

## Human Tissue in Research

### SOP - Maintenance and Monitoring of Cold Storage Units

#### 1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to set out the requirements for the maintenance and monitoring of refrigerators, freezers and liquid nitrogen dewars used to store relevant material held either under HTA licence 12651 for research purposes or stored for NHS REC-approved studies.

The Human Tissue Authority (HTA) standards for research require that there are processes and instructions in place to ensure the robust maintenance and monitoring of storage units housing human samples stored for research. Maintenance and monitoring records will form part of the internal HTA quality management audits.

#### 2. Scope

This SOP applies to all Swansea University (SU) staff and students involved in research projects intending to store human tissue samples considered relevant material under HTA licence 12651 for research purposes or stored for NHS REC-approved studies with or without planned storage under the licence at the end of the study.

This SOP also sets out best practices for any type of human tissue sample, including material that is not considered relevant under the HT Act, human DNA and RNA, acellular human biological fluid, and human-derived cell lines.

#### 3. Roles and Responsibilities

The Designated Individual (DI) is responsible for ensuring that processes are in place to provide assurance and evidence of compliance with the HTA standards.

The Human Tissue Compliance Manager (HTCM) is responsible for ensuring that this SOP remains fit for purpose.

The Chief/Principal Investigator (CI/PI) is responsible for ensuring that all research activities conducted under their supervision comply with this SOP and that all members of their team adhere to the requirements.

All staff and students involved in storing or managing human samples for research must follow the requirements set out in this SOP and any associated procedures or guidance.

## 4. Procedure

### 4.1 Cold Storage Governance, Monitoring and Maintenance

All new fridges and freezers, liquid nitrogen dewars must meet laboratory standards and be appropriately validated, identified and controlled.

#### Valid

Domestic fridges/freezers are prohibited.

Manufacturer's instructions for the operation of each unit should be made available to users (digital or paper).

#### Identified

Each cold storage unit must be assigned a **unique identifier**.

Standardised SU HTA signage must be affixed to the front of each unit that will include:

- Study Titles
- Study Ethics reference numbers REC/IRAS/HTA licence
- Contact details of the CI/PI responsible for the samples stored  
*(Postdoctoral researchers or student contact details are **not suitable** due to turn-over; it must be a permanent member of staff).*
- Contain a QR code linking to the SU Human Tissue Governance User Group | Microsoft Teams

Contact the Human Tissue Compliance Officer for the appropriate laminated signage.  
[HTA-TEMPLATE-Storage Sign](#)

#### Controlled

Freezers, fridges and cold rooms storing relevant material must use the **essential power supplies (red plugs)** to ensure a backup power supply from the building generators if the power supply fails.

**A temperature monitoring system** must be in place for all cold storage units with relevant material.

**Maintenance** of storage units holding relevant material must be undertaken and recorded. You should establish within your local department/school/faculty if any maintenance is carried out centrally, by whom and how it is recorded.

## 4.2 Temperature Monitoring Requirements

Where samples are held under the HTA license or NHS REC approval, **continual temperature recording must be in place.**

The Estates team monitor the Building Management System (BMS), which senses ambient temperatures across the university's various offices and labs. However, it is always best practice to **raise a service request** if you believe the ambient temperatures in your area are too high and may be stressing the cold storage units' freezer cycles.

### 4.2.1 Digital Temperature Monitoring Systems

Where available, temperature probes linked to a continuous digital monitoring system must be used.

#### FMHLS – ILS1, ILS2, Grove & Vivian Tower

Monitoring is available for ULT Freezers and Cold rooms and Dewars via the **T-Scan system.**

For details, contact: [FMHLS Technical Support Compliance](#)

#### FSE – Engineering East (Sport Science)

Monitoring is available for ULT Freezers via **Invisible Systems Ltd.**

For details, contact: [Primary Designated Individual for Satellite Site](#)

Both systems:

- Record temperatures continuously (24/7)
- Retain logs retrievable on demand
- Trigger alerts (email/SMS/telephone) to named contacts when alarm limits are breached
- Trigger alerts in the event of power loss

All users storing human tissue in monitored units must:

- Be registered as named alarm contacts
- Ensure their contact details remain up to date
- Respond to alarms in accordance with their documented Contingency Plan

## 4.2.2 Manual Monitoring (*Where Digital Systems Are Not Available*)

The level of monitoring required must be **justified within the HTA Risk Assessment** for the study or collection.

