QUEEN'S UNIVERSITY BELFAST

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Assessment of Risk to Human Tissue**		
SOP Reference Number:	QUB-HTA-006	Date prepared:	03 January 2013
Version Number:	v 6.0	Revision Date:	14 March 2024
Effective Date:	28 February 2013	Review Date:	March 2026

	Name and Position	Signature	Date
Originally Authored by:	Mr Ken Arthur Chief Biomedical Scientist		
Reviewed by:	Human Tissue Steering Group	----------	
Approved by:	Professor Christopher Scott, Chair Human Tissue Steering Group	----------	

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

Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
FMH&LS/SOP/008/01	03/01/2013	Reformat because of integration to Research Governance	v1.0
Final v 1.0	07/01/2015	Periodic Review	Final v 2.0
Final v 2.0	10/04/2017	Review in response to Human Tissue Authority's Codes of Practice and Standards update.	Final v3.0
Final 3.0	17/05/2019	Periodic review. Logo and name of Chair updated on cover page. Web links updated.	V4.0
Final 4.0	05/11/2021	Periodic review. Logo and name of Chair updated on cover page. Web links updated.	V5.0
V5.0	14/03/2024	Updated to include generic HTA Risk Assessment template Updated to include commercial companies operating under the University's HTA Licence	V6.0

1. Purpose

This Standard Operating Procedure (SOP) describes the process by which a risk assessment is carried out, recorded and controlled in connection with the handling of relevant material as defined by the Human Tissue Act 2004 (HT Act).

Within each lab the risks to the relevant material should be identified and minimised.

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.

A risk assessment is defined as "a systematic examination of the hazards associated with the work, an evaluation of the risks (in this instance) to human tissue from those hazards and a judgement of the measures required to eliminate or control the risk to the tissue". It is essential that all risk assessments which occur during the course of a scheduled purpose are appropriately recorded and acted upon. Where necessary, multiple assessments may be made where different activities/processes yield different risks to the tissues.

All reasonable precautions MUST be taken to reduce both the possible severity and likelihood of the hazards and consequently the risk to human tissues. Having carried out the assessment, any activity which is deemed “likely” to cause damage, loss or destruction[1] should be avoided and a safer mode of work designed. A new risk assessment will be required.

The risk assessment should consider the risk to the tissue from all reasonable relevant events. An example would be a risk assessment in the event of the failure of a freezer or other storage in which human tissue is held, or for the transportation of tissue to another location.

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 removal, storage, use of relevant material for scheduled purposes.

This SOP also applies to all commercial companies operating on University premises who are involved in the removal, storage or use 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 risk assessment procedures are in place**.**

[1] Destructive testing which is part of the experimental design and which is consented to as appropriate does not constitute hazard or risk to tissues.

4.2 Person Designated

The Person Designated (PD) is responsible for providing advice and guidance on human tissue risk assessment procedures in their area as required.

4.3 Chief Investigator or Custodian

The Chief Investigator (CI) (or person to whom responsibility has been designated) is responsible for ensuring that all activities carried out under their supervision have had appropriate risk assessment and that any risks identified during the assessment are dealt with via the implementation of appropriate control measures.

4.4 Researcher and Support Staff or Commercial Company Staff

The researcher and/or other support or commercial company staff delegated tasks involving relevant material must ensure that these tasks are carried out in accordance with the risk assessment and that appropriate control measures are applied as necessary.

5. Procedure

All applicable health and safety policies and procedures, including the University's Biological Safety Guidance and Chemical Safety Policy, should be adhered to when working with human tissue (https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/).

Risk assessment and the application of appropriate control measures should be approached through careful consideration of the following paragraphs.

Commercial companies operating on University premises must follow the relevant health and safety policies and procedures of their employers.

