Human Samples in Research Standard Operating Procedure 4
Storage

Version:	2.1	Effective Date:	24/02/2024
Issue Date:	30/06/2023	Review Date:	14/07/2025
Author:	Professor Geraldine Hartshorne, Designated Individual (Research License)		
Review Lead:	Mathew Gane, Research Governance & QA Manager, Research & Impact Services (R&IS)		
Reviewers:	Professor Geraldine Hartshorne, Carole Harris, Mathew Gane, Dale Topley, Dr Natasha Kriznik		
Approved by:	Human Samples Steering Group (HSSG) / Professor Geraldine Hartshorne, Human Tissue Designated Individual (DI) – Research License		

Contents

1. Purpose and scope 4
2. Background 4
3. Responsibilities 4
4 Policies 5
5. Procedures 6
5.1 Risk assessments of stored material 6
5.2 Consent 6
5.3 Storage facilities 6
5.3.1 Management of the storage facilities 6
5.3.2 Storage units 7
5.3.3 Monitoring of storage units 7
5.3.4 Storage unit labelling 8
5.3.5 Security of storage facilities 8
5.3.6 Sample labelling 9
5.3.7 Sample tray numbering and labelling 9
5.3.7 Use of chemicals 9
5.3.8 Equipment maintenance, cleaning and decontamination 10
5.3.9 Equipment monitoring 10
5.3.10 Equipment failure 10
5.4 Sample Register 10
5.5 Temporary storage 11
5.6 Disposal 11

6. Training 11
7. Advice and guidance 11
8. Monitoring and audit 12
List of Abbreviations 12
Templates/Associated Documents 12
Storage Unit Labelling 13
Sample Tray Labelling 16

Revision Chronology:	Effective date:	Reason for change:
HSR SOP 4_V1.02	13 December 2010	Clarification of University policy – QMS applies to all human samples. Creation of the role of Administrative Officer, Deputy DI and changes to the role of PD. Reorganisation of Biological Sciences to form the School of Life Sciences. Additional data fields in *Tissue Register.* Requirement for patient data confidentiality in storage records.
HSR SOP 4_V1.03	10 January 2012	Changes in staff, room numbers and external links.
HSR SOP 4_V1.04	25 February 2015	Changes to University governance structures relating to human samples.
HSR SOP 4_V2.0	14 July 2023	Various updates including changes made for clarity, accuracy and readability, removed sections duplicated in each SOP (to be included in Quality Manual), added reference to University's agreed three-tier 'risk-based' approach, links to HTA guidance updated as appropriate.
HSR SOP 4_V2.1	24 February 2024	Links updated

NOTE*:* SOPs will be reviewed on a 2-yearly schedule.

The definitive version of this SOP is available here: https://warwick.ac.uk/services/ris/research-compliance/human-tissue/hereatwarwick/sop/

Printed copies are outside the document control system. Ensure you are using the most up to date version.

Storage

1. Purpose and scope

The purpose of this Standard Operating Procedure (SOP) is to ensure that all staff and students understand the requirements and procedures for the storage of human samples, covered by the Human Tissue Act 2004 (HT Act), the Human Tissue Authority's (HTA) Codes of Practice, the University's HTA licence for research and the University's Quality Management System for the governance, storage, use and disposal of human samples for research.

2. Background

This SOP forms part of the University's Human Samples in Research Quality Management System (QMS). All research involving human samples at the University of Warwick must comply with this Quality Management System.

The University requires that all human samples defined as relevant material by the HTA and held at the University for Research shall meet the standards of quality management set out in its standard operating procedures. For the avoidance of doubt, this includes any cellular human material, regardless of whether it has current REC approval, unless it is a cell line that has been passaged at least three times. A risk-based approach will be applied.

This SOP has been produced in accordance with the HT Act which came in to force on 1 September 2006, and should be read in conjunction with the HTA's *Codes of Practice*, available at: https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation.

3. Responsibilities

The Registrar (as the Licence Holder's Representative) and the Designated Individual (DI) are responsible for ensuring that appropriate procedures are in place, and that staff and students involved in research using human samples are appropriately trained. The DI should ensure that facilities for storage are suitable and properly maintained and that procedures allow for traceability of human samples.

