



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

SOP HTA-A1000 UoL

Document Control

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

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 RGO 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.

2.0 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:

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 Process

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

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 A. Revision numbers, dates and reasons for change will be logged centrally by the RGO.

Each new or revised HTA SOP will be generated by the RGO, some might be in collaboration with the Persons Designated. The first version will be circulated for

review to the Designated Individual and the Chair of the Human Tissue Governance Committee (HTGC) followed by the circulation to the HTGC committee members, which includes all the Person Designated under the HTA Research Licence. Once these comments have been reviewed and the documentation amended by the RGO, the first draft will be sent to Human Tissue Governance Committee (HTGC) members for ratification. A final version will be sent to the DI for approval.

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

All PDs 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 3 yearly basis by the HTA Monitor or equivalent post within the RGO.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Creation and tracking of all HTA SOPs. Comments reviewed and amended as appropriate. SOP publication on RGO webpages.
Person Designated (PD)	Person Designated (PD)	Collaboration of SOPs applicable to processes. Review of HTA SOPs.
Designated Individual (DI)	Designated Individual (DI)	Review of HTA SOPs Approval of final version.
HTGC Chair	HTGC Chair	Review of HTA SOPs.
HTGC Committee	HTGC Committee	Ratification of SOPs.

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 	28/11/2024

6.0 Review Record

This table is used to track the changes made across document revisions.

Date	Version number	Reviewed by	Description of changes (If any)
Nov 2024	v2.0	A Sutcliffe	<ul style="list-style-type: none"> • Administrative changes • Change review period from 2 to 3 years