



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

SOP HTA-A1010 UoL

Room Temperature Monitoring HTA rooms

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 and Scope

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](#).

Where samples are not required to be kept frozen or refrigerated e.g., fixed tissue blocks, ambient temperature monitoring must be documented to ensure compliance with the Human Tissue Authority (HTA) Research standards for Premises, Facilities and Equipment (PFE2c).

2.0 Purpose and scope

The purpose of this SOP is to ensure that all UoL staff, students and external visitors understand the requirements of the Human Tissue Act (HT Act) regarding the procedure for the monitoring the room temperature where HTA-relevant materials stored at room temperature.

Definitions:

CI	Chief Investigator
DI	Designated Individual
HTA	Human Tissue Authority
HT Act	Human Tissue Act
PD	Person Designate
PFE	Premises, Facilities and Equipment
PI	Principal Investigator
RGO	Research Governance Office
SOP	Standard Operating Procedure
UoL	University of Leicester

3.0 Procedure

Where room temperature storage is required for HTA-relevant material, e.g., FFPE tissue blocks and FFPE sections on glass slides, in the absence of a monitoring system such as Haier Biomedical or Check IT, the ambient temperature must be documented on a weekly basis by the use of a minimum-maximum thermometer.

For example, check the temperature on Monday; document the minimum and maximum temperatures as shown on the min/max thermometer. Reset the thermometer for the following week. The following Monday document the temperature again and repeat.

The temperature documentation does not have to be on a Monday, it can be undertaken any day within the week that is most convenient for the laboratory. Once the day is chosen the temperature must be documented on that day consistently going forward.

Temperature monitoring must be documented on the Temperature Monitoring Form (appendix 1). On completion of the temperature monitoring form, a copy should be maintained in the laboratory where the blocks / slides are stored and a copy should be given to the PD to ensure it is added to the departmental HTA Masterfile as documentary evidence of the temperature being monitored.

3.1 Temperature Deviations


A temperature deviation is an unintended change in temperature which does not result in any harm or integrity to the samples.

Unintended temperature deviations not deemed to be serious do not need to be reported to HTA enquiries, but must be recorded on the temperature deviation log, an example log is available in Appendix 2, and a copy of the temperature deviation log must be retained in the PD Masterfile. Where required, a CAPA plan must be created in order to avoid reoccurrence of the deviation.

Responsibility	Undertaken by	Activity
Chief Investigator / Principal Investigator (CI/PI)	Chief Investigator / Principal Investigator (CI/PI) or delegate	Ensuring room temperature monitoring is documented for their collections.
Designated Individual (DI)	Designated Individual (DI)	Ensure suitable practices take places within the licenced establishment.
Person Designated (PD)	Person Designated (PD)	Ensuring CI/PIs adherence to room temperature monitoring.
HTA Monitor	HTA Monitor	Ensuring SOP remains up to date ensuring changed in regulations are dated.

4.0 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

5.0 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 changes. Update to changes of responsibility.