Bournemouth University

Medical Sciences Department
Human Tissue Facility

SOP title:	Reporting and managing adverse events and incidents related to human tissue
SOP Reference:	BU-HTF-PRO-002
Version number: 0.2	Date: June 2019
Effective from:	Review date:

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Amendment log

Version:	Date	Amendment(s):
0.2	June 2019	References section has been updated. An additional paragraph has been added to clarify the use of Table 2.

Abbreviations:

SOP: Standard operating Procedure

HTA: Human Tissue Authority

CoP: Code of Practice

CI: Chief Investigator

MTA: Material Transfer Agreement

QAM: Quality Assurance Manager

CAPA: Corrective and Preventative Action Plan

Purpose: The purpose of this SOP is to provide guidance to human tissue facility users on the identification, management and reporting of adverse events.

Scope: This SOP is intended for BU staff and students working with human tissue under the human tissue license number XXXX.

1. **Introduction:**

The Human Tissue Act (2004) is the legal framework which regulates the removal, storage, use and disposal of human tissue [(1)]. The human tissue authority is the regulatory body which oversees the removal, storage, and use of human tissue fur research, medical treatment, post-mortem examination, education and training, and display in public. The HTA licenses organisations conducting these activities provided they adhere to the established CoP standards. One of these standards (GQ5) requires that a system is in place to investigate all adverse events associated with human tissue, and corrective and preventative actions are implemented as appropriate [(2) (3)].

An **adverse event** is defined as any untoward occurrence associated with the sourcing, using, processing, storage and distribution of human tissue, which leads or has the potential to lead to:

- The loss or damage of stored human tissue
- The harm to staff or visitors
- A breach of security of the premises and the contents therein
- A breach of the Human Tissue Authority or the code of practice
- The need for an internal enquiry

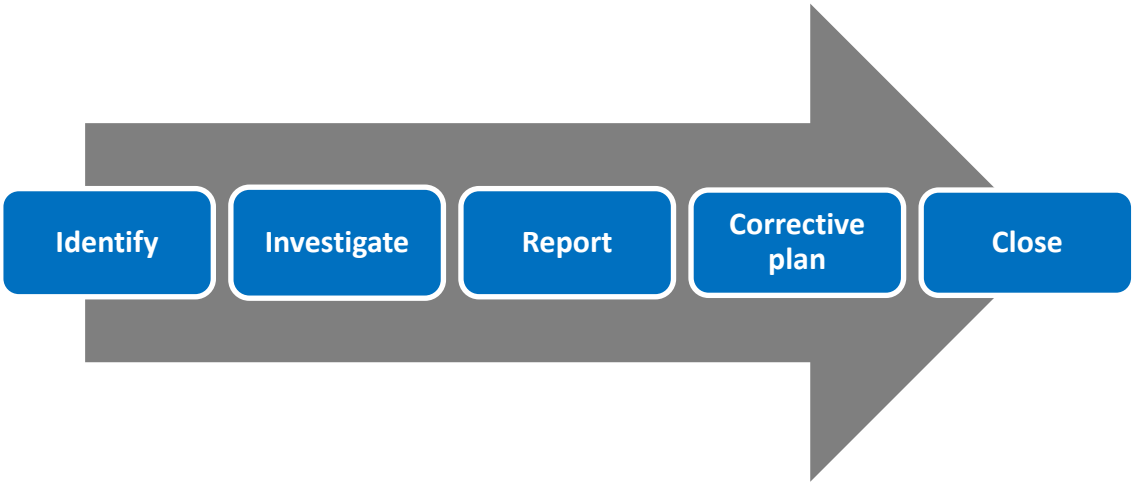
An **incident** is defined as any untoward event or sequence of events:

- That caused or had the potential to cause harm, damage, or a direct negative impact to an organisation's business, security, reputation, facilities, personnel, safety, health and environment
- Where an important policy, procedure or practice was not followed by staff leading to a detrimental or the potential detriment of the above

A **near miss** is defined as an event which could have been adverse if an intervention had not been made.

2. **Procedure**:

The process for identifying, managing and resolving adverse events/incidents can bne summarised as follows:



2.1 Identify

Staff working with human tissue must be alert at all times and readily identify and report any event they believe may compromise BU's compliance with the licensing terms under the HTA license. Examples of adverse events are provided in table 1 below.

CONSENT
• Person seeking consent is not appropriately trained • Tissue stored without appropriate consent • Tissue used without appropriate consent • Tissue used for project that has not been REC approved
SAMPLE TAKING
• Wrong type of specimen • Specimen from wrong patient • Incorrectly labelled specimen
TRACKING
• Labelling error • Tissue database failure • Failure to trace sample due to incomplete record • No record of stored sample on database
STORAGE
• Alarm failure • Material loss due to equipment failure • Any other issue which compromised tissue integrity
GOVERNANCE AND QUALITY
• Breach of data protection/confidentiality

• Material sent off without an MTA • Conduct of non-licensed activities • Wrong version of SOP in use
TRANSPORTATION
• Sample lost in transport • Sample integrity compromised in transport
DISPOSAL
• Failure to document reason for sample disposal • Failure to dispose of material appropriately • Incorrect labelling of human tissue waste

2.2 Investigate

Once and adverse event has been identified, an investigation must be conducted in order to determine of the event is real or a false alarm. If the event is real, the root cause must be determined, and a corrective or preventative action must be identified.

