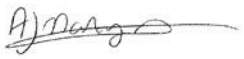
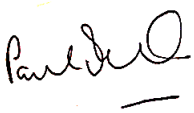
SOP Ref:	UOS_HT_SOP_12
SOP Title:	Maintenance and Monitoring of Human Tissue Storage Areas
Effective Date:	26/06/2023
Preceded by:	*1.0 (formerly UOS_HTA_SOP_014)*
Version Number	*2.0*
Review Date:	26/06/2026

Approval History				
Version 1.0	Name	Role	Signature	Date
Written By:	Abbe Martyn	Hub PD		27.02.2020
Approved By:	Matt Purcell	Director of H&S		14.05.2020
Version 2.0	Name	Role	Signature	Date
Revised by:	Linda McLatchie	Hub PD (acting)		03.06.2023
RIGO approval:	Gill Fairbairn	Interim Director R&I Services		26.06.2023
DI approval:	Paul Townsend	DI		19.06.2023

1. INTRODUCTION

Human tissue samples retained for research purposes must be stored in conditions that maintain sample integrity and security to ensure traceability and prevent deterioration or loss. The management of human tissue samples must also be in accordance with any relevant legislation, and this includes performing checks and maintaining records of storage conditions to demonstrate sample integrity has not been compromised. It also includes maintenance and monitoring of storage areas.

The University of Surrey adheres to the requirements of the Human Tissue Act (HT Act) for handling relevant materials. The Human Tissue Authority's (HTA) Code of Practice for Research sets out the Traceability Standards that must be followed. This includes ensuring that there is full traceability from the point of sample collection to final disposal/destruction and that human tissue samples are stored in an appropriate manner.

The procedures set out in this SOP are based on the HTA Codes of Practice and apply to all human tissue research taking place at the University.

2. SCOPE

This SOP applies to all projects (including Research Ethics Committee (REC) approved studies) using any type of primary human material including material that is considered relevant by the HT Act, any non-relevant human material, human DNA, RNA, any human biological fluids and any cell lines being derived by the researcher from primary material.
All individuals, whether staff, student or visitor, conducting research with human material under the auspices of the University of Surrey must comply with this SOP.

3. RESPONSIBILITIES

3.1 The Designated individual (DI) has *a legal duty to ensure that statutory and regulatory requirements are met. They are responsible for supervising licensed activities and ensuring suitable practices are taking place.* They are responsible for ensuring that all areas in which human tissue is stored meet the HTA's premises, facilities, and equipment licensing standards.

3.2 The Persons designate (PD) *assist DIs in ensuring compliance with HTA standards.* There is a PD for each of the areas; Stag Hill; (Hub PD and FEPS PD), Leggett, VSM, VSP and Surrey CRB. They are responsible for monitoring the designated human sample storage areas and making sure that, storage areas are kept clean, and that storage equipment is regularly serviced, checked, and monitored and that alarms are installed and tested. They are also responsible for overseeing the allocation of storage space and notifying the DI of any problems.

3.3 The Human Tissue Research Operations Group (HTROG) is the governing body overseeing all handling of human tissue under the HTA licence.

3.4 Research Integrity Governance Office (RIGO) are responsible for maintaining a central log of storage area locations, premises, facilities, and equipment audits and keeping a record of any incidents or adverse events.

3.5. The Principal Investigator (PI) or in the case of students, their supervisor, is ultimately responsible for ensuring samples are stored in an appropriate manner. They are also responsible for ensuring that only appropriately trained individuals are allowed to handle human samples for their studies.

3.6 Laboratory technical staff are responsible for ensuring designated storage areas are cleaned regularly and storage equipment and equipment required for tissue processing are regularly serviced. Fridges and freezers should be regularly de-iced and defrosted, and alarms regularly tested. Any problems or concerns should be reported to the PD.

3.7 All individuals working with human material must ensure that they adhere to this SOP with regards to maintenance, monitoring and recording of faults for all designated HTA storage areas of human samples. It is the responsibility of all individuals to report any faults or concerns in relation to storage of their samples to the Person Designated (PD). In the event of a failure of a storage area holding samples under the HTA licence, individuals must notify the named PD or Technical Team immediately. They must assist with enacting the business continuity plan, support any investigation and comply with any identified corrective and preventative action(s).

4. PROCESS

4.1 Requirements. All storage areas must be fit for purpose and kept clean with equipment well maintained to reduce the risks of equipment failure leading to sample loss. They should be secure and have sufficient storage space for the numbers and types of samples held. All cold storage should have 24- hour monitoring in place such any problems can be picked up and acted on quickly reducing the risk of sample loss. Alarms should be regularly tested, and equipment serviced and defrosted on a regular basis.

