

**STANDARD OPERATING PROCEDURE**

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| **Reference Number** | **MMUHTA\_008** |
| **Title** | **Training for HTA Compliance** |
| **Effective Date** | **19th January 2023** |
| **Review Date** | **2nd March 2025** |
| **Superseded Version Number & date** | **V1.2 2nd March 2023**  |
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# Background

The University has introduced a quality management system for the governance of the acquisition, storage, and use of human tissue.

This system will ensure that all work is carried out to the highest standard and that the University complies with the licensing obligations of the Human Tissue Act (HTA, 2004).

This SOP forms part of a suite of SOPs (MMUHTA\_001 – MMUHTA\_019) that support implementation of the quality management system and should be used as directed in conjunction with Manchester Metropolitan University’s HTA Code of Practice.

# Purpose

The purpose of this SOP is to set out a standard template for training for those who are using material which falls under the Human Tissue Act (2004).

# Definitions

## Human Tissue

Any, and all, constituent part/s of the human body containing cells.

# Scope (of this SOP)

All Manchester Metropolitan University staff participating in work/projects involving human tissue.

# Procedure

All staff proposing to undertake research with human tissue must complete appropriate competency-based training prior to commencement of the work. This will include familiarisation with relevant documentation (codes of practice, standard operating procedures, and risk assessments) and undertaking appropriate training courses where required.

Training requirements should be determined according to the role of the individual and reviewed before the commencement of each new project/activity.

The training requirements of individuals and subsequent achievement of the required competencies should be identified and recorded by the relevant Research Administrative Group. This will differ between Faculties and specific advice should be taken from the designated individual.

The minimum training required for all users is to take the online Medical Research Council (MRC) training, attend an Induction session and a general laboratory 3rd floor health & safety session.

The MRC training can be found on [https://byglearning.co.uk/mrcrsc-lms/course/index.php? categoryid=1](https://byglearning.co.uk/mrcrsc-lms/course/index.php?%20categoryid=1) and the course to be completed is: [**Research and human tissue legislation assessment - England, Wales & NI**](https://byglearning.co.uk/mrcrsc-lms/course/view.php?id=43)

As proof of completion of the course individuals should send the Certificate to the DI and PDs for archiving.

The HT induction session checklist ensures that HT users at the University have been trained on, and are made aware of, official HTA guidelines, MRC HT training, ManMet’s HT procedures (SOPs, risk assessments, ethical approval, consent training), sample traceability in ItemTracker and the Tutela freezer alarm system. The goal of the induction is to familiarise HT users with the suite of resources available that will ensure sample acquisition and traceability are as required by the HTA.

During the induction, the HT user is signed off if they meet all the below:

* Obtained University ethical approval or external approval where needed.
* Completed MRC training (it is a requirement that this training is renewed every two years)
* Undertaken consent training by watching the [Human Tissue Act (HTA) consent video - mmutube](https://mmutube.mmu.ac.uk/media/Human%2BTissue%2BAct%2B%28HTA%29%2Bconsent%2Bvideo/1_gogi84jl)
* Read all Manchester Metropolitan University’s SOPs, risk assessments and HTA Code of Practice (HTA Code A & E) related to the HTA
* Been allocated space to store human tissues samples
* Given access to HTA SharePoint
* Viewed training PowerPoint for ItemTracker
* Training and understanding how the Tutela alarm system operates
* Have sufficient and suitable racking for storage of samples
* Have sample labels that fulfil the criteria for use in ItemTracker
* Been advised about the quarantine of sample when they arrive until they receipt them and place them on ItemTracker

In cases where additional training is required, as a part of updates and changes to existing SOPs, all additional training must be carried out within four weeks of being notified of the changes. If training is not completed within the four week period, access to the HTA storage freezers will be revoked and research halted until training is complete.

# Additional Information

If PIs have visitors joining them to conduct work on their research, the HT compliance team (DI/PDs) should be notified to ensure that the visitor has MRC training, and a HT induction session is provided. It’s the PIs responsibility to ensure that the visitor is working within HTA guidelines during their stay at the University.

# Version Control

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| **Version** | **Reason for change** | **Date** |
| 1.0 | N/A | 14th June 2021 |
| 1.1 | A new SOP was added to the suite therefore writing changed to state ‘SOPs (MMU-HTA001 – MMU-HTA016)’ rather than SOPs (MMU-HTA001 – MMU-HTA015) | 25th November, 2022 |
| 1.2 | Changes in writing to indicate new SOPs were added in the suite (MMU-HTA001 – MMU-HTA018) + added more information about the training process mainly the HT Induction session and visitors working with HT. | 19th January, 2023 |
| 1.3 | Author & Reviewer fields added to title table + changed writing to state ‘SOPS (MMUHTA\_001 – MMUHTA\_019)’ rather than SOPs (MMU-HTA001 – MMU-HTA018) + Minor grammatical & formatting changes | 2nd March, 2023 |
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