NCT# 05692947

The Validity of CORE Sensor in Heat Training for Male and Female Endurance Athletes

Informed Consent Document

Last Edited 08/23/2023

UNIVERSITY OF OREGON

Consent for Research Participation

Title: "The Validity of CORE Sensor in Heat Training for Male and Female Endurance Athletes"

Sponsor: Wu Tsai Human Performance Alliance

Researcher(s): Samantha Chacon, Christopher Minson, PhD, and colleagues, University of Oregon

Researcher Contact Info: 541-357-9782
mritzow@uoregon.edu

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider
• **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation. • **Purpose**. The purpose of this research is to test the accuracy of the CORE body temperature monitoring devices on athletes exercising in a variety of environments. • **Duration.** It is expected that your participation will last four to six hours spread across three visits. • **Procedures and Activities.** You will be asked to undergo a test to measure your aerobic fitness and to exercise on a treadmill or cycle ergometer in a heated chamber while wearing a body temperature measurement device. You will be asked to swallow a small temperature sensing device the size of a pill. You will participate in a high-intensity exercise test and exercise in the heat. • **Risks.** Some of the foreseeable risks or discomforts of your participation include headache, fatigue, shortness of breath, nausea, and dizziness from exercising in the heat. • **Benefits**. You will not receive any direct benefit from participating in this study. However, the researchers hope to learn whether the CORE monitor is a reliable system for athletes to track their core body temperature rise during exercise. You will be financially compensated for your time and effort. • **Alternatives.** Participation is voluntary and the only alternative is to not participate.

Why is this research being done?

The purpose of the research is to verify the claims of CORE™ body temperature monitors to accurately calculate core body temperature from skin temperature and heart rate during exercise under varying environmental conditions. This device, and its algorithm for calculating core body temperature are experimental. The devices are not FDA approved or cleared for the intended uses of this study. You are being asked to participate because you are a highly trained athlete between the ages of 18 and 59. About 40 people (20 females and 20 males) will take part in this research.

How long will I be in this research?

We expect that your participation will last the duration of this screening visit (1-2 hours) and 1.5 – 2 hours on two experimental visit days (separated by at least one week), for a total of four to six hours over a seven-to-ten-day period.

What happens if I agree to participate in this research?

If you agree to be in this research, your participation will include a VO_2 Peak test to measure your aerobic fitness level and two exercise sessions in a heated chamber with varying levels of humidity, detailed below.

Screening session (0.5 - 1 hour). During this visit we will ask you some questions about your health history to see if you qualify for this study. You will meet with one of the investigators of the study to discuss the project, read this form, view the laboratory, go over any questions you might have, and sign this form if you want to participate. You can choose to take this form home with you if you want more time to decide whether to participate. If you are a person who can become pregnant, you will be asked to undergo a pregnancy test. The pregnancy test we use is commonly used in medical settings such as hospitals and doctor's offices. Tests have shown this method has a 1.6% false negative rate. This means there is a chance (about 1 in 62) our test will give the result, "not pregnant" even though a pregnancy exists. For the pregnancy test, you will be asked to collect a sample of urine in a private restroom in the lab. If the test is positive, indicating that you are pregnant, you will not be allowed to participate and will be advised to see your physician or the University of Oregon Health Center. After having reviewed all the information about this study, if you choose to participate, we will give you an exercise test (VO_2 Peak) during the same visit, as described below.

VO_2 Peak/Max Test (0.5 - 1 hour). After your screening session, you will have your peak aerobic power and maximal heart rate determined with a graded maximal cycle ergometer or treadmill running test. This means, you will either run on a treadmill or ride on a stationary bicycle while we increase the exercise intensity in a stepwise manner. This test will be used to assess your levels of aerobic fitness and monitor heat related changes to your performance. We will monitor your heart rate with a strap that you will place around your chest. You will cycle on a stationary cycle ergometer (a stationary bicycle with adjustable resistance settings) or run on a treadmill while wearing a mouthpiece and nose clip. After 4 minutes of spinning/running at a comfortable speed, the resistance of the ergometer or the speed and incline of the treadmill will increase each minute until you reach exhaustion. This is to measure your overall aerobic fitness level. It normally takes 8 to 12 minutes for people to reach their maximal effort. This test will measure your maximal oxygen uptake and will be used to select an appropriate workload for the heated exercise sessions. Upon completion of the exercise test, you will be offered a snack (granola bar) and fluids (12 oz Gatorade) to eat and drink. You should notify the investigator immediately if you feel any significant discomfort or concern about your well-being at any time during the exercise test. Some examples of discomfort include fatigue and muscle soreness.

