	Title: Procedure for reporting adverse events and complaints	Author: G. Cockerill	Date: 2/Oct/2012
	No: SOP_R11	New Author: P. Madhou	Date: 28/April/2025
	Version: 8		Review Date March 2027

SOP_R11: PROCEDURE FOR REPORTING ADVERSE EVENTS AND COMPLAINTS

Disclaimer

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Out of date documents must not be relied upon and should be destroyed.

8	April 2025	Amended Section 3 and 4 to provide more details	PM	
7	Sept 2024	City merge. Review & formatting	AS/PM	HTLRG
6	Sept 2023	New DI, update contacts & formatting	AS	HTLRG
6	Sept 2022	New DI, Add PD & Review	AS	HTLRG
5	Oct 2021	Review as part of CAPA plan	PL	HTLRG
4	July 2020	Review (Section 1.1, 3.5 & 5.1)	AS/PL	HTLRG
3	March 2018	Reviewed & Amended (New Author)	AS	PL
3	July 2017	Reviewed and PD contact details updated	AS	PL
3	July 2017	Reference to HTA codes updated	PL	HTLRG
3	July 2017	Reviewed and PD contact details	PL	HTLRG
2	Dec 2016	Update contact list	AS	PL
2	Oct 2016	DI change details	AS	MF
2	March 2016	Issued for use	GC	HTLRG
1	Nov 2012	Issued for use	GC	HTLRG
0	Oct 2012	Issued for discussion	GC	

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Rev	Date	Amendment	Approved by	Authorised by

Glossary of terms

AE	Adverse Event
CAPA	Corrective Action Preventative Action
DI	Designated Individual
HTLRG	Human Tissue Licence Review Group
MTA	Material Transfer Agreement
PD	Person Designated
PI	Principal Investigator
SOP	Standard Operating Procedure

1. Purpose/Background

1.1 The purpose of the Standard Operating Procedure (SOP) is to ensure that all staff and students understand what constitutes a human tissue-related adverse events, including complaints, arising in connection with activities covered by the CSGUL Research Licence and are aware of the requirements and mechanisms for reporting adverse events (AE).

Such events include, but are not limited to:

- Verbal or written expressions of dissatisfaction related to tissue consenting and archiving by staff.
- Errors in processes concerning activities covered under the terms of this licence.
- Examples: loss of specimens during transport, transfer of samples without appropriate Material Transfer Agreement (MTA), loss of specimens due to freezer breakdown, destruction of specimens, mislabelling of tissue samples, etc.

1.2 More information on categorisation of grades and examples of adverse events/incidents is shown in Section 4 below.

2. Scope

2.1 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 the Human Tissue Authority (HTA) Codes of Practice only.

2.2 Any AE that results in a Health and Safety incident/accident, such as a chemical spill should be reported separately to the SHE office by completing this form.

3. Responsibilities

3.1 All staff and students who become aware of an incident affecting human tissue samples' integrity has a responsibility to report and investigate it as described by this SOP.

3.2 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.

3.3 Persons Designated (PD) has a responsibility for supporting and overseeing the implementation of measures to address deficiencies identified.

3.4 The DI and PD are responsible for ensuring that all events covered by this SOP are properly investigated and reported.

3.5 Principal Investigator (PIs) are responsible for ensuring that risk assessments are carried out for their projects to minimise the likelihood of an AE occurring. They are then responsible for submitting and AE report if an AE occurs by following the process highlighted in this SOP.

3.6 The DI and PD are responsible for maintaining a log of all submitted AEs and ensuring that 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 a non-compliance with the HT Act and the HTA Codes of Practice.
Incident: *Near miss* – An event that does not result in non-compliance but has the potential *Undesired circumstances* – A set of conditions or circumstances that have the potential for non-compliance e.g. untrained staff or inexperienced students handling human tissue

4.1dentification of Adverse event

All staff and students working with or responsible for human tissue should become familiar with Table 1. This will enable them to identify an AE. Further guidance can be obtained from the DI.

Table 1. Examples of Adverse Events with their associated shortfall category

Types of AE	Examples of AEs	AE shortfall category
Consent	Human tissue is removed from a donor without appropriate and valid consent	Critical
	Consent sought or obtained by an untrained individual	Critical
	Human tissue is used for purposes not consented to	Critical
	Consent for use of human tissue not filed or retained correctly	Major
	No evidence of consent was sought from third party providers	Major
	Temporarily misplaced consent record	Minor
Governance and Quality	Human tissue used and stored outside the governance of a Research Ethics Committee (REC) approved study	Cirtical
	Breach of data protection/confidentiality	Critical
	Loss of sample/participant records	Critical
	Material transferred without appropriate review, authorisation or documentation (MTA/contract)	Major
	Labelling errors that led to incorrect use of samples	Major
	Incorrect version of Standard Operating Procedures (SOPs)/consent in use	Minor
	No evidence of regular SOPs and Risk assessment review	Minor
Traceability	Unique relevant material cannot be recovered	Critical
	Incorrect tissue type stored/transferred/used	Critical
	Loss/compromise of relevant material and/or patient records during transportation	Critical
	Unlabelled or mis-labelled material	Major
	Sample location/log discrepancy	Major
	Samples imported from overseas without approval	Major
	Accidental compromise of samples during transportation	Major
	Human samples not disposed of appropriately	Major

