Joint Research Management Office Standard Operating Procedure for:			
Site Agreements for Barts Health, Queen Mary Sponsored Studies			
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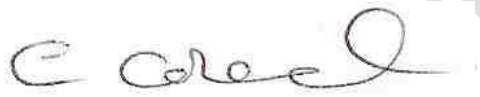
Authorship & Review:	
Author:	Gerry Collins – Head of Costing & contracts
Reviewer:	Anam Hoque – Costing & Contracts Manager Barts Health
Reviewer:	Jason Terranova – Senior Costing & contracts Officer

Authorisation:			
Name/Position:	Coleen Colechin, Senior Operations Manager (Pre-Award)		
Signature:		**Date:**	06.11.2023

Purpose:
To map the process for the preparation of site 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 sites 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 Chief Investigator (CI) or delegate, for granting sponsorship including the review process and sponsorship confirmation. To be used for the contracting of site 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, JRMO Amendments Officer and Contracts Officers. For the purposes of this SOP: JRMO designated person who can sign MHRA regulated studies: Contacts include Director of Research Services and Operations Manager Pre-Award. JRMO designated person who can sign Interventional and Research studies: Contacts include Director of Research Services and Operations Manager Pre-Award.

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Abbreviations:	
Barts Health	Barts Health NHS Trust
CI	Chief Investigator
JRMO	Joint Research Management Office
NIHR	National Institute for Health Research
OID	Organisation Information Document
PI	Principal Investigator
Queen Mary	Queen Mary University of London
R&D	Research & Development
RM	Research Management
SoECAT	Schedule of Events Cost Attribution Template
UK	United Kingdom

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 Sites 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 Sites (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 sites, e.g.: • Consumables, e.g. tissue kits, equipment, device/s being supplied to the site • Funding • Investigational Medicinal Product (IMP) Or whether the sites 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 *SOP 7 Associated Document 2: 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 site agreement has been agreed in principle by the CI. At

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		the same time confirm that the primary contracts (funding and IMP supply) are in progress with terms agreed, or fully executed.
2.	Pre-Award Team	**MHRA Regulated Studies only – Sponsorship with conditions.** Request confirmation in writing from Costing and Contracts that site 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 Provisional sponsorship review, identify if the sponsor (Queen Mary or Barts Health) is distributing any of the following to research sites: funds, devices or equipment (including loaning/gifting). Notify the Contract Officer that a template site agreement will be required. See *SOP 12b –Sponsorship of Interventional and Research Studies– Guide for JRMO Staff* for guidance.
4.	Governance 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: • Sites are being paid. • Equipment is being provided or loaned to sites. • Consumables are being provided to sites
6.	PI	**The Study Team, in liaison with the NIHR AcoRD Specialist, undertakes the following:** • Identifies the attribution of site activities in line with the AcoRD guidance. • Prepare an HRA Schedule of Events for each site type. • Notifies Governance Office and Contracts Officer of site(s) and activity.
7.	CI	**For all study types: Prepare all site-specific documents**. • Prepare site 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 site PI. • Ensure that the site agreement identifies the responsibilities of the Sponsor and any devolved site responsibilities from the Sponsor. Any queries should be discussed with the GCP or Governance team. • Ensure that the site agreement details clear deliverables in line with the protocol and other agreements, as applicable. • Ensure that the site 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.

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		• Ensure that the site 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 Manager's review of the delegation of responsibilities, at the end of template site agreements before issuing them to sites
9.	Governance Team	**MHRA Regulated studies only** Review the delegation of responsibilities in site 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 CTU/NCC) to the PI. 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 Pre-Award Senior Operations Manager 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 Senior Operations Manager 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 ReDA 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.

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		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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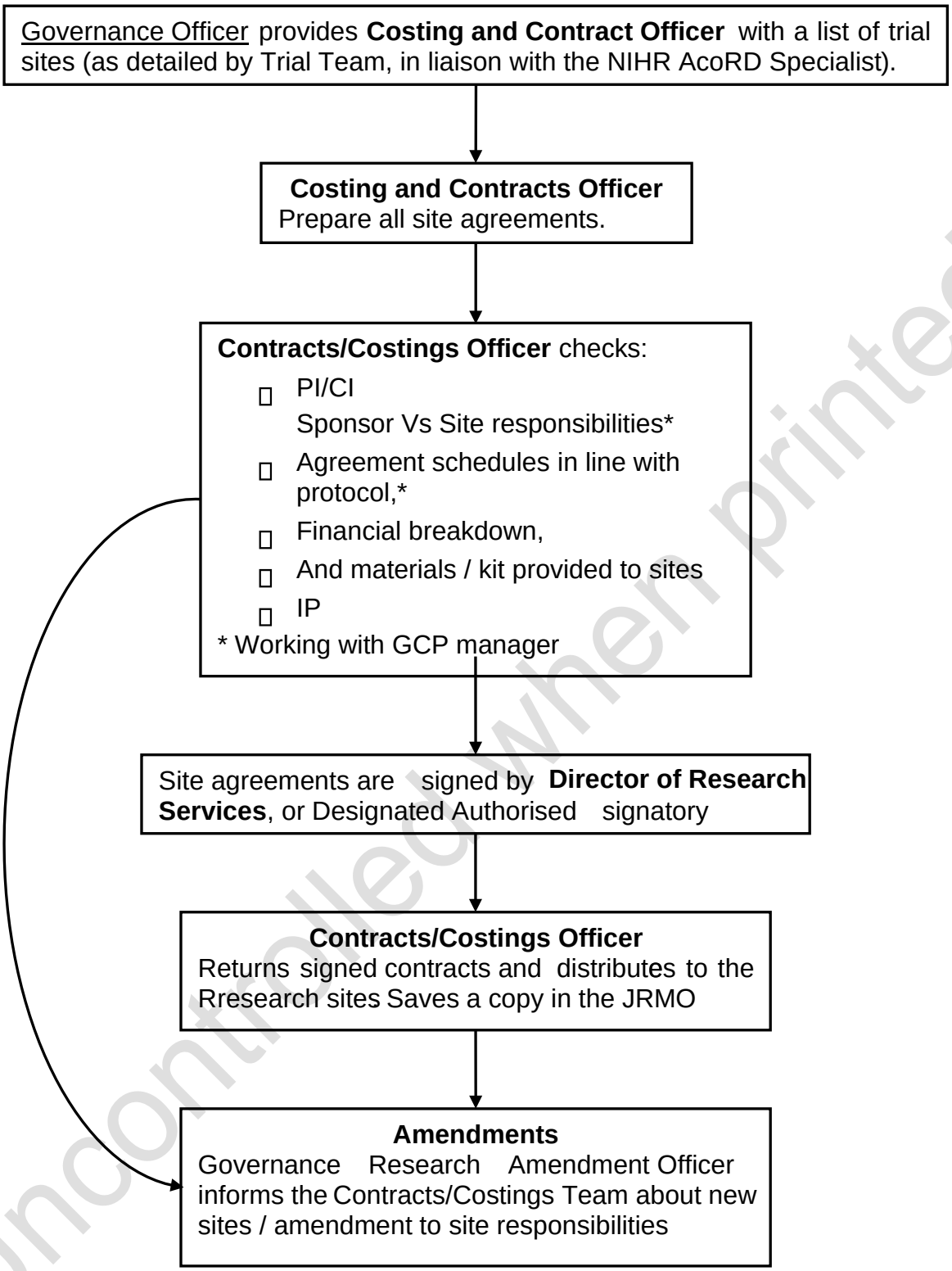

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