United States Army Research Institute of Environmental Medicine (USARIEM)

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: Effect of Ration Formulations on Warfighter Energy Balance and Physical Performance during a Field Training Exercise

Principal Investigator: Alan Dawson, PhD, RD

Introduction: You are being asked to participate in this research study because you are a generally healthy member of the U.S. military participating in a 7-day field training exercise (FTX) at Joint Base Lewis-McChord (JBLM). You do not have to take part in this research. It is your choice.

WHO CAN BE IN THE STUDY?

You are eligible to participate in this research study if you are:

- Active-duty male or female military personnel who are actively participating in the 7-day strenuous military training exercise.
- Willing to consume only foods/beverages provided by study staff during the training exercise, except for coffee and water.

You are NOT eligible to participate in this research study if you have:

- Any injury or health condition limiting full participation in the 7-day training exercise.
- Any food allergies, lactose intolerance, or practice a vegetarian diet.
- Not willing to participate in all study procedures.

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 this research study so that you can make an informed decision. This process is called informed consent. • 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	The purpose of this research is to evaluate if different military ration formulations impact how much you eat and how well you physically perform. The information gathered will help researchers develop new combat rations to fuel Soldiers during military operations.
Duration	You will be in this study for about 13 days.
Procedures	While you are in the study, you will: • Eat **only the food and drinks** provided by study staff and avoid consuming any other food and beverages (except water and coffee) during the training exercise. • Complete **two** short physical performance test bouts before and after the training exercise. (You will **not be allowed** to consume caffeinated drinks or dietary supplements before the tests). • Drink a water beverage (**doubly labeled water**) and provide urine samples (up to 11 total). • Complete surveys before, during and after the training exercise.
Risks	The **main** risks from being in this study are: • Lower-body injury such as ankle or knee sprains during exercise (vertical jump, strength pull, and sprint test.) • Abdominal discomfort (such as gas, bloating, cramping) from a change in diet or eating new foods. Steps to lessen the risks are described later in this consent form.
Benefits	There is no direct benefit to you, but we believe that results from this study will help in the development of new products for use as rations in field feeding.
Alternatives	Your alternative is to not participate.
Payment	You <u>will not</u> be paid for your participation in this study.

WHY IS THIS RESEARCH BEING DONE?

Combat rations are continuously evolving to meet the needs of Warfighter and Army modernization priorities. The purpose of this research is to examine the impact of different ration formulations on energy intake, performance, and health outcomes. We are also measuring how different ration formulations impact appetite, gastrointestinal symptoms, and acceptability. The information collected during this study will help researchers improve combat rations.

WHAT WILL HAPPEN DURING THIS RESEARCH?

If you agree to participate in this research, you will be randomly assigned to consume different formulations of ration products during the 7-day FTX, the rations will provide same number of

calories and have similar packaging, and you will not be able to tell them apart. Both rations are issued as one per day and contain fewer calories than three Meal, Ready-to-eat (MREs).
Before and after the training exercise, we will measure:

- Height (only before the training)
- Weight
- Physical performance (strength pull, vertical jump, and sprint test)

During the training exercise, we will measure:

- The energy, carbohydrate, fat, and protein you consume
- The amount of energy your body uses (must provide urine samples each morning)
- Appetite, intestinal symptoms, and ration acceptability

More details about study procedures are listed below. A study timeline is also provided to show you on what day each task will be performed.

Table 1. Study Timeline

	Baseline (Study days)	Training Exercise							Post
	-5 to 0	1	2	3	4	5	6	7	8
Height/Weight	x								
Physical performance tests[1]	x								x
Doubly labeled water	x								
Urine sample	x	x	x	x	x	x	x	x	x
Study diet and food log		x	x	x	x	x	x	x	
Short surveys	x	x	x	x	x	x	x	x	x

[1]Will be assessed with the pull strength test, vertical jump, and sprint test.

Study procedures:

Height: We will measure height once at the beginning of the study.

Body weight: Your body weight will be measured before and after completing the 7-day training exercise. You will be measured after an overnight fast (≥ 8 hours) and will be wearing light athletic wear.

Questionnaires: You will be asked to complete a questionnaire about your health, nutrition habits, and physical activity at the beginning of the study. You will be asked to record your food intake and complete questionnaires that ask about the acceptability of the ration, each day during the training exercise. You will complete surveys regarding your appetite, and gastrointestinal symptoms before, during, and after the FTX. You will also complete an exit survey after the training event to indicate which ration you believe you received and assess your nutrition attitudes and behaviors, stress, cognition, and gastrointestinal symptoms that occurred during the field training.