However, the following minimum controls must be in place if storing relevant material:

- **Temperature recorded manually** at regular intervals (daily/weekly) using a temperature log ([HTA-TEMPLATE-Temperature Log](#)) attached to the door of each unit.
- Each log should be completed with the unit identifier and optimal operating **temperature range**. (e.g. max and min temperature)

### For -20°C Freezers and Fridges:

- Min/Max thermometer monitoring linked to a **built-in audible alarm**
- Logged maintenance checks of the alarm [HTA-TEMPLATE-Maintenance Log](#)

### For Liquid Nitrogen Dewars:

Liquid nitrogen **refill log** must be maintained. Unless the dewar is fitted with a continuous liquid level monitoring system or temperature probe with remote monitoring. Where continuous remote monitoring is used, monitoring records must be retained and made available for HTA audit upon request

## 4.3 Temperature Alarm Limits

Users must set temperature limits for the local alarm and cloud-based digital monitoring systems (**e.g. T-Scan/Invisible Systems**) for cold rooms, fridges and freezers which hold human tissue considered relevant material for research to ensure the integrity of the samples is maintained. It is recommended that the temperature shouldn't fluctuate more than  $\pm 10^{\circ}\text{C}$ .

| Unit               | Low alarm | Set point | High alarm |
|--------------------|-----------|-----------|------------|
| Fridges/cold rooms | 2°C       | 4°C       | 8°C        |
| -20°C freezer      | -30°C     | -20°C     | -10°C      |
| -40°C freezer      | -50°C     | -40°C     | -30°C      |
| -70°C freezer      | -90°C     | -70°C     | -60°C      |

To support sustainability and aid all labs to achieve a **LEAF award status**, it is recommended that all **ULT freezers maintain -70°C**.

*This has two major benefits:*

1. It can reduce energy consumption by 30% and prolong the life of the freezer.
2. ULT freezers emit large amounts of heat. By setting the freezers to -70°C, they will produce less heat and reduce the pressure on both the freezer's condenser cycles and the building ventilation systems.

## Temperatures critical for long-term storage of samples:

- The crystallisation (freezing) point of water is at 0°C
- 1st re-crystallisation is at -60 to -63°C
- 2nd re-crystallisation point is at -130 to -135°C.

Therefore, storage at -70°C is recommended and is safe for most samples. -80°C is not a critical temperature; storage at -80°C must be justified to technical support staff.

## 4.4 Response to Alarm Activation

When an alarm is triggered, the responsible or attending individual must:

- Assess the cause of the alarm
- Check door seals and closure (where applicable)
- Check any alarm batteries (if applicable)
- Check temperature limits
- Review for ice build-up
- Invoking the contingency plan linked to the storage unit

The responsible person must also submit an [Adverse Event Form](#) for:

- Equipment malfunction
- Unexplained temperature deviation
- Power failure affecting storage
- Near-miss events

Following any of the above-listed malfunctions, as part of a CAPA plan, the responsible person must:

- Review the temperature logs for at least one-month post-malfunction
- Complete an HTA-Form-Maintenance Report
- Complete any other CAPAs where required

**Note:**

**FMHLS** - Before purchasing a **new freezer/fridge or equipment** that is not a replacement, **approval should be sought**. Refer to [Laboratory Working> Purchasing Lab Equipment - Swansea University faculty webpage](#).

**FSE** - Any new equipment purchases should be discussed and agreed to with the local **technical/technician's support team and estates**.

## **4.5 Monitoring System Verification**

Monitoring systems must be periodically verified to ensure reliability.

### **4.5.1 FMHLS – T-Scan System**

- Temperature probes are serviced and calibrated annually by authorised T-Scan technicians.
- Annual certification documentation is available via the T-Scan portal (Settings > Document Centre)
- Certificates must be retrievable for HTA inspection.

Routine manual probe challenge testing by laboratory users is not required.

### **4.5.2 FSE – Invisible Systems**

Engineering East satellite site (Sports Science), ULT freezers are monitored using the Invisible Systems temperature monitoring system.

