

Joint Research Management Office Standard Operating Procedure for:

Location Agreements for Barts Health, Queen Mary Sponsored Studies

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Authorship & Review:

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Purpose:

To map the process for the preparation of location agreements where Queen Mary University of London (Queen Mary) or Barts Health NHS Trust (Barts Health) are the sponsor of a research study.

Scope:

This Standard Operating Procedure (SOP) applies to all Barts Health/Queen Mary sponsored research studies where participating locations are in the UK or outside the UK.

This SOP applies to all staff in the Joint Research Management Office (JRMO) and describes the JRMO procedure, in response to receiving a formal sponsorship request from a Coordinating Investigator (CI) or delegate, for granting sponsorship including the review process and sponsorship confirmation.

To be used for the contracting of location agreements when Queen Mary or Barts Health are Sponsoring a clinical trial and incorporating the roles of the Good Clinical Practice (GCP) and Governance Manager, Governance Team and Contracts Officers.

For the purposes of this SOP:

JRMO designated person who can sign Medicines and Healthcare products Regulatory Agency (MHRA) regulated studies: Contacts include Director of Research Services, Head of Pre-Award and Barts Health Costing & Contracts Manager.

JRMO designated person who can sign Interventional and Research studies: Contacts include Director of Research Services, and Head of Pre-Award and Barts Health Costing & Contracts Manager. Operations Manager Pre-Award.

Abbreviations:		
Barts Health	Barts Health NHS Trust	
CI	Coordinating Investigator	
GCP	Good Clinical Practice	
IMP	Investigational Medicinal Product	
JRMO	Joint Research Management Office	
MHRA	Medicines and Healthcare products Regulatory Agency	
NIHR	National Institute for Health Research	
Queen Mary	Queen Mary University of London	
SOP Text		
Responsibility		Activity
Preparation for Sponsorship with conditions (Study is in set-up after funding has been awarded).		
1.	Pre-Award Team	MHRA Regulated Studies Only Hold the kick-off Meeting to identify Research locations and primary contracts. The purpose of the Kick-Off Meeting is for the JRMO and CI to identify all contracts required before the JRMO can issue Confirmation of Sponsorship . This includes the use of Nationally agreed model templates (Non-Commercial) and the drafting of applicable schedules. During the meeting, identify the number and names of Research locations (including countries and national coordinating centres). Document this in the Costing and Contract Checklist in accordance with SOP 7a Contracting for MHRA Regulated Studies and SOP 11b Sponsorship for MHRA Regulated Studies (Process for JRMO Staff). During the meeting, it is the Contracts Officer's responsibility to establish whether any of the following are being provided to the research locations, e.g.: • Consumables, e.g. tissue kits, equipment, device/s being supplied to the site • Funding • Investigational Medicinal Product (IMP) Or whether the locations will be required to provide a service, e.g.: • Laboratory (storage, analysis) • Pharmacy (labelling etc.) • Device maintenance See SOP 11b Sponsorship for MHRA Regulated Studies (Process for JRMO Staff) and SOPa 7 Associated Document 1: JRMO Contract Checklist for Meeting Guidance. All studies covered by the scope of this SOP must be fully costed (this must include a full NHS costing where applicable) by a JRMO costing officer. Funding gaps that were identified should be flagged to CI and GCP and Governance Managers and/or underwritten. It is the Costing and Contract Officers responsibility to provide written confirmation to the GCP and Governance Manager, Research Management and Governance Officer that the template location agreement has been agreed in principle by the