Physical Performance (vertical jump test, pull strength test, and sprint test): We will assess your physical performance before and after the training by asking you to perform a pull strength test, vertical jump, and sprint test after an overnight fast (≥ 8 hours). Prior to the testing, you will be asked to perform a standardized warm-up prior to the testing, which will include preparation drills (Bend and reach, rear lunge, squat bender, windmill, prone row). You should not drink caffeinated beverages or take dietary supplements (i.e., beta-alanine, branched-chain amino acids, creatine) before the tests.

Vertical jump test: You will place your feet at shoulder width while standing on a flat, clean mat (Just Jump System). First, your standing reach height will be measured using your dominant hand/arm. Then, you will be given two submaximal efforts to practice the vertical jump technique, followed by t maximal effort attempts with approximately 30 to 60 seconds of recovery between each attempt. During the vertical jumps, you will perform an arm swing and a countermovement to a self-selected depth. You will tap the fins of the Vertec™ at peak jump height. You will receive detailed instruction and demonstration by study staff and will be given up to two familiarization jumps that will not be used for data analysis.

Pull strength test: You will stand on the footplate of the dynamometer (see picture) with your knees flexed at about 120 degrees and will pull the bar straight up as hard as you can (like a deadlift movement). You will be given a familiarization attempt followed by 3 attempts with approximately 30-60 seconds of rest between attempts.

The sprint test: The test involves twelve repeated 25-yard sprints (300-yard shuttle sprint). You will start in a ready position with your foot on the start line, and sprint on the command “Go”. You will sprint to a cone 25 yards away, touch your foot on the line and sprint back to the start line. The process will be repeated five more times for a total of twelve 25-yard sprints (300 yards total). You will be given the opportunity to familiarize yourself with the testing protocol before the test begins.

Tracer Drink: To determine how much energy your body burns during the training exercise: 30 participants will be asked to drink a stable isotope-labeled tracer drink known as doubly labeled water (DLW). The DLW method involves having you drink a special water that contains specific isotopes (variants) of the hydrogen and oxygen atoms.
When you drink the labeled water, it mixes throughout your body fluids. As you go about your normal activities, the isotopes are lost from your body through urine, sweat, breathing, etc. The rate at which the isotopes are lost provides a very accurate estimate of your metabolic rate. Specifically, the hydrogen isotopes are lost as water, while the oxygen isotopes are lost both as water and carbon dioxide. By comparing the elimination rates of the two isotopes, researchers can calculate your carbon dioxide production. From this, we can derive your total energy expenditure over the course of the study period.

The doubly labeled water method is considered the "gold standard" for measuring energy expenditure in free-living people because it does not require any change to your normal activities. You drink the labeled water and go about normal life while the isotopes are monitored. This provides an accurate picture of calories burned under real-world conditions. You will be supplied with urine collection containers labeled with your subject ID and study day. You will be asked to clean your hands prior to and after collecting a urine sample. After the urine collection,

you will ensure the container's cap is tightly sealed and will place the sample in the sealed plastic bag provided. Study staff will collect urine samples from you.
On the morning of baseline testing, you will arrive fasted having not eaten or drank anything other than water for approximately 10 hours from the night before. You will provide a urine sample before you consume the DLW. You will provide additional urine samples approximately 4 hours and 6 hours after you consume DLW. You will not be allowed to eat or drink anything other than water for 4 hours after consuming DLW. You will provide urine samples each morning of training immediately after you wake up and the morning after training immediately after you wake up (up to 11 in total).

No genetic tests will be performed in this study on your urine samples. Biological specimens (urine samples) will not be used commercially under any circumstances.

Study Diet: During the 7-day training we will provide you with a ration daily and you will eat as much or as little as you desire, however sharing rations or consuming non-study foods/drinks (except water and coffee) are not allowed. We will ask you to fill out a food log daily and return your food wrappers and uneaten food the next morning to determine how many calories you are eating each day during the training exercise. You will be taught how to complete the food log which will include what items, and how much of those items, you consumed.

Military Performance: We will collect from cadre your performance of physical tasks, which may include but not limited to movement to contact, breach of an obstacle, integrate direct and indirect fires, conduct reconnaissance, dismounted marches, individual and crew weapons familiarization, and individual and crew weapon systems testing. We understand the FTX is a training event and not a certifying event.

HOW LONG WILL I BE IN THE STUDY?

The total length of time for study participation is up to 13 days.

WHAT PRECAUTIONS DO I NEED TO TAKE?

