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SOP Title:	Transfer of human tissue into and out of the University, including import and export.
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Approval History				
Version 1.0	Name	Role	Signature	Date
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Version 2.0	Name	Role	Signature	Date
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1. INTRODUCTION

The purpose of this Standard Operating Procedure (SOP) is to ensure that staff understand the requirements under the Human Tissue Act (HT Act) and follow University procedures when either bringing human tissue that has been collected elsewhere into the University or sending human tissue collected at the University to other establishments. When such transfer involves sites outside England, Wales and Northern Ireland (NI) where the HT Act applies, including Scotland, this is termed import and export. In all cases it is important to ensure that samples are only transferred between sites if this is in accordance with the donor's consent and that their use, handling, storage, transportation and disposal are all in accordance with this consent.

2. SCOPE

This SOP applies to any University of Surrey researcher (staff, student or visitor) wishing to transfer human samples into or out of the University of Surrey. The terms import and export are used when this is from areas outside those covered by the HT Act. Import of samples is not a licensable activity under the HT Act however the storage of relevant material once arrived is. The HTA also stipulates that human tissue should only be imported when the purpose for which it is to be used cannot be adequately met by comparable tissue from within England, Wales or Northern Ireland, or is for a particular purpose that justifies import.

3. RESPONSIBILITIES

3.1 The Designated Individual (DI) has *a legal duty to ensure that statutory and regulatory requirements are met. They are responsible for supervising licensed activities and ensuring suitable practices are taking place.* They should ensure that only samples with appropriate consent and legal agreements are brought into the University or sent to other establishments and that researchers meet the HTA standards for traceability when transferring samples.

3.2. The Persons Designated (PD) *assist the DI in ensuring compliance with HTA standards.* There is a PD for each of the areas; Stag Hill (Hub PD and FEPS PD), Leggett, VSM, VSP and Surrey CRB. They are responsible for assisting the DI in ensuring that all samples arriving or leaving the University have appropriate consent, are fully tracked and have a MTA or equivalent document in place.

3.3. The Principal Investigator (PI) is responsible for ensuring they have the correct informed consent from all the participants for the proposed transfer of samples and have a material transfer agreement (MTA) or equivalent document that covers all the samples to be transferred. They must ensure that all samples are labelled, tracked and shipped correctly to minimise the risk of loss and ensure full traceability and when importing samples, justify why the samples need to be imported and cannot be sourced within England, Wales or Northern Ireland.

3.4 The Research Contracts Team are responsible for drafting, negotiating and agreeing the MTA (or equivalent document) with external parties.

3.5 The Human Tissue Research Operations Group (HTROG) are the governing body who are responsible for overseeing all work involving human tissue at the University.

3.6. All persons who wish to use human tissue samples that are not collected within the University must have read and follow this SOP and must not sign any legal documents on behalf of the University, this should only be done by a member of the legal Contracts team.

4. PROCESS

4.1 Apply for a Material transfer agreement, or an equivalent document.

4.1.1 Researchers should contract the research contracts manager for their faculty via the email addresses found on (https://surreynet.surrey.ac.uk/research-contract-services) to discuss drafting of an MTA or approval of a MTA or alternative legal document.

4.1.2. This will involve clarification of;

- Contact details of sender and recipient
- Details of material (type, how much, risk of contamination etc)
- Purpose of transfer (what it will be used for, brief detail of research)
- Details of funder
- Details of potential IP, commercial interest
- Storage details (e.g., HTA licenced premises if non-NHS REC)
- Whether tissue should be kept/returned/disposed of at the end of study
- Planned duration of use of the samples
- Clarification of each party's access to the results of the research
- Clarification of which institution is taking responsibility for consent
- Details of transport and who will pay
- Whether students or non-employees will be involved

4.1.3. The research contracts team will then liaise with the external organisation and agree the details of the document.