Unlike FMHLS sites, annual probe verification testing must be conducted locally by the users or local technicians and recorded on SafetyCulture as part of the in-house maintenance checks. It is the CI/PI's responsibility to ensure that this maintenance is carried out.

### **Before conducting an alarm challenge:**

- All named alarm contacts must be notified in advance.
- Notification must include date, approximate time, unit ID and tester name.

### **Alarm challenge procedure:**

- Using appropriate gloves, remove the probe carefully from the freezer and place it into room temperature water.
- Place a thermometer into the same water at the same time.
- Confirm alarm activation with all users.

- At the end of the test, confirm that the final temperature reading from the probe matches the thermometer reading.
- Record the outcome in SafetyCulture.

## If the Alarm Fails:

- Submit an [Adverse Event Form](#)
- Transfer samples to contingency storage.
- Repeat the challenge successfully before returning the unit to service.

## 4.6 Routine Maintenance of Cold Storage Units

User maintenance for fridges and freezers:

- Do not store items on top of fridges/freezers.
- Store samples in appropriate cold storage boxes and racks for quick retrieval.
- Avoid large empty spaces in freezers as this increases energy requirements.
- Ensure internal doors within a freezer are closed properly before closing the outer door.
- Keep door opening to a minimum and for short periods at a time (less than a minute).
- Ensure any grills and vents are not obstructed.
- Position freezers in a well-ventilated space away from sources of heat (sunlight, warm rooms) and/or where ambient temperatures are high.

### 4.6.1 Maintenance Records

All maintenance must be recorded, including any undertaken by users, where a local Maintenance Log or [HTA-TEMPLATE-Maintenance Log](#) (paper or digital) must be evidenced. Where SafetyCulture is used, this constitutes acceptable evidence.

### 4.6.2 Freezer Maintenance: Monthly, Quarterly & Yearly

The following maintenance checks for **ULT freezers** are carried out by the Technical and Compliance teams and recorded through the **Safety Culture** system on a monthly, quarterly & yearly basis. Except for full defrosting, this must be conducted by the users.

However, it is the research group's responsibility to undertake the following maintenance checks for any other **fridge or freezer** storing relevant material and complete **Maintenance Logs** to evidence the activity.



## **Monthly Maintenance Check:**

- Wipe down all surfaces with a mild detergent.
- Check door/lid seals - *If damaged, arrange for a repair.*
- Check the audible alarm works.
- Check if the freezer needs defrosting - *Clear away any frost and ice build-up using a soft cloth, dustpan and brush or rubber mallet. Do not use sharp tools and take care not to damage rubber seals and gaskets. If the ice layer is too thick to remove gently, follow the procedure for full defrosting and inspect the unit to identify any damaged seals that may need replacement.*

## **Quarterly Maintenance Checks:**

- Clean the air take grill.
- Clean the air take filter - *Clean the freezer filter by vacuuming or by rinsing in clean water and allowing it to dry before replacing it. Filters must never be removed from units for any reason other than cleaning.*
- Clean the condenser coils – *Use a vacuum or brush.*

## **Yearly Maintenance Checks:**

- Replace the alarm battery.
- Only for FSE – In-house probe and Inviabile system alarm check (see section 4.5.2)

It is also recommended that fridges be **cleaned internally annually**. Consult the manufacturer's user manual for specific instructions for each fridge type, taking specific note of the safety precautions required for any cleaning procedure:

- Notify users
- Relocate samples if required
- Disinfect interior
- Clean exterior
- Inspect ventilation areas
- Clean condensation tray



### 4.6.3 Fridge & Freezer Defrosting Procedure:

When the ice build-up can't be removed gently, it is the research groups responsibility to defrost the unit. Appropriate PPE must be worn throughout the procedure.