4.2. Access to storage areas and equipment.

4.2.1. Access to rooms holding human material must be to authorised personnel only. Typically for laboratories this will be personnel working within the laboratory.

4.2.2 Access to the specific Freezers, Fridges, Room Temperature cupboards, and liquid nitrogen should be restricted as much as possible. Where multiple occupancy, makes this more difficult, human material should be segregated from other laboratory samples and clearly labelled.

4.2.3. Locks should be used where possible to limit access and to help ensure doors and lids of storage containers are properly closed.

4.3. Signage. All areas and storage equipment that contains human samples must be clearly labelled with signage such as that shown in figure 1 below that says, either:

- "**Human Tissue Samples**" if the samples are held under REC approval.
- "**Relevant Material held under HTA Licence**" if the samples are held under the University's HTA Licence.

Figure 1: Storage area signage for human tissue Storage Areas

There should additionally be signage on the equipment to show the location of the samples within it, such that in the event of a failure and the samples needing to be moved they can be located easily. Templates for this can be found on the HTA facilities Teams page under signage.

4.4. Types of storage

4.4.1. Cold storage, Freezers -80°C /-20°C and +4°C Fridges. When being used to hold human tissue samples these should be:

- In rooms with suitable air-conditioning to prevent excessive heat build-up in warmer seasons that could cause damage to the compressors.
- Regularly serviced (usually annually)
- Regularly defrosted (usually on a documented, annual basis)
- On the University Building Management System or equivalent
- Continuously monitoring by an independent electronic temperature monitoring and recording device.
- Have temperature alarms with both audible (sound) and visual (digital) outputs.

4.4.2. Room temperature cupboards. These should be in a good state of repair and kept clean and locked. A temperature probe should be used to monitor the temperature and make sure that it does not fall outside the range for optimal storage of the types of samples contained.

4.4.3. Liquid Nitrogen (LN_2). When being used to hold human tissue samples liquid nitrogen vessels should:

- Be regularly serviced and kept in a good state of repair.
- Have a monitoring system to detect low LN_2 levels or temperature rises.
- Have levels of LN_2 checked and logged regularly (unless on automatic top-up)
- Be padlocked to keep the lid correctly in place where the lid is fully removable.
- Have the nearest backup listed on the signage

Additionally, users should be fully trained by attending the University Cryogenic Gas Safety Training and local LN_2 training and only access the LN_2 with a buddy to reduce the risk of accidents that could not only cause personal harm, but also lead to loss of samples or sample integrity.

4.5. Monitoring of cold storage areas

4.5.1. 24-hour a day monitoring: Cold storage that is used to hold human tissue must be connected to a 24-hour a day monitoring system that either contacts security or autodials a set of numbers directly if the temperature reaches the pre-set values shown in table 1 below.

- In the case of -80°C storage this monitoring system will usually be the Building Management System (BMS).
- The system should be tested every 6-months unless it has been triggered naturally. This should be done by temporally altering the alarm activation parameters rather than physically warming up or disconnecting the probe as there is a risk that the storage unit temperature could be compromised whilst the probe is being accessed and challenged.
- The alarm should have both audible (sound) and visual (digital) outputs.
- A record of tests should be kept by the lab manager together with evidence of acknowledgment of the alarm by the first responder who may be security, or the lab or technical manager contacted via the BMS system or via phone or email.
- Where security is the first responder their response to a temperature alarm will be in accordance with the University Building Continuity Plans (BCP) per building and the HTA BCP. The contact list for all BCP is updated bi-annually or when staff are known to have changed or are on annual leave.

Fridge/Freezer Temperature	Alarm temperature High and/or Low	Temperature requiring relocation of samples
+4 °C	+2 °C /+8 °C	+10 °C
-20 °C	-16 °C	-10 °C
-80 °C	-65 °C	-50 °C

Table 1: Fridge/freezer alarm thresholds and sample relocation temperatures.

4.5.2. Temperature logging system: all cold storage should additionally be monitored at a minimum of 15-minute intervals using a suitably calibrated temperature sensor or data logger.

- Temperature records must be downloaded and checked monthly. The records must be checked for unexplained short-term (days) or rapid (hours) changes to temperatures within and more gradual drifts over longer periods (weeks and months). Any changes observed must be reported to the PD who will decide if an adverse incident report is required or any further action.

- Probes should be checked for accuracy annually and re-calibrated if necessary. A record of any re-calibration should be kept.

4.6 Maintenance

4.6.1. Logging: For storage areas holding material under the HTA licence, all maintenance activities, interruptions to power and alarms arising from adverse incidents should be logged on the HTA facilities Teams page by the lab manager. Where sample integrity is affected or the issues result from equipment failure, they should also be logged on an Adverse event and incident form as detailed in UOS_HT_SOP_11.

