UNIVERSITY OF LEICESTER

Paper copies of this document might not be the most up to date version.

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-A1007-UoL

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Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
Author	Amanda Sutcliffe	HTA Monitoring Officer		08/02/2021
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 number of nation and international companies have started to sell human tissue for researchers to be able to access tissue for their research purposes. It has therefore become possible to procure relevant material without any knowledge of its source or of its ethical approval given to obtain its collection. Researchers must be aware that purchase of human material under these circumstances would be considered unethical in the UK.

Samples may be obtained via these sources providing the material being procured can be proven to be collected in an ethical manner and with the appropriate consent in place from the donor.

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 procurement of relevant material for research purposes.

This SOP does not apply to the procurement 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).

Definitions:

DI	Designated Individual
HEFA	Human Embryology and Fertilisation Authority
HRA	Health Research Authority
HTA	Human Tissue Authority
HT Act	Human Tissue Act
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.
PD	Persons Designated
REC	Research Ethics Committee
REGI	Research Governance Ethics and Integrity
RTB	Research Tissue Bank
SOP	Standard Operating Procedure

UoL University of Leicester

Roles and Responsibilities

It is the responsibility of the Designated Individual (DI) to ensure all material that is procured for research has their oversight to ensure the material has been obtained to ensure that material has been collected with the appropriate ethical considerations and to ensure that there is valid consent for the material to be used in such circumstances that they are being obtained for.

It is the HTA monitoring officers' responsibility to ensure this SOP is updated to reflect any regulatory or legislation changes. It is their responsibility to assist in ensuring that any documentary evidence relating to ethical approval and consent considerations relating to the procured material are obtained and assessed to ensure that there has been due diligence undertaken on the material that is to be sourced from commercial sources.

The Person Designated (PD) are responsible for supporting the individuals that collect, store and use human tissue for research, this is ensuring that researchers are aware of the HTA SOPs and ensuring researchers in their area comply and follow the HTA SOPs. The PD must also ensure any materials that are obtained via the procurement process is logged on their tissue register and are brought to the attention of the HTG committee.

It is the researchers responsibility to ensure they apply to the DI and the HTA Monitoring Officer for the items to be procured so that due diligence around the materials being procured can be obtained. It is the researchers' responsibility to ensure all tracking and tracing of the materials once purchased are undertaken in compliance with the UoL HTA licence. In addition, it is the researchers' responsibility to ensure that material are used only in designated areas that are covered by the UoL HTA research licence.

Procedure to follow

The DI has the responsibility of oversight of what materials are stored under the auspices of the HTA Research licence. To facilitate the oversight, there is the internal application form that is required to be submitted before the procurement of material can be initiated. This is to ensure any material that is going to be sourced commercially has had due diligence undertaken on the origin of the material and it has been sourced with the appropriate ethical and consent provisions.

Please ensure that you application is submitted with plenty of time for the due diligence to be undertaken, as the due diligence can be quite time consuming as it

may require input from the suppliers and any third parties that they use to obtain the materials to submit their documentation.

Internal Application

To facilitate this there is the internal application of samples process that requires to be followed. This enables the DI to have oversight and to ensure the due diligence is undertaken before the material can be procured.

In the first instance researchers wishing to procure the material should fill in *SOP HTA-A1007 Appendix 1* completed as much as possible to ensure there is no delay in the procurement process. This should be emailed to HTAenquiries@leicester.ac.uk the HTA Monitoring Officer, will contact the supplier to obtain due diligence documents to ascertain due diligence around the provenance of the samples to ensure they have been sourced ethically, with the appropriate consent and to ensure there is an appropriate contract to govern the transfer of the materials.

Once the due diligence documents have been received, the HTA Monitoring officer and the DI will assess the due diligence documents to ensure the supplier has obtained the material ethically and with the appropriate consent before giving the approval for the transfer to commence.

Purchases from overseas

There are different requirements to be aware of when purchasing material from overseas, particularly as many overseas companies will not be aware of the compliance regulations that we have to follow for sourcing relevant material for research purposes. Researchers should use smarter purchasing for the generation of a purchase order for the procurement of their material. However, some departments do have access to a purchasing card for the use of purchasing items for research.

VAT Compliance when using purchasing cards

Where the purchase of material from overseas will use a departmental purchasing card, the University has an obligation to declare the VAT to the HMRC. Purchasing card holders must ensure that on receipt of their purchasing card statement, the correct VAT code is applied to transactions within SAP.

Please refer to the import export SOP for further information regarding the importation of relevant material HTA, specifically around the retention of documentation (*HTA-A1005*).

Research Tissue Banks

Establishments such as Research Tissue Banks (RTBs), may charge for providing human material for researchers, so that their running costs are recovered. Where there is a cost recovery system, or an alternative charging mechanism is in place, it is important that establishments are able to satisfy themselves the information provided to the donors of the material is clear and transparent that their tissue samples maybe shared for such, subject to a fee being charged. Where an RTB has NHS Research Ethics Committee (REC) approval, the cost recovery will have been assessed by the REC committee. It is recommended that establishments ensure transparency by providing accessible information about how and why they charge, and to whom they would supply the material to. This is important to ensure that the consent sought form the donors of the material are fully informed.

On application from a researcher to the DI and HTA Monitoring Officer to procure tissue from a RTB, the same due diligence is required. In addition, to the required due diligence for the procurement, the DI and HTA Monitoring Officer will have to satisfy themselves to ensure the cost recovery for the materials are transparent to the participants that donate their material for research.

Due diligence validity

A due diligence process will be carried out before executing any transaction relating to obtaining relevant material for the purposes of research. The exception to the rule are when a recent due diligence assessment, within the last (one year) has been carried out on the proposed supplier and where this assessment relates to activities that are similar.

The due diligence should remain valid for one calendar year, however, the DI and HTA Monitoring Officer may determine an earlier re-assessment is required where circumstances indicate that;

- There is a significant change in the companies circumstances such as re-structuring
- A shorted period is deemed more appropriate

Depending on the information that is obtained from the company, further legal advice maybe required to be sought from the HTA. There is usually a 10 working day turn

around for the advice being sought from a HTA Compliance Manager, so please ensure you apply giving plenty of notice for the due diligence to be undertaken, otherwise this may delay any purchases.

Once the HTA Monitoring Officer and the DI have assessed to documentation, if the documentation is compliant with the HTA requirements, then HTA Monitoring Officer will instruct the researcher to continue with the procurement of the material. The researcher will get a conformation email from the DI stating that they have the green light to proceed with their purchase.

Procurement documentation

The researcher should keep copies of the procurement documentation for a minimum of 5 years after the disposal of the material to ensure it complies with the HTA import/export requirements. Copies of such, should be stored in the HTA PD Masterfile for audit purposes and for the inspection by the HTA, as well as the researcher retaining a copy for their own information.

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