Preparation of Research SOPs

Division: Strategy & Transformation

Specific staff groups to whom this policy directly applies	Likely frequency of use	Other staff who may need to be familiar with policy
All policy authors, reviewers, research governance and quality assurance managers/officers, senior management committee	As required	Staff involved as part of the policy consultation/ratification process

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Consultation:	Research & Development Senior Team Research and Development Sponsorship Team
Approval Authority (Committee/ Group/ Lead Clinician):	Helen Lewis-White - Deputy Director of Research Trust Research Group
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Version:	RD/QMS/SOP/001 - Version 3.4
KEYWORDS:	Research, Amendments, Sponsor, Submission, Observational, CTIMPs, Research and Development, Chief Investigator
Summary of changes since the previous version	Scheduled update, amendments made include SOP naming convention from RI/QMS/SOP/001 to RD/QMS/SOP/001. Name changed from R&I to R&D. SOP access and training changed from MLE to LEARN.

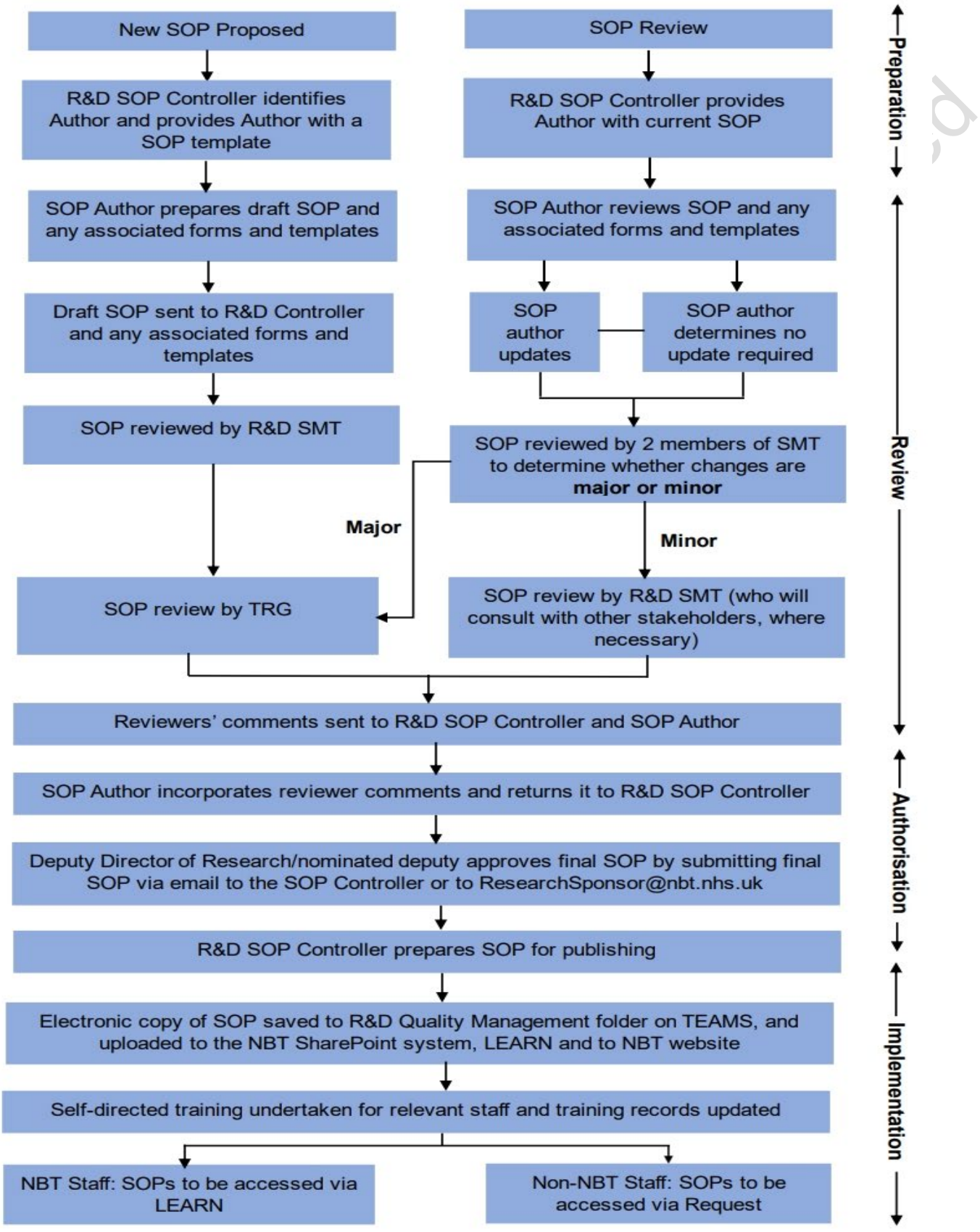
1. Purpose	**This document describes the process for writing, reviewing, approving, and implementing NBT research SOPs. SOPs relating to NBT trust-wide systems and processes for research are produced and managed by R&D.**
2. Key Messages	• The International Conference on Harmonisation Guidelines for 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"* • SOPs are essential in clinical research to ensure consistency, compliance and quality across our processes. • For all research studies sponsored by NBT, it is expected that R&D research SOPs will apply. • When collaborating with external stakeholders, such as Clinical Trials Units, on NBT-sponsored projects, it may be appropriate to utilise external SOPs to ensure proper project governance and the fulfillment of delegated roles and responsibilities. In such instances, both the external stakeholder and the NBT sponsorship team must ensure that the external SOP aligns with the procedures outlined in this SOP. If there is a conflict between the external SOP and NBT's procedures, the NBT SOP will take precedence, except in exceptional cases where approval is obtained from the Research Operations Manager or the Deputy Director of Research. • For research studies hosted but not sponsored by NBT, R&D 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&D for advice. • All