North Bristol NHS Trust

Standard Operating Procedure

Preparation of Research SOPs

REFERENCE:	RI/QMS/SOP/001
VERSION NUMBER:	3.3
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REVIEWED BY:	R&I Senior Team
APPROVED BY:	Deputy Director of Research
CONTROLLER:	Contracts & Quality Management Officer

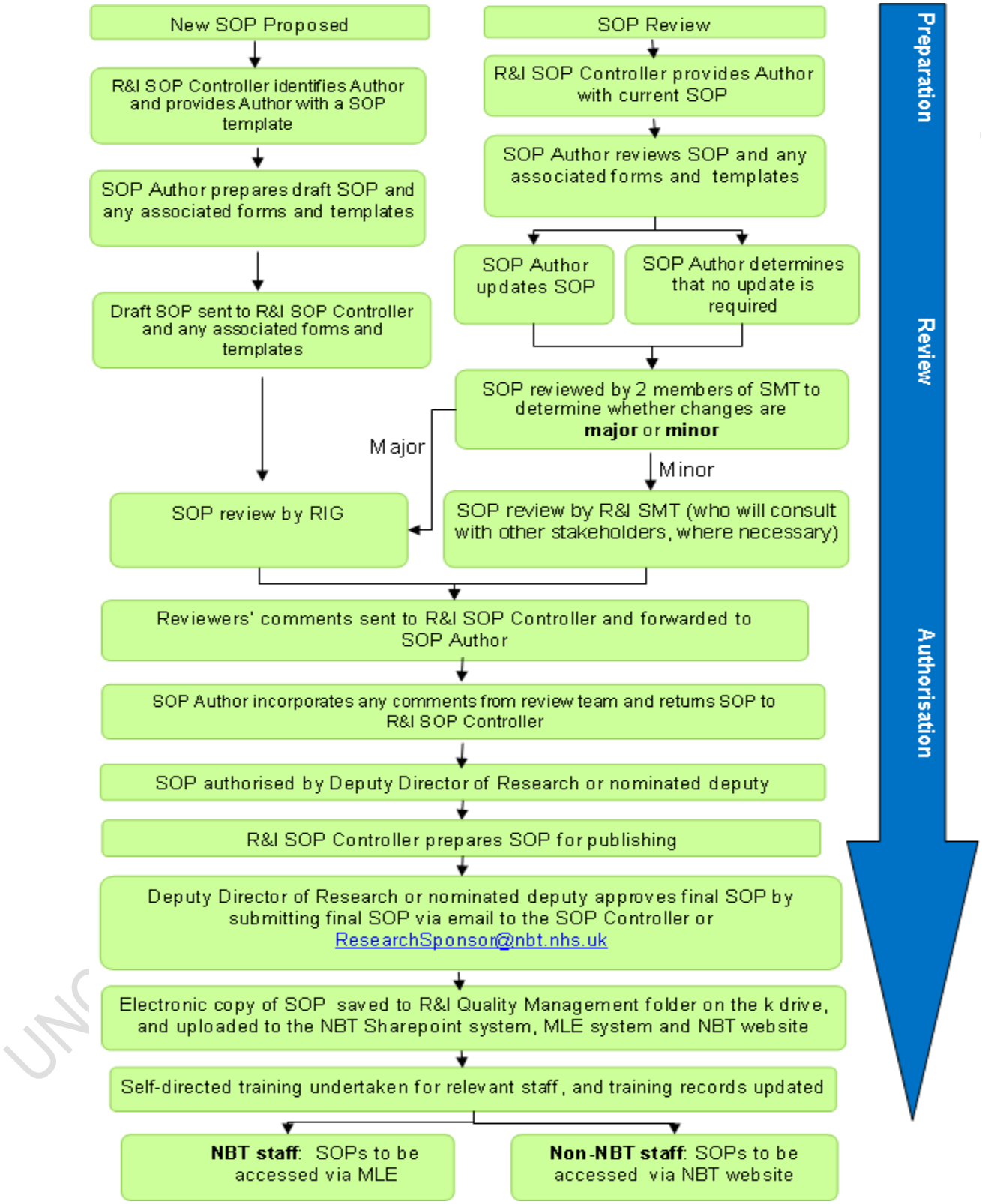
Document Version History

VERSION NUMBER	EFFECTIVE DATE	REASON FOR CHANGE
1.0	01-03-12	SOP renamed, updated in line with new template and recoded from ISOP-S01
2.0	08-02-16	Change to the SOP review and authorisation process
3.0	01-09-16	Minor updates to version control section and confirmation that the Deputy Director of Research may nominate a deputy
3.1	01-08-17	Updated to include SOP training on MLE for NBT staff, and clarification that study-specific procedural documents for NBT-sponsored CTIMPs require approval by the sponsor
3.2	28-03-18	Removal of requirement to sign and store paper copies of SOPs

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT CHECKING IT IS THE LATEST VERSION

Current versions of all Research & Innovation SOPs and accompanying documents are available online. If you are reading this document in printed form, please check that the version number and date match the most recent version on the Research & Innovation website: www.nbt.nhs.uk/research

i. SOP Flowchart



1 PURPOSE AND SCOPE

This document describes the process for writing, reviewing, approving and implementing NBT research SOPs. SOPs relating to NBT trust-wide systems and processes for research are produced and managed by R&I.

