United States Army Research Institute of Environmental Medicine (USARIEM)

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: Acceptability of new foods for military rations

Principal Investigator: J. Philip Karl, PhD, RD

Introduction: You are being asked to participate in this research study because you are a healthy male or female between 18-39 years old (or between 17-39 years old for Active Duty personnel). You do not have to take part in this research. It is your choice.

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	In this study, we will be evaluating the acceptability of new food products for military rations when consumed as part of a normal diet.
Duration	You will be in this study for about 3-5 weeks. Your total time commitment is expected to be about 10.5 hours.
Procedures	While you are in the study, you will • Be asked to **eat only study foods and beverages** provided by study staff and avoid consuming any other food and beverages (except for water) on **4 separate days**. • Be asked to eat breakfast, lunch, and 1 snack at the study site on 4 separate days. • Complete short questionnaires while eating provided foods. • Record your dietary intake on **7** separate days. • Maintain your normal diet and physical activity levels throughout the study except on certain days of the study.

Restrictions	• **Not be allowed** to consume alcohol or participate in strenuous physical activity on certain days of the study. • **Not be allowed** to take certain dietary supplements or use nicotine during the study. • **Not be allowed** to follow a highly restrictive or vegan/vegetarian diet during the study. • **Not try** to lose or gain weight during the study.
Risks	The **main** risk from being in this study is: • Abdominal discomfort (such as gas, bloating, cramping) from a change in diet or eating new foods.
Benefits	There is no direct benefit to you, but we hope that results from this study will help in the development of new products for use as rations in field feeding.
Payment	Participants who are **not** Active Duty military or federal government employees will be paid up to $90 for study participation.
COVID Risk Mitigation	Study staff and participants will comply with all COVID-19 risk mitigation procedures in place at USARIEM during the time of data collection. As such, you may be asked to wear facemasks at all times (unless eating) and use hand sanitizer prior to entering the lab. Depending on local guidance, you may also be asked to take a COVID test one or more times during the study.

WHY IS THIS RESEARCH BEING DONE?

Combat rations are continuously evolving in order to meet the needs of the warfighter in the battlefield. This study is evaluating the acceptability of new food products being developed for combat rations when eaten with other foods throughout the day. Findings from this study will be used to improve the development of current and future combat ration products.

WHAT WILL HAPPEN DURING THIS RESEARCH?

If you agree to participate in this research, you will be asked to do the following (also see Table 1):

Baseline Period:
If you agree to participate, you will complete screening questionnaires and if you are a civilian, you will have your height and weight (wearing light clothing) measured to determine if you qualify for the study. If you qualify, you will be provided with and instructed to complete a 3-day food and activity record, which will be reviewed by study staff.

Study Phases:
You will participate in **4 study phases**, each lasting 3 days. Each phase will be exactly the same and will involve 1 day (Test Day) where you will be asked to eat only the study foods provided to you. You will eat breakfast, lunch, and an afternoon snack in the lab and will be sent

home with snacks and food to eat for dinner that evening. The next day, you will bring back the containers, food wrappers and any uneaten food. There will be 3 test ration products provided during the Test Day, and you will be required to eat all of those products (breakfast bar, chicken salad sandwich, and cheesecake). The remainder of the food provided is not required to be eaten if you choose not to eat it. However, you will not be allowed to eat any outside food or beverages other than water. The activities during each phase will be as follows:

- **Day 1 (Test Day; ~90 minutes):**
  The day prior to Day 1 you will refrain from strenuous physical activity and alcohol.

  On Day 1 you will:
  - Report to the lab in the morning for a fasting (at least 8 hr of not eating) body weight measurement and eat breakfast;
  - Report to the lab for lunch;
  - Report to the lab for afternoon snack;
  - Complete questionnaires on your opinion of the food provided, feelings of fatigue, appetite, and any gastrointestinal symptoms you experience;
  - Eat dinner foods and snacks (provided by study staff) as desired;
  - Eat 3 test ration products (one during breakfast, one during lunch, and one as an afternoon snack);
  - Refrain from strenuous physical activity, alcohol, and consuming any foods or beverages (except water) that are not provided by study staff.

- **Day 2 (<15 minutes):**
  On this day you will:
  - Return containers, trash wrappers, and any uneaten food from Day 2;
  - Complete a food and activity record throughout the day,
  - Refrain from strenuous physical activity and alcohol.

- **Day 3 (<30 minutes):**
  - Staff will review your Day 3 food and activity record with you in the lab or by phone.

- **Repeat:**
  - Days 1-3 will be repeated for 3 additional Phases.
  - Study staff will work with you to schedule each Phase in order to best accommodate your schedule so that Days 1-3 can occur without interruption

Additional activities for COVID-19 risk reduction

If COVID-19 risk reduction procedures need to be implemented, we will ask you to do the following:

- **COVID-19 Screening:** At the beginning of each in-person study visit, you will be asked if you are experiencing any COVID-19 related symptoms (for example, fever, cough, etc) and if you have been in contact with anyone diagnosed with COVID-19 within the past 14 days.
- **Masks, distancing and hand sanitizing:** We will ask you to use hand sanitizer or wash your hands prior to entering the lab. We will also ask you to adhere to local guidelines regarding masking and social distancing.

Additionally, depending on local guidance in place at that time, you may be asked to complete a COVID test at USARIEM the day before your Test Day. Throughout the study, if you test

positive for COVID-19, are feeling unwell, or have been recently exposed to someone with COVID-19, you will not be allowed to participate in study activities on that day. You will be referred for medical screening instead, and allowed to continue study activities once medically cleared.

Table 1. Study Timeline and Activities:

Study Period →	**Baseline**	**Phase 1**			**Phase 2**			**Phase 3**			**Phase 4**		
Day →		1	2	3	1	2	3	1	2	3	1	2	3
Height	x												
Body Weight	x	x			x			x			x		
Food/Activity record	xxx		x			x			x			x	
Food/Activity record review	xx			x			x			x			x
Eat Study Food		x			x			x			x		
Questionnaires		x			x			x			x		
Return Food Trash			x			x			x			x	
No strenuous exercise or alcohol		x	x		x	x		x	x		x	x	

HOW LONG WILL I BE IN THE STUDY?

Your study participation will last from 3-5 weeks depending on your availability for scheduling. The total time commitment is expected to be about 10.5 hours.

WHAT PRECAUTIONS DO I NEED TO TAKE?

You will need to avoid nicotine, maintain your normal diet and physical activity levels, and not try to lose or gain body weight during your time in the study. It is important that you inform study staff if you are currently taking any prescription medications or dietary supplements. They may ask you to refrain from taking certain supplements (such as fat burners, workout boosters) during your time in the study. Additionally, you will be asked to refrain from alcohol and strenuous physical activity (any activity the makes you breathe much harder than usual or any activity longer than 15 minutes that makes you breathe somewhat harder than usual) during certain days (see study schedule above). You will be fed meals on certain days during the study. Therefore, it is important that you inform study staff of any existing food allergies, restrictions or intolerances (for example gluten, dairy or nuts). Finally, you must not follow a vegetarian/vegan diet or other highly restrictive diet (e.g., ketogenic diet, very high protein diet, Paleo diet) for two weeks prior to and throughout the study.

HOW MANY PEOPLE WILL BE IN THE STUDY?

This study requires 20 participants to complete. In order to meet that goal, we may enroll up to 100 individuals.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

You will be provided study foods to eat for a full day on 4 occasions during the study. If you are not used to eating certain foods, sudden changes to your diet may cause abdominal discomfort such as gas, bloating, cramping, diarrhea, constipation or other discomfort. Staff will ask you about any known food sensitivities you have in order to minimize the occurrence of this. Most foods you will be provided are commonly available commercial items. If we cannot modify the study menu to accommodate a specific allergy or intolerance, you will either be withdrawn or not enrolled in the study.

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?

Research results will not be shared with you.

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

The only alternative to participating in this research is to not participate.

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

If you do not live on the Natick Soldier System Center, you will be responsible for paying for your transportation to and from the center. You will not be reimbursed for any travel costs or other costs related to participation in this research.

WILL I BE PAID TO TAKE PART IN THIS RESEARCH?

No compensation will be provided for Active Duty military personnel or Federal Employees. If you are a civilian volunteer who is not a federal government employee, you will be compensated up to $90 for completing the study. If the study is not completed your compensation will be prorated based on the study activities completed at the time your participation ends. The following payment schedule will be used to prorate compensation for your time: $10 for completing the baseline testing, $20 for completing each study phase (there are 4 total phases).

You will receive payment within approximately ten weeks of study completion. Your social security number (SSN) will be needed to process your payment, as required by law. This information will be carefully protected.

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

All data obtained from you will be considered privileged and held in confidence. To protect your privacy, any of your research-related records and answers to questionnaires will be “coded” with an assigned research participant ID number that will not include your name or any other identifying information such as your social security number, address, date of birth, zip code, etc. This participant ID number will be used on all data collection sheets and questionnaires. The

principal investigator and the project coordinators will keep the link between your participant number and your research records in separate locked cabinets or in a password-protected computer file. The principal investigator and project coordinators are the only people who will be able to match your research participant number with any of your personal identifying information. The master key linking your ID number to your name will be destroyed when the study is closed. Any collected data will be stored indefinitely using your participant identification number. Financial information, such as social security number and bank account number that is required for direct deposit of compensation for research will be destroyed upon project completion and compensation is complete.

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

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

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity to others. No photographs, videos, or audio-tape recordings of you will be taken.

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, Office of Research Quality and Compliance
- Combat Capabilities Development Command-Soldier Center, Office of Research Quality and Compliance

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 USARIEM or DEVCOM-Soldier Center.

If you decide to withdraw, you will be compensated for the portion of the study you completed. The data collected from you will be retained by study investigators and may be used when analyzing the results of this research. If you decide to withdraw from participation, please notify the principal investigator or a study staff verbally or in writing.

WHAT COULD END MY PARTICIPATION IN THE RESEARCH?

You will be withdrawn from the study without your consent if you do not pass study screening, if you have a dietary intolerance to any of the study foods provided that cannot be accommodated (or there are no alternative options to provide you), or if you do not adhere to study procedures and restrictions. You may be withdrawn if you become ill or if it would not be in your best interest to continue.

WHAT IF ANY NEW INFORMATION IS FOUND OUT?

During the course of the research, the investigators will tell you of any new findings that might cause you to change your mind about continuing in the study. If you receive any new information, the investigators will obtain your consent to continue participating in this study.

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 Dr. Phil Karl (the principal investigator); Office phone: 508-206-2318; Cell phone: 617-823-8074

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@mail.mil. 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@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