SOPs produced by R&D 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&D as the Sponsor, prior to implementation. This will be checked as part of the monitoring process for CTIMPs. **ABBREVIATIONS/DEFINITIONS** **CI** - Chief Investigator **CTMP** - Clinical Trial of an Investigational Medicinal Product **NBT** - North Bristol NHS Trust **TRG** - Trust Research Group **R&D** - NBT Research & Development **SOP** - Standard Operating Procedure **R&D SMT** - R&D Senior Management Team **SOP Controller** - R&D Research Compliance Manager
3. Relevant Policies & Guidance	The following NBT documents are available on LEARN, the NBT website or by contacting the R&D Office (Research@nbt.nhs.uk) **RD/QMS/SOP/005** - Research Staff Training **RD/QMS/SOP/010** - Archiving **Other related documents:** Policy for the Development and Management of Trust Procedural Documents. C01. NBT Standard Operating Procedure Template v2.3
4. Operational Areas Included	This SOP should be referred to whenever an R&D SOP is written, reviewed, approved, or implemented.
5. Operational Areas Excluded	None
6. Who should read this	This SOP is applicable to all R&D staff who are involved in writing, reviewing, approving, and implementing SOPs relating to NBT trust-wide systems and processes for research.

7. Roles responsible for carrying out this procedure	**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&D. **All authors** involved in the development of the SOP must ensure that the document is reviewed by the relevant individuals, incorporating their feedback as necessary. It is essential to use the Trust's official template and coordinate with the Research Communication Team to ensure the SOP aligns with Trust policies and adheres to branding guidelines. All **research staff** have a responsibility to identify changes in policy, legislation and procedures that affect R&D SOPs and for bringing this to the attention of R&D. Any problems with a SOP should be notified directly to R&D who will decide whether a formal immediate review is required

8. Procedure:

Flowchart illustrating the process of preparing, reviewing, approving, and implementing NBT Standard Operating Procedures (SOPs)



8.1 SOP Drafting

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

b. The R&D 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 SOP template to be used for drafting SOP's should align with the NBT Trust template, this is available on the Trust intranet or via the R&D SOP Controller.

