



Human Samples in Research

Maintenance and Monitoring of Fridge and Freezer Storage Units

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1. Purpose

The purpose of this 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. This SOP also sets out best practice for samples of non-relevant material or those samples that are held under NHS REC approval for which storage for future research studies under the licence is not planned.

2. Background

The Human Tissue Authority 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.

3. Roles and Responsibilities

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

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

The HTA Governance Officer 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 be subject to initial acceptance testing before use, followed by ongoing checks (refer to <https://www.swansea.ac.uk/research/researchintegrity/hta/templates/> for template validation plans)
- All freezers should be given a unique identifier and a person with responsibility for monitoring and maintenance identified. Details will be held by the relevant quality management team (ABM UHB) or freezer database co-ordinator (Swansea University) 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. For Swansea University freezers contact the freezer database coordinator to arrange this.
- A maintenance log (*HTA-07-TEMPLATE Maintenance Log*) or similar departmental maintenance log must be appended to the front of each freezer.
- A daily temperature log (*HTA-12-TEMPLATE Temperature Log*) or similar departmental temperature log must be appended to the front of each freezer unless an electronic monitoring system or data logger is in place.
- Details of contents of the freezer must be appended to the freezer, including REC approval letters for all samples held under REC approval.

4.3 Temperature Monitoring

The temperature of fridges and freezers which are not connected to a continual monitoring system should be manually recorded daily using the temperature log attached to the door of each unit. Each log should be completed with the unit identifier and operating temperature range.

Where samples are held under the HTA licence, continual temperature recording must be in place (e.g. chart recorder, data logger or electronic monitoring system).

4.3.1 Temperature Alarm Limits

The following alarm limits (local, remote or both) should be set on all fridges and freezers which hold human samples for research. It is acknowledged that many holders of frozen material are content to store at -70°C rather than -80°C; in these instances the low and high alarms should be set at a maximum of +/- 10°C of the set point for ultra-low temperature freezers.

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
-80°C freezer	-70°C	-80°C	-90°C

Swansea University – Users must set these limits for the local alarm and the remote Building Management System or alternative alarm (e.g. Tutela) for each fridge and freezer.

ABM UHB Laboratory Medicine and Cellular Pathology - limits for research freezers should be set as above in liaison with the respective Kelsius system manager.

4.3.2 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 system, that is manned 24/7.

Swansea University

Freezers and cold rooms in the university may be linked to the Building Management System (BMS) or an alternative remote alarm system.

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

Freezers and cold rooms that are linked to the BMS will alert the University security desk when an alarm is triggered. Security will contact the named contact for the relevant floor/laboratory. The alert will be triggered in the following circumstances:

- When the high or low temperature limits are reached for ultra-low temperature freezer or cold rooms
- When the alarm plug is removed from any ultra-low temperature freezer
- When any ultra-low temperature freezer is switched off

NB:

- If a freezer or cold room is in alarm on a particular floor no additional BMS alerts for other units on that floor will be sent to security.
- **Alarm connectivity must be reset on BMS following any repairs.**

Whenever an alarm is activated, the temperature log for the affected freezer / fridge or relevant electronic temperature management system must be completed by the attending individual with details of remedial actions taken. Where the alarm is caused by freezer failure, details of any repair should also be recorded.

The Tutela system will record instances when the alarm was triggered and is updated by the responsible / attending individual with details of the remedial actions taken.

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

ABM UHB Laboratory Medicine

Fridges and freezers that are used to store human samples for research are connected to the Kelsius temperature monitoring system and managed in accordance with the departmental document *LMS-A-SOP Kelsius Temperature Monitoring System* which is available to laboratory staff and stored on the Laboratory Medicine Q-Pulse document management system as a controlled document.

ABM UHB Cellular Pathology

Fridges and freezers that are used to store human samples for research are connected to the Kelsius temperature monitoring system and managed in accordance with departmental documentation:

CEL-A-SOP Temperature Monitoring

CEL2376; CEL-A-LI Disabling and Enabling Alarm on Kelsius Control Box

CEL2375; CEL-A-LI Remedial/Corrective actions for Kelsius Temperature Monitored Equipment

All documents above are available to Cellular Pathology laboratory staff and stored on the Cellular Pathology Q-Pulse document management system as controlled documents.

4.3.3 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 up around the probe.

Freezers containing human samples stored for research must be subject to weekly alarm challenge. This can be achieved by placing a gloved hand (glove suitable for use in an ultra-low temperature 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.

Should a freezer fail to alarm when the alarm limits are reached, record the details on the maintenance log and arrange for a maintenance visit. Samples should be re-located to a contingency freezer until the problem has been resolved. Repeat challenge should be performed successfully and documented before the freezer is returned to service.

4.3.4 Temperature Audits

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



Reviewed

logs should be annotated with comments and actions taken and signed and dated by the reviewer. An audit form (HTA-7b-FORM-Freezer Audit Record or suitable alternative form) should be completed for each audit and copies submitted to the HTA Governance Officer for review at the relevant HTA committee on a quarterly basis.

