UNIVERSITY OF LEICESTER

Paper copies of this document might not be the most up to date version.

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-A1000-UoL

Version Number: 1.0

Effective Date: January 2021

Supersedes: HTA-1000-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

Background

SOPs are method sheets sufficiently detailed to be unambiguous, but not so detailed and inflexible that continuous amendments are required. They are intended to outline the processes and / or procedures for a given purpose or policy application.

The REGI HTA SOPs will be used for reference and the training of research active personnel. They are also used as evidence to assure compliance with the regulatory agencies and HTA frameworks necessary to govern the practices of tissue collection, use, storage and disposal within HTA licenced research facilities.

SOPs describe working practices, which should be adhered to. However, occasionally specific circumstances may require variations from an SOP. Formal written explanations/justifications of such deviations must be recorded in the appropriate research site files, and where necessary, revised SOPs drawn up and implemented appropriately.

This SOP is to define the procedures for preparation, approval, distribution, amendment and storage of Standard Operating Procedures used for the purposes of HTA Governance within HTA research licenced facilities of the UoL.

Purpose and Scope

This SOP applies to all UoL staff and students and any external individuals who conduct research within HTA research licenced facilities of the UoL. This is to ensure all staff and students are working to the approved and active version of all documents.

Definitions:

CI	Chief Investigator
DI	Designated Individual
HRA	Health Research Authority
HTA	Human Tissue Authority
MTA	Material Transfer Agreement – A contract that governs the transfer of tangible research materials between two organisations, when the recipient intends to use it for his or own research purposes.
PI	Principle Investigator

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.

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

It's the responsibility of the Persons Designated (PD) to assist the DI in implementing and adhering to the governance processes.

Procedure to follow

University-wide documentation related to the HTA licence is created centrally and controlled by the REGI Office.

All SOPs will be given a unique document number, title, version number, author, effective date, review date and page numbers. SOPs will be numbered sequentially starting from 1000 and prefixed with HTA. Revision numbers, dates and reasons for change will be logged centrally by the REGI Office.

Each new or revised HTA SOP will be generated by the REGI Office. The first version will be circulated for review to the HTA Persons Designated working group. Once these comments have been reviewed and the documentation amended by the REGI Office, the first draft will be sent to Human Tissue Governance Committee (HTGC) members for ratification. A final version will be sent to the Designated Individual (DI) for approval and signature.

Once approved, all SOPs will be published on the pages of the *University's REGI Website*.

All Persons Designated and relevant departmental HTA contacts will be notified by email when the latest version of the document is available.

All SOPs will be reviewed on a 2 yearly basis by the REGI Office or equivalent post within Research Governance.

Training Requirements

Individuals are required by the HTA regulations to keep a record of SOPs read and training that they have undertaken. The signing of the *SOP Read Log (Appendix 1)* is a means to record an individual's understanding of an SOP. The SOP read log must be kept in the departmental HTA File as an aid to monitor the training of individuals.

Where it has been identified that study personnel have not been adequately trained, or the training certification has lapsed, the non-compliance HTA SOP *HTA-A1024-UoL* will be implemented and a minimum of 'other' finding reported.

Retention

The REGI Office will hold a working file of all current SOPs. All active documents will be uploaded to the University REGI Website for access by all staff.

Archiving

The REGI Office will keep an archive file with all superseded documentation for reference.

Study Specific SOPs

As a general rule, there should be no study HTA specific SOPs. Where it is necessary to produce procedural documents they must be written in accordance to this SOP. SOPs should contain the following; unique document number, title, version number, author, effective date, review date, page numbers and approval signature. The active version of the document should be controlled and available.

Any departmental SOPs generated that relate to collection, storage, use and disposal of research samples that are covered by a HTA Research License shall be forwarded to the REGI Office for review before approval by the department.

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)

Distribution Record:

Date	Name	Department	Received Y/N