4.1.4. Once the MTA or equivalent document has been agreed both parties must sign it, which will be done on behalf of the University by a member of the Research Contracts team. **Researchers must not under any circumstances sign the document themselves. This includes commercial agreements for tissue that is being purchased, which should also be sent to the Research Contracts Team for checking and signing.**

4.2. Applying for permission to bring samples into the University. Before any samples are transferred to the University, the PI or person responsible must:

4.2.1 Prepare all the documents detailed in UOS_HT_SOP_02, Applying to use human tissue in research including following the guidance in 4.1 to ensure that they have a MTA or equivalent legal document in place that covers all the samples to be received.

4.2.2. Ensure that consent obtained for the samples covers their use at the University of Surrey and was obtained following the same standards expected by the University and in accordance with local regulations and practices. The PI must submit copies of the original blank consent forms used and details of the consent process as part of their ethics and governance application.

4.2.3 Where having ethical approval in place is specified as a condition of consent to transfer the samples it is also necessary to have received ethical approval for the proposed research project from the University Ethics Committee (UEC) or other ethics body, before the samples are sent. If this is not the case, although it is still preferred and strongly advised for ethical approval to be in place before the samples arrive, this can be in progress or if essential applied for after their arrival. It is not however, University policy to store tissue unless either ethical approval to use them is being actively sought or clear scientific justification has been made. Where ethical approval is not in place samples will be placed in quarantine from arrival until ethical approval is given.

4.3. Applying for permission to send samples out of the University. Before sending any human tissue samples from the University to another organisation the PI or person responsible must:

4.3.1 Check that the consent obtained for all samples to be sent covers their transfer, storage and use at their destination.

4.3.2 Follow the guidance in 4.1 to ensure that they have a MTA or equivalent legal document in place that covers all the samples to be sent.

4.3.3 If ethical approval is required as part of consent this must also be in place before sample transfer.

4.4. Importing human tissue samples.

4.4.1 Although the consent provisions of the HTA act do not apply to imported tissue the HTA considers it good practice for there to be mechanisms in place to ensure that consent is obtained in the source county and the University of Surrey will therefore not accept imported samples unless there is evidence that informed consent has been given and that this covers their import into England.

4.4.2. Before importing samples into the University all researchers should have in place, policies which clearly set out the evidence indicating how informed consent was obtained, including safeguarding the confidentiality of all information relating to consent. If a separate organisation is importing the material, a documented agreement should be in place demonstrating that there is a record of consent in a suitable format. All material should be sourced consistently with the legal and ethical review requirement in England, Wales and Northern Ireland.

4.4.3 Anyone wishing to import human tissue into the University must also be able to demonstrate that the purposes for which they wish to import the material cannot be adequately met by comparable material available from sources within England, Wales and Northern Ireland, or that it is for a particular purpose which justifies import. This must be documented and available to be inspected if requested.

4.4.4 It is also good practice to obtain ethical approval from a research ethics authority either in the source country or here before importing the tissue. Ethical approval from a research ethics committee in the source country can in some cases act as suitable assurance that the material has been sourced appropriately.

4.4.5 The supplier's record and any other documents relating to the import of tissue should be kept for at least five years after the disposal of the last sample.

4.4.6 The infection status and any other potential risks arising from the country of origin of the samples should also be considered and the tissue categorised appropriately for transport and use. Only where there is a specific research need for tissue which carries a high infection risk should such tissue be imported to the University.

4.4.7. Disposal of imported material should be the same as for samples sourced within England, Wales and Northern Ireland and as documented in UOS_HT_SOP_13, unless return of the material to the country of origin has been specified as part of consent or MTA.

4.4.8 Imports of human tissue must also be declared to HM Revenue and Customs.

4.5. Exporting human tissue

4.5.1 Any human material to be exported must be procured, used, handled, stored, transported and disposed of in accordance with the consent that was given and with due regard for the safety considerations and with the dignity and respect accorded to human tissues samples provided for in the Codes for England, Wales and Northern Ireland. Donors must be given adequate information and have consented to their samples being exported aboard.

4.5.2 It is the responsibility of the recipient country to ensure that before export the tissue has been handled appropriately and meets the required standards of that Country.

