

## STANDARD OPERATING PROCEDURE - TRANSPORT OF HUMAN TISSUE

<b>Reference Number</b>	<b>MMU-HTA 004</b>
<b>Effective Date</b>	<b>1<sup>st</sup> January 2017</b>
<b>Review Date</b>	<b>31<sup>st</sup> December 2017</b>
<b>Superseded Version Number &amp; date</b>	<b>MMU-HTA 004 (V1 2012)</b>
<b>Authorisation</b>	<p><b>Designated Individual</b>  <b>Professor Tristan McKay</b>  Signature .....  </p>

### 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 (2004).

This SOP forms part of a suite of SOPs (MMUHTA 001 – MMUHTA011) that support implementation of the quality management system and should be used as directed in the Quality Manual:

### Purpose

The purpose of this SOP is to set out the procedures for the transport of human tissue to and from Manchester Metropolitan University.

### Definitions

#### Human Tissue

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

#### Scope (of this SOP)

All human tissue transfers to and from Manchester Metropolitan University where Manchester Metropolitan University is responsible for arranging the transport of the tissue, with the exception of tissue transferred to SRCL (<http://www.srcl.com/>) for disposal.

Transport may be undertaken by a member of University staff, post-graduate student or by an approved courier.

### Procedure

#### *Material Transfer Agreement*

The University Material Transfer Agreement (MTA) can be found on the Manchester Metropolitan University Ethics webpages.

Where material transfer is needed, University staff and/or students should explicitly agree the terms and conditions with the materials exchanged in a MTA. All human tissues and cells classified as relevant material can only be transferred under the terms of the MTA.

The MTA leaving Manchester Metropolitan University (hereby referred to as the ‘outgoing’ MTA) must be used for samples from a Manchester Metropolitan University collection/bank (which must be licenced by the HTA).

Where a request is received for release of tissue for use in research with current ethical approval, and where the person/laboratory holding the tissue is not directly involved in the research<sup>1</sup>, the custodian of the tissue must obtain confirmation in writing that there is ethical approval and that consent/consent exemption is in place. This should be recorded on the form in appendix 1. A MTA is always required for a transfer to a third party, if that third party is not part of a study. The written confirmation will be obtained prior to the transfer of the material and will be reviewed by the Designated Individual (DI) prior to the MTA being signed.

A MTA may be used for the transfer of material as part of a research project, if this is considered appropriate by the DI; for example to protect intellectual property rights, or if transferring to another country. Legislation may be different in the receiving country, an MTA will ensure that the conditions of the transfer of the conditions are adhered to.

Researchers transferring material must contact the Research Ethics and Governance team ([research.governance@mmu.ac.uk](mailto:research.governance@mmu.ac.uk)) who will facilitate the signing of the MTA. If changes are requested by the other party, the matter must be referred to the legal team for negotiation. Where this is the case, the DI should also be informed and updated on the progress.

The draft agreement should be forwarded to the recipient and the custodian of the material to be agreed. When both parties agree on the terms of the MTA, the original will be sent to the Research Ethics and Governance (REG) team ([ethics@mmu.ac.uk](mailto:ethics@mmu.ac.uk)), to be reviewed by the Director of Research and Knowledge Exchange (RKE). Once the content has been agreed, it will be signed be signed by the Director of RKE and then signed by the DI, before it is sent to the recipient. The University will sign more copies upon request. An authorised recipient countersigns the original MTA, keeps a copy for their records then returns the original to the DI. For all MTA signatures, an original signature is required. Electronic signatures will not be accepted. A copy is then sent to the researcher for their records.

When material is transferred onto the university site an ‘incoming’ MTA (as provided by the supplier) must be sent to the DI and REG team ([ethics@mmu.ac.uk](mailto:ethics@mmu.ac.uk)) for review, following their review, it will then be sent to the legal team. The incoming MTA must be signed by the DI. The hard copy will be stored by the DI; signed electronic copies will be stored by the Research Ethics and Governance team in Research and Knowledge Exchange.

The researcher responsible for transferring or receiving transferred relevant material must keep his/her own records detailing which samples have been transferred, where the samples have been transferred to/from and dates of their sample transfer. This should also be recorded on the University sample tracking software.

