Standard Operating Procedures (SOP) for:			
Site Agreements for BH, QMUL Sponsored Studies			
SOP Number:	**08**	Version Number:	**5.0**
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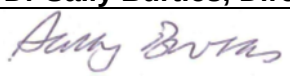
Signature	
Date	**19/12/2016**

Purpose and Objective:

To map the process for the preparation of site agreements where QMUL or Barts Health NHS Trust are the sponsor of a research study.

Scope:

To be used for the contracting of site agreements when QMUL or Barts Health NHS Trust are Sponsoring a clinical trial and incorporating the roles of the GCP Manager, JRMO Amendments Officer and Contracts Officers.

For the purposes of this SOP:

- JRMO designated person who can sign CTIMP Contacts include Director of Research Services and Operations Manager Pre Award.
- JRMO designated person who can sign Non-CTIMP Contacts include Director of Research Services and Operations Manager Pre Award.

Abbreviations:

ATMP	Advance Therapy of Medicinal Product
BH	Barts Health NHS Trust
JRMO	Joint Research Management Office
QMUL	Queen Mary University of London
CTIMP	Clinical Trial of Investigational Medicinal Products
CI	Chief Investigator
NCC	National Coordinating Centre
PI	Principal Investigator
CTU	Clinical Trials Unit

Definitions *(if needed)*:

Site: For purposes of this SOP a site is an NHS Trust or Non-NHS organization that is, as a minimum, recruiting participants onto the research study.

Fully Executed (contract): A contract which is fully signed and dated by all parties.

Relevant SOPs:

SOP 8 – Site Agreements for BH, QMUL Sponsored Studies

SOP 11a – BH/QMUL Sponsorship of CTIMPs, ATMPs and Clinical Trials of Non-CE Marked Medicinal Devices – Process for Researchers

SOP 11b – BH/QMUL Sponsorship of CTIMPs, ATMPs and Clinical Trials of Non-CE Marked Medicinal Devices – Process for JRMO Staff

