Joint Research Management Office Standard Operating Procedure for:			
Quality Management System			
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Purpose:

The purpose of this standard operating procedure (SOP) is to describe the methods employed by the Joint Research Management Office (JRMO) to implement and maintain a Quality Management System (QMS), ensuring studies are designed, implemented, documented, and recorded to a high scientific standard.

Scope:

The QMS applies to all staff members actively involved in studies with both Queen Mary University of London (Queen Mary) and Barts Health NHS Trust (Barts Health).

The QMS meeting group will maintain oversight of the QMS as defined in the QMS terms of reference.

Abbreviations:

Barts Health	Barts Health NHS Trust
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
JRMO	Joint Research Management Office
QA	Quality Assurance
QMS	Quality Management System
Queen Mary	Queen Mary University of London
SOP	Standard Operating Procedure

SOP Text:		
	Responsibility	**Activity**
1.	Quality Assurance (QA) Manager, Research Governance Operations Manager, or delegate	**Document control** The secure management of documentation relating to the JRMO QMS is the responsibility of the Research Governance Operations Manager and maintained by the QA Manager. Oversight will also include the relevant QMS meeting group members where delegated. The QA manager is responsible for maintaining the list of current versions of controlled documents as identified by section operation managers. The JRMO QMS index provides a real-time inventory of all documents to include: • Current Documents: SOP's, Associated Documents, Templates and Appendices • Documents under review • Superseded Documents An up-to date inventory is also maintained for the following categories of documents: • Non-compliance index • Internal review reports • External Audit/Inspections (Excluding JRMO Study Audit Reports) JRMO staff are encouraged to liaise with the QA manager should a need for a new SOP be identified, or an unscheduled update to a current SOP. This will be agreed at the QMS Meeting. Clinical Trial Units (CTU)/Study groups are permitted to have their own SOPs and work procedures however must be compliant with JRMO SOPs. These SOPs are to be controlled, maintained, and reviewed in accordance with *SOP 29*. As part of the JRMO oversight each CTU/Study group is required to send an index of their SOPs (as per SOP 41; *JRMO Oversight of CTG or Study Specific SOPs*) with a statement of compliance to the JRMO's overarching SOPs every 6 months.
2.	QA Manager, Research Governance Operations Manager and designated Team Leader	**Training** The JRMO QMS requires that all JRMO staff maintain training records to confirm competency to perform tasks as stipulated by individual job descriptions. The JRMO requires completion of a comprehensive induction following employment. The JRMO training matrix specifies role specific training. It is the responsibility of the Line Manager/Team Leader to ensure training records are maintained in accordance with *SOP 34b; JRMO Staff Training and Induction* and review will take place on an annual basis through staff appraisal schemes. The JRMO QMS requires researchers working on Barts Health/Queen Mary studies to attend JRMO GCP training or have evidence of acceptable external training or an agreed external supplier, such as National Institute for Health Research (NIHR). Site specific training records are also required in accordance with *SOP 34a; Researcher*

		training and all personnel should be adequately trained prior to commencing work on the study.
3.	QA Manager and delegated QMS group member.	**JRMO and study Non-compliance** The JRMO QMS in accordance with *SOP 31; Non-Compliance* details the process for the management of research non-compliance to include: • Identification and reporting of non-compliances. • Reviewing severity and assessing need for escalation • Maintaining the non-compliance log to document each stage. • Identification of non-compliance trends The QA Manager will work with the GCP & Governance Managers or delegate to ensure all non-compliances are actioned and closed; and that all relevant documentation is filed in the JRMO sponsor oversight file. Ongoing events will be reviewed as part of the JRMO QMS meeting and escalated where appropriate.
4.	QA Manager, Research Governance Operations Manager and Senior GCP and Governance Manager	**Internal QMS review** Refers to the internal review of JRMO processes and procedures. This is separate to the audit schedule defined by the Clinical Research Auditor, documented in *SOP 22: Audits*. QA is an essential requirement of an established QMS to ensure confidence in the processes and procedures. Quality control measures are implemented to fulfil the quality assurance requirements. The JRMO Management team and QA manager have established quality objectives to outline the commitment to continued improvement (*Associated Document 1*). An internal QMS review schedule will be drafted annually to monitor and measure the quality objectives.
5.	QA Manager or delegate	**Management review** The QMS quality objectives will be reviewed as part of the scheduled QMS meetings and any non-compliance will be actioned appropriately from there. The quality objectives will be updated/amended based on non-compliance findings. The internal QMS review schedule will reflect these findings. Internal QMS review outside the remit of the agreed schedule may be necessary. Circumstances for such ad-hoc review may include the following but are by no means exclusive: • Implementation of new SOPs • Regulatory and legislative amendments/updates • User feedback Ad-hoc review will be brought forward by the QA Manager and discussed in the QMS meeting.

Change control.

Section	Change
All	Minor administrative changes throughout.
All	Review of all delegated responsibilities
Section 1	Removal of the structure and organisation section.
Section 2	Clarification on document storage through the QMS

List of appendices

No appendices included in the SOP.

List of associated documents

Document ref.	Document name
1	JRMO QMS Quality Objectives