The Principal Investigator, as custodian of the samples, or their appropriately trained delegate, is responsible for following the appropriate procedures, attending training and updating, and ensuring that they and members of their team comply with the University's Human Samples in Research Quality Management System. They are responsible for the record keeping by their team and for ensuring the safekeeping of all human samples within their laboratory. If they elect not to use the core HTA storage facilities for HTA-relevant material, they are responsible for ensuring that their laboratory's own storage facilities meet HTA requirements. PIs remain responsible for samples and for providing contact details and responding to call outs in the event of incidents or equipment failure.

Individual researchers are responsible for accurate and up to date record keeping and for ensuring that all human samples in their care are stored appropriately and uniquely labelled with full traceability, following procedures in this SOP.

Persons Designated (PD) are responsible for ensuring that the centralised HTA storage facilities are monitored and managed appropriately and for advising others about safe storage practices according to the SOPs. PDs also respond to incidents and storage equipment failure as notified by the auto-alert system on a best-efforts basis, and contact relevant PIs as necessary.

Heads of Department are responsible for ensuring that members of their department comply with the SOPs for working with human material.

The Human Samples Steering Group (HSSG) is responsible for reviewing all SOPs and overseeing their suitability for the purpose. Substantial amendments to existing SOPs, the creation of new SOPs and changes to the Quality Management System will require approval by the HSSG.

4 Policies

4.1 Materials in storage will be handled according to the University's Quality Management System for human samples in research. Materials will be managed according to a 3-tier system (LINK TO DOCUMENT REQUIRED HERE) with material considered relevant by HTA in Tier 1 (https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004) and human-derived material such as serum, in Tier 2. Tier 3 comprises established human cell lines and non-relevant materials such as DNA and breath, which are outside this quality management system.

4.2 In line with HTA guidance, imported tissue will be treated in the same way as tissue originating from participants in England, Wales and Northern Ireland (and the same exceptions to licensing apply).

4.3 All human material must be stored in such a way as to ensure the integrity, security and traceability of the material, and to minimise the risk of contamination and protect the health and safety of individuals handling the material.

4.4 All those involved in the acquisition, storage, use and disposal of human samples must be appropriately trained (HSR SOP 7 Training) and demonstrate due care and respect for human samples at all times. Staff must use suitable protective clothing, material and equipment in keeping with laboratory and Health and Safety requirements.

4.5 Where practical, human samples should be stored separately from other biological samples used for research. The research facilities and laboratories where human samples are being stored and used must be secure, clean, well maintained and subject to a programme of planned preventative maintenance.

4.6 Most human material is stored in -80°C freezers or liquid nitrogen, as the most readily controlled environments to support tissue integrity in long term storage. -80 and liquid nitrogen facilities will be provided for storage of human material as a central facility, where possible. Other conditions of storage, if required for particular cell types, will not normally be provided as a central facility and monitoring will be the responsibility of the Principal Investigator. Units at -20oC or +4oC may be used for short term storage.

4.7 Persons Designated should be appointed for each department active in human tissue storage, to assist with ensuring that this SOP is followed.

5. Procedures

5.1 Risk assessments of stored material

Risk assessments must be undertaken on all human samples stored at the University of Warwick, and logged on a biological risk assessment form that has been assessed by the University's Genetic Modification and Biosafety Committee (GMBSC) to determine:

- Nature of the material;
- Significant biological hazards;
- Location of proposed work;
- Personnel at risk;
- Protocols employed;
- Handling requirements;
- Training requirements;
- Rendering material safe;
- Disposal of material;
- Decontamination of equipment or personnel;
- Storage of material;
- Emergency provisions;
- Vaccination recommendations.

5.2 Consent

Appropriate consent must be in place for all human material stored at the University of Warwick, in accordance with HSR SOP 2 Consent.

5.3 Storage facilities

5.3.1 Management of the storage facilities

Management of the storage facilities at the hub site (Clinical Sciences Research Laboratories, CSRL) is the responsibility of the Technical Manager, CSRL.

Management of the storage facilities at the satellite site (Gibbet Hill and Main Campus) is the responsibility of the Technical Facility and Services Managers of the relevant department where storage is taking place.

Most human material at the satellite site is used by The School of Life Sciences (SLS) and Warwick Medical School (WMS). SLS and WMS have a joint laboratory management team. Management of SLS and WMS facilities is in accordance with the SOP "Management of -80°C freezer facilities within SLS and WMS" (https://warwick.ac.uk/fac/sci/lifesci/intranet/staffpg/support/safety/sops/generalsops/sop_slswms028_management_of_minus_80c_freezers_v2_may_2020.pdf).

