UNIVERSITY OF NORTH CAROLINA AT GREENSBORO

CONSENT TO ACT AS A HUMAN PARTICIPANT

Project Title: Efficacy of an Investigational Thermal Rehab Machine on Body Cooling in Hyperthermic Individuals

Principal Investigator and Faculty Advisor (if applicable): William M. Adams, PhD, ATC

Participant's Name:

What are some general things you should know about research studies?
You are being asked to take part in a research study. Your participation in the study is voluntary. You may choose not to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. There may not be any direct benefit to you for being in the research study. There also may be risks to being in research studies. If you choose not to be in the study or leave the study before it is done, it will not affect your relationship with the researcher or the University of North Carolina at Greensboro. Details about this study are discussed in this consent form. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. If you have any questions about this study at any time, you should ask the researchers named in this consent form. Their contact information is below.

What is the study about?
This is a research project. Your participation is voluntary. Given the importance of quickly cooling the body in the event of a heat illness occurring, it is necessary to identify useful cooling devices that can be used in various settings. Therefore, in this proposed study, we aim to examine the cooling rates of the investigational Thermal Rehab Machine (developed by Polar Breeze ®, Clearwater, FL), an investigational device, and rotating ice towels, a cooling method often recommended by sports medicine professionals as an alternative to cold-water immersion, in individuals with exercise-induced hyperthermia to investigate the application of these methods in the acute management of EHS.

Why are you asking me?

You may be included in this research study if you are a recreationally active (regularly exercise at a minimum of 4-5 times per week for greater than 30 minutes per session) male between the ages of 18-35. You will be screened via a medical history questionnaire to ensure that you meet the following criteria: 1) no chronic health problems, 2) no fever or current illness at the time of testing, 3) no history of cardiovascular, metabolic, or respiratory disease, 4) no current musculoskeletal injury that limits your physical activity, and 5) no history of exertional heat illness in the past three years.

What will you ask me to do if I agree to be in the study?
If you agree to take part in this study, you will be asked to partake in 4 visits to the laboratory; one baseline visit (approximately 60 minutes) followed by 3 separate visits to the research laboratory (approximately 150 minutes each [2.5]). Your total time involved in this study will be 510 minutes (8 hours 30 minutes).

Procedures.

The exercise and cooling portions of this study will be conducted in the climatic chamber with ambient temperature at approximately 40°C and relative humidity at 30~40%. All participants will exercise until their rectal temperature reaches 39.99°C (or one of the criteria described in the *Exercise Trials* below is met), and will be cooled by one of the three different cooling methods described below. You will arrive to the laboratory normally hydrated (urine specific gravity (USG) <1.020), but will be restricted from consuming fluids for the duration of the exercise and cooling portions of the session. If the USG is > 1.020, you will be given 500 mL of water to consume prior to exercise to ensure proper hydration before exercise begins.

Trials:

(0) Familiarization

(1) Exercise + Cooling using the investigational thermal Rehab Machine (Polar Breeze, Statim Technologies)

(2) Exercise + Rotating Forearm Ice Towels

(3) Exercise + Passive cooling (Control)

You will be randomly assigned to the trials (1) - (3) after (0) is complete. Treatment order will be counterbalanced amongst the participants. Testing sessions will occur with a minimum of one day between testing. This will allow for adequate recovery of the participant and allow you to return to baseline after exercise in the heat.

Familiarization Session

Upon arrival to the laboratory, your nude body mass, body fat percentage using Jackson & Pollack's 3-site skin fold measurement, height, urine color, and urine specific gravity will be measured. You will be instructed on the use of the investigational Thermal Rehab Machine (Polar Breeze, Statim Technologies), and self-administration of rectal thermometer. The rectal thermometer is a small (4mm [0.15 inch diameter) flexible probe. You will also be familiarized with three perceptual measures: Environmental Symptoms Questionnaire (ESQ), Rating of Perceived Exertion (RPE) and Thermal sensation scale. Lastly, the familiarization session will also involve an assessment of the your cardiovascular fitness, which will be used to determine the exercise intensities during each exercise session.

Exercise Trials

You will be asked to drink 500 mL of water prior to going to bed and an addition 500 mL of water upon waking to ensure proper hydration. Upon arrival to the lab, nude body mass will be taken using a scale calibrated to the 0.01kg. Privacy will be afforded for you while obtaining body mass measures by taking measurements behind a closed door with only yourself in the room where the scale is located and the door locked behind you. After the nude body mass is measured, a clean urine cup will be handed to you to collect a urine sample, which will be used to measure urine specific gravity and urine color to ensure euhydration prior to the start of exercise. You will then privately insert a rectal thermometer 15 cm beyond the anal sphincter. Finally, you will don a heart rate monitor, running shorts, socks, and sneakers that will be worn during the exercise trials.

