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SOP Title:	Material Transfer Agreement for human tissue
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1. INTRODUCTION

There are several regulations and standards that govern the use of human material in research including the Human Tissue Act (HT Act), the Human Fertilisation and Embryology Act, the Data Protection Act and the UK Policy Framework for Health and Social Care. It is therefore important for researchers to ensure the samples they acquire are managed in accordance with relevant regulations and standards and used for the purpose for which they are intended.

As an establishment holding a Human Tissue Authority (HTA) Research Licence, the collection, use, and storage of human tissue for research must be in accordance with the Human Tissue Authority (HTA) Code of Practice for Research: Code E: Research and the associated Research Standards and Guidance. These codes set out the standards which must be met, including that for the transfer of human tissue. It specifically states:

> *If human tissue is to be transferred between establishments, consideration must be given to minimise the likelihood of theft, damage or loss during transport. Some form of formal transfer arrangement, for example, as part of a Material Transfer Agreement (MTA) should define how the human tissue is preserved, any potential contamination risks associated with it; and who is responsible for disposal, if applicable…Transportation procedures should also give sufficient detail to ensure the integrity of the tissue.*

This SOP describes the procedure that should be followed when a Material Transfer Agreement (MTA) is required for the transfer of human tissue either to or from the University.

2. SCOPE

This SOP applies to individuals intending to transfer, to another establishment, any type of human sample, including: material that is considered relevant under the HT Act; non-relevant human material; human DNA and RNA; human biological fluid; and human-derived cell lines.

All individuals, whether staff, student or visitor, conducting research with human samples under the auspices of the University of Surrey on or off site must follow the requirements set out in this SOP if intending to transfer samples between the University and parties external to the University. This applies to material being transferred into the University as well as out of the University.

3. RESPONSIBILITIES

3.1 All individuals working with human samples must ensure that they adhere to this SOP when transferring samples. It is the responsibility of all individuals to report any problems or

concerns in relation to the transfer of samples to the Person Designated (PD) for their site and the Research Integrity and Governance Office (RIGO).

3.2 The Principal Investigator (PI), or student supervisor, is ultimately responsible for ensuring an MTA is in place before transferring samples between the University and external parties.

3.3 The Legal Contracts Team are responsible for drafting, negotiating and agreeing the MTA with external parties.

3.4 The Designated Individual (DI) is accountable to the HTA for research samples stored under the University's HTA licence.

3.5 The Persons Designated (PD) are responsible for supporting the training of individuals who collect, store or use human samples under this SOP. The University's Human Tissue Research Operations Group (HTROG) is the governing body overseeing this process.

3.6 RIGO is responsible for maintaining a central log of research projects and for conducting audits to ensure this SOP is being followed.

3.7 The PDs and RIGO are responsible for keeping the DI informed of any problems or breaches of this SOP regarding transfer of human samples between the University and other parties.

4. PROCESS

4.1 Samples being transferred out of the University

4.1.1 No samples must be transferred out of the University until the process below has been completed.

4.1.2 For new studies, the PI must inform RIGO of their intention to transfer samples to an external party when applying for ethics approval. This should be declared on the application to use human tissue (UOS_HTA_SOP_001: Applying to use human tissue in research) when submitting the ethics and governance application.

4.1.3 For an existing study, an amendment to the study should be submitted to RIGO.

4.1.4 For existing holdings from previously completed studies, which are intended to be transferred to an external party, a new ethics and governance application should be made.

4.1.5 Contact RIGO (rigo@surrey.ac.uk) if you require any help with the submission process that must be followed.

4.1.6 The submission must:

- include a copy of the blank consent form and participant information sheet;
- provide details of the external party;
- describe the purpose of transfer;
- describe clearly what is to be transferred including details of any personal information that will be sent;
- describe the method of transfer and the process of receipt;
- a risk assessment to cover sample tracking, transportation, sample integrity etc.
- describe how samples will be tracked through transit, including sample labelling, logs and sample ID that will be used;

- provide details of the responsibility of the external party including storage, tracking and disposal or return of samples;
- it is expected that the above information will be included in the study protocol agreed by all parties.
- A completed instruction sheet (Annex 1) to capture information specifically for the MTA. A word version can be accessed on the RIGO webpage under Human Tissue Research SOPs and templates.

4.1.7 On receipt, RIGO will allocate the submission to the University Ethics Committee (UEC) to conduct an ethics review and in parallel a member of RIGO will perform a governance check.

4.1.8 The governance check by RIGO will assess the details with regards to transferring samples to an external party and will determine whether appropriate processes and consent is in place to allow for this material transfer. They will also assess whether any personal data will be transferred and where necessary, seek advice from the University's Information Compliance Unit to ensure compliance with data protection legislation and the University's policies.

4.1.9 If appropriate consent is in place and ethics approval is provided by the UEC and there are no data protection concerns, RIGO will inform the legal contracts team and the PI to proceed with an MTA.

4.1.10 A member of the legal contracts team will liaise with the researcher and draft an MTA, taking into consideration any funder requirements and where possible using a template agreement, for review and agreement by the external party. Only University authorised persons can sign the MTA, no researchers can do this themselves.

4.1.11 The PI must provide all the necessary information required to draft the MTA as detailed in Annex 1.

4.1.12 It is important that the PI ensures that the persons receiving the samples are aware and comply with the terms of the MTA.

4.2 Samples being transferred in to the University

4.2.1 If a researcher wishes to receive samples from an external party into the University, they must first contact RIGO (rigo@surrey.ac.uk) BEFORE any transfer takes place.

4.2.2 For new studies, the PI must inform RIGO of their intention to transfer samples to the University from an external party. This should be declared on the application to use human tissue (UOS_HTA_SOP_001: Applying to use human tissue in research) when submitting the ethics and governance application.

4.2.3 For an existing study, an amendment to the study should be submitted to RIGO.

4.2.4 Where samples are being received in a collaborative capacity (e.g. to help analyse samples for a non-University of Surrey study), an application to use human tissue should still be made before samples are received.

4.2.5 Contact RIGO (rigo@surrey.ac.uk) if you require any help with the submission process that must be followed.

4.2.6 The submission must:

- include a copy of the blank consent form and participant information sheet;
- provide details of the external party;
- describe the purpose of transfer;
- describe clearly what is to be transferred including details of any personal information that will be received;
- describe the method of transfer and the process of receipt;
- describe how samples will be tracked through transit, including sample labelling, logs and sample ID that will be used;
- a risk assessment to cover sample tracking, transportation, sample integrity etc.
- provide details of the responsibility of the University researcher including storage, tracking and disposal or return of samples;
- it is expected that the above information will be included in the study protocol agreed by all parties.
- A copy of the MTA being provided by the external organisation.
- A completed instruction sheet (Annex 1) to capture information specifically for the MTA. A word version can be accessed on the RIGO webpage under Human Tissue Research SOPs and templates.

4.2.7 On receipt, RIGO will allocate the submission to the University Ethics Committee (UEC) to conduct an ethics review if required, and in parallel a member of RIGO will perform a governance check.

4.2.8 If appropriate consent and ethics approval is in place and there are no data protection concerns, RIGO will inform the legal contracts team and the PI to proceed with an MTA.

4.2.9 A member of the legal contracts team will liaise with the researcher and review, negotiate and agree the MTA that has been provided by the external organisation. Only University authorised persons can sign the MTA, no researchers can do this themselves.

4.2.10 The PI must provide all the necessary information required to draft the MTA as detailed in Annex 1.

4.2.11 It is important that the persons receiving the samples are aware and comply with the terms of the MTA.

4.3 Preparing the MTA

The MTA will usually include the following information:

4.3.1 Contact details of sender and recipient

4.3.2 Details of material (type, how much, risk of contamination etc)

4.3.3 Details of the purpose of transfer (what it will be used for, brief detail of research)

4.3.4 Details of funder

4.3.5 Details of potential IP, commercial interest

4.3.6 Storage details (e.g. HTA licenced premises if non-NHS REC)

4.3.7 Details of handling tissue on completion of study (e.g. continued storage, return, disposal)

4.3.8 General provisions concerning liabilities, confidentiality, duration etc.

4.4 Finalising the MTA

4.4.1 The MTA must be signed by both parties before any transfer of samples takes place. If this happens, it will be considered a breach of University policy and will be investigated as such.

