Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Assessment of Risk to Human Tissue**		
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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

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.

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 risk assessment procedures are in place.

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.

[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.

4.3 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

The researcher and/or other support 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 (http://www.qub.ac.uk/directorates/HumanResources/OccupationalHealthandSafety/HealthandSafetyPolicy/PolicyandGuidance/).

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

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.

An exemplar recording sheet is attached (Appendix 1). 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 9 - research
http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code9research.cfm (last access January 2015)

Human Tissue Authority definition of relevant material
http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm (last accessed January 2015)

QUB Health and Safety
http://www.qub.ac.uk/directorates/HumanResources/OccupationalHealthandSafety/HealthandSafetyPolicy/PolicyandGuidance/ (last accessed January 2015)

QUB Safety Service Risk Assessment Guidance
http://www.qub.ac.uk/directorates/HumanResources/OccupationalHealthandSafety/RiskManagement/ (last accessed January 2015)

7. Appendices

Appendix 1 Example Risk Assessment (Health and Safety)

Example Risk Assessment (Health and Safety)

School/Department/Unit:	Work activity:	
Assessment completed by:	Date completed:	Review Period:

Activity (task step)	Hazards	Outcome	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
Disposal of human tissue slides	Risk of inappropriate disposal (disposal of slides which should be retained)	Complete loss Destruction	Follow appropriate steps of SOP NI-MPL -SOP-036-Waste Disposal. Ensure data to be recorded in that SOP, including quantities & identifiers is checked and recorded. Signed records retained.	2	1	L	N/A		
Disposal of human tissue samples other than slides. (Slides are considered lower risk due to usually being replaceable)	Risk of inappropriate disposal (disposal of samples which should be kept)	Complete loss Destruction	Follow appropriate steps of SOP NI-MPL -SOP-036-Waste Disposal. Ensure data to be recorded in that SOP, including quantities & identifiers is checked and recorded. Signed records retained.	4	1	M	N/A		
T-Scan 300/Freezer temperature monitoring of CPH freezers:	Circuit trip to power supply for T-Scan data logger.	Complete loss, Destruction	Data logger has built -in battery back-up.	2	2	M	N/A		

Activity (task step)	Hazards	Outcome	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.	Complete loss, Destruction	T-Scan weekly reports backed up to hard drive of alternative computer. It is planned to provide an external hard-drive to further back-up this computer data. Daily monitoring by t-Scan and automatic data storage on parallel computers within t-Scan Also automatic data streaming to QUB university mainframe computer which is backed up daily.	3	2	H	N/A		
	Deviation (rising/falling) of freezer temperatures from set parameters.	Complete loss, Destruction	T-scan alert received. Cause determined & freezer engineers called for investigation where necessary.	3	2	H	N/A		
	T-Scan sensors fail to send data. Failure of T-Scan system	Complete loss, Destruction	Sensor check-in failure email received Notify T-Scan engineer who can check system remotely. Monitor affected freezers manually	4 4	2 1	H M	N/A		
	Failure of QUB Internet/Network	Complete loss, Destruction	Notify QUB Estates & Information Services Monitor all freezers manually until internet services restored.	4	2	H	N/A		

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

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.

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

Risk Rating	
Score	Risk Level
1-2	Low
3-6	Medium

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.