The Leeds Teaching Hospitals NHS NHS Trust UNIVERSITY OF LEEDS **S**tandard **O**perating **P**rocedure	Title	**LTHT / UoL Human Tissue Act (HTA) Standard Operating Procedures applying to the Research Licence** **Reporting HTA related Adverse Events and Near Misses**				
	Scope	**Details of the procedure for reporting Adverse Events under the LTHT and UoL Human Tissue Authority Research Licence, expanded on review to include Near Misses**				
	Version	**2.0**	Date issued	**April 2020**	SOP ID	**LRTB SOP M08**
	Planned Review date			2022		

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Section A LTHT / UoL Standard Operating Procedure

1. What is an adverse event?

1.1 Adverse events (AEs) are not defined by the Human Tissue Authority for the research licence. A general definition is an event which does not meet the required HTA Standards of Consent, Governance and Quality, Traceability and finally Premises, Facilities and Equipment.

1.2 Another important definition is an event that has the potential to cause distress to patients, other donors or their families and in a wider context could result in adverse publicity that may lead to damage in public confidence in the Trust or the University.

1.3 Specific examples include absence of documented consent to store donor identifiable samples, specimen loss, incorrect documentation, equipment failure or inappropriate disposal.

2. What is a near miss?

2.1 A near miss in the context of the research licence is when an error or failure is corrected in time to prevent an adverse event. It includes deviations from agreed practices.

2.2 Examples include:
- errors in the completion of the consent form that are corrected with the donor before a sample is used;
- a freezer failure, whether due to interruptions to power supply or a failure of the freezer itself, that is corrected in time to prevent specimen loss.

3. Process for reporting an adverse event

3.1 All AEs must be reported in “real time”.

3.2 Any member of staff who suspects a HTA related AE has occurred should contact the Person Designated (PD) for their area immediately. In the absence of the PD, in the first instance, the individual should contact the academic lead for their research group or their line manager. Local forms of reporting, including deviation reports, can be used alongside this SOP.

3.3 The Leeds Teaching Hospitals NHS Trust (LTHT) and the University of Leeds (UoL) incident reporting requirements, as per appropriate policies, should continue as appropriate.

3.4 The Person Designated (PD)/Research Lead/Line Manager, must, in the first instance contact the Designated Individual (DI) for the Research Licence or the HTA Manager immediately with details of the incident, location and staff involved, completing the AE reporting form in appendix A.

3.5 Any AE must be investigated and a root cause analysis undertaken. Depending on the level of severity and which organisation’s (LTHT or UoL) processes are followed, the investigation may be performed independently from HTA-related staff. The results of the investigation

must be made available to the PD, DI and HTA Manager, who will jointly review the Corrective and Preventative Action (CAPA) plan to ensure that it is consistent with compliance with HTA standards.

3.6 A named individual will be responsible for the delivery of the CAPA plan. A final report must be submitted to the DI and HTA Manager.

3.7 The DI will be responsible for escalating any AEs, particularly those that are systematic, through the accountable officers identified in the joint policy for the storage and use of human tissue.

3.8 It is also the responsibility of the DI to determine if an incident warrants rapid referral to the HT Authority for transparency, guidance and/or sharing of good practice.

3.9 The DI will include a summary of the AE in their assurance report to the HTA Management Group.

4. Process for reporting near misses

4.1 Any member of staff who suspects a HTA related near miss has occurred should contact the Person Designated (PD) for their area immediately. In the absence of the PD, in the first instance, the individual should contact the academic lead for their research group or their line manager. Local forms of reporting, including deviation reports, can be used alongside this SOP.

4.2 LTHT / UoL incident reporting requirements, as per appropriate policies, should continue as appropriate.

4.3 The causes of the near miss must be investigated and measures put in place to prevent a re-occurrence.

4.4 Details regarding near misses should be collectively prospectively based on appendix B.

4.5 The PD will be provided with a spreadsheet with all the data items listed in appendix B. This spreadsheet must be submitted to the DI and the HTA Manager every six months and include all near misses in the PD's area of responsibility.

5. Process for sharing and learning

5.1 All reports of AEs and near misses will be reviewed at the six monthly HTA Research Subgroup meeting which includes all PDs and associated staff.

5.2 This will allow the identification of trends in the occurrence of AEs and near misses including the types of incidents, their location and causes.

5.3 If common causes are identified, a CAPA plan will be developed and implemented. A named lead for the development of the plan will be nominated by the HTA research subgroup, and she/he will be supported by named members of staff as appropriate. The timeline for completion will also be agreed.

5.4 The DI is responsible for reporting all AEs and near misses and resulting actions within the compliance report that must be submitted to the HT Authority every two years. The compliance report is a requirement for the continuation of the research licence.

Appendix A

Leeds HTA Research Licence
Adverse Event (AE) Reporting Form

Name of Person Designated (PD)	
Name and contact details of person reporting the event if not the PD	Name: Contact details:
Date of AE	
Date AE discovered	
Date AE reported to the DI and HTA manager	
Reasons for delay in discovery or reporting if applicable	
Name and contact details of the local manager(s) informed	Name: Contact details:
Location where the event took place	
Employment status of the staff involved (select one and complete details)	LTHT substantive contract - honorary UoL contract yes/no UoL substantive contract – honorary LTHT contract yes/no Other
Lead for the internal investigation	Name: Contact details:
Anticipated date of completion of the investigation	

Event details

Part of process the event was linked to	☐ Consent ☐ Transportation ☐ Procurement ☐ Processing ☐ Storage ☐ Distribution ☐ Other – please specify: _____
Description of event	
Suspected cause of the event	

Action taken to date	

Appendix B

Note: This will be provided as a spreadsheet to PDs to complete with all near misses every six months.

