

## 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 and freezers used to store relevant material held either under HTA licence 12651 for research purposes or stored for NHS REC-approved studies with planned storage under the licence at the end of the study.

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 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

All staff and students who store human samples for research, either as part of their research or as part of their professional role supporting research are responsible for compliance with this SOP.

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 Governance Officer (HTGO) is responsible for ensuring that this SOP remains fit for purpose.

## 4. Procedure

### 4.1 Validation of new fridges and freezers

- All new fridges and freezers must meet Laboratory standards and include an internal temperature alarm as minimum. Domestic fridges/freezers are prohibited.
- All freezers should be given a unique identifier and a person with responsibility for monitoring and maintenance identified. Details will be held by the freezer database coordinator and posted on the front of the freezer.
- Manufacturer instructions for the operation of each unit should be made available to users.

### 4.2 Documentation

- Each existing or new freezer or fridge that contains human samples for research must be given a unique identifier.
- Details of the contents of the freezer must be appended to the freezer, including REC approval letters for all samples held under REC approval.
- Maintenance of storage units holding human tissue 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. For example, the FMHLS **iAuditor** system records the maintenance checks carried out by the Technical and Compliance Officer (TCO) and stores them digitally so that they can be accessed on demand.

If maintenance checks are not carried out or recorded in your local area by technical staff, the research group/department must carry out the maintenance of the storage units. A log ([HTA-TEMPLATE-Maintenance Log](#)) or similar departmental maintenance log must be stored in a file or digitally and made available upon request.

- It is best practice that temperature measurements of cold storage units are recorded electronically and monitored using a cloud-based monitoring system i.e. **T-Scan**. The daily logs can be accessed on demand.

If the research group/lab is manually recording a storage unit's daily temperature, documentation must be appended to the front of each freezer using a log. Refer to the [HTA-TEMPLATE-Temperature Log](#) or use a similar departmental temperature log.

## 4.3 Temperature Monitoring

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

To support sustainability and aid all labs to achieve a LEAF award status, it is recommended that all Ultra Low Temperature (ULT) freezers maintain -70°C. This has two major benefits, it can reduce energy consumption by 30%, and in doing so it can prolong the life of the freezer. ULT freezers emit large amounts of heat, which can affect the ambient temperature in the lab. This rejected heat must be removed by the building ventilation systems to prevent ambient temperatures from rising. 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.

Storage at -70°C is safe for most sample, the crystallization (freezing) point of water is at 0°C, the 1st re-crystallization is at -60 to -63°C and 2nd re-crystallization point is at -130 to -135°C. All listed temperatures are critical temperatures for long-term storage of samples, -80°C, however, is not a critical temperature.

As previously mentioned it is best practice to monitor the daily temperature of fridges and freezers storing human tissue with temperature probes linked to a continuous monitoring system, where logs are available on demand i.e. **T-Scan**. If the use of an electronic monitoring system is not available, the temperature should be manually recorded daily 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 operating temperature range.

## 4.4 Temperature Alarm Limits

The following alarm limits (local, remote or both) should be set on all, cold rooms, fridges and freezers which hold human samples for research to ensure the integrity of the samples is maintained. It is recommended that temperature shouldn't fluctuate more than ±10°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
-80°C freezer	-90°C	-80°C	-60°C

Users must set these limits for the local alarm, cloud-based digital monitoring systems (e.g. **T-Scan**) and the Building Management System for each fridge and freezer.

## 4.5 Temperature Alarms

All fridges and freezers that hold human samples for research must have an audible and visual alarm. This alarm must be in a place, or linked to a digital system that monitors temperatures 24/7.

Freezers and cold rooms that are linked to the T-Scan system or other temperature monitoring systems must trigger direct alerts to named contacts in the event of a temperature breach.

As a minimum, freezers and cold rooms must use the essential power supplies (red plugs) to ensure backup power supply from the building generators if the power supply fails.