4.6.2. Service contracts: All equipment used to store or process human tissue should be regularly serviced by a reputable company to help minimise the risk of any failures of equipment, by regular pre-preventative maintenance. Where applicable, servicing contracts will be put in place by the Technical Services Managers with procurement and then organised by the laboratory managers. Any faults found will be addressed and rectified. A log of all maintenance carried out will be kept by the laboratory manager.

4.6.3. Fridge and freezer defrosting: Fridges and freezers should be de-iced and defrosted on a regular basis to reduce the build up of ice that could lead to issues with keeping the temperature constant. Documentation of this should be kept by the lab manger.

4.6.4. Cleaning and decontamination: All rooms used to store human tissue should be cleaned, including the floors at least every 3 months and more regularly if usage is high and a record of all cleaning activities kept by the lab manager. All work tops, lab benches and other surfaces where human tissue is processed or used should be wiped down after use with suitable disinfectant and left tidy by the person using them.

4.6.5. Storage facility checks. All storage areas should be checked regularly by laboratory technical staff so that any problems can be identified as soon as possible. These will include checking ice build-up around doors and door seals.

4.7. Failure of equipment – relocation of samples and reporting

4.7.1 Equipment failure: In the event of failure of storage equipment holding human tissue samples including those under the HTA licence the following actions should be taken:

1) The PD or technical team must be notified immediately who will identify the designated back up/relocation storage location in accordance with the Human tissue contingency plan. Nearest back-up locations should also be displayed as part of the signage on all cold storage areas.

2) Relocation of samples should take place, using ice where possible to keep samples cold. This must be done accurately, to prevent disorganisation of sample locations and mix-ups.
3) If emergency action is required, the Estates team should be phoned (x9230).
4) The temporary storage locations should be written on the logs on the front of the fridge/freezer.
5) The PI(s) for the samples must be informed at the earliest convenience.
6) The failure should be reported via the university "report a fault" estates and facilities system via https://www.surrey.ac.uk/information-university-surrey-staff.
7) A note should be added to the sample records to indicate that the samples have been moved and if the samples will need to remain in the new location for more than 5-working days the records should be fully updated to the new location by the lab manager or PD.
8) All reported faults should be assessed as per the university BCP plans. Estates are required to give a timeline of remedial action and an estimated completion of works date, to prevent any loss of samples or work time.
9) All failure of equipment used to store human samples under the HT licence should be reported on an AE/I form as detailed in, UOS_HT_SOP_11.

4.7.2 Large scale failures: In the event of large failures (e.g. power outages across the site) university estates and facilities will follow the BCP plans for the buildings and storage areas, supplying a solution in a timely manner to prevent the loss of integrity of samples. Risk assessments will provide details of the locations of alternative storage facilities across the University Campus that can be used in the event of a large-scale power failure as well as which storage locations have generators.

4.7.3. Adverse event and incident reporting: Short-term cold storage failure, alarm failure, cold storage failure and alarm failure resulting in material loss, and any other event which compromises tissue integrity, storage or security must be reported as detailed in UOS_HT_SOP_11 Adverse Event and Incident Reporting.

5. ASSOCIATED DOCUMENTS

UOS_HT_SOP_03: Training requirements for using human tissue.
UOS_HT_SOP_11 Adverse Event and Incident Reporting

6. REFERENCES

- Code of Practice and Standards, E, Research, Human Tissue Authority

7. TRAINING

Before commencing any work with human tissue samples anyone wishing to do so must have completed all the training detailed in UOS_HT_SOP_03, Training requirements for using human tissue.

In addition, all persons using equipment for processing human tissues must first be fully trained in its use to reduce the risk of damage to the tissue, equipment and person performing the process. Appropriate PPE should be worn at all times.

8. USEFUL ABREVIATIONS

HTA – Human tissue authority
HRA – Human Research Authority
HT act – Human Tissue act
LH - Licence holder
DI- Designated individual
RIGO – Research Integrity and Governance Office
HTROG – Human Tissue Research Operations Group
PD- Person Designate
SOP-Standard Operating procedure
AE/I - Adverse event or incident
GCP – Good Clinical practice
MTA – Material Transfer Agreement
REC – Research Ethics Committee
UEC- University Ethics Committee

9. REVISION HISTORY

Version number	Revision details	Author	Date
1.0	New document (UOS_HTA_SOP_014)	Abbe Martyn	22.02.2020
2.0	Major revision including new numbering (UOS_HT_SOP_12)	Linda McLatchie	03.06.2023