- **No** sharing of rations or consuming non-study foods/drinks
- **No** drinking (other than water) or eating at least 10 hours before drinking the doubly labeled water (primary dosing method)
    - OR **No** drinking (other than water) or eating at least 4 hours before drinking the doubly labeled water (alternative dosing method)
- **No** caffeinated beverage or dietary supplements (i.e., beta alanine, branched-chain amino acids, creatine) before physical performance testing

HOW MANY PEOPLE WILL BE IN THE STUDY?

60 participants are expected to enroll in this study.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Physical performance (strength pull/ vertical jump/ sprint test): The risks due to the strength pull and sprint test may include ankle or knee sprains when pulling, changing direction, and sprinting. You may feel discomfort and fatigue in your muscles during and shortly after exercise and mild to severe muscle soreness may continue for one to seven days. Some

individuals may experience nausea and/or vomiting because of high-intensity effort. We will monitor you closely during testing and provide you with detailed instructions and demonstrations to perform the tests safely and allow you to warm up before the physical tests. If you throw up or feel like throwing up, you will be given time to recover before resuming exercise.

Tracer Drink: The isotopes used in this study are safe, non-radioactive, occur naturally in foods, are already present in your body, and pose no risk.

Study Diet: Sudden diet changes can cause gastrointestinal distress such as, gas, constipation, nausea, vomiting, diarrhea, abdominal pain, or cramping. If you have extreme gastrointestinal symptoms that render you unable to participate in training, you may be withdrawn from the study. The study diet rations contain fewer calories (approximately 800 calories less) than three MREs.

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS RESEARCH?

There are no direct benefits to you for participating in this study. However, results from this study are expected to help in the development of new ration products that will be eaten by future Warfighters.

WILL RESEARCH RESULTS BE SHARED WITH ME?

Your body composition and physical performance results will be shared with you upon request.

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

The only alternative is not to participate in the study.

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

There is no cost to you during this research.

WILL I BE PAID TO TAKE PART IN THIS RESEARCH?

There will be no compensation for participating in this study.

WHAT HAPPENS IF I AM INJURED AS A RESULT OF TAKING PART IN THIS RESEARCH?

If at any time you believe you have suffered an injury or illness because of participating in this research, please contact:

Alan Dawson, PhD
U.S. Army Research Institute of Environmental Medicine
Building 42a, Room 19
10 General Greene Ave
Natick, MA 01760
Phone: 508-206-2278
Email: Michael.a.dawson62.mil@health.mil

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 entitled to medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided. No 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. If you believe you have sustained a research-related injury, please contact the Principal Investigator (PI). If you have any questions, please contact the PI.

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

To protect your privacy, all research-related records will be labeled or "coded" with an assigned research volunteer number that will not include your name or any other form of identifiable information. The principal investigator or project coordinator will keep the link between your number and your research records in a locked cabinet. Any documents that will require your name, such as the consent form, will be kept in a locked cabinet separate from any research documents that contain your ID number. The principal investigator and project coordinator is/are the only person/people who will be able to match your research number with any of your personal identifying information.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity to others. If photographs, videos, or audio-tape recordings of volunteers are used for educational purposes, your identity will be protected or disguised. All identifiable or recognizable information (e.g., names and faces) will be covered in any photographs unless you agree to sign a photo release form. If you do not sign a photo release form, any photographs taken of you will be destroyed.

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

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:

- U.S. 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
- US Army Research Institute of Environmental Medicine's Office of Research Quality & Compliance (ORQC)

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

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.

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 unit or its leadership or with USARIEM.

If you a decide to withdraw, no further data will be collected from you. You will be asked to return food logs, surveys, food wrappers and any uneaten food. Any data/samples collected up until the point of withdrawal will be retained for future analysis and stored with all other study data.

WHAT COULD END MY PARTICIPATION IN THE RESEARCH?

The investigators may withdraw you from participating in this research if:

- You are not willing to follow study guidelines
- You become ill or injured, or to protect your health and safety

The investigator will make the decision and let you know if it is not possible for you to continue. Your taking part in the study may be stopped without your consent if it is determined by the investigator that remaining in the study might be dangerous or harmful to you.

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:

Alan Dawson, PhD
U.S. Army Research Institute of Environmental Medicine
Building 42a, Room 19
10 General Greene Ave
Natick, MA 01760
Phone: 508-206-2278
Email: Michael.a.dawson62.mil@health.mil

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-usamrmc.other.irb-office@health.mil. Alternatively, you can also contact the USARIEM Office of Research Quality and Compliance at 508-206-2371 or by email to usarmy.natick.medcom-usariem.mbx.usariem-rqc-protocol@health.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