University of Colorado
Colorado Springs (UCCS)
Consent to be a Research Subject

Title: **The effectiveness of emergency room protocols for treating hyperthermia**

Principal Investigator: Nathan Morris

Funding Source: University of Colorado at Colorado Springs

Key Information
Your consent to participate in this study is being requested and participation is voluntary. If you choose to give your consent to participate in this study, you are free to withdraw from the study at any time. This study consists of a ~one-hour preliminary session and five ~3-hour experimental sessions, equaling a ~16-hour total time commitment. The purpose of this research is to test the effectiveness of three cooling protocols (cooling packs; "ice sheets", which are bed sheets soaked in ice water, wrapped around the participant, while a fan blows air on them; and a body bag filled with ice) commonly used in emergency departments to treat hyperthermia, as well as a negative control (passive cooling in air-conditioned room) and a positive control (cold water immersion). It is reasonable to expect that you will feel uncomfortably hot and tired at the end of each heating protocols, and potentially uncomfortably cold during some of the cooling protocols. We do not expect you to gain any specific benefit from participating in this study. This study will help us as scientists and clinicians understand how effective commonly used cooling protocols in emergency departments are, and which of the protocols is the most effective.

Introduction
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. A member of the research team will describe this study to you and answer any questions. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.**

Before making your decision:

- Please carefully read this form or have it read to you.
- Please ask questions about anything that is not clear.

Feel free to take your time thinking about whether you would like to participate. By signing this form, you will not give up any legal rights.

Study Overview The purpose of this research is to test the effectiveness of three cooling protocols (cooling packs; "ice sheets", which are bed sheets soaked in ice water, wrapped around the participant, while a fan blows air on them; and a body bag filled with ice) commonly used in emergency departments to treat hyperthermia, as well as a negative control (passive cooling in air-conditioned room) and a positive control (cold water immersion). We expect that all three cooling protocols will fall somewhere between passive cooling and cold-water immersion in terms of cooling effectiveness. Ultimately, the findings from this research may be published in scientific journals or maybe presented at scientific conferences.

Inclusion and exclusion criteria You are being asked to be in this research study because you are an active, healthy person**,** between the ages of 18-65, is not pregnant and is not planning to become pregnant during your participation in this study, who does not have a pacemaker, are not currently taking any prescribed or over the counter medications or nutritional supplements known to influence thermoregulatory responses, have not been diagnosed with any

cardiovascular diseases, do not have any lingering pain from a previous musculoskeletal injury (i.e. no knee, hip, or back pain), are not pregnant, and do not use tobacco/nicotine products.

Procedures If you agree to be a research participant, you will be scheduled for one preliminary visit in the cardiovascular lab (room 313) and five experimental visits in the climate chamber (room 334) located in the Hybl Sports Medicine and Performance Center on the UCCS campus. All visits are voluntary.

Preliminary Visit: This visit will begin with a measurement of your body composition using a body scanner. This scanner uses dual-energy X-ray absorptiometry to determine your body composition. It is often referred to as a DXA scanner. You will lie on your back on the DXA scanner operated by a trained staff member. This test takes approximately 5 minutes. During the testing, you will be exposed to X-rays by the DXA. The DXA machine exposes you to minimal radiation of 0.001 mSv, equivalent to less radiation than what a person is exposed to during a coast-to-coast airplane flight and well below the maximum dose allowed per year, which is 20 mSv. Next you will move into another room and be prepared for a maximal exercise test. You will wear a heart rate monitor, face mask or mouthpiece with a nose clip which will have a tube connected to a computer analysis system. The tube will collect the air you breathe out and analyze it. You will complete a maximal exercise test to exhaustion on a motorized treadmill. Initially, the test will start with you running at a comfortable, self-selected running speed, at a 1% incline. After five minutes at this speed, the speed will be increased by 0.5 mph every 2 minutes until you reach a point where you are either no longer able to continue exercise or the investigator determines that the test is over (whichever comes first). This visit will last approximately one hour.

