Joint Research Management Office Standard Operating Procedure for:			
JRMO Controlled Documentation: Creating, Maintaining and Distribution			
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Purpose:

The purpose of this standard operating procedure (SOP) is to describe the procedures to be followed for the management of controlled documents developed by the Joint Research Management Office (JRMO).

This SOP also describes the process for creating, maintaining, and distributing JRMO controlled documents. This SOP provides guidance to ensure that all JRMO controlled documentation adheres to a uniform standard format, are written, reviewed, and released in a timely manner, and that both internal and external Barts Health (Barts Health) and Queen Mary University of London (Queen Mary) research staff are informed of any new or revised JRMO documents when they are released.

Scope:

This SOP applies to all controlled documents developed by the JRMO and to all JRMO staff involved in preparing, reviewing, and managing JRMO controlled documentation.

Abbreviations:

Barts Health	Barts Health NHS Trust
GCP	Good Clinical Practice
JRMO	Joint Research Management Office

QA	Quality Assurance
QMS	Quality Management System
Queen Mary	Queen Mary, University of London
QMS	Quality Management System
SOG	Sponsor Oversight Group
SOP	Standard Operating Procedure

Definitions:

Controlled Documents

For the purpose of this SOP, controlled documents are defined as documents governed within the JRMO Quality Management System (QMS) :

- SOPs
- Supporting documents to include associated documents, templates, appendices (For further clarification, please see Associated Document 1 Writers Guide)
- Template Study documents e.g., protocols, monitoring plans

QMS meeting group

Comprising of the Senior Operations Manager, Governance Operations Manager, Good Clinical Practice (GCP) & Governance Managers, Research Governance Team Leader, and the Quality Assurance (QA) Manager, the group meets to ensure members of the JRMO review and, where relevant, escalate issues relating to the management and implementation of the JRMO QMS. This is achieved by:

- Undertaking regular review of the JRMO QMS including policies, controlled documents, and training requirements
- Discussing any issues and implementing actions to resolve them
- If relevant, escalating issues to the JRMO Sponsor Oversight Group (SOG)

Relevant SOPs:

- SOP 34b JRMO staff training and induction

SOP Text:

	Responsibility	Activity
		Document Control
1.	JRMO Operations Managers	**Identify all documents used within the JRMO teams which must be controlled.** To assess the need for documents to be controlled, the following should be considered: • Is this document in place to ensure regulations or polices are met and adhered to? • Is the document a template with fields that should not be changed? • Is this a supporting document to an SOP? • Do multiple staff use the same documents?

		It is the responsibility of the Operations Managers along with the Senior GCP manager and Quality Assurance Manger to ensure that documents used within the JRMO are regularly reviewed and remain fit for purpose. Request for new documentation or updating prior to the review date is discussed and implemented as part of the QMS meeting. If a team member identifies the need for a new document or an amendment to an existing document, they must report this to their team leader, who will liaise with their Operations Manager who will review and approve this before the new/amended document is made available to staff. Ensure the JRMO QA Manager is informed of any amendments or additional documents required and is provided with a copy.
2.	JRMO QA manager	**Create and maintain a master index of all controlled documents in the JRMO.** The master list of controlled documents includes the following: 1. JRMO Document Index • A list of all current effective controlled documents 2. JRMO SOP Calendar • A list of all controlled documents detailing the review process in a real time mode. 3. Superseded Controlled Documents • A list of all superseded controlled documents 4. Current SOP discrepancies • A list of all discrepancies/concerns raised against effective controlled documents. The master index is located in the JRMO Quality Management System folder stored in the Finance and Procurement J-Drive or equivalent SharePoint location. Access to this is restricted to the Senior Operations Manager, Governance Operations Manager, Senior GCP and Governance Manager and QA Manager.
Creating New JRMO Controlled Documents		
3.	JRMO staff	**Identify need for new Controlled Document.** When the need for a new controlled documentation is identified, inform the relevant Team Leader/QA Manager/Operations Manager. This will be noted and brought forward to the next scheduled QMS meeting.
4.	QMS Meeting group	**Assign author and reviewers.** The QMS meeting group will assign an author and subsequent reviewers to the controlled document and offer support to the individuals throughout the draft process.

