

St Olaf College

INFORMED CONSENT

Study Title: Investigation of the effect of environmental temperatures on non-contact thermal imaging for core body temperature measurement

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Please read through this document thoroughly to ensure you understand the nature of the study and the potential risks and benefits. Please ask questions if there is anything you do not understand. Your participation is voluntary, and you may withdraw at any time.

Information on the Research

The purpose of this study is to examine how the environment affects the accuracy of non-contact thermal imaging for human body temperature measurement. We will be working with groups of up to 10 people at a time, so please refrain from disclosing personal information you do not wish disclosed, as we have no control over what other participants may overhear. During this 2-hour study, you will spend up to 10 minutes in tents and rooms that have been set up with different air temperatures ranging from approximately 68F to 87F. You may wear warm clothing as desired but we will ask that you do not cover your face near your eyes in any way during the study. We will be taking two types of temperature measurements several times throughout the study, one type will use a clinical oral thermometer (referred to as the oral temperatures) and the other type will use one of several non-contact infrared temperature scanners (referred to as the imaging temperatures).

Oral Temperatures: Your temperature will be taken with an oral thermometer multiple times, including prior to the start of the study to determine whether you may have an elevated temperature. We ask that you refrain from breathing excessively with your mouth, consuming food or drink, placing gum or other objects inside your mouth, and talking excessively for the 10 minutes before each oral temperature, because these actions can distort the oral temperature. For each measurement, we will insert the probe into your mouth under your tongue and ask you to try to keep the tip under the rear pocket of one side of the tongue (this is critical to obtain the most accurate reading), and then to keep your mouth closed until the measurement is complete. While a quick temperature estimate is provided after 8 seconds, we need a more accurate measurement that will take a little over a minute.

Imaging Temperatures: The non-contact infrared imaging temperatures will be obtained by standing in front of one of several thermal imaging cameras, as directed by study personnel. If you are wearing glasses, you will be directed to remove your glasses for each imaging measurement. You will be instructed to look towards the camera and remain still until the device reports a temperature on its display, typically requiring one second. Each time we collect

imaging measurements, the first camera measurement will be repeated two more times. The other non-contact systems will be recorded only once each time through.

Study Process: Don't worry about losing track of this information, the study coordinators are here to make sure you are in the right place at the right time.

You will be given a sheet of paper to complete while waiting at the start of the study. This sheet contains an NFC sticker that you will use to mark each scan. **Please do not lose this sheet or exchange it with someone else's or we cannot use any of your data.** During the study, we will direct you to one of the rooms to wait for 10 minutes while your skin gets used to the air temperature inside and we collect measurements of your face temperature. While inside the room, please refrain from excessive movement, touching your face near your eyes and stressful content because this can alter the temperature of your face. For this reason, we ask that you do not use cellphones to browse anything other than light reading during these equilibration phases. Please avoid any cognitively-demanding or emotional material as this might affect the temperature slightly. When directed by the study coordinator, you will move to the scanning area for the imaging temperature and oral temperature measurements.

This process will repeat with study personnel directing you to different rooms. In some of these rooms you will receive imaging temperatures while you are inside the room instead of outside the room. Either at the beginning or the end of the study, we will ask you to wear your eyeglasses or sunglasses, if you brought these with you to the study, and to get an imaging temperature measurement, one for each type of glasses you brought with.

Risks and Discomfort

The risks of this study are those of a clinical oral temperature measurement and remaining in a room that may be as warm as 87F for 10 minutes. If you experience discomfort while receiving an oral temperature measurement, please inform the study personnel performing the oral measurement so they can halt the measurement and determine the cause and allow you to decide whether you wish to proceed. If you experience discomfort while remaining in a warm room, please inform the study personnel nearby so they can help you leave the warm environment if you feel it necessary and allow you to decide whether you wish to proceed.

In the unlikely event of injury caused by participating in this research, medical treatment is available, but your medical insurance must pay the cost of treatment. St Olaf College will not voluntarily provide compensation for medical expenses or research-related injuries.

Benefits

The only tangible benefit of this study is the compensation provided for your participation, in the form of a \$20 electronic cash card. Please note you may withdraw from the study at any time without loss of benefit. There may be no other anticipated benefit to you from this investigation. The future benefits to other patients or science or the general public may include improved detection of potentially communicable fever-causing diseases.

Privacy and Confidentiality

The medical and research information recorded about you will be used within St Olaf College and/or disclosed outside St Olaf College as part of this research. Your access to research information about you will be limited while the study is in progress. Preventing this access during the study keeps the knowledge of study results from affecting the reliability of the study.

Your research information may be disclosed in a de-identified form to the U.S. Food and Drug Administration, and other outside collaborators or laboratories that are participating in this study, if any, that are listed as follows: Thermal Diagnostics LLC. St Olaf College and Thermal Diagnostics LLC must comply with legal requirements that mandate disclosure in unusual situations. Otherwise, the information recorded about you as part of this research will be maintained in a confidential manner. While this study does not record any personally identifiable information, it is possible that information disclosed about your data outside St Olaf College could be re-disclosed and no longer protected by federal privacy laws.

The information recorded during this study is designed to collect no personal identifiers which means the data is de-identified. However, the imaging data includes images of your face, which is potentially identifiable. Therefore, the imaging data will be cropped to only include the eye regions before being shared outside the collaborators participating in this study.

Voluntary Participation

Your participation in this study is completely voluntary. You can choose not to participate, or stop participating at any time without fear of penalty or loss of medical care. You will be informed of any significant new findings developed during the course of the research that may relate to your willingness to continue participating in the study.

If you have any questions about the research or develop a research-related problem, you should contact Dr Erik Beall (Thermal Diagnostics LLC), at Phone: 440-941-5489. If you have questions about your rights as a research subject, you should contact the St Olaf College Institutional Review Board at irb-administrator@stolaf.edu.

I have read the above information and have all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. A copy of this consent will be provided to you. By signing below, I agree to take part in this research study.

Date

Subject Signature

Date

Witness/Person Obtaining Consent Signature