The International Conference on Harmonisation Guidelines for Good Clinical Practice (ICH GCP paragraph 1.55) defines Standard Operating Procedures as *"detailed, written instructions to achieve uniformity of the performance of a specific function."*

For all research studies sponsored by NBT, it is expected that R&I research SOPs will apply.

For research studies hosted but not sponsored by NBT, R&I SOPs should be considered the default procedures to be used, except where study-specific procedures are specified in the protocol. Where they exist, study specific procedures take precedence. Full details must be included as a written statement in the study file. If there are any doubts as to which SOP to use, the researcher should contact R&I for advice.

All SOPs produced by R&I must be used in conjunction with other NBT SOPs, policies and procedures.

This SOP may be used as guidance for the preparation of study-specific procedural documents, which will require local tailoring by researchers and study teams to meet the requirements of individual projects.

Where study-specific procedural documents are required, for example work instructions, flowcharts, SOPs etc. then the responsibility for preparing and reviewing these is delegated to the Chief Investigator. In the case of NBT-sponsored CTIMPs, all study-specific procedural documents and their amendments must be approved by both the CI and R&I as the Sponsor, prior to implementation. This will be checked as part of the monitoring process for CTIMPs.

2 DEFINITIONS/ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
NBT	North Bristol NHS Trust
RIG	Research & Innovation Group
R&I	NBT Research & Innovation Office
SOP	Standard Operating Procedure
R&I SMT	R&I Senior Management Team
SOP Controller	R&I Contracts & Quality Management Officer

3 WHO SHOULD USE THIS SOP

This SOP is applicable to all R&I staff who are involved in writing, reviewing, approving and implementing SOPs relating to NBT trust-wide systems and processes for research.

All staff working on research studies sponsored or hosted by NBT are required to be fully aware and compliant with the Trust's research SOPs issued by R&I.

All members of research staff have a responsibility to identify changes in policy, legislation and procedures that affect R&I SOPs and for bringing this to the attention of R&I. Any problems with a SOP should be notified directly to R&I who will decide whether a formal immediate review is required. Any user may choose to review a SOP at any time.

4 WHEN SHOULD THIS SOP BE USED

This SOP should be referred to whenever an R&I SOP is written, reviewed or approved or implemented.

5 PROCEDURE

5.1 **SOP Drafting**

(a) Where a member of staff identifies the need for an R&I SOP, or an update to an existing SOP, a request should be made to the R&I SOP Controller.

(b) The R&I SOP Controller will identify the most appropriate member(s) of staff who is/are involved in the work described to draft or update the relevant SOP. A SOP may have more than one author.

(c) The R&I SOP template, available from the R&I SOP Controller, must be used to set the standard style, layout and content of R&I research SOPs.

(d) SOPs must be written in a concise, step-by-step and clear format so that someone with limited experience or knowledge of the procedure, but with a basic understanding, can successfully carry out the procedure with limited supervision. Titles should be used rather than names.

(e) Where applicable, any associated forms, templates and guidance documents should also be drafted/updated and referenced within the SOP.

(f) The draft SOP, together with any associated forms, templates and guidance documents, should be sent to the R&I SOP Controller to co-ordinate review.

Standalone forms, templates and guidance documents will not form appendices to the SOPs due to the likely frequency of review required, but where applicable will be referenced to by the relevant SOP. These standalone documents will be version controlled and will require review

and authorisation via an R&I Senior Manager (i.e. a member of R&I SMT) prior to implementation.

5.2 **SOP Review**

R&I SOPs will indicate on their front cover when they require a review. Each SOP will have an effective date (date of implementation following authorisation) and a review date which should be no more than two years from the effective date.

SOPs will also be reviewed on an ad hoc basis as a result of amendments to legislation, process or organisational change. It is the responsibility of any user to notify the R&I SOP Controller if they believe a SOP needs reviewing before the review date.

R&I SOPs will be reviewed and agreed by either the R&I SMT or RIG as described below. This may be done electronically or via a full meeting. Comments will be documented and addressed as required. Where necessary, other stakeholders will be consulted to guarantee that the SOP is workable in practice.

Review of SOPs should take account of current working practices, planned changes to working practices or personnel, regulatory guidance and overarching policies and strategies.

(a) *New SOPs*

New SOPs will be reviewed and agreed by the RIG and authorised by the Deputy Director of Research or their nominated deputy on behalf of the RIG.

