University of Leicester Research Governance Office Standard Operating Procedures relating to the Human Tissue Act 2004

SOP HTA-A1022 UoL

Adverse Events

Version 2.0

Effective Date: 01 December 2024

This SOP will be implemented in line with this document's effective date for all UoL HTA SOPs.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used.

1.0 Introduction

This document has been produced in accordance with *The Human Tissue Act 2004* (HT Act). It should be read in conjunction with the University's 'Policy on compliance with the Human Tissue Act in Research', and the Human Tissue Authority's *(HTA) Codes of Practice*.

The Human Tissue Act must be followed by all researchers working under the University's HTA Research Licence and those transferring HTA-relevant material as part of an ethically approved research project.

2.0 Scope

This SOP to provide guidance for researchers, Persons Designated (PD), and staff working under direction of Designated Individual (DI) so that they are fully aware of the procedures required for reporting adverse events/incidents in areas encompassed by the HT Act 2004 and HTA Research Licence.

Definitions:

AE	Adverse Event
CI	Chief Investigator
DI	Designated Individual
HT Act	Human Tissue Act
HTA	Human Tissue Authority
HTGC	Human Tissue Governance Committee
PD	Persons Designated
PI	Principal Investigator
RGO	Research Governance Office
SOP	Standard Operating Procedure
UoL	University of Leicester

3.0 Procedure

Below outlines the definition of an adverse event (AE) and the procedures that are required to be followed should an AE require reporting.

3.1 Definitions

An AE is any event that: (i) caused harm or had the potential to cause harm to staff or visitors, (ii) led to or had the potential to lead to a breach of security of the premises, (iii) led to or had the potential to lead to loss or damage to the premises and its contents, (iv) led to or had the potential to lead to damage to, or loss of, HTA-relevant material (v) gave rise to an internal inquiry.

An incident can be considered an untoward event or sequence of events that has caused or has the potential to cause damage; harm; or a direct negative impact to an organisation's business, security, reputation, facilities, personnel, safety, health, environment; an event where an important policy, procedure, or practice was not

followed by staff leading to detriment or the potential detriment of the above. Complaints shall be treated as an “incident”.

3.2 Reporting and timescales

Any AE/incident that occurs in relation to the UoL HTA Research Licence must be recorded and reported.

Initial reporting of an AE/incident related to the HTA Research Licence must be made to the local PD, DI, HTA monitor and RGO within 24 hours of the AE/incident occurring or being known, by completing the Incident and Adverse Events report Appendix 1 and sending it to the DI, HTA Monitor (HTAenquiries@leicester.ac.uk) and RGO (rgosponsor@leicester.ac.uk).

A full report/update of the AE/incident, action taken and further planned activities must be submitted to the DI within 5 working days of the AE/incident occurring or being known to the RGO office.

3.3 Investigating AE / incidents

All AE/incidents must be followed-up until closure. Refer to appendix 3 for Adverse Events Flow Chart.

Where HTA-relevant material is affected by the adverse event, it is the responsibility of the custodian of the samples (usually the CI/PI from the original study) to undertake the reporting in line with this SOP. PD(s) and any designated staff are responsible for carrying out an immediate local investigation which should be communicated to the DI and other contacts listed in section 4.2. The PD/departmental HTA contact and or RGO should discuss the AE/incident with local staff and inform them of immediate remedial/corrective action to mitigate the risk from reoccurring.

Depending on the severity of the AE/incident, there will be a number of actions which need to be taken in the subsequent hours and days after an AE/incident, namely, a preliminary meeting/discussion with the DI, RGO Office and other appropriate Senior Managers and contacting external bodies for advice (e.g., HTA) as appropriate. The severity of AEs/Incidents should be assessed in line with Appendix 2.

The PD/departmental HTA contact and or RGO Office should discuss the AE/incident with local staff and inform them of immediate remedial/corrective action.

A root cause analysis (What happened? Why did it happen? How did it happen? What can be done to prevent/reduce it happening again?) and a review of risk assessments is mandatory.

If the AE/incident is likely to result in immediate media interest, the DI will contact appropriate personnel at the University of Leicester e.g., Communications Dept.

The RGO office and DI will monitor local AE/incident trends and take appropriate action to address any system failures.

The outcome of serious AE/incidents will be reported to the College of Life Sciences Human Tissue Governance Committee (HTGC) and higher University management via the Registrar who is the Licence holder.

In the event of an adverse event, were applicable the local contingency plan must be updated.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigator / Principal Investigators (CI/PI)	Chief Investigator / Principal Investigators (CI/PI) or delegate	Completion of appendices relating to the adverse event. Investigation / root cause analysis
Person Designated (PD)	Person Designated (PD)	Support the investigation / provide regular updates to RGO
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Seek advice from external bodies (if applicable). Collate all information for final report / Report to HTGC
Designated Individual (DI)	Designated Individual (DI)	Ensure suitable practice take place within the licenced establishment.

5.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Amanda Sutcliffe	HTA Monitor	UoL Human Tissue Governance Committee (HTGC)	Professor Peter Bradding 	28/11/2024

6.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)
November 2024	v2.0	A Sutcliffe	• Administrative updates • Addition of flow diagram