Appendix D: Standard Operating Procedures - Field Survey and Measurements

SOP 5.0 Day Prior Indoor Temperature Monitoring Sensor Installation (Hygrochron iButton)

Figure 1: Hygrochon ibutton temperature and relative humidity data logger used for indoor residential monitoring.

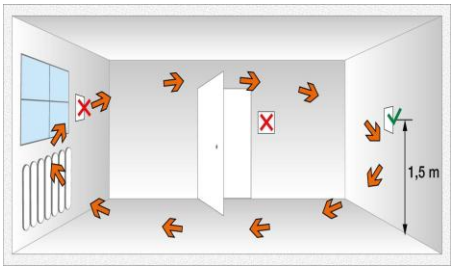


Figure 2. Illustrative indoor sensor placement approximately 1.0-1.5 m above the sleeping surface and away from direct heat or sunlight.

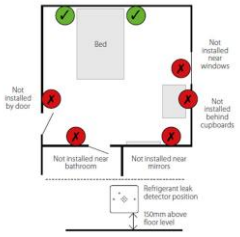


Figure 3. Example room layout showing preferred and non-preferred locations for indoor sensor placement.

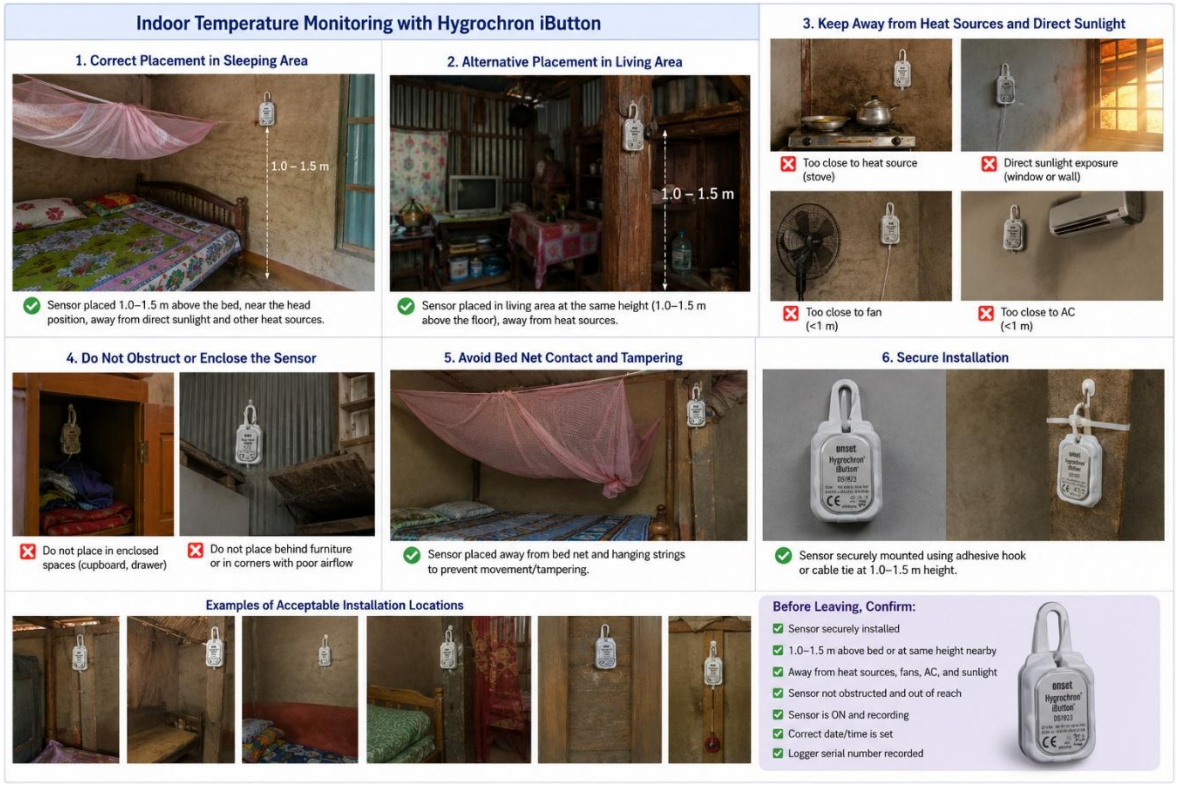


Figure 4. Indoor temperature monitoring with Hygrochron iButton: correct placement, unsuitable locations, secure installation, and final field checks.

Purpose

To standardize the installation of the Hygrochron iButton temperature logger in the participant's usual sleeping area one day before occupational heat exposure monitoring, enabling continuous measurement of indoor temperature and relative humidity throughout the monitoring period.

Personnel

- Trained Field Research Assistant (minimum 2 years' experience in field data collection)
- Field Supervisor (present during the participant's first installation visit)

Equipment Required

- Hygrochron iButton temperature and humidity logger
- iButton protective holder
- Mounting materials (adhesive strip, cable tie, or hook)
- Measuring tape
- KoboToolbox Indoor Monitoring Form (HTS-Indoor-01)
- Participant Identification Labels
- Field tablet
- Permanent marker

Before Installation, Ensure That:

- Written informed consent has been obtained.
- Participant eligibility has been confirmed.
- Hygrochron iButton has been initialized and synchronized with study time.
- Battery status and memory capacity have been verified.
- Device serial number has been linked with the participant ID.
- HTS-Indoor-01 is open and ready for data entry.

Indoor Temperature Sensor Installation Procedure

Step 1. Visit the Participant Household

Visit the participant's household during the evening before the scheduled monitoring day, when the participant is at home.

Introduce the study procedures and confirm that the participant will sleep in their usual sleeping location.

Step 2. Confirm Sleeping Location

Ask the participant to identify the location where they normally sleep during the heat season.

If the participant uses different sleeping locations during hot weather, identify the location where they are most likely to sleep during the monitoring period.

Record the sleeping location in HTS-Indoor-01.

Step 3. Select an Appropriate Installation Site

Select a location that best represents the participant's sleeping environment.

The installation site should:

- be approximately 1.0-1.5 m above the sleeping surface
- be within approximately 1 m of the participant's head position during sleep
- be away from direct sunlight
- be away from doors and windows receiving direct solar radiation
- be at least 1 m away from fans, air conditioners, cooking stoves, televisions, refrigerators, or other heat sources
- allow unobstructed air circulation

Do not install the sensor:

- inside cupboards
- inside drawers
- under pillows
- under mattresses
- directly attached to mosquito nets or bed nets
- immediately beside electric appliances

Step 4. Install the Hygrochron iButton

Secure the Hygrochron iButton firmly using the approved mounting method.

Ensure that:

- the device is stable
- the sensor is exposed to ambient room air
- the participant cannot accidentally knock the sensor down during routine activities

Step 5. Verify Installation

Confirm that:

- device identification matches the participant ID
- installation height is correct

- sensor location is appropriate

Record:

- Device serial number
- Installation date
- Installation time
- Installation height
- Room type
- GPS coordinates (if available) in HTS-Indoor-01.

Step 6. Participant Instructions

Explain that the sensor only measures environmental conditions.

Advise the participant:

- not to touch or move the sensor
- not to cover the sensor with clothes or bedding
- not to remove the device
- to notify the research team if the sensor becomes detached or damaged

During the Monitoring Period

The Hygrochron iButton should remain installed continuously throughout the monitoring period.

Field staff should visually inspect the sensor during daily visits whenever possible.

Record any:

- accidental movement
- removal
- obstruction
- equipment malfunctions in HTS-Indoor-01.

Sensor Retrieval Procedure

On the final day of outdoor monitoring, retrieve the Hygrochron iButton.

Inspect the device for damage.

Download and verify the recorded data.

Clean the sensor using approved disinfectant wipes.

Store the device according to study procedures.

Record retrieval date and time in HTS-Indoor-01.

Critical Checks

Before leaving the participant's home, confirm that:

- Sensor is securely installed.
- Device serial number matches participant ID.
- Sensor is not exposed to direct sunlight.
- Sensor is not adjacent to heat sources.
- Sensor is unobstructed.
- Installation has been documented.

Quality Control

- Verify synchronization of device clocks before deployment.
- Confirm correct participant-device linkage.
- Inspect installation during field visits.
- Document any equipment movement.
- Download and verify data immediately after retrieval.
- Record equipment issues in the Equipment Maintenance Log (HTS-EML).

Safety Considerations

- Install the sensor where it does not interfere with normal household activities.
- Avoid creating trip hazards with mounting materials.
- Respect participant privacy while selecting the installation location.
- Do not install equipment in unsafe household structures.

Documentation

- Complete and maintain:
- HTS-Indoor-01 (Indoor Temperature Monitoring Form)
- Equipment Maintenance Log (HTS-EML), if applicable
- Protocol Deviation Log (if applicable)

Before Leaving the Household

Ensure that:

- Sensor has been securely installed.
- Device serial number has been recorded.
- Participant has received monitoring instructions.
- Installation has been documented.
- Indoor monitoring has commenced successfully.

SOP 5.1 Pre-Shift Participant Screening and Field-Based Informed Consent

Figure 5. Illustrative participant engagement and consent process in a field setting.

Figure 6. Illustrative body temperature screening before field-based procedures.

Purpose

To ensure that participants meet the study eligibility criteria and provide voluntary informed consent before field-based study procedures, measurements, capsule administration, wearable monitoring, biological sample collection, and structured work-shift observation are conducted.

Personnel

- Trained field research assistant (minimum 2 years' experience in field data collection)
- Field supervisor (present on first observation day per participant)

Equipment Required

- Informed Consent Form (English and local language)
- Eligibility screening checklist (KoboToolbox form: HTS-Screen-01)
- Non-contact infrared thermometer (for axillary temperature screening)
- Participant ID sticker labels
- Clipboard and pen

Before starting participant screening, ensure that:

- Field tablet is fully charged and KoboToolbox is functioning.
- Screening form (HTS-Screen-01) is available.
- Consent forms are available in the participant's preferred language.
- Thermometer is functioning properly.
- Participant ID labels are prepared.