	No records of samples disposed, not retained or incomplete	Major
	Transfer records misplaced temporarily	Minor
Premises, Facilities & Equipment	Freezer/alarm failure caused non-recoverable loss of unique relevant material	Critical
	Unexpected failure of storage facility leading to compromise of tissue integrity	Major
	Tissue loss or compromised due to unauthorised access to storage facilities	Major
	Tissue integrity compromised because of incorrect storage conditions	Major
	Unauthorised access to storage facilities with no resulting compromised tissue	Minor
	Fridge/freezer/storage unit failure with no loss of tissue	Incident (Near miss)

The AE examples in Table 1 is not exhaustive but provide some guidance to identify AE relating to the human tissue research activities and the severity with which they would be categorised.

4.2 Reporting an Adverse Event/Incident

- **4.2.1** In the event of an adverse event, staff must immediately report the incident to the DI or PD and assist in any corrective action that can be safely performed to minimise risk to others or damage to human tissue samples.
- **4.2.2** Once all immediate actions have been taken, the reporting staff member must complete the Adverse Event Reporting Form and return it to the DI as soon as practicably possible.
- **4.2.3** Upon receipt of the adverse event report, the DI will immediately initiate an investigation into the adverse event, documenting the process in the Adverse Event Reporting Form.
- **4.2.4** The DI or PD will meet with the Principal Investigator (PI) whose tissue was involved in the adverse event. The reporting staff member will be invited to present the details of the event. Additional staff members with relevant expertise may also be asked to attend the meeting.

- **4.2.5** A root cause analysis will be conducted to discuss the circumstances surrounding the adverse event. An action plan, including Corrective and Preventative Actions (CAPAs), will be agreed upon, with a review date set to ensure appropriate precautions are implemented.

  The root cause analysis should consider the following areas:

  - **People**: Are tissue users appropriately qualified? Is additional supervision, training, or support required? Are other staff members better suited for the task?
  - **Management**: Are local SOPs sufficient? Are procedures reviewed frequently enough? Are procedures accessible to all staff? Is additional training needed? Are monitoring procedures in place?
  - **Procedure**: Were appropriate procedures used for tissue acquisition, use, storage, or disposal? Could changes to the SOP prevent recurrence? Are additional safeguards required?
  - **Equipment**: Was the correct personal protective equipment worn? Was the equipment appropriate and regularly checked? Is additional equipment or checks required?
  - **Materials**: Were the tissues or chemicals appropriate for the task?
  - **Environment**: Is there sufficient space? Are storage facilities secure? Is access properly restricted? Are facilities adequate for the task? Are additional warnings or instructions needed for staff or visitor safety?

- **4.2.6** All factors contributing to the adverse event should be documented. An action plan for CAPA will be formulated, including a reasonable timeframe for completion.
- **4.2.7** The action plan and review timescale will be agreed upon by the DI and PI.
- **4.2.8** At the review date, the DI and PI will assess whether all objectives have been met. If further actions are required, they will be noted and reviewed at a subsequent meeting. If all actions have been successfully implemented, the DI and PI will close the report.
- **4.2.9** Reports of all complaints and events under this SOP, including outcomes, will be presented at the next HTLRG meeting.

4.3 Verbal Complaints

- **4.3.1** Verbal complaints should be addressed immediately by the staff member receiving them, and an appropriate record of the complaint and action taken should be made. The DI must be informed and sent the complaint record.
- **4.3.2** Written complaints should be forwarded to the DI and acknowledged within two working days.

- **4.3.3** The DI will determine an appropriate investigation process and reach a conclusion regarding any issues raised under this SOP.
- **4.3.4** The goal is to provide a response within 20 days of the complaint.
- **4.3.5** Complaints will be handled with confidentiality, complying with the Data Protection Act 2018, General Data Protection Regulation (GDPR), and the Freedom of Information Act 2000.
- **4.3.6** Reports of all complaints, including outcomes, will be presented at the next HTLRG meeting.

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

5. Related Documents

- **5.1** HTA Licence 12335: Collection and storage of relevant materials for scheduled purposes.
- **5.2** Adverse Reporting Form – Available from the CSGUL Portal page.

6. References

- **6.1** Human Tissue Authority Codes of Practice:
  - Code A: Guiding Principles and the Fundamental Principle of Consent.
  - Code E: Research.

7. Amendment of SOPs

7.1 If a modification that could improve this SOP is identified during its application, users should inform the Person Designated (PD) so that the suggested changes can be reviewed and implemented.

8. **Contacts** DIs and PDs

Research Licence	DI	Dr Priya Madhou	Ext 1603	pmadhou@sgul.ac.uk
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	PD	Ms Lara Painter	Ext 3077	lpainter@sgul.ac.uk