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 Human Tissue Act 2004 (HT Act) and Human Tissue Authority (HTA) Codes 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.

Principal Investigators (PIs) are responsible for ensuring that risk assessments are carried out for their studies to minimize 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 Governance Officer (HTGO) is responsible for maintaining a log of all submitted AEs and ensuring this SOP remains fit for purpose.

4. Procedure

Adverse events 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 HTGO 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**
Consent:	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.	**Serious**
	Incorrect tissue type stored/transferred/used	**Serious**
	Loss/compromise of relevant material and/or patient records during transportation.	**Serious**
Traceability	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 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

All staff and students working with human tissue who encounter an event should liaise with their PI or local PD to generate an Adverse Event Reporting Form and submit the form to the HTGO within 30 days.

Any AEs occurring concerning collections held under SU's HTA licence must be reported to the HTGO & DI within 24 hours.

Following an AE, the PI/PD is responsible for undertaking an immediate local investigation. The investigation must attempt to:

- Identify type of AE
- 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)

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

4.2.1 Notification to Corporate Licence Holder

All AEs under the licence and categorised as serious occurring under the research HTA licence will be notified by the DI/HTGO to the representative of the corporate licence holder as soon as possible.

4.3 Corrective and Preventative Action (CAPA) Plan

Once the HTGO receives the 'Adverse Event Reporting Form' they will review the report to ensure correct classification, log the event, assign a reference and liaise with the responsible PI/PD to generate an appropriate Corrective and Preventative Action (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.

Documented review of study/collections risk assessment(s) must form part of the CAPAs.

Once a CAPA plan has been generated, the HTGO will inform the DI and summaries of all human tissue-related AE and CAPA plans will be reported to the Swansea University HTA Sub-Committee for review.

The PI/PD responsible will be required to implement the identified actions within the defined timescales indicated in the CAPA plan. This will help to avoid the recurrence of the event.

The HTGO will work with PI/PD and track the progress of the plan to closure.

Both the PI/PD and the HTGO will retain signed copies of the AE forms and CAPA plans for their records.

The HTGO will follow up no later than 3 months after the event to ascertain progress and arrange future audit dates for the study/collection.

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

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Effective Date:	01/04/2024	**Next Review Date:**	12/03/2024