



Middlesex University Policy of Working with Human Tissue in Research

Review History			
<u>Version</u>	<u>Date</u>	<u>Author</u>	<u>Summary of changes</u>
2	Jan 2024	Stephanie Bee	Update link – page 4 https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004

1. Training

- Anyone who works in the Faculty of Science and Technology (S&T) with human samples relevant or non-relevant in research, whether under an HTA license or a 'recognised' REC approval, must undertake training on the Human Tissue Act, Human Tissue Authority (HTA) and its related codes of practice.
- Staff working with HTA license 12533 outside of the Faculty of S&T for example in Art, are required to complete HTA training as well.
- Training must be completed before starting work with human samples and updated every two years.
- The chief or principal investigator is responsible for ensuring that they, all their staff, and any students in their research group are appropriately trained for their role and that proof of completion is available for auditing purposes.
- Please contact the designated individual (DI) Dr Lucy Ghali (l.ghali@mdx.ac.uk) to arrange training session.

2. Informed Consent

- Staff involved in seeking consent must undertake training, this is a legal requirement. Training on informed consent is provided by Dr Lucy Ghali. Please contact Dr Lucy

Ghali by email (l.ghali@mdx.ac.uk) to organise consent training before starting consenting participants for the donation of their body material for the purpose of research. A form will be provided to sign and is uploaded on the MORE system as part of ethics approval process. A hard copy will be kept for proof and for audit purposes

- Chief or principal investigators are responsible for ensuring all applicable staff has appropriate and up-to-date consent training (**renewed every three years**) and that proof of completion is available for auditing purposes

In addition to completing HTA training and consent training where applicable, make sure you read through the checklist below and that you are familiar with this local information.

Checklist

1. **Do you work under Middlesex University HTA research licence 12533?**
 - You work under the licence if you work with one or more human tissue samples/relevant materials that are registered under it e.g. existing holdings
 - **This includes, but is not limited to:**
 - Lab staff who physically handle tissue samples
 - **Anyone who is involved in applying for ethical approval to collect or use material**
 - All are considered to be working with human tissue although they do not all work under an HTA licence.
 - The Human Tissue Act 2004 applies to everyone, even though the licensing requirements do not
 - The PIs/CIs responsible for groups working with human tissue
 - If you are unsure whether you work under MDx HTA licence, please contact one from the HTA management team, contact details below
 - PI/CI must have full records of the type of samples that are under the HTA licence and those that are not
 - Freezer doors or storage areas should display the type of samples stored in them

- Many collections under an HTA licence will also have **foreign REC approval** for processing. These collections must also be stored under Mdx HTA licence
- Ethical approvals from a recognised REC or Mdx relevant ethics committee for all collections must be documented and the DI is aware of their existence.

2. Do you know what is held under a license and what is held under current ethical approval from a recognised Research Ethics Committee?

- All relevant material for use in research must be held under HTA licence **except exempted collections**. The most common exemptions from licensing are storage of non-relevant material (for example serum, cell-free plasma, DNA) or current and **valid approval from an NHS research ethics committee (REC)**
- Please be aware that REC approvals expire and that only samples stored for the activities explicitly approved by the REC are exempt from licensing (check MTA)

3. Is there consent for all stored tissue under your custodianship?

- There should be valid consent forms, either on site or that can be recalled from the archive by PI/CI or a valid research agreement e.g. Material Transfer Agreement MTA **signed by a University signatory (not a PI)** that guarantees consent.
- If none of these is in place, ask the HTA management team for advice.

4. How and where do you access documents relevant to your work e.g. SOPs, policies etc

All documents relevant to your work are found by accessing the link below.

<https://mdx.mrooms.net/course/view.php?id=12277> (Staff and Students - Via myunihub account, the link should take you mylearning and Middlesex Online Research Ethics page. If you are not signed in it will ask you to do so. Please scroll down to folder 9- Human Tissue Authority Information, where all the Standard Operating documents can be found)

<https://moreform.mdx.ac.uk/> (Staff and Students – the HTA Standard Operating Procedures (SOPs) are all found in MOREform under the Help tab at the top of the screen and then

select templates. Please use the search function to find the document needed (HTA Management of Records)

There are different Standard Operating Procedures for the different activities involving the use of relevant human material in research. You need to read and familiarise yourself with all of them before handling, collecting, or starting to work on human tissue for scheduled purposes.

5. **For more information you can visit the below links.**

[Human Tissue Act](#)

[HTA codes of practice](#)

[Human Tissue Authority](#)