

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.

The QMS is a centralised system which regulates the procedures relating to the Good Clinical Practice (GCP) and Research Governance, the Pre-award teams (Contracts and Costing) and some aspects of the Post-award teams of the JRMO for Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary) sponsored and hosted studies. This organised structure is designed to ensure compliance with study procedures across Queen Mary and Barts Health sites. Adhering to the QMS ensures that studies meet legislative requirements, including GCP, are conducted according to approved/regulated protocols and procedures, and foremost the wellbeing and protection of study participants.

Scope:

The QMS applies to all staff members actively involved in studies with both Queen Mary and Barts Health.

Definitions:

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*.

Abbreviations:	
Barts Health	Barts Health NHS Trust
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
JRMO	Joint Research Management Office
NIHR	National Institute for Health Research
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
Queen Mary	Queen Mary University of London
RG	Research Governance
SOP	Standard Operating Procedure
Relevant SOPs:	
<ul style="list-style-type: none"> SOP 22 Audits SOP 29 Document Control SOP 31 Non-Compliances SOP 34a Researcher Training SOP 34b JRMO Staff training and induction SOP 41 JRMO Oversight of CTG or Study Specific SOPs 	

General procedure and considerations		
<p>Overall responsibility of the JRMO QMS SOPs lies with the Senior Operations Manager (Pre-Award) and day to day oversight is delegated to the JRMO Governance Operations Manager and allocated Research Governance (RG) and GCP and Quality Assurance (QA) managers.</p> <p>All QMS SOPs are written in accordance with SOP 29: <i>Document control and creating, maintaining & distributing JRMO standard operating procedures</i></p> <p>The JRMO QMS has been subdivided into 6 categories:</p> <ol style="list-style-type: none"> 1. Organisation structure and responsibilities 2. Document Control 3. Training and assessment 4. Non-compliance management 5. Internal QMS review 6. Management review 		
SOP Text:		
	Responsibility	Activity
1.	Senior Operations Manager (Pre-Award) JRMO Governance	<p>Organisation structure and responsibilities</p> <p>The JRMO High-Level structure is located via the JRMO website; http://www.jrmo.org.uk/media/jrmo/docs/about-us/JRMO-organogram-high_level-Sept20.pdf</p>

	<p>Operations Manager</p> <p>RG and GCP Managers</p> <p>QA Manager</p>	<p>All services including points of contact, can be found on the JRMO website (http://www.jrmo.org.uk/media/jrmo/docs/about-us/JRMO-Service-Catalogue-Oct-2020.pdf)</p> <p>Roles and responsibilities for the QMS will be defined under each category.</p>
2.	<p>JRMO Governance Operations Manager</p> <p>QA Manager</p>	<p>Document control</p> <p>The secure management of documentation relating to the JRMO QMS is the responsibility of the Governance Operations Manager and maintained by the QA Manager. The QA manager is responsible for maintaining the list of current versions of controlled documents as identified by section operation managers.</p> <p>The JRMO QMS index provides a real-time inventory of all documents to include:</p> <ul style="list-style-type: none"> • Current Documents: SOP's, Associated Documents, Templates and Appendices • Documents under review • Superseded Documents <p>An up-to date inventory is also maintained for the following categories of documents:</p> <ul style="list-style-type: none"> • Archived generic JRMO and trial-related materials • Non-compliance index • Internal review reports • External Audit/Inspection Reports • Meeting minutes and correspondence <p>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.</p> <p>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.</p> <p>As part of the JRMO oversight each CTU/Study group is required to send an index of their SOPs (as per SOP 41; <i>JRMO Oversight of CTG or Study Specific SOPs</i>) with a statement of compliance to the JRMO's overarching SOPs every 6 months.</p>
3.	<p>Senior Operations Manager (Pre-Award)</p> <p>JRMO Governance Operations Manager</p> <p>RG and GCP Managers</p>	<p>Training</p> <p>The JRMO QMS requires that all JRMO staff maintain training records to confirm competency to perform tasks as stipulated by individual job descriptions.</p> <p>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 to ensure training records are maintained in accordance with SOP 34b; <i>JRMO Staff Training and Induction</i> and review will take place on an annual basis.</p>

	QA Manager	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; <i>Researcher training</i> and all personnel should be adequately trained prior to commencing work on the study.
4.	<p>Senior Operations Manager (Pre-Award)</p> <p>JRMO Governance Operations Manager</p> <p>RG and GCP Managers</p> <p>QA Manager</p>	<p>JRMO and study Non-compliance</p> <p>The JRMO QMS in accordance with SOP 31; <i>Non-Compliance</i> details the process for the management of research non-compliance to include:</p> <ul style="list-style-type: none"> • 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 <p>The QA Manager will work with the GCP & Governance Managers 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.</p>
5.	<p>Senior Operations Manager (Pre-Award)</p> <p>JRMO Governance Operations Manager</p> <p>RG and GCP Managers</p> <p>QA Manager</p>	<p>Internal QMS review</p> <p>QA is an essential requirement of an established QMS to ensure confidence in the processes and procedures. Quality control (QC) measures are implemented to fulfil the quality assurance requirements.</p> <p>The JRMO Management team and QA manager have established quality objectives to outline the commitment to continued improvement (Associated document 1).</p> <p>An internal QMS review schedule will be drafted annually to monitor and measure the quality objectives.</p>
6.	<p>Senior Operations Manager (Pre-Award)</p> <p>JRMO Governance Operations Manager</p> <p>RG and GCP Managers</p> <p>QA Manager</p>	<p>Management review</p> <p>The QMS quality objectives will be reviewed as part of the scheduled QMS meetings and any non-compliance will be actioned appropriately from there.</p> <p>The quality objectives will be updated/amended based on non-compliance findings. The internal QMS review schedule will reflect these findings.</p> <p>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:</p> <ul style="list-style-type: none"> • Implementation of new SOPs • Regulatory and legislative amendments/updates • User feedback <p>Ad-hoc review will be brought forward by the QA Manager and discussed in the QMS meeting.</p>

Change control

Section	Change
All	Minor administrative changes throughout.
Associated documents	Merging of AD1 and AD2

List of appendices

No appendices are included in the SOP

List of associated documents

Document ref.	Document name
1	JRMO QMS Quality Objectives