The Estates team use the Building Management System (BMS) to monitor ambient temperatures in labs or rooms within labs where ULT freezers are placed. The BMS will alert when ambient temperatures rise above 30°C or below 25°C.

*Note: All new freezers must be reported to Estates to identify a suitable location with sufficient ventilation, request ambient temperature monitoring using the BMS and set alarms if the room temperature exceeds the 25-30°C limits.*

The alerts **must be triggered** in the following circumstances:

- When the high or low-temperature limits are reached for cold rooms, fridges and ULT freezers
- When any cold room, fridge or ULT freezer loses power

## 4.6 Temperature records reviewed following an alarm

Whenever an alarm is activated, a copy of the temperature logs of the affected freezer/fridge over the following month should be reviewed. The responsible/attending individual should complete the [HTA-Form-Maintenance Report](#) with details of remedial actions taken.

Where the alarm is caused by freezer failure, details of any repair should also be recorded in an [HTA-Form-Adverse Event Report](#) and sent to the [HTGO](#).

**The T-Scan** system will record instances when the alarm was triggered and will be updated by the responsible/attending individual with details of the remedial actions to be taken. This information will be made available to the research group/department.

Any alternative temperature monitoring system must be configured to ensure a 24/7 response in line with the principles of this SOP.

## 4.7 Alarm Testing

Sole reliance on internal temperature probes may result in temperature readings that are not representative of the internal temperature, and failure of alarms to activate, particularly where the freezer contains ice-build around the probe.

Freezers containing human samples stored for research must be subject to a monthly alarm challenge. This can be achieved by placing a gloved hand (glove suitable for use in a ULT freezer) around the internal temperature probe (or similar appropriate challenge) until the high alarm set point triggers the alarm. Record the alarm challenge and any comments on the equipment maintenance log appended to the storage unit or stored digitally.

If maintenance checks are carried out and recorded through the FMHLS **iAuditor** system, a report of the alarm failure will be provided to the responsible/attending individual.

Should a freezer fail to alarm when the alarm limits are reached, the responsible/attending individual must record the details on the maintenance log, complete an [HTA-Form-Maintenance Report](#) and send it to the [HTGO](#). You should then arrange for a maintenance visit. Samples should be relocated to a contingency freezer until the problem has been resolved. Repeat challenges should be performed successfully and documented before the freezer is returned to service.

## 4.8 Temperature Monitoring

Manual and electronic temperature monitoring logs and alarm challenge logs should be reviewed monthly as a minimum to check for temperature fluctuations/trends.

If a review of the monthly log demonstrates a potential issue (e.g. fluctuations/trends approaching set limits) an [HTA-Form-Maintenance Report](#) should be completed and a copy sent to the [HTGO](#).

## 4.9 Preventative Maintenance

Routine annual preventative maintenance should be conducted by trained personnel for all freezers (ULT and -20°C) and fridges that are on maintenance contracts. Repairs should be performed only by a qualified service technician.

This should always be supplemented by regular user maintenance.

All user maintenance should be documented in maintenance logs recorded digitally or attached to the front of each unit. Any digital maintenance logs and records should be archived and must be available upon request for internal audit and inspection by the HTA.

Individual fridge and freezer user manuals or ratified departmental SOPs should be followed for preventative maintenance.

The following user maintenance is provided as a guide where manufacturer instruction or departmental SOPs are not available.

For fridges and freezers (ULT and -20°C):

- Do not store items on top of fridges/freezers.
- Clear signage on the unit of what is stored in each shelf/compartment.
- Store samples in boxes and racks for quick retrieval.
- Maintain up-to-date inventories of all samples for each unit detailing the location including the shelf and exact box/rack position.
- Clearly label all samples using a method that won't degrade.
- Where appropriate, label samples with an expiry or disposal date to facilitate good sample management and to facilitate sample audits.

