Document Title: Reporting and managing HTA related Adverse Events

Document Number: R&D SOP133

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Summary of Amendments

Version Number	Modification:
1.0	New SOP

Key Related Documents	DN001 Document Control Procedure GD044 R&D Laboratory User Manual GD060 Human Tissue Quality Manual SOP012 Adverse Event Reporting SOP132 Adverse Event Reporting – Non-Papworth Sponsored Studies FRM119 HTA related Adverse Event Reporting Form

Key Points of this Document

- This SOP defines what is classified as an Adverse Event in relation to human tissue research. It only applies to the reporting of Adverse Events related to human tissue, resulting in non-compliance with the Human Tissue Act 2004 (HT Act) and Human Tissue Authority (HTA) Codes of Practice.
- Any AE that results in a health and safety incident/accident, such as chemical spills, should be reported separately following the guidance in Laboratory Manual GD044 and the DATIX system where appropriate.
- Any R&D study related AE should be reported as per SOP012 for Papworth Sponsored studies and SOP132 for non-Papworth Studies.

1 Purpose and Contents

- The purpose of this SOP is to describe the process of identifying, reporting and taking action on Adverse Events and near misses associated with the acquisition, storage, use and disposal of human tissues for research purposes.

2 Roles & Responsibilities

This SOP applies to all personnel that are conducting research at the Trust relating to human tissue in compliance with the Human Tissue Act 2004 (HT Act) and Human Tissue Authority (HTA) Codes of Practice.

Under the HTA licence for Research:

a. Designated Individual (DI) for the HTA licence has a responsibility to oversee the management of an individual event to closure.

b. Person(s) Designate (PD) has a responsibility for supporting and overseeing the implementation of measures to address deficiencies identified within their area.

c. All individuals operating under the Trust's HTA licence have a duty to:

- Understand their responsibilities under the HT Act.

- Treat donated material with dignity and respect.
- Maintain data confidentiality and donor privacy.
- Identify when material must be stored under HTA licence: inform PD or the DI and ensure the material is stored in a designated location.

3 Policy

This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance may result in disciplinary procedures.

4 Procedure

4.1 What is an Adverse Event (AE)?

a. The HTA does not provide specific definitions of AEs, other than a general definition of an event *which does not meet the required HTA Standards of Consent, Governance and Quality, Traceability and finally Premises, Facilities and Equipment*.

b. The HTA definition of an Adverse Event is an event that **causes or has the potential to cause harm**, such as a breach of security, or a negative impact on the organisation's business, security, reputation, health, or the environment.

c. Examples of AEs are included in Table 1.

4.2 What is a near miss?

a. A near miss is when an error or failure in practice is corrected in time to prevent an AE. This will include a deviation from agreed practice/protocol.

b. Examples of a near miss include:

- Freezer failure that is dealt with in time to prevent loss of specimen integrity.
- Identifying a mistake in a consent form that is corrected before a donated sample is collected/used.

4.3 Process for reporting an Adverse Event

a. AEs must be reported within 24 hours of knowledge of the event.

b. The AE's level of severity of the shortfall will be confirmed (using the information in Table 1 and /or discussion at HTA Governance meeting), the AE investigated, and a root cause analysis done if required.

c. When a member of staff identifies a HTA related AE has occurred they should complete the HTA related Adverse Event reporting form (FRM119) and send it to the QA safety reporting inbox: papworth.safety-reporting@nhs.net. The QA team will then forward the form to the appropriate Person Designate (PD).

d. The PD will review the form and gather any additional information required from the member of staff reporting the event.

e. The PD must then complete the Adverse Events and Near Miss Reporting Log for either Tissue Bank or Mesobank referring to the complete FRM119 for the event details. The PD will inform the DI of the Adverse Event if it is serious, otherwise the Adverse Events will be reported to the DI at the HTA Governance meeting.

f. Adverse Events will be recorded on DATIX unless it is deemed not to be suitable for DATIX, justification for this decision will be documented on the Adverse Events and Near Miss Reporting Log.

g. The DI will decide if an Adverse Event should be reported to the HTA outside of the routine self-assessment reporting process.