You will enter the climatic chamber (~40°C, 30-40% relative humidity) and seated for 10 minutes to become equilibrated to the environmental conditions. After baseline measures of heart rate, rectal temperature, and perceptual measures (ESQ, RPE, and Thermal sensation), you will repeat 3 sets of a 20 minute exercise bout (walk on a treadmill at an intensity of 30% VO_{2max} at a 5% incline for 5 minutes, followed by a jog on a treadmill at 70% VO_{2max} at 1% incline for 15 minutes) until one of the following: 1) rectal temperature reaching 39.99°C, 2) you requests to stop, 3) altered or uneven gait, 4) heart rate > age-predicted maximum heart rate (220-age) for 5 minutes, 5) 60 minutes of exercise. Heart rate and rectal temperature will be monitored throughout the trial as a safety precaution. RPE and Thermal sensation will be recorded every 20 minutes from the beginning and also at the termination of the exercise if it was not at minute 20, 40, or 60. ESQ will be recorded just before the exercise (after the 10-minute equilibration), immediately post exercise, and immediately after the cooling. At the completion of exercise, you will follow one of the three cooling trials described below.

Cooling Trials

All cooling trials will last until the rectal temperature reaches 38.25°C. During this time heart rate and rectal temperature will be measured continuously throughout cooling. The perceptual scales will be collected pre and post cooling.

The cooling trials are:

1. Cooling using the investigational Thermal Rehab Machine – Upon completion of the exercise trial, you will don the investigational Thermal Rehab Machine. The investigational Thermal Rehab Machine consists of a hood connected by a tube to the thermal rehab machine that will be placed over your head. The investigational Thermal Rehab Machine will circulate air conditioned air into the hood to allow for body cooling. Pulse oximetry via photoplethysmography of the index finger on your right or left hand will be measured throughout cooling. In addition, tympanic (your ear canal) temperature will be measured periodically throughout cooling. To prevent the air conditioned air influencing tympanic temperature, you will insert a standard ear plug into their ear prior to the start of cooling. You will then sit quietly in the climatic chamber.

2. Cooling using Rotating Forearm Ice Towels– You will sit with their arms resting at their sides. Researchers will place ice-towels (towels that are wetted with ice-water) on your arms up to your elbows. Towels will be rotated (replaced with freshly wetted towels) every two minutes. In addition, tympanic temperature will be measured periodically throughout cooling.

3. Passive rest– You will sit quietly in the climatic chamber. In addition, tympanic temperature will be measured periodically throughout cooling.

Following cooling in all trials, you will exit the climatic chamber and the heart rate monitor and rectal thermometer will then be removed and properly cleaned and disinfected. You will provide a final nude body mass. Amount of fluid lost during the trial will be replenished by instructing you to consumer water at a volume that is equivalent to the difference between post-trial nude body mass and the body mass measured at the start of the trial.

What are the risks to me?

The Institutional Review Board at the University of North Carolina at Greensboro has determined that participation in this study poses minimal risk to participants. The risks of participation in this study are as follows. It is possible that participants will experience musculoskeletal injury, exercise-induced muscle

cramps, or delayed onset muscle soreness. It is possible that participants will strain a muscle, sprain a ligament or tendon, or incur a stress fracture in bone. There are no known risks of using the investigational Thermal Rehab Machine, however, the cooling procedure may cause risks which are currently unforeseeable. Other possible risks include: (a) a fall during the treadmill walking/running protocol (b) although very unlikely, it is possible that a disturbance of heart rhythm will occur, (c) the risk of symptomatic exertional heat stoke is very low, since we will be monitoring the rectal temperature and clinical signs and symptoms throughout the study, (d) rectal thermometry may cause inconvenience due to any discomfort the participants may have with insertion, removal, and movement with the device.

Risk Mitigation

The following steps will be taken to limit the aforementioned risks.

1. Involving young, healthy participants who have been screened for contraindications to vigorous exercise and a history of heat illnesses.

2. Educating participants about the symptoms and signs of heat exhaustion and heatstroke, with instructions to stop exercise if these symptoms or signs develop.

3. Monitoring rectal temperature, heart rate, as well as clinical signs and symptoms.

4. Exercise testing will be terminated if *one* of the following criteria is met: (1) rectal temperature reaching 39.99°C, (2) participant requests to stop, (3) altered or uneven gait, (4) heart rate > age-predicted maximum heart rate (220-age) for 5 minutes, and (5) 60 minutes of exercise. (Note: it is very unlikely that any participant will reach one of these safety limits, considering the safety precautions and medical supervision that will be available during the trials. A certified athletic trainer, with expertise in the prevention, recognition, and treatment of exertional heat illness, will be on site during each exercise session.)

