Adverse Incident Reporting: Relating to Human Tissue for Research

Document History	
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The University Of Sheffield.

1. Background

This is an SOP for use in the University of Sheffield Medical School Biorepository to identify, report and take action on Adverse Incidents associated with the acquisition, storage, use and disposal of human tissues for research purposes.
Detailed within this SOP are type of events that fall under the category of Adverse Incidents. The reporting mechanism for an Adverse Incident and the responsibilities staff members, along with the level of escalation necessary dependent on the seriousness of the incident.

2. Responsibilities

Biorepository Staff
It is the responsibility of the staff to ensure that:

- They adhere to the Incident reporting procedure outlined in this SOP.
- They report any Incident to the Biorepository Manager or the STH HTA Lead

Biorepository Manager
It is the responsibility of the Biorepository Manager to ensure that:

- An Incident form has been completed by the staff member and reviewed for accuracy.
- All reasonable enquiries or investigations relevant to the Incident have been made.
- Steps have been taken to prevent a recurrence of an Incident and information has been given to staff.
- Notify via email the DI.
- Incidents are reported to the University Medical School HTA committee at the next timetabled meeting.
- The HTA are informed of any Incident associated with the human application sector.
- Other relevant University/NHS staff have been informed of the Incident by those who compile the report.
- To ensure an Incident is followed up until completion.
- To monitor any Incident trends and take appropriate action to address system failures using the adverse incidents log file.

HTA Committee

It is the responsibility of the University Medical School HTA committee to ensure that:

- An appropriate Incident reporting procedure is in place
- To liaise with senior management within both UoS and STH regarding Incidents which have broader implications.

3. Definitions

Adverse Incident

Any event that:

- Caused harm or had the potential to cause harm to staff or visitors
- Led to or had the potential to lead to a breach of security of the premises and the contents contained therein
- Caused harm or had the potential to cause harm to stored human tissue (including loss)
- Gave rise to an internal inquiry

Any untoward event or sequence of events:

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

Categorisation of Adverse Incident associated with UoS-STH HTA Licensable Activities:

HIGH Catastrophic Loss of unique relevant material

- Loss of participant identification records in public area or during transportation
- Untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity.
- Unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life threatening, disabling, incapacitating or which results in, or

prolongs, hospitalisation or morbidity.

HIGH Major Relevant material removed from a participant, stored or used without appropriate consent.

- Staff member seeking consent who has not been appropriately trained.
- Relevant material used for a research study which has not been approved by NHS REC.
- Breach of Data protection/confidentiality.
- Incorrect type of specimen acquired or from wrong participant, specimen incorrectly labelled, specimen in wrong format.
- Freezer/ Nitrogen back-up and alarm failure resulting in destruction of material.
- Unauthorised access to storage facility
- Relevant material placed with non-clinical or animal waste for disposal.
- Relevant material lost or quality compromised during transport.

MEDIUM Relevant material transport to or from the Biorepository without appropriate contract/ MTA in place

- Labelling error that can be accurately rectified
- Not using the CloudLIMS system to record material acquisition, storage, use and disposal
- Inappropriate transport of specimens

LOW Minor incorrect version of policy or SOP in use. Not registering new SOPs or updating existing ones in the SOP folder.

LOW Insignificant incident occurred which resulted in no compromise of relevant material.

LOW Near miss: Incident could have happened if intervention had not been made.

4. Procedures

Any Incident that occurs under the HTA licence must be reported to the Biorepository Manager immediately. The Biorepository Manager will give a preliminary grading to the Incident. Any Incident graded '**HIGH**' will immediately be escalated Biorepository Director. Incidents graded

'**MEDIUM**' will be escalated at the discretion of the Biorepository Director. The DI will liaise with relevant bodies, senior management and other partners.

- Remedial action must be taken immediately where staff, visitors, premises, relevant material, data and facilities are at risk.
- Appropriate UoS-STH staff must be informed where an Incident falls under their jurisdiction.
- Within 24 hours details of the Incident should be recorded on the Incident form and submitted to the Biorepository Manager.
- Biorepository Manager will re-grade the incident, according to the detailed report. Reports from Incidents graded as **HIGH** will be forwarded to the DI, Biorepository Director immediately.

Incidents rated **HIGH:**

- Biorepository Manager will notify the HTA of any serious adverse event.
- The Biorepository Manager will provide a full report/update on the Incident, action taken and further planned activities. This will be disseminated to members of the UoS HTA Committee, PD's and other staff working under the HTA licence.
- Where appropriate updates will be provided to the UoS HTA Committee and PD's along with relevant bodies until the final outcome is reported.
- The Biorepository Manager will submit a report on the HTA once local investigations have been completed.

5. Reporting

A summary of all Incidents discussed by the UoS must be included in the committee minutes. Outcome reports of Incidents must be disseminated to all staff working under the UoS HTA Licence. The Biorepository Manager must monitor and report to the UoS HTA Committee any trends in Incidents occurring on their premises.

6. Associated Documents

	Document	Document Reference
1	Incident form	BIO:FORM:05
2	Adverse Incident Log	BIO:FORM:20
3		
4		
5		
6		
7		


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Of
Sheffield.