PIs storing human material in other departments will be responsible for maintaining appropriate facilities and monitoring them in accordance with this SOP, with assistance from the Persons Designated.

Planned preventative maintenance should be undertaken on a regular basis, for example, to ensure that filters are cleaned and servicing is conducted. Records should be kept.

The DI will visit all storage facilities across different departments of the University periodically to check their suitability.

5.3.2 Storage units

All human samples must be stored in appropriate storage units which must be lockable and labelled clearly. If a lock is not integral to the unit, a padlock must be used. Storage units containing human samples must remain locked at all times when samples are not being used. Storage units available include:

- Cabinet/cupboard at room temperature e.g. for paraffin blocks; microscope slides/sections;
- Refrigerator at +4°C;
- Freezer at -20°C;
- Freezer at -40°C;
- Freezer at -80°C;
- Liquid nitrogen dewar at -196°C.

All storage units containing human tissue must be logged on the Sample Storage Units Log, with the following data recorded:

- Description (e.g. -80°C freezer);
- Location (room number and bay number, where applicable)
- Manufacturer (e.g. manufacturer – Sanyo);
- Model number (e.g. MDF-U74V);
- Serial number (e.g. 50100620);
- Lead Investigator, Person Responsible, Technical Support or DI.

5.3.3 Monitoring of storage units

All storage units containing human tissue should be monitored on a regular basis to ensure the appropriate storage conditions are maintained. The frequency of monitoring will depend upon the nature of the material in storage, the type of storage unit and the temperature required. Some materials are more resilient to temperature variations than others, and some materials are more easily replaceable than others in the event of deterioration. The PI is responsible for ensuring that monitoring is appropriate for their human samples.

The centrally provided -80 freezers and liquid nitrogen facilities are monitored automatically using a 'Britannia' alarm system which sends a text alert in the event of temperature deviation beyond set tolerances (see HSR SOP 5 Adverse Events and (https://warwick.ac.uk/fac/sci/lifesci/intranet/staffpg/support/safety/sops/generalsops/sop_slswms028_management_of_minus_80c_freezers_v2_may_2020.pdf). Text alerts are monitored by the technical services staff who are alerted in the event of temperature deviations. In the event of an emergency, technical staff will contact the PI using the phone number on the storage unit.

PIs are responsible for monitoring their own equipment, which may be done manually on a daily basis, or using electronic monitoring systems which generate alerts. Records should be kept.

5.3.4 Storage unit labelling

All storage units used for human samples must be clearly labelled in accordance with the instructions given in Appendix 1.

There are three types of storage units for human samples:

- Units containing material used on active research projects – all materials have appropriate consent and ethical approval, and are being used on projects that are currently active.
- Units containing material held under licence – material not being used on any active project, or without current ethical approval.
- Emergency freezers – for use in the event of another freezer malfunctioning.

5.3.5 Security of storage facilities

Storage units containing human samples must be lockable and located in rooms within buildings that are access-controlled and accessible only to University-authorised personnel. University card-controlled access must be in operation to enter the building and the storage of human samples held under licence must be held in locked storage units.

The emergency freezers will remain unlocked whilst on stand-by to be available to receive samples from another freezer due to a malfunction or other serious adverse event at any time. Once human samples have been transferred to an emergency freezer, it will be locked. For further information on the procedures in the event of a freezer malfunction or other incident, see HSR SOP 5 Adverse Events.

Storage units may be lockable using keys, padlocks or coded locks.

Keys or key-codes for storage units containing human samples will be held as follows:

At the Hub site (CSRL), the key safe is attached to the large dewar and opens on a code which is shared only with those working on HTA material:

Storage	Key safe in freezer room 00096	Lead Investigator
Emergency	✓	
Material under licence	✓	
Material used on active research projects	✓	✓

At the Satellite site:

Storage	PD's Office	Lead Investigator

Emergency	✓	
Material under licence	✓	
Material used on active research projects	✓	✓

For samples used on active research projects, the Lead Investigator or Person Responsible, will keep a copy of the storage unit key securely in their office or laboratory and take responsibility for access to the samples by their research team, as appropriate.

5.3.6 Sample labelling

In line with HTA standards, all human samples (and any sub-samples or aliquots) must be uniquely identifiable to ensure traceability. The identification coding must not contain patient or donor identification. Each code must be robustly secured to the sample container, be clearly readable, and appropriate to the storage conditions under which it will be held.

