

**STANDARD OPERATING PROCEDURE**

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| **Reference Number** | **MMUHTA\_001** |
| **Title** | **Obtaining Consent** |
| **Effective Date** | **19th January 2023** |
| **Review Date** | **19th January 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| **Superseded Version Number & date** | **V1.2 2nd March 2023** |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 Manchester Metropolitan University’s HTA Code of Practice.

# Purpose

The purpose of this SOP is to set out procedures for obtaining consent for the acquisition of material that falls under the Human Tissue Act (2004).

# Human Tissue Definition

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

# Scope (of this SOP)

All instances where Manchester Metropolitan University staff are responsible for obtaining informed consent from research participants for the use of their tissue(s) for research.

Informed Consent is an agreement by a person to receive treatment, undergo procedures, or participate in research after the risks and benefits have been adequately explained to them.

Informed consent should be sought in advance of commencing any procedure(s) or intervention(s). A Participant Information Sheet (PIS) and the provision of any further requested information should support the informed consent.

Investigators are expected to be trained to be aware of the HTA requirements, be trained in taking informed consent ([Human Tissue Act (HTA) consent video - mmutube](https://mmutube.mmu.ac.uk/media/Human%2BTissue%2BAct%2B%28HTA%29%2Bconsent%2Bvideo/1_gogi84jl)) and are expected to remain proficient in obtaining consent.

# Provision of Participant Information

It is expected information will be provided to the participant by an individual who is qualified to obtain informed consent. This process should be supported by a written, or audio, Participant Information Sheet (PIS). Following the provision of this information, individuals should be given time to consider whether to participate in the research. The time provided should be considered on a case-by-case basis considering the type of research and the participant group.

Individuals should be given the opportunity to ask any questions they have about the research when they are considering whether or not to participate.

# Informed Consent

The Human Tissue Act does not specify the format in which consent should be given or recorded for research. It is, however, considered best practice for written informed consent to be obtained.

Once the individual has considered the information provided and wishes to participate in the research, informed consent can be taken. Consent for participation in research must be confirmed in writing, or another, e.g. audio record, form that can be stored, and the signatures, full name and date of the consenting participant and the researcher must be detailed on the form.

For consent to be valid it must be given voluntarily by an appropriately informed person who has the capacity to give consent.

The individual seeking consent should be suitably trained and qualified and have sufficient knowledge of the proposed investigation or treatment. For research where several areas of specialist knowledge are involved participants should be offered access to specialists if they require additional information.

A copy of the consent form should be given to the participant and the original should be kept by the researcher. The consent forms will be stored securely.

This SOP does not apply where research involves an existing holding transferred using a Material Transfer Agreement and consent is held at the donor institution. Consent is not required if tissue was obtained from a living person before 1 September 2006 or if samples are AND anonymised AND the project is NHS REC approved.

# Right to withdraw

Individuals should be informed that after giving informed consent, they have a right to withdraw from the research at any time, without having to provide a reason. Participants who have been recruited from the NHS or other health care settings should also be informed that if they decide to withdraw from the research, this will not adversely affect their relationship with those providing care, or the care they receive now or in the future.

If consent is withdrawn for (a) sample/s, the PI is responsible to ensure they:

* Communicate the information with any PDRAs / PhD students involved in the research study.
* The sample/s are located (permitting to the stage that the sample is in during that research study), removed from storage and disposed as per guidelines in SOP [MMUHTA\_007](https://stummuac.sharepoint.com/%3Aw%3A/r/sites/pro-rke-hta/Shared%20Documents/SOPs/MMUHTA_007%20Disposal%20of%20Human%20Tissue_V1.4.docx?d=w4222511a38554309849b27b912302401&csf=1&web=1&e=lu2b0S) ‘Disposal of Human Tissue’.
* If the consent form is held on-site, this should be located and disposed via confidential waste measures. Any digital copies should also be deleted appropriately off the HTA SharePoint.
* Updated Itemtracker by deleting the sample off the database and filling in the deletion reason fields including consent withdrawn, date of withdrawal (date) and consent form disposed via confidential waste (yes/no), date consent form disposed (date).
* A copy of the written withdrawal consent instructions is maintained in the HTA SharePoint under the appropriate study folder.

# Vulnerable Groups

There are specific requirements for obtaining consent from vulnerable groups, which include:

* Children under 18 years of age
* Adults without capacity to give consent

For research involving these groups, it is important that all relevant legislation and requirements are considered when developing the consent process and associated documentation.

Additionally, it is important to develop an appropriate process for gaining informed consent from participants whose first language is not English.

# Procedure for obtaining informed consent

# Useful resources

HTA Codes of Practice and Standards - Guiding principles and the fundamental principle of consent <https://www.hta.gov.uk/guidance-professionals/codes-practice>

# Version control

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| **Version** | **Reason for change** | **Date** |
| 1.0 | N/A | 10th June,2021 |
| 1.1 | Added the Consent video link + A new SOP was added to thesuite therefore writing changed to state ‘SOPs (MMU-HTA001 – MMU-HTA016)’ rather than SOPs (MMU-HTA001 – MMU-HTA015) | 21st November,2022 |
| 1.2 | Instructions added to SOP on PI’s responsibilities once consent is withdrawn for samples + New SOPs were added to thesuite therefore writing changed to state ‘SOPs (MMU-HTA001 – MMU-HTA018)’ rather than SOPs (MMU-HTA001 – MMU-HTA016) | 18th 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 improvements | 2nd March,2023 |
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