Standard Operating Procedure

Title: Production and Control of Standard Operating Procedures

Purpose

The purpose of this SOP is to describe the procedure to be followed to ensure that SOPs are produced in a consistent format and that they are adequately controlled so that staff work to the same closely controlled standards.

Scope

The scope of this SOP covers writing, review, approval and release of new procedures and review and update of existing procedures. This SOP also describes the procedures to be followed when SOPs are withdrawn from use.

Document Detail	
Reference Number	KCL HTA105/SOP
Version	4
Effective From	June 2009
Review Date	May 2012/ May 2015/ July 2017/Sept 2019/Nov 2021/Sept 2024/ Sept 2026
Author	Dr Cheryl Gillett
Approved By	KCL HTA Governance Committee [30-Sep-2024]

Revision status

Each document has an individual record of amendments. The current amendments are listed below. The amendment history is available from the document control system

On issue of revised or new pages each controlled document should be updated by the copyholder.

Amendment Number: Date	Version no. Discarded	Insert Version no	Page	Section(s) involved	Amendment
1. 16/6/09	1	2	3 4 7	1 2 3	Change in responsibilities Change in process reflecting new responsibilities New appendices
2. 17/6/10	2	2.1	5	2.3	Biennial Review
3. 28/5/13	Review Only				No Changes
4. 8/6/2015	2.1	3.1	3 4	1.3.6 2.2.2	Change from annual to biennial review SOP number may also start with Department identifier
5. 4/9/2017	3.1	3.2	4	1.4	Include use of GSTT SOP template
6. 20/11/2019	3.2	3.3	4	2.2	Clarification on sample numbering. Requirement to evidence reading of SOP
7. 12/09/2022	3.3	4	4 6	1.7 2.5	Include role of staff and students GDPR compliance
8. 30/09/2024	4	4			No changes

Any minor amendment must be handwritten on the SOP without obscuring existing text. An asterisk should be placed in the adjacent margin to highlight the alteration. Alterations should be signed and dated by either the person designated or nominated individuals and then forwarded to the document controller. The SOP must be retyped, authorised and reissued as soon as possible. Amendments requiring immediate action should be dealt with in the same way but highlighted as high priority. Major changes must result in the immediate review of the procedure Document amendment does not replace the review process.

1 Responsibilities

1.1 KCL HTA Governance Group

1.1.1 The KCL HTA Governance Group will ensure KCL HTA Persons Designated (PD) and those staff who work under the HTA Licence are aware of their responsibilities to produce and maintain standard operating procedures for all HTA – associated activities.

1.1.2 To support PD in their role as Document Recorder

1.1.3 To review and authorise all SOPs for 'core' HTA associated activities that are standardised across the College.

1.2 Person Designated (Document Recorder)

The PD is responsible for:

1.2.1 Maintaining a register of all HTA activity associated SOP's for the groups they oversee (appendix 3.1).

1.2.2 Ensure that SOP numbering complies with KCL HTA Governance Group requirements

1.2.3 Ensure that groups supply all relevant information to allow completion of the SOP register

1.2.4 Monitor SOP review dates and where appropriate contact the author/ Principle Investigator to request SOP review

1.3 Group SOP Controller

The Group SOP controller is responsible for:

1.3.1 Ensuring SOPs have a standard format and include:

a. Title
b. SOP number
c. Version Number
d. Date created
e. Revision Date
f. Author
g. Reviewer/Authoriser

1.3.2 Supplying SOP templates.

1.3.3 The assignment of SOP numbers, the distribution of uncontrolled copies of SOPs for review and the co-ordination of the SOPs prior to filing and release.

1.3.4 Updating all appropriate staff on the release of a new or updated SOP

1.3.5 Keeping a record of all local SOPs in use

1.3.6 The biennial review of SOPs and their re-issue if necessary, prior to expiry date

1.3.7 Informing the PD of new, updated or reviewed SOPs

1.3.8 The maintenance of records of archived SOPs

1.4 Author

The author is responsible for the preparation of a clear and concise procedure. The SOP should fully describe the roles and responsibilities of individuals, materials and methods to be used and a description of data recording and

retention requirements. The SOP should be written in the KCL HTA Licensed Laboratories format, an example of which is given in appendix 3.2. The author should ensure:

1.4.1 The SOP, if necessary, should include procedural checks or quality control for the activity in question.
1.4.2 The SOP should be of sufficient detail to guide a trained operator to perform the procedure defined.
1.4.3 The SOP should include a description of any protective equipment and/or precautions necessary to allow the Procedure to be performed safely.

1.5 Authoriser/ Reviewer

1.5.1 Reviewers are responsible for checking that the content of the SOP is technically correct and that the procedure in the SOP is comprehensible.
1.5.2 The reviewer cannot also be author.