4.4.2 A signed copy of the MTA must be held by both parties and a copy sent to RIGO to be held centrally with the project details. This must be made available during internal and external audits (e.g. for HTA).

4.4.3 The PI is responsible for ensuring all samples transferred with an accompanying 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. are labelled and tracked to the required standard and for ensuring full traceability and shipped in accordance with UOS_HTA_SOP_07 Transportation of Human Tissue.

4.4.4 All samples should be shipped, packaged and transported in accordance with UOS_HTA_SOP_07 Transportation of Human Tissue.

5. GLOSSARY OF TERMS

DI	Designated Individual
HT Act	Human Tissue Act
HTA	Human Tissue Authority
HTROG	Human Tissue Research Operations Group
NHS REC	National Health Service Research Ethics Committee
PD	Person Designated
RIGO	Research Integrity and Governance Officer
SOP	Standard Operating Procedure

6. ASSOCIATED DOCUMENTS

UOS_HTA_SOP_001: Applying to use human tissue in research
UOS_HTA_SOP_07 Transportation of Human Tissue

7. REFERENCES

Human Tissue Authority main website: https://www.hta.gov.uk/
Human Tissue Authority Codes of Practice and Standards: https://www.hta.gov.uk/hta-codes-practice-and-standards-0

8. TRAINING

Individuals involved in research using human samples must attend face-to-face and online training before using this SOP. They must ensure they read, understand and follow this SOP.

9. REVISION HISTORY

Version number	Revision details	Author	Date

Annex 1:

MATERIAL TRANSFER AGREEMENT (MTA) INFORMATION SHEET For Human Tissue
(Legal Contracts team document)

Please complete the following details and answer the following questions, so that the Legal Contracts Team may determine whether the standard template or proposed MTA from the third party is acceptable to the University and arrange for signature of the MTA, if appropriate.

1. Please state below the name of the principal investigator, any co- investigator(s), and in each case his/her department or faculty.

2. Please state the name of the organisation providing the materials and a description of the materials.

3. What is the intended use of the materials? (Please give a brief 2 to 3 sentence synopsis of the research).

4. If applicable, please give details of any non-commercial funding for the research in which you will be using the material. (eg EPSRC grant; Wellcome Trust etc).

5. Will any industrial or commercial funding (including "in kind" contributions) be used for your research using the material, or is the research otherwise conducted under any written agreement?

If yes – please specify name of Sponsor organisation and the nature of the funding, support or agreement.

6. Will any students or visiting fellows be working on the research using the materials? Or anyone who would not be classed as an employee of [Institution]? If so – please identify them and give details of the funding sources for such persons.

7. If students will be using the materials, will their research using the materials form part of a thesis?

Yes No

8. Do you intend to modify the material in any way? If yes – please give details:

9. Do you intend to incorporate the material into something else or combine it with other material?

If yes – please give details:

10. Will the materials be used together with other materials provided by a third party?

If yes – please give details of the other materials and which organisation provided them. (If you are aware of an MTA for the other materials please specify the date of signing):

11. Is the material:

Yes No

of human origin

to be used in humans (in your research)

covered by the Nagoya Protocol

known to be toxic

readily available from another source available commercially

If so please indicate cost: £ ……

12. In your opinion, how likely is it that your research with the materials will generate any invention or significant intellectual property?

Extremely unlikely

Unlikely

Possible

Difficult to say

Please don't hesitate to add any further information that you think may be relevant or helpful.

Depending on your responses to the above questions, the proposed MTA may require amendments in order to (i) protect your/[Institution's] intellectual property and (ii) to ensure that it does not conflict with existing research contracts with other sponsors.

The legal contracts team will endeavour to negotiate any amendments as quickly as possible and appreciate your cooperation during this process.