Keele University
Institute for Science and Technology in Medicine

Standard Operating Procedure

**SOP Number: HTA-32** **Version: 1.0**

# Title: **Reporting adverse events**

**Purpose:** This SOP describes the process of reporting adverse events that occur in relation to the acquisition, use, disposal or storage of human Tissues

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| Written By: | Alan Harper | Date: 20.09.16 |
| Approved By: | Nicholas Forsyth | Date: 23.09.16 |
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**SOP History:**

| VERSION | AMENDMENT | CURRENT VERSION |
|---|---|---|
| 1.0 | None | |
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## 1. Introduction:

Establishments licensed by the Human Tissue Authority (HTA) must be able to evidence compliance with the requirements of the Human Tissue Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the HTA codes of practice. The HTA are the UK body responsible for implementing the EU Tissue and Cells Directive 2007. As part of their research sector licensing standard the HTA require that license premises have systems to ensure that all adverse events are investigated promptly. This includes a requirement to ensure that corrective and preventative actions are taken to ensure similar occurrences do not occur in the future through changes in procedures and practices. (Source: HTA licensing standards)

## 2. Definitions

An adverse event is defined as any event that either:

i) Causes harm or has the potential to cause harm to staff, visitors or research volunteers.
ii) Leads to or could lead to a breach of security of the premises and any relevant materials held within.
iii) Causes harm too, or have the potential to, cause harm to stored human tissue samples.
iv) Triggers an internal enquiry.
v) Is in breach of the Human Tissue Act or HTA codes of practices.

[Source:*https://www.**hta**.**gov**.**uk**/sites/.../Guide_to_Completion_of_the_**Tissues**_and_Cells.pdf]*

## 3. Completing the Adverse Event Reporting Form (HTA-32)

**3.1 Part 1** - Reporting an adverse event

**3.1.1** In the event of an adverse event, Staff should immediately report the incident to Technical Support staff at the Guy Hilton Research Centre (Katy Cressy or John Misra) or Huxley Building (Jayne Bromley) and then assist in corrective action that can be safely performed to minimize risk to others or damage to human tissue samples.

**3.1.2** As soon as all reasonable actions have been performed the reporting staff member will be asked to complete Part 1 of the Adverse Event Reporting Form held by the technical staff. This must be returned as soon as is practically possible to the Human Tissue Officer (a.g.s.harper@keele.ac.uk).

**3.1.3** Upon receipt of the adverse event report, the Human Tissue Officer will immediately begin an investigation into the adverse event. This investigation will be recorded in Part 2 of the adverse event reporting form.

**Part 2** – Investigating an adverse event

**3.2.1** The Human Tissue Officer (HTO) will request an urgent meeting with the Principal Investigator (PI) whose tissue had been the subject of the adverse event. The reporting member of staff (rMOS) will be invited to report on the adverse event. Depending on the preference of the rMOS, this will occur either prior to the meeting to give an anonymous report of the event, or in combination with the PI. In addition, the HTO may ask other members of staff to attend the meeting who will be able to provide relevant experience to the analysis of the work (e.g. other human tissue users of the group, Health and safety adviser, COSHH supervisor). All attendees will be recorded on the HTA-32 form

**3.2.2** The events surrounding the adverse event will be discussed as part of a root cause analysis, and an action plan will be agreed to try to put in place corrective and preventative actions (CAPAs) are put in place. This will include a review date to ensure appropriate precautions have been implemented.

**3.2.3** The PI, rMOS, HTO and other relevant member of staff will discuss the adverse event and decide a statement which summarises what went wrong (the “effect”). This should be recorded in the box provided on the right-hand side of the fishbone diagram.

**3.2.4** Now the group will discuss each of the following six areas in turn to see if they can reasonably identifying any underlying issue in this area that may have contributed to the occurrence of the adverse event (i.e. the “*causes*”)

- ***People*** – Are the tissue users appropriately qualified? Is additional supervision, training or support required in handling tissue, use of equipment or performing task? Are other members of staff better suited to perform this task?
- ***Management*** – Are local standard operating procedures sufficient to ensure appropriate activities are performed? Are procedures reviewed frequently enough? Could the HTA officer facilitate tissue use more effectively? Are procedures visible and available to all members of staff? Are more staff training opportunities required? Are appropriate monitoring procedures in place?
- ***Procedure*** – Have appropriate procedures been used for the acquisition, use, storage or disposal of tissue? Would changes to the SOP prevent this even recurring? Are additional safeguards required for this task?
- ***Equipment*** – Has correct personal and protective equipment been worn? Is the equipment appropriate for the task? Has equipment been checked regularly? Is additional equipment required to do this task more safely/effectively? Could additional checks of the equipment have prevented failure?
- ***Materials*** – Are the tissues or chemicals used inappropriate for the task attempted?
- ***Environment*** - Is there sufficient space for the procedures? Are storage facilities secure? Is access restricted sufficiently to appropriately qualified people? Were facilities in the room appropriate for the task attempted? Are additional warning signs or other instructions required for staff or visitor safety?

**3.2.5** All possible factors that might have contributed to the adverse event should be detailed in part 4 of the proforma as well as added to the fishbone diagram. At the end of the session the principal cause(s) of the adverse event should be indicated on the fishbone diagram. An action plan of CAPAs will be formulated at the meeting, including agreement of a reasonable timeframe for their completion.

**3.2.6** The action plan of CAPAs will be signed off at the meeting by both the Principal Investigator and the Human Tissue Officer, and the report sent to the Designated Individual (DI) to agree the action plan and the timescale for review of appropriate implementation of CAPAs.

**Part 3** – Following-up an adverse event

**3.3.1** At the review date, the Human Tissue Officer and Principal Investigator and their research team will meet to review the action plan to ensure all objectives have been met. Additional relevant staff members may also be invited to the meeting to provide expert input.

**3.3.2** If further actions are still required these will be noted and the case reviewed at a subsequent meeting. If all actions have been successfully implemented the Human Tissue Officer and Principal Investigator will acknowledge this and the report returned to the Designated Individual to acknowledge the completion of this process.

**3.3.3** If CAPAs have not been put in place then the HTO should report this to the DI, who can then decide if any disciplinary procedures are required for the PI and/or their associated tissue users.

## 4. References:

**HTA licensing Standards**: https://www.hta.gov.uk/policies/research-sector-hta-standards
**HTA codes of Practice**: https://www.hta.gov.uk/guidance-professionals/codes-practice
**Definition of adverse event**:
https://www.**hta**.**gov**.**uk**/sites/.../Guide_to_Completion_of_the_**Tissues**_and_Cells.pdf]