Standard Operating Procedure

Research Governance

Title:	**External Transfer and Export of Relevant Material**		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
009/003	11/01/2013	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	21/02/2024	Updated to include commercial companies operating under the University's HTA Licence	V 6.0

1. Purpose

This Standard Operating Procedure (SOP) describes the processes involved and requirements for the external transfer and export of relevant material from Queen's University Belfast.

2. Introduction

The Human Tissue Act 2004 (HT Act) came into force on the 01 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 exporting human tissue.

The HTA defines 'export' as transfer from England, Wales or Northern Ireland to a place outside these countries. Transfer of relevant material to Scotland is defined as export. External transfer is transfer from the University to premises within England, Wales and Northern Ireland.

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 with the transfer or export of relevant material from Queen's University Belfast.

This SOP also applies to all commercial companies operating on University premises who are involved in the receipt, labelling, tracking and storage 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 transfer and export 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 transfer and export of relevant material for 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 transferred or exported in accordance with the requirements of this SOP and that appropriate records are maintained.

4.4 Researcher and Support 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 transfer or export 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

Exported material must be used, handled, stored, transported and disposed of in accordance with the consent provided by the donor of the material. Prior to external transfer or export of relevant material, the sender (CI or custodian) must check the terms of the donor consent and ensure that there is consent for the sample transfer and if appropriate consent for use in future research.

5.2 Anonymisaton

Samples must be sent in an anonymised form, unless there is explicit consent for transferring identifiable information from the research participant and this has been approved by a Research Ethics Committee.

5.3 Material Transfer Agreements

Academic research

In circumstances where material collected before or after the implementation of the HT Act, is being transferred from the University licensed site to another organisation, and there are no existing research agreements in place to govern the transfer (eg service level agreement, collaboration agreement or clinical trial agreement) then a Material Transfer Agreement (MTA) or equivalent contractual agreement is required.

MTAs define the terms and conditions of sample transfer, including requirements for ethical approval, confidentiality, intellectual property and commercial use, publication rights, liability, description of material, intended use and disposal/return arrangements of the material following completion of the research.

A Contracts Request Form (available via QOL) must be completed and submitted to the Research Contracts Team, prior to any external transfer. Research Governance and the Contacts Team will liaise to ensure a MTA is drafted and that sign-off from an authorised University signatory is obtained. Individual CIs or researchers cannot sign a MTA on behalf of the University.

Where a MTA is required, authorised signatories from the sending and receiving organisations must both sign the agreement before any samples are sent.

Commercial Companies

Commercial companies that are operating under the University's HTA licence are responsible for ensuring appropriate contractual arrangements are in place to allow for the transfer of any samples to third party organisations. The companies must ensure the terms of any contractual agreements with other parties covers donor consent and compliance with the HT Act as appropriate.

Where contractual agreements are required, authorised signatories from the sending and receiving organisations must both sign the agreement before any samples are sent.

5.4 QOL Tissue Register and Records

The CI (or designated researcher) must maintain a register of when the samples were transferred and to whom.

An audit trail must be maintained, which includes details of, when the material was transferred, and to whom. The QOL Tissue Register is primarily used for this purpose and must be updated when any relevant material is externally transferred or exported from the University (see QUB-HTA-001).

Records of transport and delivery, Material Transfer Agreements (MTAs) or Service Level Agreements (SLAs) must be maintained locally.

In addition, Research Governance will maintain a central register of all HTA MTAs for which QUB is a party. For Commercial Companies copies of such agreements must be submitted to Research Governance who will maintain a central record in the event of an inspection.

5.5 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 accessed 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/HealthandSafetyPoliciesandGuidance/SafetyPolicy/ (last accessed February 2024)

QUB-HTA-007
Appendix1