






Standard Operating Procedure

Research Governance

Title:	External Transfer and Export of Relevant Material		
SOP Reference Number:	QUB-HTA-007	Date prepared:	11 January 2013
Version Number:	v 2.0	Revision Date:	07 January 2015
Effective Date:	28 February 2013	Review Date:	January 2017

	Name and Position	Signature	Date
Author:	Dr Paula Tighe Research Governance Manager		23/3/2015
Reviewed by:	Human Tissue Steering Group		23/3/15
Approved by:	Professor James McElnay, Chair Human Tissue Steering Group		23/05/2015

This is a controlled document.
When using this document please ensure that the version is the most up to date by
checking the Research Governance Website

Do Not Copy

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

Do Not Copy

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 8 - Import and export of human bodies, body parts and tissue 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 Anonymisation

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

Do Not Copy

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 8 - Import and export of human bodies, body parts and tissue

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code8importandexport.cfm> (last accessed February 2015)

Human Tissue Authority definition of relevant material

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm> (last accessed February 2015)

QUB Safety Service Transport of Dangerous Goods

<http://www.qub.ac.uk/directorates/HumanResources/OccupationalHealthandSafety/GuidanceNotes/TransportofDangerousGoods/> (last accessed February 2015)

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 <i>If yes, give details:</i>	Yes/No
Retain samples	Yes/No
Disposal	Yes/No
Other contracts	
Are there any other contractual arrangements (eg funding stipulations) pertaining to the samples? <i>If yes, give details:</i>	Yes/No

Do Not Copy

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.....

