Bournemouth University

Medical Sciences Department
Human Tissue Facility

SOP title:	Assessing risk of human tissue projects
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	Signature and date	
Approver:	Name and role	
	Signature and date	

Amendment log

Version:	Date	Amendment(s):
0.2	June 2019	References section has been updated. Introduction section has been updated.

Abbreviations:

SOP: Standard operating Procedure

HTA: Human Tissue Authority

CoP: Code of Practice

CI: Chief Investigator

MTA: Material Transfer Agreement

Purpose: The purpose of this SOP is to describe the process by which risks are assessed and managed in terms of compliance with the Human Tissue Act 2004 or the associated HTA CoP.

Scope: This SOP is intended for BU staff (academic, support and honorary) and students working with the removal, storage, use or disposal of human tissue. These activities should always be conducted under strict adherence to the HTA standards and CoP as stated under license number XXXXX.

1. Introduction:

The Human Tissue Act (2004) provides the legal framework which regulates the acquisition, storage, use and disposal of human tissue [(1)] .The HTA licenses establishments involved in research using human tissue specimens, provided they adhere to the required standards. One of these standards requires that risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored (GQ6) [(2)]. A risk assessment is defined as a systematic examination of the hazards associated with a given activity. The result is a judgment of the measures required to eliminate, control or mitigate the risk.

Risk assessment for human tissue research should include the risks relating to the premises, practices and procedures under the terms of the Human Tissue license [(3)(4)(5)].This assessment shall cover:

- Risks to the management and operation of the facility and the samples and data it holds (reputation, staff, premises, facilities and equipment).
- Minimisation and mitigation of those risks
- Contingency plans, including emergency procedures.
- Roles and responsibilities of key staff in implementing the contingency plans

All research projects using relevant material as defined by the human tissue act must submit a risk assessment considering all potential areas in which the project could potentially fail to comply with the HTA or associated CoP. The main objective of the process is to ensure that researchers have considered the pitfalls of the research before the work commences and a plan is implemented in order to eliminate or minimise the likelihood of any significant damage occurring as a result. The risk assessment must be completed in addition to any other relevant governance or regulatory requirement.

2. **Procedure**:

2.1 Identification of risks

When acquiring/using human tissue, researchers are required to complete the risk assessment form (Appendix 1). When completing the form, they should consider all five main stages of the process: acquisition, transportation, storage, use and disposal. For each stage consider the potential risk associated with the human tissue in question. A list of

generic risks is given in table 1. It is expected that these generic risks will be considered in all risks assessments. If a risk is not applicable, state this and explain why this is the case (for example, tissue may be obtained internally in which case transportation is not relevant).

Investigators should also consider procedures which could conceivable lead to **damage to the tissue sample, staff, students or visitors**. These can be added to the list and scored as for the generic risks.

A risk assessment should be completed by the CI for all projects involving human tissue. The assessment should be undertaken using the risk assessment form BU-XXXXX

Table 1

Stage	**SEVERITY**			
	1	2	3	4
Collection	Favourable opinion by a REC in place; appropriate consent obtained; MTA (or contract) in place. However, donor withdraws consent.	Favourable opinion by REC in place and appropriate consent obtained, but no MTA	Favourable opinion by REC, consent and MTA obtained, but not available for auditing/inspections	Neither REC approval nor consent obtained
Transportation	Material arrives on site unexpectedly, not collected promptly. No records of delivery. However tissue remains viable.	Packaging damaged or leaking. Cooling requirements sub-standard. However tissue is still viable.	Tissue lost or no longer viable. However the tissue is replaceable.	Tissue lost or no longer viable. The tissue is irreplaceable.
Storage	Material arrives on site unexpectedly. As a result, it's not stored promptly. Tissue still viable.	Minor systems failure. Tissue is not stored correctly but the sample has not been damaged. Failure of storage conditions or equipment but tissue still viable.	Major systems failure. Tissue lost or destroyed but replaceable	Major systems failure, tissue lost or destroyed and irreplaceable
Use	Experiment poorly planned or inexperienced staff/students leading to tissue wastage	Incorrect or unauthorised use, some tissue wasted but majority of tissue still in storage. Failure of experimental equipment leading to some tissue loss, but	Incorrect or unauthorised use, some tissue wasted. Only a small amount of tissue left in storage. Failure of experimental equipment leading to some tissue loss, only a small	Material used inappropriately or for work not covered under ethics/consent. Failure of equipment or inappropriate use, leading to complete loss or

