UNIVERSITY OF LEICESTER

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

SOP HTA-A1011 UoL

Equipment Management and Maintenance

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.

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*.

The Human Tissue Act (HT Act) and the HTA require a robust system of management and maintenance of all equipment that is used throughout the acquisition and processing of HTA-relevant material (from collection through to disposal). These procedures represent good practice for the handling of all tissue samples and other types of relevant material as defined by the HTA. They must be followed by all researchers working with HTA-relevant material that is held under the UoL HTA Research Licence, including samples collected from projects with University Ethics and Integrity Committee approvals (UEIC).

The term equipment used in the context of HTA-relevant material may include, but not be limited to:

- Refrigerators and freezers
- Centrifuges
- Incubation systems
- Dewars
- Analysers
- Safety Cabinets
- Microtomes

The HTA expects that the equipment life cycle in terms of acquisition, use and disposal will be managed appropriately to reduce the risks of equipment failure which may impact on the integrity of HTA-relevant material. It is required that all relevant equipment be subject to quality assurance processes (evidenced by appropriate records), including but not limited to:

- Calibration records
- Scheduled cleaning and decontamination
- Planned basic maintenance
- Preventative maintenance contracts (where appropriate)
- Contingency plans for equipment failure
- Documented reporting process for equipment failure
- Adverse events reporting
- Risk Assessment

2.0 Scope

The purpose of this SOP is to provide staff and students with guidance on the required standards for the management and maintenance of equipment related to the storage and use of human HTA-relevant material in research. This SOP should be read and used, in conjunction with the HTA Codes of Practice for Research.

Definitions:

CI	Chief Investigator
DI	Designated Individual
HT Act	Human Tissue Act
HTA	Human Tissue Authority
PD	Person Designated
PI	Principal Investigator

RGO	Research Governance Office
SOP	Standard Operating Procedure
UEIC	University Ethics and Integrity Committee
UoL	University of Leicester

3.0 Procedure

This SOP will outline the procedure to follow for the routine maintenance and calibration of equipment. This is required to ensure the longevity and proper functioning of the equipment, so that the integrity of the samples exposed to that equipment is maintained (where appropriate), and the data generated are robust.

3.1 Routine Maintenance

All equipment used in the process of collecting, using, storing and disposal of relevant material should be subject to regular planned maintenance. The maintenance schedule will usually be defined by the equipment manufacturer. Maintenance must be documented whenever this is performed. Evidence of scheduled maintenance must be available for internal audit or inspection by the HTA. Examples of routine maintenance are:

- Cleaning
- Decontamination
- Defrosting
- Air Filter Checks
- Functional Checks

For fridge/freezer maintenance and management please refer to HTA-A1009-UoL and the corresponding appendices.

3.2 Routine Calibration

Equipment (e.g., centrifuges) used to prepare, and store HTA-relevant material must be subject to routine calibration.

3.3 Maintenance Contracts

Where equipment is critical for the preparation, storage or use of HTA-relevant material, a maintenance contract should be in place to ensure that a program of planned, preventative maintenance is in place. Inspection dates should be scheduled and monitored accordingly.

3.4 Equipment Failure

HTA-relevant material used for scientific research should be stored under conditions that preserve its integrity through the life cycle of the sample(s). Contingency arrangements should be in place for the failure of critical equipment and such arrangements should be documented in a SOP, and back-up processes and equipment should be available.

3.5 Fridge / Freezer 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. See SOP HTA_A1009 for further information regarding the prevention and management of cold storage unit failure.

3.6 Failure of other Equipment

Failure of any equipment impacting the integrity of HTA-relevant material must be reported as an adverse event (see SOP HTA_A1022).

Failure of equipment not considered to be critical to the integrity of HTA-relevant material (e.g., equipment that has an impact on health and safety) should be reported to an appropriate member of staff immediately (e.g., PI, Laboratory Manager, Technical Services Manager) and dealt with as per departmental procedures.

3.7 Adverse Events

Equipment-related adverse events should be reported in accordance to HTA_A1022-UoL.

Examples of events are:

- Storage unit failure
- Damage to critical equipment e.g., centrifuges, freezers
- Incorrect operation of critical equipment leading to loss of sample integrity
- Failure to adhere to maintenance schedules

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 refer to SOP HTA-A1022-UoL.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigators / Principal Investigators (CI/PI)	Chief Investigators / Principal Investigators (CI/PI) or delegates	Ensuring equipment used for HTA licenced material are covered by appropriate contracts and undergo regular maintenance and calibration. Ensuring lab technicians assist in preventative maintenance i.e., clearing of freezer filters, ensuring freezers are defrosted routinely where applicable.
Person Designated (PD)	Person Designated (PD) or delegate	Assisting in the investigation of storage failures that impact HTA licenced material.
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Ensure SOPs remain up to date and updated with changes due to regulatory updates
Designated Individual (DI)	Designated Individual (DI)	Ensuring suitable practices are in place for complying with the HT Act.

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 updates