QUEEN'S UNIVERSITY BELFAST

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Receipt, Labelling, Tracking and Storage of Human Tissue**		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
FMS&LS/SOP/003/002 QUB-HTA-02	08/10/12	Rewrite because of integration to Research Governance	v1.0
Version 1.0	20/06/13	Clarification on the procedures to be followed when samples are released to University researchers from the Northern Ireland Biobank. Addition of information for recording and tracking cell cultures which contain cells created inside the human body.	v2.0
Version 2.0	06/10/14	Periodic review. Queen's Online replaced by Research Governance Website included on cover page. Appendix 1 details updated to reflect new Tissue Register content.	v3.0
Version 3.0	10/04/2017	Review in response to Human Tissue Authority's Codes of Practice and Standards update.	v4.0
Version 4.0	17/05/2019	Periodic review. Logo and name of Chair updated on cover page. Web links updated.	v5.0

1. Purpose

This Standard Operating Procedure (SOP) describes the process for labelling, tracking and storage of human tissue 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. In order to meet the requirements of the HT Act all human tissue, defined as relevant material, must be labelled appropriately, stored under suitable conditions and entered on the Queen's Online (QOL) Tissue Register to ensure traceability. This SOP should be read in conjunction with the Human Tissue Authority (HTA) Code of Practice and Standards E, Research.

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 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 within the Northern Ireland Biobank (NIB) will have their own procedures and requirements and should not follow this SOP. Academic and support staff in receipt of samples from the NIB must follow this SOP.

4. Responsibilities

4.1 Designated Individual

The Designated Individual (DI) is responsible for ensuring that appropriate labelling, tracking and storage 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 labelling, tracking and storage procedures 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 received, labelled and stored appropriately and entered on the QOL Tissue Register in accordance with the requirements of this SOP. The CI or custodian must ensure that any individuals delegated these responsibilities are suitably trained to undertake the tasks.

4.4 Researcher and Support Staff

The researcher and/or other support staff delegated the task of receiving, labelling, storing and/or tracking human tissue samples must ensure that these tasks are carried out in accordance with this SOP and that appropriate records are maintained.

5. Procedure

5.1 General

Consent is the fundamental principle of the HT Act. Appropriate consent must be in place for the removal, storage and use of human tissue for research purposes. Consent is also required for the storage of 'bodily material' (bodily material includes hair and nails from the living and gametes) with the intention of analysing DNA. The Research Governance SOP Informed Consent for Research (QUB-ADRE-004) details the process for obtaining informed consent.

There are exceptions to the consent requirements under the HT Act. Consent for research is not required if:

(i) The material is an 'existing holding' (ie collected prior to the 1st September 2006);
(ii) The material is imported;
(iii) The material is from a living person and the researcher is unable to identify the person and the specific research project is approved by a recognised Research Ethics Committee (REC) (ie ORECNI or the equivalent statutory ethics committee). A University REC is not considered to be a recognised REC.

It should be noted that although consent is not required for imported material, mechanisms must be in place to provide assurance that the tissue has been obtained with valid consent.

The HT Act defines relevant material as material that has come from the human body and consists of or includes human cells (see HTA website http://www.hta.gov.uk/ for a full list of relevant material). Where relevant material is processed, treated or lysed and as a result of the process or treatment is rendered acellular, then the material may be regarded as such. This includes cells divided and created outside the human body and the freezing or thawing of cells only where that process is intended to render them acellular. The process whereby material is rendered acellular must always be documented and recorded.

All relevant material must be labelled and stored in such a manner as to ensure the traceability, integrity and security of the sample from removal, use and disposal.

Facilities in which human tissue samples are stored must be of suitable size and construction to meet the requirements of the HTA licence. The licenced storage areas must be secure, clean and well maintained.