SOP 17a – Process for JRMO - Amendments for Sponsored Studies

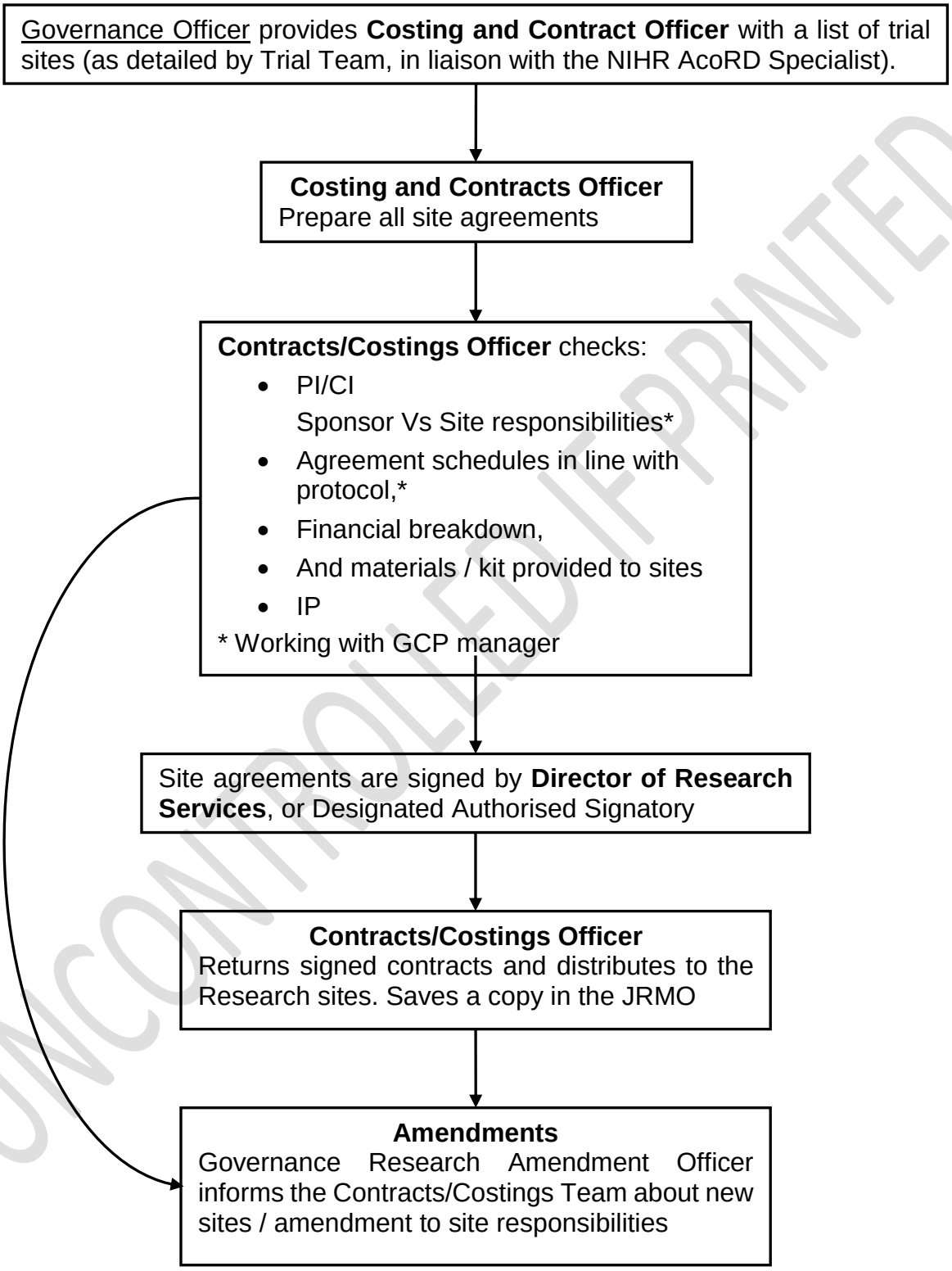
SOP Text:		
	Responsibility:	Activity:
Preparation for Provisional Sponsorship (Study is in set-up after funding has been awarded).		
1.	Contract Officer	**CTIMPs Only** **Hold the Kick-off Meeting to identify Research Sites and primary contracts.** The purpose of the Kick-Off Meeting is for the JRMO and CI to identify all contracts required before the JRMO can issue the Final Declaration 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 7 - Costing and contracts* and *SOP 11b – Sponsorship of CTIMPs – 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 • IMP Or whether the sites will be required to provide a service, e.g.: • Lab (storage, analysis) • Pharmacy (labelling etc.) • Device maintenance See *SOP 11b – Sponsorship of CTIMPs – Process for JRMO Staff*, and *Associated Document 2: JRMO Contract Checklist for Meeting Guidance*. All trials 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 managers and/or underwritten. It is the Costing and Contract Officers responsibility to provide written confirmation to the GCP Manager, Governance Officer that the template site 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 Officer	**CTIMPs only – Provisional Approval.** Request confirmation in writing from Costing and Contracts that site agreement and all other contracts have been agreed in principle before issuing Provisional Sponsorship Approval (see *SOP 11b – Sponsorship of CTIMPs – Process for JRMO Staff*).
3.	Governance Officer	**Sponsored Non-CTIMPs only.** During the Provisional sponsorship review, identify if the sponsor (QMUL or BH) 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 – BH/QMUL Sponsorship of Non-CTIMPs – Guide for JRMO Staff* for guidance.
4.	Governance Officer	**Ensure Contracts and all required documents are received by the Governance Officer.**

5.	Contracts Officer	**Sponsored Non-CTIMPs 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.	Trial Team and NIHR AcoRD Specialist	**The Trial 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.	Contracts Officer	**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 (non-CTIMP studies) or GCP team (CTIMPs) for confirmation. • Ensure that the site agreement gives financial breakdown and a breakdown of the supply of materials, consumables, drugs etc., if applicable. CTIMPs only: as a reference, consumables will be documented in the Contract Checklist – see *SOP 7 Associated Document: JRMO Contract Checklist*.
8.	Contracts Officer	**CTIMPs, ATMPs and Medical Device trials only.** Request GCP Manager's review of the delegation of responsibilities, at the end of template site agreements before issuing them to sites.
9.	GCP Manager	**CTIMPs, ATMPs and Medical Device trials 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 CTIMPs, including right to monitor, audit and inspect • Reporting serious breaches • IMP (including pharmacy role i.e. labelling) • 'Other responsibilities' i.e. labs, imaging

10.	Costing and Contracts Team	**Conduct final contract review and pass to Pre-Award 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 Operations Manager Pre Award, Director of Research Services or other designated person within the JRMO for signature.
11.	Operations Manager Pre Award or Designated Authorised signatory.	**Review, sign and date the final contract.** Pass contract back to the Costing & Contracts Team for circulation, final processing and filing.
12.	Contracts officer	**Process fully executed copy of contract.** Ensure all parties to the contract have signed (wet ink signature is needed for all CTIMPS) 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 CTIMP 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 green light. Prepare and maintain contents page for all contracts in hard copy file held in JRMO.
Ongoing Site Contract Management		
13.	Amendments Officer	**Amendment Officer needs to ensure that Contracts Officers are updated about inclusion of additional sites.** During the course of the study, provide the Contracts Officers with a list of ongoing sites for any study Sponsored by QMUL or Barts Health that has an amendment to include additional sites. See *SOP 17a – Process for JRMO – Amendments for Sponsored Studies* for further details.
14.	Contracts Officer	**Draft and distribute additional site agreements.** Follow steps 7-12 above.