(b) *Existing SOPs*

i. Updates to existing SOPs will be reviewed by a minimum of two members of the R&I SMT to determine whether the changes made are minor or major as follows:

- **Minor changes** constitute an amendment to the document that does not substantially affect the main body of the document (e.g. changes to references and standard forms).
- **Major changes** constitute an amendment to the document that will result in a change of practice.

ii. Minor changes to a SOP will be reviewed and agreed by R&I SMT. Major changes to a SOP will be reviewed and agreed by the RIG.

5.3 **SOP Authorisation**

(a) Once an R&I SOP has been satisfactorily reviewed and, if necessary, updated, it will be authorised by the Deputy Director of Research or their nominated deputy (on behalf of either the R&I SMT or RIG as outlined in section 5.2) and notified to the R&I SOP Controller.

(b) The R&I SOP Controller shall prepare the SOP for publishing as follows:

i. Each SOP will be issued with a unique reference number (using the format RI/QMS/SOP/x), an effective date and a review date.

ii. Each form and template associated with a SOP will be coded with the same reference number as the relevant SOP followed by a letter 'a', 'b', 'c' and so on. So if the reference number of a SOP is RI/QMS/SOP/001, the first form or template will be coded RI/QMS/SOP/001a, the next form or template, RI/QMS/SOP/001b and so on.

iii. The version history table on the front page of the SOP will be updated.

iv. SOPs will be labelled with an "UNCONTROLLED DOCUMENT WHEN PRINTED" watermark.

(c) The R&I SOP Controller shall request approval of the final SOP from the Deputy Director of Research or their nominated deputy prior to publishing. An electronic copy of the final approved SOP submitted by the Deputy Director of Research or their nominated deputy via email to the SOP Controller or ResearchSponsor@nbt.nhs.uk will constitute such approval. A copy of the approval email will be saved on the k drive.

(d) An electronic copy of the final SOP will be saved to R&I's Quality Management folder on the k drive and uploaded to the Trust Sharepoint system. The R&I Communications Officer will upload the final SOP to the NBT website as described in section 5.4.

5.4 **SOP Distribution**

R&I SOPs will be uploaded to the NBT website (www.nbt.nhs.uk/research) and the Managed Learning Environment (MLE) system on the NBT intranet as read-only documents.

Where applicable, any associated templates, forms and guidance documents will be uploaded to the NBT website as separate documents for ease of use.

It is the responsibility of all staff to check MLE and the website regularly to see if SOPs have been added or amended.

R&I will endeavour to notify research staff of any SOP developments that may be relevant to them.

A list of any new or updated SOPs will be provided to the RIG at their quarterly meeting.

5.5 **Version Control**

SOPs will be labelled "draft" until they have been authorised. During the drafting/ redrafting phase, versions will be updated using an applicable version number increase (e.g. version 1.1).

The first published version of a SOP will be version 1.0. New published versions with major amendments will be updated with an increased major version number (e.g. version 2.0). New

published versions with minor amendments will be updated with an increased minor version number (e.g. version 1.2).

Final published SOPs will be accessed via the NBT website as appropriate and only the online published version will be listed as the active controlled document. Any printed SOP will be classed as an uncontrolled document and readers will be referred to the online list for up-to-date versions.

5.6 **Training**

Careful consideration must be given at study set up as to which SOPs will apply to a specific study. Full details must be included as a written statement in the study site file.

When a new SOP is authorised, or when an existing SOP is revised, self directed training must be carried out by all staff to which the SOP is relevant and this training documented in their training record.

(a) For NBT staff, R&I research SOPs should be accessed and read via the Managed Learning Environment (MLE) system on the Trust intranet. The MLE system provides the staff member and the Trust with an electronic record of training. By accessing each SOP on MLE, it is deemed that the individual has read, understood and will conduct their research in line with the standards detailed in the SOPs.

(b) For non-NBT staff, R&I research SOPs should be accessed via the NBT website (www.nbt.nhs.uk/research) and this training should be documented in the site file. By reading each SOP on the website, it is deemed that the individual has read, understood and will conduct their research in line with the standards detailed in the SOPs.

Staff should take time to read and fully understand the SOP and relevant documents, ensuring that they are able to implement the SOP when required. If clarification is needed then the staff member should approach R&I who will arrange additional training. All staff are responsible for maintaining their own training logs and copies must be made available to study monitors on request. See SOP on Research Staff Training (RI/QMS/SOP/005) for further information on training.

5.7 **SOP Archiving**

Electronic copies of superseded SOPs will be moved to a folder named ‘Superseded SOPs’ within the R&I Quality Management folder on the k drive.

6 RELATED SOPS AND DOCUMENTS

- The following NBT documents are available on the R&I website: www.nbt.nhs.uk/research

RI/QMS/SOP/005	Research Staff Training
RI/QMS/SOP/010	Archiving

- Other related documents

RI/QMS/SOP/001a	R&I SOP Template