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 establishments premises and facilities are appropriate for their licensed activities and are safe, secure and clean.

Establishments should also utilise systems for management and monitoring key equipment involved in the collection, use, storage and disposal of human tissue. They should ensure that equipment is appropriately and suitably maintained and that it does not present an impediment to the staff using it or impact the integrity of the tissue collection and reliability of the research.

The term ‘equipment’ in the context of human tissue use may include, but is not limited to:

- Refrigerators and freezers
- Centrifuges
- Water baths
- Incubation systems
- Liquid Nitrogen Dewars
- Analysers
- Safety cabinets
- Pipettes
- Consumables

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.

Principal investigators (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 Governance Officer (HTGO) 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 may impact on the integrity of a tissue collection. These organisations also require that all relevant equipment be subject to quality assurance processes.

Records that must be kept as evidence:

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

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.

4.1 Equipment Use

Instruction manuals or SOPs should be available to all individuals using a piece of equipment. Such documents 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 risk assessed and an appropriate level of personal protection should be defined and always used.

4.2 Equipment Maintenance

All equipment used in the process of collecting, using, storing and disposal 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
- Defrosting
- Air filter checks
- Functional checks

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

4.3 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.

4.4 Service Contacts

Where critical equipment is used to prepare or store human tissue, a servicecontract should be in place to ensure a program of planned, preventative maintenance , particularly where the equipment (e.g. centrifuge) is used to render the tissue acellular. Servicing dates should be scheduled and monitored. All routine servicing must be carried out by an authorised service technician.

Note:
Servicing of centrifuges is usually arranged by the school/faculty but please check that this is in place before starting a study that requires their use for human tissue preparation.

4.5 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 involved in the collection, processing, storage and use of human tissue. Such arrangements should be documented in a contingency plan and backup processes and equipment should be available.

4.5.1 Freezers/Fridges

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

Each storage unit containing human tissue should be labelled with a unit identifier, name of PI and contact information in the event of a failure in line with HTA-CORE-SOP-Storage.

All sample storage units **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.

All storage unit failures should be reported as an adverse event and records stored in the study file.

4.5.2 Other Equipment

Failure of all other equipment considered to be critical to the integrity of human tissue **must** also have a contingency plan, 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).

4.6 Adverse Events

Equipment-related adverse events should be reported following 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

Author	**Name and role**	Dr Bethan Rhian Thomas Human Tissue Governance Officer (HTGO)	
	Signature and date	Signed copy held by HTGO	
Approver	**Name and role**	Professor Catherine Thornton Designated Individual (DI)	
	Signature and date	Signed copy held by HTGO	
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