

Standard Operating Procedure for:

Barts Health NHS Trust/Queen Mary University of London sponsorship of MHRA-regulated studies: Process for JRMO staff

SOP Number:	11b	Version Number:	10.0
Effective Date:	15 th May 2026		15 th May 2029

Authorship:		Signature and Date:
Author:	Nadia Rahman, GCP and Governance Manager	Nadia Rahman Digitally signed by Nadia Rahman Date: 2026.04.29 15:47:56 +01'00'
Reviewer:	Rebecca Newton Senior GCP and Compliance Manager	Rebecca Newton Digitally signed by Rebecca Newton Date: 2026.04.29 16:23:38 +01'00'

Authorisation:		Signature & Date:
Name/Position:	Mays Jawad, Associate Director of Research Quality	Dr Mays Jawad Digitally signed by Dr Mays Jawad Date: 2026.05.01 12:39:51 +01'00'

Purpose:

To outline the actions and steps undertaken by the Joint Research Management Office (JRMO) before agreeing to sponsor Clinical Trials of Investigational Medicinal Products (CTIMPs) or Advanced Therapy Medicinal Product (ATIMP) studies.

Scope:

This SOP applies to staff in the JRMO Governance section and JRMO pre-award team who work on Barts Health/Queen Mary sponsored CTIMPs or ATIMPs.

For sponsorship of Medicines and Healthcare products Regulatory Agency (MHRA)-regulated Clinical Investigations, please refer to [SOP 9 Sponsorship of Clinical Investigations and other MHRA-regulated Medical Device Studies](#).

ATIMP	Advanced Therapy Investigational Medicinal Product
CI	Coordinating Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
IMP	Investigational Medicinal Product
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
QC	Quality Control
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
RGS	Research Governance Specialist
SOG	Sponsor Oversight Group
SOP	Standard Operating Procedure

SOP Text:		
	Responsibility	Activity
Early Engagement		
1.	Governance Team	Governance Team will guide researchers and offer their support in set up of their study. The level or type of support and guidance will depend on what type of study and experience of the researcher. Ensure that the researcher is aware of the use of appropriate protocol template (SOP 11a Associated Document 2) the submission checklist (SOP 11a Associated Document 3) and local processes.
2.	Costing and Contracts Officer (CCO)	Where relevant, whilst costing the study, inform the Good Clinical Practice (GCP) Manager of all potential MHRA-regulated studies. Confirm costings. Agree the appropriate study costs with the allocated GCP Manager in line with SOP 7a Costing and Contracting and SOP 11a Associated Document: Costing MHRA regulated studies guidance.
3.	GCP Manager (GCP) and/or delegate	Assess study with regards to regulatory categorisation, acting as legal representative, and inclusion of any international sites. <u>Categorise the study.</u> Confirm the study falls under the scope of the UK regulations. <u>Studies with international sites.</u> The GCP Manager must approve the study to be run internationally and, as sponsor representative, reserves the right to refuse. Appeals to the JRMO's decision may be made to the Sponsor Oversight Group (SOG). For guidance refer to Associated Document 1 Guidance for GCP and Governance section.
4.	GCP Manager/Clinical Trial Facilitator (back up Research Governance Specialist (RGS))	Create the project on EDGE as per EDGE Manual. Using the information available, create the project on EDGE with the status as 'concept'. Start completing the relevant forms and workflows.
5.	GCP Manager or RGS/Delegate	Upon funding confirmation, hold an Early Engagement meeting ensuring critical members present. See Associated Document 1 Guidance for GCP and Governance section Appendix A.
6.	GCP Manager	Agreeing CI suitability for the study If the CI has not previously worked as a CI on a Barts Health or Queen Mary sponsored MHRA-regulated study, it may be necessary to discuss their proposal to be the CI with the SOG. If