5.1 Risk control measures

Judgement on the risk control measures necessary should be based on the following:

- What assurances are in place to prevent the use of relevant material without appropriate consent?
- What state(s) is the tissue in during storage and/or processing (fresh, fixed, frozen, processed)?
- What are the processes or storage conditions likely to cause loss or damage to tissue?
- SOPs for all processes involving relevant human material;
- What damage and degree of damage might be caused by the processes or storage?
- Minimising or limiting damage;
- Use of alarms to give warning of equipment malfunction which could give rise to loss or damage;
- Appropriate training of staff/students and competency assessment to ensure correct treatment of tissues;
- Appropriate maintenance of equipment used in processes and/or storage;
- Efficient procedures put in place to ensure prompt and safe collection, transportation, reception and storage of tissues;
- Suitable storage facilities with effective security measures to prevent unauthorized access to tissues;

- Appropriate record keeping of processes.

5.2 Recording risk assessments and control measures

Due to the diversity of activity in different laboratories in which human tissue is handled, each laboratory should have a local SOP, informed by the content of this general SOP. An important part of the local SOP will be a proforma used in the process to record both risks to the tissues and control measures to minimise those risks.

It is not necessary to complete a risk assessment every time an activity is carried out. A risk assessment should be completed once, placed on file and kept available for reference. It must be duly signed and dated by any new worker carrying out the activity. Risk assessments should be reviewed regularly and revised if the activity or any hazards associated have changed substantially. Is hold be noted that the same activity carried out in different locations may have differing risks (due to differences in premises, equipment, engineering, etc) and therefore may require a different assessments.

A generic risk assessment for HTA related activity is attached in Appendix 1.
This can be used to demonstrate compliance or, if appropriate, it can form the basis for a more in-depth Risk Assessment. All completed proformas should be filed with other paperwork associated with a particular project (e.g. project protocol, completed consent forms).

Local SOPs must be maintained and made available upon request.

6. References

Human Tissue Authority Code of – Practice and Standards E Research
https://www.hta.gov.uk/codes (last access March 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 March 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 March 2024)

QUB Safety Service
https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/ (last accessed March 2024)

7. Appendices

Appendix 1 Risk Assessment Human Tissue

Risk Assessment (Human Tissue)

School/Department/Unit: University Wide	Work activity: Human Tissue Activity	
Assessment completed by: Human Tissue Steering Group	Date completed:	Review Period: 3 years

Activity (task step)	Hazards	Who or What might be harmed	Existing Control Measures (What are you already doing?)	Severity (1-4)	Likelihood (1-4)	Risk Level (L,M,H, VH)	What further action is necessary	Final risk rating	Action by whom & by when

Activity (task step)	Hazards	Who or What might be harmed	Existing Control Measures (What are you already doing?)	Severity (1-4)	Likelihood (1-4)	Risk Level (L,M,H, VH)	What further action is necessary	Final risk rating	Action by whom & by when
Receiving and/or storing specimens without appropriate consent documentation	Risk of Obtaining Human Tissue without appropriate consent	Research Participant Reputational Risk	Staff are suitably trained in relation to the Human Tissue Act requirements and consent. Informed Consent SOP (QUB-RGEI-004) is followed. Study participants are asked to give their consent at the start of the study. They are also informed at enrolment of study that they can withdraw consent at any stage and their samples will be disposed of according to HTA regulations. Consent Forms are stored securely. Material Transfer agreements and contractual agreements are put in place when obtaining human tissue samples from or transferring human samples to external organisations or new custodians. This is verified during premises and study specific audits.	3	**1**	M	None		

Activity (task step)	**Hazards**	**Who or What might be harmed**	**Existing Control Measures (What are you already doing?)**	Severity (1-4)	Likelihood (1-4)	Risk Level (L,M,H, VH)	**What further action is necessary**	**Final risk rating**	**Action by whom & by when**
Storing Human Tissue	Storing or using human tissue after consent withdrawal	Research Participant	Staff are suitably trained in relation to the Human Tissue Act requirements and consent. The SOP for Withdrawal of Consent – Human Tissue (QUB-HTA-010) is followed, and the HT Database is updated. Staff training is reviewed as part of the ongoing audit programme.	3	**1**	M	None		

