

Core Temperature Measurement via Rectal Thermometer
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Short Title	Rectal Temperature Measurements
Effective Date	
Approved by REB	
Version Number	1
Next Review Date	

A. PURPOSE AND BACKGROUND

Rectal temperature measurements provide a safe and accurate measurement of core temperature, an important variable in many studies within the field of environmental physiology. The purpose of this document is to outline standardized procedures for authorized researchers to follow for rectal temperature measurements using a multiple-use core thermistor. The intention is to ensure that rectal temperature measurements are taken in a safe and efficient manner while minimizing the risks of infection to the participants and the researchers. This document also outlines the protocol for safe disinfecting of core temperature probes between use by participants.

B. PROCEDURES/STUDY PROTOCOL

Are there any controlled act(s) to be performed: Yes No

If you checked yes, list the controlled act(s) below:

Due to the probes being self-inserted, there are no controlled acts performed.

Terms and definitions

(1) Multiple use. This refers to probes designed to be disinfected and reused either by the same participant across multiple sessions of a single study, or by multiple participants within the same study or across different studies. Where quantities are sufficient, best practice is to assign individual probes to each participant for the duration of the study. The participant always retains the right to request a new probe if they desire.

(2) Anal sphincter. Entrance barrier between the rectum and the external environment, controlled by a ring of smooth muscle.

Steps and procedures

Rectal Temperature Measurements – Probe Insertion

1. Prior to each trial, the researcher should visually inspect the probe for any deterioration to the probe housing (e.g., cracks). If any obvious deterioration exists, the probe should be discarded and a new one provided.
2. The participant will wrap a small strip of hypoallergenic surgical tape at the 15 cm mark of the temperature probe. The researcher may assist the participant with the correct placement of the surgical tape.

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3. The participant will self-insert the core probe in the rectum using a water-based lubricating jelly (if desired). A gauze sling may be used to keep the probe secured depending on experimental needs. The probe should be inserted 15 cm beyond the anal sphincter (i.e., the probe is inserted to the level of the surgical tape). Probe insertion should take place in the privacy of a washroom.
4. The participant should ensure that the probe connection is outside the clothing and accessible to the researcher.
5. The participant will tape the probe in place on the back of the hip to ensure that the probe does not move during the experimental protocol.

Rectal Temperature Measurements – High Level Disinfection of Probe

1. Following the experimental protocol, the researcher will provide the participant with a graduated cylinder filled with the appropriate disinfectant (e.g., Glutacide®).
2. The participant will don non-sterile gloves and remove the core probe in the privacy of a washroom.
3. The participant will wipe the probe clean using a bathroom tissue and alcohol wipe.
4. The participant will place the core probe in the graduated cylinder containing disinfectant and will return the probe to the researcher. The participant should wash their hands following removal and disposal of the non-sterile glove.
5. The probe will remain in the disinfectant for 20 minutes.

Rectal Temperature Measurements – Probe Storage

1. Following the 20-minute disinfection time, the researcher will don non-sterile gloves, remove the probe from the graduated cylinder and rinse with water. The disinfectant will be disposed of in the sink.
2. The probe will be dried, returned to the original packaging, and taped shut. The researcher will then remove and dispose of the gloves, then wash their hands.
3. If the probe is being reused by a participant within a study, the number associated with the participant's name will be clearly written on the package. The sheet containing the corresponding name to the number given will be stored on a password protected computer in the lab. The probes will be stored in a locked and clearly labeled drawer.

C. EQUIPMENT

1. General purpose core temperature probe. These should be stored in individual packages in a drawer, cabinet, or box dedicated to this purpose.
2. Individual packet lubricating jelly.
3. Individual alcohol wipes.
4. Gauze "sumo" sling (if necessary)
5. Hypoallergenic surgical tape (e.g., 3M Transpore®)
6. Small graduated cylinder (~250 mL).
7. Disinfectant (e.g., Glutacide®)
8. Nitrile gloves (non-sterile)
9. Ruler or measuring tape

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Training required for researchers

Safety training courses that are required for the researchers:

1. Science Safety
2. Biosafety

D. DESCRIPTION TO STUDY PARTICIPANTS

Describe in writing (consent form) and orally (during study) how a study participant would experience the procedures and equipment.

The following standard text should be placed in the Consent document under "Potential Benefits and Risks"

Insertion of the flexible rectal probe may cause slight discomfort. You will be given instruction about how to prepare the probe and will self-insert the probe in a private room. You will be provided with water-based lubricant if necessary and will secure the probe with a soft gauze "sumo sling" harness which will keep it in place during exercise. There is a slight but real risk of perforation of the bowel from the insertion of the rectal probe, though the investigators are unaware of this ever occurring in a research setting. The rectal probe will be sterilized and used through the duration of the research. After sterilization, the package will be taped shut, your participant identifier code clearly written on the package, and the probe will be stored in a locked and clearly labeled drawer.

The following standard text should be placed in the Consent document in a separate section titled "Rectal Probe"

When performed in a healthcare setting, insertion of the rectal probe is a controlled act as set out in the Regulated Health Professions Act. While this act does not extend to research outside of a healthcare setting, you should be aware of the following potential risks:

- Insertion of the rectal probe can stimulate the vagus nerve which can cause slowing of the heart rate which may lead to fainting. This is more likely to happen if you have a low resting heart rate.
- Perforation of the bowel can lead to peritonitis, a serious infection of the abdominal cavity.

E. RISKS

1. PARTICIPANTS

- a. Participants may feel discomfort during insertion and removal.
- b. There is a theoretical risk of stimulation of the vagus nerve which can cause slowing of the heart rate or fainting.
- c. There is a theoretical risk of bowel perforation, although this has never been reported in the research community or literature.

Core Temperature Measurement via Rectal Thermometer**2. RESEARCHERS**

- a. There is the risk of transmission of fecal matter and associated pathogens.

F. SAFEGUARDS/SAFETY PROCEDURES**1. PARTICIPANTS**

- a. Rectal temperature probes are self-inserted. Participants should cease insertion should they experience any pain.
- b. Participants have agency and an active role in the disinfection of their own probe.
- c. Non-sterile gloves are provided during removal and disinfection.

2. RESEARCHERS

- a. Gloves are worn during disinfection of the probe. The researcher disposes of gloves in an appropriate container and washes hands thoroughly with soap and warm water.

G. REFERENCES (if applicable)**H. REVISION HISTORY**

Version	Review Date	Summary of Changes
1	September 14, 2020	N/A
2	October 27, 2020	Edits made for specificity