Standard Operating Procedure
Research Governance

Title:	**Recording Human Tissue Act Related Adverse Events**		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
FMH&LS/SOP/006/01	14/02/2013	Rewrite because of integration to Research Governance	V 1.0
V 1.0	06/02/2015	Periodic Review: Queen's Online replaced by Research Governance Website details on cover page	V 2.0
V 2.0	10/04/2017	Review in response to Human Tissue Authority's Codes of Practice and Standards update.	V 3.0
V 3.0	17/05/2019	Periodic review. Logo and name of Chair updated on cover page. Web links updated.	V 4.0
V 4.0	05/11/2021	Periodic review. Web links updated.	V 5.0
V 5.0	20/02/2024	Updated to include commercial companies operating under the University's HTA Licence	V 6.0

1. Purpose

This Standard Operating Procedure (SOP) outlines the procedures to be followed when identifying, recording, reporting and handling adverse events (AEs) involving relevant material as defined by the Human Tissue Act.

2. Introduction

The Human Tissue Act 2004 (HT Act) came into force on the 01 September 2006 and provides a framework for regulation of research involving the removal, storage, use and disposal of human tissue. The Human Tissue Authority requires licensed premises to have procedures in place for reporting and recording AEs.

3. Scope

This SOP applies to all University staff and students who, within the scope of the Human Tissue (HT) Act (2004) are involved with the removal, storage and use of human organs and other tissue for scheduled purposes.

This SOP also applies to all commercial companies operating on University premises who are involved with the removal, storage and use of human organs and other tissue for scheduled purposes as defined by the HT Act (2004).

4. Responsibilities

4.1 Designated Individual

It is the responsibility of the Designated Individual (DI) to review all AEs and provide input on any preventive or corrective action as required.

4.2 Person Designated

The PD is responsible for assessing the severity of any AE affecting premises and completing the HTA Adverse Event Notification form and reporting the AE to the DI and Research Governance.

4.3 Chief Investigator or Custodian

The Chief Investigator(CI)/Custodian is responsible for assessing the severity of the AE for his/her specific research study/project and for informing the DI and PD of all suspected or actual AEs.

4.4 Research and Support Staff or Commercial Company Staff

Researchers and/or other support staff, including commercial company staff operating under QUB's HTA Licences, involved in HT Act regulated activities are responsible for reporting any AEs observed or suspected to the PD and/or CI/Custodian for the area as appropriate.

4.5 Research Governance

Research Governance is responsible for maintaining records of all reported HT Act related AEs and for collating reports on AE occurrences for review by the Human Tissue Steering Group (HTSG).

5. Procedure

5.1 Identification of an AE

A HTA related AE is any event which:

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

Examples of AEs are provided below. These examples are not exclusive and further advice on the identification of an AE may be sought from Research Governance or the area PD if necessary.

Examples of AEs:

- Loss of relevant material (eg freezer breakdown, during transportation);
- Lack of appropriate consent for removal, storage or use of relevant material;
- Incorrect labelling of relevant material;
- Incorrect disposal of relevant material;
- Relevant material not stored in appropriate conditions (eg location is not secure);
- Relevant material transferred without an appropriate Material Transfer Agreement in place;
- Information not entered on QOL Human Tissue Register.

5.2 Assessment of an AE

The DI and PD for the area must be informed as soon as practicable when an AE is observed or suspected.

For study specific AEs the CI/Custodian will assess the extent of the event and initiate any immediate measures that may be required.

Upon notification of an AE involving premises the PD, in consultation with the DI, will assess the extent of the event and initiate any immediate measures that may be required.

5.3 Reporting and recording of an AE

Any AE observed or suspected must be reported to the DI, PD and CI/Custodian (if study specific) as soon as practicable (and no later than 48 hours).

Initial reporting should detail:

- Name of individual who reported the AE;
- The name of the CI;
- Full title of the research study;
- The location where the AE occurred;
- Date/time AE occurred and/or was identified;
- Details of the AE;
- Details of any initial corrective actions.

All AEs must be recorded using the HTA AE report form (see Appendix 1). The HTA AE report form must include information on the time, location and nature of the event, the names of those involved and any action taken. The CI/Custodian (study specific) or PD (premises) is responsible collating the information required for the HTA AE report form and for submission of this form to Research Governance. The CI/Custodian or PD must report the AE to Research Governance as soon as possible and no later than within 5 working days of notification. Research Governance must maintain records of all AE reported.

Consideration must also be given to other areas that may be affected by the AE. If an AE results in health and safety, legal, scientific or physical resource implications then it must be reported appropriately to the relevant area (eg Estates Directorate, Head of School, Safety Service) within the University. For commercial companies the staff within the company are responsible for reporting to their relevant department as appropriate

5.4 Further action and implementing corrective action

The CI/custodian or PD in consultation with the DI must determine any action to be taken to prevent a reoccurrence of an AE.

Upon receipt of a HTA AE report form, Research Governance in consultation with the DI must determine if any further investigation or audit is required.

HTA AE reports will be collated for consideration by the Human Tissue Steering Group.

6. References

Human Tissue Authority Code of Practice and Standards E Research
https://www.hta.gov.uk/codes
(last accessed February 2024)

Human Tissue Authority definition of relevant material
https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004 (last accessed February 2024))

7. Appendices

Appendix 1 HTA Adverse event report form
Appendix 2 HTA Adverse event flowchart

HTA Adverse Event Notification Form

Individual reporting the AE:
Research study details *(if applicable)*
Chief Investigator/Custodian:
Study Title:
AE details
Date of occurrence:
Location:
Circumstances of the event *(Attach copy of a detailed report if necessary):*
Implications of the AE:
Action taken:

Please return completed form to Research Governance (researchgovernance@qub.ac.uk)

Date received by Research Governance:_____

HTA Adverse Event Notification Flowchart