Joint Research Management Office Standard Operating Procedure for:			
Contracting For MHRA Regulated Studies			
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Purpose:

To map the process for the preparation of contracts for MHRA Regulated studies.

Scope:

To be used for contracts for Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary). This Standard Operating Procedure (SOP) is mandatory for all sections.

For this SOP, the definition of Contracted Partner could be considered to be, but not limited to:

- Funder
- Drug Supplier
- Device Supplier
- Laboratory
- Data Management Company

For the purposes of this SOP, the terms Chief Investigator (CI) and Principal Investigator (PI) are used in their governance context meaning CI is overall study investigator whilst PI is responsible at a site level.

Abbreviations:	
Barts Health	Barts Health NHS Trust
CI	Chief Investigator
JRMO	Joint Research Management Office

PI	Principal Investigator
Queen Mary	Queen Mary University of London
SOP	Standard Operating Procedure
WT	Worktribe Research Management System

Relevant SOPs:

SOP 7b Contracting for Interventional and Research
SOP 11b Barts Health/Queen Mary sponsorship of MHRA-regulated studies: Process for JRMO staff
SOP 40 Vendor Assessment

SOP Text:

	Responsibility	Activity
1.	CI	**Initial Contact** The CI should approach the Joint Research Management Office (JRMO) to inform them of possible collaboration or service with an external organisation. This may come in through a number of routes within the JRMO – Governance, Pre Award, Post Award or an Individual.
2.	Contracts Officer	**Attend the early engagement meeting where relevant and Sponsor Kick Off Meeting** See SOP 11b Barts Health/Queen Mary sponsorship of MHRA-regulated studies: Process for JRMO staff for meeting guidance. Liaise with the Good Clinical Practice (GCP) Manager associated with the study. Contracts Officer is responsible for creating and completing the contract checklist (see Associated Document 1) and sending a draft to the GCP manager and CI for confirmation that all contracts had been identified. A draft contract checklist is saved on the shared drive in the relevant SharePoint MHRA regulated study folder under the relevant CI. The allocated Contracts team member is responsible for maintaining the Contract Checklist. Where appropriate see SOP 40 Vendor assessment for guidance on organisational policy and procurement.
3.	Contracts Officer	**Initiate Worktribe Contract ID** Set up a unique WT ID giving access to CI/GCP Manager/Contracts Manager as appropriate
4.	Contracts Officer	**Commence contract negotiations in accordance with SOP 7b** Ensure that study has been costed on Worktribe and liaise with costings officer as necessary throughout contract negotiation process. Log and update progress on Worktribe.

5.	Contracts Officer	**Identify which organisations template should be used.** Establish if JRMO template or other contracting party's template should be used as starting point of contract negotiations.
6.	CI	**Inform external vendor representative of JRMO point of contact**. Ensure that any company representative is made aware of the JRMO point of contact for all costing and contractual negotiations who will liaise on behalf of the CI and relevant organisation.
7.	Contracts Officer	**Negotiate the price , terms and milestones.** Negotiate the price and terms with funder or contracted partner. Terms and delegation of duties will be discussed and reviewed by the GCP manager where relevant to ensure oversight of regulatory aspects, where the terms and duties are negotiable. Due notice should be paid to Barts Health or Queen Mary insurance policy and scope and if necessary prepare a draft contract using the JRMO's contract suite of templates or review contract sent by provider ensuring all governance, IP, financial and indemnity issues are addressed. Ensure appropriate governing law is inserted to ensure appropriate action can be taken should the need arise. If relevant, work in liaison with GCP manager and the Clinical Trial Coordinator to ensure any milestones are viable and deliverable. It is the Contract Officer's responsibility to provide confirmation to the GCP Manager, and Governance Officer that the primary contracts (funding and IMP supply) are in progress with terms agreed, or fully executed).
8.	GCP manager	**Review draft contracts.** Where appropriate review draft contracts for adherence to GCP and the UK regulations. All funding milestones should be discussed with the CI, Clinical Trial Coordinator, GCP manager and Contracts Manager to ensure that unrealistic dates are not set.
9.	Contract Officer	**Faculty/School/Division authorisation** Prior to any contract being allocated to the authorised signatory for final signature, where there is a financial project set-up within WT the officer must ensure that the workflow authorisation has been completed and approved. Where there is no financial element the officer should request authorisation from the faculty or school authoriser via the WT system. This should be recorded within the system
10.	Contracts Officer	**Conduct final contract review and pass to relevant authorised signatory for signature.**
11.	Operations Manager Pre Award, Director of Research and Development,	**Check and sign the final contract before passing back to the Contracts Officer for distribution.** Officer should alert authorised signatory of request for signature and be in a position to provide any information as required.

	Associate Director of Operations or Designated signatory	The signatory should check WT / Edge or other systems to ensure all is in order prior to signing.
12.	**Contracts Officer**	**Process fully executed copy of contract.** Ensure full execution of contract. Scan contract and save on Worktribe, shared drive in JRMO and upload an electronic copy to EDGE. Ensure MHRA Regulated contracts and vendor excel spreadsheets are updated. Email a copy to the Trial Coordinator where relevant. All contracts must be fully executed prior to issuing Sponsor confirmation of sponsorship with permissions to activate sites. Update Contracts Checklist where relevant.
13.	Contracts Officer	**Attend the Final Governance Meeting.** Attend Final Governance meeting (as arranged by the GCP manager) to ensure all external vendors are identified and clearly summarised on the Contracts Checklist**.**
14.	Contracts Team	**Finalise the Contracts Checklist.** Following the Final Governance meeting the Contracts Checklist should be completed fully and sent to the CI for signature. Signed copy of Contract Checklist should be filed within JRMO Sponsor oversight files. A scanned copy should be saved in EDGE, Worktribe and the contract shared drive. Inform the GCP Manager and Governance Officer once the Contract Checklist is complete and signed by CI, and send a scanned copy.

Change control

This section outlines changes from version to version

Section changed	Summary and description of changes
All	Administrative corrections throughout and to separate out MHRA regulated studies from Interventional and Research studies

List of appendices

There are no appendices associated with this SOP.

List of associated documents

Document ref.	Document name
Associated Document 1	Contract Checklist for MHRA regulated studies