Standard Operating Procedure:

QMS Development and Management

# Purpose

This standard operating procedure (SOP) describes why and how a quality management system (QMS) is developed for clinical research at the University of Birmingham (UoB). This SOP also includes how a QMS is managed, the role of stakeholders, and how documents are prepared, reviewed, authorised and implemented.

# Scope

The SOP applies to all quality management system(s) that relate to clinical research that is undertaken at the UoB, and/or is (co-)sponsored by the UoB.

# Implementation plan

This SOP will be implemented in line with this document’s effective date.

# Stakeholders

* QMS manager (or delegate)
* Senior management providing oversight, e.g. the Clinical Trials Oversight Committee (CTOC) for clinical trials
* Clinical Research Compliance Team (CRCT)

# Background and rationale

A QMS is a structured programme of standard operating procedures and associated policies that describes how relevant tasks should be performed. Along with the UoB’s relevant policies and codes of practice, a QMS for clinical research at the UoB should also encapsulate any applicable regulations, national and international standards.

The UoB’s quality management system was developed by the Clinical Research Compliance Team (CRCT). It is an overarching clinical research QMS (hereafter referred to as UoB QMS) that is designed to cover clinical research activity (including work with human tissue) undertaken at the UoB, and/or is (co-) sponsored by the UoB. It is a collection of policies, standard operating procedures (SOPs) and where applicable, mandatory quality control documents (QCDs), that must be adhered to. The CRCT maintains the UoB QMS as detailed in the CTOC- and HTOC-approved QMS management plan, in line with this SOP and the Clinical Research Quality Manual (UoB-CQM-POL-001).

Teams or units within the UoB that are responsible for the management or oversight of a portfolio of clinical research projects, such as a clinical trials unit, may choose to set up their own QMS to capture their own local processes (‘local QMS’). It is not expected that a local QMS would be set up for a single research project. A local QMS must be set up in line with this SOP and be based on the UoB QMS. Developing a local QMS is a significant undertaking that is time and resource heavy. Before committing to this course of action, research teams/units should carefully consider the advantages and disadvantages of developing and maintaining their own local QMS.

A research team or unit can also use work instructions to provide staff with further details and/or guidance on the requirements of specific tasks. Where developed, work instructions must comply with the UoB’s SOPs, be version controlled, and be maintained to reflect current practice. Work instructions should be reviewed and approved by a senior team member who has relevant knowledge and expertise.

For further information on UoB policies regarding a QMS see the Clinical Research Quality Manual (UoB-CQM-POL-001).

# Process map



# Procedure

## Set up a QMS-document-development process

1. Senior management will decide whether a QMS is needed. If so, they will allocate the role of QMS manager to a team member, ensuring suitable resources are made available to support the activity.
2. The QMS manager (or delegate) will ensure that the QMS does the following in relation to document development.

* Clarifies who will undertake each of the required QMS roles, i.e. manager, author, reviewer, authoriser.
* Ensure that reviews are performed by individuals with a suitable level of expertise.
* The QMS manager, in their role as an authoriser, will review all QMS documents to confirm that they incorporate all relevant regulations and policies, adhere to the UoB QMS, are cross-referenced appropriately, reflect best practice, are clear and easy to understand, and are easy to use.
* Where a local QMS has been developed (e.g. the UoB’s UKCRC-registered clinical trials units), the CRCT will conduct a pre-finalisation review of local policies and SOPs to ensure adherence to the UoB QMS and applicable standards and regulations. This includes the periodic review of live documents. Local QMS documents should be sent to the CRCT mailbox at [crct@contacts.bham.ac.uk](mailto:crct@contacts.bham.ac.uk). The results of any review will be confirmed via email.
* For the UoB’s UKCRC-registered CTUs only: the CRCT’s review will be completed within 10-working days of receiving the draft document unless otherwise agreed between the CRCT and the CTU.
* Develops a process for QMS-document development, review, authorisation, finalisation and implementation (including training). The process should cover the periodical review of, updates to, and archiving of, finalised QMS documents. The process should also include:
* appropriate version control, see the Essential Documents Development and Maintenance SOP (UoB-ESD-SOP-001) for detail on developing a version control system
* use of effective dates and review dates for QMS documents
* Includes a process for finalised QMS documents relating to their distribution, storage, recall and archiving.

## Set up a QMS-management process

1. The QMS manager (or delegate) will ensure that the process for managing the QMS portfolio, as outlined below, is detailed within the QMS.

* Schedule a periodic review of QMS documents, where each document is typically reviewed every 2 years.
* Identify, log, prioritise and implement any changes required to the QMS e.g. as a result of changes in legislation, standards, policies and/or procedures.
* Create a QMS management plan to document the status of each QMS document, detailing:
* all current, authorised documents contained within the QMS, including version number, effective date and review date
* feedback from stakeholders on an existing document and a plan for incorporating their feedback when the document is next reviewed
* all new documents that are scheduled to be included, along with their planned effective date.
* Review the QMS portfolio status regularly, typically every 6 months.
* Prioritise QMS-document development and maintenance, using a risk-based approach, documenting the reason for any reprioritisation.
* Incorporate oversight by reporting to senior management about the QMS’s management, including any proposed reprioritisation of document development and maintenance.
* It is recommended that reports on the status of the QMS portfolio are available in a single document for review/auditing purposes.