Any queries related to the transfer of relevant material should be directed to the DI.

### ***Transfer of samples – packaging***

The total packaging must include:

- A watertight, leakproof primary receptacle;
- A watertight, leakproof secondary packaging;
- Primary and secondary packaging must be able to retain their integrity at the temperature of transport;
- Outer packaging of sufficient strength for its capacity, mass and intended use.

For transport at ambient temperature, the primary receptacle should be plastic, metal or glass. If screw caps are used they should be reinforced with adhesive tape to ensure a leak-proof seal.

---

<sup>1</sup> For example: tissue blocks stored in laboratory archives are requested for use in research at a collaborating university.

Containers, boxes and labels for human tissue transfer can be purchased from general laboratory suppliers.

For transport in dry ice, the dry ice should be placed around the secondary packaging (whilst wearing freezer gloves and goggles) and the secondary packaging, and the outer packaging must allow the release of carbon dioxide gas to avoid the build-up of gas and potential rupturing of packaging or explosion.

#### *Transfer of samples – Labelling and paperwork*

Before samples are transferred, the following information should be included on the label

Sample Reference Number:

Tissue Type:

Details of medium/preservative if applicable:

Date of packing:

UN 3373 warning label

([https://www.tnt.com/dam/tnt\\_express\\_media/global\\_media\\_library/images/ppdownloads/2015\\_Guidance Document for regulations and restrictions UN3373 Jan2014.pdf](https://www.tnt.com/dam/tnt_express_media/global_media_library/images/ppdownloads/2015_Guidance_Document_for_regulations_and_restrictions_UN3373_Jan2014.pdf))

Paperwork, including a list of contents, must be placed in waterproof packaging, and placed between the secondary packaging and the outer packaging. Labels on the primary and secondary packaging should be waterproof and, where handwritten, should be in permanent black ink. Labels on the outer packaging must be durable, legible and clearly visible. They should contain the delivery address and the senders details. If transporting in dry ice, the words 'DRY ICE' should be clearly visible on the outside of the package.

A copy of the signed and countersigned MTA must accompany all human material released from the HTA licenced site. A copy of the donor consent form(s) should remain at the site; however a copy of the consent form may be sent to the third party upon request, but only if this does not contravene donor confidentiality or the terms of the ethics approval.

#### *Transfer of samples – Transport*

It is important that researchers check that the Courier SOP's are in place to ensure compliance with the Human Tissue Act (2004) and any other appropriate legislation, Integrity of the sample, security of the sample and the respect for the dignity of the donor.

Transport of human tissue samples by air requires additional documentation and, if transporting samples in dry ice, additional regulations must be adhered to.

Samples which require storage at different temperatures should be packaged separately.

All persons undertaking any role in the transport chain should be properly trained to carry out their responsibilities to the required standards. They must appreciate the risks involved and have a detailed understanding of the relevant regulations. The level of training required varies but should be commensurate with the role and the associated responsibilities and must be recurrent to take account of the changes in the regulations.