At the end of this visit, we will give you an ingestible core temperature pill and show you how to use it. You will swallow this pill the night before (or 5-10 hours before) you come for the experimental visit.

Experimental Visit (1.5-2 hours). The exercise sessions in a heated environment will take place in an environmental chamber in the Bowerman Sports Science Center in Hayward Stadium at the University of Oregon. The chamber is a 12 ft x 12 ft x 12 ft room where we can control temperature, humidity, and wind speed. We will ask you to arrive hydrated (drink water before arriving), having abstained from intense exercise for 24 hours, and wearing or bringing clothes appropriate for exercise training in the heat. We will ask you to

wear the same clothing for your second session (at least seven days later). We will ask you to record what you ate that day and to consume a similar meal prior to your second experimental visit.

Your core temperature will be measured with an ingestible temperature pill, manufactured by HQ Inc or BodyCap, that you will swallow the night before. These temperature pills have been tested for safety and accuracy and given approval by the U.S. Food and Drug Administration (HQ Inc) or the European Medicines Agency which regulates drugs and devices in the European Union (BodyCap). Both models have been validated by various research studies. Although BodyCap has not been approved by the FDA [Pending approval], it has passed safety and compatibility testing in the European Union. The single-use core temp pill is the size of a multivitamin and will harmlessly pass through your system within 2 days. When you arrive, we will check that the pill is properly communicating with the sensor. In the unlikely event that we are unable to detect the temperature pill with the sensor, we may ask you to use a temperature sensing probe that you will insert into your rectum or to come back on a different day after swallowing another temperature pill. If you opt to use the rectal thermistor (temperature-measuring flexible probe), you will be given instructions on how to self-insert, as well as how to remove and clean it. It is made of a thin flexible rubber material that is inserted 10 cm (approximately 4 inches) past the anal sphincter. The thermistor will remain in place throughout the entire exercise session. The thermistor has a "tail" that will be connected to an external apparatus. The procedure may be a little uncomfortable at first (during insertion), but it should not be painful at any time. Once in place, you may not feel the thermistor at all. This technique is widely used, and it's considered the gold standard procedure for measuring body (core) temperature.

Before each session, you will be asked to collect a small urine sample in a private restroom in the lab to ensure you are sufficiently hydrated and to test for pregnancy. If the test is positive for pregnancy, you will not be able to participate. We may ask you to drink some water before starting exercise in the heat. You will also be provided with water during the heat exercise session. While in the restroom, we will ask you to remove your clothing and step on a scale so we can record your nude body weight. The readout for the scale is outside the bathroom and will be recorded by a researcher who is the same sex as you. Nude body weight will be measured at the beginning and end of the experimental sessions in order to calculate fluid losses due to sweat. This allows us to ensure you drink enough water during the heat stress conditions to prevent dehydration. You will change into your exercise attire after your nude body weight has been recorded.

You will be instrumented with a Garmin® heart rate chest strap in order for the CORE devices to work appropriately and not safety purposes regarding your heart rate. Research personnel will attach from 4 - 8 skin temperature sensors at various locations on your body. Additionally, a CORE™ Body Temperature Sensor and a *Calera Research* monitor by CORE™ will both be attached to the heart rate strap about 20 cm (~8 in) below each arm pit. You will rest at room temperature while the temperature sensors adjust to your body temperature. Then, we will collect thirty minutes of temperature and heart rate baseline readings. At the end of the baseline measurements, you will enter the chamber which has been set to one of the following conditions, randomly assigned for each visit:

1. Hot/dry (38°C/100.4°F with 10-20% relative humidity)
2. Hot/humid (28°C/83°F with 80-100% relative humidity)

We have included a range for the relative humidity (RH) setting, because the climate camber may not have the capacity to hold a steady RH at extreme levels and while participants are exercising and sweating.