Screening Procedure

Step 1. Prepare for Screening

- Arrive to the field site 60minutes prior to work shift.
- View the list of participants for the day.
- Establish who will be observed.

Step 2. Confirm Participant Identity

- Use the study roster to confirm participants identity.
- Establish the name of the participant along with their study number (if previously enrolled).

Step 3. Conduct Eligibility Screening

Using HTS-Screen-01, run the eligibility checklist.

Confirm that the participant:

- All the study inclusion criteria are fulfilled.
- Does not meet exclusion criteria
- No new medical conditions since last enrollment.

Step 4. Measure Body Temperature

- Axillary temperature measured by a non-contact infrared thermometer.
- Enter the temperature in KoboToolbox.

Do not continue any study procedures in the event the participant has a temperature greater than 37.5°C. Notify the Field Supervisor and document exclusion reason.

Step 5. Obtain Written Informed Consent for Field-Based Procedures

Present the participant with the informational form and describe field-based study procedures involving work-shift observation, core temperature monitoring, wearable activity monitoring, biological sample collection and fluid-intake assessment. Inform participants that urine and

blood samples will be collected before the work shift, immediately after the work shift, and (where applicable) the following morning for assessment of kidney function, hydration status, and heat-related physiological responses.

Explain:

- Purpose of the study
- Study procedures
- Potential risks and benefits
- Confidentiality
- Voluntary participation
- Right to withdraw at any time without consequences

Allow sufficient time for questions.

If participant agrees to be part of the study:

- Get written informed consent.
- Signed consent forms (by a witness if needed)
- Give the participant their copy of signed consent.

Do not perform any study procedures until written informed consent has been obtained.

Step 6. Participant Identification number Assignment or Verification

Give a Participant ID to newly enrolled participants. For SOP 5.0 comodules, confirm that the existing Participant ID is correct.

This will assign a unique Participant Id in the format below:

- HTS-[Site]- [3-digit number]
- The Participant ID label is applied to:
- Data collection forms
- Biological specimen labels (if applicable)
- Study instrument allocated to the participant

Step 7. Complete Documentation

- Record the following in HTS-Screen-01:
- Date
- Time

- Participant ID
- Screening outcome
- Body temperature
- Consent status
- Name of Field Research Assistant

Save and verify the completed form before proceeding.

Critical Checks

Before beginning any study measurements, confirm that:

- Participant meets all eligibility criteria.
- Body temperature is ≤37.5°C.
- Written informed consent has been obtained.
- Participant ID has been assigned correctly.
- Screening form has been completed and saved.

Quality Control

- Use only calibrated thermometers.
- Verify participant identity before assigning a Participant ID.
- Review each completed screening form for missing information.
- The Field Supervisor should observe the screening and consent process for each participant's first observation day.
- Report any protocol deviations to the Field Supervisor immediately.

Safety Considerations

Participants with:

- Body temperature >37.5°C
- Acute illness
- Any newly identified exclusion criteria

must not proceed with study procedures until reviewed by the Field Supervisor or designated medical personnel.

Documentation

Complete and maintain the following records:

- HTS-Screen-01 (KoboToolbox Screening Form)
- Signed Informed Consent Form
- Participant ID Assignment Log
- Daily Screening Log

Before Leaving the Participant

Ensure that:

- Screening has been completed.
- Written informed consent for field-based procedures has been obtained.
- Participant ID has been assigned.
- All required documentation has been completed.
- Participant is cleared to proceed to SOP 5.2 -Pre-Shift Anthropometric Measurements.

SOP 5.2 Anthropometric and Blood Pressure Measurements (Pre- and Post-Shift)

Figure 7. Portable stadiometer used for standardized height measurement.

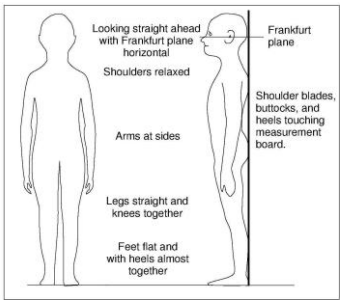


Figure 8. Correct standing posture and Frankfurt plane for height measurement.

Figure 9. Digital weighing scale used for body weight measurement.

Purpose

To obtain accurate and standardized measurements of participant height, body weight, and blood pressure before the work shift, and to repeat body weight and blood pressure measurements immediately after the work shift to assess physiological changes associated with occupational heat exposure. Body Mass Index (BMI) will be calculated using pre-shift height and weight measurements.

Personnel

- Trained Field Research Assistant

Equipment Required

- Portable stadiometer (range: 60-210 cm; precision: 0.1 cm; calibration verified weekly)
- Calibrated digital weighing scale (range: 0-200 kg; precision: 0.1 kg; calibrated against certified weights monthly)
- Validated automated digital upper-arm blood pressure monitor
- Appropriate blood pressure cuffs (small, standard and large sizes)
- KoboToolbox Anthropometry Form (HTS-Anthro-01)
- Alcohol wipes or disinfectant wipes

Before taking measurements, ensure that:

- The stadiometer is assembled correctly and placed on a firm, level surface.
- The digital weighing scale has been calibrated and reads 0.0 kg before each measurement.
- The blood pressure monitor has passed routine calibration checks and is functioning properly.
- An appropriate cuff size is available for the participant.
- Equipment has been cleaned according to study procedures.
- KoboToolbox form (HTS-Anthro-01) is open and ready for data entry.
- Participant has completed SOP 5.1 -Pre-Shift Participant Screening and Informed Consent.

Height Measurement Procedure

Step 1. Prepare the Participant

Ask the participant to:

- Take off shoes and socks.
- Take off any hat, cap, or head covering that can obstruct measurement.
- If possible, get rid of extra fluffy hairstyles or accessories.

Step 2. Position the Participant

Ask the participant to stand:

- Stand on the stadiometer platform with head upright.
- Feet together on the ground and flat.

- Heels on the backboard
- Legs straight.
- Hands down along the sides.
- Shoulders level.

Ensure that the:

- Heels
- Buttocks
- Upper back
- Back of the head

are touching the vertical board whenever possible.

Align the head of the participant to the Frankfurt Plane and look into their eyes, straight ahead.

Step 3. Measure Height

- Bring the headpiece down close to the crown of the head.
- Level the headpiece so that heads is not squished too much.
- Take the measurement at eye level
- Measure height to the nearest 0.1 cm

Step 4. Repeat Measurement

- Measure height a second time.
- If the two measures differ by more than 0.5 cm, take a third measurement.
- Store median value as the height.

Weight Measurement Procedure

Step 5. Prepare the Participant

Ask the participant to:

- Remove shoes.
- Empty pockets.
- Remove heavy outer clothing or items that may affect weight.

Step 6. Position the Participant

Position the weighing scale on a hard, level surface.

Ask the participant to:

- Stand on the centre of scale
- Place both your feet evenly.
- Stand without an object.
- Let both arms lay at your sides.

Step 7. Measure Weight

- Wait for the display to stabilise.
- Weighing to the nearest 0.1 kg.

Step 8. Repeat Measurement

- Measure weight a second time.
- If the two readings differ by more than 0.2 kg, measure again a third time.
- Record the median value as the final weight.

Blood Pressure Measurement Procedure (Pre-Shift)

Step 9. Prepare the Participant

Ask the participant to:

- Sit quietly for at least 5 minutes before measurement.
- Keep both feet flat on the floor.
- Keep legs uncrossed.
- Rest the back against the chair.
- Relax the arm on a flat surface at heart level
- Avoid talking during the measurement.

Select the appropriate cuff size according to the participant's arm circumference.

Step 10. Measure Blood Pressure

- Place the cuff on the participant's upper arm according to the manufacturer's instructions.
- Start the automated blood pressure monitor.
- Record:
    - Systolic Blood Pressure (SBP)
    - Diastolic Blood Pressure (DBP)

- Pulse Rate (if displayed)

Immediately record the measurements in HTS-Anthro-01.

Step 11. Repeat Blood Pressure Measurement

Wait 1-2 minutes.

Repeat the blood pressure measurement.

If:

- SBP differs by more than 10 mmHg, or
- DBP differs by more than 5 mmHg,

take a third measurement.

Record the median value as the final blood pressure.

BMI Verification

In HTS-Anthro-01, Body Mass Index (BMI) will be calculated automatically.

Before saving the record please verify that automatically calculated BMI is reasonable.

If the calculated BMI does not seem right, before submitting the form, please check the height and weight you entered.

Figure 10. Measurement of pre-shift blood pressure using a validated automated digital blood pressure monitor during a household visit before commencement of field procedures.

Figure 11. Standardized blood pressure assessment performed by a trained field research assistant using an automated digital blood pressure monitor, with data entered directly into the electronic data collection system (KoboToolbox).

Blood Pressure Measurement Procedure (Post-Shift)

Immediately after completion of the participant's work shift and before biological sample collection:

Repeat the following measurements:

- Body Weight (repeat Steps 5–8)
- Blood Pressure (repeat Steps 9–11)

Record all post-shift measurements in HTS-Anthro-01.

Height measurement is not repeated.

Critical Checks

- Before proceeding to the next study procedure, confirm that:
- Height has been measured twice.
- Pre-shift body weight has been measured twice.
- Pre-shift blood pressure has been measured twice.
- Post-shift body weight has been measured twice.
- Post-shift blood pressure has been measured twice.

- Additional measurements have been taken if required.
- Final values have been recorded correctly.
- BMI has been verified.
- Data have been saved successfully in KoboToolbox.

