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The definitive version of all University of Leicester (UoL) Human Tissue Authority (HTA) Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that the up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Research Governance Ethics and Integrity (REGI) Website.

SOP: HTA-A1008-UoL

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Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
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Reviewer	All members of the College of Life Sciences Human Tissue Governance Committee	College of Life Sciences Human Tissue Governance Committee	N/A	N/A
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Background

A Material Transfer Agreement (MTA) is a contract that governs the transfer/exchange of materials used for research purposes where the recipient intend intends to use it for research purposes or as part of a research project. MTAs are designed to protect propriety rights in the material and as such should be initiated by the supplying organisation. These agreements can be used to ensure control over the use of the material is maintained and to ensure its use is within the terms of the original consent that the sample(s) were obtained under. This is a legal requirement for the transfer of HTA licensable material.

Purpose and Scope

The purpose of this SOP is to ensure that all UoL staff students and external visitors understand the requirements of the Human Tissue Act (HT Act) regarding the transfer of relevant material that is reported under the UoL HTA licence.

This SOP does not apply to the transferring of human materials that fall outside of the HT Act (Gametes and other cells) that come under the remit of the Human Embryology and Fertilisation Authority (HEFA) and materials that have been processed to become acellular material (certain types of plasma, serum).#

this does not mean that acellular material does not require a contract. All tangible sharing of research materials requires a Material Transfer Agreement.

Definitions:

CA	Collaboration Agreements
DI	Designated Individual
HT Act	Human Tissue Act
HRA	Health Research Authority
HTA	Human Tissue Authority
MTA	Material Transfer Agreement – A contract that governs the transfer of tangible research materials between two organisations, when the recipient intends to use it for his or own research purposes.
PFE	Premises, Facilities, and Equipment
REC	Research Ethics Committee
RED	Research and Enterprise Division
REGI	Research Governance Ethics and Integrity

RTB	Research Tissue Bank
SLA	Service Level Agreement
SOP	Standard Operating Procedure
UoL	University of Leicester

Roles and Responsibilities

It is the responsibility of the researcher to ensure all the applicable information in the MTA checklist is supplied to the contracts team for all transfers of licensable material being sent outside of UoL and that the information supplied is accurate.

The research and enterprise division (RED) contracts team will be responsible for ensuring the contract is facilitated, ensuring all the information is embedded into the agreement.

It is the HTA Monitoring Officer's responsibility for ensuring this SOP remains fit for purpose taking into consideration any changes in legislation.

Procedure to follow

In the event that a researcher would like to send some of their HTA licenced materials outside the University of Leicester (UoL), the researcher should in the first instance contact the RED contracts team on redcontracts@leicester.ac.uk. RED contracts team are a team of specialists in drafting a vast array of different contracts that are required for researchers and academics to ensure the UoL is protected contractually. These range from MTAs, collaboration research agreements (CA) to service level agreements (SLA) to list a few.

A Contracts Officer will decide what type of contract you require and will allocate your request to a member of the team, based on the College, Department and workload involved at the time. You may also be sent a form to complete in order to provide additional details about the materials and the research required for drafting or reviewing a contract. You will then be informed of the team member allocated to your request, who will then be in contact and begin negotiating the contract with the company.

The role of RED Contracts

Where an 'incoming' MTA (as provided by the supplier) is received or an outgoing MTA is required (when UoL is required to draft an MTA for sending UoL materials),

the RED Contracts Team must be contacted. The contracts team will gather information from the researcher/academic to help identify the type/nature of the contract that is required, in addition to negotiating the terms of the agreement. The RED Contracts Team will keep a record of the signed MTA and will provide the researcher with a copy of this for the researcher's records.

If data is also to be shared between the two organisations, a separate data sharing agreement would also be required or data sharing terms to be embedded within the MTA, which will outline what data has agreed to be shared between the parties and will specify how the data can be used, including the type of data; anonymous, linked-anonymous, identifiable.

Signatories

Each organisation will have authorised signatories to sign on their institution's behalf. It is essential that only these individuals sign on behalf of their organisations and researchers do not undertake signing the contract themselves. This is to ensure exchange of materials adhere to any local processes and specifically for compliance with the Human Tissue Act (HT Act). For the UoL, only members of the RED contracts team are authorised to sign MTAs.

Outgoing Samples

Where the transfer of any sample(s) relate to HTA relevant materials the contracts team may request advice from the HTA & Monitoring Officer; 1) to ensure any research conducted with them is within the scope of the consent that was given with the samples 2) To ensure that the samples will be used as per the original REC approval that they were collected under.

For the export of samples outside the UK, this SOP should be read in conjunction with the import/export of samples *SOP HTA-A1005* to ensure HTA compliance with the import and export of relevant material.

Incoming samples

Incoming samples include samples from any other UK academic institutions, NHS organisations, overseas sources, and include samples from Research Tissue Banks (RTBs). Please refer to *HTA-A1005-UoL* SOP for further guidance required for

imported samples i.e. samples imported from outside of England, Wales, and Northern Ireland.

Incoming samples are subject to the completion of the internal transfer application form HTAISA001 submitted to HTAenquiries@leicerster.ac.uk as per SOP *HTA-A1005*. This is to ensure there is oversight of the samples being brought in to the UoL. This is particularly relevant if they are classified as licenced material as the Designated Individual (DI) requires oversight of these to ensure that sample storage, use and disposal complies with the requirements of the HT Act.

The University has a requirement to have documentary evidence of where all samples originated from, in addition to a contract, whether it be an MTA / CA or other agreement that is more applicable for transferring the samples to us (this might depend on the reason for the samples being transferred to us). This is to ensure that all samples comply with all the HTAs research standards: consent, governance and quality systems, traceability and premises, facilities and equipment (PFE) as per the HTA Codes of Practice.

MTA Checklist

An MTA covering HTA-licenced material should include the following information to ensure that appropriate governance for the samples can be maintained.

It should include the identification of both parties involved in the transfer (i.e. the supplier and the recipient).

Details of the material should include:

i. Statement that the sample(s) are 'relevant material' as defined by the HTA according to the Human Tissue Act (2004).
ii. Statement that the sample(s) is HTA licenced material (i.e. it is not from a HTA tissue bank, part of an approved NHS REC approved study or from a deceased individual where more than 100 years have elapsed since the individuals' death).
iii. Whether the sample was obtained prior to 1st Sept 2006.
iv. Accurate description of the material and the quantity of the material. E.g. whole blood/bone/tissue biopsies/tissue sections on slides.

v. Whether the sample(s) were obtained from the living at the time of the collection or the deceased.
vi. Whether the sample(s) and if applicable (associated data) is anonymised, and details of the process. i.e. fully anonymised, linked anonymised, identifiable.
vii. Whether the material will be provided with some donor information (and some granular detail of what this data contains.
viii. Whether there are any restrictions on the recipients used of the material (i.e. any restrictions on consent).

Compliance with the Human Tissue Act (2004) to include:

i. Details of the HTA licences held by the supplier and the recipient.
ii. Details of the permitted use.
iii. Details of the disposal at the end of the permitted use. i.e. to include whether there are any special considerations for the disposal. Or what should happen to any surplus material that is left over from the research i.e. should the surplus material be returned to the sender and if so, how it should be returned.
iv. Requirements to maintain and audit trail documenting any transfer or disposal of the material.
v. Requirement that the material must be stored at all time in an area with appropriate temperature monitoring equipment.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)

Distribution Record:

Date	Name	Department	Received Y/N