	Title : Creating and reviewing a Standard Operating Procedure	Author: G. Cockerill	Date: 2/Oct/2012
	No: SOP_GEN1	New Author: P. Madhou	Date: 1/Sept/2024
	Version: 6		Review Date March 2026




**SOP GEN 1 : CREATING AND REVIEWING STANDARD OPERATING PROCEDURE**

**Disclaimer**

When using this document, please ensure that the version you are using is the most up to date either by checking on the City St George's /PORTAL/HTA website for any new versions or contact the HTA coordinator to confirm the current version.

**Out of date documents must not be relied upon and should be destroyed.**

6	Aug 2024	City Merge, Review & formatting	PM	HTLRG
5	Sept 2023	New DI, update contacts & formatting	AS	HTLRG
5	Sept 2022	New DI, Add PD & Review	AS	HTLRG
4	July 2020	Review	AS/PL	HTLRG
3	March 2018	Reviewed & Amended (New Author)	AS	PL
3	July 2017	Reviewed and PD contact details updated	PL	HTLRG
2	Dec 2016	Update contact list	AS	PL
2	Oct 2016	New DI	AS	MF
2	March 2016	Amended Issued for use	GC	HTLRG
2	September 2013	Issued for discussion	GC	
1	November 2012	Issued for use	GC	HTLRG
0	October 2012	Issued for comment		

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## Purpose/Background

### 1. Purpose/Background

- 1.1. A Standard Operating Procedures (SOP) is a formal document that describes the procedures that must be followed to complete a defined task.

All SOPs used in connection with licences issued by the Human Tissue Authority must, where appropriate, be read and used in conjunction with associated City St George's Policies and Procedures.

### 2. Scope


- 2.1. It covers all processes involved in the creation, approval, review, and revision of SOPs, and communication about them to those who need to use them in connection with the following HTA licences:
- HTA 12335 Storage of relevant material which has come from a human body for a scheduled purpose
  - HTA 12330 Carrying out of an anatomical examination.

### 3. Responsibilities

- 3.1. The overall responsibility for ensuring that the required SOPs are created and adhered to, rests with the Governance Manager acting on behalf of the Licenced Holder, hereafter referred to as "the Licence Holder".
- 3.2. Responsibility for creation, approval, review and revision of SOPs and for ensuring that the processes defined in this SOP are properly carried out rests with the Governance Manager in the Joint Research Enterprise & Services of SGUL.
- 3.3. Responsibility for timely review and final approval of SOPs lies with the Human Tissue Licence Review Group (HTRG).

### 4. Procedure

- 4.1 SOPs will be created or revised as required on the instructions of the Licence Holder, a Designated Individual on a City St George's HTA Licence, or the Governance Manager, taking account of licence requirements and operational issues that may arise.
- 4.2 All SOPs will be given a unique document number, title, version number, author, effective date and page number.
- 4.2 An SOP will generally include the following sections, although on occasions one or more sections will be omitted where it is appropriate so to do.

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Sections – Purpose, Scope, Responsibilities, Procedures, Flow chart, Related documents (considering contingencies or eventualities), References.


- 4.4 SOPs will be approved for a period of up to 12 months by the Licence Holder.
- 4.5 Within a period of 12 months following initial approval of a SOP, it shall be reviewed and approved by the HTLRG (with appropriate revision where necessary).
- 4.6 SOPs will generally be approved for a maximum period of 2 years. Towards the end of that time, they must be put to a meeting of the HTLRG for review.
- 4.7 When approved (in initial or in final form), SOPs shall be circulated to all those responsible for its implementation. The Governance Manager shall be responsible for ensuring that training in the implementation of each SOP is carried out, and that those who are so trained certify completion of training by signing the master copy of the SOP.
- 4.8 Master copies of SOPs shall be kept by the Governance Manager in paper and electronic formats. Responsible Persons (RPs) nominated to be responsible for each tissue collection (see SOP HTA – 3), shall retain a copy of all SOPs relating to HTA Licence 12335, and shall confirm that they have read each SOP by signing the master copy held by the Governance Manager. All SOPs will be published on the University's Research portal page under Human Tissue Act section.
- 4.9 All members of staff carrying out work on a tissue collection covered by HTA Licence 12335 shall retain a copy of all the SOPs relating to it and shall confirm that they have read each SOP by signing the master copy held by the Governance Manager.
- 4.10 The Governance Manager, Designated Individual or Persons Designate will be responsible for providing copies of SOPs to those requiring responsible for its implementation.

## 5 Related documents

- 5.1 HTA Licence 12335 Storage of relevant material which has come for a scheduled purpose.
- 5.2 HTA Licence 12330 Carrying out of an anatomical examination.
- 5.3 City St George's SOP/GEN 2 Human Tissue Licence Review Group
- 5.4 City St George's SOP/GEN3v2 Management and Records of Human Tissue Collections
- 5.5 City St George's SOP/A12v2 Dissection Room Audit
- 5.6 City St George's SOP/A10 Dissection Room Records

## 6 Amendment of SOPs

If, in the course of applying this document, the user identifies a modification which will improve this document, please bring the suggested changes to the attention of the Person Designated (PD) so that amendments can be reviewed and implemented.

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## 7. Contacts DIs and PDs

<b>Research Licence</b>	DI	Dr Priya Madhou	Ext 1603	<a href="mailto:pmadhou@sgul.ac.uk">pmadhou@sgul.ac.uk</a>
	PD	Mr Ash Sameja	Ext 2428	<a href="mailto:asameja@sgul.ac.uk">asameja@sgul.ac.uk</a>
	PD	Ms Lara Painter	Ext 3077	<a href="mailto:lpainter@sgul.ac.uk">lpainter@sgul.ac.uk</a>
<b>Anatomy Licence</b>	DI	Miss Georga Longhurst	Ex 5208	<a href="mailto:glonghur@sgul.ac.uk">glonghur@sgul.ac.uk</a>
	PD	Mr Paul Carter	Ext 5228	<a href="mailto:pcarter@sgul.ac.uk">pcarter@sgul.ac.uk</a>
	PD	PATHOLOGY MUSEUM Dr Carol Shiels	Ext 0729	<a href="mailto:cshiels@sgul.ac.uk">cshiels@sgul.ac.uk</a>