Experimental sessions
There will be five experimental trials, where a different cooling protocol will be used in each: 1) cool-air exposure, 2) cooling packs application, 3) use of “ice sheets”, which are bed sheets soaked in ice water, wrapped around the participant, while a fan blows air on them, 4) a body bag filled with ice, or 5) immersion up to the collarbone in an ice bath (35°F water). For these trials, upon arrival to the laboratory, you will change into athletic clothing (shorts as well as sports bras for female participants) and provide a urine sample. You will then be instrumented with the equipment detailed below. Following the instrumentation, you will enter a climate chamber regulated at 104°F and 40% relative humidity and your mass will be measured. You will then rest for 10 min to acclimate to the environmental conditions. Next, you will complete an exercise protocol, which consists of running on a motorized treadmill for three sets of 20 min of exercise, consisting of a five-minute walk on a 5% incline at a speed equal to 30% of your VO2peak, followed by a 15-minute jog on a 1% incline at a speed equal to 70% of your VO2peak. Exercise will continue until: 1) rectal temperature reaches 104°F, 2) you ask to stop, 3) the research team notices that you are swaying while running, 4) your heart rate is 5 beats per minute above the maximum heart rate you attained during your preliminary study visit for five minutes, or 5) 60 minutes of exercise has elapsed. Once one of these criteria have been met, you will be weighed again and then removed from the climate chamber into an adjoining room that is regulated at ~68°F and 50% relative humidity, where the cooling interventions will be applied until your core temperature is reduced back down to 100°F. At this point, you will be weighed one last time, de-instrumented, and able to leave the laboratory. If you are unable to reach a core temperature of at least 102°F in your first experimental visit, you will not be asked back to complete further trials.

In preparation for the experimental trials, you will be asked to consume two cups of water and a small meal (e.g. granola bar or a small sandwich) one hour before arriving to the lab and abstain from alcohol, caffeine, marijuana, NSAIDS (e.g. Advil or ibuprofen, anti-histamines, and severe or prolonged physical activities for 24 hours prior to all sessions.

Throughout the study, the following equipment will be used:

- Expired gas analysis - In the preliminary trial, you will be asked to wear a mask over your nose and mouth. This mask will be connected to a machine that samples your expired breath for oxygen and carbon dioxide. This mask does not interfere at all with your breathing and you will be able to breathe normally throughout the test.

- Rectal probe – To measure core body temperature, you will be asked to self-insert, in the privacy of a bathroom stall, a flexible probe though the anus into the rectum (10-12 cm).
- Skin temperature probes: Eight skin probes will be taped to your skin surface with hypoallergenic tape. These probes give an indication of skin temperature. Some hair may need to be shaved (by the use of disposable razors) in order to secure the probes adequately to the skin surface.
- Heart rate - Heart rate will be monitored using electrocardiogram by placing five sticky electrodes on your chest. This is the same technique used in hospitals to perform cardiovascular assessments.
- Body weight measurement - You will be weighed on a wide platform scale immediately before the start of exercise and immediately after exercise has been completed.
- Rating of perceived exertion scale - Every five minutes, you will also be asked to rate your level of perceived effort to perform the exercise verbally on a 14 point scale that ranges from 6 (very very light) to 20 (very very hard).
- Whole body thermal sensation - Every five minutes, you will be asked to report your whole-body thermal sensation scored verbally on a standardized 9-point scale for thermal sensation (ranging from very cold to very hot).
- Whole body thermal comfort - Every five minutes, you will be asked to report your whole-body thermal comfort scored verbally on a standardized 9-point scale for thermal comfort (ranging from very comfortable to very uncomfortable).
- Urine specific gravity – The researchers will also ask you to provide a very small urine sample prior to the start of each study visit. The purpose of this is to ensure that you are properly hydrated. Urine specific gravity will be analyzed before the start of the trial, and all urine will then be poured into the toilet and flushed.

Other people in this study: Up to 50 people will participate in this study.

Risks and Discomforts

It is likely that you will experience at least some level of discomfort owing to increases in body temperature and the exertion of exercise. You will be informed exactly as to when temperatures will increase and be continuously monitored for your own safety. However if you feel that the level of discomfort is too much please let one of the investigators know immediately and they will work to fix the problem. The potential risks and discomforts that are associated with all of the procedures are very small and detailed below.

