Queen's University Belfast

Research and Enterprise

Standard Operating Procedure

Research Governance

Title:	**Import of Relevant Material**		
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	Name and Position	Signature	Date
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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
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 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 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 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 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

The researcher and/or other support staff 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. 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, 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) must be completed and submitted to both the DI and the Research Governance Team. The DI must approve the import prior to the transfer of any samples into the University.

5.5 QOL Tissue Register and Documentation

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

Material Transfer Agreements (MTAs) or Service Level Agreements (SLAs) governing the import of relevant material must be reviewed by the Contracts Team and 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.

Records of transport and delivery, MTAs or SLAs must be maintained. Records relating to the import of material must be retained 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/hta-codes-practice-and-standards
(last access 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

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 Authority to Import Human Samples

Queen's University Belfast

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		
Name:	Title:	
Contact details: E-mail: Telephone:	Address/Centre:	
Study Details		
Research Study Title:		
Appropriate consent obtained?		*Yes/No*
Are you a named Co-investigator?		*Yes/No*
Ethical Approval Number/School Ethics Number		
Materials Transfer Agreement reference (if appropriate)		
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 *If yes, give details:*		*Yes/No*
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..... Date.....

Authorisation

I authorise Import of these human samples:

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