Quality Control

- Verify that the stadiometer is vertical before each measurement.
- Confirm the weighing scale reads 0.0 kg before every participant.
- Verify that the blood pressure monitor has passed routine calibration checks.
- Use the correct cuff size for every participant.
- Ensure participants rest quietly for at least 5 minutes before BP measurement.
- Clean equipment between participants using approved disinfectant wipes.
- Handle equipment carefully during transport to prevent damage or loss of calibration.
- Record routine equipment calibration and maintenance activities in the Equipment Maintenance Log (HTS-EML).
- The Field Supervisor should periodically observe anthropometric and blood pressure measurements to ensure adherence to study procedures.

Safety Considerations

- Assist participants who have difficulty standing steadily.
- Do not force participants into position if they experience pain or discomfort.
- Stop the procedure immediately if a participant feels dizzy or unwell and inform the Field Supervisor.
- If systolic blood pressure is ≥180 mmHg or diastolic blood pressure is ≥120 mmHg, repeat the measurement after 5 minutes and notify the Field Supervisor or Field Medical Officer immediately.

Documentation

- Complete the following records:
- HTS-Anthro-01 (KoboToolbox Anthropometry Form)
- Pre-shift blood pressure measurements
- Post-shift blood pressure measurements
- Pre-shift body weight measurements
- Post-shift body weight measurements

- Equipment Maintenance Log (HTS-EML), if calibration or equipment issues are identified

Before Leaving the Participant

Ensure that:

- Height has been measured and recorded.
- Pre-shift body weight has been measured and recorded.
- Pre-shift blood pressure has been measured and recorded.
- BMI has been verified.
- Anthropometric and blood pressure data have been recorded and saved.
- Equipment has been cleaned and stored safely.
- Participant is ready to proceed to SOP 5.3-Ingestible Core Temperature Capsule Administration.

Note: Post-shift body weight and blood pressure measurements will be completed immediately after the participant finishes the work shift and before biological sample collection.

SOP 5.3 Ingestible Core Temperature Capsule Administration

Figure 12. The e-Celsius receiver, activator and ingestible temperature capsule.

Figure 13. Ingestion of core body temperature capsule which is swallowed whole with clean drinking water.

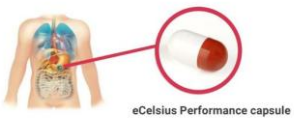


Figure 14. Gastrointestinal core temperature monitoring by ingestible capsule.

Purpose

To safely administer the ingestible core temperature capsule and to determine continuous core temperature monitoring over a participant's work shift

Personnel

- Field Research Assistant (trained in capsule administration; certificate on file)
- Field Medical Officer (on-call; must be reachable within 30 minutes)

Equipment Required

- e-Celsius Performance ingestible telemetry capsule
- e-Celsius Activator
- e-Celsius Performance receiver/monitor
- 200 mL clean drinking water
- KoboToolbox Capsule Administration Form (HTS-CoreTemp-01)
- Participant symptom checklist

Prior to capsule administration ensure that:

- The Participant has already completed SOP 5.1 -Pre-Shift Participant Screening and Informed Consent
- Eligibility for capsule usage
- Capsule batch no. & expiry date is verified.
- Receiver battery is fully charged.
- Receiver date and time are properly synchronized.
- The HTS-CoreTemp-01 is live and accessible to input data.

Capsule Activation Procedure

Step 1. Prepare the Capsule

- Take the capsule out of the packaging.
- Capsule Batch No and Expiry validation.
- Write the information to HTS-CoreTemp-01

Step 2. Activate the Capsule

- Insert the capsule into the cradle of e-Celsius Activator.
- Press the activation button for about 3 seconds.
- Make sure that the LED flashes green (activation successful)

Step 3. Verify Signal Transmission

- Turn on the receiver.
- Confirm that the receiver detects the capsule signal within 30 seconds.

- Record the baseline core temperature.

If the receiver does not detect the capsule on the first attempt, repeating this procedure of activation one additional time may yield success. If it continues, replace capsule and record fail unit in HTS-CoreTemp-01.

Capsule Administration Procedure

Step 4. Timing of Administration

Capsule to be given 40 minutes before the participant's scheduled work shift.

Step 5. Instruct the Participant

Administer 200 mL of clean drinking water to the subject.

Instruct the participant to:

- Swallow the capsule without breaking it.
- Do not chew, crush or cut the capsule.

Step 6. Confirm Successful Ingestion

- Observe the participant swallow the capsule.
- Instruct participant to open their mouth after swallowing to confirm they have swallowed.

Step 7. Verify Temperature Reading

Within 2 minutes of ingestion:

- Ensure the receiver shows an actual time temperature.
- Check that the baseline temperature is within the anticipated physiological range.

Step 8. Attach the Receiver

Attach the receiver to the subject using one of the following:

- Wrist strap, or
- Belt clip.

The receiver should be safe, convenient positioning without affecting usual work.

Step 9. Provide Participant Instructions

Instruct the participant to:

- Carry the receiver around with them during their working hours.
- Do not remove or interfere with the receiver.
- Do not eat or drink for 15 minutes after taking the capsule:

- Report any discomfort or symptoms immediately to the research team.

Recording Settings

- When the participant begins working, set the receiver recording interval to 1minute.
- Do not modify the recording frequency during the observational time.

Safety Monitoring

Track workers across the shift.

If core temperature reaches 38.5°C:

- Notify the Field Supervisor.
- Increase frequency of observations

If core temperature reaches 39.0°C:

- Remove the participant from work immediately.
- Take the participant to a shade.
- Offer them cool drinking water and ORS.
- Call the Field Medical Officer.

If the core temperature reaches 39.5°C or develops severe symptoms (e.g., dizziness, confusion, vomiting) in the participant:

- Manage as a medical emergency.
- Initiate emergency medical protocols.
- Always keep the participants in sight.

Critical Checks

Check that Before the participant starts working,

- Capsule started properly.
- Receiver detecting the capsule signal
- Collected Baseline Temperature
- Receiver is mounted firmly.
- The interval of recording is I min.
- This has been recorded with capsule administration on HTS-CoreTemp-01.

Quality Control

Check expiry date of the capsule prior to administering.

- Verify activation of the capsule before ingestion.
- Verify receiver battery level before use.
- Ensure receiver date and time is synchronized.
- Any unsuccessful activation attempts, breaks in the signal or failure of a part of the equipment are to be noted in HTS-CoreTemp-01.
- The Field Supervisor should periodically observe capsule administration procedures to ensure compliance with the study protocol.

Safety Considerations

Inform participants that:

- The capsule should transit the gastrointestinal track naturally within 24-48 hours.
- The capsule doesn't need to be recovered post-passage.
- Participants need to inform the research team immediately if severe discomfort or symptoms develop during monitoring.

Documentation

Complete the following records:

- HTS-CoreTemp-01 (Capsule Administration Form)
- Participant Symptom Checklist

Protocol Deviation Log (if needed)

Before Leaving the Participant

Ensure that:

- The capsule has been successful in being swallowed.
- Receiver is recording correctly.
- Baseline temperature has been validated.
- All study instructions and safety precautions are understood by Participant.
- All necessary documents have been filled out and saved
- Key Participant is ready to move on with SOP 5.4-Environmental Heat Exposure Monitoring.

SOP 5.4 Environmental Heat Exposure Monitoring

Figure 15. Portable agro-environmental station established in agricultural field.

Figure 16. Tripod-mounted portable environmental monitoring instruments.

Figure 17. Black Globe Thermometer used to measure radiant heat exposure.

Purpose

To assess environmental heat exposure during the working shift of the participant using standardized environmental monitoring devices.

Personnel

- Field Research Assistant, trained in environmental monitoring

Equipment Required

- Data logger for environmental measurement unit (EMU) portable weather station
- EMU storage case and components (electronics hub, black globe, aspiration chamber, anemometer, antenna)
- Tripod mount
- Additional power banks and charging cords
- Hotspot device
- PC for extracting data
- Data download cable
- KoboToolbox Environmental monitoring Form (HTS-Env-01)
- GPS-based field tablet (optional, depending on availability)

Make sure before deploying environmental monitoring instrumentation that:

- All equipment is working properly.

- Battery of EMU is charged properly.
- Network and time synchronized with field tab.
- Sensor calibration checks have been performed.
- HTS-Env-01 is open and available for input of data
- The monitoring place is recognised.

Monitoring Site Selection

Step 1. Select the Monitoring Location

Select a location that best reflects the thermal environment of the participant.

The monitoring site should:

- Be within 10 metres of the primary work area.
- Be exposed to the same environmental conditions as the participant.
- Be free from artificial heat sources.
- Avoid shaded areas that are not representative of the work environment.

Do not place equipment near buildings, vehicles, machinery, or other structures that may influence measurements.

Equipment Setup Procedure

Step 2. Install the Tripod

- Set the tripod on solid and flat ground.
- Make sure the tripod is stable and upright.

Step 3. Install the Weather Station

- Securely attached the EMU electronics hub to the tripod.
- Connect all components (black globe, aspiration chamber, anemometer and antenna) to the electronics hub;
- Ensure all components receive unimpeded sunlight and surrounding airflow.
- Mount the electronics hub at a height of about 1.1 m off the ground.

Step 4. Verify Equipment

Before beginning data collection:

- Confirm that all sensors are functioning.
- Set the EMU running for 10 minutes Check air temperature, relative humidity, wind speed and globe temperature readings

- Document first environmental observations in HTS-Env-01.

Step 5. Configure the Data Logger

Recording interval = 5 minutes

Confirm that:

- Date is correct.
- Time is correct.
- Have started the record successfully.

