Human Tissue in Research

HTA-CORE-SOP-Adverse Event Reporting

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure that all staff and students understand what constitutes a human tissue-related adverse event and are aware of the requirements and mechanisms for reporting adverse events (AE).

A key part of quality management is a robust system for reporting and investigating AE. The Human Tissue Act (HT Act) and Human Tissue Authority (HTA) require evidence of the licensed organization's internal systems to identify and manage events and this is mandatory for compliance with licensing requirements.

2. Scope

This SOP applies to adverse events related to human tissue in research, resulting in non-compliance with the HT ActCodes of Practice only.

Any AE that results in a health and safety incident/accident, such as chemical spills or equipment failure, should be reported separately using Swansea University's (SUs) adverse event reporting system, Report It!

3. Roles and Responsibilities

All staff and students who become aware of an incident affecting the integrity of human tissue samples have a responsibility to report and investigate it in the manner described in this SOP.

The Designated Individual (DI) has a responsibility to implement and maintain a system of AE reporting and monitoring which improves quality standards and oversees the management of individual incidents to closure.

The Person(s) Designate (PD) has a responsibility for supporting and overseeing the implementation of measures to address deficiencies identified within their area.

The Chief Investigator (CI) / Principal Investigator (PI) is responsible for ensuring that risk assessments are carried out for their studies to minimise the likelihood of an AE occurring. They are then responsible for submitting an AE report if an AE occurs, following the process described herein.

The Human Tissue Compliance Manager (HTCM) is responsible for maintaining a log of all submitted AEs and ensuring this SOP remains fit for purpose.

4. Procedure

AEs are defined as either an accident or an incident:

Adverse Event (AE)	
Accident:	
An event that results in non-compliance with the HT Act and HTA Codes of Practice.	
Incident:	
Near miss	An event that does not result in non-compliance but has the potential.
Undesired circumstance	A set of conditions or circumstances that have the potential for non-compliance e.g. untrained staff/student handling human tissue.

4.1 Identification of Adverse Event

To be able to identify an AE, all staff and students working with, or responsible for, human tissue should familiarise themselves with the table below. Further guidance can be obtained from the HTCM or the DI.

Examples of Adverse Events with their associated shortfall category		
Type of AE	**Examples of AEs**	**AE Category**
Consent:	Human tissue is removed from a patient/participant without appropriate and valid consent.	**Serious**
	Consent sought/obtained by an individual without appropriate training.	**Serious**
	Human tissue is used for purposes not consented to.	**Serious**
	Human tissue is used for purposes not consented to. Consent for use of human tissue not filed/retained correctly.	**Moderate**
	No evidence of consent was sought from third-party providers.	**Moderate**
	Temporarily misplaced consent record.	**Minor**
Governance & Quality	Human tissue used or stored outside the governance of a Research Ethics Committee (REC) approved study.	**Serious**
	Breach of data protection or confidentiality.	**Serious**
	Loss of sample/participant records.	**Serious**
	Material transferred without appropriate review, authorisation or documentation (MTA/contract).	**Moderate**

	Labelling errors that lead to the incorrect use of samples.	**Moderate**
	Incorrect version of SOP/Consent/PIS in use.	**Minor**
	No evidence of regular SOPs and RAs review.	**Minor**
Traceability	Non-recoverable loss of unique relevant material during transfer of samples from one location to another.	**Serious**
	Incorrect tissue type stored/transferred/used	**Serious**
	Loss/compromise of relevant material and/or patient records during transportation.	**Serious**
	Unlabelled / Miss-labelled material.	**Moderate**
	Sample location/log discrepancy.	**Moderate**
	Samples imported from outside UK without approval.	**Moderate**
	Accidental compromise to relevant material during transport.	**Moderate**
	Inappropriate disposal of human samples.	**Moderate**
	Records of disposal of human tissue are absent, not retained or incomplete.	**Moderate**
	Temporarily misplaced transfer records.	**Minor**
Premises, Facilities & Equipment	Non-recoverable loss of unique relevant material through freezer/alarm failure.	**Serious**
	Unpredictable storage unit failure resulting in compromise to tissue integrity.	**Moderate**

	Unauthorised access to storage facilities resulting in tissue loss or compromise.	**Moderate**
	Incorrect storage conditions/units for sample type compromising tissue integrity.	**Moderate**
	Unauthorised access to storage facilities with no resulting compromised tissue.	**Minor**
	Storage unit failure with no loss of tissue.	**Incident**

The table of AE examples is **not an exhaustive** list but should provide you with sufficient guidance to identify an AE relating to your human tissue research studies and to understand the severity with which they would be categorised.

