Development and Management of Standard Operating Procedures

SOP Number: BTC-SOP-QM-001

SOP Version: 2.0

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	NAME	TITLE
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Reviewer	Melanie Lewcock	Head of Bristol Trials Centre Strategy
Authoriser	Melanie Lewcock	Head of Bristol Trials Centre Strategy

Release Date:	26/02/2024	**Implementation Date:**	26/03/2024

Review Due:	26/03/2026

Implementation plan

This Standard Operating Procedure (SOP) should be implemented within two weeks from Release Date to allow for staff training.

Note to User:

It is your responsibility to ensure you are using the latest approved version of this SOP. Please note that versions may be superseded before their initial review date.

THIS IS AN UNCONTROLLED VERSION WHEN PRINTED.

If you are reading this document in printed form, please check that the version number and date match the most recent SOP's details. Current versions of all Bristol Trials Centre (BTC) SOPs and accompanying documents are available on the BTC Teams Channel.

Contents

1. PURPOSE

This Standard Operating Procedure (SOP) describes the procedures to be followed for the development and administrative management of the SOPs at the Bristol Trials Centre (BTC).

2. SCOPE

This SOP applies to all members of the BTC staff involved in the preparation, review, approval and release of new BTC SOPs and review and update of existing SOPs; it covers all SOPs developed within the BTC.

“Research study” (or “Study”) refers to health or social care related research projects (interventional trials or observational studies) involving people, samples and/or data, that are aimed at evaluating a medical, surgical, or behavioural intervention, or studying certain outcomes and certain groups of people. It includes clinical trials of investigational medicinal products, medical devices or advanced therapy medicinal products.

NB: Throughout this document the terms ‘research’, ‘study, ‘research project’, and ‘trial’ will be used interchangeably to denote those projects which fall under the remit of the UK Policy Framework for Health and Social Care Research 2017, unless a clear distinction is made.

3. DEFINITIONS

Author – Any member of BTC staff or a group working collaboratively, familiar with the activity covered by the SOP and given the responsibility to create or revise the SOP.

NB: An author cannot also authorise a SOP.

Reviewer - Any member of BTC staff or a group working collaboratively, appropriately qualified or experienced to check the accuracy of the procedure covered by the SOP.

Authoriser - The Quality Assurance manager, Director of the BTC or other authorised signatory.

NB: The Reviewer and Authoriser can be the same person.

SOP Group – Group comprising representatives from all functional areas across the BTC, established to develop the first versions of the BTC-wide SOPs.

Release Date – The date when the SOP is made available to the BTC staff.

Implementation Date – The latest date from which the SOP shall be in effect. Training shall be given to all concerned personnel before the Implementation Date. Up to four weeks may be allowed for staff training and for the procedure to be embedded in local structures.

Review Date – The date when the SOP shall next be reviewed. SOPs may be reviewed before the planned Review Date if major amendments are required.

Quality Management System (QMS) – The system comprising the tools, processes and procedures for ensuring that the BTC functions are performed to the highest standards and the research studies conform to all relevant ethical and regulatory requirements and satisfy contractual obligations.

Quality management documents – The collection of **standard operating procedures** and supporting documents (templates, forms, work instructions, etc) known as **process documents** which are part of the BTC quality management system.

For all other definitions, acronyms and common abbreviations refer to the BTC-RES-TM-001 Definitions and Acronyms document available on the BTC Teams channel.

4. RESPONSIBILITIES

4.1 SOP Author(s)

It is the responsibility of the SOP author(s) to:

- Write a new SOP or revise an existing SOP describing the procedure(s) in a clear and concise manner, providing sufficient detail to guide a trained member of staff to perform the procedures defined.
- When a group or individual is tasked to create an SOP, work collaboratively to promote its production in a timely fashion.
- Ensure that SOPs are reviewed and amended as required (see section 5.7 for review schedule).
- Ensure that new SOPs are created using the current template BTC-TEMP-QM-001 available on the BTC Team.
- Update existing SOPs as per the process described in this SOP.
- Ensure that the SOP remains fit for purpose.
- Make an assessment of any training requirements and facilitate training and provision of education materials as appropriate to ensure that staff are aware of their responsibilities in relation to SOP content and management.