5. Musculoskeletal injury risks will be minimized by thorough instruction of the task to the participant by one of the researchers.

6. If deemed necessary (i.e., core temperature reaches 40°C and there is obvious central nervous system dysfunction indicating possible exertional heat stroke), cold water cooling will be available to decrease body temperature. If you are unable to walk to the location of the cold water tub, a wheelchair will be available or cooling will take place using the shower located inside the laboratory.

If you have questions, want more information or have suggestions, please contact William M. Adams, PhD, ATC who may be reached at (336) 256-1455 or via email at wmadams@uncg.edu. If you have any concerns about your rights, how you are being treated, concerns or complaints about this project or benefits or risks associated with being in this study please contact the Office of Research Integrity at UNCG toll-free at (855)-251-2351.

Are there any benefits to society as a result of me taking part in this research?
The knowledge to be gained from this study is the utility of the investigational Thermal Rehab Machine (Polar Breeze, Statim Technologies) as a cooling modality for hyperthermic individuals. More importantly, this investigational device may allow for the mitigation of body temperature during physical activity to assist in preventing exertional heat illness. Specifically, this may be a useful method of body cooling for individuals in situations where it may not be feasible to remove protective equipment (i.e., firefighters) while performing physical activity in hot environments.

Are there any benefits to *me* for taking part in this research study?
There are no direct benefits to participants in this study. Should you request it, information about your body mass, body fat percentage, height, and cardiovascular fitness level can be disclosed to you following completion of this study.

Will I get paid for being in the study? Will it cost me anything?
You will be compensated monetarily for your time and effort. Compensation is determined based on your time commitment in addition to the nature of the exercise sessions they will be completing (i.e., exercise in the heat). You will receive up to $325 as monetary compensation. As we anticipate a small amount of attrition, payment has been pro-rated as shown below.

Phase Completed	Monetary Allotment
Familiarization	$50
Testing Sessions: 3 sessions x $75/session	$225
Completion Bonus	$50
Total Possible Compensation	**$325**

No course credit will be given for participation. All participants will receive compensation at the end of their involvement in the study. For example, a participant who completes a familiarization trial and one testing session but chooses to withdraw will receive $125 at that time; whereas a participant who completes the entire experimental protocol will receive $325 upon completion of the last testing session.

How will you keep my information confidential?
All information obtained in this study is strictly confidential unless disclosure is required by law. Recorded information will remain in a locked cabinet in the principal investigator's office. When information is entered into computer databases (that is password protected), the information will not include any identifiable information. You will only be identified by a participant number on data sheets. There will only be one master list of the participant numbers that will be stored in a separate locked cabinet in the principal investigator's office. Information will be accessible only by the principal investigator and the student researchers. Your information, the information listed on the one copy of the master list with participant numbers and signed consent form will be kept on file for three years from the time that the study is closed per federal regulations.

All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. Data that will be shared with others will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. All deidentified data will be kept indefinitely. This is in the event a journal requires the researchers to share deidentified data as more journals are requesting this: De-identified data from this study may be used in future studies and may be shared with other researchers or publicly as part of a data repository. A data repository is a large database where information from

many studies is stored and managed. De-identified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. There may be a slight chance that someone could figure out that the information is about you. With an easier way to share, researchers hope to learn new and important things more quickly than before.

Because the study involves the use of an investigational device / drug, the FDA, the sponsor and UNCG's Office of Research Integrity may review the study's data if applicable. A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if I want to leave the study?
You have the right to refuse to participate or to withdraw at any time, without penalty. If you do withdraw, it will not affect you in any way. If you choose to withdraw, you may request that any of your data which has been collected be destroyed unless it is in a de-identifiable state. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

What if I get injured? UNCG is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research study. However, we will provide you with a referral to student health or your primary care physician. You do not waive your legal rights by signing this consent form.

What about new information/changes in the study?
If significant new information relating to the study becomes available which may relate to your willingness to continue to participate, this information will be provided to you.

Are there other treatment (cooling options) available?
The cooling options discussed above, the investigational Thermal Rehab Machine, forearm ice towels and passive cooling are the only cooling options in this trial. If there is suspicion of a heat related illness, rectal temperature >40 Degrees Celsius with obvious altered mental status, cold water immersion cooling will be used as a cooling method to cool your body.

Voluntary Consent by Participant:
By signing this consent form/completing you are agreeing that you read, or it has been read to you, and you fully understand the contents of this document and are openly willing consent to take part in this study. All of your questions concerning this study have been answered. By signing this form, you are agreeing that you are 18 years of age or older and are agreeing to participate, in this study described to you by William M. Adams, PhD, ATC.

Signature: _____ Date: _____