University of Leicester Research Governance Office Standard Operating Procedures relating to the Human Tissue Act 2004

SOP HTA-A1009 UoL

Management of Fridges, Freezers and Liquid Nitrogen

Version 2.0

Effective Date: 01 December 2024

This SOP will be implemented in line with this document's effective date for all UoL HTA SOPs.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used.

1.0 Introduction

This document has been produced in accordance with *The Human Tissue Act 2004* (HT Act). It should be read in conjunction with the University's 'Policy on compliance with the Human Tissue Act in Research', and the Human Tissue Authority's *(HTA) Codes of Practice*.

This document has been produced in accordance with the Human Tissue Act 2004 (HT Act). This describes the management of fridges and freezers that hold HTA-relevant materials (RM).

2.0 Scope

The purpose of this SOP is to ensure that all UoL staff, students and external visitors understand the requirements of the HT Act regarding the management of storage units (such as fridges/freezers and Liquid Nitrogen Vessels (LN2)) that store HTA-relevant material for research purposes.

This document is to provide guidance for the Designated Individual (DI), Person Designated (PD) and staff working under their direction so that they are fully aware of the requirements for management of freezers that hold HTA-relevant material.

Definitions:

CI	Chief Investigator
CoP	Codes of Practice
DI	Designated Individual
HT Act	Human Tissue Act
HTA	Human Tissue Authority
LN2	Liquid Nitrogen
NHS	National Health Service
PD	Person Designated
PFE	Premises, Facilities and Equipment
PI	Principal Investigator
RGO	Research Governance Office
SOP	Standard Operating Procedure
UEIC	University Ethics and Integrity Committee
UoL	University of Leicester

3.0 Procedure

To ensure compliance with HTA standards, the establishment's premises, facilities, and equipment (PFE) must meet the set criteria for licensed activities. Failure to do so could jeopardise the University research licence, resulting in a detrimental effect on the University's research output.

Meticulous record keeping is essential. Clear cold storage management and quality management systems must be established and disseminated to all personnel involved with the collection, storage, and use of human tissue.

Complete records and documentation for all cold storage devices that hold HTA-relevant material must be kept from collection to transfer or disposal. The following points must be adhered to:

1. Names of contacts in the event of a storage area failure must be visible on all freezers / fridges / cryovessels (Freezer Template Notice Appendix 1).
2. The contents of each fridge/freezer/LN2 storage unit must be clearly labelled, and the location of each sample within the unit clearly described.
3. Each storage unit must have a clear label stating “This fridge/freezer/LN2 storage units contains HTA-relevant material”.
4. Equipment used for the storage of relevant material must be cleaned and decontaminated on a regular basis. It is recommended that this is undertaken annually and is documented (Cleaning Log Appendix 2).
5. A schedule for defrosting freezers must be available, and defrosting must be documented. It is recommended that freezers are defrosted annually to ensure minimal ice build-up. This helps with freezer electrical efficiency as well as reducing problems of failing seals that are damaged due to ice build-up (see Defrosting Log Appendix 3).
6. All fridges/freezers holding HTA-relevant material must have a 24/7 temperature monitoring system i.e., Haier Biomedical.
7. Trends of the fridge/freezer temperatures should be documented on a monthly basis and reviewed quarterly (Temperature Trend Log Appendix 4).
8. Fridge/freezer alarms should be manually challenged. It is recommended that this be undertaken on a quarterly basis to ensure they are functioning properly. The challenging of alarms must be documented (Freezer Alarm Challenging Log Appendix 5).
9. An active service contract for all freezers that hold HTA-relevant material must be in place.

Clear record systems must be in place to ensure that all adverse events are recorded, and action taken as appropriate. For adverse events and incidents please see SOP HTA-A1022-UoL (Adverse Events).

3.1 Fridge/Freezer/LN2 Failure

There must be local contingency processes in place that detail the actions to be taken in the event of failure of a temperature-controlled storage unit. Each storage unit containing relevant material should be labelled with an identifier name, name of the PI and contact information in the event of a failure in line with HTA-A1023-UoL.

Human tissue samples from a failed unit should be relocated to a designated contingency storage facility i.e., spare fridge/freezer where this is applicable. The relevant material moved to a contingency storage unit should be labelled with the appropriate information for its duration of storage within the contingency unit. Contingency units containing relevant material should be locked while in use to ensure security of the material within the freezer. All storage unit failures should be reported as an HT Act-related adverse event (refer to HTA-A1022-UoL), and the CI/PIs of the implicated studies should be informed. Immediate arrangements should be made for the repair or replacement of the related equipment. Relevant checks of correct operation should be made and documented before the repaired equipment is used again.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigator / Principal Investigator (CI/PI)	Chief Investigator / Principal Investigator (CI/PI) or delegate	Ensuring freezer management is undertaken as outlined in this SOP for freezers that store their HTA licenced samples and samples being stored from UEIC approved studies. Ensuring appropriate documentation as per required by this SOP. Ensuring lab staff undertake routine preventative maintenance such as cleaning freezer filters and ensuring freezers are cleared of ice / defrosted regularly.
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO.	Ensuring SOP remain up to date incorporating any regulatory changes or changed to CoP.
Person Designated (PD)	Person Designated (PD)	Assist in implementing and adhering to HTA governance processes.
Designated Individual (DI)	Designated Individual (DI)	Ensuring suitable practices are in place within the licenced establishment.

5.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Amanda Sutcliffe	HTA Monitor	UoL Human Tissue Governance Committee (HTGC)	Professor Peter Bradding 	28/11/2024

6.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)
November 2024	v2.0	A Sutcliffe	• Administrative Changes • Addition of section 3.1 taken from HTA_A1011_UoL • Update to main SOP title