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 and contingency planning where human tissue considered relevant material is collected, stored, used or disposed of for research.

For compliance with the HT Act and the HTA Codes of Practice, 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 Human Tissue Authority (HTA) requires that all critical processes involving relevant material, including consent, transportation, use, storage, traceability and disposal, including before the activity commences.

Risk assessments (RA) 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 Human Tissue Act 2004 (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 (PI) of each research project to ensure that risks related to their research and tissue use are assessed and reviewed. PIs, 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 Governance Officer (HTGO) is responsible for ensuring that this SOP remains fit for purpose.

4. Procedure

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.

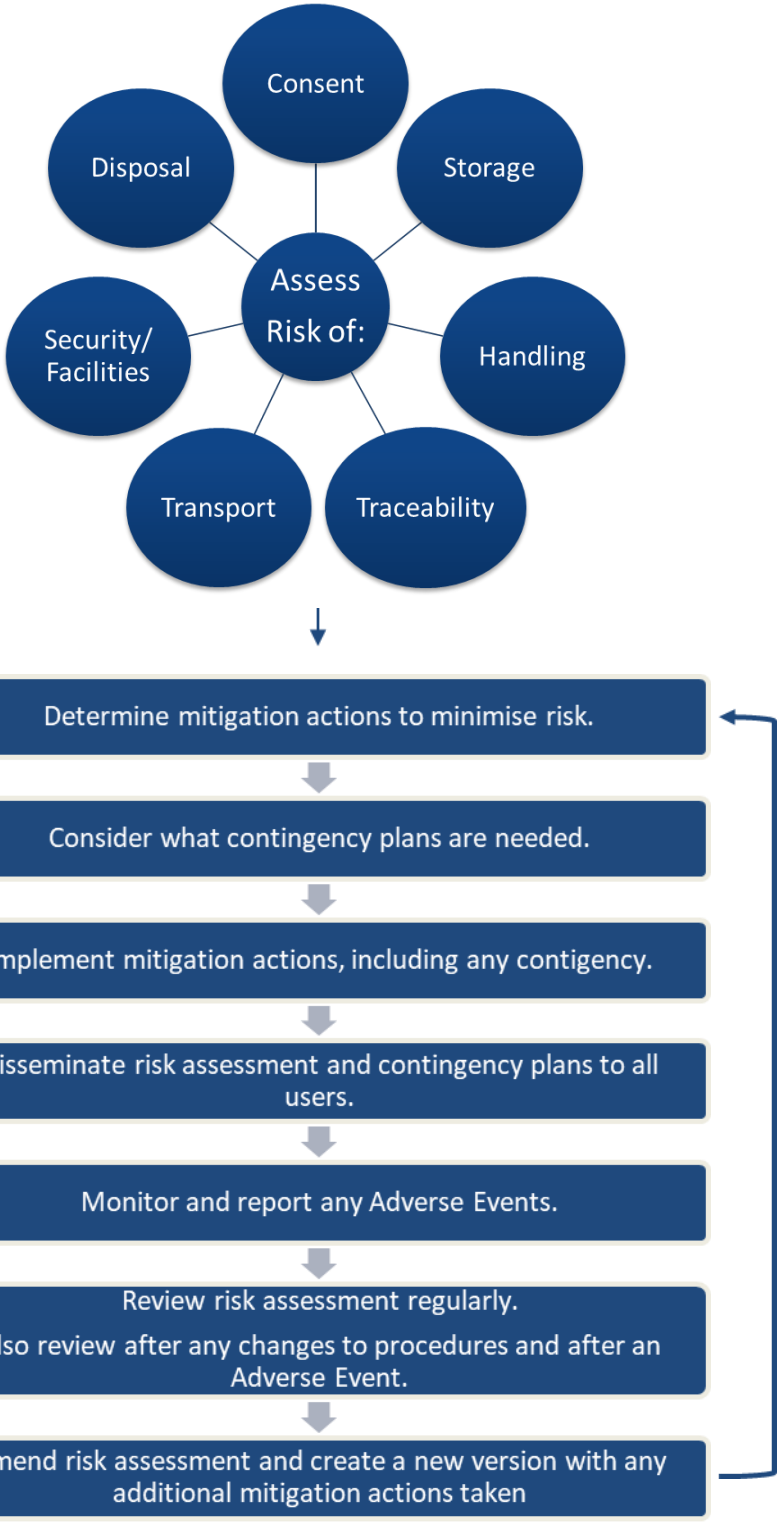
Therefore, when carrying out the project-specific RA focus on identifying and minimising the risks to the integrity of tissue and respect for the donor first. The health and safety of handlers is a secondary focus, as RAs for health and safety should already be in place for usually laboratory activity.

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 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

A HTA-Template-Risk Assessment can be downloaded from the 'HTA Forms and Templates' webpage on SU's website. The template will need to be adapted to your study/collection and local procedures. You should link RA mitigations to SOPs whenever appropriate.


Consent
Disposal
Storage
Assess Risk of:
Security/ Facilities
Handling
Transport
Traceability
Determine mitigation actions to minimise risk.
Consider what contingency plans are needed.
Implement mitigation actions, including any contigency.
Disseminate risk assessment and contingency plans to all users.
Monitor and report any Adverse Events.
Review risk assessment regularly.
Also review after any changes to procedures and after an Adverse Event.
Amend risk assessment and create a new version with any additional mitigation actions taken

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. The review period should ideally be one year and a maximum of three years.

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

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

4.3. 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 require a contingency plan.

You can download and amend a Contingency Plan Template from SU's website.

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

It is recommended where possible that QR codes are used to avoid affixing large printed documents to storage units making them visually unclear. QR codes will allow SU staff/students to access contingency plans securely saved to OneDrive ensuring the most up-to-date version is available. Refer to HTA-SOP-QR code labels.

When the samples have been transferred to the continency unit, the temporary storage must be labelled with details of where the samples came from, the date of transfer, PI details and where the samples are now stored within the contingency freezer.

An example temporary storage label is shown below:

HUMAN TISSUE

Human Tissue relocated from [insert fridge/freezer location and ID]

Date of transfer:

Name of Principal Investigator:

The temporary storage of tissues are located on shelves: XXX

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 Principal Investigator / or another responsible individual must submit an adverse event report 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

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