Joint Research Management Office Standard Operating Procedure for:			
Barts Health NHS Trust/Queen Mary University of London sponsorship of MHRA-regulated studies: Process for researchers			
SOP Number:	**11a**	Version Number:	**4.0**
Effective Date:	**15th May 2026**	Review date:	**15th May 2029**

Authorship:		**Signature and Date:**
Author:	Nadia Rahman GCP and Governance Manager	Nadia Rahman Digitally signed by Nadia Rahman Date: 2026.04.29 14:39:44 +01'00'
Reviewer:	Rebecca Newton Senior GCP and Compliance Manager	Rebecca Newton Digitally signed by Rebecca Newton Date: 2026.04.29 14:41:18 +01'00'

Authorisation:		**Signature & Date:**
Name/Position:	Mays Jawad, Associate Director of Research Quality	Dr Mays Jawad Digitally signed by Dr Mays Jawad Date: 2026.04.29 15:07:48 +01'00'

Purpose and Scope:

This Standard Operating Procedure (SOP) is applicable to Coordinating Investigators (CI) who wish to have Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary) act as sponsor for an Medicines and Healthcare products Regulatory Agency (MHRA)-regulated study and the Joint Research Management Office (JRMO) staff involved in the process for granting Barts Health or Queen Mary sponsorship.

It describes the actions required by the CI to formally request sponsorship and the JRMO procedure for granting sponsorship including the review process, sponsorship with conditions and confirmation of sponsorship.

The CI's substantive employer will be the sponsor organisation for MHRA regulated studies. Also, for Barts Health and Queen Mary single location sponsored MHRA regulated studies, CI and local Investigator will be the same person unless there are agreed exceptional circumstances.

For sponsorship of MHRA-regulated Clinical Investigations, please refer to *SOP 9 Sponsorship of Clinical Investigations and other MHRA-regulated Medical Device Studies*

Abbreviations:

ATIMP	Advanced Therapy Investigational Medicinal Products
Barts Health	Barts Health NHS Trust
CI	Coordinating Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
GCP	Good Clinical Practice

FIH	First in Human
HRA	Health Research Authority
IMP	Investigational Medicinal Product
ISRCTN	International Standard Registered Clinical/social study Number
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
RGS	Research Governance Specialist
SOG	Sponsor Oversight Group
SOP	Standard Operating Procedure
TMF	Trial Master File

SOP Text:		
	Responsibility	**Activity**
1.	CI	**Categorise the Study** If there is any ambiguity as to whether a study is a MHRA-regulated study, the CI should discuss this with the JRMO Good Clinical Practice (GCP) and Governance Manager. The CI should consider if the study uses any of the following: • Drugs. • Vitamins. • Nutritional supplements. • Food supplements. • Devices that deliver drugs e.g., stents. • Non-CE marked devices • Probiotics. • Imaging tracers. Not all First in Human research / Advanced Therapy Investigational Medicinal Products (ATIMP) Trials can be sponsored by Queen Mary and/or Barts Health, so these studies should be flagged to GCP team as early as possible. It is the CI's responsibility to comply with the applicable regulations for MHRA-regulated studies or revise the protocol or grant proposal so that it is no longer classified as a MHRA-regulated study.
2.	CI	**Work with the JRMO to obtain an accurate cost for the study.** The CI is responsible for ensuring that their study is accurately and realistically costed in the formative stages to ensure that it has adequate funding to be deliverable, successful, and compliant.

