UNIVERSITY OF LEICESTER

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The definitive version of all University of Leicester (UoL) Human Tissue Authority (HTA) Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that the up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Research Governance Ethics and Integrity (REGI) Website.

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Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
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Reviewer	All members of the College of Life Sciences Human Tissue Governance Committee	College of Life Sciences Human Tissue Governance Committee	N/A	N/A
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Background

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

Purpose and 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 RM material for research purposes.

This document is to provide guidance for the Designated Individual (DI), Persons Designated (PD) and staff working under their direction so that they are fully aware of the requirements for management of freezers that hold RM as defined by the HTA.

Definitions:

DI	Designated Individual
HT Act	Human Tissue Act
HTA	Human Tissue Authority
LN2	Liquid Nitrogen
NHS	National Health Service
PFE	Premises, Facilities and Equipment
HRA	Health Research Authority
HTA	Human Tissue Authority
REC	Research Ethics Committee
REGI	Research Governance Ethics and Integrity
RM	Relevant Material
SOP	Standard Operating Procedure
UEIC	University Ethics and Integrity Committee
UoL	University of Leicester

Roles and Responsibilities

It is the responsibility of the DI to ensure that suitable practices take place within the licensed establishment and that systems are in place to comply with the HTA Codes of Practice.

It is the responsibility of the HTA Monitoring Officer to ensure this SOP remains fit for purpose taking into consideration any changes in legislation and/or the HTA Codes of Practice for research.

It's the responsibility of the PD to assist the DI in implementing and adhering to the governance processes and to help ensure researchers store their RM in the designated areas/freezers to ensure compliance with the HTA licence.

All researchers involved in storing RM beyond the scope of the original research project from an approved NHS REC or for samples collected from staff/student/external visitors from a University Ethics and Integrity Committee (UEIC) approved project must ensure that all RM stored in freezers is stored in freezers/fridges and liquid nitrogen (LN2) vessels that are appropriately managed as documented in this SOP.

Procedure to follow

To ensure compliance with the 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 license, which could have a detrimental effect and impact on the University's research output.

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

Proper records and documentation for all freezers that hold RM must be kept from collection to transfer or disposal. This should include:

Names of contacts in the event of a storage area failure must be visible on all Freezers / Fridges / Cryovessels (*SOP HTA-A1009 Appendix 1*).

Equipment that is used for the storage of RM must be cleaned and decontaminated on a regular basis. It is recommended that this is undertaken annually and is documented (*SOP HTA-A1009 Appendix 2*).

Equipment that is used for storing RM should be cleaned more regularly. At a minimum, it is recommended that an item is cleaned annually and documented *(SOP HTA-A1009 Appendix 2).*

There should be a schedule of defrosting the freezers, which 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 *(SOP HTA-A1009 Appendix 3).*

Trends of the freezers / fridges temperatures should be documented on a monthly basis and reviewed quarterly *(SOP HTA-A1009 Appendix 4).*

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 *(SOP HTA-A1009 Appendix 5).*

An active service contract for all freezers that hold RM to ensure freezer longevity must be in place.

All freezers holding RM must have a 24/7 temperature monitoring system, such as Tutella or Haier Biomedical.

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*.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)

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Date	Name	Department	Received Y/N