All applicable health and safety policies and procedures, including the University's Biological Safety Guidance and Chemical Safety Policy, must be adhered to when working with human tissue (see https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/). Risk assessments must be completed for all research activities involving human tissue to minimise the risk of contamination and protect the health and safety of staff, students and visitors.

5.2 Receipt

All samples transferred into University premises must be assessed on arrival to ensure that the physical integrity of the sample has been maintained during the transfer (including any temperature maintenance requirements). This process should be documented in local records.

Upon receipt, sample labels should be checked to verify the correct samples have been received and the expected number of samples accounted for. Where there are discrepancies between the samples received and those expected, the sender must be informed and the issue investigated.

If human tissue samples are found to have been compromised during transfer then the sender must be notified and any adverse event reporting procedures followed.

5.3 Labelling

All human tissue samples should be labelled in accordance with local SOPs for sample labelling as necessary.

As a minimum, all human tissue samples must be labelled with a unique code for identification purposes and to ensure traceability. The unique sample number must not contain personal details of the participant (eg health and social care number or date of birth).

Sample labels must be in legible condition, securely affixed to the sample container and suitable for the storage conditions in which the sample is to be held.

When samples are grouped together in containers for storage (eg in sarstedt boxes) the external container should be labelled appropriately in accordance with local procedures as necessary.

At a minimum the external container must be labelled with the unique study code (eg REC reference number, NIB application number, CTIMP number). The labelling must enable the identification of the CI or custodian of the samples. Consideration should be given to the inclusion of the type(s) of material, the sample number range contained within and the year/month of collection if appropriate.

5.4 Sample tracking – QOL Tissue Register and Records

All relevant material (including material collected as part of a recognised REC approved study and material transferred to the University) must be logged on the QOL Tissue Register within one month of collection or receipt.

The sample details on the Register must be maintained to ensure traceability. The Register must be updated when samples are moved from one storage location to another or when samples are disposed of (eg at the end of a study).

Local records (eg lab book or research project specific records) must detail the storage, processing and use of all samples.

Appendix 1 details the data fields to be completed on the QOL Tissue Register.

Access to the QOL Tissue Register is arranged by the Research Governance Team (contact researchgovernance@qub.ac.uk). Access to the Register will only be permitted for individuals who have completed HT Act training.

5.4.1 Cell Cultures and Tracking

Cell cultures which contain cells that were created inside the human body (eg original cells from a biopsy or blood sample) are considered to be relevant material and are stored under a licence from the HTA. Once cells in culture have divided outside the human body they are no longer considered to be relevant material. Researchers will need to make a judgement as to when cells in culture no longer contain original cells.

Cell cultures containing original cells do not have to be logged onto the QOL Tissue Register providing the cells divide within a maximum of 30 days and there are no original cells present. However, local records of storage and use of all cell cultures containing original cells must be maintained by the researcher to ensure traceability. These local records may be subject to internal and external audit or inspection.

5.5 Storage

All human tissue samples must be stored in appropriate and secure conditions. The storage units (cabinets, freezers or equivalent) must be lockable or the area in which the storage units are located must have access control procedures in place.

Study specific samples should be grouped together for storage in a logical and organised manner. The use of freezer racks, trays and boxes to enable easy locating of samples is encouraged.

For human tissue samples requiring temperature maintenance, the storage unit must be monitored and alarmed. Responsible individuals who are required to respond when an alarm is raised, must be identified for each storage area. Evidence of temperature monitoring and actions taken in the event of deviation from the acceptable temperature range should be retained.

Freezers or fridges that contain relevant material must be appropriately labelled. Guidelines for freezer labelling are attached in Appendix 2.

Local procedures for cleaning and decontamination of facilities and storage units must be established.

Procedures for maintenance and calibration of storage units should be in place as appropriate.