Rectal probes - Perforation of the rectum can theoretically occur during insertion of the temperature probe, potentially causing inflammation and infection. Perforation of the rectum is extremely rare and no such incident has ever occurred in any of the five laboratories the principal investigator has worked in, which has involved hundreds of these types of insertions, nor has the principal investigator ever heard of a perforation occurring in any research lab. The risk of transmission of infectious disease is negligible as each subject has his or her own sterile probes that will be disposed of after each trial. To further mitigate discomfort, pediatric (i.e. made for children) temperature probes will be used as they are smaller and more flexible than those used for adults.

Physical activity/elevations in body temperature - There are some minor physical risks associated with any form of exercise. There is essentially no major risk for people while performing the submaximal exercises. During all experimental protocols, you will be under close examination by the investigators. Further, core body temperatures will be monitored continuously during the experimental trials, and exercise will be terminated if a rectal temperature of 104°F is reached. If you become light-headed or dizzy, exercise will be terminated and you will be rapidly cooled with the cooling intervention on hand for the day or in a cold shower next door to the lab for the passive cooling trial, rehydrated with an electrolyte replacement drink (Gatorade, for example) and continuously monitored until your core temperature returns below 100°F.

Radiation – This research study involves exposure to a very small amount of radiation from x-rays. The effective dose of

radiation from this study is about 0.03 millisieverts (mSv). For comparison, everyone receives a dose of about 2 mSv each year from natural sources as part of everyday living, so the study is equivalent to a few days of natural "background" radiation. No harmful effects have been demonstrated at this level and the risk is minimal. Please inform our researchers if you have participated in any research study in the last five years where you were exposed to radiations. If you volunteered for another research study in the next 5 years, you should take this statement with you and show it to the researcher.

Benefits This study is designed for the researcher to learn more about the effectiveness of commonly used cooling methods in emergency departments and these findings may be of benefit to the greater scientific and medical community, however, you are not expected to gain any specific benefit from this study.

Compensation There is no monetary compensation for your participation in this study. If you would like, you may choose to receive Volunteer Hours.

Confidentiality

You will be assigned a subject number so that the researchers can keep your personal information secret. One copy of the key that links your personal information to your subject number will be kept in Dr. Morris' office in a locked cabinet. All physiological data collected will be deidentified and stored on computers protected by passwords.

Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.

Certain offices and people other than the researchers may have access to study records. Government agencies and UCCS employees overseeing proper study conduct may look at your study records. These offices include the UCCS Institutional Review Board, and the UCCS Office of Sponsored Programs and Research Integrity. UCCS will keep any research records confidential to the extent allowed by law. A study number rather than your name will be used on study records wherever possible. Study records may be subject to disclosure pursuant to a court order, subpoena, law or regulation.

Additionally, there may be instances where the researcher(s) cannot keep information you provide them confidential, including reports of abuse or neglect of a child, at-risk adult, dependent adult, or elder. If such information is reported to the researcher(s), they may have to report it to the appropriate authorities.

If you would like to report an incident, please contact the Office of Institutional Equity at 719-255-4324 or via email equity@uccs.edu or for additional resources visit their website https://equity.uccs.edu/

Your de-identified data collected during this study could be used for future research studies without additional consent. Also, your de-identified data may be made available to the scientific community in an online format as required by publishers of scientific manuscripts.

Voluntary Participation and Withdrawal from the Study

Taking part in this study is voluntary. You have the right to leave a study at any time without penalty. Withdrawal will not interfere with your future care or services at UCCS. You may refuse to do any procedures you do not feel comfortable with, or answer any questions that you do not wish to answer. If you withdraw from the study, you may request that your research information not be used by contacting the Principal Investigator listed above and below.

Contact Information

Contact (PI's info): Dr. Morris – nmorris6@uccs.edu

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research, or

- if you would like information about the survey results when they are prepared.

Contact the Research Compliance Program Director at 719-255-3903 or via email at irb@uccs.edu:

- if you have questions about your rights as a research participant, or
- if you have questions, concerns or complaints about the research.

Consent

A copy of this consent form will be provided to you.

Are you interested in being contacted about future research I may conduct? ☐ Yes or ☐ No.

I understand the above information and voluntarily consent to participate in the research. By signing this consent, I am confirming that I am 18 years of age or older.

Signature of Participant _____ Date _____