# Human Tissue in Research

## HTA-CORE-SOP- Equipment Management

### 1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide staff and students with guidance on the required standards for the management and maintenance of equipment related to the use and storage of human tissue in research.

This SOP should be read and used in conjunction with relevant Human Tissue Authority (HTA) Codes of Practice and the World Health Organisation (WHO) Good Clinical Laboratory Practice document.

### 2. Scope

HTA-licenced establishments must meet set standards; one standard is to demonstrate that the establishment's premises and facilities are appropriate for their licensed activities and are safe, secure and clean.

This SOP applies to laboratory equipment that is used to store, process, or dispose of relevant human material held under the Swansea University HTA Human Tissue Research Licence.

The term "**equipment**" in the context of human tissue governance refers to equipment whose function may impact:

- The **integrity** of human tissue
- The **classification** of material as relevant or non-relevant
- The **traceability** of samples
- The **safe storage** of human tissue

This includes, but is not limited to:

- **Refrigerators and freezers** used for tissue storage
- **Liquid nitrogen dewars**
- **Biological safety cabinets** used for tissue handling
- **Centrifuges** or processing equipment where failure could compromise sample integrity
- Any equipment used to **render material acellular**

Establishments must be able to demonstrate systems for management and monitoring key equipment, demonstrating that the equipment is appropriately and suitably maintained.

## 3. Responsibilities

The Designated Individual (DI) is responsible for oversight of the development and implementation of a system of equipment management and maintenance.

The Person(s) Designated (PDs) support the DI to ensure compliance with the Human Tissue Act (2004), within their local environment by acting as local ambassadors for the Act.

Chief/Principal investigators (CI/PI) and individual researchers are responsible for identifying areas of non-compliance with this SOP, rectifying and where appropriate, reporting them as Adverse Events.

The Human Tissue Act Compliance Manager (HTCM) is responsible for ensuring that this SOP remains fit for purpose and supporting PDs and PIs to ensure compliance.

## 4. Procedure

The HTA expect the equipment life-cycle in terms of acquisition, use and disposal to be managed in a planned manner to reduce the risks of failure, which might impact the integrity of a tissue collection. They also require that all relevant equipment be subject to quality assurance processes.

All equipment directly involved in the acquisition, processing, storage, or analysis of human tissue must be:

- Suitable for its intended purpose
- Maintained in good working order
- Routinely monitored
- Accompanied by traceable documentation where appropriate

Typical records that must be kept as evidence include:

- Equipment manual (readily available)
- Validation records
- Calibration records
- Scheduled cleaning and decontamination
- Planned maintenance reports (these can be internal)
- Servicing contracts
- Risk assessment of premises and equipment
- Contingency plans for equipment failure
- User training records (where appropriate)
- User logs to record errors/failures
- System for reporting equipment problems

See Table 1 for examples of typical study equipment and the records that should be in place.

*Table 1: Example Equipment and Record*

| Equipment Type | Monitoring Type | **Records to be kept or accessible** |
|---|---|---|
| **ULTs, fridges** | Daily/weekly temperature checks, alarm tests | **Temperature log, service log, maintenance report** |
| **$LN_2$ Dewars** | Fill level checks, ice removal, visual inspection | **Level check log, maintenance notes** |
| **Centrifuges** | Service sticker, visual check before use | **Service certificate, error log (if needed)** |
| **Pipettes** | Periodic service or replacement | **Internal log, sticker, or external service report** |
| **Water baths / incubators** | Functionality check, clean/decontaminate | **Cleaning log, visual inspection record** |
| **Biological Safety Cabinets** | Annual service + internal checks (filter/alarm) | **Certificate of testing, sticker, internal checklist** |
| **Analytical equipment** | Functionality check or calibration. Software diagnostics, and service where required | **Maintenance/service log, user guide link** |

### 4.1 Equipment suitability and installation

- Equipment should be installed and set up by competent personnel following the manufacturer's instructions.
- Where possible, a copy of the ***user manual*** should be retained (paper or digital link).
- Manufacturer ***warranties*** or delivery notes should be kept as evidence of specification and suitability (paper or digital).
- For certain equipment, high-risk or regulated equipment (e.g. Biological Safety Cabinets, analytical instruments, temperature-controlled storage), a manufacturer or certified contractor may provide at the time of delivery:
    - Installation Qualification (IQ),
    - Operational Qualification (OQ)
    - Performance Qualification (PQ)

  Where such documents are provided, they should be retained as evidence of the correct setup and suitability for the purpose.

### 4.2 Equipment Use

Instruction manuals or SOPs should be available to all individuals using a piece of equipment. Equipment SOPs should be reviewed periodically for fitness for purpose in line with the requirement by the HTA for all research-related documents to be managed. Where appropriate, training in the use of a piece of equipment should be undertaken and documented before use.

The use of equipment should be **H&S risk-assessed, and an appropriate level of personal protection should be defined and consistently** used.

### 4.3 Equipment Maintenance

All equipment used in the process of collecting, using, storing and disposing of human tissue should be subject to regular, planned maintenance. The requirements for maintenance will usually be defined by the supplier and should be documented whenever performed. Evidence of scheduled maintenance must be available for internal audit or inspection by the HTA. Examples of routine user maintenance are:

- Cleaning
- Decontamination
- Functional checks

A template maintenance log is available for local adaptation where required.

