Human Tissue in Research

SOP – Risk Management

1. Purpose

Risk management is a process of systematically identifying potential risks and the subsequent implementation of measures to minimise risk and plan suitable contingency arrangements.

The purpose of this Standard Operating Procedure (SOP) is to set out the processes and procedures for risk assessment (RA) and contingency planning where human tissue considered relevant material is collected, stored, used or disposed of for research.

For compliance with the Human Tissue Act (HT Act) and the Human Tissue Authority (HTA), all practices and processes relating to human tissue research require documented risk assessment.

2. Scope

This SOP applies to all Swansea University (SU) staff and students involved in research projects intending to use any type of human sample considered relevant under the HT Act. However, the procedure detailed here should also be applied to non-relevant material as best practice.

The HTA requires that all critical processes involving relevant material, including consent, transportation, use, storage, traceability and disposal, including before the activity commences.

RAs should include the risks relating to the premises, practices and procedures connected with HTA Standards, including:

- Receiving and/or storing specimens without appropriate consent
- Storing or using human tissue after consent withdrawal
- Storage failure or other damage affecting human tissue quality for useful research
- Loss of human tissue
- Sample mix-up or loss of traceability
- Transport of specimens to and from the establishment
- Security arrangements
- Incorrect disposal

3. Responsibilities

The HTA requires that the Designated Individual (DI) be responsible for ensuring that appropriate procedures and practices are in place for the management of risk related to the use of human tissue in research and that these processes are adhered to.

The Person(s) Designated (PD) carries the role of directing others undertaking research which falls under the HT Act. As part of this role, they should assist the DI in implementing CORE SOPs to ensure compliance with the HT Act and HTA licensing requirements.

It is the responsibility of the Principal Investigator/Chief Investigator (PI/CI) of each research project to ensure that risks related to their research and tissue use are assessed and reviewed. PI/CIs, individual researchers and research groups should ensure they hold copies of all local RAs and contingency plans related to human tissue and ensure that they are regularly reviewed and available for internal audit and HTA inspections.

The HTA Compliance Manager (HTCM) is responsible for ensuring that this SOP remains fit for purpose.

4. Procedure

HTA-RA for compliance with the HTA Codes of Practice, refers to the risk associated with adhering to the HTA standards rather than risks to researchers/handlers.

Therefore, when carrying out the project-specific HTA-RA first focus on identifying and minimising the risks to the integrity of tissue and respect for the donor. The health and safety of handlers is a secondary focus, as RAs for health and safety should already be in place for usually laboratory activity.

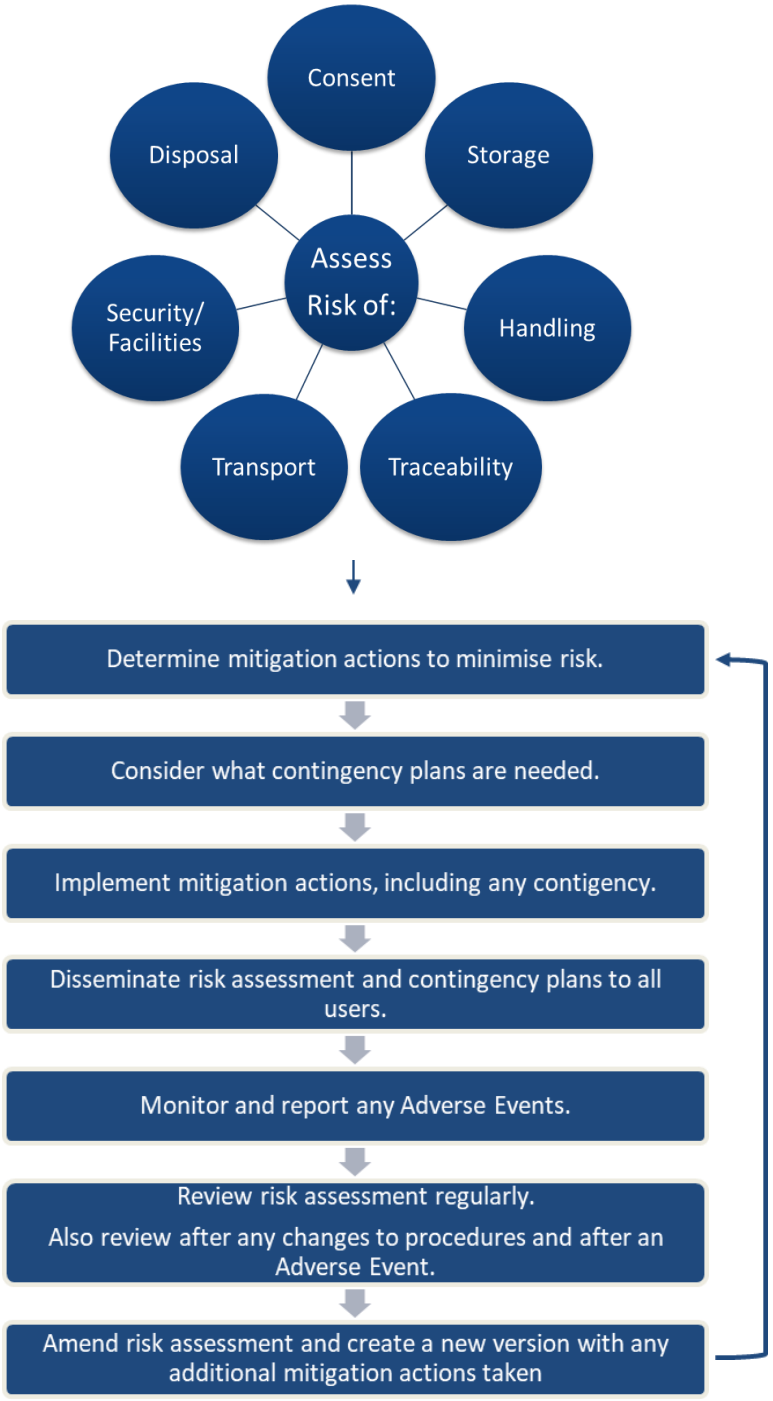
Any SOPs involving laboratory safety (e.g. chemicals or equipment) should have a separate assessment of risk that complies with the university's laboratory safety policies. Information on laboratory safety, training and RA templates can be found here.