Once you start to feel hot, we will use box fans to make you more comfortable. We will continuously check in with you to ask if you feel dizzy, nauseous, or uncomfortably warm. Following our standard lab practices, we will remove you from the heated chamber if your core temperature exceeds 39.5°C (103.1°F), even if you feel fine, or if you report any of the previously mentioned symptoms.

You will mount the cycle ergometer or treadmill in the chamber and will be permitted to do warm-up exercises for five minutes. When you are ready to begin, you will cycle or run in these conditions for 45 minutes at an absolute workload of 60% VO_2 Max/Peak. While in the chamber, you will be allowed to drink as much room temperature water as you like but ask you not to pour any water over your body. Your temperature and heart rate will be monitored in real time for the duration of the exercise session. We will ask you if you are feeling any adverse effects or unpleasant symptoms from exercising in the heat. We will stop you from exercising if any of the following experimental end points occur:

- Subject voluntarily stops exercising or is not able to maintain the pace at 60% VO_2 Max.
- Internal core temperature reaches 39.5°C (core pill)
- Subject completes 45 minutes of exercise
- Subject experiences light-headedness, confusion, nausea, or any symptoms of heat illness.

If any of these situations occur, you will be removed from the chamber to rest and cool off. Symptoms of heat exhaustion do not typically occur until core temperature rises above 40°C/104°F. All symptoms subside upon lowering core temperature. Ice packs will be on hand if rapid cooling is necessary. We will continue to monitor your temperature and heart rate until you have fully recovered.

At the end of the heated exercise period (45 minutes), you will be transferred out of the chamber and to a recovery chair. We will continue to monitor your core temperature until it has fallen below 38.5°C (101.3°F). If your core temperature remains high or if you report feeling too hot, dizzy, or nauseous, you will be cooled down more quickly with cold packs. Once your core temperature is below 38.5°C and you feel fine, we will remove any sensors from your body. Then, you will enter the private bathroom to provide your nude body weight and have the opportunity to change your clothes. We will offer you a snack (e.g., granola bar) and fluids (e.g., 12 oz Gatorade) to eat and drink. You will be asked to return in about one week to repeat the procedure under the other heat and humidity conditions listed above.

We will tell you about any new information that may affect your willingness to continue participation in this research.

Possible reasons for withdrawal. The investigators may stop you from participating in this study. The reasons for withdrawal might include:

- It is in your best interest
- You have a symptom that requires stopping the research
- You need a treatment not allowed in this research
- You become pregnant
- The research is cancelled by the FDA, the sponsor, or the IRB
- You are unable to keep your scheduled appointments

What happens to the information collected for this research?

Information collected for this research will be used to determine whether CORE™ is accurate at calculating the core body temperature of athletes exercising in a variety of hot environments. It may be used in published reports and

conference presentations. Your name will not be used in any published reports or conference presentations about this study. Identifiers might be removed from identifiable private information collected in this research. After removal of identifiers, the information may be used for future research or distributed to another investigator for future research without obtaining additional consent.

How will my privacy and data confidentiality be protected?

We will take measures to protect your privacy including conducting research in a private setting and using secure data collection platforms. Despite taking steps to protect your privacy, we can never fully guarantee your privacy will be protected.

It is possible that some of the sessions may involve more than one subject participating at the same time, so subjects may learn each other's identities. However, optional privacy measures are available upon request including:

- Scheduling your sessions when no other subjects are present
- "Do not disturb" door sign
- Privacy screens to partially or completely block the view of other subjects and non-essential research staff

We will take measures to protect the security of all your personal information including coding all data collected in connection with this study by assigning a subject identification number. The document that links your identity with your subject number will be kept in a password protected file on a password protected computer in the lab, separated from all data. The coded list of names will be destroyed when study results are published or 24 months after completion of the study, whichever comes first. Any information that can be identified with you will remain confidential and will be disclosed only with your permission. Other information (de-identified) may be stored by the researchers indefinitely. Despite these precautions to protect the confidentiality of your information, we can never fully guarantee confidentiality of all study information.

Heart rate data will be collected in conjunction with the CORE. All heart rate data is coded such that no identifiable information will be accessible.

Biospecimens (urine) collected as part of this research will not be used or distributed for future research studies. The urine samples will be immediately disposed of after testing for hydration levels and pregnancy (if applicable). There is absolutely no chance that your specimens could ever be used for commercial profit.

