QUEEN'S UNIVERSITY BELFAST

Research and Enterprise

Standard Operating Procedure

Research Governance

Title:	**Transferring samples into the University and Import of Relevant Material**		
SOP Reference Number:	QUB-HTA-008	Date prepared:	03 January 2013
Version Number:	v 6.0	Revision Date:	20 February 2024
Effective Date:	28 February 2013	Review Date:	November 2025

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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
009/003	03/01/2013	Rewrite because of integration to Research Governance	v1.0
V 1.0	07/01/2015	Periodic Review	V 2.0
V 2.0	10/04/2017	Review in response to Human Tissue Authority's Codes of Practice and Standards update.	V 3.0
V 3.0	17/05/2019	Periodic review. Logo and name of Chair updated on cover page. Web links updated.	V 4.0
V 4.0	05/11/2021	Periodic review. Web links updated.	V 5.0
V 5.0	22/11/2023	Updated to include commercial companies operating under the University's HTA Licence and to make clear requirements for transferring material into the University	V 6.0

1. Purpose

This Standard Operating Procedure (SOP) describes the processes involved and requirements for the import of relevant material as defined by the Human Tissue Act 2004 (HT Act).

2. Introduction

The HT Act came into force on the 1 September 2006 and provides a framework for regulation of research involving the removal, storage, use and disposal of human tissue. The Human Tissue Authority (HTA) Code of Practice and Standards E Research provides guidance on the standards expected for establishments importing human tissue.

The HTA defines 'import' as import into England, Wales or Northern Ireland from a place outside England, Wales or Northern Ireland. Transfer of relevant material from Scotland is defined as import.

3. Scope

This SOP applies to all members of University staff; both academic and support staff as defined by Statute 1 and including honorary staff and students who are involved in transferring material into the University, including the import of relevant material in the areas under the HTA research licences at Queen's University Belfast.

This SOP also applies to all commercial companies operating on University premises who are involved in transferring material into the University, including the import of relevant material in the areas under the HTA research licences at Queen's University Belfast.

Note: Human tissue samples collected as part of a clinical trial of an investigative medicinal product (CTIMP) or samples acquired and stored in the Northern Ireland Biobank will have their own procedures and requirements and should not follow this SOP.

4. Responsibilities

4.1 Designated Individual

The Designated Individual (DI) is responsible for ensuring that appropriate import procedures are in place and that the storage premises are suitable as required by the terms of the HTA licence**.**

4.2 Person Designated

The Person Designated (PD) is responsible for providing advice and guidance on the import of relevant material in their area as required.

4.3 Chief Investigator or Custodian

The Chief Investigator (CI) or custodian of the material is responsible for ensuring all relevant material is imported in accordance with the requirements of this SOP and that appropriate records are maintained.

4.4 Researcher and Support Staff or Commercial Company Staff

The researcher and/or other support staff, including commercial company staff operating under QUB's HTA Licences, undertaking tasks related to the import of human tissue

samples must ensure that these are carried out in accordance with this SOP and that appropriate records are maintained.

5. Procedure

5.1 Consent

Consent is the fundamental principle of the HT Act.

Any agreements under which HTA relevant material is transferred to the University for use for a scheduled purpose (whether imported material or material from an external organisation within England, Wales or Northern Ireland) must have appropriate contractual arrangements in place that cover the transfer to the University. Where material is brought in from an external organisation researchers should obtain copies of the ethical approval, consent form and participants information sheets used in the research to evidence donor consent as appropriate.

Although consent is not a legal requirement for imported material, mechanisms must be in place to provide assurance that the tissue has been obtained with valid consent.

Imported material should be stored, used and disposed of in accordance with the consent given by the person from whom it came.

5.2 Justification

CIs and researchers are required to justify the need for import of tissues in terms of accessibility, quality, timeliness of supply, cost effectiveness, risk of infection and research need. Researchers must demonstrate that the purpose for which they wish to import such material cannot be adequately met within England, Wales and Northern Ireland.

5.3 Ethical Approval

Researchers must ensure that any material intended for import is sourced consistent with the legal and ethical review requirements in England, Wales and Northern Ireland. Where possible and appropriate, approval should be obtained from a Research Ethics Committee (or equivalent) in the source country.

5.4 Authority to Import Form

An Authority to Import Form (Appendix 1) along with any supporting documentation (eg evidence of consent process, ethical approval, and/or MTA or other contractual arrangements if commercial company) must be completed and submitted to the Research Governance Team. The DI must approve the import prior to the transfer of any samples into the University. The Research Governance Team will liaise with the DI to ensure regarding authorisation and check to ensure MTAs or equivalent contractual arrangements are in place.

