UNIVERSITY OF LEICESTER

University of Leicester Research Governance Office Standard Operating Procedures relating to the Human Tissue Act 2004

SOP HTA-A1008 UoL

Contracts for the transfer of HTA-relevant material

Version 2.0

Effective Date: 01 December 2024

This SOP will be implemented in line with this document's effective date for all UoL HTA SOPs.

1.0 Introduction

This document has been produced in accordance with *The Human Tissue Act 2004* (HT Act). It should be read in conjunction with the University's 'Policy on compliance with the Human Tissue Act in Research', and the Human Tissue Authority's *(HTA) Codes of Practice*.

A Material Transfer Agreement (MTA) is a contract that governs the transfer/exchange of materials where the recipient intends to use it for specified purposes such 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 ensure control over the use of the material is maintained and that it is used within the terms of the original consent that the sample(s) were obtained under. This is a legal requirement for the transfer of HTA licenced material.

2.0 Scope

The purpose of this SOP is to ensure that all Chief and Principal Investigators (CI/PIs), UoL research 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 and materials that have been processed to become acellular material (certain types of plasma, serum#). Nor does this apply to (materials that are under current ethical approval#), although the same principles apply.

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
CI	Chief Investigator
DI	Designated Individual
HT Act	Human Tissue Act
ICF	Informed Consent Form
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 them for their own research purposes.
PACs	Pre-Awards and Contracts
PFE	Premises, Facilities, and Equipment
PI	Principal Investigator
PIS	Participant Information Sheet
RGO	Research Governance Office
RTB	Research Tissue Bank
SLA	Service Level Agreement
SOP	Standard Operating Procedure
UoL	University of Leicester

3.0 Procedure

Where materials are to be shared as HTA-relevant material outside UoL or into UoL, they should in the first instance submit a new contract request via the Worktribe™ platform. This will be received by the PACs team. Relevant contracts range from MTAs, collaboration research agreements (CA) to service level agreements (SLA) to list a few.

The PACs team 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 will then be informed of the team member allocated to your request, who will then be in contact to obtain any additional information required and begin negotiating the contract with the recipient.

The PACs team will keep a record of the signed contract and will provide the CI/PI with a copy of this for the CI/PI's records.

If data is also to be shared between the two organisations, a data sharing agreement would also be required or data sharing terms 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.

3.1 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 CI/PI's do not undertake signing the contract themselves. This is to ensure exchange of materials adhere to any local processes and specifically for compliance to further regulatory requirements such as the Human Tissue Act (HT Act). For the UoL, only members of the PAC team are authorised to sign MTAs.

3.2 Outgoing Samples

Where the transfer of samples relates to HTA-relevant materials the contracts team may request advice from the HTA Monitor; 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 appropriate approvals are sought for the use of the material.

For the export of samples outside the UK, this SOP should be read in conjunction with the import/export of samples SOP HTA-A1005-UoL to ensure HTA compliance with the export of relevant material. The same due diligence of the material would be conducted by the HTA Monitor i.e., templates of the PIS and ICF. If these are in a foreign language, a translated copy would be required to ensure we comply with the terms that the samples were collected with.

3.3 Incoming samples

Incoming samples include samples from any other UK academic institutions, NHS organisations, overseas sources, and 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@leicester.ac.uk as per SOP HTA-A1005-UoL. This is to ensure there is oversight of the samples being brought into UoL. This is particularly relevant if they are classified as licenced material as the 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 samples originate from, in addition to a contract, whether it be an MTA / CA or other agreement that is more applicable (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. Incoming samples will have due diligence undertaken on the by the HTA Monitor. This will includes assessing the original study documentation, and any agreements associated with them. If these are in a foreign language, a translated copy would be required to ensure we comply with the terms that the samples were collected with.

3.4 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).

In the Worktribe™ contract request, the Assessment tab should be completed to contain all of the below information (Question 9: Material Transfer). Anything additional can be uploaded to the Document tab (e.g., as a Word document).

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 of whether the samples are HTA licenced material and must be held under the licence (i.e., they are not from an NHS REC-approved 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 such as no consent for DNA analysis, restrictions on the type of parties the samples and data can be shared with, unable to share with 3rd parties).

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, 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 an audit trail documenting any use, 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.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigator / Principal Investigator (CI/PI)	Chief Investigator / Principal Investigator (CI/PI) or delegate	To ensure the appropriate contract is sought via the contracts team, via Work Tribe.
Pre-Award and Contracts (PACs)	Pre-Award and Contracts Officers/Managers	Drafting of contract and negotiation.
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Ensure SOPs remain up to date and updated with changes due to regulatory updates. Due diligence on undertaken on the provenance on the samples and ensuring HTA processes are followed. Discuss any agreements with the DI, so they maintain oversight.
Designated Individual (DI)	Designated Individual (DI)	Ensuring suitable practices are in place within the licenced establishment. Maintaining oversight of collections.

5.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Amanda Sutcliffe	HTA Monitor	UoL Human Tissue Governance Committee (HTGC)	Professor Peter Bradding 	28/11/2024

6.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)
November 2024	v2.0	A Sutcliffe	• Administrative changes. • Addition of Work Tribe for engaging with PACs Team. • Update to contracts team to PACs