5.6 Temporary Storage

The HTA allows for temporary storage of relevant material if it is incidental to transportation and if the material is not held for longer than 7 days prior to being transferred to another establishment. In the event that material is held for less than 7 days before transfer to another establishment then the material does not have to be recorded on the QOL Tissue Register. The material however, must still be labelled appropriately to allow identification and stored under the correct

conditions to maintain sample integrity. Local records must also be maintained to ensure traceability and record the receipt and transfer of the material. Any material transferred to another establishment must have an agreement (eg MTA, Service Level Agreement or clinical trial agreement) in in place which covers the transfer, prior to the onward transferal.

For material is held prior to processing which will render the material acellular, the material will not require registration on the QOL Tissue Register provided that the processing takes place within a matter of hours or days and certainly no longer than one week. Any samples rendered acellular must still be labelled appropriately to allow identification and stored under the correct conditions to maintain sample integrity. Local records (eg lab books) must also still be maintained to ensure traceability and record the processes which took place to render the material acellular.

5.7 Contingency plans

All premises which store human tissue must have contingency arrangements in place in the event that a freezer breakdown or power failure occurs that renders the storage unit or area unsuitable. Contingency plans must also identify the individuals responsible for responding in the event of an alarm or system failure.

6. References

Human Tissue Authority Code of –Practice and Standards E Research
https://www.hta.gov.uk/hta-codes-practice-and-standards
(last access May 2019)

Human Tissue Authority Code of Practice A Guiding Principles and the Fundamental Principle of Consent
https://www.hta.gov.uk/hta-codes-practice-and-standards (last access May 2019)

Human Tissue Authority definition of relevant material
https://www.hta.gov.uk/policies/list-materials-considered-be-%E2%80%98relevant-material%E2%80%99-under-human-tissue-act-2004 (last accessed May 2019)

QUB Safety Service
https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/ (last access May 2019)

7. Appendices

Appendix 1 QOL Tissue Register (htdb) data fields and notes
Appendix 2 Freezer labelling instructions

QOL Tissue Register (htdb) data fields and notes

STUDY DETAILS

Study Fields	Guidance
Study Title	Title of the research study.
Study Reference Number	Research Ethics Committee reference number or tissue bank application number (eg 14/NI/0813, NIB10-0067).
MTA Number	Material Transfer Agreement (MTA) reference number. Reference numbers are assigned by Research Governance to all new MTAs.
Consent	Tick 'Yes' if consent is obtained from research participants for use of their tissue in this research project. Tick 'Not required' if consent exceptions apply (eg no consent from participant but the study is approved by ORECNI or the equivalent).
Ethical Expiry Date	End of study date.
Study Closed	Tick 'Yes' if study has ended. For studies with approval from an NHS Research Ethics Committee (eg ORECNI), an End of Study Declaration must be submitted in order for a study to be closed.
Retain Samples	Tick 'Yes' if the intention is to retain the samples for future research after the end of the project. Tick 'No' if samples are to be disposed of at the end of the study.
Staff Details	Enter Chief Investigator (CI) name or the name of the staff member with responsibility for the human tissue samples stored on QUB premises (if the CI is not a QUB member of staff). Other staff or students involved in the project can be added as researchers. Note all researchers added in this section will have the ability to modify the study sample records and therefore should only be added if this function is necessary. Staff and postgraduate students can be searched by surname.

SAMPLE DETAILS

Sample Fields	Guidance	Mandatory Field
Participant ID	Unique identifier assigned to a participant on a particular study. Free text field.	Yes
Sample ID	Unique sample identifier assigned by the researcher. Free text field.	Yes
Specimen Type	Type of relevant material. Choose from drop down menu. Contact Research Governance if specimen type is not available on the menu.	Yes
Tissue Site	Where organs have been selected under specimen type, additional information on tissue	Yes – only if organ selected in

