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Human Tissue Act
SOP - Risk Assessment

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Version	Date	Reason for Change
V2.0	29/7/2014	To reflect merger of BSMS and SoLS practices for UoS
V3.0	17/07/2017	Change to reflect the update to DI
V4.0	20/04/2018	Changes to reflect updates in Codes and Standards

1.0 Purpose

In accordance with the conditions of the Research Licence 12119 issued by the Human Tissue Authority, the University is required to ensure that risk assessments of practices and processes in relation to licensable activities are completed.

This document outlines the course to be followed for assessing the risk associated to human tissue whilst stored and used on the premises under the HTA licence, this process should include risk monitoring and contingency planning.

2.0 Introduction

Risk assessments form part of a systematic risk management strategy and should identify and analyse potential risk/hazards and decide on a method of eliminating or mitigating, any identified risk, as far as possible.

Risk assessments for Human Tissue samples should include the risks relating to the premises, practices and procedures connected with licensed activities. Including;

- receiving and/or storing specimens without appropriate consent documentation
- storing or using human tissue after consent withdrawal
- storage failure or other damage affecting human tissue quality for useful research
- loss of human tissue
- sample mix-up or loss of traceability
- transport of specimens to and from the establishment
- security arrangements
- incorrect disposal.

Risk assessments must be carried out and reviewed regularly for, processes and procedures for the entire project including:

- Acquisition – including consent
- Transportation – including damage or loss during transit
- Storage – including potential failure
- Use – including use of equipment and potential failure
- Disposal

Contingency planning is required to limit the extent of risk and to allow control of the situation as fast as possible.

3.0 Procedure

All research projects using human tissue should have a risk assessment which should include all work undertaken within the project, this risk assessment should be completed by the PI for the project using the Sussex University Human Tissue Risk Assessment form.

Subjects to be considered when completing a risk assessment include ethics and consenting during acquisition, damage or breakdown of packaging, delay or loss in transit (including around campus), malfunction of storage facilities, failure of laboratory equipment, unauthorised access to tissue samples, incorrect or unconsented for procedures being carried out, untrained personnel handling the tissue and any other hazards that result in tissue loss.

Risk should be calculated for an existing activity taking into account any control measures in place. This is estimated by considering both the likelihood of exposure to a risk and the severity of the consequences of such an exposure.

The calculation of risk should be done as follows:

Select an appropriate number for both Likelihood and Severity from the bottom of the table and multiply them together. Cross reference your score on the coloured part of the table and this is your risk rating.

Likelihood

4	Almost Certain	Will undoubtedly happen/recur, possibly frequently. (81-100% chance of occurrence
3	Very Likely	Will probably happen but is not a persisting issue. (51-80% chance of occurrence)
2	Possible	Might happen or recur occasionally. (21-50% chance of occurrence
1	Unlikely	Is not expected to happen or occur but it is possible that it will do so. (0-20% chance of occurrence)

Hazard

Procedure	Hazard			
Acquisition	Ethics, material transfer agreement and consent in place. Donor withdraws consent	Ethics and consent in place but records not auditable	Partial ethics and consent acquired and auditable	No ethical approval and no consent acquired
Transportation	Material arrives to site unexpectedly and not collected promptly No records of delivery	Packaging damaged or cool packing has dissipated - tissue is usable. Leaking packaging potential infection risk	Tissue lost or destroyed but replaceable	Tissue lost or destroyed and irreplaceable
Storage	Material arrives to site unexpectedly, storage not effected promptly	Minor systems failure a. Unauthorised access to tissue b. Tissue not stored correctly but no damage or loss c. failure of storage systems, tissue not damaged	Major systems failure, tissue lost or destroyed but replaceable	Major failure of systems. Tissue lost or destroyed and irreplaceable
Use	Experiment not well considered or inexperienced staff/students using material leading to tissue wastage	a. Incorrect or unauthorised use, leading to some tissue loss but majority of tissue in storage b. Failure of equipment leading to some tissue loss but majority of tissue in storage	a. Incorrect use, leading to some tissue loss - a small amount of tissue remaining in storage b. Failure of equipment leading to some tissue loss - a small amount of tissue remaining in storage	a. Material used inappropriately or for work not covered under ethics/consent. b. Failure of equipment or inappropriate use, leading to irredeemable loss or damage to tissue

Disposal	Delay in disposal due to equipment failure	a. Disposal method inappropriate not according to local SOP b. Donors wishes as to disposal of material not recorded	Some material not disposed of according to donor's wishes	Material not disposed of according to donor wishes
Severity	**1**	**2**	**3**	**4**

Score for each element

Likelihood

4	Almost Certain	**4**	**8**	**12**	**16**
3	Likely	**3**	**6**	**9**	**12**
2	Possible	**2**	**4**	**6**	**8**
1	Unlikely	**1**	**2**	**3**	**4**
	Severity	**1**	**2**	**3**	**4**

A risk grid should be carried out for each process, and the following action should be taken:

Unacceptable – Red	Stop, or do not commence, until improvements are made, including the option to use alternative methods or substances of lower hazard. Proactive management required
Significant - Orange	Proceed with caution but improvement is high priority. Revisit the procedure to either lower the hazard or improve risk control.
Tolerable - Yellow	Proceed but plan to improve
Insignificant - Green	Any improvements low priority

Once completed, a copy of the risk assessment must be sent to the DI, relevant PD, in addition each laboratory using human material should have an easily accessible folder in which this paperwork is contained.

Reviews of risk assessments must be carried on a 2 yearly basis, or if there is any significant change to the project. Risk assessments should also be reviewed following an incident.

If there are any changes to the risk assessment all old copies must be replaced with the new copy, including those held by the DI and relevant PD.

If there is a significant change in practice/procedure before the review date, or if any serious adverse event has occurred, the risk assessment should be revisited and reassessed to identify any further potential hazards or reduce the risk rating of hazards previously identified. For example where there is new information on the hazard indicating a higher or lower level of risk, personnel changes, changes in equipment or substances used, change of location, following an accident or incident.

Processes and procedures

Where appropriate processes and procedures are standardised the relevant SOP should show the reference to any safety assessments.

Equipment

The use and maintenance of all laboratory equipment should be detailed in specific equipment SOPs. Where applicable the relevant SOP will have an equipment specific risk assessment contained within the document.

All equipment should be regularly cleaned, maintained and serviced to reduce any potential risk as detailed in SOP8.