Queen's University Belfast

Research and Enterprise

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
Final v 1.0	07/01/2015	Periodic Review	Final v 2.0
Final v2.0	10/04/2017	Review in response to Human Tissue Authority's Codes of Practice and Standards update.	Final v3.0

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.

Note: Human tissue samples collected as part of a clinical trial of an investigative medicinal product (CTIMP) or samples acquired from 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 Staff

The researcher and/or other support staff 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

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) 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 Request for External Transfer or Export of Human Tissue form (Appendix 1) must be completed and submitted to the Research Governance Team prior to any external transfer. Research Governance will liaise with the Contacts Team 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.

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.

The QOL Tissue Register 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.

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/hta-codes-practice-and-standards
(last accessed April 2017)

Human Tissue Authority Code of Practice and Standards A Guiding Principles and the Fundamental Principle of Consent:
https://www.hta.gov.uk/hta-codes-practice-and-standards (last accessed April 2017)

Human Tissue Authority definition of relevant material
http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm (last accessed April 2017)

QUB Safety Service Transport of Dangerous Goods
http://www.qub.ac.uk/directorates/HumanResources/OccupationalHealthandSafety/GuidanceNotes/TransportofDangerousGoods/ (last accessed April 2017)

7. Appendices

Appendix 1 Request for External Transfer or Export of Human Tissue Form

Request for External Transfer or Export of Human Tissue

To be completed by the Chief Investigator or Custodian responsible for undertaking the external transfer or export of relevant material from the University and submitted to the Research Governance Team (researchgovernance@qub.ac.uk).

Chief Investigator/Custodian details		
Name:	Title:	
Contact details: E-mail: Telephone:	Address/Centre:	
Study Details		
Research Study Title:		
Has appropriate consent for the use of the samples been obtained?		*Yes/No*
Are you a named co-investigator?		*Yes/No*
Ethical Approval Reference Number		
Materials Transfer Agreement (MTA) reference (if appropriate)		
Recipient details		
Name of recipient organisation		
Address/country of recipient organisation		
Name of the recipient		
Name of the authorised signatory for the recipient organisation		
Sample details		
Type of sample (eg liver biopsy)		
Quantity of samples (eg 10 x 0.5g)		
Storage Conditions		
Under what conditions will the samples be stored? (eg -80°C)		
Use/Analysis		
Description of how the relevant material will be used:		
Planned fate of samples following project completion *(in accordance with the terms of the MTA or other agreement)*		
Return to Queen's University Belfast		*Yes/No*
Transfer to another organisation *If yes, give details:*		*Yes/No*
Retain samples		*Yes/No*
Disposal		*Yes/No*
Other contracts		
Are there any other contractual arrangements (eg funding stipulations) pertaining to the samples? *If yes, give details:*		*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/export of the tissue samples.

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

Date.....