Standard Operating Procedures (SOP) for:			
JRMO Oversight of Clinical Trial Group and Study Specific SOPs			
SOP Number:	**41**	Version Number:	**3.0**
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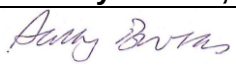
Signature	
Date	**22/8/16**

Purpose and Objective:
To document the process for oversight by the Joint Research Management Office (JRMO) of Clinical Trial Unit SOPs, and SOPs of groups which coordinate BH or QMUL sponsored CTIMPs, and to ensure compliance of these with JRMO SOPs. Please note Creation, Maintenance and Distribution of JRMO SOPs is detailed in SOP 30.
Scope:
This SOP applies to the R&D Governance Operations Manger, the GCP team, and all staff within Clinical Trial Units (CTU) /groups and individuals which coordinate BH or QMUL sponsored CTIMP studies.

	Responsibility	Activity
		Clinical Trial Groups SOPs (generic SOPs)
1.	Clinical Trial Units/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 supplying the JRMO QA Manager with a full SOP index at 6 monthly intervals or following any changes. Each submission should be accompanied by a statement by the group lead stating that the group's suite of SOPs comply with JRMO SOPs and/or highlighting any deviations.
2.	JRMO QA Manager	**Acknowledge receipt of SOP index and statement of compliance.** To ensure any deviation highlighted is reviewed and logged on the JRMO Deviations Log. To perform internal audits on a sample of CTU/groups SOPs in order to confirm compliance. This will be performed on a rolling basis as part of the QMS internal audit program
		Deviations and Waivers
The JRMO does not expect Clinical Trial Groups or Investigators to need to routinely deviate from the JRMO SOPs.		
3.	Chief Investigator and Clinical Trial Group lead	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 Manager for discussion. The waiver must not be actioned prior to the JRMO granting written confirmation that this is acceptable.
4.	JRMO	The JRMO QA Manager will acknowledge any SOP waiver requests within 2 working days and record all requests on the Deviations and Waivers Log (located in the JRMO shared file/QMS deviations).

		All requests will be discussed and reviewed by QA Manager and study GCP Manager and the decision made will be communicated to the Chief Investigator or Clinical Trial Group lead within 10 working days. 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 Deviations and Waivers Log (located in the JRMO shared file/ QMS deviations).
		Study Specific SOPs
5.	Chief Investigators and Trial Coordinators	**Write and create any study-specific SOPs.** All SOPs should be compliant with JRMO SOPs. The use of the JRMO template is suggested but not mandatory. When writing an SOP, the following fields/items are necessary: - SOP name (stating what the SOP is about) - SOP number/reference code - Version number - Effective date - Review date - Author and reviewers - Authorisation (name/role, date, signature) - 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) Optional extras that would also be desirable (but are not essential): - 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 - Diagrammatic representation of the duties and procedures (e.g. flow chart) - 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 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.	Governance and GCP Managers	**Prior to issuing Green Light to recruit**, **the GCP 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). Governance and GCP 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.	Study Monitors	**Monitors must document any existing study specific SOPs at each monitoring visit.**

Change Control

This section outlines changes from version 2.0 to version 3.0 of this SOP.

Summary and description of change (detail section changed if applicable)
Routine review and correction of grammar where applicable. QA Manager responsibilities added.

List of Associated Documents *(these are standalone documents)*

	Document name
Associated Document 1	Statement of Compliance Report