		The CI should discuss the proposed study with the JRMO GCP and Governance Managers as early as possible, i.e., at the funding application stage so that advice on the resources required in a funding application can be included (See *Associated Document 1 Costing MHRA regulated studies* for further guidance). The JRMO cannot guarantee the approval of any sponsorship application for studies that are considered to have insufficient funds to support the study design or its management. Before committing to milestones with funders, the CI should consult with the GCP and Governance Manager to ensure deadlines for Research Ethics Committee (REC) approval, first participant recruited or for reporting results are realistic. Studies that will be managed by a Clinical Trials Unit (CTU) or established research centre at Barts Health or Queen Mary should involve them early to ensure that their costs are captured in the funding application. If a CTU/research centre will not be involved the CI must demonstrate to the JRMO that they have adequate study management support, i.e., a dedicated Study Manager, and sufficient experience to deliver the study compliantly.
3.	CI	**Write the protocol.** Always aim to use the JRMO protocol or Clinical Investigation Plan template (*Associated document 2 or SOP9*) as this complies with the necessary regulatory requirements for swift reviews. Protocols not written using the JRMO template will only be accepted in exceptional circumstances (e.g. sponsorship transfers), and only where a pre-approved CTU protocol template is used. In these cases, the CI is responsible for ensuring that all required elements are included. Where required elements are missing, the GCP Manager may invalidate the submission.
4.	CI	**Send protocol/proposal to JRMO and meet with GCP and Governance Manager and Costing and Contract officer.** Attend Costings Assessment meetings with the JRMO as necessary. The CI should send the protocol to the GCP and Governance Manager and Costing and Contract Manager for review. At the costing meeting, all the support functions, governance issues, potential study costs or supply of the Investigational Medicinal Product (IMP) can be addressed. Following the meeting the CI is expected to work with the Costing and Contract Manager on their funding applications (see *SOP 07 Costing and contracting*).
5.	CI	**Allocate an independent named statistician to the study (not the CI or local Investigator).** For studies within the remit of this SOP a named qualified and experienced statistician must be allocated for the study's duration. The CI or local investigator cannot act as the statistician. The statistician provides independent, expert advice throughout the study and must be consulted on modifications affecting statistics or data integrity. It may be necessary to contract an external statistician, as determined during the JRMO contract meetings (*see SOP 07 Costing and contracting).*
6.	CI	**Discuss the assignment of a new CI with the JRMO.** If the CI has not previously worked on a Barts Health or Queen Mary sponsored MHRA-regulated study, they should discuss their proposal to become CI with the GCP and Governance Manager. As well as having a substantive contract with

		the sponsor organisation, the CI must be qualified in the therapeutic area. If the CI is not a doctor or dentist, they will need to identify a doctor or dentist willing to act as the medical assessor on behalf of the sponsor for the duration of the study. The following previous experience may be considered by the SOG: • CI / local Investigator on non-commercial or commercial regulated studies, multi- location / international studies, experience on non-MHRA regulated studies. • GCP and regulatory compliance. • working on MHRA-regulated studies. • safety assessments / pharmacovigilance responsibilities. The CI does not necessarily have to be the grant holder but needs to be centrally involved in the protocol writing and development. For new CI's, the JRMO will work with the research team, Clinical Director or equivalent at Barts Health or Queen Mary Institute to assess their experience and determine whether additional peer support, training, or study management support is required. The new CI may be assigned a mentor for support.
7.	CI	**Once funding is secured, and the protocol is developed arrange appropriate review and Clinical Director / Institute review of the protocol.** Send the protocol for comprehensive, independent peer review to ensure it is scientifically sound, understandable, comprehensive, consistent, and compliant with the regulations (see *SOP 14 Peer Review*). The CI must address and document all peer reviewers' comments before submitting the study to the JRMO for sponsorship. Attend Early Engagement Meeting with GCP Team and other key trial team members.
8.	CI	**Location feasibility assessment.** The CI is responsible for conducting a location feasibility assessment (*see SOP 46 Location selection, location initiation and location activation*) early in the study design phase to ensure the protocol is practicable. A feasibility assessment considers whether the study is logistically possible at each location(s). This must be completed and the protocol adapted to include feedback from location(s) and collaborators where applicable, before the location is approved by the sponsor and regulators (i.e. prior to being listed on an Integrated Research Application System (IRAS) form). If the MHRA-regulated study is to have international research locations, please contact the JRMO Governance section for oversight advice. The CI should discuss plans to include international locations with the GCP and Governance Manager. International elements introduced post initial funding require GCP and Costings approval.
9.	CI	**Coordinate approvals of the protocol from support departments.** At the design stage, the CI should obtain input into the protocol from each support department. The support departments' risk assessments and feedback should be included in the protocol development.

