Joint Research Management Office Standard Operating Procedure for:			
JRMO Oversight of clinical trial groups and study specific SOPs			
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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 ensure oversight of SOPs developed by clinical trials units (CTUs) and clinical trials groups who coordinate Medicines and Healthcare products Regulatory Agency (MHRA)-regulated studies sponsored by Barts Health NHS Trust (Barts Health) or Queen Mary, University of London (Queen Mary).This SOP also describes methods to ensure compliance of these SOPs with JRMO SOPs.

Please note creation, maintenance and distribution of JRMO SOPs is detailed in SOP 29.

Scope:

This SOP is applicable to the JRMO Research Governance Operations Manager, JRMO Good Clinical Practice (GCP) team, and all staff within CTUs/clinical trials groups and individuals who coordinate Barts Health or Queen Mary sponsored MHRA-regulated studies.

Definitions:

CTU: For the purpose of this SOP, the term CTU refers to CTUs and Groups who coordinate studies on behalf of the sponsors.

SOPs: For the purpose of this SOP, the reference to SOPs will include the SOP itself and all supporting associated documentation.

Abbreviations:	
Barts Health	Barts Health NHS Trust
CI	Chief Investigator
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
QA	Quality Assurance
QMS	Quality Management System
Queen Mary	Queen Mary University of London
SOP	Standard Operating Procedure
Relevant SOPs:	
• SOP 29	Document control and creating, maintaining & distributing JRMO standard operating procedures

SOP Text:		
CTU/Clinical trial groups SOPs (generic SOPs)		
	Responsibility	**Activity**
1.	CTU/clinical trial groups	**Ensure all SOPs are compliant with JRMO SOPs.** The CTU/groups are responsible for the control, maintenance, and review of their SOPs. The CTU/groups are responsible for providing the JRMO Quality Assurance (QA) Manager with a full SOP index at 6 monthly intervals or following any changes. Each submission should be accompanied by a compliance statement by the group lead stating that the group's suite of SOPs complies with JRMO SOPs and/or highlighting any deviations. (*Associated Document 1 Compliance Statement)*
2.	JRMO QA Manager	**Acknowledge receipt of SOP index and statement of compliance.** Ensure any deviation highlighted is reviewed and logged on the JRMO non-compliance log. Perform internal review on a sample of CTU/groups SOPs in order to confirm compliance. This will be performed on a rolling basis as part of the Quality Management System (QMS) internal review program.
Deviations and Waivers		
The JRMO does not expect clinical trial groups or investigators the need to routinely deviate from the JRMO SOPs.		
3.	Chief Investigator (CI) and Clinical Trial Group lead	**Request waiver.** If any Investigator or clinical trial group lead feels that they have justification for deviating from a JRMO SOP, a waiver should be requested. Any requests for an SOP waiver should be sent in writing to the JRMO QA Manager and the study GCP & Governance Manager for discussion.

		The waiver must not be actioned prior to the JRMO granting written confirmation that this is acceptable.
4.	JRMO QA Manager	**Acknowledge and record deviation/waiver.** The JRMO QA Manager will acknowledge any SOP waiver requests within 2 working days and record all requests on the JRMO non-compliance log All requests will be discussed and reviewed by JRMO QA Manager and study GCP and Governance Manager. All requests will be proportionally assessed in respect to the risk category of the study and may require further discussion through the non-compliance meeting group. If the waiver is accepted, duration and scope should also be assigned (for example, for study 1234, for duration of study). The JRMO QA Manager will record the outcome on the JRMO non-compliance log.
		Study specific SOPs
5.	CI and Trial Coordinators	**Write and create any study-specific SOPs.** All SOPs should be compliant with JRMO SOPs. The use of the JRMO template (SOP 29 Associated Document 1) is suggested but not mandatory. When writing an SOP, the following fields/items are necessary: - SOP name - SOP number/reference code - Version number - Effective date - Review date - Author, reviewers and authorisation personnel - Scope - A sequential list of duties and procedures that should be completed, with the name of the role responsible for them - Change control summary (between versions) - A footer containing SOP number, version, page numbers - A statement that the SOP is a controlled document (and should not be reproduced without permission) Non-essential elements that may be incorporated include: - SOP objectives - Abbreviations and definitions - Appendices for relevant documents that are relevant to the SOP but do not need to be in the SOP itself - Watermark - Details of the role to whom the SOP should be issued. - Evidence that of SOP distribution. Evidence of who has read, and been trained in the SOP. Ideally, this would be held by the individual but can be associated with the SOP. The CI is responsible for the control, maintenance, and review of their study-specific SOPs. When requested or if a study team is uncertain of the content, a draft should be sent to the study GCP & Governance Manager for review. A full index of study-specific SOPs should be provided to the JRMO as part of the monitoring plan and each submission should be accompanied by a statement

		by the CI stating that their SOPs comply with JRMO SOPs and/or highlighting any deviations.
6.	GCP & Governance Managers	**Prior to issuing confirmation of sponsorship and permission to activate sites, the GCP & Governance Managers will work with the CI and study team to ensure that all relevant SOPs are in place** (including any necessary generic, as well as study-specific, SOPs). GCP & Governance Managers can, if felt necessary, be initially sent all study-specific SOP drafts for review.
7.	CI and Study teams	**SOPs should be reviewed for compliance with JRMO SOPs as well as compliance with all applicable guidelines, regulations and policies.**
8.	Clinical Trial Monitors	**Monitors must document any existing study specific SOPs at each monitoring visit.**

Change control

This section outlines changes from version **4.0** to version **5.0**

Section changed	Summary and description of changes
All	General administrative changes

List of appendices

There are no appendices for this SOP.

List of associated documents

Document ref.	Document name
Associated document 1	Statement of compliance report