		the CI is not medically qualified and/or inexperienced, the SOG must endorse assignment of CI. The use of a CI mentor may be recommended. The CI must have a substantive contract with the sponsor (Barts Health or Queen Mary accordingly), be appropriately qualified in the therapeutic area and be able to prescribe the Investigational Medicinal Product (IMP).
7.	GCP Manager and Assigned RGS	Insurance review If this is a Queen Mary sponsored study, ensure current insurance covers the study activities. See Associated Document 1 Guidance for GCP and Governance section for more information. If the Queen Mary study has any elements from the list of Insurance Review mentioned in Associated Document 1 Guidance, then Queen Mary Insurers are to be notified with copy of the protocol to confirm if premium insurance needed or not.
Sponsorship Application		
8.	Governance Administrator	Studies are triaged on receipt, and allocated All correspondence and governance decisions (including in meetings) must be documented and saved in the study file (See SOP 27 Internal Filing Process). The allocated GCP Manager should be copied into all correspondence.
9.	RGS or delegate	Assess sponsorship submission for validity(see SOP 11a Associated document 2) Respond to researcher as soon as possible confirming valid submission or rejection. Once valid, locate “concept” project in Edge and update status to in set-up. The date of ‘sponsorship submission’ is the date the JRMO receives a complete valid submission application. The JRMO’s clock will not start until a valid submission is received.
10.	RGS or delegate.	Proceed with sponsorship review. RGS’s performs primary sponsorship review using Sponsorship EDGE workflow. Ensure the relevant sponsor pharmacist, and other support department(s) are aware of the study and have access to all up-to-date documentation. See Associated Document 1 Guidance for GCP and Governance section These actions occur in parallel with the actions in the next point.
11.	GCP Manager	Undertake sponsorship review and risk assessment of the protocol and study.

		These actions occur in parallel with the actions in the preceding point. Review the study documents from a GCP perspective. Follow SOP 23 and perform risk assessment using the form completed by the study team. Send feedback to RMGO/delegate. Complete JRMO GCP manager checklist part 1 workflow on EDGE. Allocate a JRMO Clinical Trial Monitor to the study. Include the JRMO Clinical Trials Monitor in any meetings about the study to share information.
12.	RGS/Delegate	RGS to collate governance and GCP comments from GCP Manager and feedback to the researcher as a single response.
13.	GCP Manager or delegate	Organise, host, and document the Kick-off meeting. The following roles are required to be present at Kick-off meeting: Coordinating Investigator (CI), Clinical Trial Unit representative, study Coordinator or Trial Manager Sponsor pharmacist – for notifiable low risk trials Pharmacy attendance at KOM is not mandatory if written confirmation can be provided that the Pharmacy have enough information to give Sponsor approval and enough information to set up the study. . Clinical Trial Monitor or delegate to attend and minute the meeting. For meeting guidance see <i>Associated Document 1 Guidance for GCP and Governance section Appendix B</i> <u>Send out minutes/actions of meeting.</u>
14.	Costings and Contracts Officer	Attend the Kick-off meeting and administer contracts to full execution. Complete the contract checklist and confirm with CI all contracts identified. • Save the signed contract checklist in the indemnity folder • Inform the RGS and GCP Manager that the first stage of the checklist is completed. • Ensure milestones are discussed with GCP Manager. • Once the primary funding contract has been executed, inform the GCP Manager and RGS. For guidance see SOP 7 Costing and Contracting (Associated Document 1: Costing and contract checklist).
15.	GCP manager	GCP managers to confirm agreement to proceed with Sponsorship with Conditions Once all actions from kick off meeting and the JRMO GCP managers Checklist part 1 workflow on EDGE have been

