UNIVERSITY OF LEICESTER

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The definitive version of all University of Leicester (UoL) Human Tissue Authority (HTA) Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that the up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Research Governance Ethics and Integrity (REGI) Website.

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Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
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Reviewer	All members of the College of Life Sciences Human Tissue Governance Committee	College of Life Sciences Human Tissue Governance Committee	N/A	N/A
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Background

This document has been produced in accordance with Human Tissue Act (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 for Research.

Purpose and 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
REC	Research Ethics Committee
REGI	Research Governance Ethics and Integrity
SOP	Standard Operating Procedure
UoL	University of Leicester

Roles and Responsibilities

It is the responsibility of the Designated Individual (DI) to ensure that suitable practices take place within the licensed establishment that comply with the HTA Codes of Practice.

The HTA Monitoring Officer is responsible for ensuring this SOP remains fit for purpose taking into consideration any changes in legislation and/or changes to the HTA Codes of Practice.

It's the responsibility of the Persons Designated (PD) to assist the DI in implementing and adhering to the governance processes. A Risk Assessment is required for each department and area that holds licence material.

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 licenced area.

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

- Acquisition of research samples— including consent
- Transportation –including damage and loss during transit
- Storage –including potential failure
- Use – including use of equipment and potential failure
- 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 is possible.

Risk assessment Process

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 hazard –

Physical: Suitability of premises i.e. lifting, awkward postures, slips and trips, noise, dust, machinery etc.

Biological: including tuberculosis, hepatitis and other infectious diseases faced by healthcare workers, home care staff and other healthcare professionals.

2. Identify the risks – what, why and how events can happen.

- Equipment not fit for purpose;
- Loss of 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;

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

Procedure 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 SOP HTA-A1021 Appendix 2)* and reviewed annually by PD and/or HTA departmental contacts

Risk Assessments must be reviewed every two years.

The PD must report risks with residual scores of 15 to the REGI Office for inclusion in the centrally held Register of HTA related risks.

The DI will review risks in accordance with this SOP and in line with the (*HTA risk matrix SOP HTA-A1021 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*) and will be forwarded to the University leadership team. 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).

Non-Compliance Reporting

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

The risk assessment process can be facilitated using the *Risk Assessment form in SOP HTA-A1021 Appendix 1.*

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)

SOP identifiers	SOP details
ID number	HTA-A1021-UoL
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Distribution Record:

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