



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

SOP HTA-A1023 UoL

Emergency Planning

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.

1.0 Introduction

This document has been produced in accordance with The Human Tissue Act 2004. It should be read in conjunction with the University's 'Policy on Compliance with the Human Tissue Act in Research', HTA Standards and the HTA Codes of Practice. The Human Tissue Act must be followed by all researchers working under the University's Research Licence and those transferring HTA relevant material as part of an ethically approved research project.

2.0 Scope

This SOP describes the process that should be followed in the event of an emergency relating to human tissue samples held under the UoL HTA Research Licence in the following circumstances (Note: this list is not exhaustive):

- loss of power to building or laboratory
- freezer breakdown
- catastrophic damage to building or laboratory due to e.g., flood, fire, smoke etc.
- lack of staff

This SOP applies to all individuals working under the University's Research Licence, RGO staff and members of the Human Tissue Governance Committee (HTGC).

Definitions:

DI	Designated Individual
HTA	Human Tissue Authority
HTGC	Human Tissue Governance Committee
PD	Person Designated
RGO	Research Governance Office
SOP	Standard Operating Procedure
UoL	University of Leicester

3.0 Procedure

All areas should have a local contingency plan documented and filed within their PD Master File; (HTA-1018_PD Masterfile Document Section 5D – Local Contingency Plan).

When putting together the contingency plan, the following factors should be taken into consideration:

- The actions to be followed depending on the amount of time that an incident is expected to last - i.e., short, medium or long term. (e.g., the expected length of time power will be cut from a building if this is prespecified planned work or laboratory, whether a freezer breakdown can be repaired immediately, within a couple of hours or whether permanent breakdown has occurred etc, loss of lab space [flood, fire]).

- All freezers and fridges with HTA relevant material should be labelled so that in the event of an emergency, staff are able to identify which freezer or fridge have priority to be saved above others.
- Whether there is back up storage within the same department or in another department.
- Whether there is back up storage available externally.
- Whether staff from other departments can be seconded into the affected area.

In the event of an incident requiring initiation of the contingency plan, the DI and RGO must be informed. An Adverse event/Incident form **must** be completed to document the event and subsequent action taken (see SOP HTA-A1022 Adverse Events).

Following resolution of the incident the local contingency plan should be updated where necessary.

Local contingency plans should be reviewed every two years.


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

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Person Designated (PD)	Person Designated (PD)	Re-review contingency plans for your areas on two yearly basis
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Incident resolution follow up should the contingency plan be initiated.
Designated Individual (DI)	Designated Individual (DI)	Ensure suitable practices take place within the licenced establishment.

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 (Designated Individual) 	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	<ul style="list-style-type: none">• Administrative updates• Removal of Appendix 1 – instead refer out to duplicate document within PD Masterfile (Section 5D)