During the Observation Period

- Do not touch the equipment during the monitoring period.
- Carefully check the equipment over from time to time for stability and proper work.
- Swap power bank without stopping data recording when possible.

If equipment needs to be moved for safety or operational purposes:

- Note down the justification for moving.
- Write down the moving time.
- Save the new GPS location.
- Record the transition in HTS-Env-01.

Critical Checks

Verify the following before you leave the monitoring station:

- The weather station is accurately mounted.
- Globe thermometer is correctly situated.
- Combined Date and Time.
- First environmental measurements have been taken.
- HTS-Env-01 are completed

Quality Control

- Check all sensors prior to each observation day.
- Check regular calibration according to the manufacturing instructions.
- Ensure the tripod is not shaking during the observation time.
- To monitor for unintentional movement or blockage of equipment.

- Store record for equipment failure or interruptions to HTS-Env-01.
- The Field Supervisor should intermittently confirm that equipment is appropriately placed when visiting the field.

Safety Considerations

- Place equipment where it will not obstruct workers or work tasks.
- Make sure tripods are not a tripping hazard.
- Do not put equipment where it could be damaged by vehicles, machinery, or livestock.
- Provide specific details regarding the setup of equipment or procedures during thunderstorms/other hazardous weather events in which personnel must suspend on-going activities.

Documentation

Complete the following records:

- HTS-Env-01 (Environmental Monitoring Form)
- If there are calibration or equipment issues, an Equipment Maintenance Log (HTS-EML).
- Protocol deviation log (optional if applicable).

Before Leaving the Monitoring Site

Ensure that:

- All environmental sensors are functioning correctly.
- Data logging has started successfully.
- Monitoring equipment is securely installed.
- Initial environmental measurements have been recorded.
- All required documentation has been completed.
- Environmental monitoring is ready to continue throughout the participant's work shift.

SOP 5.5 Physical Activity and Metabolic Heat Production Monitoring

Figure 18. Waist-worn tri-axial accelerometer placement for activity monitoring.

Purpose

To continuously measure participants' physical activity throughout the work shift using a waist-worn tri-axial accelerometer for subsequent estimation of activity intensity, energy expenditure, and metabolic heat production.

Personnel

- Trained Field Research Assistant

Equipment Required

- Tri-axial waist-worn accelerometer (e.g., ActiGraph wGT3X-BT or equivalent) with adjustable waist belt
- ActiLife software (or equivalent)
- Adjustable wrist strap
- Antiseptic wipes
- KoboToolbox Device Initialization Form (HTS-Activity-01)
- Data download cable
- Field tablet or laptop

Before deploying the accelerometer, ensure that:

- Device battery is at least 80% charged.

- Device date and time are synchronized with the field tablet.
- Recording epoch has been set to 30 seconds.
- Participant ID has been assigned correctly.
- HTS-Activity-01 is open and ready for data entry.
- Initialized device for correct participant.

Device Initialization Procedure

Step 1. Initialize the Device

Using ActiLife software (or equivalent):

- Fill in the Particpant ID
- Check the date of observation.
- Syncs the device clock
- Change the recording epoch to 30 seconds.
- Persist the initialization configurations.

Step 2. Verify Device Function

Before deployment:

- Confirm the device is recording.
- Check battery status.
- Record the device serial number in HTS-Activity-01.

Device Placement Procedure

Step 3. Prepare the Participant

- Explain the purpose of the accelerometer.
- Ask the participant to expose the waist area where the device will be worn.
- Ensure the waistband or belt area is clean and dry before attaching the device.

Step 4. Attach the Accelerometer

Secure the accelerometer:

- On an adjustable waist belt positioned over the participant's right hip (or according to the manufacturer's recommendation)
- Ensure the device is positioned firmly against the body.

- Ensure the device is upright and securely fastened.

Confirm that the belt is snug but comfortable and does not restrict movement or breathing.

Step 5. Check Device Fit

Confirm that:

- The device is secure.
- The participant is able to move comfortably.
- Device is functional and does not disrupt regular work process.

Record the following in HTS-Activity-01:

- Device serial number
- Waist placement (right hip/left hip, if applicable)
- Placement time
- Participant ID

Step 6. Provide Participant Instructions

Advise the participant to:

- Wear the accelerometer on the waist throughout the entire work shift.
- Never remove or try to manipulate the device.
- Notify the research team at once if the device is loose or uncomfortable.

During the Observation Period

- Periodically verify that the accelerometer remains securely attached to the participant's waist.
- Document the removal, adjustment, or malfunction in HTS-Activity-01.
- Do not swap or move the device unless absolutely needed.

Data Download Procedure

By the end of observation day:

- Take off the accelerometer.
- Download the data collected with ActiLife software (or equivalent)
- Check that the record is full.
- Raw Data Save as study file naming convention: [SiteID][ParticipantID][YYYYMMDD]
- Download the data and upload it instantly to the secure study server.

Critical Checks

Before concluding observation, ensure that:

- Device was properly initialized.
- The recording was started correctly.
- The device remained properly worn throughout the work shift.
- Data successfully downloaded
- Backups of raw data.
- Backups of raw data.
- HTS-Activity-01 - Completed

Quality Control

- Verify device synchronization before each deployment.
- Inspect wrist straps for wear or damage before use.
- Recharge devices after each observation day.
- Check downloaded data for missing recording periods.
- Document any equipment malfunction or participant non-compliance in HTS-Activity-01.
- The Field Supervisor should periodically observe device placement procedures to ensure consistency.

Safety Considerations

- The waist belt must be fastened tight, but be careful that the thigh does not restrict normal movement and breathing.
- If participant shows signs of skin burning or discomfort, immediately take off the device.
- After each use of the device, it will be cleaned and disinfected following study procedures.

Documentation

Complete the following records:

- HTS-Activity-01 (Device Initialization Form)
- Equipment Maintenance Log (HTS-EML), if equipment issues are identified
- Protocol Deviation Log (if applicable)

Before Leaving the Participant

Ensure that:

- The accelerometer is safely mounted on the waist.
- The device is recording correctly.
- Participant understands the study instructions.
- All the paperwork is done.
- Participants are prepared to resume the shift while wearing the accelerometer.

SOP 5.6 Biological Sample Collection

Figure 19. Venous blood sample collection using EDTA and serum vacuum tubes.

Figure 20. A urine collection container with sterile covering for sample collection.

Figure 21. Ice gear to transport and keep the biological sample cold chain.

Purpose

Collecting, processing, labeling, storing and transporting blood and urine specimens at pre-specified study time points for the assessment of hydration status, renal injury biomarkers, kidney function and physiological responses to occupational heat exposure.

Personnel

- Phlebotomist or Nurse trained in blood sampling
- Trainee Field Research Assistant (collecting urine samples)

Equipment Required

Blood Collection

21-gauge butterfly needle

5 mL of EDTA vacuum blood collection tube

5 mL Plain (serum) tube used for vacuum collection

Tourniquet

Antiseptic swabs

- Sterile gauze
- Adhesive bandage
- Disposable gloves
- Container for disposing of sharps

Urine Collection

60 ml sterile cup for urine sample collection

Sample labels with pre-labelled

Portable Urine Refractometer

Pipette (single-use, if necessary)

Sample Storage and Documentation

- A cooler box containing ice packs (2-8°C).
- KoboToolbox Blood Sample Form (HTS-BioSample-01)
- KoboToolbox Urine Sample Form (HTS-BioSample-02)
- Sample Transport Manifest

Ensuring the following before collecting a biological sample:

- Has participant finished work shift.
- Identity of the participants have been verified.
- Labels for samples have been created.
- 2-8°C Temperature of cooler box
- Available all collection material.
- Wearing the proper protective gear.
- There are two bookmarks that have been opened for data entry HTS-BioSample-01 and HTS-BioSample-02.

Sample Collection Schedule

Time Point	**Blood Samples**	**Urine Samples**
Pre-shift	HbA1c, Creatinine, Cystatin-C, Osmolarity	USG, Albumin, Creatinine, IGFBP7, TIMP-2, NGAL
Post-shift	Creatinine, Cystatin-C, Osmolarity	USG, Creatinine, IGFBP7, TIMP-2, NGAL

Next morning	Creatinine, Cystatin-C, Osmolarity	Creatinine, IGFBP7, NGAL

Blood Sample Collection Procedure

Step 1. Prepare the Participant

Ask the participant to:

- Sit comfortably.
- Rest quietly for approximately 5 minutes before blood collection.
- Rest for 5 mins before the blood draw.
- Describes the procedure and addresses questions.

Step 2. Prepare the Collection Site

- Perform hand hygiene.
- Use disposable gloves.
- Apply the tourniquet.
- Choose the right antecubital vein.
- Disinfect the puncture site with a swab of antiseptic.
- Air dry the skin completely.

Step 3. Collect Blood Samples

Using standard venepuncture procedures:

- Take 5 mL in the EDTA tube.
- Collect 5 mL into the plain (serum) tube.
- Release the tourniquet before withdrawing the needle.
- Apply sterile gauze with gentle pressure.
- Secure the site with an adhesive bandage.
- Dispose of the needle immediately in the sharp's container.

Blood Analyses

Pre-shift blood specimens will be analysed for:

- HbA1c
- Creatinine

- Cystatin-C
- Serum Osmolarity

Post-shift blood specimens will be analysed for:

- Creatinine
- Cystatin-C
- Serum Osmolarity

Next-morning blood specimens will be analysed for:

- Creatinine
- Cystatin-C
- Serum Osmolarity

Step 4. Label and Store Samples

Immediately label each tube with:

- Participant ID
- Date
- Time of collection
- Sample type

Gently invert the EDTA tube several times to mix the anticoagulant.

Place both tubes immediately into the cooler box.