10.	CI	**With the Costing and Contract officer, begin the contract negotiations with external parties.** Where Queen Mary Innovation (QMI) or the Business Development Unit (BDU) staff have been involved in the contract negotiations, the CI must ensure that the JRMO is informed, as QMI or BDU 's input will be required during subsequent meetings and negotiations. Certain contracts may be expected to be in place prior to HRA, REC and MHRA submissions e.g., non-disclosure agreements with the IMP supply company / device manufacturer if the company's confidential information is required for REC or MHRA submissions. Contracts must only be signed by Queen Mary or Barts Health authorised signatories (*see SOP 7 Costing and Contracting*). The CI must disclose any conflicts of interest that could influence professional judgment concerning participant welfare, or the validity of research data. This includes financial interests, vested interests or relationships with third parties. As sponsor, the JRMO must be made explicitly aware of any competing interests that the CI or members of their team may have.
Sponsorship with Conditions and Confirmation of Sponsorship		
11.	CI or delegate	**Prepare and submit a valid sponsorship application pack to the JRMO l– this must be reviewed and approved by JRMO prior to applying to the HRA / REC or competent authority (MHRA in the UK).** Once funding has been secured, and all the relevant actions above have been addressed, submit a valid submission pack to JRMO via research.governance@qmul.ac.uk Use the 'JRMO submission checklist' (*see Associated Document 3*) to ensure the pack is valid. Include all documents to be reviewed by the HRA, REC, MHRA or other regulatory body, in one submission package. Incomplete submissions will delay the sponsorship review and approval process. Apply for National Institute for Health Research (NIHR) Research Delivery Network (RDN) support via the RDN non-commercial portfolio application service in CPMS. HRA will automatically register clinical trials approved through combined review with International Standard Registered Clinical/social study Number (ISRCTN) registry. This applies to both clinical trials of investigational medicinal products (CTIMP) and combined trials of investigational medicinal product and a medical device (IMP/device). EU based CTIMP trials and locations will be automatically publicly registered on the European Medicines Agency (EMA) Clinical Trials Information System. CIs not benefitting from automatic registration must manually register their projects on ISRCTN Registry.
12.	CI or delegate	**Revise documents to incorporate feedback (and answer any questions) from the JRMO.** To avoid delays in sponsorship review and approval, please answer any questions the JRMO may have and return tracked-changed documents incorporating any feedback from the JRMO reviewers. The JRMO welcomes meetings to discuss areas of concern with the research team.
13.	CI and research team	**Attend the Kick-off meeting with the JRMO.**

		The JRMO will invite the CI and coordination team to attend the Kick-off meeting. This meeting can take place at any time between receipt of valid submission by the JRMO and 'sponsorship with conditions'. The purpose of this meeting is to ensure that all stakeholders in the JRMO and the CI's team are aware of: • the key information about the study • the requirements for 'sponsorship with conditions' to be issued • the contracts and agreements that need to be put in place • the actions that must be completed once the study has been submitted for regulatory approval. It is mandatory for the CI and any other roles as requested by GCP Manager, to attend the Kick-off meeting, and it is recommended that the Study Coordinator/ Manager or CTU representative (if applicable) also attends. The 'CI-Sponsor agreement' will be discussed and ideally signed during this meeting.
14.	CI or delegate	**Request sponsor (i.e., JRMO) authorisation on the Combined Review IRAS form, submit to regulators and inform JRMO of all correspondence with the regulators, including Requests for further information.** Unless otherwise agreed between the JRMO and CI the admin contact in IRAS should be the sponsor representative. Once the 'sponsorship with conditions' email has been received by the CI, they should request research.governance@qmul.ac.uk for sponsor authorisation of the Combined Review IRAS form once finalised. The CI should email the RM and Governance Officer once this is complete so that they can coordinate the authorisation. Forward the confirmation email from your online booking service and REC reference number (https://www.hra.nhs.uk/about-us/committees-and-services/online-booking-service/) to research.governance@qmul.ac.uk. Any changes to sponsor approved documents requested by the HRA, REC or MHRA must be reviewed by the sponsor before resubmission to the regulators. Send the revised documents to the Research Governance Specialist (RGS) and GCP and Governance Manager for approval prior to ensure that the sponsor has oversight of the changes that may impact upon the conditions of sponsorship and indemnity.
15.	CI	**Whilst the application is with the regulators, continue study specific management set-up including preparation of SOPs, databases, and facilitate contract negotiations.** During submission to the regulators, the CI and research team should continue with setting up the study, including: • Setting up the trial master file (TMF) and investigator location files (*see SOP 45 Essential documentation and TMF*). • Finalise eCRF/database design and validation, and design and validation of any associated computer programs (*see SOP 38a Use of computerised equipment in research studies*). • Sending a copy of the protocol to the statistician to ensure the Case Report Form matches the protocol.