4.2 SOP Reviewer(s)

It is the responsibility of the SOP reviewer(s) to:

- Provide input into the SOP as an expert; the reviewer should have extensive knowledge of the process covered by the SOP or should be performing the process in question at the time of the review.
- Check the accuracy of the processes and procedures described in the SOP and ensure the content of the SOP is comprehensible.

4.3 SOP Authoriser

It is the responsibility of the SOP authoriser to:

- Ensure that all procedures in the SOP are documented accurately and meet the requirements of the SOP.
- Authorise the SOP.

4.4 Quality Assurance (QA) Manager or delegate

It is the responsibility of the QA manager (or delegate) to:

- Coordinate and oversee the writing, reviewing, authorisation and release of BTC SOPs.
- Ensure that existing and proposed SOPs cover the work, equipment and procedures within the BTC.
- Recommend updates or early reviews to existing SOPs and propose development of new SOPs where appropriate.
- Review any requests for updates and for developing new SOPs from other members of staff.
- Identify appropriate individuals to prepare new SOPs and/or review current SOPs.
- Monitor SOP review dates and contact the author to request SOP review in advance of the review date.
- Make an assessment of any training requirements and, if required, coordinate SOP specific training prior to the Implementation date.
- Ensure that SOPs are adhered to.
- Maintain a register of all BTC SOPs.

4.5 SOP User

It is the responsibility of the SOP user to:

- Read this SOP in a timely manner, undertake any relevant training and record training according to instructions given at the time of SOP release.
- Review procedures during use of the SOP and inform the QA manager of any changes required using the Change Request mechanism on BTC Teams.
- Ensure compliance with this document.

5. SPECIFIC PROCEDURES

5.1 Identifying the need for a new or revised SOP

The requirement for a new SOP or revisions to an existing SOP may be identified as a result of new or amended legislation, an audit finding, a gap analysis or another reason.

Any member of the BTC staff can request a new SOP or revisions to an existing SOP. They must contact the QA manager if a new SOP is proposed or complete a Change Request Form available on the BTC Teams to record suggested revisions to an SOP.

The QA manager will review the existing quality management documents before deciding if a new document or a revision is required and will allocate a priority of 'high' or 'normal'. Those allocated as 'high' priority shall be addressed immediately. Those allocated as 'normal' shall be reviewed at the next scheduled SOP review.

The QA manager will agree on an appropriate title (if a new SOP is required), author(s) and a review and approval team, as appropriate. Where possible, the initial author(s) should be contacted to make revisions to an existing SOP.

5.2 SOP categories, naming conventions and version control

The BTC SOPs should be prefixed with letters relating to their SOP category. SOP categories are as follows:

- QM – Quality Management: These SOPs describe procedures relating to quality management systems at the BTC, e.g. SOP development, document management, confidentiality and data protection, staff training, audits, etc.
- TM - Trial Management: These SOPs describe clinical research procedures common to all research studies, e.g. protocol development; the TM SOPs are grouped according to the study stage (start up, conduct and closedown).
- IT – Information Technology: These SOPs describe procedures relating to management of research data (e.g. data collection, electronic data entry, data validation) and to the design, implementation, testing and maintenance of databases.
- ST - Statistics: This SOP describes the statistical work conducted for studies undertaken in association with the BTC, covering blinding, randomisation, sample size, analysis plans, Data Monitoring Committee reports etc.
- LAB – Laboratory: This SOP describes procedures relating to management of samples collected or processed for research.
- QR – Qualitative Research: This SOP describes how to design and conduct the qualitative component of a study.
- HE – Health Economics: This SOP describe the conduct of economic evaluations alongside research studies in health and social care.

