# Human Samples in Research

## Equipment Management and Maintenance

| | | | |
|---|---|---|---|
| **Document Identifier** | | HTA-10-SOP-Equipment Management | |
| **AUTHOR** | **Name and role** | Dr Lisa Wakeman<br>HTA Governance Officer | |
| | **Signature and date** | Signed copy held in ABM UHB R&D Office | |
| **APPROVER** | **Name and role** | Professor Catherine Thornton<br>Designated Individual | |
| | **Signature and date** | Signed copy held in ABM UHB R&D Office | |
| **EFFECTIVE DATE:** | 01.05.18 | **REVIEW DATE:** | 01.05.20 |

| 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 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

## 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. Background

The Human Tissue Act (HT Act) and the HTA require that there be in place a robust system of management and maintenance of all equipment that is used in the path taken by tissue from collection to disposal.

The term 'equipment' in the context of human tissue use may include, but not be limited to:

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

The HTA and MHRA 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 organizations also require that all relevant equipment be subject to quality assurance processes (evidenced by appropriate records) including but not limited to:

- Records of calibration
- Records of validation, including:
    - installation qualification (i.e. commissioning, confirmation of lack of defects)
    - operational qualification (i.e. evidence of being fit for purpose)
    - performance qualification (i.e. data to evidence ongoing fitness for purpose during lifetime of equipment)

- Scheduled cleaning and decontamination
- Planned basic maintenance
- Planned preventative maintenance contracts where appropriate
- Contingency plans for equipment failure
- Documented reporting processes for equipment failure
- Adverse event reporting systems
- Risk assessment
- Availability of current instructions for use

## 3. Roles and 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) carries the role of directing others in relation to the HT Act. As part of this role they have the ability to reasonably assist the DI in implementing procedures to ensure compliance with the HT Act and HTA licensing requirements.

All staff and students working with human tissue are responsible for ensuring they practice in accordance with this SOP and are aware of the requirements for robust equipment management and maintenance.

Principal investigators (PI) and individual researchers are responsible for identifying areas of non-compliance with this SOP and for appropriate escalation of deficiencies including reporting such instances as adverse events in line with *HTA-11-SOP-Adverse Event Reporting.*

The Human Tissue Act Governance Officer is responsible for ensuring that this SOP remains fit for purpose.

## 4. Procedure

4.1 Equipment Procurement

Where the need for new or replacement equipment is identified, a specification of user requirements should be developed in order to assess the suitability of equipment options from a range of suppliers. Comparison of the options should follow a documented methodology and records of assessment be retained. Such records provide evidence of fitness for intended purpose for inspection by HTA or the MHRA.

The specification of user requirements may include some or all:

- Applicable standards
- Exact description of the item required
- Functional and operational requirements
- Training requirements
- Maintenance and contract requirements
- Documentation requirements
- Software requirements

Relevant procurement processes of each organization should be adhered to as appropriate.

4.2 Equipment Validation

Once obtained, equipment should be subjected to a process of validation. The stages of validation are defined by the MHRA and serve to satisfy the requirements of the HTA and MHRA for the use of equipment in human tissue-related research. Templates for equipment validation are available on the University website. The stages are:

4.2.1 Installation Qualification – verification of correct installation and receipt of correct equipment and documentation including:

- Operator manual
- Commissioning documents from engineer
- Calibration certificates
- Serial number
- Verification of correct positioning (e.g. size of room is appropriate / safe positioning / co-located to essential utilities)

4.2.2 Operational Qualification – verification of correct and safe operation of the equipment for the intended purpose including:

- Verification of operation through intended range
- Challenging system features – e.g. alarm activation, locking systems
- Verification of consistent temperature within freezer units (temperature mapping) where temperature is critical to sample integrity.

4.2.3 Performance Qualification - Ongoing demonstration that the equipment is consistently functioning as required. Evidence may include:

- Regular temperature mapping
- Regular inspection of visual alerts (e.g. freezer temperature/centrifuge speed displays)
- Checks for damage

### 4.3 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 used at all times.

### 4.4 Equipment Maintenance

#### 4.4.1 Routine 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 (*HTA-07-TEMPLATE-Maintenance Log*) for local adaptation where required.

#### 4.4.2 Routine Calibration

Equipment used to prepare and store human tissue must be subject to routine calibration, particularly where the equipment (e.g. centrifuge) is used to render the tissue acellular.

4.4.3 Maintenance Contracts

Where critical equipment is used to prepare or store human tissue, 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.

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 failure of critical equipment. Such arrangements should be documented in a SOP and back-up processes and equipment should be available.

4.5.1 Freezer and Fridge Failure

- Local contingency processes must be in place to detail the actions to be taken in the event of failure of a temperature controlled storage unit.
- Each storage unit containing human tissue should be labeled with a unit identifier, name of PI and contact information in the event of failure in line with *HTA-03-SOP-Storage*.
- Human tissue samples from a failed unit should be relocated to a designated contingency storage facility of the same type (e.g. fridge, -20℃, -80℃ freezer).
- All human tissue moved to a contingency storage unit should be labeled as below:

| **HUMAN TISSUE** |
| --- |
| Human Tissue relocated from [insert fridge/freezer location and ID] |
| Date of transfer: |
| Name of Principal Investigator: |

- Contingency freezers containing relocated human tissue should be locked.

- All storage unit failures should be reported as HTA adverse events (refer to *HTA-11-SOP-Adverse Event Reporting*) and PIs of implicated studies should be informed.

- Immediate arrangements should be made for repair or replacement of critical human tissue related equipment. Relevant checks of correct operation should be made and documented before repaired equipment is returned to use.

4.5.2 Failure of other Equipment

Failure of equipment not considered to be critical to the integrity of human tissue (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).

4.6 Adverse Events

Equipment-related adverse events should be reported in accordance with *HTA-11-SOP-Adverse Event Reporting*. 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). WHO, Geneva, Switzerland (2009) 28 pp. ISBN 978 92 4 159785 2 [DOI: 10.2471/TDR.09.978-924-1597852]
HTA Code of Practice A: Guiding Principles and the Fundamental Principle of Consent
https://www.hta.gov.uk/sites/default/files/files/HTA%20Code%20A.pdf

HTA Code of Practice E: Research; Code of Practice and Standards
https://www.hta.gov.uk/sites/default/files/Code%20E.pdf

## 6. Risk Assessment

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

## 7. Definitions

**Chief Investigator (CI)** – The individual who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the Chief Investigator takes responsibility for the

design, management and reporting of the study, co-ordinating the investigators who take the lead at each site.

**Designated Individual (DI) –** The person who is authorised and who supervises activities under a licence issued by the Human Tissue Authority.

**Human Tissue –** Any and all constituent parts of the human body formed by cells.

**Human Tissue Authority (HTA) –** The governing body set up to regulate activities that come under the HT Act. The HTA is a watchdog that supports public confidence by licensing organisations that store and use human tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions.

**Person Designate (PD) –** A person to whom the licence applies and to whom the authority conferred by the licence extends. Each School operating under an HTA Licence should have at least one Person Designate.

**Principal Investigator (PI) –** is the appropriately qualified individual at each project site who has responsibility for the conduct of the project at that site.

**Standard Operating Procedure (SOP)** – Detailed, written instructions to achieve uniformity of performance of a specific function.

**Validation** – the act of providing objective evidence that any procedure, process, equipment, material, activity or system actually leads to the expected result.