		• Drafting study specific SOPs (e.g., randomisation, unblinding, IMP management plan for multi-location studies). • Progressing contract negotiations. • Preparing the location initiation training. (For a PowerPoint presentation template *see* *SOP 46 Location selection, location initiation and location activation*). • Preparing trial committee charters. (For guidance and template charters *see* *SOP 47 Trial Committees*). • Preparing the monitoring plan with the GCP and Governance Manager. (For a template monitoring plan *see* *SOP 28 Monitoring*). • Recruiting / assigning study specific research posts e.g., research nurse / study coordinators. • Attending the REC meeting to answer any questions raised by the committee (so that their decision can be made during the meeting).
16.	CI or delegate	**Send local document pack to locations once HRA Initial Assessment Letter has been received.** Once the HRA initial document package has been received, the CI should send the local document package to participating locations so that they can begin assessing Capacity and Capability (see *SOP 46 Location selection, location initiation and location activation*).
17.	CI or delegate	**Send REC, MHRA and HRA approvals to the JRMO. Continue with NHS set-up.** Send the RGS all approvals from the regulators and evidence that the conditions of their approvals have been met. The approved versions of the finalised study documents should be submitted to the RGS, including the final protocol signed by the CI and statistician.
18.	CI and Research team	**Prepare for and attend the Final Governance meeting with the JRMO.** Once regulatory approvals are received, the GCP and Governance Manager will schedule the 'Final Governance meeting' to identify outstanding items before issuing the confirmation of sponsorship and permission to activate locations. The meeting agenda will follow the 'final governance meeting report' (*SOP 11b Associated Document 9*). The GCP and Governance Manager will complete and distribute the report, and any outstanding items will be emailed to the CI for resolution. The CI should be able to demonstrate that they have TMF and SOPs/systems in place (*see* *SOP 45 Essential documentation and TMF*). If needed a JRMO monitor will review the TMF prior to confirmation of sponsorship. The 'CI-Sponsor agreement' will be reconfirmed verbally and documented during this meeting.
19.	CI	**Sign the Costing and Contract checklist and complete all items outstanding in the Final Governance meeting report.** Following the Final Governance meeting, the GCP and Governance Manager the final governance meeting report (SOP 11b *Associated Document 6*). It is the CI's responsibility to complete all actions identified in this report and send evidence to the GCP and Governance Manager.

		Once all contracts are fully executed, the Costing and Contract officer will send the CI the 'Contracts Checklist.' This must be signed and returned to the JRMO before confirmation of sponsorship is given.
20.	CI	**Receive the confirmation of sponsorship from the Governance officer.** Following all relevant checks and GCP manager agreement, the Governance officer will send the CI an email giving the confirmation of sponsorship. Initiation and activation of locations can then begin in accordance with *SOP 46 Location selection, location initiation, and location activation*. **NB:** NHS Confirmation of Capacity and Capability is issued separately to Confirmation of Sponsorship and does NOT give permission to begin recruiting to the study. **The CI must receive the 'Confirmation of Sponsorship' email to activate locations (see below) and NHS Confirmation of Capacity and Capability before recruiting any participants.**
21.	CI	**Ensure SOP 10 (Confirmation of Capacity and Capability) is followed for local (Barts Health and/or Queen Mary) location approval.** NB: Permission to activate locations is a separate document to local location approval.
Notes regarding: First in Human (FIH) / ATIMP Research		
22.	CI	**All FIH studies will be assessed on a case-by-case basis.** Factors that will be assessed include: • Risk of IMP • IMP Pharmacology • Design of study • Study population • Manufacture agreement • Reason why manufacturer cannot sponsor • Comments from Independent scientific reviewers • Proposed delivery location/facilities of study
23.	SOG	**Final decision to sponsor a FIH study will be taken by the Sponsor Oversight Group (SOG).** The GCP and Governance manager will present the study to the SOG who will review the risks involved and confirm ability to sponsor the study.
24.	CI	**In order for Barts Health or Queen Mary to consider sponsoring FIH studies this SOP, and additional points below must be adhered to:** • Additional requirements: Use delivery department/facility that is phase I accredited or can evidence that they meet the standards outlined. • CI should be an experienced CTIMP/ Advanced Therapy Investigational Medicinal Products (ATIMP) CI preferably with early phase experience. • Study coordination team should be experienced in CTIMPs/ATIMPs and preferable early phase studies. • The group should be established groups like a CTU, who are able to evidence written procedures and processes. • The statistician should have early phase clinical trials experience or be able to evidence other appropriate experience or mentor or supervision.

		• Liaise with the JRMO Pre-award team to ensure team appropriate contract is in place to evidence agreement, publication in favour of Queen Mary/Barts Health. • Obtain written agreement from organisation insurance team or representative that this study is covered.

Change control

This section outlines changes from version to version

Section changed	Summary and description of changes
Background	Removal of background information
Purpose and Scope	Streamline of purpose and scope information
Definitions	Removal of definitions section
Relevant SOPs	Removal of relevant SOPs section in place of hyperlinks
Throughout	Update to terminology in line with ICH E6 R3

List of appendices

There are no appendices for this SOP.

List of associated documents

Document ref.	Document name
Associated Document 1	Costing MHRA regulated studies guidance
Associated Document 2	Protocol Template for MHRA regulated studies
Associated Document 3	JRMO document submission checklist