1.6 Other Personnel (staff, students, visitors)

1.6.1 Make senior staff aware when new activities require a SOP.
1.6.2 Must acknowledge they have read and understood the SOP. Evidence of this to be made available and retained by the SOP Controller.
1.6.3 Provide feedback on the comprehensiveness and accuracy of the SOP.

2 Procedures

2.1 SOP Control

2.1.1 SOPs must have a standard format. The current KCL SOP template can be supplied by the SOP Controller.
2.1.2 A digital or paper folder should be maintained with all current SOPs, which is accessible to personnel on a read only basis.
2.1.3 Only the SOP Controller can update, edit or delete SOPs.
2.1.4 It is the responsibility of the local SOP Controller to ensure the information is disseminated to appropriate personnel working under the HTA licence.
2.1.5 Earlier version SOPs should be retained and archived, preferably in digital format.

2.2 New SOP Procedures

2.2.1 SOPs can be written by staff or students but can only be approved for use by management.
2.2.2 Once a new SOP is identified, the title is forwarded to SOP Controller to be numbered and logged. SOP numbers must be unique to the Department.
2.2.3 Once the SOP number and version is allocated, the new/revised document will be returned to the author to finalise the SOP and for it to be authorised.
2.2.4 An author cannot also authorise a SOP

2.2.5 The SOP Controller will add the new SOP to the folder on the local server/PC and inform all appropriate staff (by e-mail) that a new SOP has been added.
2.2.6 Staff must acknowledge that they have read and understood the new SOP and evidence of this retained by the SOP Controller.
2.2.7 The SOP Controller will inform the Person Designated when a new SOP has been added to their local document folder.

2.3 Review and update of existing procedures

2.3.1 SOPs will be reviewed biennially, unless changes are required before this time has elapsed. The SOP Controller will keep a record of review dates for each SOP.
2.3.2 For SOPs which have reached their natural review date, the SOP controller will issue a request to the author to review the document. The author should update the SOP if appropriate. Changes should be detailed on the 'Revision Status' section of the SOP. If major changes have been made to an SOP it must again be authorised. The author should return the updated document to the SOP Controller for a new version to be issued.
2.3.3 If no changes are required the author must notify the SOP controller by e-mail that no update is required. The SOP Controller will record that no amendments are required and update this on the 'Revision status'
2.3.4 If a SOP needs to be changed prior to the natural review date of the procedure, the person making the changes should update the SOP, detail amendments on the 'Revision status' and forward the revised SOP to the SOP controller.
2.3.5 The amended SOP will be given the next consecutive version number, and the SOP registers updated.
2.3.6 When an SOP is updated, staff will be requested to destroy all copies of the previous version of that SOP.
2.3.7 Staff must acknowledge that they have read and understood the revised SOP and evidence of this retained by the SOP Controller.

2.4 Withdrawal of SOPs

When an SOP is no longer required, the SOP Controller and Person Designated must be notified, the register updated and the SOP removed from the current SOP folder.

2.5 SOPs and GDPR

2.5.1 Author or Reviewer name and signature on a SOP may be visible to the immediate user group but should be excluded from SOPs with larger audience eg websites?
2.5.2 Author or Reviewer name and signature on a SOP can remain after either of them have left the group/KCL until the automatic SOP review period. Details must be updated to current personnel.
2.5.3 Personnel who need to formally acknowledge they have read and understood a SOP can record this on their own SOP record list, which can

also be visible to the SOP Controller, line manager and current team. This may require a change from having sign off sheet for each SOP to having sign-off sheets per individual.

2.5.4 When either staff or students leave the group or KCL, an individuals' record of reading SOPs should be archived with the SOP Controller and have regulator access only.

3 Appendices

3.1 Person Designated/ Document Recorder Register of SOPs

SOP Number	Title	Version Number	Date Created	Review Date	Author	Reviewer/ Authoriser

3.2 SOP Template Page 1

King's College London
Human Tissue Authority
Licensed Laboratories

Standard Operating Procedure

Title:

Purpose

Scope

Document Detail	
Reference Number	
Version	
Effective From	
Review Date	
Author	
Approved By	

3.2 SOP Template Page 2

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3.					
4.					
5.					
6.					

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1 Responsibilities

List responsibilities of users, line-managers, administrators and senior staff in ensuring that activity is carried out in an appropriate manner and in accordance with documented procedures.

2 Materials

List any equipment, consumables or other materials required to carry out the procedure

3 Procedures

Provide a clear and concise, step-by-step account of the procedure. This should be in sufficient detail for a trained operator to carry out the procedure defined. The section should also include a description of data recording and retention requirements. If necessary should include procedural checks or quality control for the activity in question.

4 Health & Safety

Include a description of any protective equipment and/or precautions necessary to allow the procedure to be carried out safely.
Note: This does not replace a requirement to undertake a formal risk assessment.

5 Cross Reference SOPs

List by number and title and SOP's, which relate to the activity described.