Gloucestershire Hospitals
NHS Foundation Trust

SOP 01: Preparation, Review and Approval of Standard Operating Procedures for Research

SOP reference:	SOP 01	
Version:	5.1	
Author:	Chris Ford	
Approved by Commercial Director:	Claire Richardson	
	29/11/2023	
Implementation date of current version:	03/01/2024	
Date of Review:	03/01/2026	

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https://www.gloshospitals.nhs.uk/about-us/research-our-hospitals

The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol NHS Foundation Trust who gave permission to adapt their templates in the development of these SOPs.

Version History Log

This area will be updated with details of all changes made to the SOP whether due for full review or not.

Version	Details of Change	Date Implemented
1.0	Original SOP	October 2012
2.0	Incorporated into the Gloucestershire Consortium of SOPs	November 2014
3.0	Updating SOP preparation, terminology and timelines Rebranding to Gloucestershire Hospitals NHS Foundation Trust	17th January 2018
4.0	Updating contact details Revised process for writing, reviewing and signing off SOPs Suggested training strategies	Not implemented
5.0	Removal of reference to scanned copies Use of e-signatures Correction of typos Removal of roles due to staff changes Insertion of a glossary Altered SOP Development Process	28th June 2023
5.1	Removal of SOP categories and change of reference codes Updated format Changed R&D to R&I	3rd January 2024

This SOP will be reviewed every two years unless changes to any relevant legislation require otherwise

Related Documents:

SOPs
All GHNHSFT SOPs.

Glossary

CTIMPs	Clinical Trials of Investigational Medicinal Products
HRA	Health Research Authority
SMT	Senior Management Team
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
CI	Chief Investigator
PI	Principal Investigator
R&I	Research & Innovation

Contents

1. Introduction, Background and Purpose

The Research & Innovation (R&I) Department develops, collates and manages research related Standard Operating Procedures (SOPs) on behalf of Gloucestershire Hospitals NHS Foundation Trust.

The purpose of these SOPs is to define and formalise the tasks that researchers and other staff must adhere to in relation to designing, setting up, approving and delivering Clinical Trials of Investigational Medicinal Products (CTMPS) and other projects defined as research or service evaluation by the Health Research Authority (HRA) and/or R&I Department.

This SOP describes the process for preparing, developing, reviewing, approving and implementing R&I SOPs.

2. Who should use this SOP?

Members of the R&I team have the responsibility for the development of SOPs as the need for them arises, also the review and amendment to R&I SOPs on a regular basis. The Senior Research Team have overall responsibility for co-ordinating drafting of R&I SOPs.

Any member of staff may offer to develop new and existing SOPs, they will be required to use this template and submit SOPs for review to the R&I Senior Team (SMT Governance) for approval under the guidance in this document and processes as outlined in Appendix 1. The R&I SMT Senior Research Team comprised of:

- Head of R&I,
- Research Matrons
- Lead Research Nurses
- Research Pharmacist
- Research Therapeutic Radiographer
- and other experienced staff as applicable.

All members of staff using the SOPs have a responsibility to identify changes in policy, legislation and procedures that affect the R&I SOPs and must bring this to the attention of R&I by emailing the R&I department on ghn_tr.glos.rdsu@nhs.net . Any problems with this document or any SOP should also be communicated to the R&I Senior Research Team on receipt of the email within R&I, will decide in 14 days using a risk-based assessment if there is a need for a review prior to the next formal date (see SOP log for planned review dates).

3. When this SOP should be used

This SOP should be referred to whenever an SOP is written, reviewed, amended or approved. All SOPs will be developed using the guidance herein. Any SOPs submitted to R&I Senior Research Team that have not been developed with reference to this SOP will not be accepted for review until they are in the appropriate format.

4. How to Create/Amend an SOP

The process for developing new or amending existing SOPs is outlined below, but is also shown in the flowchart in Appendix 1.

4.1 Developing a New SOP

Any member of staff can suggest a new SOP to the R&I Department or the requirement for a new SOP may be identified by the R&I Senior Research Team.

The member of staff identifying the new SOP will draft the SOP using the SOP template attached in appendix 2. This will then be reviewed by the R&I Senior Research Team at the governance meeting.