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&D 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&D Senior Manager (i.e. a member of R&D SMT) prior to implementation.

8.2 SOP Review

R&D 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 three years unless relevant legislation or guidance determines that an earlier review is required.

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&D SOP Controller if they believe a SOP needs reviewing before the review date.

R&D SOPs will be reviewed and agreed by either the R&D SMT or TRG 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 TRG and authorised by the Deputy Director of Research or their nominated deputy on behalf of the TRG.

b) Existing SOPs

i. Updates to existing SOPs will be reviewed by a minimum of two members of the R&D 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&D SMT. Major changes to a SOP will be reviewed and agreed by the TRG. The approved, final pdf version of Trust wide documents will be uploaded onto the NBT website within two months of the Committee approving it.

8.3 SOP Authorisation

Once an R&D 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&D SMT or TRG as outlined in section 8.2) and notified to the R&D SOP Controller.

The R&D SOP Controller shall prepare the SOP for publishing as follows:

i. Each SOP will be issued with a unique reference number (using the format RD/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 RD/QMS/SOP/001, the first form or template will be coded RD/QMS/SOP/001a, the next form or template, RD/QMS/SOP/001b and so on.

iii. All SOPs will be labelled with an “UNCONTROLLED DOCUMENT WHEN PRINTED” watermark.

iv. All SOPs will meet the required accessibility standards as well as branding alignment, the R&D SOP controller will seek input from R&D communications team, as required.

The R&D 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 TEAMS.

An electronic copy of the final SOP will be saved to R&D's Quality Management folder on TEAMS and uploaded to the Trust SharePoint system. The R&D Communications Officer will upload the final SOP to the NBT website as described in section 8.4.

8.4 SOP Distribution

R&D SOPs will be uploaded to the NBT website (www.nbt.nhs.uk/research) and the LEARN system on the NBT intranet as read-only documents, with support of the R&D communications team.

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

R&D will notify research staff of any new or amended SOP's that have undergone a major change via the following routes:

- Direct email to all R&D employed staff
- Direct email to Chief Investigators with NBT sponsored studies
- Inclusion in R&D departmental meetings which occur every 4-6 weeks.
- Notification via R&D Department Teams channel

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

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

8.5 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 of the document can be deemed as the Trust version – paper copies should not be available or encouraged. In exceptional circumstance (such as staff groups who do not have access to a computer) a printed version can be made available, but this must be replaced regularly to ensure the most up-to-date version is presented. It is the responsibilities of R&D SOP Controller to ensure staff have access to the correct documents. Web-link to the 'Adding and Editing policies to LINK' guideline can be found here : https://link.nbt.nhs.uk/Interact/Pages/Content/Document.aspx?id=13836

8.6 Training

Careful consideration must be given at study set up as to which SOPs will apply to a specific study.

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

a) For NBT staff, R&D research SOPs should be accessed and read via the LEARN system on the Trust intranet. The LEARN system provides the staff member and the Trust with an electronic record of training. By accessing each SOP on LEARN, 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, A list of R&D research SOPs will be available on the NBT Website (www.nbt.nhs.uk/research), non-NBT staff may request a copy of the relevant SOP by emailing the R&D Office (Research@nbt.nhs.uk), once reviewed this training should be documented in the site file. By reading each SOP, 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&D 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 (RD/QMS/SOP/005) for further information on training.

8.7 SOP Archiving

As part of R&D SOP management electronic copies of superseded SOPs will be moved to a folder named ‘Superseded SOPs’ within the R&D Quality Management folder on TEAMs.

As for SOPs added to NBT Trust website, the intranet has the facility to archive previous versions of documents for future reference. When a new version of the document is uploaded to the intranet, the previous version automatically becomes archived. If a document becomes redundant, it must be moved to the area’s archive rather than deleted to ensure its version history remains intact. It should then be made ‘inactive’ to ensure it is only accessible to R&D SOP Controller.