Joint Research Management Office Standard Operating Procedure for:			
Barts Health /Queen Mary Sponsorship of Research Studies – Process for researchers			
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This SOP was also reviewed by Jennifer Harrison, HRA Approval Change Manager and as part of a wider JRMO working group.

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Purpose and Scope:

The purpose of this Standard Operating Procedure (SOP) is to outline the process required for obtaining sponsorship from Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary) for Research Studies.

At the Joint Research Management office (JRMO), studies are classified into Medicines and Healthcare products Regulatory Agency (MHRA) regulated (See SOP 11a / SOP 9a), Interventional (See SOP 12a) and Research (this SOP) Studies.

Please refer to Study Approval Reference Table (Associated Document 1) for specific approval requirements for studies involving:

- Tissues
- Data
- NHS Staff only involvement
- Student involvement
- Primary Care

This SOP also describes the actions required by the Chief Investigator (CI) or delegate to formally request sponsorship and the JRMO procedure for granting sponsorship including the review process and sponsorship confirmation. For further information on research study approvals, please see SOP 13b Associated Document 2 Sponsorship review guidance document for Interventional and Research Studies.

This SOP is also applicable to non-NHS studies that are to be approved by Queen Mary Ethics of Research Committee (see SOP 15 QM Ethics of Research Committee application and approval procedure) but are deemed high-risk and therefore require dual review and sponsorship.

Abbreviations:	
BDU	Business Development Unit
Barts Health	Barts Health NHS Trust
CAG	Confidentiality Advisory Group
CI	Chief Investigator

CRF	Case Report Form
HRA	Health Research Authority
IRAS	Integrated Research Application System
JRMO	Joint Research Management Office
NIHR	National Institute for Health Research
QMI	Queen Mary Innovations
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
RMGO	Research Governance & Management Officer

SOP Text		
	Responsibility	**Activity**
1.	CI/ CI delegate	**Work with JRMO Costing Team to obtain an accurate cost for the study.** The CI is responsible for ensuring that their study(s) are accurately and realistically costed in the formative stages to ensure that it has adequate funding to be deliverable, successful, and compliant. For further details see SOP 7b Contracting for Interventional and Research Studies, SOP 8 Site agreement for clinical trials and SOP 1 Research project applications for costing questions with prompts. The CI should complete a Pre Costing Questionnaire https://webapps2.is.qmul.ac.uk/ecosting/ or email jrmo-helpdesk-preaward@qmul.ac.uk if they do not have a Queen Mary login to request support from the costing team with the costs. The CI is encouraged to discuss the proposed study with the JRMO Governance Team if they wish to do so. All studies cost money to deliver, however if the CI wishes to undertake this study at no extra cost then they should complete SOP 12a Associated Document 4 Approval for Non-Funded Projects (New Studies) and get this approved by the head of Institute or Clinical Board Research Director. Before agreeing to any milestones with funders, the CI should discuss their feasibility with the JRMO Governance team. This is to avoid agreeing to milestones such as deadlines for Research Ethics Committee (REC) approval, first patient recruited or for reporting results that may not be realistic or take into consideration the regulatory and site approval timelines or protocol design. Please follow SOP 14 Review of Research Including Peer Review and Departmental Authorisation to obtain grant application and scientific peer review approvals.
2.	CI/ Delegate	**Write the protocol.** The CI or delegate must write a protocol using JRMO research studies protocol template that is in line with regulatory requirements (see Associated Document 2a or 2b if setting up a Research Tissue Bank or Research Database). Care should be taken to ensure that no template wording or guidance remains in the submitted protocol. The JRMO is not responsible for the scientific development of the protocol but will ensure it is compliant with Good Clinical Practice, Health Research Authority (HRA) and other applicable regulatory requirements and guidance.

3.	CI/Delegate	**Arrange Scientific and Departmental Review of Protocol** Send the protocol for comprehensive and independent peer review. The peer review includes (but is not limited to) whether the protocol is scientifically sound, understandable, comprehensive, consistent and compliant with the regulations. (Full peer review guidance is found in *SOP 14 – Peer Review*). It is the CI's responsibility to address all peer reviewers' comments (and evidence this) before submitting the study to the JRMO for sponsorship review. Student studies may use supervisor to replace independent scientific reviews.
4.	CI/Delegate	**Arrange Patient and Public Involvement and Engagement activity** Ensure study and patient facing documents e.g. patient information sheet have been reviewed by appropriate PPIE groups. https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/ https://www.jrmo.org.uk/performing-research/involving-patients-in-research/ppi-resources-for-researchers/
5.	CI/Delegate	**Consider allocation of statistician to the study** For Research Studies, it is recommended that a named statistician should be allocated to the study for the duration of the study and who is independent of the study team. The staff member taking on the role of statistician must be suitably qualified and experienced, which will be evident from their CV. It may be necessary to contract an external statistician so please discuss with the JRMO costing and contracts team (see SOP 07b – Contracting for Interventional and Research studies).
6.	CI	**Discuss the assignment of a new CI with the JRMO.** For Research Studies sponsored by Barts Health/Queen Mary, the CI should have a substantive contract with the sponsor (Barts Health/Queen Mary accordingly). Where the researcher is not substantially employed by Barts Health/Queen Mary but wants these organisations to provide sponsorship, then as a minimum the funding needs to be awarded to Queen Mary/Barts Health for sponsorship request to be considered and mutual agreement with the CI's substantive employer on any possible misconduct is agreed at the outset. Please discuss with the JRMO Research Governance Operations Manager (research.governance@qmul.ac.uk). The CI should have the appropriate level of experience to conduct the study.
7.	CI/Delegate	**Site Feasibility Assessment** It is the CI's responsibility to undertake a site feasibility assessment (see SOP 46 - site selection, site initiation and site activation) at the early stage in the study design to ensure that the study design and protocol are practicable. If the Research Study is to have international research sites Only Queen Mary can sponsor international research, with a Queen Mary substantively employed CI with a legal representative in Europe for EU sites. Barts Health (with NHS's Clinical Negligence Scheme for Trusts indemnity) cannot sponsor international studies. The CI must notify the JRMO about their plans to open internationally at the beginning of study set-up. This will include information about any Contract Research Organisation and/or National Coordinating Centre that will be used to coordinate and secure international regulatory approvals (see SOP 40 – Vendor Assessments).

		All requests for addition of international sites must be reviewed by the JRMO Research Management Governance Officer (RMGO), Post Award Officer and Pre Award Officer within the JRMO. Only once approval is granted can these international sites be added to the study.
8.	CI/Delegate	**Coordinate approvals of the protocol from support departments** At the design stage, the CI or delegate should obtain input into the protocol from each support department. The support departments' risk assessments and feedback should be included in the protocol development and their costs included in funding requests. These might include the following support departments: • Imaging • Laboratory leads • Pathology • Tissue storage For contact details please refer to Research Studies submission checklist (Associated Document 3).
9.	CI	**With the Costing and Contracts Manager, begin the contract negotiations with external parties where applicable** Where Queen Mary Innovation (QMI) or the Business Development Unit (BDU) / JRMO EU staff have been involved in the contract negotiations, the CI must ensure that the JRMO are kept informed, as QMI/EU team or BDU's input may be required. Certain contracts may be expected to be in place prior to HRA, REC and Confidentiality Advisory Group (CAG) submissions. Contracts must only be signed by Queen Mary/Barts Health authorised signatories (*see SOP 7b – Contracting for Interventional and Research Studies*). The CI must disclose all conflicts of interest that may exist when professional judgment concerning the patients' welfare or the validity of research may be influenced by a secondary interest. As sponsors, the JRMO must be made explicitly aware of any competing interests that the CI or members of their team may have.
Confirmation of Sponsorship		
10.	CI/Delegate	**Submit a valid Sponsorship application pack to the JRMO prior to applying to the HRA, REC or CAG** Once funding has been secured, and all the relevant actions above have been addressed, submit a valid application pack to JRMO via research.governance@qmul.ac.uk. Use the JRMO submission checklist (see Associated Document 3) to ensure the pack is valid. This submission should include all documents that will be reviewed by the HRA,REC and CAG or other regulatory bodies. The Sponsor CI agreement should also be signed and submitted (see Associated Document 4a and 4b). Only when a valid document pack is received will sponsorship review commence.
11.	CI/Delegate	**Obtain support department approvals** If the study involves support departments, obtain approval to proceed to ethics submission:

