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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.

SOP: HTA-A1010-UoL



Version Number: 1.0

Effective Date: January 2021

Supersedes: HTA-A1003-UoL

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Development and Approval Record for this Document

| Role | Name | Job title | Signature | Date |
|------------|---|--|--|------------|
| Author | Amanda Sutcliffe | HTA Monitoring Officer |  | 08/02/2021 |
| 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 |
| Authoriser | Professor Peter Bradding | Designated Individual |  | 08/02/2021 |



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| SOP identifiers | SOP details |
| ID number | HTA-A1010-UoL |
| Title | Room Temperature Monitoring |
| Version | 1.0 |
| Page Number | Page 2 of 4 |

Background

Where samples are not required to be kept frozen or refrigerated i.e. 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).

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 licenced samples are required to be stored at room temperature.

Definitions:

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| DI | Designated Individual |
| HTA | Human Tissue Authority |
| HT Act | Human Tissue Act |
| PFE | Premises, Facilities and Equipment |
| 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 to establish systems in place to comply with the HTA Codes of Practice.

It is the responsibility of the HTA Monitoring Officer to ensure this SOP remains fit for purpose taking into consideration any changes in legislation and changes to the HTA Codes of Practice for Research.

It's the responsibility of the Persons Designate (PD) to assist the DI in implementing and adhering to the governance processes and to ensure relevant material within their areas that are stored at room temperature and that the custodian/researchers of those samples are monitoring the temperature as per this SOP.

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|-----------------|-----------------------------|
| SOP identifiers | SOP details |
| ID number | HTA-A1010-UoL |
| Title | Room Temperature Monitoring |
| Version | 1.0 |
| Page Number | Page 3 of 4 |

It is the responsibility of researchers that use and store the material to ensure that the temperature is documented by using the temperature logging form that is associated with this SOP.

Procedure to follow

Where ambient temperature monitoring is a requirement for FFPE tissue blocks and FFPE sections on glass slides, in the absence of a monitoring system such as Haier Biomedical or Tutella, the ambient temperature must be documented on a weekly basis by the use of a minimum maximum thermometer.

As an 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.

The temperature monitoring is required to 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.

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) |
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|-----------------|-----------------------------|
| SOP identifiers | SOP details |
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| Title | Room Temperature Monitoring |
| Version | 1.0 |
| Page Number | Page 4 of 4 |

Distribution Record:

| Date | Name | Department | Received Y/N |
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