5.3.7 Sample tray numbering and labelling

All individual, uniquely identifiable human samples must be stored in an orderly and consistent manner in all storage units, and be easy to locate. Individual samples should be grouped in trays to ensure they are not loose and could be damaged when removed from their storage unit. A rack must be assigned a number.

Where appropriate to do so, samples not held under the University's HTA Licence, such as those in Tier 2) may be stored as a collection of similar samples and be recorded on the Sample Register under a single entry.

For samples held specifically under the University's HTA Licence, the following system is suggested for recording the location of each sample within a tray (sample position number):

Rack rows: A-Z (alphabetic)

Rack columns: 1-100 (numeric)

Numbering could start at the back of a tray, running left-to-right (an example of a 96-sample tray is given in Appendix 2).

5.3.7 Use of chemicals

All use of human materials is subject to the University's safety requirements (https://warwick.ac.uk/services/healthsafetywellbeing) including those for chemical handling. For example, formaldehyde may sometimes be used for fixation of human samples. Control of Substances Hazardous to Health (COSHH) (see http://www.hse.gov.uk/coshh/index.htm) requires exposure to formaldehyde to be minimised and below the maximum exposure limit (2ppm). The area must therefore be adequately ventilated to control exposure. This may include monitoring of levels and continuously operating extract ventilation.

5.3.8 Equipment maintenance, cleaning and decontamination

Calibration and maintenance of storage units must be in line with the manufacturer's guidance. Records of calibration, monitoring of storage conditions and maintenance will be kept at both the hub and satellite sites. The Technical Manager Technical Services and Facilities Managers at the hub and satellite sites will be responsible for ensuring these records are accurate, complete and up-to-date, and available for inspection as required.

5.3.9 Equipment monitoring

Freezers at -80°C, liquid nitrogen dewars, and certain freezers at -40oC and -20°C used for the storage of human samples have independent alarm systems supplied by Britannia Alarms. These alarms are separate from built-in alarms. They function by wireless transmitters to alert the technical staff by text to establish a response.

The freezers at -80°C and -40°C and the liquid nitrogen dewars and room temperature cupboards are located in rooms with controlled and monitored air conditioning maintaining an average room temperature of 20°C. The Britannia Alarm system triggers emergency alert texts when:

- room temperature has risen to 35°C;
- any -80°C freezer's temperature has risen to -65°C;
- any -40°C freezer's temperature has risen to -30°C;

The temperature in each freezer is monitored every 15 minutes and the emergency alarms have a 45-minute delay. Alarms are triggered only if three consecutive readings are recorded above the set temperature limit.

5.3.10 Equipment failure

Incidents potentially affecting storage, such as equipment failure, power failure, are presented in HSR SOP 5 Adverse Events.

5.4 Sample Register

An electronic version of the Sample Register is held centrally and securely, under the overall management of the DI. It is the responsibility of the Lead Researcher or their appropriately trained delegate to ensure that all human samples are logged on the Sample Register by notifying the DI at hta@warwick.ac.uk and that sample records remain accurate and up-to-date.

During the course of a research project, it is the responsibility of the Lead Researcher or their appropriately trained delegate to ensure appropriate laboratory records are kept of the use of and any processing of the samples and that the Sample Register is updated when samples are disposed of, and that the records in the Sample Register are updated at the end of the project.

Samples and their records in the Sample Register will be subject to review and audit (as described in the HSR SOP 8 Audit).

Recorded data held on the PI's log and the Sample Register should include:

- Sample unique identifier code (but NO patient identifiable data)
- Sample location (freezer, shelf and/or rack number);
- Sample type;
- Amount of sample when acquired (wt/vol);
- Name of Lead Investigator;
- Supplying individual or organisation;
- Import reference number;
- MTA reference number;
- Ethical approval reference number;
- Date of import;
- Date of export/transfer or disposal.

Where appropriate to do so, samples not held under the University's HTA Licence may be stored as a collection of similar samples and be recorded on the Sample Register under a single entry.

Any material without appropriate ethical approval and legal agreements in place can only be held under the University's HTA licence, in the designated, secure storage facilities, and will be the responsibility of and managed by the DI with assistance from the PDs. No other individuals will be allowed to access or use the samples until all appropriate documentary evidence has been approved by the DI. The documentation required is explained in HSR SOP 3 Acquisition and Transfer.

5.5 Temporary storage

Under the HT Act, where human material is in storage pending transfer elsewhere, providing it is held for a matter of hours or days and certainly **no longer than a week**, then storage is considered incidental to transportation and the samples do not need to be held under licence.

