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

# SOP HTA-A1007 UoL

## Procurement 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.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used.

## 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*.

National and international companies sell human tissue for scientific research. It is therefore possible to procure HTA-relevant material for research without any knowledge of its source, associated ethical approval or consent clauses. Researchers must be aware that purchase of human material under these circumstances would be considered unethical in the UK.

Human biological samples may be procured via these sources providing it can be proven that they were collected in an ethical manner with appropriate consent from the donor. This SOP is to ensure that appropriate due diligence is undertaken around the provenance of procured HTA-relevant material.

## 2.0 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 HTA-relevant material for research purposes, such as blood, tissue blocks and tissue microarrays.

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.

Definitions:

| | |
|---|---|
| CI | Chief Investigator |
| DI | Designated Individual |
| 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 | Person Designated |
| PI | Principal Investigator |
| RGO | Research Governance Office |
| RTB | Research Tissue Bank |
| SOP | Standard Operating Procedure |
| UoL | University of Leicester |

## 3.0 Procedure

All research involving humans or their materials require some form of ethical approval. Where HTA-relevant samples are to be purchased for a research project, that project should be submitted for review / approval via the Universities Research Management System.

The DI has the responsibility for oversight of materials stored under the HTA Research Licence. To facilitate this, there is an internal application form that must be submitted before the procurement of material can be initiated.

Please ensure that your application to obtain samples is submitted with plenty of time for the relevant due diligence to be undertaken, as this can be time consuming in requesting and waiting for the appropriate documentation to be sent through from the suppliers. In some circumstances it may require input from the suppliers and any third parties they use to obtain the materials.

## 3.1 Internal Application

In the first instance researchers wishing to procure HTA-relevant material must fill in the HTAPRO001 form (Appendix 1). This should be emailed to the HTA Monitor at HTAenquiries@leicester.ac.uk . The HTA Monitor, will contact the supplier to obtain due diligence documents regarding the provenance of the samples, ethical approval, and donor consent. They will also ensure there is an appropriate contract to govern the transfer of the materials. Research approvals can be submitted in parallel via the Universities Research Management System.

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

## 3.2 HTA-relevant material 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 must follow for sourcing HTA-relevant material for research purposes. While evidence of consent is not a legal requirement for the import of HTA-relevant material from outside the UK, it is best practice to ensure that this was obtained, in addition to other ethical considerations. Therefore, the HTAPRO001 form (Appendix 1) must be completed and the process followed as detailed in section 3.1.

## 3.3 Purchase and 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-UoL).

## 3.4 Research Tissue Banks

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, on application from a CI/PI or delegate to the DI and HTA Monitor to procure tissue from an RTB, the same due diligence is required. In addition, the DI and HTA Monitor will have to ensure that the cost recovery for the materials charged by the RTB are transparent to the participants that donated their material for research.

## 3.5 Due diligence and Validity

Due diligence process will be performed before executing any transaction relating to obtaining HTA-relevant material for the purposes of research. The exception to the rule is when a recent (within one year) due diligence assessment has been carried out on the proposed supplier

and same materials. However, the DI and HTA Monitor 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 shorter period is deemed more appropriate

Once the HTA Monitor and the DI have assessed the relevant documentation, if this is compliant with the HTA requirements, then HTA Monitor will instruct the CI/PI or their delegate to continue with the procurement of the material.

### 3.6 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 CI/PI or delegate retaining a copy for their own information.

## 4.0 Responsibilities

| Responsibility | Undertaken by | Activity |
|---|---|---|
| Chief Investigator / Principal Investigator (CI/PI) | Chief Investigator / Principal Investigator (CI/PI) / or delegate | Submission of project for review / approval via the Universities Research Management System.<br>Completion of HTA of HTAPRO001 and submission to HTAenquiries.<br>Ensuring tracking and traceability is maintained.<br>Ensuring research is conducted in a licenced building. |
| Person Designated (PD) | Person Designated (PD) | Escalation to HTA Monitor where the PD is aware of the procurement taking place.<br>Inclusion of PD report where samples are Relevant Materials.<br>Appropriate documentation filed in PD report. |
| HTA Monitor | HTA Monitor | Due diligence and review of appendix 1. To refer to DI for approval as necessary.<br>Expert Review on the Universities Research Management System. |
| Designated Individual (DI) | Designated Individual (DI) | Approval on reviews where these are escalated for a definitive decision.<br>Ensuring suitable practices are in place within the licenced establishment. |

## 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<br>• Update to Addition of the Universities Research Management System<br>• Inclusion of sample reporting on PD reports |