4.4 Process for reporting near miss

a. When a member of staff has knowledge of an HTA related near miss they should complete the Adverse Events and Near Miss Reporting Log for either Tissue Bank or Mesobank.

b. The causes of the near miss must be investigated and measures put in place to prevent it re-occurring.

4.5 What to do after the reporting of the AE or Near Miss

- The AE and near misses will be discussed at the monthly HTA Governance meetings and a Corrective and Preventive Action (CAPA) plan agreed for AE or near miss and a root cause analysis will be performed if requested by the DI. A named individual will be allocated responsibility to complete the CAPA and report back to the HTA Governance meeting and Tissue Bank Operational Group as appropriate.

- The log will be reviewed at the relevant R&D group: Tissue Bank Operational Group, the Mesobank Operational Group, Quality Assurance Group and R&D Laboratory User Group.

4.6 Lessons learned

- R&D has a Quality Assurance Group which will review The Adverse Events and Near Miss Reporting Log for Tissue Bank and related CAPA as a regular item on its agenda and further recommendation will be made if required.

- Outcome of an investigation of an AE or near miss will be discussed at the Laboratory User Group and appropriate information disseminated to the wider R&D group via the monthly BUZZ meeting.

Table 1: examples of Adverse Events and the level of severity of the shortfall

HTA standard	Example of Adverse Event	Level of Shortfall
Consent	Material sample is taken without appropriate consent, e.g. consent had been withdrawn but the person collecting the sample hadn't checked the records.	**Critical**
	Material is used for purposes it was not consented to be used for.	**Critical/Major**
	Documentation for consent was not retained correctly.	**Major**
	Documentation for consent was not completed correctly. An incorrectly completed consent form that is intercepted and corrected should be a near miss (as section 4.2).	**Minor**
	Temporarily misplaced consent documentation.	**Minor**
Governance & Quality	Material used without REC approval granted by TBOG/Mesobank.	**Critical**
	Breach of data protection.	**Critical**
	Material transferred without authorisation or correct documentation.	**Major**
	Labelling errors that lead to incorrect use of samples.	**Major**
	Material supplied to a Tissue Bank/Mesobank project when a project had been fully supplied.	**Major**

	Incorrect version of SOP/PIS used for a sample collection.	**Major/Minor** (specific Adverse Event details will be considered)
	No proper review of RAs or SOPs – refer to DN290 Risk Assessment Procedure.	**Minor**
Traceability	Non-recoverable loss of unique relevant material.	**Critical**
	Loss/compromise of material and/or patient record during transportation.	**Critical/Major**
	Sample log/sample location discrepancy.	**Major**
	Labelling error results in incorrect material being supplied to a project.	**Major**
	Record of disposal of material not retained or incomplete.	**Major**
	Inappropriate disposal of human samples.	Major
	Miss-labelled material / Unlabelled. If not corrected this would become Major.	**Minor**
	Transfer records temporarily displaced.	**Minor**
Premises, Facilities & Equipment	Freezer failure results in loss of material.	**Critical**
	Freezer monitoring system down.	**Major if for an extended period of time**
	Unauthorised access to storage facilities resulting in tissue loss or compromise.	**Major**
	Incorrect storage conditions/units for sample type compromising tissue integrity.	**Major**
	Temperature recovery compromised following retrieval / maintenance – outside threshold.	**Major**
	Unauthorised access to storage facilities with no resulting compromised tissue.	**Minor**
	Freezer unit failure without loss of material.	**Minor/other**

5 Risk Management / Liability / Monitoring & Audit

The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current approved version date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (and any subsequent amendments) UK Policy Framework for Health and Social Care Research version 3.3 (07/11/17) and authorised amendments thereafter Human Tissue Act Codes of Practice

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Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

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