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| ACQUISITION & TRANSFER | |
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| Author: | Jenny Baker |
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| Approved by: | Ian Hitchcock |
| Reviewed by: | Jenny Baker |
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| VERSION HISTORY LOG | | |
| Version | Date Implemented | Details of significant changes |
| 02 | 08-08-2017 | Alteration of CoP reflecting changes in legislature |
| 02 | 17-04-2018 | Added a “review by” date |
| 02 | 23-04-2018 | Added in request for shippers to keep record and/or forward courier tracking and proof of delivery to PD |
| 03 | 23-04-2019 | Hyperlinks updated |
| 03.1 | 05-04-2020 |  |
| 03.2 | 30-04-2021 | Hyperlinks updated & Expected date of project completion added to Import/acquisition/transfer form |
| 03.3 | 19-04-2022 | Minor changes and updated hyperlinks |
| 03.4 | 05-05-2023 | Change of author, minor changes |

This SOP will be reviewed every year or if changes are required.

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE MOST UP TO DATE VERSION IS BEING USED. Out of date copies must not be used and hard copies should be destroyed.

Acknowledgements

This SOP has been produced with valuable advice and input from colleagues and with reference to SOPs used at a number of other UK universities and NHS Trusts, particularly The University of Warwick. Their input was gratefully received.

1. INTRODUCTION, BACKGROUND AND PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to ensure that all staff and students understand the requirements and procedures to acquire (receive or import) or transfer (despatch or export) human material, tissue and samples for their storage and use in research, covered by the Human Tissue Act 2004 (HT Act), the Human Tissue Authority’s (HTA) Codes of Practice and the University’s HTA licence for research.

This SOP forms part of the University’s Quality Management System (QMS) for the governance of the acquisition, storage, use and disposal of human samples for research. Successful implementation of the QMS will ensure that all research involving human samples is carried out in compliance with the licensing obligations of the HT Act and to the standards required by the HTA.

2. RESPONSIBILITIES

Under the University’s HTA licence for the storage of human samples for research, it is the responsibility of the Designated Individual (DI) to ensure that appropriate procedures and practices are in place and followed, that those involved are appropriately informed and trained and that the conditions of the licence are complied with relating to the storage of human samples.

It is the responsibility of the Principal Investigator (PI) or the Person Responsible (PR: as delegated by the PI and appropriately trained), as custodian of the samples, to understand and follow the appropriate procedures and practices in place, attend training and updating, and comply with the conditions of the HTA licence, under the supervision of the DI.

3. PROCESS

Human samples may be acquired/purchased from, or transferred to, another organisation, research institution, collaborator on a research project, a tissue bank or a commercial supplier of human samples for storage and use for research.

Under the HT Act, imported human samples are those that come from outside England, Wales and Northern Ireland.

The transfer, import or export of all human samples should be handled with respect, and caution as all samples have the potential to transmit disease. For example, brains, brain tissue, spinal cord and cerebrospinal fluid (fresh, fixed or frozen) carry the risk of spreading infectious diseases. Appropriate risk assessment must be undertaken and documented to ensure that all who come into contact with the samples are protected from the presence of any infectious agents.

All staff and students working with human samples are required to register and undertake appropriate training, in accordance with HTA-SOP-066 –Registration & Training, before transferring or working with any human tissue.

The HTA licence will be applied to all human samples even if they are to be held only for a short period of time, prior to transfer or export to another organisation.

Consent is a central tenet of the HT Act and it specifies whose consent is needed in all relevant circumstances. Appropriate consent must be in place to acquire, store and use relevant material, taken from the living or deceased, for research. Appropriate consent is also required to hold bodily material with the intention of analysing its DNA. For further information on consent, please refer to the HTA-SOP-063 - Consent, which should be read in conjunction with the HTA’s **Code of practice A: Guiding principles and the fundamental principle of consent**: <https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice>

Failure to comply with the requirements of this SOP may result in samples being secured and inaccessible to the researchers and the research project being delayed.

3.1 PROCEDURE BEFORE ACQUISITION OR IMPORTATION

Authority to Acquire / Import Human Samples form

An application to work under the HTA license must be completed and submitted for approval to the Persons Designated (PD), with appropriate supporting documentation and risk assessment(s), in advance of the date for receipt of any human samples to be transferred into the University. Application form is available on the [University’s human tissue web pages](https://www.york.ac.uk/biology/intranet/human-tissue/).