Sample	Collection Time	Primary Analyses
EDTA Blood	Pre-shift	HbA1c, Creatinine, Cystatin-C, Osmolarity
EDTA Blood	Post-shift	Creatinine, Cystatin-C, Osmolarity
EDTA Blood	Next morning	Creatinine, Cystatin-C, Osmolarity
Urine	Pre-shift	USG, Albumin, Creatinine, IGFBP7, TIMP-2, NGAL
Urine	Post-shift	USG, Creatinine, IGFBP7, TIMP-2, NGAL
Urine	Next morning	Creatinine, IGFBP7, NGAL

Urine Sample Collection Procedure

Step 5. Prepare the Participant

Provide the participant with a pre-labelled sterile urine collection cup.

Explain how to collect a midstream clean-catch urine sample.

Step 6. Collect the Sample

Ask the participant to:

- Collect the urine sample in privacy.
- Secure the lid tightly after collection.
- Return the sample immediately to the research team.

Step 7. Measure Urine Specific Gravity

Immediately after collection:

- Measure urine specific gravity using the portable refractometer.
- Record the result in HTS-BioSample-02.

Step 8. Store the Sample

Transfer the required sample volume into the labelled collection container if required by laboratory procedures.

Place the sample immediately into the cooler box maintained at 2-8°C.

Urine Analyses

Pre-shift urine specimens will be analysed for:

- Urine Specific Gravity (USG)
- Albumin
- Creatinine
- IGFBP7
- TIMP-2
- NGAL

Post-shift urine specimens will be analysed for:

- Urine Specific Gravity (USG)
- Creatinine
- IGFBP7
- TIMP-2
- NGAL

Next-morning urine specimens will be analysed for:

- Creatinine
- IGFBP7
- NGAL

Step 9. Next-Morning Urine Sample

Provide the participant with:

- A pre-labelled sterile collection container.
- Instructions for collecting the first-morning urine sample.

Instruct the participant to:

- Collect the first urine after waking.
- Keep the sample in a cool place until collection.
- Return the sample to the research team as instructed.

Sample Transport

Transport all biological samples to the laboratory according to study procedures.

Maintain the cold chain throughout transport.

Complete the Sample Transport Manifest before dispatch.

Critical Checks

Before transporting samples, confirm that:

- All samples have been labelled correctly.
- Collection time has been recorded.
- Samples are stored at 2-8°C.
- Sample transport documentation has been completed.
- All KoboToolbox forms have been completed and saved.

Quality Control

- Verify participant identity before sample collection.
- Use sterile, single-use collection equipment.
- Inspect all sample tubes for damage or leakage.
- Monitor cooler box temperature throughout the field day.
- Record any collection difficulties or protocol deviations.
- The Field Supervisor should periodically observe sample collection procedures to ensure protocol compliance.

Safety Considerations

- Follow standard infection prevention and control procedures.

- Wear appropriate PPE during sample collection.
- Dispose of sharps immediately after use.
- Never recap used needles.
- Clean any biological spills according to study biosafety procedures.
- Seek medical assistance immediately in the event of a needlestick injury or accidental exposure.

Documentation

Complete the following records:

- HTS-BioSample-01 (Blood Sample Collection Form)
- HTS-BioSample-02 (Urine Sample Collection Form)
- Sample Transport Manifest
- Protocol Deviation Log (if applicable)
- Sample collection time point (Pre-shift/Post-shift/Next morning)
- Laboratory biomarker request form
- Chain-of-custody documentation

Before Leaving the Participant

Ensure that:

- Blood and urine samples have been collected successfully.
- Samples are labelled correctly.
- Samples have been placed in the cooler box.
- Participant has received instructions for the next-morning urine sample (if applicable).
- All required documentation has been completed.
- Samples are ready for transport to the laboratory.

SOP 5.6A Blood Sample Processing, Aliquoting, Storage, and Transportation

Purpose

To standardize the receipt, processing, centrifugation, aliquoting, short- and long-term storage, cold-chain transportation, documentation, and quality control of blood specimens collected at pre-shift, post-shift, and next-morning time points.

Scope

This SOP is applicable to all blood specimens collected from enrolled participants in the Study. The process starts immediately after collecting venous blood and extends up to the point when specimens enter the designated laboratory, are stored in the appropriate location, and entered into inventory within the lab.

Responsibilities

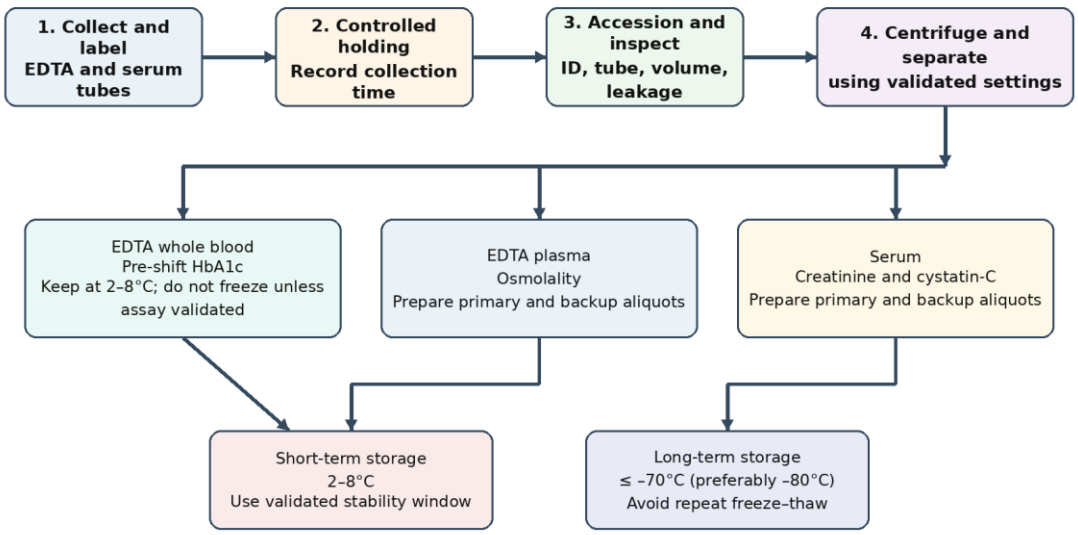
1. Phlebotomist: draw blood according to SOP 5.6; confirm participant identity, tube type, time point and labels
2. Laboratory technologist: receive, inspect, centrifuge, separate, aliquot, store, and document specimens.
3. Field Supervisor: ensure field cold chain is maintained, check transport manifest and dispatch on time.
4. Courier/Authorized Transporter: ensures that packages remain intact and specimens are submitted without improper access.
5. Laboratory Supervisor: review and approval of temperature excursions, specimen deviations, acceptance or rejection decisions.

Specimen plan

Time point	Collection tube / matrix	Planned analysis	Recommended aliquots	Routine storage
Pre-shift	EDTA whole blood	HbA1c	Retain 0.5–1.0 mL in the original EDTA tube or a validated secondary tube	2–8°C; do not freeze unless permitted by the assay IFU
Pre-shift	EDTA plasma	Osmolality	Two aliquots, target 0.5 mL each: primary + backup	2–8°C for short-term testing; ≤–70°C for longer storage
Pre-shift	Serum	Creatinine and cystatin-C	Two aliquots, target 0.5 mL	2–8°C for short-term testing; ≤–70°C

Time point	Collection tube / matrix	Planned analysis	Recommended aliquots	Routine storage
			each: primary + backup	for longer storage
Post-shift	EDTA plasma	Osmolality	Two aliquots, target 0.5 mL each	2–8°C for short-term testing; ≤–70°C for longer storage
Post-shift	Serum	Creatinine and cystatin-C	Two aliquots, target 0.5 mL each	2–8°C for short-term testing; ≤–70°C for longer storage
Next morning	EDTA plasma	Osmolality	Two aliquots, target 0.5 mL each	2–8°C for short-term testing; ≤–70°C for longer storage
Next morning	Serum	Creatinine and cystatin-C	Two aliquots, target 0.5 mL each	2–8°C for short-term testing; ≤–70°C for longer storage

Blood Sample Processing and Aliquoting Workflow



Equipment and materials

1. Use of personal protective equipment (PPE), including disposable gloves, lab coat/gown, eye protection and any other locally required PPE.
2. The rack with tubes, contaminations bag, absorption material and a sharps container
3. A bench centrifuge capable of providing a report based on the relative centrifugal force (×g) with an established maintenance and calibration schedule.
4. Calibrated pipetes, and sterile disposable tips resistant to aerosols.
5. Low-binding screw-cap polypropylene cryovials (0.5–2.0 mL) with O-ring seals.
6. Cryogenic labels or a resoluble permanent marker, targeted specifically to solvents.
7. Storage conditions: Fridge 2–8°C, Monitor freezer −70°C (preferably −80°C)
8. Kit consists of a validated transport cooler for conditioned ice packs, secondary leakproof container, rigid outer container and/or calibrated temperature logger.
9. Blood Sample Processing Log, Aliquot Inventory Log, Freezer Log, Sample Transport Manifest, Chain-of-Custody Form, and Protocol Deviation Log.

Procedure

1. Immediate actions after collection

1. Check that each tube is adequately labelled with Participant ID, study site, date, exact time of collection and time point (PRE, POST or NM). Specimen labels must not include participant names.
2. Immediately after collection, gently invert EDTA tubes 8â€“10 times. Do not shake.
3. Serum tubes should be kept upright and left at room temperature away from direct sunlight for 30 minutes to allow the blood to clot. Clotting should not exceed 60 minutes unless specified by the tube manufacturer.
4. Document all difficult draw, extended tourniquet use, visible clot in the EDTA tube, under-filling of the tube and leakage or suspicion of haemolysis.

