

STANDARD OPERATING PROCEDURE

Material Transfer Agreements for the Transfer of Human Tissue

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Standard Operating Procedure: STH Researcher Material Transfer Agreements

This SOP has been produced in accordance with the Human Tissue Act 2004 and the Codes of Practice issued by the Human Tissue Authority. This SOP will outline the procedure to be followed when a Material Transfer Agreement (MTA) is required to cover the transfer of human tissue.

Definition & Background

The Law governing the transfer of tissue is the Human Tissue Act 2004. Any tissue transferred into or out of STH for the purposes of medical research will be transferred, handled and stored in accordance with the Codes of Practice issued by the Human Tissue Authority under the Human Tissue Act 2004.

An MTA is required when 'relevant' material, as defined in the Human Tissue Act is transferred out of (or into) STH. This involves generally any material that contains cellular material, such as tissue samples, whole blood and urine but excludes DNA/RNA, serum and plasma.

An MTA is a contract that governs the transfer of one or more materials from the custodian of material to a recipient (researcher or an organisation) wishing to use the material for research purposes.

Where another contract is to be used, for example the model agreements, it may be necessary to either additionally sign an MTA or insert the main terms of the Trust template MTA to outline the transfer and receipt of relevant material as an appendix, as per discussion with the HTA Lead.

In general an MTA will cover:

- Permitted use of the material
- Ownership of the material
- Access to the results of the materials used
- Confidentiality
- Indemnification/warranty
- Governing Law

In coming MTAs

The provider of a relevant material will usually have an MTA which they will require the recipient (STH) to sign. If no such agreement exists then an agreement should be put in place before the material is received in to STH.

Out going MTAs

All relevant material transferred out of STH must be approved by the STH Research Department and an MTA must be signed by both STH and the receiving party.

Wherever an STH based investigator is involved in the transfer of relevant material, the STH Research Department is responsible for reviewing, approving and signing incoming and out going MTAs on behalf of STH. Any investigator wishing to transfer tissue out of STH, or receive tissue from a third party, must contact the STH Research Department to discuss the arrangements in place for the safe transfer of the tissue and obtain local approvals as necessary (e.g. Directorate approval, R&D approval).

Procedure

A. Transfer of Tissue out of STH

1. The STH Investigator will notify the STH Research Department of the intention to transfer tissue derived from STH patients or staff out of STH.
2. The STH Investigator will provide details of the research project connected with the transfer of tissue. The Research Co-ordinator will record the requirement for an MTA on the Research Management System (RMS) diary page.

3. The Research Coordinator will check that all necessary Research Ethics Committee and Trust approvals (e.g. R&D Research Governance authorisation, Directorate Approval) are in place for the transfer of tissue out of STH to an external party.

4. The Research Coordinator will send the MTA template for review and approval by the external party.

4.1. If there are any financial implications in an MTA, review by the STH Research Accountant and finance approval in RMS is required.

5. The Research Coordinator will examine patient information sheets and consent forms used in connection with the MTA to ensure that consent for the transfer of tissue is explicit within these documents.

6. The Research Coordinator will arrange for the MTA to be signed by the authorised representative of STH and by the receiving party. One copy of the fully signed MTA will be kept in the Research Department Master file for the project and one copy by the STH Investigator. The receiving party will keep a signed copy of the MTA.

7. The STH Investigator will maintain a tissue log detailing the samples collected within STH. The tissue log will detail:

- Nature of tissue collected
- Date of tissue collection
- Place of tissue storage
- Signature of Investigator

The STH Investigator will maintain a log of tissues transferred outside STH. This tissue transfer log will detail:

- Nature of tissue to be transferred
- Date of tissue transfer
- Details of Recipient
- Signature of Investigator

B. Transfer of Tissue in to STH

NB: The transfer of tissue into STH for the purposes of research is unlikely. It will be far more common for tissue to be received by a Clinical Academic for the purposes of University laboratory based research which does not involve STH. Where STH is involved in the receipt of tissue from an external organisation for the purposes of research the following procedure applies:

1. The STH Investigator will notify the STH Research Department of the intention to receive tissue from an external organisation for the purposes of research. The STH Investigator will provide details of the research project connected with the transfer of tissue.

2. The Research Co-ordinator will record the requirement for an MTA on RMS
The transfer of tissue may not be in connection with a specific research project registered with the STH Research Department. Any transfer of tissue not connected to a specific registered project must be brought to the attention of the STH Research Department Lead for use of tissue in research.

3. The Research Coordinator will check that all necessary REC, Directorate and R&D approvals are in place for the transfer of tissue into STH from an external party.

4. The Research Coordinator will ask the Investigator to provide a copy of the MTA produced by the provider of the tissue. The STH Research Department Lead for use of tissue in research will review the MTA.

5. The Research Coordinator will arrange for the MTA to be signed by the representative of STH upon receipt of the signed MTA from the tissue provider. One copy of the fully signed MTA will be kept in

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the Research Department Master file for the project and one copy by the STH Investigator. The provider will keep a copy of the signed MTA.

6. The STH Investigator will maintain a tissue log detailing the samples received by STH. The tissue log will detail:

- Nature of tissue received
- Date of tissue receipt
- Place of tissue storage
- Use of tissue
- Signature of Investigator

7. The STH Investigator will submit an annual report to the STH Research Department detailing the tissue transfer transactions carried out that year.

Appendix 1. Associated documents

	Document	Research Department Network Location	Website	Database	Created by
1	STH Template MTA	Directory\Research Governance\Project Authorisation\Templates	No	No	LB