The PD, by authorising the transfer of samples into the University, must be satisfied and have the appropriate auditable evidence that:

* + - * An appropriate Materials Transfer Agreement (MTA) or equivalent is in place;
* A minimum level of consent is in place before the tissue is transferred to the University;
* The PI and all other staff handling human tissue complies with all HTA SOPs;
* Researchers involved in the storage or use of the samples transferred to the University are registered, suitably qualified and appropriately trained.

Materials Transfer Agreement (MTA)  
The acquisition and receipt of any human samples transferred into the University from another organisation must be under an appropriate legal agreement – usually an MTA.

In accordance with the University’s Financial Regulations, all legal agreements and contracts related to research at the University must be processed through and formally signed by the appropriate personnel in Research, Innovation and Knowledge Exchange ([Contracts Team](https://www.york.ac.uk/staff/research/about-re/who-to-contact-in-the-research-ke-contracts-team/)) on behalf of the University (who have the appropriate delegated authority). It is common for the researcher in receipt of the imported material to be named on and be a signatory to an MTA but only in addition to the official signatory on behalf of the University.

*No individual member of staff, head of an academic department or student can officially accept an agreement on behalf of the University.*

The Contracts Team have developed a University standard MTA that can be used and negotiated with suppliers of human tissue and will also advise on MTAs received from their organisations, and the terms and conditions of commercial suppliers. The DI must be notified of every instance of human material transferred into the University not covered by an NREC and their approval must be obtained, by completion of the “Authority to Acquire / Purchase / Import Human Samples” form (appendix 2).

Consent and Ethical Approval

Although the consent requirements of the HT Act do not apply to samples transferred into the University from countries outside England, Wales and Northern Ireland, the HTA advise that it is good practice for a mechanism to be in place that provides assurance that human material is imported with appropriate consent.

Samples transferred into the University from sources within England, Wales and Northern Ireland should have appropriate consent.

As the importing organisation, the University should ensure that, with due assurance from collaborators overseas, that any material for import is sourced consistently with the legal and ethical review requirements in England, Wales and Northern Ireland. It is good practice for approval (i.e. a favourable ethical opinion) to be obtained from a research ethics authority or local equivalent in the source country before the samples are transferred to the University. Many countries have research ethics arrangements that operate to agreed standards. The ethical review in the source country may, in some cases, be considered to provide appropriate assurances for the importing of human material into this country.

Ethical approval by the [Biology Ethics Committee](https://www.york.ac.uk/biology/intranet/ethics/bec/appforms/) (or other such University Research Ethics Committee) must have been given before the Authority to Acquire/Import form (Appendix 2) is completed.

3.2 WHEN SAMPLES ARRIVE

Checks on samples and documentation

Samples and their accompanying documentation must be checked and samples stored securely, under the appropriate conditions. All samples must be labelled in accordance with HTA-SOP-065 - Storage & Equipment. Any discrepancies with the Authority to Import Human Samples form or related documentation must be highlighted to the PD. Any adverse event or incident involving the samples (e.g. damage to the packaging, damage to the samples) should be reported and investigated in accordance with HTA-SOP-061 - Adverse Events.

Records

The PI or Person Responsible, receiving the human samples, is responsible for ensuring the laboratory tissue records are updated with the details of the samples transferred to the University.

Records must not contain any patient identifiable data including, for example; patient name, date of birth, date of death, address, NHS number, GP.

3.3 PROCEDURE FOR TRANSFER OUT OR EXPORT

All human samples transferred out of the University should be done under a Materials Transfer Agreement. Human samples should not be transferred from one organisation to another unless both organisations have ethical approval from a recognised research ethics committee or are subject to an appropriate HTA licence and operating in accordance with HTA standards and Codes of Practice.

It is the responsibility of the PI transferring the material to ensure that the recipient has National Research Ethics Service (NRES) approval or they are operating under a valid and appropriate HTA license. This must be evidenced with a copy of the NRES approval or approval from the DI at the recipient institution.