There will be a suite of SOPs reviewed formally each quarter and any new SOPs will be added to the next SMT Governance meeting the staff member who has drafted the new SOP will be invited to attend. Once agreed and approved by the R&I Senior Research Team the new SOP will be added.
The new SOP will be given a version number and date and recorded on the SOP log in the R&I shared drive. The version number and date will be recorded in the following format – Version X.X, Xth Month Year

The SOP will also be recorded on the Version History Log on page 2 of the SOP.

The new SOP will then be electronically signed and dated by the Author of the SOP and the Head of R&I.

The original document will be saved on the RDSU drive S:\RDSU\~New Drive\PORTFOLIO\7. GOVERNANCE\SOPs\SOPs in the specific folder for that SOP. The process used to update the SOP will be documented on an excel spreadsheet ensuring this is completed once the new version is saved on the RDSU drive. A Research Portfolio Manager will liaise with the Trust Communications Team to get the ratified and signed off new/ revised SOP uploaded to the Trust R&I internet page and update the SOP table on the intranet page (see example in appendix 3).
Once the SOP is uploaded to the Trust internet site the Research Portfolio Manager will announce the new/revised SOP is available to use via the research bulletin which is incorporated within the Trust staff update email.
All staff working within research will be requested as part of this announcement to read/request training of this new/revised SOP and document this training as per their local practice.
The R&I team/Research Staff who use EDGE will record their SOP training compliance on EDGE. Please refer to SOP 03Training Appendix 2 EDGE training record and certificate depository for details.

4.2. Amending an existing SOP

A suite of SOPs will be formally reviewed each quarter in line with the formal SOP review plan. Where a member of staff identifies the need for an amendment to an existing SOP, the following process will apply.

The requested change will be assessed by the appropriate member of the R&I Senior Research Team and a decision made as to whether the change is considered substantial or not.

4.2.1 Non-Substantial changes

A non-substantial change would be considered anything that was typographical, changes to personnel or contact details that do not have a material effect on the process outlined by the SOP.

A non-substantial change will be made by the appropriate member of the R&I Senior Research Team and the SOP Index and records updated.

Non-Substantial amendments will progress the version number from x.0 to x.1.

Non-substantial amendments to the SOPs will not change the specified review date – see section 5

4.2.2 Substantial changes

A substantial change is anything that alters the process outlined by the SOP and/or that would need to be implemented with immediate effect by those using the SOP to maintain patient safety and data integrity.

On identifying the need for a substantial amendment, the appropriate member of the R&I Senior Research Team will create a new draft version of the SOP incorporating the requested changes and it will be reviewed at the next SMT

Governance meeting. A substantial amendment will progress the version number from 1.x to 2.x.

Substantial amendments will reset the review date on the front of the SOP as detailed in section 5.

5. Update Review of SOPs

All SOPs will be written with a review date on the front page of the SOP, 2 years from the date that the SOP was signed off.
All SOPs will require formal review every two years, although additional reviews will be made, as required or requested, to allow for interim amendments and substantial amendments in relation to changes in legislation that affect the way processes in the SOPs are to be delivered. For those who have access to the RDSU drive, the tracking table of SOP versions and review dates can be found here. For those who do not have access to the RDSU drive, this can be accessed via the R&I internet page.

All staff have a responsibility to notify R&I of changes in process and/or legislation that may have an effect on the current SOP.

All SOPs will be reviewed by their review date regardless of whether there is any identified need at the time.

At the time of review the SOP will be circulated to members of the R&I Department giving a date by which comments will be expected back. All those asked to review the SOP will be expected to reply back by the given date even if it is to say no comment. A did not respond will not be interpreted as 'no changes needed'. Once this initial review has occurred a decision will be made to whether a wider review is required or whether no changes are required. If no changes are required this will be ratified and agreed at the SMT governance meeting. If a wider review is required this will commence. Once the review is complete the revised SOP will be ratified and agreed at the SMT meeting.

Members of the SMT governance meeting will be provided with the SOP to view prior to the meeting.

If there are no changes needed, the SOP version number would remain the same, but the date will be changed and a new 2-year review date set. This will be recorded on the SOP History Log and in the SOP Index.

Following the formal update review where there have been substantial changes, the version number will be updated, the date of next review will be added to the front of the SOP (2 years on from the current date) and the changes detailed in the details of changes log on page 2 of the SOP.