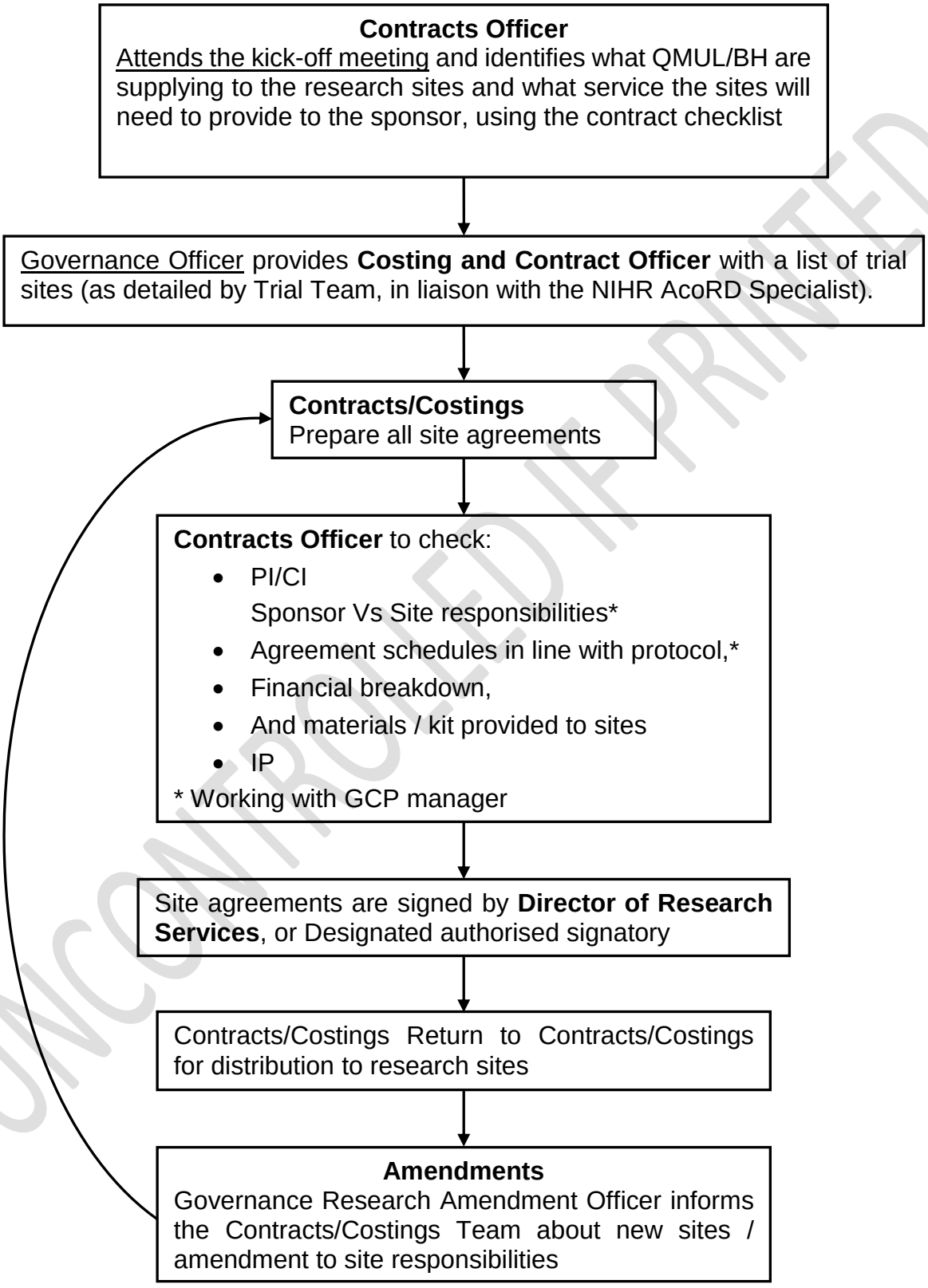
FLOW CHART:

NON-CTIMPs



FLOW CHART:

QMUL/ BH Sponsored CTIMPs



Change Control

This section outlines changed from version 4.0 to version 5.0.

Section Changed	Summary and description of change
Entire Document	Whole document re-write. Additional responsibilities for CTIMPs added. Addition of flow-chart for CTIMP & Non-CTIMP. Addition of references to relevant HRA process/documentation.
Version Control	During the editing process of v5, multiple unpublished drafts were made (v5.1 to 5.6). For the sake of continuity, and to avoid confusion, this final release version was renumbered **v5.0**.