For ULT freezers:

- 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). This prevents warm air from entering the freezer and reduces the build-up of ice and frost.
- Do not overfill freezers, ensure any internal grills and vents are not obstructed.
- Do not cover or store items near external grills and vents to ensure that airflow to coolers is not obstructed as this will compromise temperature control and create a hazard.
- Avoid large empty spaces in freezers as this increases energy requirements.
- Position freezers in a well-ventilated space away from sources of heat (sunlight, warm rooms) and/or where ambient temperatures are high. Operating freezers in high ambient temperatures increases energy consumption and the risk of freezer failure.

## 4.10 Fridge Maintenance

Fridges that are used to store human samples for research should be regularly maintained. All maintenance should be documented on a maintenance log and stored digitally or appended to the fridge door and available upon request.

Recommended **quarterly** maintenance is below – always 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 all lab users in advance and, if necessary, request all users to relocate their samples before the cleaning takes place.
- If necessary, inform users that any samples that are not removed will be temporarily relocated; state where they will be relocated to and who will be responsible for moving and returning these samples and the planned date of return.
- If necessary, move samples to temporary locations, and maintain low temperatures as best as possible.
- Disinfect the fridge interior using a disinfectant solution e.g. Virkon/Chlor-Clean.
- Clean the fridge exterior with a mild detergent e.g. Decon.
- Inspect the ventilation area for dust accumulation.
- Check and clean the condensation tray.

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

All maintenance should be recorded on the freezer maintenance log. Where a freezer requires monthly or quarterly maintenance earlier than required, this should be performed on an ad-hoc basis and recorded on the maintenance log and, if necessary, an [HTA-Form-Maintenance Report](#) should be completed.

##### **For ULT Freezers:**

If maintenance checks are carried out and recorded through the FMHLS **iAuditor** system, most of the following Monthly, Quarterly & Yearly Maintenance will be undertaken by a Technical and Compliance Officer (TCO) for ULT freezers. Except for full defrosting.

If your local area does not use **iAuditor** it is the responsibility of the research group/department to ensure these checks are carried out regularly and recorded.

##### **For -20 Freezers:**

It is the responsibility of the research group/department to carry out the below-listed systematic maintenance including defrosting of the the freezers if required.

##### **Monthly Maintenance**

- Wipe down all surfaces with a mild detergent.
- Check the vacuum release vent.
- Check door/lid seals - *If damaged arrange for a repair.*
- Check 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**

- 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**

- Replace the alarm battery.
- Full defrost (if required).

### **Defrosting procedure:**

When the ice build-up can't be removed gently a full freezer defrost must be performed. Gloves 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. Move samples to temporary locations, in stages if needed to maintain ULT as best as possible.
4. Before unplugging the freezer, manually remove as much ice as possible to reduce the amount of pooled water.
5. For freezers that are connected to **T-Scan** (or other digital monitoring system) inform all linked users that the freezers will be switched off so if they receive an alarm in this period they do not need to respond and change the alarm temperature limits temporarily.



6. 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.
7. Unplug the freezer, open the main door and internal compartment doors and allow the internal ice to melt.
8. Once thawed, remove pools of water and wipe the internal surfaces and doors dry. Clean the inside of the freezer with a disinfectant solution e.g. 70%ethanol/Virkon/Chlor-Clean. Be mindful of whether the contents of the freezer are biohazardous and wear gloves at all times.
9. Clean the exterior of the freezer with a mild detergent e.g. Decon.
10. 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.
11. Switch the freezer back on and allow 24 hours to stabilise to the desired temperature before returning the contents.

**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.*

#### 4.12 Maintenance Reviews and Reports

Maintenance logs and maintenance checks carried out monthly should be reviewed to ensure that the required maintenance outlined in this SOP is being performed and appended to the storage unit or archived digitally. If they are not archived locally because they are automatically stored on a cloud system (e.g. T-Scan), they must be available upon request.

The [HTA-Form-Maintenance Report](#) should be completed 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

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

## 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. 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
<b>Author</b>	<b>Name and role</b>	Dr Bethan Rhian Thomas Human Tissue Governance Officer (HTGO)		
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