brighton and sussex medical school

Brighton and Sussex University Hospitals NHS Trust

This is a controlled document
Any printed versions of this document will be classed as uncontrolled

SOP Writing & Review

SOP Reference:	**SOP/RD/001**
Version Number	**Version 5.0**
Date:	**05th January 2017**
Effective Date:	30th Jan 2017
Review by:	30th Jan 2020

Author: Gemma Earl **Designation:** Head of Trial Management and Quality Assurance, Research and Development BSUH	**Signature**	**Date** 05th Jan 17
Authorised by: Scott Harfield **Designation:** Head of Research and Development BSUH		5/1/17

Version	Date	Reason for Change	Author
1.0	13th Aug 2009	Change in review and implementation policy	Gemma Earl
2.0	2011	2 yearly review. Clarifying SOP writing and amending process.	Gemma Earl
3.0	04th June 2013	2 yearly review. GAS committee now referred to as OMG committee	Hannah Butler
4.0	28th May 2015	Training section updated. Training Matrix to be used. Review of SOPs to occur every 3 years or sooner if relevant	Gemma Earl

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the process for writing, implementing and reviewing Research & Development (R & D) SOPs within Brighton & Sussex University Hospitals NHS Trust (BSUH NHS Trust).

2.0 INTRODUCTION

An SOP is a formal document that describes the procedures that must be followed to complete a task. All SOPs produced by the R & D department must be used in conjunction with other BSUH NHS Trust policies and procedures.

3.0 RESPONSIBILITIES

Quality Assurance Lead
The production and maintenance of the R & D SOPs will be the responsibility of the Quality Assurance Lead.

A Master Copy file will be maintained in the R & D office containing signed hard copy originals for audit, inspection and monitoring purposes; these will also be scanned and stored as PDF documents on the R & D shared network drive.

Research Governance & Quality Assurance Committee
The OMG Committee is responsible for authorising all R&D SOPs. The SOPs will be signed off by the Chair of the Committee. At the time of authorisation, an effective date for the SOP should be assigned.

All BSUH Staff Participating in Research
It is the responsibility of each employee involved in research to ensure they undertake the appropriate training for relevant SOPs and that this is documented in line with the training requirements for the SOP.

4.0 PROCEDURE

4.1 SOPs Requiring Review

The Quality Assurance Lead (QAL) will keep a list of controlled SOPs. The revision dates of current SOPs will be monitored and review of SOPs should begin at least 60 days prior to the review date. All SOPs will be reviewed every three years and on an ad-hoc basis following changes to legislation, processes or policies.

4.2 New SOPs Required

All SOPs will be written using the standard template (Appendix 1). Draft SOPs will be passed to appropriate members of the R & D Department for review. The review should consider readability, conciseness and accuracy of information.

Expert review and authorisation will be required when the procedure falls outside of R & D practice and training. Details of the "expert" will be included on the front sheet and their signature will be required.

Each SOP produced by the R & D office will be assigned a unique SOP reference number in the format SOP/RD/Number.

All SOPs will contain the following sections:

- Purpose – A brief statement explaining the purpose of the SOP
- Introduction – A brief statement that provides background and context to the SOP
- Responsibilities – A statement of those persons who are responsible for the major tasks within a particular SOP
- Procedure – A statement of the detailed procedure to be undertaken; including any specific equipment, documentation and materials required. Specific Health & Safety requirements should also be included.
- Training – Details of training in the SOP and how to document evidence of this should be provided if applicable.
- Cross Reference SOPs – All cross referenced SOPs should be listed.
- References – a list of references should be provided.

4.3 Draft SOPs

The Quality Assurance Lead will work with the appropriate R&D staff member to ensure SOPs are updated or created when required. The author of the amendment to an existing SOP or the new SOP will amend the version control to vX.1, label the document draft and save a tracked changes document to clearly illustrate the changes.

4.4 Review of Draft SOP & Final Review of SOP

The reviewers and authoriser of the amendment or new SOP will be sent the document with tracked changes by the author, for review. Any comments or suggested changes will be discussed and the author will update the SOP,as required, updating the version control to vX.2 and so on until those involved are satisfied with the document. When all issues have been resolved a final draft will be sent to the reviewers for wet ink signatures. This will be labelled vX+1.

4.6 SOP Authorisation

Once the reviewers have signed off the SOP, the Research Governance & Quality Assurance Committee must authorise the document before it can be implemented. This authorisation will be indicated by a "wet-ink" signature and date on the Master Copy of the SOP by the Chair of the Committee. At the time of authorisation, the Committee will assign an effective date for the SOP. The type of training required for the SOP will be considered and adequate time will be given between authorising the document and implementation.

4.7 SOP Release Date & Training

Once authorised, all R & D SOPs will be saved on the R&D shared network drive: T:\Research & Development\R&D SOPs & Policies
It is the responsibility of all staff involved in research to check the shared drive regularly to ensure they are following the latest SOP.