#### Steps:

1. Before performing a full defrost, notify all lab users in advance. Append a notice to the freezer which states the date the freezer will be defrosted, and how long it will be out of use and requests all users to relocate their samples before the defrost takes place.
2. Inform users that any samples that are not removed will be temporarily relocated; state where they will be relocated and who will be responsible for moving and returning these samples and the planned date of return.
3. For freezers that are connected to a digital monitoring system, disable the alarms for the required period.
4. Move remaining samples to a temporary location.
5. Set up hazard signs to alert users that the floor will become wet and slippery. Where possible, restrict access to the area completely for the duration of the defrosting process.
6. Unplug the freezer, open the main door and internal compartment doors and allow the internal ice to melt.
7. Clean the inside with 70%ethanol/Virkon/Chlor-Clean.
8. Check that all internal parts of the freezer (doors, hinges, clips and seals) are in good condition. Report any problems to the person who is responsible for the freezer to organise a repair.
9. Switch the freezer back on and allow 24 hours to stabilise to the desired temperature before returning the contents.
10. Notify all users they may return their samples.

**Note:** *Well-maintained freezers may not require full defrost at yearly intervals and may be defrosted on an as-needed basis providing that all routine maintenance is documented.*

### 4.6.4 Liquid Nitrogen Dewars

Monthly / Quarterly / Yearly checks carried out by the Technical and Compliance teams and recorded on **Safety Culture** are:

- Visual damage inspection
- Cleanliness check
- Protective cap condition

- Handle condition
- Secure mounting
- Serial number present
- Correct labelling

Records are retrievable for inspection.

## 4.7 Maintenance Reviews and Reporting

The **CI/PI or a deputised member** of the research team, responsible for the tissue collection or study, must **regularly review** (e.g. monthly/quarterly/annually) maintenance logs and maintenance checks to ensure that the maintenance requirements outlined in this SOP are being performed.

They should review:

- Required maintenance checks have been completed
- Any issues identified have been addressed
- Records are complete and legible

Maintenance records can be:

- Stored locally (paper or digital maintenance logs), or
- Automatically archived within digital monitoring systems (e.g. T-Scan or Safety Culture).

If deficiencies or maintenance issues are identified during review, they should complete a [HTA-Form-Maintenance Report](#) and a copy sent to the [HTGO](#) if there are **deficiencies noticed** during the monthly reviews.

## 5. Risk Assessment

A risk assessment for this HTA governance SOP is not required.

## 6. Definitions

A list of useful definitions of technical terms used within SU's HTA Core SOPs can be found in the [HTA-Research Quality Manual](#).

## 7. Reference

<https://www.freezerchallenge.org/sample-storage-temp-info.html>

# Human Tissue in Research HTA-SOP-Maintenance and Monitoring of Cold Storage Units

## 8. Document History

| Document History |                    |                                                                                                                                                                                                                                                                                                                                             |                                                                  |                      |
|------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|----------------------|
| Version          | Review Date        | Comment                                                                                                                                                                                                                                                                                                                                     | Replaces                                                         | Reviewed by          |
| 1.0              | N/A                | New document                                                                                                                                                                                                                                                                                                                                | N/A                                                              | N/A                  |
| 2.0              | 07/02/2024         | New Human Tissue Governance Officer revised SOP to reflect the separation of the previous joint HTA licence between SU and SUHB and to establish new SU procedures moving forwards.<br>SOP Title altered to 'Maintenance and Monitoring of Cold Storage Units'. Previously 'Maintenance and Monitoring of Fridge and Freezer Storage Units. | 1.0                                                              | Bethan R Thomas & DI |
| 3.0              | 15/04/2026         | Updated SOP to reflect new templates and additional annual maintenance probe test for FSE.                                                                                                                                                                                                                                                  | 2.0                                                              | Bethan R Thomas & DI |
|                  |                    |                                                                                                                                                                                                                                                                                                                                             |                                                                  |                      |
| Author           | Name and role      |                                                                                                                                                                                                                                                                                                                                             | Dr Bethan Rhian Thomas<br>Human Tissue Governance Officer (HTGO) |                      |
|                  | Signature and date |                                                                                                                                                                                                                                                                                                                                             | Signed copy held by HTGO 15/05/2026                              |                      |
| Approver         | Name and role      |                                                                                                                                                                                                                                                                                                                                             | Professor Catherine Thornton<br>Designated Individual (DI)       |                      |
|                  | Signature and date |                                                                                                                                                                                                                                                                                                                                             | Signed copy held by HTGO 18/06/2026                              |                      |
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