United State Army Research Institute of Environmental Medicine

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: Physiological responses to heat stress during high-risk events

Principal Investigator: Gabrielle E.W. Giersch, Ph.D.

Introduction: You are being asked to participate in this research study because you are in the military and participating in training. 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	To characterize the typical body responses to training events such as timed runs and ruck marches.
Duration	You will be in this study for 1-3 days and involves up to about 4 hours over 7 visits.
Procedures	While you are in the study, you will complete a **regularly scheduled** training event (i.e. ruck march, timed run) and have measures taken before, during and multiple times after the event. Measures taken may include: • Core temperature (measured with an ingested pill) • Heart rate (measured with a heart rate monitor on chest) • Skin temperature (measured with a patch put on your chest) • Up to 6 total blood draws • Filling out a form authorizing us to collect medical and fitness data from an Army database called SPHERE

Restrictions	• No history of obstructive disease of the gastrointestinal tract (i.e. diverticulosis, diverticulitis and inflammatory bowel disease, peptic ulcer disease, Crohn's disease, ulcerative colitis) • Cannot be on a physical profile that restricts participation in training • No allergies to skin adhesives • No blood donations greater than 460mL (~1 pint or unit) in the past 8 weeks • No MRI scheduled during or two weeks after the study
Risks	The **main** risks from being in this study are: • Blood draws may cause pain, dizziness, fainting, bruising, nausea, or vomiting. • Skin irritation from heart rate monitor or skin temperature patch Steps to lessen the risks are described later in this consent form.
Benefits	There are no direct benefits to participating in this study, but results of this study may benefit the Warfighter population by enhancing understanding of the body responses to training.
Payment	You will be paid for your participation in this study.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to characterize the normal responses of Warfighters that complete training events and do not suffer exertional heat stroke.

Exertional heat stroke is a form of heat illness that has substantial negative outcomes. Most cases of exertional heat stroke in Warfighters occur during events such as ruck marches or timed runs in the heat.

To identify responses that may be associated with an increased risk of exertional heat stroke during training events in the heat, it is important to study the typical responses of people that complete the training events without exertional heat stroke. This information may help improve prevention and return-to-duty guidance following exertional heat stroke.

WHAT WILL HAPPEN DURING THIS RESEARCH?

If you agree to participate in this research, you will be asked to do the following:

You will complete a maximum of 7 visits over the course of 1-3 days (see Figure 1).

The first visit will include an ***orientation*** where you will sign paperwork and fill out questionnaires (background and activity; menstrual history [females]). Some of the paperwork may be completed on a later visit. You will also receive a core temperature pill with instructions on how to ingest it. Lastly, you will receive a urine cup and a urine jug with instruction on usage of each.

The second visit will occur prior to your scheduled training. We will ask you a series of questions at this visit or one of the follow up visits (e.g. how much did you sleep last night?, when was the last time you ate?, have you consumed any caffeine today?). We will then ensure that the core temperature pill is working. If the pill is not reading, you may be asked to insert a new pill as a rectal suppository or to ingest a new pill if fluids are not going to be consumed during the training event. If you are carrying water during training, it may be weighed before and after to calculate how much water you consume during training, or a device may be attached to estimate how much water was consumed. Study staff will then collect a blood sample. We will then fit you with a heart rate monitor on your chest and a patch may be placed on your chest and a small monitor strapped to your chest to measure the temperature of your skin.

You will then do your *typical training with no interference* from the study staff.

Immediately following your training, you will be seated for about 20 minutes. During this time, we will download your core temperature data and collect a blood sample. You will also be asked to provide a urine sample, if able, behind a privacy screen. Lastly, we will give you a urine jug to collect urine until the next visit.

You will have up to 4 additional visits at 1-2 hours, 6 hours, 12 hours, and 24 hours after the training. These visits will consist of us collecting the urine jug from the previous visit, collecting a blood sample, and giving you a new urine jug. These visits will be dependent on your training schedule and may not occur. If you have additional training scheduled, any visits after the post-training visit will be cancelled. If collecting urine in jugs interferes with training then we may skip the urine jug collections.

No genetic tests will be performed in this study on your blood or urine samples. Blood and urine samples will not be used for commercial gain.

You will be asked to provide your DoD identification number (DoD ID) and Social Security number (SSN) and complete a HIPAA authorization document to allow access to data on your race, sex, age, rank, military occupational specialty, height, weight, previous heat illness profiles, medication, and fitness test scores, as well as other data pertaining to temperature regulation or heat illness risk if approved by the Institutional Review Board in an amendment. Signing the HIPAA authorization document allows the research team to use and share your health information from an Army database to determine whether your body size, recent fitness, medications, or any previous heat illnesses may have influenced your responses to training in the heat. If you do not sign the HIPAA authorization document and provide DoD ID and SSN, you will not be allowed to participate.

Core Temperature:
You will swallow a temperature sensor pill ~6-10 hours prior to the start of your scheduled training event. A credentialed study staff member will activate the pill and record its pill identifier (number). The pill is easy to swallow (about the size of a large vitamin), and water can be used to help swallow the pill. In the case that the pill is not reading prior to your training, you may be asked to insert a new pill as a rectal suppository or to ingest a new pill if fluids are not going to be consumed during the training event. Instructions will be given and lubrication will be provided.

Venipuncture (Blood draw):
Blood measures will be obtained by a trained, credentialed phlebotomist using sterile techniques. We will take blood samples by putting a needle into a vein in your arm; this is called venipuncture. This is the standard method used to obtain blood for tests.

There will be 6 scheduled venipunctures during this study if you complete all possible visits. Approximately 15 mL (approximately 3 teaspoons) will be collected for each venipuncture visit. Sometimes the technicians may miss a vein or not get enough blood for the test. They may ask to repeat the venipuncture on a different vein in your arm. You have the right to refuse these repeat attempts. A maximum total of about 90 mL of blood will be taken for research purposes over the course of this study.

Figure 1. Study timeline for *Physiological responses to heat stress during high-risk events*

	Visit 1	Visit 2	Visit 3	*Visit 4*	*Visit 5*	*Visit 6*	*Visit 7*
	Baseline	Pre-Ex	Post-Ex	*1-2h Post*	*6h Post*	*12h Post*	*24h Post*
Briefing and Consent	Questionnaires Core temperature pill receipt and instruction Urine jug/cup receipt and instruction	Blood sample (~15mL) Urine jug drop-off Sleep and meal questions	Blood sample (~15mL) Urine sample* Urine jug receipt	*Blood sample (~15mL)* *Urine jug drop-off and receipt*	*Blood sample (~15mL)* *Urine jug drop-off and receipt*	*Blood sample (~15mL)* *Urine jug drop-off and receipt*	*Blood sample (~15mL)* *Urine jug drop-off*

*Denotes, *if able*
Italics, denotes if schedule allows with times approximate (i.e., +/- ~1 hour).

HOW LONG WILL I BE IN THE STUDY?

You will be participating in the study for a maximum of 7 visits over 1-3 days (each visit is about 30 minutes)

WHAT PRECAUTIONS DO I NEED TO TAKE?

If you choose to participate you will **not** be able to have an MRI during the study. You may not participate if you have an MRI scheduled during or two weeks after the study.

HOW MANY PEOPLE WILL BE IN THE STUDY?

We will collect data on up to 150 volunteers for this study.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Source of Risk	Risk(s)	How We Will Minimize
Blood Draw	Pain, swelling, infection, bleeding, bruising, tenderness, dizziness, fainting, nausea/vomiting, discomfort/pain from needle insertion	• Only trained phlebotomists will draw blood • Use of sterile techniques • You will be seated
Core Temperature Pill	Damage to mucous membranes, not compatible with MRI, potential damage to rectum as rectal suppository	• Can swallow pill with water • Given detailed instructions and lubrication if pill is used as rectal suppository • Medical alert (no MRI) bracelet • Excluded from study if MRI planned within 2 weeks of taking the pill
Heart Rate Monitor, Skin Temperature Patch	Skin irritation	• Staff will monitor site for irritation

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS RESEARCH?

There are no direct benefits to participating in this study. However, results of this study may benefit the Warfighter population by enhancing understanding of the body responses to training events.

WHAT IF UNEXPECTED INFORMATION IS LEARNED ABOUT MY HEALTH?

If any unexpected information is learned about your health, the Principal Investigator (PI; Dr. Giersch) will direct you to see your primary care physician (PCP). No diagnoses will be made by research personnel. Some results perceived to be clinically relevant may not be shared, as some biological samples will not be analyzed until after the study is completed. Complete confidentiality cannot be promised for military personnel because information bearing on your health may be required to be reported to appropriate medical or command authorities.

WILL RESEARCH RESULTS BE SHARED WITH ME?

If you are interested in your results, we can share your heart rate and core temperature data once you finish exercise. However, no clinically relevant results will be available to share with you, as biological samples will not be analyzed until after you have finished data collection.

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

The only alternative is to not participate in the study.

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

There are no anticipated costs for this study. We will not reimburse you for expenses paid for travel in order to allow you to participate in the study.

WILL I BE PAID TO TAKE PART IN THIS RESEARCH?

All military personnel will be eligible for $50 per blood draw (up to $300 total). If a blood draw is repeated during a visit (e.g. because a vein was missed on the first attempt) you will only be paid for one blood draw for that visit. In the case that not all blood draws are completed, you will be paid a prorated amount for the blood draws that were completed.

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 as a result of participating in this research, or if you have any questions, please contact the PI (Gabrielle Giersch; gabrielle.e.giersch.civ@health.mil; (508) 206-2421).

If you are injured because of your participation in this research, you are entitled to medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary.

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 PI. If you have any questions, please contact the PI.

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

The PI will keep records of your participation in the research. To protect your privacy, all of your blood samples and research-related records including data sheets will be labeled or "coded" with an assigned research identification (ID) number that will not include any identifiable information such as your name or social security number. The PI will keep the link between your participant number and your **name** in a locked cabinet or protected computer file. The PI and study coordinator are the only people who will be able to match your research participant 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. Specific permission to use photographs videos, or audio-tape recordings for presentations at academic conferences and/or for marketing, online posts or public affairs 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
- US Army Research Institute of Environmental Medicine's Office of Research Quality and Compliance

Once information that personally identifies you is removed from your data or specimens, then your de-identified 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.

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

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.

Upon request (via notifying the PI), you are entitled to removing any of your specimen/data which have been collected. Deciding not to participate now or withdrawing at a later time does not harm, or in any way affect, your future relationships with the United States Army Research Institute of Environmental Medicine or the United States Army. You may withdraw verbally or by emailing or phoning the study PI (Dr. Gabrielle Giersch (gabrielle.e.giersch.civ@health.mil; (508) 206-2421).

If you do decide to withdraw, any of your data and/or biological specimens that were collected up to that point may be used without your further consent. Your compensation will be prorated based on how many of your blood specimens were collected.

WHAT COULD END MY PARTICIPATION IN THE RESEARCH?

You may be removed from the study if circumstances arise which warrant doing so such as if you are unwilling or unable to complete the study procedures. The Principal 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 PI that remaining in the study might be dangerous or harmful to you.

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.

The PI and/or designee will inform you of any new information verbally and/or with a written document.

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. Gabrielle Giersch (gabrielle.e.giersch.civ@health.mil; (508) 206-2421).

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 or 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

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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