You will be asked to complete a medical history form for screening purposes. This form will list personal identifying information (name, address, phone, emergency contact info) so that in the unlikely event of a medical emergency in which we would activate the emergency medical system, we would be able to provide this information to emergency healthcare providers. This document will be retained in a locked file cabinet in the lab. When your involvement in the study ends, identifiable information will be redacted from this document. Deidentified data may be kept on file indefinitely.

Individuals and organizations that conduct or monitor this research may be permitted access to and inspect the research records. This may include access to your private information and medical results. These individuals and organizations include:

- The Institutional Review Board (IRB) that reviewed this research
- Government regulatory agencies

- The Food and Drug Administration

If data is shared with researchers outside of the University of Oregon physiology lab for the purpose of statistical analysis, all personally identifiable information will be removed.

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 the results. You can search this Web site at any time.

What are the risks if I participate in this research?

Exercise testing: There is some minor discomfort associated with exercise testing, including temporary fatigue, shortness of breath, and muscle soreness. These sensations resolve within minutes after the test is completed. There is the possibility of some residual muscle soreness in the few days following the exercise test. There is also the risk of a heart attack or death during an exercise test. The risk of a complication requiring hospitalization is about 1 incident in 1000. The risk of a heart attack during or immediately after an exercise test is less than 1 incident in 2500. The risk of death during or immediately after an exercise test is less than 1 incident in 10,000.

Core temperature pill: Your core temperature will be measured with a core temperature pill that is the size of a multivitamin and is designed and approved for human use. The risks of using the temperature pills include discomfort during swallowing and irritation (pain, swelling) of the lining of the digestive tract, which can be avoided by drinking enough water with the pill. It will harmlessly pass through your system within about 2 days. The pill is disposable and is not recovered. Other risks may include discomfort with swallowing. Hundreds of thousands of core temperature pills have been distributed since the 1960's with only one known case of an adverse event. In this case, the pill became lodged in an individual's digestive tract, which required surgical removal. No other risks have been identified. Volunteers with a history of obstructive diseases of the gastrointestinal tract (blockages in your digestive system) including diverticulosis (bulging pouches in the colon wall), diverticulitis (inflamed pouches in the colon wall), inflammatory bowel disease (chronic inflammation of the digestive tract), peptic ulcer disease (sores in the lining of the stomach, Crohn's disease (chronic inflammation of the digestive tract, ulcerative colitis (inflammation and sores in the colon), or previous GI surgery should not use a core temperature pill. Before swallowing the pill, please inspect the pill for cracks or any other damage before ingesting. If you notice a crack or any other damage, do not take the pill and contact the researchers. The BodyCap core temperature pill we are using to monitor your temperature is not yet cleared or approved by the Food and Drug Administration (FDA) so we don't know how safe or effective it will be at measuring your core temperature and there may be unknown risks from using this pill.

Rectal thermistor *(optional)***:** The use of rectal thermistors to measure core temperature carries minimal risk. The primary risk is damage to the lining of the rectum; however, this risk is very slight as we use a flexible thermistor that is designed for this purpose. You will be asked to self-insert the rectal temperature probe. If someone is not available to assist you, there may be a slight increased risk of discomfort. Individuals with recent rectal, anal, vaginal, or prostate surgery should not use a rectal thermistor. In addition, those who have a personal history of heart disease should not use a rectal thermistor, as the use of a rectal thermometer can cause a vagal reaction (sudden drop in heart rate and blood pressure in reaction to a stressor), increasing the potential for arrhythmias (irregular heartbeat) and fainting. There is also the risk of infection. The risk of infection is similar to that of having a bowel movement and is considered minimal.

Heat exposure: There are some risks associated with heat exposure, including: fatigue, light-headedness, muscle cramps, dehydration, and neurological detriments (i.e. heat stroke). However, these symptoms do not typically

occur until core temperature rises above 40°C (104° F). Your core temperature will be constantly monitored (by ingestible pill or rectal probe), and you will be removed from the heat immediately if either core temperature reaches 39.5°C or you experience any symptoms of heat-related illness. You will be instructed to notify the investigators immediately if you experience any of these symptoms. All symptoms subside upon lowering core temperature. Ice packs will be on hand for rapid cooling if necessary.