4.4 Preventative Maintenance

Routine annual preventative maintenance will be conducted by trained personnel for all freezers 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 attached to the front of each unit. Completed logs should be archived for each laboratory and available 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:

4.4.1 Day to Day Good Practice for all Freezers

- Ensure internal doors within freezers 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 entering the freezer and reduces the build-up of ice and frost.
- Prepare up to date inventories of all samples for each unit detailing what is stored in each compartment and append to the front of the unit.
- 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.
- Store samples in boxes and racks for quick retrieval.
- 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 creates a hazard.



- Do not store items on top of freezers.
- 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) where ambient temperatures are high. Operating freezers in high ambient temperatures increases energy consumption and risk of freezer failure.

4.4.2 Freezer Maintenance

All maintenance should be recorded on the freezer maintenance log. Where a freezer requires monthly or six-monthly maintenance earlier than required, this should be performed on an ad-hoc basis and recorded on the maintenance log.

4.4.2.1 Monthly Maintenance

- 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 defrost and inspect the unit to identify any damaged seals that may need replacement.
- Check and clean gaskets and rubber seals. If any seals are damaged arrange for a repair.
- Clean the freezer filter by vacuuming or by rinsing in clean water and allow to dry before replacing. Filters must never be removed from units for any reason other than cleaning.
- **DISCONNECT POWER SUPPLY** and clean the condenser coils with a vacuum or brush.
- **DISCONNECT POWER SUPPLY** and check and clean the freezer exterior, ensure the back of the radiator is clean and free from dust.

4.4.2.2 Six Monthly Maintenance

- Perform a full defrost – Completion of daily, monthly and quarterly maintenance should minimise the requirement for a full freezer defrost. When the ice build-up can't be removed gently a full freezer defrost must be performed. Gloves must be worn throughout the procedure.



- 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, how long it will be out of use and requesting all users to relocate their samples before the defrost takes place.
- 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.
- Before unplugging the freezer, manually remove as much ice as possible to reduce the amount of pooled water.
- For freezers that are connected to the BMS, inform security that the freezer will be switched off so that they know not to action an alert to the named contact.
- 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.
- Unplug the freezer, open the main door and internal compartment doors and allow the internal ice to melt.
- 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 Virkon/Chlor-Clean. Be mindful where the contents of the freezer may have been of a biohazardous nature and wear gloves at all times.
- Clean the exterior of the freezer with a mild detergent e.g Decon.
- Check that all internal parts of the freezer (doors, hinges, clips and seals) are in good condition. Report any problems to the person who has responsibility for the freezer to organize a repair.
- Switch the freezer back on and allow 24 hours to stabilize to the desired temperature before returning the contents.

NB: well -maintained freezers may not require full defrost at 6 monthly intervals and may be defrosted on an as needed basis providing that all routine maintenance is documented.

4.4.3 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 appended to the fridge door. Recommended monthly maintenance is below – always consult the Manufacturers user manual for specific instructions for each fridge type taking specific note of the safety precautions required for any cleaning procedure:

- 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

4.4.4 Maintenance Audits

Maintenance logs should be reviewed monthly to ensure that the required maintenance is being performed as outlined in section 4.4. An audit form (HTA-7b-FORM-Freezer Audit Record or suitable alternative form) should be completed for each audit and copies submitted to the HTA Governance Officer for review at the relevant HTA committee on a quarterly basis.

5. Definitions

Human Tissue – Any and all constituent parts of the human body formed by cells.

Human Tissue Act 2004 - Legislation that regulates the removal, storage and use of human tissue, defined as material that has come from a human body and consists of, or includes, human cells. The HT Act covers England, Wales and Northern Ireland. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The Human Tissue Act lists the purposes for which consent are required (Scheduled Purposes).

Human Tissue Authority – The independent regulator established by the HT Act to protect public confidence by ensuring human tissue is used safely and ethically, and with proper consent. The HTA licenses and inspects organisations that collect, store and use human tissue for the Scheduled Purposes, for which appropriate consent is required (unless exemptions apply).

HTA Codes of Practice - Provide guidance and lay down expected standards for each of the sectors regulated by the HTA (e.g. research) and under the HT Act. They are designed to support professionals by giving advice and guidance based on real-life experience.

HTA Standards - Core standards in four key areas that must be met for an organisation to obtain an HTA licence, relating to the provisions in the HT Act and the regulatory requirements: Consent; Governance and Quality Systems; Premises, Facilities and Equipment; Disposal.

Relevant Material – Any material, other than gametes, removed from the body which consists of or includes human cells. In the HT Act references to relevant material from a human body do not include:

- embryos outside the human body
- hair and nail from the body of a living person
- cell lines or any other human material created outside the human body



- serum, plasma, DNA and RNA

Research - A study that addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new

knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications of new knowledge.

Standard Operating Procedure – Detailed, written instructions to achieve uniformity of the performance of a specific function which an integral part of a quality management system. In the context of research using human samples, SOPs document all the processes that affect the quality and safety of those samples (e.g. acquisition, storage, transfer and disposal).

Storage – Maintaining the tissue under appropriate controlled conditions.

Validation – Prospective evaluation of equipment to ensure compliance with user requirements, relevant standards and usability.