Where human samples are held whilst being processed with the intention to extract DNA or RNA, or other sub-cellular components that are not relevant material (i.e. rendering the tissue acellular), the HTA views this as analogous to the incidental transportation exception above. Such samples do not need to be held under licence, providing that no sample is stored for longer than a week prior to processing.

5.6 Disposal

When a research project is finished, human samples may only be kept if there is consent to do so, or the samples are existing holdings (collected before 1 September 2006). All other samples should be disposed of in accordance with the original Materials Transfer Agreement and/or HSR SOP 6 Disposal.

6. Training

All those involved in research involving human samples are required to read this SOP and to understand how the storage requirements relate to their research.

7. Advice and guidance

Further advice on the storage of samples for the purposes of research and the provisions of this SOP may be sought from the DI. The DI may seek advice directly from the HTA when appropriate.

8. Monitoring and audit

Regular monitoring of the effectiveness of the implementation of this SOP will be undertaken by the DI and/or others nominated by the DI. In addition, audits may be undertaken by the DI, the University's Internal Audit Service or the HTA, in accordance with HSR SOP 8 Audit.

List of Abbreviations

HTA	Human Tissue Authority
HT Act	Human Tissue Act 2004
DI	Designated Individual
HSSG	Human Samples Steering Group
PD	Persons Designated
PI	Principal Investigator
R&IS	Research & Impact Services
SOP	Standard Operating Procedure

Templates/Associated Documents

Appendix 1: Storage Unit Labelling
Appendix 2: Sample Tray Labelling

Appendix 1

Storage Unit Labelling

All storage units used for human material must be labelled clearly in accordance with the following instructions:

1 Labels for all storage units containing human material will be typed on card, laminated and fixed to the outside front face of the storage unit in the top left hand corner, affixed with Velcro pads.

2 All storage units will have an identifier number on the front in the top left-hand corner, for example:

Freezer 25

3 Storage units containing human samples that are being used on active research projects will be clearly identified as such, for example:

Contains human samples

To be kept locked

4 In addition, storage units containing human samples that are being used on active research projects sign will also have the contact details of the lead investigator on the project, for example:

Contact in event of malfunction

Professor A N Other:

Contact number: ……..

5 Storage units containing relevant material that is held under the University's HTA Licence will contain the following information:

Contains human samples

There is NO access to samples in this freezer
Please direct all enquiries to the
Designated Individual (Professor Geraldine Hartshorne)

In the event of a malfunction, please contact:

- **Technical Manager (mobile phone no)**
- **Designated Individual – Geraldine Hartshorne (07973 802528)**

6 Emergency freezers to be used in the event of a freezer malfunctioning will have the following information displayed:

Emergency Freezer

Not for general use

In the event of a malfunction, please contact:

- **Technical Manager (mobile phone no)**
- **Designated Individual – Geraldine Hartshorne (07973 802528)**

7 If the handling of human samples requires the user to wear gloves for protection and to avoid contamination of the samples, the following sign must be affixed to the outside of the storage unit;

8 If the handling of human samples may cause a user to be at risk then the following warning sign should be placed on the front of the freezer. Each risk should be individually assessed and if necessary a gloves required sign also affixed. (see point 7)

9 It is the responsibility of the Science and Technical Services Managers at the hub and satellite sites to ensure that the labelling on all storage units used for human samples is accurate and up-to-date (including any contact names and numbers in the event of an emergency or Serious Adverse Event), and agrees with the details held on Sample Register, as appropriate.

Appendix 2

Sample Tray Labelling

Example of a 96-sample tray suitable for 2ml and 8ml tubes:

Back of Tray

A1	A2	A3	A4	A5	A6	A7	A8	A9	A10
B1	B2	B3	B4	B5	B6	B7	B8	B9	B10
C 1	C2	C3	C4	C5	C6	C7	C8	C9	C10
D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
	E2	E3	E4	E5	E6	E7	E8	E9	
	F2	F3	F4	F5	F6	F7	F8	F9	
G1	G2	G3	G4	G5	G6	G7	G8	G9	G10
H1	H2	H3	H4	H5	H6	H7	H8	H9	H10

I1	I2	I3	I4	I5	I6	I7	I8	I9	I10
J1	J2	J3	J4	J5	J6	J7	J8	J9	J10

Front of tray – labelled with freezer number, shelf number, and tray number