	site must be provided. Free text field.	specimen type
Sample Format	Choose slide, block or other (eg frozen aliquots, or dried blood spots on Guthrie cards would be considered to be other).	Yes
Storage	Choose type of storage from drop down menu. Contact Research Governance if storage type required is not available on the menu.	Yes
Location Building	Building name where the material is stored (eg HSB, MBC, ICS B). Free text field.	Yes
Location Room	Room number/name where the material is stored. Free text field.	Yes
Location Storage Unit	Storage unit number/name (eg Freezer 15). Free text field.	Yes
Notes	Free text and optional. Any additional information can be entered here.	No
Source	Source/provider of the material (eg BHSCT). Free text field.	Yes
Date Received	Date material was received into QUB. Must be entered in DD/MM/YYYY format.	Yes
Samples Disposed	If samples have been disposed select/enter 'Yes'. If samples have not been disposed field can be left blank.	No
Disposal Method	Enter disposal method (eg treated as clinical waste). Free text field.	Yes – if samples disposed indicates yes
Date Disposed	Date of disposal. Must be entered in DD/MM/YYYY format.	Yes – if samples disposed indicates yes
Reason for Disposal	Enter the reason for disposal (eg end of study, analysis complete, withdrawal of consent). Free text field.	Yes – if samples disposed indicates yes
Samples Transferred	If samples have been transferred select/enter 'Yes'. If sample has not been transferred leave blank.	No
Transferred Location	Enter location samples were transferred to. Free text field.	Yes - if samples transferred indicates yes

Transfer Date	Date material was transferred. Must be entered in DD/MM/YYYY format.	Yes - if samples transferred indicates yes

Freezer labelling Guidelines

Freezers used for the storage of human material should be labelled in a legible format.

1. Labels for freezers should be clearly visible and fixed to the outside of the freezer. All storage units should have an identifier number.

2. Freezers containing relevant material should display the following label (as appropriate to each license area):

> **FREEZER XX**
> Contains human samples held under HTA licence
>
> - Licence number: 12044
> - License holder: Prof James Mc Elnay (Pro-VC Research, Enterprise & Postgraduate Affairs)
> - Designated Individual: Dr Jackie James

3. Emergency freezers to be used in the event of a freezer malfunctioning should have the following label displayed:

> **Emergency Freezer**
> **Not for general use**
>
> In the event of a malfunction, please contact:
>
> (eg lab manager)

4. If the handling of human samples may cause a user to be at risk then the following warning sign should be placed on the front of the freezer. Each risk should be individually assessed.

5. Freezers suitable for storing HT Act relevant material but not being used for such should display the following label:

> **Does NOT contain**
> **ANY**
> **HTA relevant samples**

6. Freezer labels should enable the identification of the CI/custodian of the samples held within.

Sample freezer labelling:

1A **CI:** *CI/custodian name* **Material:** *Sample type* **Ethics No:** *Ethics Ref Number* **Location:** *eg box number*	**1B** **EMPTY**	**1C** **EMPTY**	**1D** **EMPTY**
2A **CI:** **Material:** **Ethics No:** **Location:**	**2B** **CI:** **Material:** **Ethics No:** **Location:**	**2C** **CI:** **Material:** **Ethics No:** **Location:**	**2D** **CI:** **Material:** **Ethics No:** **Location:**
3A **CI:** **Material:** **Ethics No:** **Location:**	**3B** **CI:** **Material:** **Ethics No:** **Location:**	**3C** **CI:** **Material:** **Ethics No:** **Location:**	**3D** **CI:** **Material:** **Ethics No:** **Location:**
4A **CI:** **Material:** **Ethics No:** **Location:**	**4B** **CI:** **Material:** **Ethics No:** **Location:**	**4C** **CI:** **Material:** **Ethics No:** **Location:**	**4D** **CI:** **Material:** **Ethics No:** **Location:**
5A **CI:** **Material:** **Ethics No:** **Location:**	**5B** **CI:** **Material:** **Ethics No:** **Location:**	**5C** **CI:** **Material:** **Ethics No:** **Location:**	**5D** **CI:** **Material:** **Ethics No:** **Location:**