All SOPs will be numbered in accordance with the following format: BTC-SOP-XX-001 where 'XX' indicates the SOP category and the last three digits indicate the SOP number. The SOP numbers will be allocated sequentially beginning with 001.The initial draft version of an SOP should be numbered version 0.1. When it is promoted to final, it should be numbered version 1.0. Subsequent modifications should attract an additional 0.1, and subsequent finalised (major) versions should be released as the next whole number (e.g. 2.0, 3.0 and so on). Only the most recent, authorised

version will be available for BTC staff, draft versions will only be accessible to the QA manager or delegate and the reviewers, as required.

The title of the electronic copy of the final SOP should contain the SOP number followed by a description and the version number, but no date e.g. BTC-SOP-TM-001 Study Start Up V.1.

Categories, naming conventions and version control for the BTC process documents are described in the BTC-SOP-QM-002 Quality Management SOP.

5.3 Preparing a new SOP

Once a new SOP is identified, the details will be forwarded to the QA manager to allocate a new SOP number. SOP author(s) will prepare the new SOP in accordance with this SOP and by using the SOP template BTC-TEMP-QM-001.

The SOP should be written clearly and concisely, avoiding repetition.

Definitions, abbreviations and acronyms should be defined in the BTC-RES-TM-001 Definitions and Acronyms available on the BTC Teams. Wherever reference is made to an activity covered by another SOP, the instruction “see BTC-SOP-XX-XXX” should be inserted. The version number of the referenced SOP should not be referenced to avoid references becoming out of date.

Wherever necessary, illustrations, flow charts or tables may be incorporated in the SOP, to provide better clarity and understanding.

When a draft SOP has been completed as fully as possible, it will be forwarded to the QA manager for an in-depth review. If appropriate, a group can be delegated to review. Comments should be incorporated into the draft SOP.

During review, any issues should be resolved by discussion between the author(s) and the reviewer(s) and the document should undergo further iterative drafting as needed. Several rounds of review may be required until a final draft is developed. Input from other appropriately experienced staff may be invited as required. Review should focus on the following essential elements of the SOP:

- compliance with the applicable regulations / official guidance
- accuracy of information
- readability
- likelihood of adherence (i.e. the extent to which the described procedure will be followed without deviation).

Where supporting documents (templates, forms, etc) are referenced in a SOP they should be developed in parallel to the SOP.

The drafting process is considered complete when content is agreed between the author(s) and reviewer(s). The final draft should be saved, with author(s) and reviewer(s) names and date fields completed. At this point, the author(s) should contact the QA manager to advise that the SOP is ready to be authorised (see section 5.5).

5.4 Amending an existing SOP

Amendments to existing SOPs will be undertaken by the original author(s) where possible, or by an individual with the relevant qualifications and experience.

Where an existing SOP is based on a superseded version of the SOP template BTC-TEMP-QM-001, the amended version must be created using the current template.

Where an existing SOP is based on the correct template, amendments may be made by editing the existing SOP. The QA manager or delegate will provide a master version for editing and grant edit access rights to the author(s) to make sure revisions are captured in the version history.

Brief details and reasons for the change to the SOP should be recorded in the Change History section on the revised SOP. It should be clear whether the change is minor, administrative in nature, or it involves a change in processes.

The authors should ensure that comments recorded in any Change Requests are incorporated.

All revisions should be made using the 'tracked changes' function.

Amendments will undergo the same draft and review procedure as described above until revision is complete, at which point the author should advise the QA manager that the SOP is ready for authorisation (see section 5.5).

When amending SOPs that refer to associated supporting documents (forms, templates, other SOPs, etc.), authors are required to consider the implications of the amendment in relation to those associated documents. Where amendments to a SOP require amendments to be made to the associated documents, those documents should be revised accordingly at the same time as the SOP.