Leeds HTA Research Licence Near Miss Report Details	
Name of Person Designated (PD)	
Name and contact details of person reporting the event if not the PD	Name: Contact details:
Date of near miss	
Date near miss discovered	
Reasons for delay in discovery if applicable	
Name and contact details of the local manager(s) informed (if applicable)	Name: Contact details:
Location where the near miss took place	
Lead for the internal investigation (if applicable)	Name: Contact details:
Near miss details	
Part of process the incident was linked to	☐ Consent ☐ Transportation ☐ Procurement ☐ Processing ☐ Storage ☐ Distribution ☐ Other – please specify: _____

Description of the near miss	
Suspected cause of the near miss	
Action taken	

Section B SOP details and approval process Details:

Previous Author: Clare Skinner, as Chair of the Research Subgroup, LTHT/UoL HTA Research Licence

Reviewer: Patricia Harnden, Designated Individual for the Research Licence

SOP Pages: 09

Version No. of replaced SOP: 1.0 (HTA SOP Incident Reporting)

Effective date of replaced SOP:

Review date for updated SOP: Biennially from date of approval or review

Review Date: By:

Review and Approval Process:

Draft	Circulated to	Period of circulation (dates)	Comments received from
Version 0.1	All Persons Designated and key associated staff, HTA Manager, LTHT and UoL Research and Innovation, Medical Achiever leaders	January x to February 29 2020 Discussed at the HTA Research Subgroup meeting on 13/02/2020	No written comments were received Agreement at the meeting to drop “serious” and refer only to adverse events.

Version No of the SOP	Name of DI	Date	Signature
2.0	Dr Patricia Harnden Designated Individual LTHT/UoL Human Tissue Act	07/04/2020	

Distribution & Storage:

Distribution to

Persons Designated, LTHT/UoL HTA Research Licence, HTA Research Subgroup

Location of Document

Paper: HTA Manager, Risk Management, The Trust Headquarters, St James’s University Hospital

Electronic: Research and Innovation website, UoL., http://ris.leeds.ac.uk/info/72/relevant_legislation/107/hta/2

Section C Applicability

1.1 This SOP is relevant to all staff collecting and storing human tissues relevant to the Act. The list of relevant tissues can be found on the Human Tissue Authority website by following the link:
http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm

1.2 This SOP can also be used as a training tool for new members of staff who have never worked with human tissues before, or who need to follow a new process.

1.3 This SOP does not replace incident reporting requirements within LTHT or UoL as appropriate, which should continue as is current practice.

Section D Background

1.1 Different sample types (blood or other bodily fluids, surgical resections etc) and data are collected from patients and other donors in Leeds for future unspecified research into a wide range of conditions including the investigation of normal cellular functions and their disruption in disease states, whether cancer or non-cancer. The tissue collections resulting from these different research activities are grouped under one research licence granted by the Human Tissue Authority to cover both Leeds Teaching Hospitals NHS Trust and the University of Leeds and referred to as the Leeds Research Tissue Banks. However, not all of these tissues are held within an NHS Research Ethical Committee approved research tissue bank.

1.2 The Leeds Teaching Hospitals NHS Trust is registered as the Licence Holder with the HT Authority, and the principal licensed site (‘the hub’) is St James’s University Hospital Trust. The University of Leeds main campus and Chapel Allerton Hospital are named satellites on the licence.

1.3 The Licence Holder is responsible for appointing a suitable Designated Individual (DI).

1.4 The DI plays a key role in implementing the requirements of the HT Act as the person under whose supervision the licensed activity is authorised to be carried out. The DI has the primary (legal) responsibility under Section 18 of the HT Act to secure that:

1.4.1 suitable practices are used in undertaking the licensed activity;
1.4.2 other persons, such as the Persons Designated (PDs), working under the license are suitable and;
1.4.3 the conditions of the licence are complied with.

1.2 This SOP has been written to formally establish a consistent procedure for the reporting of HTA related Near Misses and Adverse Events. In line with the relevant codes of practice for research establishments licensed by the HTA, this SOP lays out the internal system for reporting adverse events and, where necessary, instigating an investigation or root cause analysis. In a research environment, the focus may be on non-compliance with the HT Act and codes of practice or damage to the tissue integrity; for example, through inappropriate storage.

1.3 The main aim of this SOP is to ensure that relevant staff, by referencing this document, can easily follow the process of reporting of HTA related Near Misses and Adverse Events.

Section E Definitions

The Act	The Human Tissue Act, 2004
DI	Designated Individual as defined by the Human Tissue Authority
HT	The Human Tissue Authority or Act
LTHT	Leeds Teaching Hospitals NHS Trust
PD	Person Designated as defined by the Human Tissue Authority
R&I	Research & Innovation
SOP	Standard Operating Procedure
UoL	University of Leeds

Section F References

Human Tissue Act, 2004

Human tissue Authority, Codes of Practice 2017

Code A: Guiding principles and the fundamental principle of consent
Code E: Research
Code E: Research standards and guidance

Joint Policy for the Storage and Use of Human Tissue – a collaborative document agreed by Leeds Teaching Hospitals NHS Trust