



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

Import and export of human tissue for research purposes 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, Education and Training.

2. Purpose

All Middlesex University staff and students involved in research covered by the HT Act, the Human Tissue Authority's (HTA) Codes of Practice and Standards and the University's HTA licence for research should recognise and understand the procedure and mechanisms to acquire (receive or import) or transfer (despatch or export) human material for storage and use in research and recognize when tissue needs to come under an HTA Licence. This SOP must be read in conjunction with the Middlesex University HTA SOP for Transportation of Human Tissue.

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. The SOP must be used in conjunction with the Human Tissue Authority Codes of Practice and Standards 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.

Material Transfer Agreement (MTA) – Is a contract that governs the transfer of human materials, for the purpose of research between two organisations.

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

Export: according to the HT Act means export from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland.

Import: according to the HT Act means import into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland.

Anonymisation – is a procedure to ensure that if relevant material is removed from a human body, all necessary steps are taken to prevent identifying the person from whose body the material has come.

Principal Investigator (PI) – is the appropriately qualified and trained individual at each project site who has responsibility for the conduct of the project at that site. PI is responsible for ensuring all relevant material is labelled and stored appropriately and the records are complete and kept in a safe place.

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 attached document for the HTA Supplementary List of Materials

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

Person Designate (PD) – A person to whom the licence applies and to whom the authority conferred by the licence extends.

National Research Ethics Service (NRES) – NRES is the core function of the Health Research Authority (HRA) which was established on 01 December 2011. 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.

Natural Science Ethics sub Committee (NSESC) – Provides ethical review of non-clinical research involving human subjects or human material within the School of Science and Technology.

University Ethics Committee (UEC) – Develops and sustains a University-wide awareness of ethical issues arising from non-clinical research involving human subjects, human material and human data.

Research and Knowledge Transfer Office (RKTO) – The Research and Knowledge Transfer Office provides a specialist service across all research and knowledge transfer activities.

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

5. PROCEDURE

Human Tissue – Import

Before importing human tissue for the purpose of research researchers should justify the need to do so and demonstrate that the purposes for which they wish to import such material cannot be met adequately by comparable material available from sources within England, Wales or Northern Ireland.

- All Middlesex University staff and students importing material should be satisfied that risk of infection via imported material should be proportionate to the purposes for which they will use the material. Risk assessments should be adequate and in place throughout the process of acquiring, storing, using and disposing of material, where appropriate.
- Importers must be able to provide adequate assurance that this is in place and that protection against any infectious agents is upheld.
- The HTA consider it best practice to ensure mechanisms are in place in the source country for obtaining Consent. Researchers should be satisfied that consent has been considered as part of Ethical Review in the Host Country and that any material intended for import is sourced consistently with the legal and ethical review requirements in England, Wales and Northern Ireland. Middlesex as Licence Holder for this activity would expect consent to be obtained.
 - a. If ethical approval from the source country is not in place or below UK standard, the study under which the material is being imported should have ethical approval from a UK based ethics research committee.
 - b. The PERSON undertaking import and export must keep a register of all tissue transfer.
 - c. Traceability during transport and delivery:

- d. Records of Transport and delivery must be kept as detailed in SOP
- e. Material Transfer Agreements must be completed as detailed in SOP
- f. Unique Codes must be applied to as detailed in SOP
- g. Packaging must conform to international standards for the Transport of Hazardous Clinical Material. See WHO guidance note Middlesex University Transportation of Human Tissue SOP.
- The Disposal of imported goods should be dealt with as detailed in the Middlesex University disposal SOP. Specific requests must be upheld, for example returning material to its country of origin.

Human Tissue – Export

- Mechanisms should be in place to ensure that human tissue to be exported from England, Wales and Northern Ireland are used in accordance with the consent which has been obtained.
- Additional ethical consideration is not required to export human tissue providing there is appropriate consent for the exportation and subsequent use of the material.
- If the donor did not consent to their tissue being sent abroad, it can only be exported if further consent is obtained from the donor or if the tissue is from the living and ethical approval is obtained either from NSESC or UEC to export the tissue and it is anonymised.
- Human tissue to be exported must be handled, stored, transported and disposed, in a manner consistent with safety considerations, and with the dignity and respect accorded to human tissue in legislation and codes in England, Wales and Northern Ireland.
- World Health Organization (WHO) guidance on regulations for the Transport of Infectious Substances 2013-2014 must be consulted prior to exporting human tissue to ensure the correct labelling and packaging has been used. Hand carriage of Category A or Category B infectious substances is strictly prohibited by international air carriers; see the Middlesex University HTA Standard Operating Procedure for the Transportation of Human Tissue for further information.
- Appropriate modes of transport, suitable routes and arrangements with people involved must be planned and arranged in advance.
- A material transfer agreement should be in place to ensure that human tissue to be exported from England, Wales and Northern Ireland is used in accordance with the consent that has been obtained. All MTAs must go through Middlesex University Research and Knowledge Transfer Office (RKTO).

The following records of tissue transportation need to be maintained:

- Records of donor consents for export and subsequent use of the tissue must be kept for each sample being exported.
- the tissue type, quantity and sample ID of the exported tissue;
- when the tissue was transported;
- if/when the tissue was returned;
- details of transport and delivery;
- material transfer agreements with recipients of tissue;
- Service Level Agreement (SLA) with courier or transport companies;
- transportation risk assessment from the point of view of the tissue.
- All relevant details should be recorded in an appropriate register by the person undertaking the export of the relevant material. The register should be retained in a safe place and made available for inspection by the HTA on request.
- Material should be disposed of in a manner consistent with safety considerations, and with the dignity and respect accorded to human bodies, body parts and tissue in legislation and codes in England, Wales and Northern Ireland.
- The MTA should detail who is responsible for disposal of the tissue, if any of the tissue will be returned to the sender or if the recipient is responsible for the disposal.

6 REFERENCES

HTA Codes of Practice and Standards:

<https://www.hta.gov.uk/hta-codes-practice-and-standards-0>

WHO Guidance on Regulations for the Transport of Infectious Substances:

http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2007_2/en/

Referenced SOPs

- Middlesex University HTA SOP
- Middlesex University HTA SOP Management of Records
- Middlesex University HTA SOP Risk Management and Contingency Planning
- Middlesex University HTA SOP

7. Useful information

HTA news and event

<https://www.hta.gov.uk/news>

https://www.hta.gov.uk/newsletter_archive

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8. Contacts

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9. Declaration

I have read and understood fully Middlesex University HTA Standard Operating Procedure for Import & Export of human tissue and agree to follow the procedures laid out in this document.

Print Name

Sign Name

Date