Standard Operating Procedure for the Use and Storage of Human Tissue for the purposes of Research and Teaching

HTA Adverse Event SOP

Version Number : 2

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Licence No: 12533
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Appendix A - Human Tissue Adverse Event/ Incident Reporting Form
1. **Background**

The Human Tissue Act 2004 (HT Act 2004) is a framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue and organs from the deceased, for specified health-related purposes including medical research. The HT Act 2004 replaces the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplants Act 1989. The Human Tissue Act 2004 (HT Act 2004) is applicable in full to England, Wales and Northern Ireland; there is a separate legislation for Scotland. The Act was fully implemented on 1st September 2006. The HT Act set up the Human Tissue Authority (HTA) which issues licences for a number of licensable activities under the HT Act. Middlesex University is the Licence Holder for Research, Education and Training. To comply with the conditions of the Licence the University is required to log and follow up any adverse events involving human tissue.

2. **Purpose**

The purpose of this Standard Operating Procedure (SOP) is to set out the processes and procedures to follow when an (HTA) adverse event involving human tissue occurs.

*(NB there is a parallel system for reporting health and safety accidents and near misses. The Accident Report form (downloadable from: http://www.intra.mdx.ac.uk/working-here/health-safety-wellbeing/healthsafety/accident/index.aspx) is for reporting all accidents (involving personal injury) or near misses (where injury might have happened or where there is damage to equipment / property). Where incidents occur in the labs, in addition to submitting to the H&S manager (as described on the form), the form must also be submitted to the Deputy Technical Manager and the relevant PI for consideration of relevant action to be taken.)*

3. **Responsible personnel**

This SOP applies to all Middlesex University staff and students who are responsible for collecting, using or storing human tissue for research or teaching purposes. It also applies to
employees of other organisations holding relevant material under the Middlesex University HTA Licence. The SOP must be used in conjunction with the Human Tissue Authority Codes of Practice and all other relevant University and, where appropriate, local University Health and Safety policies and SOPs.

**Middlesex University HTA Governance Team** is responsible for ensuring that the SOP remains fit for purpose.

4. **Definitions**

**Human Tissue Authority (HTA)** – The governing body set up to regulate activities that come under the HT Act. The HTA is a watchdog that supports public confidence by licensing organisations that store and use human tissue for scheduled purposes.

**HTA Adverse Event (AE)** – Any undesirable incidence associated with the collection, testing, processing, storage and distribution of human tissue and cells that might lead to loss or damage of human tissue.

**Human Tissue** – Any and all constituent parts of the human body formed by cells.

**Relevant Material** – Any material, other than gametes, removed from the body which consists of or includes human cells. In the HT Act references to relevant material from a human body do not include:

- embryos outside the human body,
- hair and nail from the body of a living person,
- cell lines or any other human material created outside the human body,
- serum, plasma, DNA and RNA,

See the Human Tissue Authority website1 for the HTA Supplementary List of Materials (appendix A).

**HTA Licence Holder (LH)** – Nominally this is “Middlesex University” but represented by a named individual.
Please refer to the “Contacts” list for the name of the current LH.

**HTA Designated Individual (DI)** – Is the person authorised to supervise "licenced activities" under a licence issued by the Human Tissue Authority. Please refer to the “Contacts” list for the name of the current DI.

**HTA Person Designate (PD)** – A person to whom the licence applies and to whom the authority conferred by the licence extends. Each School operating under an HTA Licence should have at least one Person Designate. The activity of each PD is overseen by a senior PD and the DI. Please refer to the “Contacts” list for the name of the current PDs and senior PDs.

**HTA Principal Investigator (PI)** – is the appropriately qualified individual for each project who has responsibility for the conduct of projects under their control. The activity of each PI is overseen by a PD

**Standard Operating Procedure (SOP)** – Detailed, written instructions to achieve uniformity of performance of a specific function (*this document*).

5. **Procedure**

- All staff and student working with human tissue should know the possible Adverse Events (AE) that can occur in regard of working with human tissue. PIs are required to regularly complete risk assessments in relation to the collection, use and storage of human tissue in their area and share with all relevant persons. Completion of risk assessments forms will identify the likelihood of any potential adverse events and controls to minimise the likelihood and effect of such AE. The PI must ensure that risk assessments are carried out before commencing any work using human tissue. More information can be found in Middlesex University HTA SOP for Risk Management and Contingency Planning.

- Middlesex University has developed an internal system for reporting and recording HTA adverse events. An Adverse Event/Incident Reporting form (see Appendix A)
has been developed. The form is to be used by researchers storing and using human tissue under the University’s HTA Licence and should be used for recording and reporting any event that results in damage or loss of tissue, or ‘near miss’ events (where there was the potential for human tissue to be lost or damaged). The form must be completed by the PI then forwarded to the relevant PD and DI as soon as possible. The DI then reports such occurrences to the HTA and takes appropriate steps to prevent recurrence.

Follow-up of an Adverse Event

- Middlesex University Human Tissue governance will follow up three months after the AE event has been reported to see what corrective and preventative actions have been put in place. This will be evaluated, documented and its effective implementation monitored.

6. Referenced SOPs

Middlesex University HTA Standard Operating Procedure for the Management of Records

Middlesex University HTA Standard Operating Procedure for Risk Management and Contingency Planning
HTA Adverse Event/ Incident Reporting Form

To be completed by the relevant PI and forwarded to the appropriate PD and DI as soon as possible.

<table>
<thead>
<tr>
<th>Surname:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Forename:</td>
<td>Title:</td>
</tr>
<tr>
<td>Work telephone number:</td>
<td></td>
</tr>
<tr>
<td>Job Title:</td>
<td></td>
</tr>
<tr>
<td>School/ Department Name:</td>
<td></td>
</tr>
</tbody>
</table>

### Adverse event/ Incident Details

<table>
<thead>
<tr>
<th>Event/ Incident Date:</th>
<th>Time of Event/ Incident:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site:</td>
<td></td>
</tr>
<tr>
<td>Location (Please give specific details):</td>
<td></td>
</tr>
</tbody>
</table>

**Description of Adverse Event / Incident:** Please give specific detail
<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the event/ incident result in loss or damage to human tissue stored in the School/Unit? [delete as appropriate]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did the event/ incident result in any personal injuries or ‘near misses’? [delete as appropriate]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If ‘yes’, please complete a separate Accident Report as described in the AE SOP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have recommendations been made by the PD / DI to prevent a similar incident recurring? [delete as appropriate]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Please record details of action taken:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For completion by PD / DI</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Form completed by:

<table>
<thead>
<tr>
<th>Print name and position held of person completing this HTA Adverse Event form:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of School/ Department HTA Person Designate:</td>
</tr>
<tr>
<td>Has the School/ Department HTA Person Designate been notified (please tick):</td>
</tr>
<tr>
<td>Date:</td>
</tr>
</tbody>
</table>

Yes | No |

Please keep a copy of this form with you and send a copy to the relevant PI, PD for HTA and the original should be sent to:-

Lucy Ghali HTA DI  
1st Floor, Hatchcroft Building  
H138  
Middlesex University,  
Hendon Campus  
L.ghali@mdx.ac.uk

7. Contacts
8. Declaration

I have read and understood fully Middlesex University HTA Standard Operating Procedure for Adverse Event and agree to follow the procedures laid out in this document.