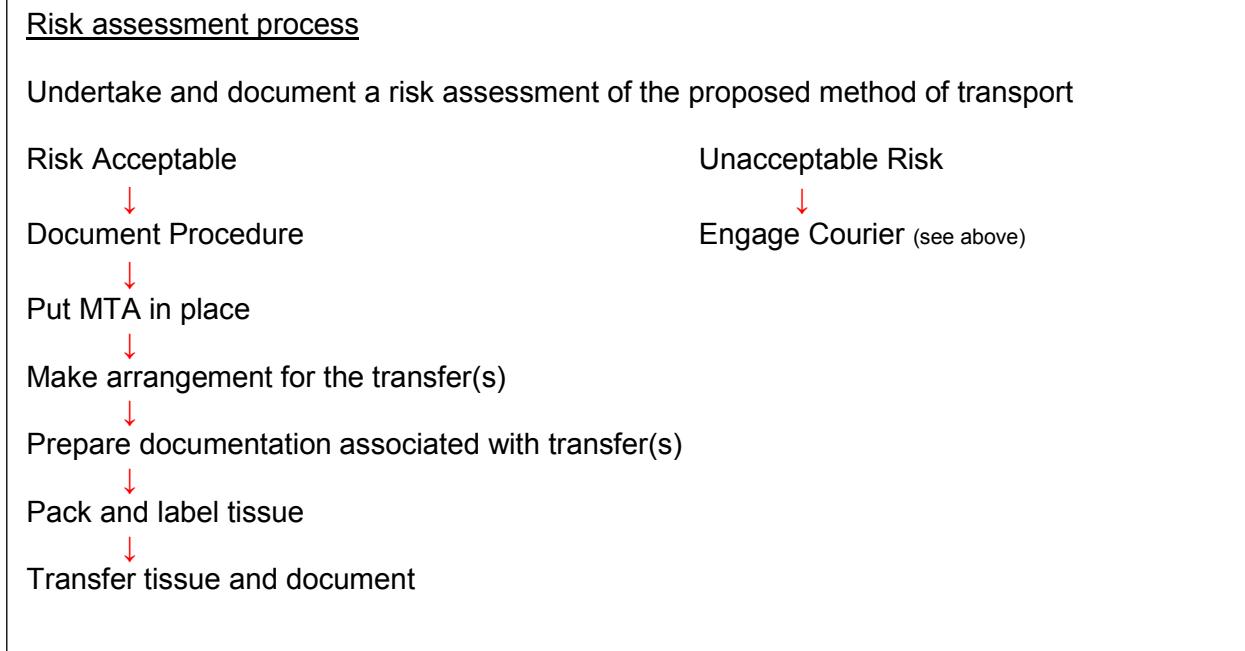
Transport of human tissue by university staff and/or students can only be undertaken if the risk associated with the transfer has been evaluated as acceptable via a university risk assessment at the Faculty level.

The Principal Investigator (PI) must be satisfied that procedures to be put in place to minimise risk are adequate and that the residual risk is acceptable.

The risk assessment should include consideration of the following:

- Personal risk to the individual undertaking the transfer;
- Risk to the public during transfer (chemical and biological hazard);
- Integrity of the sample;
- Patient confidentiality;
- Individuals involved in the transfer of human tissue are reminded that transfers should respect the dignity of the donor.

Update and document a risk assessment of the proposed method of transport.



If transporting in dry ice in a standard car, as opposed to a commercial carrier, then goods should not be transported in the same driving space that the driver/passengers occupy, and must be stored in the boot. Windows of the driver's area should always be open/ajar and when opening the boot compartment to retrieve a dry ice container the area should be allowed to ventilate to ensure any build-up of CO<sub>2</sub> gas dissipates before leaning into the area.

#### ***Transfer of samples – safety***

Be aware of the weight of the package, do not overfill.

When packaging/transporting in dry ice the following safety points should be noted:

- Avoid contact with skin and eyes;
- Never handle with bare hands, use insulated gloves and use tongs to handle blocks of dry ice. Goggles are recommended;
- Obtain dry ice in the form and size in which it will be used. Do not attempt to saw or break a block into smaller pieces;
- Transport in a well ventilated vehicle;
- Never store in an airtight container;
- Do not use in confined areas – the CO<sub>2</sub> vapour can cause rapid suffocation;
- Do not place dry ice on a tile or laminated counter top;
- Dispose of the dry ice by allowing it to sublimate in a well ventilated area where no build-up of CO<sub>2</sub> vapour can occur;
- Do not dispose of dry ice in sewers, sinks or toilets as the extreme cold can harm sink disposals and pipes.

## Appendix 1



### **Agreement for transfer of Archival tissue for projects with NHS ethical approval**

1. I confirm that the samples have been requested for a specific research project with ethical approval from an NHS Research Ethics Committee (REC).

Project Title:	
REC approval number:	
Project start date:	
Project finish date:	

2. I confirm that (initial as appropriate)

Patient(s) has/have given consent for the samples to be used in this research project.	
Consent exemption has been granted by the NHS REC	

3. I agree to abide by all relevant UK legislation pertaining to the use of human tissues and data including the Human Tissue Act (2004) and its Codes of Practice, and the Data Protection Act (1998).
4. I agree to follow good clinical and laboratory practice in handling the sample(s).
5. I agree to return the samples as soon as they are no longer required for the project and before the finish date stated above (1).

Principal Investigator:

Name:

Position:

Institution:

Signature:

Date: