	Title: Procedure for reporting adverse events and complaints	Author: G. Cockerill	Date: 2/Oct/2012
	No: SOP_R11	New Author: P. Madhou	Date: 1/Sept/2024
	Version: 7		Review Date March 2026

SOP_R11: PROCEDURE FOR REPORTING ADVERSE EVENTS AND COMPLAINTS

Disclaimer

When using this document, please ensure that the version you are using is the most up to date either by checking on the City St George's /PORTAL/HTA website for any new versions or contact the HTA coordinator to confirm the current version.

Out of date documents must not be relied upon and should be destroyed.

Rev	Date	Amendment	Approved by	Authorised by
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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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

1. Purpose/Background

1.1 This SOP describes the procedures to be followed when untoward or adverse events, including complaints, arise in connection with activities covered by the SGUL Research Licence. 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 A full categorization of grades of adverse events/incidents is shown in Appendix A.

2. Scope

2.1 The scope of this SOP is to define what constitutes an Adverse Event (AE) or Incident in relation to human tissue research and to detail the reporting mechanism for an AE/I, the responsibilities of the HTA Designated Individual (DI) and Persons Designated (PD), and the escalation process to the SGUL Human Tissue Licence Review Group (HTLRG).

3. Responsibilities

3.1 The Designated Individual (DI) and Persons Designated (PD) are responsible for ensuring that all events covered by this SOP are properly investigated and reported.

4. Procedure

4.1 Reporting an Adverse Event/Incident

- **4.1.1** 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 minimize risk to others or damage to human tissue samples.
- **4.1.2** Once all immediate actions have been taken, the reporting staff member must complete Part 1 of the Adverse Event Reporting Form and return it to the DI as soon as practicably possible.
- **4.1.3** 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.
- **4.1.4** 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.
- **4.1.5** 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?
- **4.1.6** All factors contributing to the adverse event should be documented. An action plan for CAPA will be formulated, including a reasonable timeframe for completion.
- **4.1.7** The action plan and review timescale will be agreed upon by the DI and PI.
- **4.1.8** 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.

- **4.1.9** Reports of all complaints and events under this SOP, including outcomes, will be presented at the next HTLRG meeting.

4.2 Verbal Complaints

- **4.2.1** 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.
- **4.2.2** Written complaints should be forwarded to the DI and acknowledged within two working days.
- **4.2.3** The DI will determine an appropriate investigation process and reach a conclusion regarding any issues raised under this SOP.
- **4.2.4** The goal is to provide a response within 20 days of the complaint.
- **4.2.5** 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.
- **4.2.6** Reports of all complaints, including outcomes, will be presented at the next HTLRG meeting.

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 SGUL 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.
- **6.2** Adverse Event Reporting Form – Available from the SGUL website.

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
	PD	Mr Ash Sameja	Ext 2428	asameja@sgul.ac.uk
	PD	Ms Lara Painter	Ext 3077	lpainter@sgul.ac.uk
Anatomy Licence	DI	Miss Georga Longhurst	Ex 5208	glonghur@sgul.ac.uk
	PD	Mr Paul Carter	Ext 5228	pcarter@sgul.ac.uk
	PD	PATHOLOGY MUSEUM Dr Carol Shiels	Ext 0729	cshiels@sgul.ac.uk