6. How to manage SOPs

Once signed off, GHNHSFT SOPs are only valid as they appear on the R&I internet web page. The Research Portfolio Managers will publish SOPs on this site and the Senior Research team are responsible for ensuring they are up to date.

An electronic archive of all signed and approved versions of all SOPs will be kept to ensure a clear audit trail. Paper SOP versions older than 6 years can be archived off site if space is required.

As all current SOPs can be found on the internet individuals are discouraged from printing copies, to ensure they are using the most up to date version of the SOP. Research at our hospitals (gloshospitals.nhs.uk)

Published SOPs should have “Uncontrolled Document When Printed” added as a watermark as a reminder that only those on the website are current. Draft SOPs and those under review should have suitable watermarks attached.

If SOPs are retained in Site Management Files for Research Projects, when updates occur, the old version should remain in the file, but be crossed through as superseded and the new version added to the file.

All new SOPs must adhere to this SOP and be in the format provided in appendix 2.

7. What to do if there is more than one SOP?

Some trials are supplied with SOPs, other trials may include sections in the protocol that contradict the procedures issued by the GHNHSFT R&I Department, or recommend the use of SOPs issued by a trial's unit or company. Some trials may be co-sponsored, each sponsor with their own SOPs. In these cases, it is important to be clear which SOP to use.

The SOPs supplied by the GHNHSFT should be considered the default procedures to be used for all projects except where project-specific procedures are specified by the sponsor or referred to in the protocol. Careful consideration must be given at study set-up as to which SOPs will apply to a specific trial. A Site File Note should be added to the local record to ensure clarity over which SOPs are to be followed. If there are any doubts, this should be discussed with R&I, the Head of R&I and the CI/PI if required.

Where GHNHSFT is sponsoring a trial and it is very near completion due consideration should be given to whether that trial can continue to work to the old SOP or change to the new one if the changes are not substantial and would mean discontinuity of procedure/ record keeping between earlier participants and those involved in the later stages of the trial. This only applies if it does not put current participants safety or data at risk. A site file note will be completed by the relevant Research Portfolio Manager and be filed in the site file and a note made in the SOP log to this effect.

8. Training

When new SOPs are published the R&I department will ensure that information is cascaded out to all relevant staff either through research delivery/research governance team meetings, the research bulletin in the Trust staff update emails, and alerts on the website.

With each review of a SOP a training record will be uploaded on EDGE3. There is a 5-week period between SOP approval and implementation. This is to give a one-week period for the SOP to be uploaded to the website, and then a further 4-week period to allow SOP training to be completed.

SOP awareness and training will also be delivered to local teams involved with specific studies at the point of set-up. This may be peer to peer presentations at the regular individual research teams meetings or one to one training, or any other documented sessions as well as self-directed learning. Understanding and agreement to adhere to relevant SOPs will be a requirement of Trust Approval.

Compliance with SOP training will be checked at research active staff annual appraisals.

9. Suspending or Withdrawing SOPs

An SOP may be suspended or withdrawn as necessary. If an SOP describes a process that is no longer followed, then it should be withdrawn from current use and archived.

Where a process is no longer followed, but a new process is being introduced a new R&I SOP (if required) will be drafted.