Activity (task step)	Hazards	Who or What might be harmed	Existing Control Measures (What are you already doing?)	Severity (1-4)	Likelihood (1-4)	Risk Level (L,M,H, VH)	What further action is necessary	Final risk rating	Action by whom & by when
Storing Human Tissue	Storage failure or other damage affecting human tissue quality for useful research: Circuit trip to power supply for T-Scan data logger.	Human Tissue	T-scan or other monitoring system is used. UPS attached to gateway PC for uninterrupted power supply. Email received from T-scan support to say receiver(s) or T-scan PC have lost connection with the internet. Stale Data Reports will be received for a range of sensors. Investigate locally for cause & resolve (e.g. power outage, internet down). Or request for local maintenance (Planon) or contact T-scan support as required. 24hour cover for electrician.	3	2	M	None		

Activity (task step)	Hazards	Who or What might be harmed	Existing Control Measures (What are you already doing?)	Severity (1-4)	Likelihood (1-4)	Risk Level (L,M,H, VH)	What further action is necessary	Final risk rating	Action by whom & by when
	Failure of computer hard-drive.	Human Tissue	New data will not be sent from the sensors to the gateway pc. Data is held on the web and can be accessed from another PC or device. Daily monitoring by T-Scan. Monitor all freezers manually until new gateway PC is installed. Also automatic data streaming to QUB university mainframe computer which is backed up daily.	3	2	H	None		
	Deviation (rising/falling) of freezer temperatures from set parameters.	Human Tissue	T-scan alert received. Cause determined & resolved locally if possible or freezer engineers called for investigation where necessary. Samples moved to HTA back-ups, if necessary.	3	2	H	None		

Activity (task step)	Hazards	Who or What might be harmed	Existing Control Measures (What are you already doing?)	Severity (1-4)	Likelihood (1-4)	Risk Level (L,M,H, VH)	What further action is necessary	Final risk rating	Action by whom & by when
	T-Scan sensors fail to send data. Failure of T-Scan system	Human Tissue	Sensors are monitored daily to check if there is stale data. Sensor check-in failure/stale data report (SDR) email received. Can reconnect or replace sensor battery or reboot receiver if required or notify T-Scan engineer who can check system remotely. Can contact QUB maintenance if power outage. Monitor affected freezers manually	4 4	2 1	H M	None		
	Failure of QUB Internet/Network	Human Tissue	Notify QUB Estates & Information Services. Monitor all freezers manually until internet services restored. Will also receive an email from T-scan customer support that gateway PC or named receivers have lost internet access.	4	2	H	None		

Activity (task step)	Hazards	Who or What might be harmed	Existing Control Measures (What are you already doing?)	Severity (1-4)	Likelihood (1-4)	Risk Level (L,M,H, VH)	What further action is necessary	Final risk rating	Action by whom & by when
Storing Human Tissue	Loss of human tissue	Human Tissue	Use of T-scan or other monitoring system. Alerts responded to promptly and appropriate action taken, such as removal of samples to backup storage locations. Local arrangements and rota systems are in place using real-time communication.	4	2	H	None		

Activity (task step)	Hazards	Who or What might be harmed	Existing Control Measures (What are you already doing?)	Severity (1-4)	Likelihood (1-4)	Risk Level (L,M,H, VH)	What further action is necessary	Final risk rating	Action by whom & by when
Storing Human Tissue	Sample mix-up or loss of traceability	Human Tissue	Receipt, Labelling, Tracking and Storage SOP (QUB-HTA-001) followed. As a minimum, all human tissue samples must be labelled with a unique code for identification purposes and to ensure traceability. 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. 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. Compliance is assessed through premises and study-specific audits. Reports to HTSG enable lessons learned from audits to be disseminated.	3	2	M	None		