5.5 SOP authorisation and release

Once the final version of the SOP has been produced, the QA manager will provide the document to the Authoriser.

If further edits are required by the Authoriser, the document will undergo further revision and review as described above.

If no further edits are required, the document should be amended to record the SOP as finalised e.g. update version number to a whole number etc. and the release, implementation and review dates should be entered on the front page. The review date will be two years after the implementation date, unless it's a new SOP (i.e. Version 1) when it will be six months after the implementation date.

The authorisation is complete when the Authoriser confirms that they are satisfied with the review and the SOP is authorised.

The authorised SOP will be stored electronically as a PDF on the BTC Teams in the Quality Assurance, published SOPs folder. Members of staff will be notified when the SOPs are released and will be able to access all SOPs via this system.

Any printed copies of SOPs will be identified as uncontrolled copies.

All editable Microsoft Word versions including drafts and full versions, and all superseded PDFs will be retained as part of the version history available on the BTC Filestore, with access restricted to the QA manager and delegate(s).

5.6 SOP implementation plan

The implementation date should reflect the need for the SOP and allow time for training of staff on the SOP.

Sufficient time should be given between the release date and the implementation date in order to allow for training and for the procedures to be embedded in local structures.

Where a SOP undergoes only minor, administrative revisions where no specific training is required it may be implemented within a week; otherwise up to four weeks may be allowed for the staff to read, understand and (if required) receive additional training in the new procedure.

If there is a change to a SOP during the active phase of a research study, it may be more appropriate to continue using the original SOP for the duration of the project in order to maintain continuity. Such a decision must be approved by the senior trial manager and/or QA manager and documented in the Trial Master File (TMF).

5.7 Routine review of SOPs

The QA manager will keep a SOP Review Schedule to ensure that all reviews are initiated and documented correctly.

Routine SOP review will normally be two years after the implementation date but may be sooner if required.

A review of each **new** SOP should be carried out after the SOP has been in place for six months.

Reviews must be completed within three months from the next review date. This will be coordinated by the QA manager.

If during the routine review it is agreed that there are no required changes to be made to the SOP, the document will be re-released to the relevant parties advising that the procedure is to continue unchanged. The SOP will be given a new review date, but the version number and date will remain the same. The author will note in the version log that the SOP was reviewed and required no change and therefore there was no change of version number and date.

If revisions are required, the author should update the SOP as appropriate, as described in section 5.4 above.

5.8 Withdrawal of SOPs

When a SOP is no longer required or relevant, and the QA manager, reviewer and authoriser agree, the SOP can be withdrawn. The register will be updated and the SOP removed from the Published SOPs folder in BTC Teams. SOP numbers assigned to SOPs that are withdrawn will not be re-used.

5.9 SOP Archive

A master file containing the original authorised copies of SOPs will be maintained indefinitely by BTC in the BTC filestore. The master file will include all major versions of each SOP, including obsolete documents.

6. SUPPORTING DOCUMENTS TO BE USED

Number	Title
BTC-TEMP-QM-001	SOP Template
BTC-RES-TM-001	Definitions, acronyms and abbreviations relevant to research projects and management of research
BTC-SOP-QM-002	Quality Management SOP
BTC-TEMP-QM-003	Working Instructions Templete
BTC-TEMP-QM-004	Checklist template
BTC-TEMP-QM-005	FAQ Template
BTC-TEMP-QM-006	Form Template
BTC-TEMP-QM-007	Resources Template

7. CHANGE HISTORY

Previous version and date	New version and date	Brief summary of review
NIL		New document
V1, 19 Jul 2021	No change	SOP was reviewed and required no change; review date was amended but the SOP version number and date were not changed
V1 , 19 Jul 2021	V2, 26 Feb 2024	Reference to the BTC Sharepoint was removed and replaced with BTC Teams site and BTC filestore as relevant.