		completed, send an email confirming GCP managers agreement to proceed with sponsorship with conditions to the assigned RGS.
16.	RGS/delegate	Prepare to issue sponsorship with conditions. Ensure all feedback and requests have been actioned. Liaise with GCP Manager to obtain agreement to proceed with sponsorship with conditions in writing. Ensure sponsorship workflow is updated to reflect study has now received sponsorship with conditions. Obtain sponsor pharmacy confirmation of their approval in accordance with SOP 42a IMP Management-Barts Health/Queen Mary sponsored studies. Research Governance and Performance Manager (or delegated team member) to Quality Control (QC) the study sponsor file.
17.	Research Governance and Performance Manager (or delegate)	MHRA-regulated studies - QC cross-check. Undertake an in-depth QC check of the documentation and approvals. Once satisfied complete the relevant point on EDGE workflow 'Governance team sponsorship review workflow' as evidence of the sponsor's QC check. This must be performed by someone other than the RGS who undertook the sponsorship review.
18.	RGS or Delegate	Issue Sponsorship with conditions email GCP Manager issue sponsorship with conditions email together with the sponsorship letter (<i>Associated Document 2</i>). Ensure study team is aware that requests for further information and subsequent replies from regulators should be submitted to the Governance section pre-submission for review and approval.
19.	RGS or Delegate	When ready to submit, advise the study team to request submission from sponsor for the Combined Review IRAS form as per guidance document RGS to confirm final submission on Combined Review IRAS as sponsor authorisation
20.	RGS, GCP Manager	If the REC, HRA or MHRA require changes, review the amended documents prior to resubmission. Review the tracked changes of all revised documents ensuring compliance with sponsor and regulatory requirements. Ensure the regulatory body comments are addressed. Obtain re-approval from supporting department if required
21.	GCP Manager, Clinical Trials Monitor	Notify the team of next actions required. See Associated Document 1 Guidance for GCP and Governance section for further details.
22.	RMGO or delegate	Receipt of regulatory approvals

		Ensure all parties are aware that the REC, HRA and MHRA approvals (and any other approvals required) have been received
23.	GCP Manager	Schedule and hold the Final Governance meeting. The purpose of the final Governance meeting is for the sponsor to identify all outstanding items before the GCP Manager can issue agreement to proceed with confirmation of sponsorship. The CI attendance is mandatory The final governance meeting report (Associated Document 3) should be used as an agenda and circulated before the meeting. Any actions or items outstanding identified in the meeting should be followed up to resolution. Ensure the Sponsor-CI agreement is discussed (See Associated Documents 4a and 4b).
24.	Costing and Contracts Officer	Finalise the Contracts Checklist. Following the Final Governance meeting the costing and contracts checklist should be finalised and sent to the CI for final signature (see SOP 7 - Costing and contracting). Site agreements do not need to be executed prior to completion of the contract checklist. Inform the GCP Manager and RGS in writing once the costing and contracts checklist is complete. Ensure all checklists and contracts are saved electronically in EDGE and all MHRA related spreadsheets are completed. Signed contracts should be filed in the sponsor oversight files (see SOP 27)
25.	GCP Manager	Send GCP manager's agreement to proceed with Confirmation of Sponsorship. Once all actions from Final Governance meeting and the JRMO GCP managers Checklist part 2 workflow on EDGE have been completed, send an email confirming GCP managers agreement to proceed with confirmation of sponsorship to the assigned RGS.
26.	RGS / delegate	Upon receipt of all approvals and documentation and receipt of GCP managers agreement to proceed, issue confirmation of sponsorship (Associated Document 5)
27.	RGS	Filing Complete a final review to ensure all documents are appropriately named and filed, following JRMO SOP 27. Inform relevant GCP team member once complete.
28.	JRMO Clinical Trial Monitor	Schedule first monitoring visit according to monitoring plan, set annual report reminders on ReDA. • Create a ReDA record for the study • Ensure that all annual report reminders are set before they are due, update ReDA with Development Safety Update

		Report (DSUR) and end of trial reminders (for date on IRAS from). (See SOP 19 Annual Progress Report) • Add study to Monitoring tracker and complete with relevant reminders • Ensure EDGE MHRA dossier form is up to date
29.	Clinical Trial Facilitator / Monitor	Maintain sponsor oversight file
Site approval		
30	RGS	Ensure SOP 10 (Confirmation of Capacity and Capability) is followed for local site approval.

Change control

This section outlines changes from version **9.0** to version **10.0**

Section changed	Summary and description of changes
Background	Removal of background section
Purpose and Scope	Streamline of purpose and scope section
Definitions	Removal of definitions section
Relevant SOPs	Removal of SOP section in place of direct hyperlinks
Responsibilities	Review and update to responsibilities
Regulator updates	Update 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	Guidance for the GCP and Governance section
Associated document 2	Sponsorship with conditions email template (not a public document)
Associated document 3	Final governance meeting report
Associated document 4a	Barts Health Sponsor-CI agreement (CI) (not a public document)
Associated document 4b	Queen Mary Sponsor-CI agreement (CI) (not a public document)
Associated document 5	Sponsor confirmation of sponsorship email template (not a public document)