Activity (task step)	Hazards	Who or What might be harmed	Existing Control Measures (What are you already doing?)	Severity (1-4)	Likelihood (1-4)	Risk Level (L,M,H, VH)	What further action is necessary	Final risk rating	Action by whom & by when
Storing Human Tissue	Security arrangements	Human Tissue	Receipt, Labelling, Tracking and Storage SOP (QUB-HTA-001) followed. Storage Locations must be appropriate, and access controlled. Compliance is assessed through premises and study-specific audits. Reports to HTSG enable lessons learned from audits to be disseminated.	4	1	M	None		

Activity (task step)	Hazards	Who or What might be harmed	Existing Control Measures (What are you already doing?)	Severity (1-4)	Likelihood (1-4)	Risk Level (L,M,H, VH)	What further action is necessary	Final risk rating	Action by whom & by when
Transport of specimens to and from the establishment	Delay or Loss in Transit; Damage in Transit; Use of Inappropriate Packaging;	Human Tissue	Transportation of Human Tissue SOP (QUB-HTA-009) followed. Timing for sending samples should be considered, avoiding public holidays or weekends. Check for safe receipt of samples. Use of a courier with tracking service for samples that need to be shipped. Specimens for shipping are packaged in materials and containers which comply with UN 3373 standard. Staff who prepare samples for shipping are IATA trained. This should be periodically reviewed at Centre level.	4	2	H	None		
Disposal of Human Tissue Samples	Incorrect disposal of Samples which should have been retained	Human Tissue	Personnel working with Human Tissue are appropriately trained and follow appropriate steps of Disposal of Human Tissue SOP (QUB-HTA-002). Complete HTA Disposal Form, if required, and file in Study/Trial Master File and update online HTA database.	4	1	M	None		

Put the date the assessment was completed and put in a review date, normally annually unless the task, person or equipment changes

The task or activity i.e. mowing the lawn

School/Department/Unit: Estates Gardening		Task/Work activity: Mowing lawn
Assessment completed by: A. N. Other	Date completed: 20-May 2011	Review Period: 1 Year

Activity (task step)	Hazards	Who might be harmed	Existing Control Measures (What are you already doing?)	Severity (1-4)	Likelihood (1-4)	Risk Level (L,M,H,VH)	What further action is necessary	Final risk rating	Action by whom & by when
Filling the mower with petrol	Fire, explosion	Operator and others in vicinity during filling with fuel	Fuel stored in appropriate labelled container. Petrol filling undertaken outside in open area away from sources of ignition. Pre-use checks for leaks.	3	1	M	Warning notice to be displayed in workshop. Operator to be provided with filling funnel to avoid spills.	L	A.N. Other Supervisor 20-05-11

Identify any steps in the task i.e. filling the lawn mower with petrol

Identify hazards or injury causes

Identify who may be harmed i.e. staff, students and or general public

Calculate risk rating: Probability **multiplied by** severity i.e. 3 (Probability) x 1 (Severity) = 3 Medium

	Probability			
Severity	Unlikely	Possible	Likely	Very Likely
Very Minor	1	2	3	4
Minor	2	4	6	8
Significant	3	6	9	12
Major	4	8	12	16

Risk Rating	
Score	Risk Level
1-2	Low
3-6	Medium
8-9	High
12-16	Very High

A risk matrix is a tool used in the risk assessment process, it allows the severity of the risk and probability of the event happening to be determined, by multiplying the two outcomes.

In layman's terms – How likely is it to happen and how bad it would be if it happened.
If a number of people are likely to be exposed to a hazard then this would need to be taken into consideration.
The traffic light colour scheme gives a clear indication of whether or not the classification is high, medium or low.

For scores of 8 or more (high), further action must be taken to reduce the risk.
If further advice is required contact the Safety Service.