The investigation should be conducted as soon as possible, ideally on the same day the event was identified. The persons designated (PD) for the area where the event occurred, or the DI, should be informed, and involved when necessary.

Where staff, visitors, premises, relevant material, data, and facilities are at risk, remedial action must be taken immediately. Each AE/Incident report should document clearly what corrective and preventative actions (CAPA) are required and the responsibility and time frames for the completion of these.

2.3 Report

Once the root cause of the event has been established, a report must be prepared using the incident report form (appendix 1). Report should explain the event, describe the facts, and be written in a format suitable to be understood by a lay person. It should be taken into account that reports may be read by an external person (such as a business partner or a regulator). Therefore reports should avoid acronyms, slang, or apportion blame, and instead state facts and the order of events clearly.

The incident report form should contain details such as:

- where and when the incident happened,
- the name of the person reporting the incident and who it was reported to,
- the location where the incident occurred which should contain as much detail as possible such as facility name, room number, freezer/box/shelf number, etc
- A description of the adverse event (including the estimated root cause), and containing as much detail as possible.

- Where the integrity or viability of a sample of human tissue ("relevant material" as defined by the HTA) has been compromised, this should also be described, including the extent of the damage and samples involved.
- In order to assess the severity of the incident, please refer to table 2 below. *Only catastrophic and serious events will be communicated to business partners and the HTA*. In these cases, BU will inform the partner of any major incident affecting samples shared with them within 14 calendar days of the incident or non-conformance being identified.

Table 2. Severity grading for adverse events and common examples for each category

CATEGORY	EXAMPLE OF ADVERSE EVENT
Catastrophic	• Loss of unique material which impacts on a study or future studies • Loss of participant identification records in public area or during transportation
Serious	• Conduct of non-licensed activities • Loss of relevant material not considered unique • Relevant material removed, stored or used without appropriate consent • Staff member seeking consent who has not been appropriately trained • Material used for research which has not been approved by a REC • Breach of data protection/confidentiality • Specimen incorrectly acquired, labelled, from wrong patient or in the wrong format • Freezer/nitrogen back-up and alarm failure resulting in destruction of material • Unauthorised removal of material from a storage facility • Relevant material placed with non-clinical or animal waste for disposal • Quality of relevant material compromised during transportation
Moderate	• Relevant material transported to or from BU without appropriate MTA/contract in place • Labelling error that can be accurately rectified • Not using tracking system to record material acquisition, storage, use and disposal • Inappropriate transport of specimens • Freezer failure leading to the transfer of samples to alternative locations
Minor	• Incorrect version of SOP in use • Not registering new SOPs or updating existing ones on the SOP register • Documents temporarily misplaced • Incident occurred which had no impact on relevant material

Near miss	Adverse event/incident could have happened in an intervention had not been made: • Short term cold storage failure • Alarm failure • Labelling error that was rectified

Incidents categorised as SERIOUS and CATASTROPHIC will be escalated to the DI and QAM, who will be involved in any subsequent remedial action.

Incidents categorised as MEDIUM will be escalated to the QAM and ID, who will be involved in any subsequent remedial action.

Incidents considered as minor will be communicated to the ID who will be involved in any subsequent remedial action.

3. Corrective/preventative action plan (CAPA)

In events where any corrective action was implemented immediately, this should be recorded in detail, including dates/place where the action was implemented.

When any subsequent actions are required, a full list of the actions to be implemented mist be documented, along with completion dates, to ensure actions are followed up and executed.

Any preventative actions to avoid the event occurring again should also be included, with a suitable timeframe, roles and responsibilities clearly documented. It is the responsibility of the Persons Designated in each laboratory/area to ensure that these actions are completed within the agreed timeframe, properly documented, and that the completion date is communicated to the QAM. If an issue is identified preventing the completion of the action plan, this must be discussed with the QAM and a suitable course of action must be agreed.

4. Adverse event closure

Once the QAM is satisfied that all actions have been implemented and the incident is solved, the adverse event will be marked as closed in the adverse event log, and all relevant parties will receive an email confirming that no further action is required.

5. References

(1) Human Tissue Act 2004: http://www.legislation.gov.uk/ukpga/2004/30/contents

(2) Human Tissue Authority code of practice and standards. Code E - Research: https://www.hta.gov.uk/hta-codes-practice-and-standards-0

(3) Mendy, M; E. Caboux; R.T. Lawlor; J. Wright; and C.P. Wild. 2017. Common minimum technical standards and protocols for biobanks dedicated to cancer research. International Agency for Research on Cancer (IARC) technical publication number 44.

APPENDIX 1 - ADVERSE EVENT REPORTING FORM

(To complete, please follow the steps below, using SOP XXXX above as guidance).

1. Description of the adverse event/incident

Date the incident occurred	
Site of incident	
Description of incident (continue overleaf if necessary)	
Severity of incident (as per table 1 in SOP)	

2. Reporting the adverse event/incident

Incident reported to:	Reported by:	Date:
Designated Individual		
Person designated		
HTA compliance committee		
Other (specify)		

3. Action taken since reporting the adverse event/incident

Corrective	
Preventative	
Has the incident been resolved?	

4. Any other relevant information

Please provide any other information relevant to the event/incident (you may use this space to continue the description of the event, or changes to the original CAPA).