A HTA-RA relating to human tissue research must be completed for each practice and process involving relevant material, including consent, transportation, use, storage, traceability and disposal before the activity commences.

4.1. Human Tissue Risk Assessment Template

Download and amend the HTA-Template-Risk Assessment from SU Human Tissue Governance-UsrGrp | Microsoft Teams.

The template has been prefilled with common risks for a variety of different studies/facilities but must be adapted to your study/collection and local procedures. You should link RA mitigations to SOPs whenever appropriate.



4.2. When should the risk assessment be reviewed?

All risk assessments must be part of a routine review schedule. The planned date should be recorded on the risk assessment as every 12 months. However, for studies with static procedures and no long-term tissue storage a maximum review period of three years would be acceptable.

In addition to routine review, risk assessments must be reviewed following any of the occurrences below:

- An adverse event or near miss
- Shortfalls identified during an audit (internal or external)
- Change in procedure or legislation
- Restructuring of the department

4.3. Contingency Plans

4.3.1. Development and review of contingency plans

Contingency planning is required to limit the extent of the risk arising from an adverse event or emergency and to regain control of the area as quickly as possible. For example, all sample storage units storing relevant material must have a contingency plan.

You can download and amend a Contingency Plan Template from SU Human Tissue Governance-UsrGrp | Microsoft Teams.

Approved HTA storage unit signs, available to download from the Human Tissue Governance Teams channel, include a QR code that links directly to the teams group where all members can access the shared folder HT Contingency Plans.

The contingency plan must be communicated to all staff and students who use the area, not just those directly involved with the project.

All staff and students storing human tissue under the HTA licence must ensure that the latest version of their contingency plan is uploaded to the correct subfolder corresponding to their building and laboratory room.

This system allows anyone working in the lab to scan the QR code on the storage unit and instantly access the relevant contingency plans and contact details for responsible individuals. This ensures that up-to-date contingency information is always available in the event of a storage failure, in line with HTA licensing standards.

4.3.2. Temporary Storage in dedicated Contingency Units

When samples are transferred to a contingency storage unit, the unit must be clearly labelled with details of the transfer. All dedicated contingency storage units are equipped with laminated HTA Storage Signs, which include dedicated sections to record:

- The original storage location (building, room, unit ID)
- Date of transfer
- Principal Investigator (PI) details
- New sample location within the contingency unit

A permanent marker is attached to each sign to enable immediate completion of these details at the time of transfer. This ensures compliance with HTA requirements for traceability and accurate labelling during contingency arrangements.

Maps showing the Location of all Contingency ULT Freezers & Cold Rooms are available in the Contingency Plan folder within the SU Human Tissue Governance Teams group.

For other types of contingency storage (e.g. LN_2 dewars, temporary cupboards or drawers), researchers must arrange suitable space within their facility. The HTCM can provide laminated approved HTA signs (with Velcro strips) to label these contingency units and will advise on compliance expectations.

4.4 Recording an Adverse Event (HTA Relevant Material Only)

Following the failure of the storage unit used to store relevant material or any instance where tissue integrity is compromised, the PI/CI or another responsible individual must submit an Adverse Event Form in line with the Core HTA-SOP-Adverse Event Reporting.

5. Risk Assessment

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

5. 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.

6. Document History

Document History				
Version	**Review Date**	**Comment**	**Replaces**	**Reviewed by**
2.0	21/09/2015	Updated front page and footers. Updated links. Removal of template risk assessment and contingency plan to standalone documents	1.0	Lisa Wakeman
3.0	01/09/2016	Post-licence grant review, amendment from acting designated individual reference; minor text amendments	2.0	Lisa Wakeman
4.0	18/04/2018	Amendments to reflect revised HTA Codes of Practice and Standards	3.0	Lisa Wakeman
5.0	08/02/2024	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	12/01/2026	Clarified labelling requirements for contingency storage units, referencing new approved HTA freezer signs with QR code and writable fields. Updated guidance on accessing and uploading contingency plans via Teams group. Referenced to the “Location of all Contingency ULT Freezers & Cold Rooms” resource folder. Update role title to HTCM.	5.0	Bethan R Thomas & DI

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	Signature and date	Signed copy held by HTGO 12/01/2026	
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