Suitable routes and appropriate modes of transport will need to be considered with all parties involved when planning transportation. This needs to be arranged in advance and risk assessments for the handling and transportation undertaken.

An Authority to Transfer/Export Human Samples Form (see Appendix 1) must be completed and submitted for approval to the PD, with appropriate supporting documentation and risk assessment(s), in advance of the date for transportation of any human samples out of the University.

Please follow the instructions for the transport of Biological Agents found on the departmental safety web page <https://www.york.ac.uk/biology/intranet/health-safety/biological-safety/transport/>

Please keep a record and/or forward courier shipping updates and proof of delivery to the PD.

Following shipment, the laboratory records of tissues must be updated accordingly.

4. TRAINING

All those involved in research involving human samples are required to read this SOP and maintain a record of this training activity in a Personal Training Portfolio in accordance with HTA-SOP-066 –Registration & Training. This will enable individuals to understand the requirements and procedures for storage of human material.

5. MONITORING AND AUDIT

Regular monitoring of the effectiveness of the implementation of this SOP will be undertaken by the DI, the PD and/or others nominated by the DI. In addition, regular audits will be undertaken by the DI or the PD.

Templates available:

Appendix 1: Authority to Transfer / Export Human Samples

Appendix 2: Authority to Acquire / Purchase / Import Human Samples

Appendix 1



Authority to Transfer / Export Human Samples

To be completed by the PI or Person Responsible undertaking the export or transfer of human samples from the University and submitted to the Persons Designated for approval

|  |  |  |
| --- | --- | --- |
| **PI or Person Responsible** | | |
| Name: | | Title: |
| Contact details:  Email:  Telephone: | | Department: |
| **Project Details** | | |
| Research Project Title: | | |
| Ethical Approval Number: | | |
| HTA Approval Number: | | |
| Materials Transfer Agreement reference: | | |
| **Destination Details** | | |
| Name of destination  organisation |  | |
| Address/country of  destination organisation |  | |
| If UK, details of the destinations’ HTA licence status |  | |
| **Sample Details** | | |
| Type of sample *(e.g. urine)* |  | |
| Quantity of samples  *(e.g. 100 2ml tubes)* |  | |
| **Transportation Conditions** | | |
| Under what conditions will the samples be transported?  *(e.g. refrigerated container)* |  | |
| **Date of Transfer/export** | | |
| Proposed date of transfer/export? |  | |

*I confirm that the information above is accurate and complete and that the Tissue Register will be fully updated following the transfer/export of the human samples.*

Signature of PI / Person Responsible\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*I authorise transfer/export of these human samples:*

Signature of Persons Designated \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Appendix 2

Authority to Acquire / Purchase / Import Human Samples

To be completed by the PI or Person Responsible undertaking the import or transfer of human samples into the University and submitted to the Persons Designated.

|  |  |  |
| --- | --- | --- |
| **PI or Person Responsible** | | |
| Name: | | Title: |
| Contact details:  Email:  Telephone: | | Department: |
| **Project Details** | | |
| Research Project Title: | | |
| Ethical Approval Number: | | |
| Materials Transfer Agreement reference: | | |
| **Supplier Details** | | |
| Name of supplier  Organisation |  | |
| Address/country of  supplier organisation |  | |
| **Sample Details** | | |
| Type of sample *(e.g. urine)* |  | |
| Quantity of samples  *(e.g. 100 2ml tubes)* |  | |
| **Date of Transfer/Import** | | |
| Proposed date of transfer/import? |  | |

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| **Justification for Import** | |
| Reasons why it was necessary to import tissue | |
| **Fate of samples** | |
| ***Fate of samples following project completion:***  *In accordance with the terms of the MTA* | |
| Return to supplier | Yes/No |
| Transfer to another organisation | Yes/No  *If yes, give details* |
| Retain  *Pending application for ethical approval for new research project* | Yes/No |
| Disposal  *In accordance with SOP-064 Disposal* | Yes/No |
| Expected date of project completion |  |

*I confirm that the information above is accurate and complete and that the Tissue Register will be fully updated following the transfer/import of the human samples.* ***I confirm that a Biological Material Risk Assessment Form has been completed.***

Signature of PI / Person Responsible\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*I authorise acquisition/import of these human samples:*

Signature of Person Designated \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_