4.5.3 The record of human tissue exported should be kept for at least 5 years after the latest date of destruction.

4.5.4. Exported human tissue should normally be declared to HM Revenue and Customs

4.5.5 The HT Act stipulates that human tissue **must not** be exported then re-imported to avoid the HT Act's consent requirements.

4.6 Obtaining human tissue from a commercial supplier or licenced tissue bank.

4.6.1. Any researcher purchasing human samples from a commercial supplier or licenced tissue bank must ensure that they have checked the consent form used by the supplier to make sure that the consent agreed covers their use and storage at the University of Surrey.

4.6.2. The PI should contact the Research Contracts Team as detailed in 4.1 and ask them to check and sign any commercial contract required by the company or third party supplying the tissue and to prepare a MTA where required. **No researcher should sign any legal document themselves**.

4.6.3. Where samples are being purchased to be processed and rendered acellular immediately without being stored under the HTA licence the consent should still be checked to make sure it is appropriate and covers the planned use. Full documentation of each sample bought should be kept from arrival, through processing to disposal so that they can be tracked and it is clear that they are not being stored.

4.7. Before any samples arrive or leave

4.7.1 Before any samples are transferred the local PD (when known) or if not the Hub PD (HTAlabfacilities@surrey.ac.uk) should be contacted to discuss any storage space needed and the details of samples arrival or departure. They should also send a copy of the MTA or equivalent document.

4.7.2. The PI or researcher transferring the samples should also ensure that both they and the persons handling the samples in the external organisation have read the MTA or alternative document and comply with its terms both during sample transfer and following sample arrival.

4.7.3 All shipments of samples, arriving or leaving the University must include a shipping log to the individual aliquot level completed by the sender. This must be kept as a record by the recipient in the study file with an indication that the log has been checked for correct, damaged or missing samples to the aliquot level.

4.7.4 All samples should be shipped, packaged and transported in accordance with UOS_HT_SOP_08 Transportation of Human Tissue.

4.8. Documentation

4.8.1. The PI must follow the guidance in UOS_HT_SOP_10 human tissue sample labelling, storage and tracking, to ensure that sample records on the electronic tracking system eLab Inventory or alternative when agreed, are updated appropriately, following sample arrive or shipping.

4.8.2 The PI must also ensure that all transportation documentation is added to the study folder and kept for a minimum of 5 years after the last sample is disposed of. This documentation includes:

- Evidence of shipment and courier records
- Details of transport and delivery- dates, times etc.
- MTA or equivalent legal document
- Service legal agreement with the courier used
- Risk assessment covering the risk to handlers and tissue during transport
- The shipping log of the tissue sent
- Suppliers record and consignment documentation

5. ASSOCIATED DOCUMENTS

UOS_HT_SOP_02: Applying to use human tissue in research.
UOS_HT_SOP_03 Training requirements for using human tissue.
UOS_HT_SOP_08 Transport of human tissue
UOS_HT_SOP_09 Human tissue records management
UOS_HT_SOP_10 Human tissue sample labelling, storage, and tracking.
UOS_HT_SOP_13 Disposal of human tissue

6. REFERENCES

HRA relevant material list (HTA) Website
RIGO webpage

7. TRAINING

Before commencing any work with human tissue samples anyone wishing to do so must have completed all the training detailed in UOS_HT_SOP_03, Training requirements for using human tissue.

8. USEFUL ABREVIATIONS

HTA – Human tissue authority
HRA – Human Research Authority
HT Act – Human Tissue Act
LH - Licence holder
DI- Designated individual
RIGO – Research Integrity and Governance Office
HTROG – Human Tissue Research Operations Group
PD- Person Designate
SOP-Standard Operating procedure
AE/I - Adverse event or incident
GCP – Good Clinical practice
MTA – Material Transfer Agreement
REC – Research Ethics Committee
UEC- University Ethics committee

9. REVISION HISTORY

Version number	Revision details	Author	Date
1.0	New document (Formerly: UOS_HTA_SOP_09 and UOS_HTA_SOP_010)	Andy McClave	12.03.2020
2.0	Major Revision including title and number and combining of two previous SOPs (now: UOS_HT_SOP_07)	Linda McLatchie	03.06.2023