2. Temporary field holding and transfer to the processing site

1. Place EDTA tubes upright in rack within temperature-controlled secondary container at 2–8C.
2. For serum clotting, maintain the serum tube upright at controlled room temperature and protected from light. If you were unable to centrifuge it, place your sample at 2–8°C for up up to 24 h after performing the clot.
3. Do not put tubes in direct contact with frozen ice packs. Place a divider to avoid unintentional freezing and haemolysis.
4. Bring specimens to the processing site as soon as possible; preferably within 2 hours of collection. Log the collection, dispatch, receipt, and processing times.

3. Laboratory receipt and accessioning

1. Confirm that the transport seal, temperature logger and transport manifest, as well as Participant ID, time point, tube type, collection time and number of tubes
2. Check tubes for leakage, breakage, clotting in EDTA blood, gross haemolysis, insufficient volume and label mismatch.

3. Document specimen receipt time and the condition of the specimens in the Blood Sample Processing Log.
4. Put specimens with any inconsistencies in a designated quarantine rack for the lab supervisor review.

4. Centrifugation

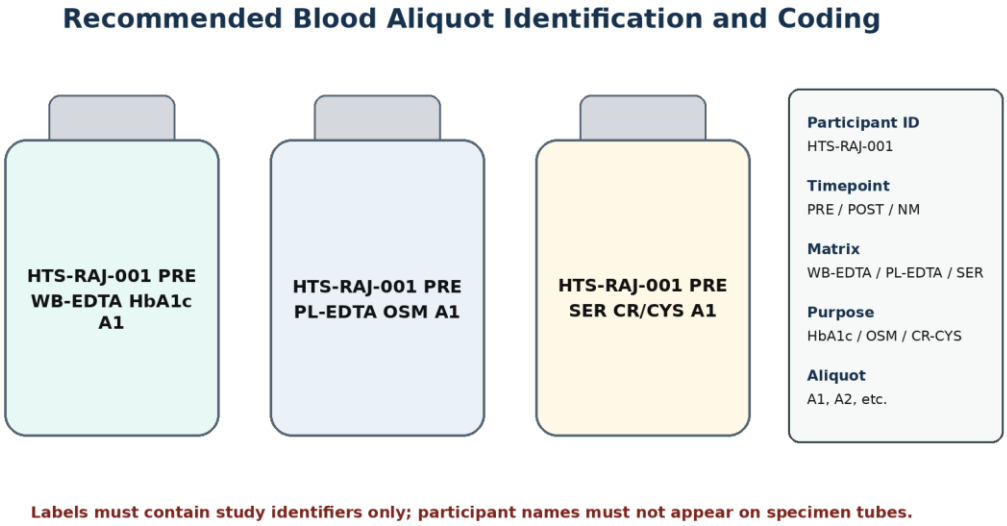
1. Centrifuge tubes balance by weight and buckets or adapters should be compatible.
2. Centrifuge EDTA tubes for plasma and clotted serum tubes at 1,500–2,000 × g for 10 minutes in room temperature or according to manufacturer instructions and laboratory-validated standard operating procedures.
3. Apply a low brake setting when possible for minimizing remixing of cells with plasma or serum.
4. Log centrifuge ID, relative centrifugal force, time duration, start time of spinning, end time of spinning and initials of individual performing the spin.
5. The EDTA whole-blood portion for HbA1c should not be centrifuged.

5. Plasma and serum separation

1. Aliquot in an appropriately designated clean, specimen-processing area and use normal biosafety precautions.
2. Aspirate plasma or serum using a calibrated pipette without disturbing the cellular layer, buffy coat, or clot.
3. Do not transfer specimens from one container to another
4. Stop transfer and record the affected aliquot if there is visual red-cell contamination.

6. Aliquot preparation

1. Use pre-labelled screw-cap cryovials. Verify each label against the corresponding source tube, prior to transferring specimen
2. Where volume allows, make primary/backup aliquots for separate use. Target volume is 0.5 mL per aliquot; record the actual if less
3. Never pool specimens from different participants or from different time points.
4. Make sure the cryovials have some head space to allow for freezing expansion. Tighten caps all the way down, and check for leaks.
5. Enter the aliquot code, matrix, purpose optimize volume of the liquid, preparation time and storage location in an Aliquot Inventory Log.



7. Aliquot coding convention

Use the following format:

HTS-[SITE]-[PARTICIPANT]-[TIMEPOINT]-[MATRIX]-[PURPOSE]-[ALIQUOT]

Example: HTS-Jamal-001-PRE-PL-OSM-A1. Recommended abbreviations: PRE = pre-shift; POST = post-shift; NM = next morning; WB = whole blood; PL = plasma; SER = serum; OSM = osmolality; CR/CYS = creatinine and cystatin-C.

8. Short-term storage

1. Store fresh whole blood, plasma, and serum at 2–8°C when analysis will occur within the laboratory-validated stability period.
2. Analyse HbA1c from EDTA whole blood as soon as practicable and within the assay manufacturer's validated stability window. Do not freeze whole blood unless the selected assay explicitly permits frozen storage.
3. Maintain continuous or minimum/maximum temperature monitoring and record refrigerator temperature at least twice daily.

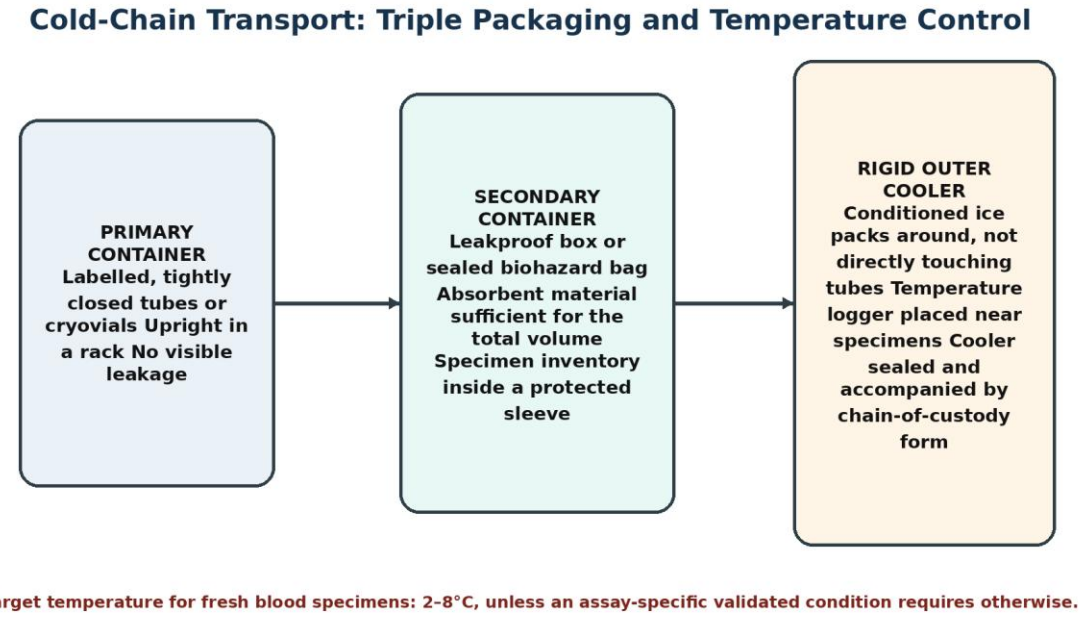
9. Long-term storage

1. When plasma or serum will not be analysed within the validated refrigerated stability period, freeze aliquots at or below –70°C, preferably –80°C.
2. Use multiple aliquots to avoid repeated freeze–thaw cycles. Thaw only the aliquot required for a specific analysis.
3. Store aliquots in labelled boxes and mapped freezer positions. Record freezer, rack, box, row, and position.
4. Freezers must have temperature monitoring, alarm or excursion notification, documented maintenance, and a contingency plan for power failure.

10. Cold-chain packaging and transportation

1. Keep the tightly closed primary tubes or cryovial upright in a rack (or holder).

2. Put the rack in a leakproof secondary container with sufficient absorbent material to contain the complete specimen volume if leakage occurs.
3. Put your secondary container inside a more rigid outer cooler. Distribute pre-conditioned ice packs around the inside of outer container, separated from specimen tubes.
4. Calibrate a temperature logger close to the specimens. Separate plastic sleeve to store transport manifest and chain-of-custody form.
5. Unless different validated transport conditions are established by the assay, maintain fresh specimens at 2–8°C during transport.
6. If using aliquots that have been frozen, a validated Frozen transport system should be used for transporting to maintain the appropriate frozen temperature. Only trained personnel can handle or package dry ice, and it should never be placed in airtight containers.
7. Close the outer container, and keep dispatch time, name of the courier with vehicle or route details along with anticipated arrival time.



11. Receipt at the testing or central laboratory

1. Log arrival time before opening the container box.
2. Check the temperature logger and record minimum, maximum and arrival temperatures
3. Cross-check the transport manifest against the number of tubes/aliquots
4. Check for freeze thaw, leaks, broken tubes, lost labels or unblinded identifiers.
5. Move accepted specimens straight to their appropriate refrigerator or freezer location.
6. Quarantine specimens subjected to a temperature excursion or documentation error. Only dispose of them when this laboratory supervisor has done a documented assessment.

Specimen acceptance and rejection criteria

Accept / process	Quarantine for supervisor review
Correct Participant ID, time point, matrix, and collection time	Unlabelled specimen or label mismatch
Tube intact and adequately filled	Leakage, broken tube, or insufficient volume
Cold-chain and processing times documented	Temperature or processing-time excursion
EDTA tube mixed and free of clot	Clotted EDTA blood
Serum/plasma adequately separated	Gross haemolysis or cellular contamination
Transport manifest complete	Missing chain-of-custody or unknown freeze–thaw history

Temperature excursion and deviation management

1. Do not automatically discard specimens after a temperature or time deviation.
2. Separate and clearly mark affected specimens as QUARANTINED.
3. Record the duration, minimum and maximum temperature, specimen type, affected aliquots, and likely cause.
4. The laboratory supervisor and Principal Investigator will determine fitness for analysis using assay-specific stability data.
5. Document the decision and any limitations in the Protocol Deviation Log and analytical dataset.

