UNIVERSITY OF LEICESTER

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The definitive version of all University of Leicester (UoL) Human Tissue Authority (HTA) Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that the up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Research Governance Ethics and Integrity (REGI) Website.

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Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
Author	Amanda Sutcliffe	HTA Monitoring Officer		08/02/2021
Reviewer	All members of the College of Life Sciences Human Tissue Governance Committee	College of Life Sciences Human Tissue Governance Committee	N/A	N/A
Authoriser	Professor Peter Bradding	Designated Individual		08/02/2021

Background

This document has been produced in accordance with The Human Tissue Act (2004). It should be read in conjunction with the University's 'Policy on compliance with the Human Tissue Act in Research', HTA Standards 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 Research Licence and those transferring HTA relevant material as part of an ethically approved research project.

Purpose and 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
DI	Designated Individual
HT Act	Human Tissue Act
HTA	Human Tissue Authority
HTGC	Human Tissue Governance Committee
PD	Persons Designated
REGI	Research Governance Ethics and Integrity
SOP	Standard Operating Procedure
UoL	University of Leicester

Roles and Responsibilities

It is the responsibility of the Designated Individual (DI) to ensure that suitable practices take place within the licensed establishment that comply with the HTA Codes of Practice.

The HTA Monitoring Officer is responsible for ensuring this SOP remains fit for purpose taking into consideration any changes in legislation and/or Codes of

Practice. In addition, it is their responsibility to ensure adverse events are followed up with appropriate actions.

It's the responsibility of the PD to assist the DI in implementing and adhering to the governance processes, and to help investigate adverse event that occur in their areas of oversight.

All staff collecting, storing or using human tissue for research under the University HTA Research Licence are accountable to the DI for undertaking work in compliance with this document. In compliance with the Research Licence issued by the HTA, the UoL expects all persons operating on the University sites to comply with the HT Act and its subsequent amendments, and to seek to comply with all Codes of Practice issued by the HTA and relevant University wide and/ or local SOPs.

Procedure to follow

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

Definitions

An adverse event (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) and the contents contained therein (iv) caused harm or had the potential to cause harm to stored human tissue (including loss) (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".

Reporting and timescales

Any AE/incident that occurs under a licence must be recorded and reported.

Initial reporting of an AE/incident under the HTA licence must be made to the DI within 24 hours of the AE/incident occurring or being known, by completing the *Incident and Adverse Events report SOP HTA-A1022 Appendix 1* and circulating to DI and REGI Office (copying in HTAenquiries@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 REGI office.

Investigating AE/incidents

All AE/incidents must be followed-up until closure.

PD(s) and any designated staff are responsible for carrying out an immediate local investigation which should be communicated to the DI. The PD/departmental HTA contact and or REGI Office should discuss the AE/incident with local staff and inform them of immediate remedial/corrective action.

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, REGI 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 the *Matrix for grading Adverse Events SOP HTA-A1022 Appendix 2.*

The PD/departmental HTA contact and or REGI 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 assessment is encouraged.

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 REGI 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 the Licence holder.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)

Distribution Record:

Date	Name	Department	Received Y/N