5.5 QOL Tissue Register and Documentation

All relevant material transferred into the University must be logged on the QOL Tissue Register within one month of receipt (see QUB-HTA-001).

Academic Research

Material Transfer Agreements (MTAs) or Service Level Agreements (SLAs) or other contractual arrangements governing the transfer and/or import of relevant material must be reviewed by the Contracts Team. MTAs or other contractual arrangements are usually generated by the provider of the material. The CI must submit the external agreement to the Contracts Team for review using the Contracts Request Form on QOL. The Contracts Team will liaise with the Research Governance Team regarding the MTA and any necessary assurances/clauses needed with respect to the HT Act.

All contractual agreements/MTAs must be signed by an authorised University signatory. Individual CIs or researchers are not permitted to sign agreements on behalf of the University. Authorised signatories from the supplying and receiving organisations must both sign the agreement prior to any samples being received.

For material transferred into the University from England, Wales or NI records of transfer and delivery, MTAs or SLAs should be retained for the duration of the or the study/project or for as long as the material is held within the University (whichever is longer).

For imported material, records of transport and delivery, MTAs or SLAs and ecords relating to the import must be retained for a minimum period of 5 years after disposal.

Commercial Companies

Commercial companies that are operating under the University's HTA licence are responsible for ensuing appropriate contractual arrangements are in place for the transfer to and import of any relevant material to University premises. The companies must ensure the terms of any contractual agreements with other parties covers donor consent and compliance with the HT Act as appropriate.

For material transferred into the University from England, Wales or NI records of transfer and delivery, MTAs or SLAs should be retained for the duration of the or the study/project or for as long as the material is held within the University (whichever is longer). Copies of such agreements must be submitted to Research Governance who will maintain a central record in the event of an inspection.

Records of transport and delivery, MTAs or SLAs must be maintained. Records relating to the import of material must be retained by the company for a minimum period of 5 years after disposal.

5.6 Disposal

Imported material must be disposed of in accordance with the University's SOP on the Disposal of Human Tissue (QUB-HTA-002).

The requirements of the MTA/SLA must be followed (eg return to supplier or transfer to another laboratory). Specific requests or stipulations regarding the disposal of imported material (eg return to country of origin for disposal) should be adhered to.

5.7 Transportation

Relevant material must be packaged and transported in accordance with any applicable regulations for hazardous material (eg the International Air Transport Association (IATA)

Dangerous Goods Regulations, European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID), International Maritime Dangerous Goods (IMDG) Code).

6. References

Human Tissue Authority Code of Practice and Standards E Research
https://www.hta.gov.uk/codes
(last access February 2024)

Human Tissue Authority Code of Practice and Standards A Guiding Principles and the Fundamental Principle of Consent
https://www.hta.gov.uk/codes
(last accessed February 2024)

Human Tissue Authority definition of relevant material https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004 (last accessed February 2024)

QUB Safety Service
https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/ (last accessed February 2024)

7. Appendices

Appendix 1 Authority to Import Human Samples

Appendix 1

Authority to Import Human Samples

To be completed by the Chief Investigator or Person Responsible for undertaking the import of relevant material into the University and submitted to the Designated Individual (j.james@qub.ac.uk (MBC/BCH) or g.j.mckay@qub.ac.uk (RVH)) and the Research Governance Team (researchgovernance@qub.ac.uk).

Chief Investigator /Custodian	
Name:	Title:
Contact details: E-mail: Telephone:	Address/Centre:/Company
Study Details	
Research Study Title:	
Appropriate consent obtained?	*Yes/No*
Are you a named Co-investigator?	*Yes/No*
Research Ethics Committee Reference/Tissue Bank Reference Number	
Materials Transfer Agreement reference (Research Governance to populate)	
Supplier details	
Name of supplier organisation	
Address of supplier organisation	
Name of supplier	
Sample details	
Type of sample (eg liver biopsy)	
Quantity of samples (eg 10 x 0.5gm)	
Storage Conditions	
Under what conditions will the samples be stored? (eg -80°C)	
Justification for Import	
Reasons why it was necessary to import tissue:	
Planned fate of samples	
Planned fate of samples following project completion: *(in accordance with terms of the MTA/SLA)*	
Return to supplier	*Yes/No*
Transfer to another organisation	*Yes/No*

If yes, give details:	
Retain samples *Pending application for ethical approval for new research project*	*Yes/No*
Disposal	*Yes/No*

I confirm that the information above is accurate and complete and that the QOL Tissue Register will be fully updated following the transfer/import of the tissue samples.

Signature of the Chief Investigator/Custodian.....
Date.....

Authorisation

I authorise Import of these human samples:

Signature of Designated Individual..... Date.....