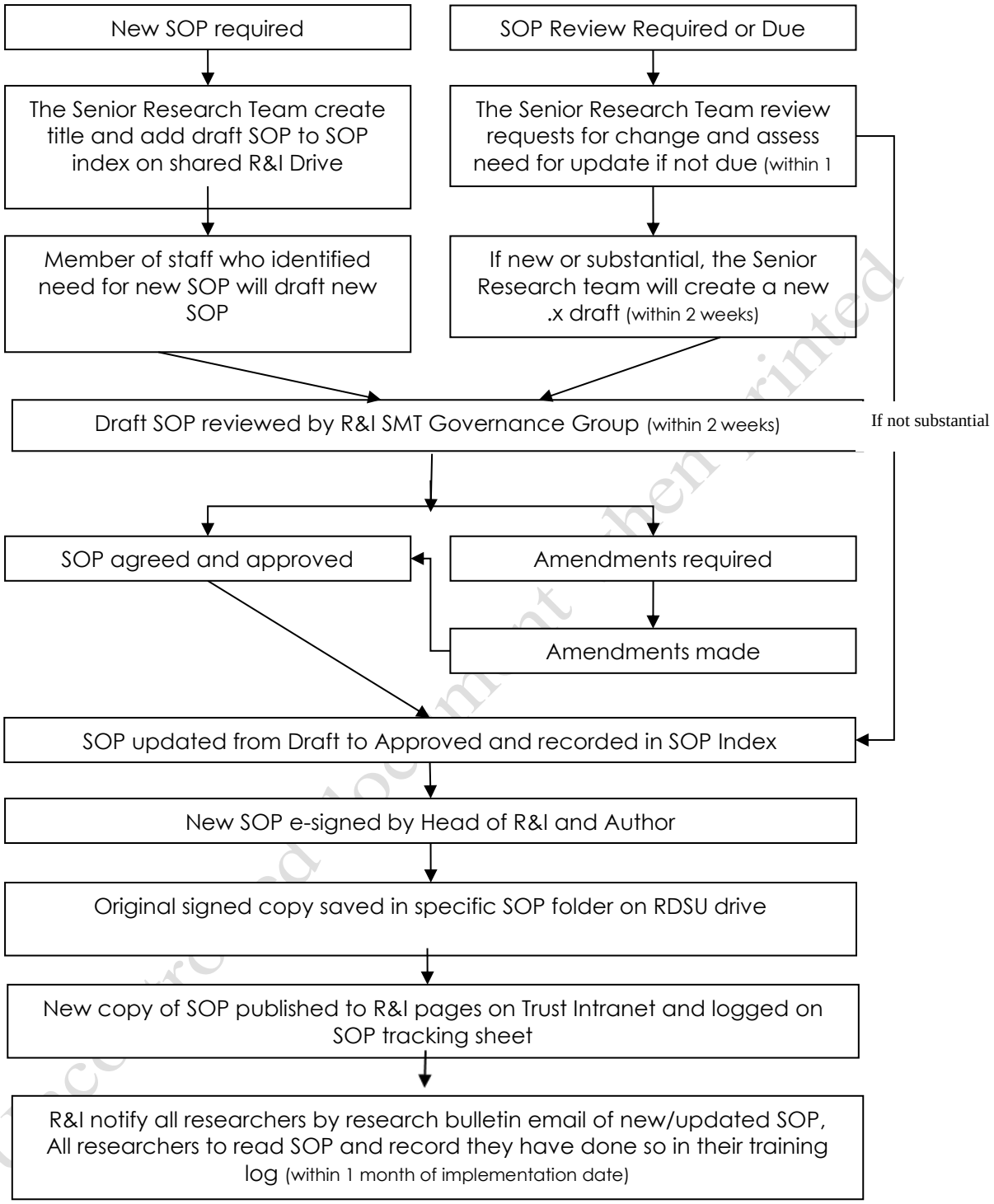
Notification of the release of new or revised SOPs, suspended or withdrawn SOPs will also be reported to the relevant staff by the R&I via the research bulletin which is incorporated within The Trust staff update email.

10. Standards

All staff should be aware that local Trust Policies and Procedures apply when planning and undertaking studies.

All Clinical Trials of Investigational Medicinal Products (CTIMPs) should be conducted to Good Clinical Practice (GCP) standards. All Investigators should be aware of their responsibilities as set out in GCP and UK Law. All Gloucestershire Hospitals NHS Foundation Trust SOPs will take into account the requirements of the Medicines for Human Use Act 2004 and all Statutory Instruments made under it (UK Clinical Trial Regulations).

Appendix 1 – SOP Development Process



Appendix 2 – SOP Template

The final SOP should include the text below as a minimum as well as the standard Header including the SOP reference. Subsequent pages should include the title of the SOP and the version/date in the header

NHS
Gloucestershire Hospitals
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TITLE (Arial 24,Bold)

SOP reference:		
Version:		
Author:		signature
Reviewed by Commercial Director:	Claire Richardson	signature
	/ /	
Implementation date of current version:	/ /	
Date of Review:	/ /	

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Related Documents:

SOPs

Glossary (if applicable)

Contents

1. Introduction, Background and Purpose (Headings Arial 14, Bold)

Aerial 12 – Line Spacing to 1.5 for whole document (Home tab, across to paragraph section, button in between paragraph alignment and colour fill)

Appendix 3 Intranet webpage index of SOPs

SOP category			
SOP ID	**Title of SOP**	**Version number**	**SOP implementation date**