## Oversee QMS management

1. The QMS manager (or delegate) will oversee the QMS’s management, ensuring that processes for QMS- document development and QMS management are adhered to.
2. The QMS manager (or delegate) at a UoB’s CTU will submit an up-to-date QMS management plan to the CTOC at least annually. If major risks are identified to any UoB-sponsored or co-sponsored trials, any trial participants and/or the organisation, the CTOC will take further action.
3. The QMS manager (or delegate) will inform stakeholders of any updates to relevant SOPs/policies. Where the CRCT has updated any SOP/policy within the UoB QMS, the CRCT’s QMS manager (or delegate) will communicate the update/change to any known stakeholders who are using their own locally developed QMS (e.g. the UoB’s UKCRC-registered clinical trials units).
4. The CRCT will maintain and oversee the UoB’s clinical research QMS. The CTOC and/or HTOC will review and approve any new policies, SOPs and mandatory quality control documents (QCDs) within the UoB QMS (and/or updates to them) as per the QMS management plan. See the Clinical Research Quality Manual (UoB-CQM-POL-001).

* In the event where two documents present conflicting statements, the document with the latest effective date (i.e. most recently issued) is deemed to supersede the statement in the opposing document (unless informed otherwise by the CRCT). Where this happens, the CRCT may update the older document to reflect the most recently issued statement, without the need for the review and approval of the CTOC and/or HTOC.

# List of expected outputs

* Defined processes for QMS-document development and QMS management that are in line with this SOP.
* Evidence of procedures followed in the management of the QMS and QMS-document development.
* A QMS management plan.

# Related documents

* UoB-CQM-POL-001 Clinical Research Quality Manual
* UoB- ESD-SOP-001 Essential Documents Development and Maintenance

Note that the UoB QMS documents can be found on the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT([crct@contacts.bham.ac.uk](mailto:crct@contacts.bham.ac.uk)) and/or from the Research Governance Team (RGT) ([researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)).

# References and frameworks

* CRCT mailbox: [crct@contacts.bham.ac.uk](mailto:crct@contacts.bham.ac.uk)
* International Organisation for Standardisation (ISO) 9000:2015 Quality management systems – Fundamentals and vocabulary.
* ISO 9001:2015 Quality management systems – Requirements.
* Medicines & Healthcare products Regulatory Agency (MHRA). Good Clinical Practice Guide, London: The Stationery Office, 2012.

# Abbreviations and definitions

| Term | Description |
| --- | --- |
| Effective date | Effective date is the date the document was authorised to go live. |
| Local QMS | A quality management system used by a research team or unit. |
| Policies | Policies are developed to describe the UoB’s approach to areas that are regulated; they explain why the UoB has its procedures. Where regulatory requirements are not explicitly prescriptive (e.g. they do not detail an implementation method), a policy may be developed to specify the way in which the UoB will meet the requirements. A policy may also be developed when the UoB’s position on an issue or area is still undetermined, but that issue or area would normally be documented within the UoB QMS. |
| QMS management plan | The plan to develop, maintain and review the quality management system. |
| QMS manager | The individual responsible for developing and maintaining a QMS. The individual may also have another job title/role. |
| Quality control documents (QCDs) | Quality control documents (QCDs) can be instructions, forms, templates or checklists. They are developed to share best practice, promote standardisation to guarantee quality standards are maintained, and reduce resources otherwise needed to develop similar documents. Unless indicated otherwise in the relevant SOP, QCDs are not mandatory and are designed to be an optional aid. |
| Quality management system (QMS) | A quality management system (QMS) is a system that includes procedures and policies to describe how certain tasks should be performed. It encapsulates any standards and/or regulatory requirements that may apply to those tasks. By adhering to the quality management system, the user and the UoB will be assured that applicable regulations are adhered to. |
| Standard operating procedures (SOP) | A SOP is a set of detailed written instructions designed to encourage best practice and help users standardise the performance of specific functions. It defines tasks, allocates responsibilities, details processes, indicates documents and templates to be used, and cross-references to other work instructions, guidance or policy documents. SOPs provide standards against which the UoB may be audited or inspected. |
| Version number | For the purposes of the UoB QMS, the version number format is based on the principle that whole numbers are used for finalised versions, and draft versions use decimal points. For example, the initial draft would have version number 0.1 and each subsequent draft will result in a changed version number (i.e. 0.2, 0.3 etcetera). Typically, the draft version number changes following an update and again at the time the updated draft is circulated for review. The first finalised version will have version number 1.0 and each draft update thereafter will have version number 1.1, 1.2. Any future finalised versions will have version numbers 2.0, 3.0 etc. |

See also the [Glossary of Terms](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/Glossary-of-Terms.aspx).