participate in this study, if the investigators are able to get enough data from other participants, then you may not be tested and your participation will end. You will be informed if your participation is not needed when an adequate number of participants have been enrolled.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Source	Risk	How we will minimize risk
Dual-energy X-ray Absorptiometry (DXA)	Exposure to a small amount of radiation Each dose of radiation is 1/3 that of a chest X-ray.	<ul style="list-style-type: none">• Health risks of very low level X-ray exposure is probably minimal. However, the risk to a fetus might be greater; therefore, you should not volunteer if you are (or might be) pregnant. You should avoid becoming pregnant while participating as a study volunteer.• Females must take a pregnancy test within 48 hours before the DXA scan.

Bioelectrical Impedance Assessment (BIA)	Slight risk of skin irritation associated to the adhesive material of the electrodes.	<ul style="list-style-type: none">• In the event of skin irritation, electrodes will be removed
Counter-movement jump (CMJ)	strain a muscle, sprain a ligament or tendon *Risk is highly unlikely as this testing is low impact relative to the demands of normal training	<ul style="list-style-type: none">• Research personnel will provide verbal instruction on safe jump and landing technique, and additionally provide vertical jump demonstration prior to participants practice attempts.• Participants will be allowed to practice vertical jumping technique prior to execution of testing procedures.

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS RESEARCH?

There are no direct benefits to you. However, the research findings may provide insight into the body composition standards of Marines.

WHAT IF UNEXPECTED INFORMATION IS LEARNED ABOUT MY HEALTH?

You will be informed of the unlikely event of discovering any important new findings that relate to your health. The DXA scan provides a measure of bone density, and it is possible to show potential issues (e.g., low bone density). In the event that a low bone density score is observed, you will be provided this information and encouraged to consult your primary care provider.

WILL RESEARCH RESULTS BE SHARED WITH ME?

You may request your own body composition data from the study team. We anticipate that our research results will eventually be published and available to you and the general public. You may contact us later for information about that publication.

WHAT ARE MY OTHER OPTIONS IF I DO NOT PARTICIPATE IN THIS STUDY?

The only alternative is not to participate in this study.

WILL I HAVE TO PAY FOR ANYTHING IF I TAKE PART IN THIS RESEARCH?

No. There are no associated costs related to participation in this research. There is no compensation for travel expenses.

WILL I BE PAID TO TAKE PART IN THIS RESEARCH?

You will not be paid to participate in this research.

HOW WILL YOU PROTECT MY PRIVACY AND THE CONFIDENTIALITY OF RECORDS ABOUT ME?

Complete confidentiality cannot be promised for military personnel, because information bearing on your health may be reported to appropriate medical or command authorities.

To protect your privacy, a unique study ID number will be assigned to you that will not contain any personal identifiers. This study ID number will be used on all data collection instruments, to include questionnaires, data collection forms, computer records, etc. The master key linking your ID number to you will be destroyed when the study is closed. When the results of the research are published or discussed in conferences, no information will be included that would reveal identity.

The principal investigator is the only person who will be able to match the research subject number with any of your personal identifying information.

When the results of the research are published, no information will be included that would reveal your identity to others. Specific permission to use photographs or video recordings of you and the manner in which they may be used will be requested and documented in an Audio/Visual Image Release form. If you do not sign the photo release form, no photos of you will be taken. If any photographs or video recordings are taken of you inadvertently, they will be destroyed immediately. You do not have to sign a photo release to participate in this study.

Authorized representatives of the following groups may need to review your research and/or medical records as part of their responsibilities to protect research participants:

- US Army Medical Research & Development Command Institutional Review Board responsible for review and oversight of human research
- DoD and other Federal offices charged with regulatory oversight of human research
- USARIEM Office of Research Quality & Compliance
- USMC Human Research Protections Office

Once information that personally identifies you is removed from your data, then your data may be used for future research studies or given to other researchers for future research studies without your permission to do so or further consent.

WHAT IF I DECIDE NOT TO PARTICIPATE IN THIS RESEARCH?

It is your choice whether you want to participate in this research. You can choose not to be in the study now without any penalty or loss of benefits to which you are entitled.

If you decide to participate, you can stop taking part in this research at any time without any penalty or loss of benefits to which you are entitled. Deciding not to participate now or withdrawing at a later time does not harm, or in any way affect, your future relationships with the Marine Corps Base Quantico. If you choose to be withdrawn from the study during participation you should notify a member of the study team, preferably the Principal Investigator, Dr. Adam Potter, by phone, email, or in person. Data collected during your participation will be retained and may be used in the research.

WHAT COULD END MY PARTICIPATION IN THE RESEARCH?

An investigator may stop your participation in the study if you are unwilling or unable to complete study procedures. An investigator may also withdraw you if you become ill or injured or it would not be in your best interest to continue.

WHO SHOULD I CALL IF I HAVE QUESTIONS OR CONCERNS ABOUT THIS RESEARCH?

If you have questions about the research at any time, you should contact the study PI: Dr. Adam Potter (adam.w.potter.civ@mail.mil, office: 508-206-2357, or cell: 508-745-3290).

If you have questions regarding your rights as a research participant, you may contact the HQ USAMRDC IRB Office at 301-619-6240 or by email to usarmy.detrick.medcom-usamrhc.other.irb-office@mail.mil. The USARIEM Office of Research Quality and Compliance at (508) 206-2371 or by email to usarmy.natick.medcom-usariem.mbx.usariem-rqc-protocol@mail.mil.

By signing below, I agree that I have been provided time to read the information describing the research study in this 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.

SIGNATURE OF RESEARCH PARTICIPANT

Printed Name of Participant

Signature of Participant

Date

CONSENT DISCUSSION CONDUCTED BY:

Printed Name

Date Received