Quality control

1. Use calibrated pipettes, centrifuges, refrigerators, freezers, and temperature loggers.
2. Verify a sample of aliquot labels and freezer locations by a second trained staff member.
3. Review daily processing and transport logs before samples are released for analysis.
4. Monitor haemolysis, insufficient-volume rates, temperature excursions, and delayed processing as laboratory quality indicators.
5. Conduct periodic direct observation of processing and packaging procedures by the laboratory supervisor.

Safety considerations

1. Treat all human blood as potentially infectious and follow standard biosafety and infection-prevention procedures.
2. Wear appropriate PPE and perform hand hygiene before and after handling specimens.
3. Never recap used needles; dispose of sharps immediately in an approved sharps container.

4. Use a biological safety cabinet for procedures with a credible splash or aerosol risk, according to institutional biosafety requirements.
5. Manage spills and occupational exposures according to the institutional exposure-management SOP.

Required documentation

1. HTS-BioSample-01 Blood Sample Collection Form
2. Blood Sample Processing Log
3. Aliquot Inventory and Freezer Location Log
4. Centrifuge Log
5. Refrigerator/Freezer Temperature Log
6. Sample Transport Manifest
7. Chain-of-Custody Form
8. Temperature Excursion and Protocol Deviation Log

Critical checks before completion

1. Match participant ID and time point for: source tubes, aliquots, forms and transport manifest
2. Assignments of whole blood, plasma and serum to the appropriate planned analyses.
3. The centrifugation settings and processing times were recorded.
4. Aliquot volumes, numbers, and freezer locations are documented.
5. The chain of custody and cold-chain temperature are intact.
6. Any deviations are quarantined and directed for the attention of the laboratory supervisor.

SOP 5.7 Fluid Intake Monitoring

Figure 22. Graduated water bottle for monitoring work-shift fluid intake.

Figure 23. Illustration of checking and recording water-bottle volume markings.

Figure 24. Example of a marked hydration bottle for tracking drinking time and volume.

Purpose

To monitor and record participants' fluid intake throughout the work shift to support the assessment of hydration status and heat strain.

Personnel

- Trained Field Research Assistant

Equipment Required

- Graduated water bottle (1.5 L)
- Additional graduated measuring container (if required)
- KoboToolbox Fluid Intake Form (HTS-Fluid-01)
- Permanent marker or participant ID label

Before monitoring fluid intake, ensure that:

- A 1.5 L graduated water bottle labelled for participant
- Water volume measured directly.
- HTS-Fluid-01 is open for registration.
- Participant comprehends the process of monitoring fluid.

Fluid Intake Monitoring Procedure

Step 1. Prepare the Water Bottle

- Give the participant a labelled graduated container containing water.
- Pour the exact amount of water into the bottle.
- Observe the initial volume on HTS-Fluid-01

Step 2. Explain the Procedure

Inform the participant to:

Drink normally during work while shift.

Utilize the water bottle as much as possible.

Advise the research team if they take fluid from any other sources.

Step 3. Monitor Fluid Intake

For each of the structured observation rounds that lasted 30 minutes:

- Monitor how much water has remained in the bottle.
- Measure the rest of the volume to 50 mL.

- Find the volume used since you last observed

Step 4. Record Additional Fluid Intake

If participant consumes fluids from a different source, documented:

- Type of beverage
- An estimate of the volume consumed
- Time of consumption
- Enter all information in HTS-Fluid-01.

Step 5. End-of-Shift Assessment

At the end of the work shift:

Measure the water volume remaining in your bottle.

Amount of fluid consumed in the observation period.

Check completeness before saving the form.

Critical Checks

Prior to completing the Take Home Fluid Intake Monitoring

- Recording of the initial water volume.
- All observations rounds included the measurement of fluid volume.
- Other drinks have been reported.
- Final volume of water has been documented.
- Total fluid consumption has been calculated.
- HTS-Fluid-01 has been completed and stored.

Quality Control

- Always use graduated bottles with a clearly visible scale.
- Measure water volume at eye level as this will improve measurement accuracy.
- Encourage him to drink from the bottle as much as possible.
- Double check all recorded volumetrics before final submission and saving of the form.
- Use HTS-Fluid-01, to record any missed observations or abnormal drinking behaviours.
- The Field Supervisor is required to review fluid intake records from time to time to ensure their completeness and consistency

Safety Considerations

The availability of potable water by the time participants arrive at work and throughout the duration of their shift,

Do not limit or promote excessive hydration beyond regular drinking habits.

Report any participant exhibiting signs or symptoms of dehydration or heat-related illness to a study physician immediately (see SOP 5.3 - Ingestible Core temperature Capsule Administration).

Documentation

Complete the following records:

- HTS-Fluid-01 (Fluid Intake Monitoring Form)
- Log of Protocol Deviations (As applicable)

Before Leaving the Participant

Ensure that:

- Initial and final water volumes have been recorded.
- Fluid intake has been documented for each observation round.
- Additional beverages have been recorded.
- Total fluid intake has been calculated.
- All required documentation has been completed.
- Participant is ready to proceed with the remaining study procedures.

SOP 5.8 Structured Observation During the Work Shift

Figure 25. Structured observation of agricultural work activities in the field.

Figure 26. Field data recording using a tablet-based data collection system.

Purpose

To systematically observe and document participants' work activities, physiological status, symptoms, and fluid intake throughout the work shift using standardized observation procedures.

Personnel

- Trained Field Research Assistant

Equipment Required

- KoboToolbox Structured Observation Form (HTS-Observation-01)
- e-Celsius Performance receiver
- Borg CR-10 Rating of Perceived Exertion (RPE) Scale
- Field tablet
- Digital watch or synchronized timer
- Participant symptom checklist

Before starting structured observations, ensure that:

- Participant has completed all pre-shift study procedures.
- Core temperature receiver is functioning properly.
- HTS-Observation-01 is open and ready for data entry.
- Observation schedule has been synchronized with the study timeline.
- Borg CR-10 Scale is available for participant assessment.

Structured Observation Procedure

Step 1. Begin Observations

Start structured observations immediately after the participant begins the work shift.

Conduct observations at 30-minute intervals throughout the observation period.

Step 2. Record Observation Time

At each observation round:

- Record the exact observation time.
- Confirm the participant's identity.

Step 3. Record Work Activity

Observe the participant's primary work activity.

Record the activity using the standardized task classification (Appendix B).

Examples include:

- Planting
- Harvesting

- Carrying materials
- Irrigation
- Digging
- Weeding
- Resting
- Other (specify)

Step 4. Record Core Temperature

Read the participant's current core temperature from the receiver.

Record the value immediately in HTS-Observation-01.

Step 5. Record Fluid Intake

Determine the participant's fluid intake since the previous observation.

Record:

- Volume consumed from the study water bottle.
- Any additional beverages consumed.

Step 6. Assess Participant Symptoms

Ask the participant the following questions:

- "Do you feel dizzy or lightheaded?"
- "Do you have a headache?"
- "Do you feel nauseated?"
- "How would you rate your fatigue on a scale from 0 to 10?"

Record all responses in HTS-Observation-01.

Step 7. Assess Perceived Exertion

Show the participant the Borg CR-10 Scale.

Ask:

"How hard does your work feel right now?"

Record the participant's reported Rating of Perceived Exertion (RPE).

Step 8. Respond to Safety Concerns

If the participant:

- Reports symptoms of heat-related illness, or

- Has a core temperature ≥38.5°C

Immediately follow the procedures described in SOP 5.3 - Ingestible Core Temperature Capsule Administration.

Record all actions taken.

Critical Checks

During each observation round, confirm that:

- Observation time has been recorded.
- Current work activity has been documented.
- Core temperature has been recorded.
- Fluid intake has been updated.
- Symptom assessment has been completed.
- Borg CR-10 score has been recorded.
- Any abnormal findings have been reported.

Quality Control

- Conduct observations as close as possible to the scheduled 30-minute intervals.
- Minimize disruption to the participant's normal work activities.
- Record observations immediately to reduce recall errors.
- Review completed observation forms periodically for completeness.
- Report any missed observation rounds or protocol deviations.
- The Field Supervisor should periodically accompany Field Research Assistants to verify consistency of observations.

Safety Considerations

- Prioritize participant safety over data collection.
- Do not interrupt work unless required for participant safety.
- Immediately report signs or symptoms of heat-related illness to the Field Supervisor.
- Initiate emergency procedures if required according to SOP 5.3.

Documentation

Complete the following records:

- HTS-Observation-01 (Structured Observation Form)

- Participant Symptom Checklist
- Protocol Deviation Log (if applicable)

Before Leaving the Observation Round

Ensure that:

- All scheduled observations have been completed.
- Core temperature and symptom assessments have been recorded.
- Fluid intake has been updated.
- Any safety concerns have been managed appropriately.
- All required documentation has been completed.
- Participant continues safely with the observation period.

SOP 5.9 End-of-Shift Procedures and Equipment Retrieval

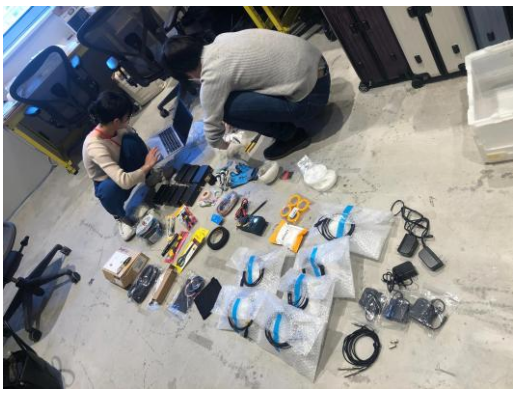


Figure 27. Study equipment organization before retrieval, cleaning, and storage.

