University of Leicester Research Governance Office Standard Operating Procedures relating to the Human Tissue Act 2004

SOP HTA-A1021 UoL

Risk Identification Analysis

Version 2.0

Effective Date: 01 December 2024

This SOP will be implemented in line with this document's effective date for all UoL HTA SOPs.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used.

1.0 Introduction

This document has been produced in accordance with *The Human Tissue Act 2004* (HT Act). It should be read in conjunction with the University's 'Policy on compliance with the Human Tissue Act in Research', and the Human Tissue Authority's *(HTA) Codes of Practice*.

It is important that all risks relating to HTA licensed material is assessed on a regular basis, and should be reviewed annually to reflect any changes in new practices or changes to the location of samples.

2.0 Scope

All risks must be systematically identified, assessed and evaluated on a continual basis. All departments must have in place processes and structures that identify anything which may interfere with compliance to the HT Act 2004.

Definitions:

DI	Designated Individual
HT Act	Human Tissue Act
HTA	Human Tissue Authority
PD	Persons Designated
RGO	Research Governance Office
SLT	Senior Leadership Team
SOP	Standard Operating Procedure
UoL	University of Leicester

3.0 Procedure

3.1 What is a risk assessment?

A HTA risk assessment is the systematic identification, assessment and evaluation of anything that can interfere with the delivery of the highest standard of compliance to the HT Act 2004. An analysis of the severity and likelihood of the risk occurring will determine the overall risk rating of the hazard identified. This will assist in the assessment of risk throughout a licensed area.

Risk assessments must be carried out and reviewed annually for the following:

- Acquisition of HTA-relevant research samples - including consent
- Receiving and/or storing HTA-relevant specimens without appropriate consent documentation
- Storing or using HTA-relevant material after consent withdrawal
- Storage failure or other damage affecting the integrity of the sample quality for research
- Loss of HTA-relevant material
- Sample mix -up or loss of traceability (on-site)
- Security arrangements
- Transportation – including damage and loss during transit
- Use – including use of equipment and potential failure

- Incorrect disposal

A risk assessment will identify the current standards and controls in place to manage the risk. The assessment will also demonstrate the requirement for further control measures that can be taken to decrease the level of risk. It is important to note that not all risk can be eliminated. There will always be some residual risk; however, risk must be minimised as far as possible.

3.2 Risk Assessment Process

The risk assessment is a document that can be located within the PD Masterfiles and should be updated when new risks come to light, and should be reviewed and updated annually.

The risk assessment process consists of identifying, analysing and evaluating risks on a continual basis. It can be seen as a 5-step continual process: -

1. Identify hazards –

   Physical: Suitability of premises e.g., secure, structurally sound, fit-for-purpose, slip and trip hazards, noise, dust, machinery.

   Biological: Risk of infection to staff (including tuberculosis, hepatitis, other infectious diseases)

   Administrative: e.g., Loss of records, tissue used outside consent

2. Identify the risks –

- Equipment not fit for purpose
- Loss of HTA-relevant material
- Tissue is collected, stored or used without consent
- Loss of material due to inadequate labelling and tracking system
- Loss of material due to storage equipment failure
- Loss of records including consent forms
- Risk of infection when handling samples of tissue, blood, urine etc.
- Loss of material due to inadequate packaging during transport
- Material transferred without REC approval, appropriate consent or to an unlicensed site
- Material disposed of by an inappropriate method/route
- Disposal records not retained for audit;
- Material disposed of in error.

3. Determine the likelihood of a hazard occurring – determine the existing controls and analyse the risk in terms of the potential consequences for the University and its likelihood in the context of the existing controls.

4. Evaluate the risks – Evaluate and rank the risks.

5. Minimise the risks – Options to minimise the risk must be identified, treatment action plans must be developed and solutions implemented.

3.3 Process to follow

Once a risk has been identified, the next step is to assess the risk. This is done by quantifying the risk. The objective of assessing the risk is to separate and prioritise risks, and to assist in the evaluation and treatment of these risks.

Risks must be quantified. This is a subjective and qualitative process. A number of factors must be taken into consideration, such as past experience of incidents, changes to practice,

significant environmental factors, and professional judgment. The decision must be assessed in the context of the existing controls and standards which have already been identified. It is also imperative that issues such as activity, performance, targets and organisational impact are taken into consideration when measuring the severity of a risk.

Every risk is given a score for severity and consequence. The risk matrix in **Appendix 1** illustrates the descriptors of measures of likelihood. To produce the overall risk rating the severity and likelihood levels attached to the risk have to be combined. This will give a risk ranking for the facility.

Risks must be collated on the (local Risk Register Appendix 2) and reviewed annually by PD and/or HTA departmental contacts. A flow diagram of the process is included in Appendix 3. The PD must report risks with residual scores of 15 or more to the RGO Office for inclusion in the centrally held Register of HTA-related risks. These will be discussed at the next HTGC meeting.

The DI will review risks in accordance with this SOP and in line with the (HTA risk matrix Appendix 1). The DI will review risks with residual scores above fifteen (15). Such risks will be referred to the Licence Holder via the governance structure (see SOP HTA-A1024-UoL. Local contingency plans should be developed to limit the risk by ensuring controls are available to reduce the risk as fast as reasonably possible.

A Risk Register will enable evaluation and management of risk thus improving the standard of research and the working environment. A copy of the local Risk Register must be kept in the local department HTA file.

Note: This policy is not intended to replace established risk assessments such as those in use across the wider University Control of Substances Hazardous to Health as they relate to biological agents (BioCOSHH).

3.4 Non-compliance Reporting

In the event of a non-compliance refer to SOP HTA-A1024-UoL.

The risk assessment process can be facilitated using the Risk Assessment form in Appendix 1.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Person Designated (PD)	Person Designated (PD)	Update and review risk assessment annually
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Review risk assessments upon completion / updates. Escalate to DI where scores are above 15.
Designated Individual (DI)	Designated Individual (DI)	Ensure suitable practices take place within the licenced establishment Review assessments where risk score is 15 or above. Escalate to SLT / Licence Holder.

5.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Amanda Sutcliffe	HTA Monitor	UoL Human Tissue Governance Committee (HTGC)	Professor Peter Bradding 	28/11/2024

6.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)
November 2024	v2.0	A Sutcliffe	• Administrative updates • Additional risk assessment criteria • Clarity around the completion of the risk assessment • Appendix 3 Flow diagram added