		majority still in storage.	amount of tissue left in storage.	damage to tissue
Disposal	Delay in disposal due to equipment failure	Disposal method in disagreement with local SOPs.		
Overall risk	No damage to individuals' or institutional reputation or tissue samples	Minor harm to individuals' or institutional reputation, or minor damage to tissue (tissue still usable for studies)	Moderate harm to individuals' or institutional reputation, or moderate damage to tissue (some tissues lost for studies)	Major harm to individuals' or institutional reputation (e.g. activity broke HTA CoP), or complete loss of tissue affecting current or future research.

For each identified risk, consider the control measures you already have built into the study. State these in the box provided, along with any monitoring measures you will put in place to ensure the effectiveness of these control measures.

For each identified risk, consider the likelihood of this risk happening during the life time of the project. Score the likelihood using the table 2 below:

Table 2

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)

Calculate a risk score (RS) for each component using the following formula: RS = likelihood X severity (multiply the scores for likelihood and severity). Enter the score in the box provided.

Assess the risk score (RS) for each project using the table below:

Likelihood	4	Almost certain	4	8	12	16
	3	Very likely	3	6	9	12
	2	Possible	2	4	6	8
	1	unlikely	1	2	3	4
			No tissue damage/loss	Minor tissue damage/loss	Tissue destroyed but replaceable	Tissue destroyed and irreplaceable
			No risk to researcher or institution	Minor risk to researcher or institution	Moderate risk to researcher or institution	Major risk to researcher or institution
			1	2	3	4
			Severity			

RS 1 - 3 (green) = Low risk (no additional control measures required)

RS 4 - 7 (orange) = Medium risk (Additional control measures should be considered. These should be introduced as far as practically possible)

RS 8 – 16 (red) = High risk (additional control measures must be introduced)

2.2 Additional control measures

For all items, consider additional control measures which could be introduced to mitigate the risks and enter in the appropriate box. For high risk items, these measures must be used. For medium risk items, these measures must be introduced when practically possible. If a control measure is not practical, the reasons why must be explained.

When the incident involves a research/business partner, BU will inform the partner of any major incident affecting samples shared with them within 14 calendar days of the incident or non-conformance being identified.

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?
- Are SOPs in place for all processes involving relevant material?
- What damage and degree of damage might be caused by the processes or storage?
- What else can be done to minimise or limit the potential damage?

3. References

(1) Human Tissue Act 2004: http://www.legislation.gov.uk/ukpga/2004/30/contents

(2) Human Tissue Authority code of practice and standards. Code E - Research: https://www.hta.gov.uk/hta-codes-practice-and-standards-0

(3) National Cancer Research Institute (NCRI)/Confederation of Cancer Biobanks: Biobank Quality Standard, collecting, storing and providing human biological material and data for research, version 1, 2014.

(4) Medical research Council (MRC) ethics series. Human tissue and biological samples for use in research: Operational and ethical guidelines. 2014.

(5) Mendy, M; E. Caboux; R.T. Lawlor; J. Wright; and C.P. Wild. 2017. Common minimum technical standards and protocols for biobanks dedicated to cancer research. International Agency for Research on Cancer (IARC) technical publication number 44.

Appendix 1 - Human tissue risk assessment form (to be used for all new tissue arriving at the facility)

Risk assessment reference number:						Date of assessment:	Review date:
Responsible person						Project title	
Type of relevant material and proposed use:							
Relevant internal SOPs:							
Relevant internal COSHH assessments							
Assessor						Date and signature	
Procedure and potential hazard	Potential outcomes	Existing control measures	Risk ratings			Are existing controls adequate?	If additional controls required, describe steps, by whom, and target date
			Likelihood	Severity	Risk score		
Collection of material							
Transportation							
Storage							
Use							
disposal							

Review of the risk assessment:

Name and role of reviewer			Signature and date:
Are control measures appropriate?	Yes	No	If not, date of next review: