Joint Research Management Office Standard Operating Procedure for:			
Barts Health/Queen Mary Sponsorship of Research Studies – Process for JRMO staff			
SOP Number:	**13b**	Version Number:	**2.0**
Effective Date:	**10th June 2022**	Review Date:	**10th June 2025**

Authorship & Review:			
Author:	**Tumi Kaminskas, Research Governance and Performance Manager**		
Signature:	*The signed original is held within the JRMO office*	**Date**	
Reviewer:	**Maria Briana, Senior Research Management & Governance Officer**		
Signature:	*The signed original is held within the JRMO office*	**Date:**	
Reviewer:	**Ginette Hoare, Interim Research Governance Operations Manager**		
Signature:	*The signed original is held within the JRMO office*	**Date:**	

Authorisation:			
Name/Position:	**Coleen Colechin, Senior Operations Manager (Pre-Award)**		
Signature:	*The signed original is held within the JRMO office*	**Date:**	

Background:

When Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary) agree to sponsor a research study, they are accepting considerable legal and regulatory responsibilities and organisational risks.

Good Clinical Practice (GCP) E6 R2 defines sponsor as: An individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.

The Health Research Authority (HRA) sets out guidance on the expectations of sponsors. This includes that sponsors should satisfy themselves that the study meets the relevant standards and that arrangements are put and kept in place for:

- Management.
- Appropriate peer review.
- Governance Sponsorship Review; Completed by JRMO team only
- Appropriate governance review.
- All supporting information being supplied to the regulators for their consideration.
- Defining roles and responsibilities for the duration of the study.
- Monitoring and audit.

- Risk assessment processes.
- Public and participant involvement in the study.
- Ensuring the training and suitability of the research team.
- Public registration of the study; Clinicaltrials.gov/ International Standard Randomised Controlled Trial Number (ISRCTN) guidance document
- Dissemination of the results.
- Study oversight.
- Guidance for academic supervisors.
- Providing on-going quality assurance.
- Providing insurance or indemnity for liabilities of the sponsor and investigator

Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline the actions and steps undertaken by the Joint Research Management Office (JRMO) before granting sponsorship for Research Studies.

This SOP is written:

a. To ensure that Barts Health /Queen Mary JRMO staff are aware of the processes for issuing sponsorship, authorising the Integrated Research Application System (IRAS) form as sponsor for Research Studies and the documentation necessary for sponsorship review.

b. To ensure all Barts Health /Queen Mary sponsored Research Studies have a formal sponsorship agreement in place to comply with the UK Policy Framework for Health and Social care research 2017 and Good Clinical Practice (GCP R2 2017).

Scope:

This 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 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.

This SOP also applies to non-NHS studies that are to be approved by Queen Mary Ethics of Research Committee (QMERC) (using SOP 15 QM Ethics of Research Committee application and approval procedure) but are deemed high-risk and therefore require dual review and sponsorship. For QMREC studies which require dual review, a full governance review needs to take place to ensure that the study is risk assessed appropriately, documentations are on the appropriate templates, appropriate contracts are in place and the study has appropriate regulatory approvals in place i.e., QMREC approval.

For regulated studies (involving an Investigational Medicinal Product fall under the EU Clinical Trial Directive or the Medicines for Human Use [Clinical Trials] 2004 Statutory Instrument, 1031) please use SOP 11b Barts Health/Queen Mary sponsorship of MHRA-regulated studies: Process for JRMO staff.

For interventional studies (research involving a change in treatment, care or other services made for the purpose of the research) please use SOP 12b Barts Health /Queen Mary Sponsorship of Interventional studies – Process for JRMO Staff.

This study involving experimental use of medical equipment and/or devices please use SOP 9 Sponsorship of Clinical Investigations and other MHRA-regulated Medical Device Studies.

Abbreviations:

AAC	Assess, Arrange and Confirm
Barts Health	Barts Health NHS Trust
CAG	Confidentiality Advisory Group
CB	Clinical Board
CI	Chief Investigator
EDGE	The research management database used by the JRMO and CRN

GCP	Good Clinical Practice
HRA	Health Research Authority
ICF	Informed Consent Form
IRAS	Integrated Research Application System
JRMO	Joint Research Management Office
NIHR	National Institute for Health Research
OID	Organisation Information Document
PI	Principal Investigator
PIS	Patient Information Sheet
QC	Quality Control
Queen Mary	Queen Mary University of London
QMERC	Queen Mary University of London Ethics of Research Committee
REC	Research Ethics Committee
R&D	Research & Development
RM	Research Management
RMGO	Research Management and Governance Officer
SoECAT	Schedule of Events Cost Attribution Template
TMF	Trial Master File
UK	United Kingdom

Definitions:

Valid submission: This submission should include all documents that will be reviewed by the Health Research Authority (HRA) and Research Ethics Committee (REC)/ Confidentiality Advisory Group (CAG) or other regulatory body, and the forms should be received in parallel so that the JRMO can review the consistency across all documents.

Research studies are those that are related to human research where no physical intervention is occurring. For Barts Health/Queen Mary *single site* sponsored studies the CI should be the Barts Health site's Principal Investigator (PI). For researchers outside Barts Health/Queen Mary organisations who want to acquire sponsorship from Barts Health / Queen Mary, the funding needs to be awarded to Queen Mary / Barts Health as a minimum for the sponsorship request to be considered.

Refer to study approval reference table to confirm approval requirements depending on study type (see SOP 13a Associated Document 1).

The HRA and UK policy framework for health and social care research define the CI as:

An individual who is responsible for the conduct of the whole study and is the overall lead researcher for a research study. The named CI should be a researcher who is professionally based in the UK, as they will be:

- Able to supervise the research effectively
- Readily available to communicate with the REC and other review bodies during the application process and where necessary during the conduct of the research.

Students Studies

Students should not normally take the role of CI at any level of study, as this function should be undertaken by supervisors or course leaders. Exception is made for an experienced care practitioner or manager undertaking an educational qualification for continuing professional development or a doctoral-level study while employed by a health or social care provider or a university, or for a researcher undertaking a doctoral-level study in receipt of a fellowship.

Although non-doctoral students should not be named as the CI, it is expected that the student will complete the application form on behalf of the CI as part of their training. The REC will invite the student to attend the meeting to answer questions about the study and will address all correspondence to the student (copied to

the CI). Supervisors are also encouraged to attend the meeting. If a favourable opinion is given by the REC, it is expected that the student will undertake the research under the supervision by the CI.

HRA currently do not review masters or undergraduate student studies- more details can be found via https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/.

Relevant SOPs:

This SOP is closely linked with:

- SOP 1 Research study application
- SOP 7 Costing and Contracting
- SOP 10 Confirmation of capacity and capability
- SOP 11b Barts Health/Queen Mary sponsorship of MHRA-regulated studies: Process for JRMO staff
- SOP 12b Barts Health /Queen Mary Sponsorship of Interventional studies – Process for JRMO Staff.
- SOP 13a Barts Health NHS Trust/Queen Mary University of London sponsorship for Research Studies - Process for Researchers
- SOP 14 Peer Review
- SOP 15 QM Ethics of Research Committee application and approval procedure
- SOP 17c Process for Researchers - Amendments for Sponsored studies
- SOP 18a Study closure: guidance for research staff of Sponsored studies
- SOP 23 Risk Assessment
- SOP 38a Use of Computerized Equipment in a research studies
- SOP 38b Trial Data Management Systems
- SOP 40 Vendor assessment
- SOP 45 Essential documentation and Trial Master File (TMF)
- SOP 46 Site selection, site initiation and site activation

SOP Text

	Responsibility	Activity
		Early engagement
1.	Governance Team	**Governance Team will guide and support researchers with the set-up of their study.** The level or type of support and guidance will depend on the type of study and experience of the researcher. Ensure that the researcher is aware of the submission checklist (SOP 13a Associated Document 3), the use of appropriate protocol template (SOP 13a Associated Document 2a & Associated 2b) and local process. The JRMO sponsorship proportionality document (SOP 12b Associated Document 2) is a good guide to help explain the 3 study types. Also, use the approval reference table as guidance for the required approvals (SOP 13a Associated Document 1).
		Confirmation of Sponsorship

2.	Assigned Research management and Governance Officer (RM & GO) GO/Research & Development (R&D) Administrator	**Upon receipt of a sponsorship submission pack, the assigned RM & GO acknowledges receipt.** Ensure that the researcher is aware that the JRMO will only begin the sponsorship approval process once the study team have submitted a valid application pack as per JRMO Research Studies Submission checklist (SOP 13a Associate Document 3), otherwise, the submission is deemed as invalid and this must be clearly communicated to the researcher. The date of sponsorship submission is the date the JRMO receives a complete valid submission application pack. The JRMO's clock will not start until a valid submission pack is received. When submissions are received via research.governance@qmul.ac.uk the R&D administrator or delegated individual will bring the study to the attention of the assigned RM & GO who will assess sponsor application pack as per JRMO Research Studies Submission checklist (SOP 13a Associated Document 3) and Retrospective data studies guidance document (Associated Document 2), if applicable. The assigned RM & GO will set up the study on EDGE and upload the paperwork to the indemnity folder. If no EDGE account is available for the CI notify the Research Information Lead.
3.	Research Information Lead	**Create EDGE account for the CI if one does not exist** Ensure EDGE training is provided where required.
4.	Assigned RM & GO	**Send valid submission/introductory email to CI or delegate and proceed to review the study.** Inform the CI or delegate that the study has been allocated and you will be the main point of contact. Confirm receipt of a valid submission or request further documents/clarification if an incomplete submission. Any concerns about the application should be brought to the attention of the Research Governance and Performance Manager and raised with the relevant Barts Health /Queen Mary expert i.e., GCP and Governance Manager, Information Governance, HTA representative, IT. Where appropriate confirmation or evidence of funding and costing of study by the costing and contracting team is required. If the study has funding awarded, then upload the funding award to EDGE and save in indemnity by accessing the documents via worktribe. The study should show as live in worktribe where funding has been awarded and contracts have been fully signed. Confirmation with Head of institute (Queen Mary via worktribe) or Clinical Board (Barts Health directly by costing officer) on any shortfalls is confirmed by the pre-award team.
5.	Assigned RM & GO	**Undertake sponsorship review and risk assessment of the protocol and study.** Upon receipt of a valid application as per submission checklist (SOP 13a Associated Document 3), the RM & GO will update EDGE with all study details and commence sponsorship workflow.

		Review all documents for completeness and consistency using the JRMO research application review form for Research Studies as a guide if required, ensuring feedback is given to the CI or delegate (see Associated Document 1). The JRMO RM & GO's review is the primary sponsorship review of documents listed on Associated Document 1 If the CI intends to access confidential patient information without consent or by individuals outside the direct care team then the CI should apply to the CAG. RM & GO can provide guidance to CI on how to make the application (guidance and process can be found on HRA website). Studies requiring CAG approval, the appropriate Caldicott Guardian will need to sign off the IRAS form appropriately. Complete a risk assessment (As per SOP 23 Risk Assessment). If the score is medium the study will be reviewed by the Research Governance and Performance Manager and if the score is high, the study will be reviewed by the Research Governance and Performance Manager with the GCP and Compliance manager. For studies that may be adopted on NIHR portfolio, advise CI to select 'yes' to question 5b of the IRAS study Filter. Information governance (IG) requires completion of a pre-screening questionnaire (See SOP 16a Associated Document 2 for full details and procedure). This will determine whether a full Data Protection Impact Assessment (DPIA) form must be completed. Where the DPIA form is required, confirmation of the assessment will be required from the IG team prior to Sponsor authorisation of the IRAS form being granted. Any concerns about the application should be brought to the attention of the Research Governance and Performance Manager and raised with the relevant Barts Health/Queen Mary expert i.e., IG, HTA representative, IT. Upon completion of the review, the RM & GO will email the research team with their feedback and request further clarification as applicable or mitigation depending on the risk score. It is advisable to arrange meeting with CI/CI delegate to discuss study, to seek clarifications and to build professional relationship. Other sections of JRMO or support departments should be involved in the review of study sponsorship if necessary (SOP 12b Associated Document 3 Early engagement meeting tool). The appropriate data fields and workflows on EDGE should be completed
6.	Assigned RM & GO	**Support CI/CI's team with the necessary support department approvals - Depending on the level of involvement this can be undertaken after the study has been submitted for Regulatory Approvals** Advise and support the research team in obtaining the approvals that may be required. The CI and their team are responsible for ensuring all local approvals have been requested and received. Depending on the level of involvement local approvals can be sought once the sponsorship letter has been issued and an application is submitted to the regulatory bodies. Check that all relevant supporting departments are aware of the study and have provided their approval (If applicable). For example: • Tissue Bank Manager • Pathology/Laboratory manager

		Identify all external vendors and their roles. Liaise with JRMO Costing and Contact team regarding costs/confirmation of funds and seek advice on contracts/agreements.. Depending on the level of involvement and current engagement, completion of contractual arrangements can be undertaken in parallel with regulatory approvals process
7.	Costing & Contracts Officer	**Confirm costings & requirement for contracts** Ensure that each activity in the HRA application has been correctly allocated according to the NIHR guidelines (Attributing the costs of health and social care research – (Association for Cooperative Operations Research and Development (AcoRD) as either: • Service Support cost • Research cost • Treatment costs Check for external vendors and agreement for tissues/data transfer. Once satisfied inform the RM & GO that the process is completed and send them a copy of the agreed documentation. Fully executed agreements do not need to be in place prior to regulatory submission. Advise on appropriateness of Contract/OID for the study. Provide Draft Contract/ OID for regulatory submission. SoECAT should be completed by CI team and reviewed by JRMO Costing and Contracts Team. Ensure that there are adequate funds to cover the cost of the study and provide confirmation to the assigned RM&GO.
8.	Assigned RM & GO	**Finalise the Governance Review & issue Sponsorship letter** Once the RM&GO is satisfied that the documentation is complete and that relevant approvals are in place or have been initiated (where it has been confirmed that review and approvals can be undertaken in parallel to regulatory review) finalise the sponsorship review. Proceed with issuing sponsorship letter and ask the CI or delegate to finalise the IRAS form and request sponsor authorisation. This should be issued as a PDF. Review study file and send (PDF) letters out to CI or delegate as appropriate. (Associated Document 6a Queen Mary Declaration of Sponsorship letter (Interventional and Research Studies) and Associated Document 6b Barts Health Declaration of Sponsorship letter (Interventional and Research Studies)) State that the study can now be submitted for regulatory approval. Advise the researcher to book the study for a review via the online booking system. Advise the researcher of the outstanding approvals and contracts that will be required prior to issuing Confirmation of capacity and capability. Insurance certificate must be issued as part confirmation of sponsorship for all Queen Mary sponsored studies.

9.	Assigned RM & GO	**Ensure EDGE and indemnity folder are updated with all relevant details and files are uploaded to EDGE** Update EDGE record and upload application pack on to indemnity folder and EDGE as applicable
Once appropriate approvals are received (REC, HRA, Administration of Radioactive Substances Advisory Committee (ARSAC), CAG is received.		
10.	Assigned RM & GO	**Request all the final HRA Approved documents following regulatory approvals** Once the relevant approvals REC, HRA, and CAG (if applicable) approvals have been received, the assigned RM & GO will request for all the final HRA approved documents as listed on the HRA approval letter. If any contracts are applicable RM & GO must request the fully executed copies.
Issuing Confirmation of Sponsorship and Permission to Activate Sites		
11.	Assigned RM & GO	**Issue Confirmation of Capacity and Capability (C&C)** Issue permission to activate sites (if applicable) email (see SOP 12a Associated Documents 7). Complete the EDGE C&C Workflow and Attributes. Ensure supporting department approval are in place and all contracts are executed. If approvals were given more than 6 months ago confirmation of continued approval should be sought. Issue C&C approval for Barts / Queen Mary, if applicable. C&C is issued recruitment may begin. Ensure EDGE record and indemnity folder are updated, and study documents uploaded.

List of Associated Documents *(these are standalone documents)*

Associated Document 1	JRMO Governance Team Sponsorship Review for research studies
Associated Document 2	Retrospective Data studies guidance document
Associated Document 3	Sponsorship and capacity and capability for retrospective anonymised data studies email template