4.2 Reporting an Adverse Event

Following an AE, the responsible **SU staff or student must inform the relevant CI/PI or local PD** and conduct a **local investigation.** The investigation should attempt to:

- Identify type of AE (e.g. Storage, Consent, Transport)
- Note immediate corrective actions already taken.
- Identify the root cause of the event, if possible
- Categorise the AE as ***Serious, Moderate, Minor or Incident (near miss)***

Following this local investigation, the **CI/PI must submit** a **Microsoft Adverse Event Form**, available via the **SU Human Tissue Governance Teams Channel** or the Swansea University **Human Tissue Act website**. Alternatively, the CI/PI may nominate a member their research team to complete the submission, however, they remain ultimately responsible for ensuring that corrective actions are completed.

- Events must be submitted **within 30 days** of occurrence.
- For **serious adverse events** related to samples held under Swansea University's HTA Licence, you must submit the AE Form **within 24 hours**.

Where a concern is raised by any other individual (e.g. participant, patient, visitor, internal/external auditor) the CI/PI or PD should ensure that an adverse event is reported on their behalf.

Once submitted, the Human Tissue Compliance Manager (HTCM) will:

1. **Review the AE** and ensure appropriate classification.
2. **Assign a reference number** (i.e. HTA-FORM-AER-ID-[Date of AE, dd-MM-yyyy)
3. **Generate a CAPA (Corrective and Preventive Action) Plan** in response to the event.
4. **Share the CAPA Document** with the submitter and the CI/PI for the study/collection.

4.3 Corrective and Preventive Action (CAPA) Plan

Upon receipt of a submitted AE Form, the HTCM will collaborate with the CI/PI or local PD to ensure completion of the CAPA Plan.

- Corrective actions are those actions that are reactive to an AE and aim to rectify the problem.
- Preventative actions are those actions that are taken to pre-empt the recurrence of the issue.

Each action will have a target date for completion and will be tracked using the live CAPA document.

The CI/PI may delegate actions to team members as appropriate but is responsible for ensuring assigned actions are completed within the defined timescales indicated in the CAPA plan.

Documented review of study/collections risk assessment(s) always form part of a CAPA plan.

- The HTCM will:
  - Work with the CI/PI and monitor completion of actions.
  - Send reminders using automated tools (e.g., Microsoft Power Automate) based on the target completion dates.
  - Use tracked changes to document modifications until all actions are signed off.

Once all actions are complete:

- The HTCM will close the CAPA.
- A signed final version will be saved securely.
- A copy will be issued to the CI/PI for study records and to be stored in the Master Site File.

If all actions are not completed **within 90 days** of the adverse event being reported, the issue will be escalated.

4.4 Oversight and Escalation:

The Designated Individual (DI) will have full oversight of submitted AE reports and associated CAPA documents via a secure, private Teams channel. This channel will be used to:

- Log all documentation
- Monitor action completion
- Facilitate governance reporting

Summaries of all human tissue-related AE and CAPA plans will be reported to Swansea University:

- **HTA Sub-Committee (licenced collections)**
- **SU Sponsorship Committee (NHS-REC approved studies)**
- **University Research Integrity: Ethics and Governance Committee (All AEs)**

5. References

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 Review History

Document History				
Version	**Review Date**	**Comment**	**Replaces**	**Reviewed by**
2.0	21.09.15	Updated header/footers and front page. Inclusion of reporting timescales; minor text amendments and removal of appendix to standalone form	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 Minor procedural amendments	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
6.0	01/12/2025	Revised Section 4.2 to mandate the use of the Microsoft Adverse Event Form for all reports. Updated CAPA process, including creation, assignment, tracking, and closure. Updated AE oversight pathways and escalation procedure for incomplete CAPA actions beyond 90 days to include relevant University governance committees.	5.0	Bethan R Thomas & DI

Author	**Name and role**	Dr Bethan Rhian Thomas Human Tissue Compliance Manager (HTCM)	
	Signature and date	Signed Copy Held with HTGO 01/12/2025	
Approver	**Name and role**	Professor Catherine Thornton Designated Individual (DI)	
	Signature and date	Signed Copy held with HTGO 1st December 2025	
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