#### 4.3.1 Cold Storage In-House Maintenance Schedules

Both the Faculty of Medicine, Health and Life Science (FMHLS) and the Faculty of Science and Engineering (FSE) have monthly scheduled in-house maintenance activities conducted by the local technical team/technicians. These in-house maintenance activities are carried out on ULT freezers and Dewars and recorded on the inspection platform 'Safety Culture'. Further details of these activities can be found in the HTA-CORE-SOP-Maintenance and Monitoring of Cold Storage.

#### 4.3.2 Regular Calibration

When advised by manufacturers' instructions, equipment used to prepare and store human tissue must be subject to routine calibration, and results should be recorded appropriately.

#### 4.3.3 Service Contacts

Where critical equipment is used to prepare or store human tissue, a service contract should be in place to ensure a program of planned, preventative maintenance. Servicing

dates should be scheduled and monitored. All routine servicing must be carried out by an authorised service technician.

Within **FMHLS**, the following core equipment is subject to **annual servicing**, arranged centrally by the Technical Support Compliance Team:

- Class II Biological Safety Cabinets
- Centrifuges
- Plate Readers
- Cryostats
- Water Purification Systems
- Autoclaves

Pipettes are typically serviced every two years, but this service is not centrally funded. Responsibility for arranging and **funding pipette servicing lies with the CI/PI**.

In contrast, **FSE** does **not maintain a central list of core equipment or servicing plans**. Investigators within this faculty must liaise with their **local technical team** to establish appropriate **maintenance and servicing schedules** for any equipment used in the storage, handling, processing, or analysis of human tissue in their study or collection. This **responsibility** lies with the **CI/PI.**

**Note:**
Equipment should not be used if the 'next service due' date has been exceeded or if there is any doubt regarding the current service status of the device.

### 4.4 Equipment Failure

Human tissue samples used in scientific research must be stored under conditions that preserve their integrity. Contingency arrangements should be in place for the failure of critical equipment used in the collection, processing, storage and use of human tissue considered relevant material.

Possible failure of any equipment critical to the integrity of human tissue or used to render material acellular, **must** be considered within the study-specific HTA Risk Assessment and mitigation planned, e.g. location of alternative equipment in different labs.

All critical equipment failures should be reported immediately as an adverse event to an appropriate member of staff (e.g. PI, Laboratory Manager) and followed by the submission of an Adverse Event Form. Records should be stored in the study file.

#### 4.4.1 Freezers/Fridges

Please refer to HTA-CORE-SOP-Maintenance and Monitoring of Cold Storage to understand all maintenance processes and records that should be managed for **cold storage units**.

In terms of contingency planning:

- Each storage unit containing human tissue should be labelled with a unit identifier, name of CI/PI and contact information in the event of a failure in line with HTA-CORE-SOP-Storage.
- All units storing relevant material **must have** a contingency plan; refer to HTA-CORE-SOP-Risk Management and available templates. The contingency plan must be communicated to all staff and students who use the equipment and those working in the same area.
- The Contingency Plan document must be uploaded as a PDF to the centralised HT Contingency Plans folder hosted within the SU Human Tissue Governance-UsrGrp Teams group and saved in the appropriate building/location subfolder.
- The Contingency Plan document must be reviewed at regular intervals and updated as required. All amendments must be version controlled in line with HTA document control procedures.
- All storage unit failures should be reported by submitting an Adverse Event Form and records stored in the study file.

### 4.5 Adverse Events

Equipment-related adverse events should be reported following the procedure detailed in the HTA-CORE-SOP-Adverse Event Reporting and using an Adverse Event Form. Examples of such adverse events are:

- Storage unit failure (with or without loss of tissue integrity)
- Damage to critical equipment e.g. centrifuges, freezers
- Incorrect operation of equipment critical to sample integrity
- Failure to adhere to maintenance schedules.

## 5. References

- WHO Good Clinical Laboratory Practice (GCLP)
- HTA Code of Practice E: Research; Code of Practice and Standards

## 6. Risk Assessment

A risk assessment for this HTA governance SOP is not required.

## 7. Definitions

A list of useful definitions of technical terms used within SU's HTA Core SOPs can be found in the HTA-Research Quality Manual.

## 8. Document History

| Document History | | | | |
|---|---|---|---|---|
| **Version** | **Review Date** | **Comment** | **Replaces** | **Reviewed by** |
| 2.0 | 21.09.15 | Update to front page and footers. Removal of maintenance log to standalone document. Alteration of identifier title to HTA-10-SOP-Equipment Management | 1.0 | Lisa Wakeman |
| 3.0 | 01.09.16 | Post-licence grant review, amendment from acting designated individual reference; minor text amendments | 2.0 | Lisa Wakeman |
| 4.0 | 18.04.18 | Amendments to reflect revised HTA Codes of Practice and Standards. Updated regulatory detail | 3.0 | Lisa Wakeman |
| 5.0 | 12/03/2024 | Revised SOP to reflect the separation of the previous joint HTA licence between SU and SUHB and to establish new SU procedures moving forward. | 4.0 | Bethan R Thomas & DI |
| 6.0 | 02/02/2026 | Reviewed and updated SOP to reflect new systems/processes and details of satellite site compliance difference e.g. FMHLS and FSE. | 5.0 | Bethan R Thomas & DI |
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| | **Signature and date** | Signed Copy Held by HTGO 02/02/2026 | |
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