		- Pathology - Imaging/radiation - Pharmacy - Clinical physics - Lung function - Ophthalmology - Information governance Early contact with support department teams is recommended to prevent delays. contact details can be found in JRMO submission checklist (see Associated Document 3)
12.	CI/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 RMGO. The JRMO welcomes meetings to discuss areas of concern with the research team. Once all requirements have been met the RMGO will issue sponsorship with conditions email (SOP 12b Associated Document 2).
13.	CI/Delegate	**Request Sponsor authorisation on the Integrated Research Application System (IRAS) form. Submit to regulators and inform JRMO of all correspondence with the regulators, including amendments.** Once the sponsorship with conditions email has been received from RMGO to the CI or delegate, they should request research.governance@qmul.ac.uk for sponsor representative electronic authorisation of the IRAS form via the IRAS authorisation tab. Any changes to the IRAS form (other than adding the REC number) will invalidate the CI and sponsor authorisations on the IRAS forms. Therefore, only request sponsor authorisation when the IRAS forms have been finalised. To apply for National Institute for Health and Care Research (NIHR) Clinical Research Network (CRN) support you should select 'yes' to question 5b of the IRAS Project Filter. Key information from your IRAS submissions will then be shared with the NIHR CRN and used to assess eligibility. For Research Tissue Bank/Research Database studies authorisation request of IRAS form to be sent to Tissue Bank Manager (Katie Ersapah k.ersapah@nhs.net) or the Information Governance/Data Protection Officer where appropriate (bartshealth.infogov@nhs.net). The CI or delegate should submit to the HRA, REC and CAG application (if applicable) in parallel to avoid delays. Once the application has been booked into the Central Booking Service (https://www.hra.nhs.uk/about-us/committees-and-services/online-booking-service/), a confirmation email will be sent to the CI, who must forward this to the research.governance@qmul.ac.uk. Once submitted to HRA, REC and CAG send copies of the documents (including all forms generated within IRAS) to the RMGO, along with all acknowledgement letters and correspondence from the regulators.

14.	CI	**Whilst the application is with regulators, begin study specific management set-up including preparation of SOPs, database validation, and facilitate contract negotiations.** During submission to the regulators, the CI and research team should continue with setting up the study, including: • Setting up Tissue/data access committee(s). • Setting up the Trial Master File and Investigator Site Files (ISF). (see SOP 45 – Essential documentation and Study Master File (TMF)) • Designing the Case Report Forms (CRF). This needs to be reviewed and approved by the CI and statistician. (see SOPs 38a – Computerised Equipment in Clinical Research and 38b – Trial data management systems) • Commencing database design and validation, and design and validation of any associated computer programs (see SOP 38b – Trial data management systems) • Sending a copy of the protocol to the statistician to ensure the CRF matches the protocol. • Drafting study specific SOPs (e.g. plan for multi-site studies). • Progressing contract negotiations if applicable • Preparing the site initiation training. (For a template PowerPoint see SOP 46 – Site selection, site initiation and site activation) • Preparing study committee charters. (For guidance and template charters see SOP 47 – Study Committees) • Recruiting / assigning study specific research posts e.g. research nurse / study coordinators. • Attending the REC/CAG meeting to answer any questions raised by the committee (so that their decision can be made during the meeting). • Obtaining final support department approvals (as applicable)
15.	CI/Delegate	**Send local document pack to sites once HRA Initial Assessment Letter has been received.** Once the HRA initial approval letter has been received, the CI or delegate should send the local document package to participating sites so that they can begin assessing capacity and capability. (see SOP 46 – *Site selection, site initiation and site activation*) In some cases, the HRA may not issue an initial assessment letter. In these cases, the CI or delegate should send the document package to sites once the HRA approval letter has been issued.
16.	CI/Delegate	**Send REC, HRA and CAG approvals to the JRMO. Continue with set-up.** Send the RMGO all approvals from the regulators and evidence that the conditions of their approvals have been met. If the regulators request amendments to the documents, send revised documents to the RMGO for approval prior to resubmission to the regulator to ensure that the sponsor has oversight of the changes that may impact upon the conditions of sponsorship and indemnity. The approved versions of the finalised study documents should be submitted to the RMGO.

17.	CI/ delegate	**Confirmation of Sponsorship and permission to activate sites (if applicable)** Once you have sent the REC, CAG and HRA approvals and all final versions of all approved documents to the JRMO, and all support departments have provided final approval, the RMGO will issue confirmation of sponsorship email (SOP 12b Associated Document 3) which is also the permission to activate the sites (if applicable).
18.	CI	**Confirmation of Capacity and Capability (C&C)** Study cannot start before confirmation of C&C is received from each site. The JRMO will also review C&C for Barts Health/Queen Mary sites and issue a separate C&C approval. Please see SOP 10 for Confirmation of Capacity and Capability for other sites.

List of Associated Documents

Associated Document 1	Study Approvals Reference Table
Associated Document 2a	JRMO protocol template for research studies
Associated Document 2b	JRMO protocol template for Research Tissue Banks and Research Databases
Associated Document 3	JRMO Research Studies Document Submission checklist
Associated Document 4a	Barts Health Sponsor-CI agreement (CI) for research studies
Associated Document 4b	Queen Mary Sponsor-CI agreement (CI) for research studies

Change Control

Background	Merger of scope and purpose and removal of background information
Relevant SOPs	Removal of list in favour of Hyperlinks
Definitions	Removal of the definitions section
Section 4	Information regarding patient and public involvement and engagement activity.
Associated Document 1	Correction of archiving length