Risks for subjects who are pregnant: Potential risks to subjects who are pregnant, in addition to the other risks already mentioned, include exercising beyond what is recommended by your doctor (see 'exercise testing' above) and potential harm to the fetus from heat exposure. There is not enough research on the effects of heat on a developing fetus. Overheating during the first trimester may result in neural tube (brain and spine) defects or miscarriage. Overheating later in pregnancy may result in dehydration of the pregnant person. Therefore, the American College of Obstetricians and Gynecologists suggests that pregnant people should avoid elevations in core body temperature. Therefore, subjects who are pregnant or trying to conceive may not participate in this study. Due to the increased risk of exercise testing and heat exposure, any subject with childbearing potential will be required to take a pregnancy test when they arrive to the lab for their informed consent and on the experimental visit days. Thus, subjects who are pregnant or trying to conceive will be excluded from the study. The risk associated with taking a pregnancy test is finding out that you are pregnant.

Emergencies: In the event of a non-life-threatening emergency, investigators will follow the established Human Physiology Emergency procedures. In the event of a life-threatening emergency, investigators will follow the established Human Physiology Emergency procedures which include an investigator providing basic first aid as appropriate (including high quality CPR and use of an Automated External Defibrillator (AED) if needed) and calling 911 to activate an emergency response. After the activation of an emergency response, the emergency personnel will determine if transport is necessary. If transport is needed, the subject will be transported by ambulance to a local emergency facility.

What are my responsibilities if I choose to participate in this research?

If you take part in this research, you will be responsible for:

- Adhering to scheduled sessions and communicating with the researchers in the event that you need to reschedule any sessions.
- Adhering to instructions from the researchers regarding when you need to fast, refrain from consuming caffeine or medications, abstain from alcohol, exercise, or heat therapy for specific testing days.

What if I want to stop participating in this research?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your relationship with the researchers or the University of Oregon.

If you choose to stop participating in this research, the data collected on you as a subject to the point of withdrawal remains part of the study database and may not be removed.

Will it cost me money to take part in this research?

There are no costs associated with participation in this research study.

What if I am injured because of participating in this research?

If you are injured or get sick because of being in this research, call the researchers immediately.

In the event you suffer a research-related injury, your medical expenses will be your responsibility or that of your insurance company (or other third-party payer), although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research. If you are a UO student or employee and are covered by a UO medical plan, that plan might have terms that apply to your injury.

If you experience harm because of the project, you can ask the State of Oregon to pay you. If you have been harmed, there are two University representatives you need to contact. Here are their addresses and phone numbers:

General Counsel/ Office of the President
1226 University of Oregon
Eugene, OR 97403-1226
(541) 346-3082

Research Compliance Services
5237 University of Oregon
Eugene, OR 97403-5237
(541) 346-2510
ResearchCompliance@uoregon.edu

A law called the Oregon Tort Claims Act may limit the amount of money you can receive from the State of Oregon if you are harmed.

Will I be paid for participating in this research?

With full participation, we anticipate you will receive $40 - $60 total ($10/hour of time in the lab) in the form of a check or deposit into your ClinCard account after completion of the study. If you decide to stop participating part way through the study, or if you are excluded for failure to comply with protocols or for another unforeseen reason, your payment will be prorated based on your time in the study.

Please be aware, compensation for participation in research may be considered taxable income. The University requires tracking for compensation that is paid to you; this may include your name and contact information. This information is stored confidentially and separate from research data. If you receive $600 or more in a calendar year, you may be contacted to provide additional information (e.g. Social Security Number) for tax reporting purposes.

Who can answer my questions about this research?

If you have questions, concerns, or have experienced a research related injury, contact the research team at:

Dr. Minson
(541) 346-4105
minson@uoregon.edu

An Institutional Review Board ("IRB") is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. UO

Research Compliance Services is the office that supports the IRB. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Research Compliance Services
5237 University of Oregon
Eugene, OR 97403-5237
(541) 346-2510
ResearchCompliance@uoregon.edu

STATEMENT OF CONSENT

I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to make a decision about my participation. I understand that I can ask additional questions throughout my participation.

I understand that by signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

I consent to participate in this study.

Name of Adult Participant	Signature of Adult Participant	Date

Researcher Signature (to be completed at time of informed consent)

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

Name of Research Team Member	Signature of Research Team Member	Date