Figure 28. Protective equipment transport case for safe storage and field retrieval of study devices.

Purpose

To ensure the safe retrieval of study equipment, completion of end-of-shift assessments, verification of data quality, and preparation of all collected data and biological samples for transport and storage.

Personnel

- Trained Field Research Assistant
- Trained Phlebotomist or Nurse (for biological sample collection, if applicable)

Equipment Required

- e-Celsius Performance receiver
- Tri-axial accelerometer
- Portable weather station and accessories
- Field tablet or laptop
- Data download cable
- Alcohol wipes or disinfectant wipes
- KoboToolbox End-of-Day Checklist (HTS-EOD-01)
- Cooler box containing biological samples (if applicable)

Before initiating end-of-shift procedures, ensure that:

- The participant has completed the work shift.
- All scheduled observation rounds have been completed.
- Biological sample collection materials are available (if applicable).
- HTS-EOD-01 is open and ready for data entry.

End-of-Shift Procedure

Step 1. Record Shift Completion

Record:

- Exact shift end time.
- Time the participant stopped their primary work activity.

Step 2. Complete the Final Observation

Conduct the final structured observation according to SOP 5.8 - Structured Observation During the Work Shift.

Confirm that all required observations have been completed.

Step 3. Retrieve the Core Temperature Receiver

- Remove the receiver from the participant.
- Inspect the device for any visible damage.
- Download the recorded data.
- Verify that the recording is complete and contains no significant gaps.

Record any missing data or equipment issues in HTS-CoreTemp-01.

Step 4. Retrieve the Accelerometer

- Remove the accelerometer from the participant.
- Inspect the device for damage.
- Download the activity data.
- Verify successful data download.

Record any equipment issues in HTS-Activity-01.

Step 5. Collect Biological Samples

Collect post-shift blood and urine samples according to SOP 5.6. Confirm that all specimens are labelled with Participant ID, collection time (Post-shift), date, and sample type. Place specimens immediately into the cooler box (2-8°C) and complete all laboratory documentation.

Step 6. Retrieve Environmental Monitoring Data

- Stop the environmental data logger.
- Download environmental monitoring data.
- Verify successful data transfer.
- Turn off and safely pack the monitoring equipment.

Step 7. Clean and Store Equipment

Clean all reusable equipment using approved disinfectant wipes.

Inspect equipment for damage or malfunction before packing.

Return all equipment to the designated transport case.

Step 8. Review Data Completeness

Review all study forms before leaving the field site.

Confirm that:

- Required fields have been completed.
- Participant identification is consistent across all forms.

- Data have been saved successfully.

Complete the HTS-EOD-01 End-of-Day Checklist.

Critical Checks

Before leaving the field site, confirm that:

- All study equipment has been retrieved.
- Core temperature data have been downloaded.
- Accelerometer data have been downloaded.
- Environmental monitoring data have been downloaded.
- Biological samples have been collected and stored appropriately.
- All study forms have been reviewed for completeness.
- HTS-EOD-01 has been completed.

Quality Control

- Verify successful download of all electronic data before deleting any device records.
- Inspect all equipment after each observation day.
- Recharge electronic devices before the next field deployment.
- Report any equipment malfunction or missing data to the Field Supervisor.
- Document protocol deviations and corrective actions.
- The Field Supervisor should review the End-of-Day Checklist before the field team departs.

Safety Considerations

- Handle all electronic equipment carefully during retrieval and transport.
- Follow biosafety procedures when handling biological samples.
- Maintain the cold chain during transport of biological specimens.
- Report any damaged equipment or accidental exposure incidents immediately.

Documentation

Complete the following records:

- HTS-EOD-01 (End-of-Day Checklist)
- HTS-CoreTemp-01 (if applicable)
- HTS-Activity-01 (if applicable)

- HTS-BioSample-01 and HTS-BioSample-02 (if applicable)
- HTS-Env-01
- Protocol Deviation Log (if applicable)

Before Leaving the Field Site

Ensure that:

- All study procedures have been completed.
- All equipment has been cleaned and packed.
- Electronic data have been downloaded and verified.
- Biological samples are ready for laboratory transport.
- All KoboToolbox forms have been completed and synchronized.
- The End-of-Day Checklist has been reviewed and signed.
- The participant has been thanked for their participation and reminded about the next-morning urine sample collection, if applicable.

SOP 6.0 Temperature Monitoring Completion and Equipment Retrieval

Figure 29. Field equipment case used for safe storage and transport of monitoring devices.

Purpose

To safely conclude participant monitoring by retrieving all study equipment, confirming data completeness, providing post-monitoring instructions, and preparing equipment for subsequent use.

Personnel

- Trained Field Research Assistant
- Field Supervisor (as required)

Equipment Required

- e-Celsius Performance receiver
- Tri-axial accelerometer
- Field tablet or laptop
- Data download cable
- Alcohol wipes or approved disinfectant wipes
- Equipment Maintenance Log (HTS-EML)
- KoboToolbox End-of-Day Checklist (HTS-EOD-01)
- Hygrochron iButton (DS1923) temperature and humidity data logger (retrieval on the final monitoring day)

Before completing the monitoring visit, ensure that:

- The participant has completed all scheduled study procedures.
- All end-of-shift observations have been completed.
- Electronic devices are available for retrieval.
- HTS-EOD-01 is open and ready for data entry.

Equipment Retrieval Procedure

Step 1. Retrieve the Core Temperature Receiver

- Remove the receiver from the participant.
- Inspect the receiver for visible damage.
- Verify that temperature recording continued throughout the monitoring period.
- Record any equipment damage or data interruption.

Step 2. Retrieve the Accelerometer

- Remove the accelerometer from the participant's wrist.

- Inspect the wristband and device for damage or excessive wear.
- Record any equipment issues.

Step 3. Retrieve the Indoor Temperature Sensor (Hygrochron iButton)

- Remove the Hygrochron iButton temperature logger from the participant's sleeping area on the final day of outdoor monitoring.
- Inspect the device for any visible damage or displacement.
- Download and verify the recorded indoor temperature and humidity data.
- Confirm that the device serial number matches the participant ID.
- Clean the device using approved disinfectant wipes before storage.
- Record the retrieval date, time, and any equipment issues in HTS-Indoor-01 and the Equipment Maintenance Log (HTS-EML), if applicable.

Step 4. Verify Data Collection

Download data from:

- Core temperature receiver
- Accelerometer
- Environmental monitoring equipment (if not previously completed)
- Hygrochron iButton temperature and humidity logger (final monitoring day only)

Confirm that:

- Data files have been saved successfully.
- No major recording gaps are present.
- Participant ID matches the downloaded data files.

Document any missing data or equipment malfunction.

Step 5. Clean Equipment

Clean all reusable equipment using approved disinfectant wipes.

Allow equipment to dry completely before storage.

Inspect all equipment for cleanliness and functionality.

Step 6. Store Equipment

Return all equipment to its designated protective carrying case.

Recharge electronic devices as soon as possible after returning from the field.

Report damaged equipment to the Field Supervisor.

Participant Instructions

Before the participant leaves:

Explain that:

- The ingestible temperature capsule will pass naturally through the gastrointestinal tract within 24-48 hours.
- The capsule does not need to be retrieved after passage.
- They should contact the research team immediately if they experience any unusual symptoms or adverse events after participation.
- If applicable, remind the participant about the scheduled next-morning urine and blood sample collection, including:
- The required collection times.
- Instructions for collecting the first-morning urine sample.
- Any pre-collection instructions provided by the study team (e.g., sample handling, storage, or fasting requirements, if applicable).
- The procedure and location for returning the samples to the research team.

Finally, thank the participant for their time, cooperation, and valuable contribution to the study.

Critical Checks

Before leaving the field site, confirm that:

- Core temperature receiver has been retrieved.
- Accelerometer has been retrieved.
- All electronic data have been downloaded successfully.
- Equipment has been cleaned.
- Equipment has been inspected for damage.
- Participant has received post-monitoring instructions.
- HTS-EOD-01 has been completed.
- Hygrochron temperature sensor has been retrieved from the participant's household (final monitoring day only).

Quality Control

- Verify that all downloaded files are complete before clearing device memory.
- Confirm that file names follow the study naming convention.

- Inspect equipment after every field visit.
- Record equipment damage, missing components, or malfunctions in the Equipment Maintenance Log (HTS-EML).
- The Field Supervisor should periodically review equipment retrieval procedures and end-of-day documentation.
- Verify that Hygrochron temperature data have been successfully downloaded before clearing the device memory.

Safety Considerations

- Handle electronic equipment carefully during retrieval and transport.
- Clean reusable equipment between participants according to study infection prevention procedures.
- Report any participant safety concerns identified after monitoring to the Field Supervisor immediately.
- Ensure all biological samples have been transported according to study procedures before leaving the field site.

Documentation

Complete the following records:

- HTS-EOD-01 (End-of-Day Checklist)
- Equipment Maintenance Log (HTS-EML), if applicable
- Protocol Deviation Log (if applicable)
- Hygrochron Sensor Installation and Retrieval Log (if applicable)

Before Leaving the Field Site

Ensure that:

- All study equipment has been retrieved.
- Electronic data have been downloaded and verified.
- Equipment has been cleaned and stored safely.
- Participant has received all post-study instructions.
- All study documentation has been completed and saved.
- Field materials are ready for the next scheduled observation.
- Hygrochron temperature sensor has been retrieved from the participant's household on the final monitoring day.