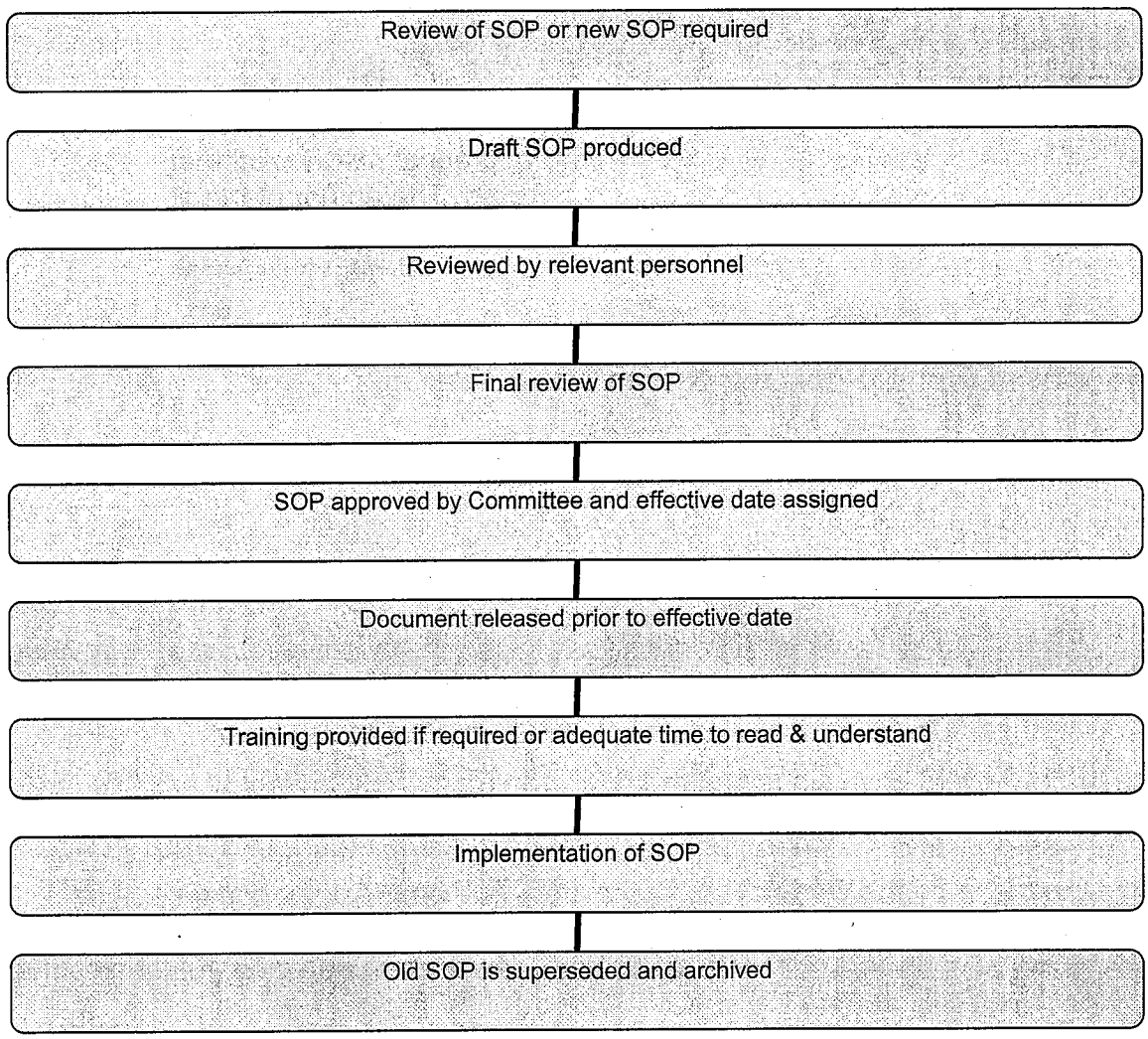
4.8 SOP Implementation

The effective date of the SOP will be assigned by the OMG Committee at the time of authorisation. The SOP should be implemented from the effective date. Adequate time will have been given for those involved in using the SOP to have been trained in the new or amended process.

4.9 Superseding and Archiving Old SOP

The old SOP will be removed from the shared drive and the original will be marked as superseded and stored in the SOP file.

4.10 Process Flow Diagram



5.0 Training

This is a 'read and understand' SOP. To evidence that you have read and understood this SOP, please complete your SOP Training Matrix.

Please note that the R&D department discourages the retention of hard copies of SOPs and can only guarantee that the most up-to-date version is on the Trust website.

6.0 Cross Referenced SOPs

No cross referenced SOPs

7.0 References

No references

Appendix 1
This is a controlled document
Any printed versions of this document will be classed as uncontrolled
TITLE

SOP Reference:	
Version Number	
Date:	
Effective Date:	
Review by:	

Author: **Designation:**	**Signature**	**Date**
Authorised By: Scott Harfield **Designation:** Head of Research and Development at Brighton and Sussex University Hospitals NHS Trust.		
Expert Authorisation **Designation:** **Contact Details**		

Version	Date	Reason for Change