		Please note, as minimum, the author's Operations Manager must be noted as a document reviewer
5.	JRMO QA Manager	**Update the controlled document master index** The QA manager will allocate a new SOP number and update the master index to reflect this.
6.	Document author/QA Manager	**Draft new document.** For new SOPs, draft using Associated Document 2 SOP draft template. Further guidance on drafting SOPs and supporting documents can be found in Associated Document 1 JRMO Document Writers Guide.
7.	Document reviewer/QA Manager	**Review document.** With support from the QA Manager, the draft document is distributed to the allocated reviewers, where all comments/concerns/resolutions are addressed and tracked. All drafts of the new documents must be forwarded to the QA Manager and retained. Guidance can be found in Associated Document 1
8.	JRMO QA Manager	**Finalise document.** Set the review date for the document. New documents will be initially given a 12-month review period in the first instance. Existing documents will be given a review period of between 2 to 3 years. This will be decided as part of the QMS meeting. Review finalised document and forward to the Senior Operations Manager/Operations Manager.
9.	Senior Operations Manager/Operations Manager	**Review and approve the final version of the document.** Review the documents. If further changes are required, then discuss them with the author and/or the QA Manager. The author, with support of the QA Manager, must amend the document and resend it to the Senior Operations Manager. Supporting documents may be finalised by the author's Operations manager if appropriate. Approve the final version and inform the QA Manager.
10	JRMO QA Manager	**Finalise and file the completed document.** Once the final draft has been agreed by all parties ensure that: • Version, Effective Date and Review Date are complete

		Note: The time between the final authorisation and Effective Date should be sufficient to allow time for staff to read and/or be trained on the document. (at least a week should be given). • Wet ink signatures/electronic signatures/email confirmation for approval have been obtained from the author, reviewers, and Senior Operations Manager. • File the signed paper copy in the JRMO Controlled Documents Master File . Should email confirmation be used to confirm final approval of a document, print a copy and file with the document paper copy. • A scanned copy of the signed document is to be filed in the appropriate QMS folders. *Note: Supporting documents do not require signatures* • File an electronic PDF version in the QMS. • Update the Controlled Document master index . *Proceed with Section D: Distribution and notification of JRMO Controlled Documents.*
Reviewing Existing JRMO Controlled Documents		
11	JRMO QA Manager	**Review and update the Controlled Document master index.** Maintain an up-to-date Controlled Document master index. Documents should be brought for review between 3 and 6 months prior to review date. This decision will be case specific and will include factors such as number of supporting documents, complexity of documents and requirements for external input/review. Documents for review will be added to the QMS meeting agenda for discussion by the QMS meeting group.
12	QMS meeting group	**Assign author and reviewers.** The QMS meeting group will confirm an author and subsequent reviewers to the controlled documents and offer support to the individuals throughout the review process. *Please note, the author's Operations Manager must be noted as a document reviewer*
13	Author/ Reviewer/ QA Manager Senior Operations Manager/Operations Manager	**Follow sections 7 to 10 for review and finalising procedure.**
14	JRMO QA Manager	**Supersede previous versions of documents.**

		Superseded or discontinued documents (both electronic and paper) should be archived in the document Archive file and the master index updated to reflect this. *Proceed with Section D: Distribution and notification of JRMO Controlled Documents.*
Distribution and Notification		
Internal distribution to the JRMO		
15	JRMO QA Manager	**Upload the new/updated documents to EDGE.** Upload the final approved versions of the document to EDGE and the JRMO website. Draft and send an email to the JRMO Office Manager detailing the new/reviewed document release. The JRMO Office Manager will notify the relevant internal staff.
16	JRMO staff	**Read and understand the documents relevant to their role as defined in the training matrix.** JRMO staff are expected to use EDGE to access latest versions of SOPs and supporting documents. Following notification of a new/revised documents, JRMO staff must: • Review the JRMO training matrix located on EDGE to see if the released document is applicable to their role. • Read the document (if applicable) and sign the individual reading log to confirm they have read and understood the new/updated document. This should be done before the document effective date. • Direct any queries regarding the new/revised SOP to the author/line manager/QA Manager
17	Operations Managers/QA Managers/ team leaders	**Review training matrix.** Review training logs annually (and following probationary periods of new staff) to ensure staff in team have read documents as directed. See SOP 34b for further information
External distribution from the JRMO		
18	JRMO QA Manager	**Email notification of new/revised documents to the JRMO Office Manager.** • Email new/revised documents to the JRMO Office Manager for external distribution using the JRMO Mailing List. • Email the Projects and Communications Manager to ensure newly released documentation is included in the JRMO R&D Bulletin.

Change control

This section outlines changes from version 7.0 to 8.0

Section changed	Summary and description of changes
All	SOP to reflect control of all relevant documentation governed by the JRMO QMS
All	General administrative changes
Associated Document	New associated document

List of appendices

There are no appendices associated with this SOP

List of associated documents

Document ref.	Document name
Associated document 1	JRMO Document Writers' Guide
Associated document 2	SOP Draft template