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

HTA Disposal of Human Tissue SOP

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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.

The HT Act makes it lawful to treat as ‘waste’ any relevant material which has come from a person who was in the course of receiving medical treatment; undergoing diagnostic testing or participating in research. It also states that material no longer used, or stored for use, for any Scheduled Purpose can be dealt with as waste.

The HTA Codes of Practice 5 – Removal, storage and disposal of human organs and tissue provides practical guidance to those carrying out activities, which lie within the regulatory remit of the HTA and details the standards expected for the disposal of human material (http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code5disposal.cfm).

The following activities require disposal in accordance with the HTA Codes of Practice 5, where human tissue/cells has:

- been removed from a person’s body for the purposes of his medical treatment;
- been removed from the body of a deceased person for the purposes of an anatomical, or
- post-mortem, examination;
- been removed from a human body for use for a scheduled purpose;
- come from a human body and been imported for use for a scheduled purpose, or
- come from the body of a deceased person which has been imported for use for a scheduled purpose.
2. Purpose
This Standard Operating Procedure (SOP) has been developed to provide guidance to all Middlesex University staff and students and to ensure that all Persons Designate (PD) and staff working under their direction are fully aware of the procedures needed to ensure that the requirements for disposal under the HT Act and HTA Codes of Practice are met.

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. This SOP must be used in conjunction with the Human Tissue Authority Codes of Practice and all other relevant University policies and SOPs where appropriate.

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

4. Definitions
**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.

**Designated Individual (DI)** – Is the person authorised to supervise "licenced activities" under a licence issued by the Human Tissue Authority.

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

**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.
National Research Ethics Service (NRES) – NRES is the core function of the Health Research Authority (HRA) which was established on 01 December 2011 and is committed to enabling and supporting ethical research in the NHS. It provides an efficient and robust ethics review service and has a dual mission:
To protect the rights, safety, dignity and well-being of research participants to facilitate and promote ethical research that is of potential benefit to participants, science and society.

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.

Principal Investigator (PI) – is the appropriately qualified individual at each project site who has responsibility for the conduct of the project at that site.

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 website below for the HTA Supplementary List of Materials


Disposal - The action of permanently disposing of, putting away, getting rid of relevant material previously stored/used for research purposes.

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

5.1. Human material must be disposed by fully trained personnel in the applicable HTA Codes of Practice.

5.2. Disposal of human material should be undertaken in accordance with the establishment disposal policy from where the material has been obtained and/or as detailed in the Material Transfer Agreement (MTA)

5.3. Confidentiality should be maintained at all times

5.4. Human remains must be disposed of with due respect for the donor of the tissue. As a minimum, stored human body parts, organs and tissue should be disposed of separately from other clinical waste.

5.5. Disposal information/documentation must include:

1. Unique sample number
2. Identification of the relevant tissue to be disposed
3. Reason for disposal
4. The date for disposal
5. Evaluation of the risk associated with the disposal
6. Total amount of tissue to be disposed of
7. Method of disposal
8. Person, site or third party undertaking disposal

6. Maintaining Proper Documentation

Proper records should be maintained and documentation for all tissue acquired or passed on to others must be kept. Records should include:

- When the material was acquired, and where from
- What has been consented to
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- The uses to which the material is put whilst in the establishment’s care and any processes applied to it
- When the material is transferred elsewhere, and to whom
- Disposal details

Please refer to the Middlesex University Management of Records SOP for further information on record keeping.

7. References

- The HTA Codes of Practice 5 –
- Human Tissue Authority website below for the HTA Supplementary List of Materials

8. Referenced SOPs
Middlesex University HTA SOP Management of Records

9. Contacts

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Lead PDs

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10. Declaration

- I confirm that I have read and understood fully the Middlesex University HTA Standard Operating Procedure for Disposal including HTA Code of Practice 5: Removal, storage and disposal of human organs and tissue.

Print Name Signature Date