		CI. At the same time confirm that the primary contracts (funding and IMP supply) are in progress with terms agreed, or fully executed.
2.	Governance Team	MHRA Regulated Studies only – Sponsorship with conditions. Request confirmation in writing from Costing and Contracts that location agreement and all other contracts have been agreed in principle before issuing Sponsorship with Conditions (see SOP 11b – Sponsorship of MHRA regulated studies – Process for JRMO Staff).
3.	Governance Team	Sponsored Interventional and Research Studies Only. During the sponsorship with conditions review, identify if the sponsor (Queen Mary or Barts Health) is distributing any of the following to research location: funds, devices or equipment (including loaning/gifting). Notify the Contract Officer that a template location agreement will be required. See SOP 12b –Sponsorship of Interventional and Research Studies– Guide for JRMO Staff for guidance.
4.	Pre-Award Team	Ensure Contracts and all required documents are received by the Governance Officer.
5.	Pre-Award Team	Sponsored Interventional and Research Studies Only. Assess and document if there is a need for a written agreement separate to the statement of activities. A separate agreement is needed if: • Locations are being paid. • Equipment is being provided or loaned to locations. • Consumables are being provided to locations (If applicable)
6.	Local Investigator	The Study Team, in liaison with the National Institute for Health and Care Research AcoRD Specialist, undertakes the following: • Identifies the attribution of location activities in line with the AcoRD guidance. • Prepare an Health Research Authority Schedule of Events for each site type. • Notifies Governance Office and Contracts Officer of location(s) and activity.
7.	CI	For all study types: Prepare all location-specific documents. • Prepare locations agreements for all participant NHS or non-NHS recruiting organisations. • Ensure the site agreement identifies the CI as outlined in the ethics application, and the location Local Investigator . • Ensure that the location agreement identifies the responsibilities of the Sponsor and any devolved location responsibilities from the Sponsor. Any queries should be discussed with the GCP or Governance team. • Ensure that the location agreement details clear deliverables in line with the protocol and other agreements, as applicable. • Ensure that the location agreement includes copies of the most up to date version of the protocol. Where there is any doubt regarding the latest

		version refer to the Governance Officer (Interventional and Research Studies) or GCP team (MHRA Regulated Studies) for confirmation. Ensure that the location agreement gives financial breakdown and a breakdown of the supply of materials, consumables, drugs etc., if applicable.
8.	Pre-Award Team	MHRA Regulated studies only Request GCP and Governance Manager's review of the delegation of responsibilities, at the end of template location agreements before issuing them to locations.
9.	GCP Team/Governance Team	MHRA Regulated studies only Review the delegation of responsibilities in location agreement template to ensure that schedule 2 'Division of Responsibilities' complies with the protocol, applicable regulations, Conditions of Sponsorship, delegation of responsibilities from the Sponsor to CI (and from CI to Clinical Trial Unit/National Coordinating Centre) to the Local Investigator. The following areas should be reviewed in detail: - Adverse Events - Regulatory compliance for MHRA Regulated Studies, including right to monitor, audit and inspect. - Reporting serious breaches - IMP (including pharmacy role i.e. labelling) - Other responsibilities' i.e. labs, imaging
10.	Pre-Award Team	Conduct final contract review and pass to Head of Pre-Award for authorisation and signature. Once all parties have agreed terms, finalise and conduct a final check of contract. Only after a final check should contracts be passed to the Head of Pre-Award, Director of Research Services or other designated person within the JRMO for signature.
11.	Signatory	Review, sign and date the final contract. Pass contract back to the Costing & Contracts Team for circulation, final processing and filing.
12.	Pre-Award Team	Process fully executed copy of contract. Ensure all parties to the contract have signed and dated. Ensure the effective date is completed where relevant. Scan contract and save on contract shared drive in JRMO and upload an electronic copy to the project in Worktribe Documents and file hard copy in Contracts file. Ensure contract database and MHRA Regulates Study, contracts excel spreadsheet are updated. Email a copy to the Trial Coordinator.

		Please see JRMO Post Award Working Practices on Implementation of a Grant; all contracts must be fully executed prior to issuing Sponsor confirmation of sponsorship. Prepare and maintain contents page for all contracts in hard copy file held in JRMO.
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Change control

This section outlines changes from version 6.0 to version 7.0

Section changed	Summary and description of changes
Throughout	Update to job titles and responsibilities
Throughout	General administrative changes
Throughout	Update to terminology in line with ICH E6 R3

Governance Officer provides **Costing and Contract Officer** with a list of trial locations (as detailed by Trial Team, in liaison with the NIHR AcoRD Specialist).

Costing and Contracts Officer
Prepare all location agreements.

Contracts/Costings Officer checks:

- ☐ PI/CI
Sponsor Vs location responsibilities
- ☐ Agreement schedules in line with protocol,*
- ☐ Financial breakdown,
- ☐ And materials / kit provided to sites
- ☐ IP

* Working with GCP manager (MHRA regulated studies)

Location agreements are signed by **Director of Research Services**, or Designated Authorised signatory

Contracts/Costings Officer
Returns signed contracts and distributes to the Research sites Saves a copy in the JRMO

Research Management and Governance Officer informs the Contracts/Costings Team about new locations/modifications to location responsibilities.