Joint Research Management Office Standard Operating Procedure or:			
Barts Health /Queen Mary Sponsorship of Interventional studies – Process for researchers			
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Background:

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

GCP E6 R2 defines the 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.
- Proportionate Governance Sponsorship Review; Completed by JRMO team only (SOP 12b Associated Documents 1 & 2)
- 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.
- 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 process required for obtaining sponsorship from Barts Health or Queen Mary for Interventional studies.

This SOP is written:

a. To ensure that Barts Health/Queen Mary research staff are aware of the process for obtaining sponsorship of Interventional Studies; also, the documentation that they need to submit to the JRMO so that sponsorship review can be undertaken.
b. To ensure all Barts Health/Queen Mary sponsored Interventional Studies have a formal sponsorship agreement in place to comply with the United Kingdom (UK) Policy Framework for Health and Social care research 2017 and Good Clinical Practice (GCP R2 2017).

Scope:

This SOP is applicable to Chief Investigators (CI) or delegate who wish to have Barts Health /Queen Mary act as sponsor for Interventional Studies and the Joint Research Management Office (JRMO) staff involved in the process for granting Barts Health/Queen Mary sponsorship.

It describes the actions required by the CI or delegate to formally request sponsorship and the JRMO procedure for granting sponsorship including the review process and sponsorship confirmation.

This SOP also applies to non-NHS studies that are to be approved by 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.

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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 trials: Process for JRMO staff.

Abbreviations:	
ARSAC	Administration of Radioactive Substances Advisory Committee
BDU	Business Development Unit
Barts Health	Barts Health NHS Trust
C&C	Capacity and Capability
CAG	Confidentiality Advisory Group
CB	Clinical Board
CI	Chief Investigator
CNST	Clinical Negligence Scheme for Trusts
CRC	Clinical Research Centre
CRE	Clinical Radiation Expert
CRF	Clinical Research Facility
CRO	Clinical Research Organisation
CRU	Clinical Research Unit
CTU	Clinical Trials Unit
EU	European Union
GCP	Good Clinical Practice
HRA	Health Research Authority
ISF	Investigator Site File
IRAS	Integrated Research Application System
ISRCTN	International Standard Randomised Controlled Study Number
JRMO	Joint Research Management Office
MPE	Medical Physics Expert
NCC	National Coordinating Centre
NIHR	National Institute for Health Research
PAF	Portfolio Adoption Form
PI	Principal Investigator
PIS	Participation Information Sheet
PRA	Preliminary Research Assessment
QMI	Queen Mary Innovations
QMERC	Queen Mary Ethics of Research Committee
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
RM & GO	Research Management & Governance Officer
SOG	Sponsor Oversight Group
SOP	Standard Operating Procedure
TMF	Trial Master File
UK	United Kingdom

Definitions:

According to the UK Policy Framework for Health and Social care research 2017, the CI is the overall lead researcher for a research study. In addition to their responsibilities if they are members of a research team, CIs are responsible for the overall conduct of a research study. For full list of responsibilities please read HRA website and Section 9.2 of the policy (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)

For Barts Health/Queen Mary *single site* sponsored Interventional Studies the CI should be the Barts Health site's Principal Investigator (PI), with exception of certain PhD student studies.

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Interventional studies: Research involving a change in treatment, care or other services made for the purpose of the 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 14 Review of Research Including Peer Review and Departmental Authorisation • SOP 15 QM Ethics of Research Committee application and approval procedure • SOP 21: Sponsorship, management, and oversight of international-only research: Regulated studies and interventional research • SOP 38a Use of Computerised Equipment, Software and Systems in Clinical Research • SOP 38b Electronic data management systems for MHRA-regulated studies • SOP 40 Vendor Assessment • SOP 45 Essential Documentation including Study Master Files (TMF) • SOP 46 Site Selection, Site Initiation and Site Activation • SOP 47 Trial Committees

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 (SOP 7 Associated Document 1 JRMO Contract Checklist). For further guidance please see SOP 11a Costing MHRA regulated studies guidance. 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 log in to request support from the costing team with the costs. The CI, together with the ACCORD specialist, should ensure that ACCORD method is used, and the costs are categorised correctly i.e., research costs, treatment costs, excess treatment costs, service support costs. The JRMO cannot guarantee the approval of any sponsorship application for Interventional Studies that are considered to have insufficient funds to support the study design or its management. The JRMO may ask the CI to seek further funding or to reduce the scope of the study design to meet the secured budget. 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. Interventional Studies that will be managed by a Clinical Trials Unit (CTU) or established research centre at Barts Health/Queen Mary should involve the CTU/research centre as early as possible to ensure that their costs are captured in the funding application. If a CTU/research centre will not be involved the CI must be able to demonstrate to the JRMO that they have adequate study

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		management support, i.e., a dedicated study manager/study co-ordinator, and sufficient experience to deliver the study compliantly. Please follow SOP 14 Review of Research Including Peer Review and Departmental Authorisation to obtain grant application and scientific peer review approvals. All studies cost money to deliver, however if the CI wishes to undertake this study at no extra cost then they should complete the 'Declaration of no cost form' (Associated Document 4) and get this approved by the head of Institute or Clinical board research director.
2.	CI/ Delegate	**Write the protocol.** The CI or delegate is advised to write a protocol using JRMO interventional studies protocol template that is in line with regulatory requirements (see Associated Document 1). 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 GCP, HRA and other applicable regulatory requirements and guidance.
3.	CI/Delegate	**Arrange Scientific and Departmental Review of Protocol (including IRMER / ARSAC reviews)** Ensure the protocol is comprehensively and independently scientifically reviewed and subsequently sent for departmental review. The 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*). 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.
4.	CI	**Allocate an independent named statistician to the study (not the CI or PI) depending on study design and requirement.** For Interventional Studies depending on study design and requirement within the remit of this SOP a named statistician should be allocated to the study for the duration of the study. The statistician must be suitably qualified and experienced. It is not suitable for the CI or PI to act as the statistician as the statistician's role is to give independent and expert advice on the study at the design phase and throughout. Should there be any amendments that may impact on the statistics or data integrity the statistician should be consulted. It may be necessary to contract an external statistician, which will be established during the contract meetings with the JRMO (see SOP 07 – Costing and Contracting). It is worth noting that no financial support will be provided to the researcher to acquire statistician review.
5.	CI	**Discuss the assignment of a CI with the JRMO.** For Interventional 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

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		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 must be medically qualified in the therapeutic area. The following experience may be considered by the Sponsor Oversight Group (SOG) (this is the group where issues relating to the conduct of clinical research are escalated to): • Previous experience as a CI/PI on non-commercial or commercial regulated studies, multi-site/international studies, experience on Interventional Studies. • Previous GCP and regulatory compliance. • Previous monitoring / audit finding (If applicable). • Previous experience of safety assessments/pharmacovigilance. The CI does not necessarily have to be the grant holder, but it is expected that the CI is centrally involved in the protocol writing and development. For new CIs, the JRMO will work with the research team, Clinical Board (CB) or Institute to assess their experience and determine whether additional peer support, training, or study management support is required.
6.	CI	**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. A feasibility assessment considers whether the study is logistically possible at each/all site(s). This must be undertaken (and the protocol adapted to include feedback from sites and collaborators) before the study is approved by the sponsor and regulators. If the MHRA-regulated study is to have international research sites please see SOP 21 Sponsorship, management, and oversight of international-only research: MHRA Regulated studies and interventional research for further details. The JRMO must approve the study expanding internationally and any issues will be escalated to the SOG as per the JRMO's escalation policy.
7.	CI	**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. See Associated Document 2 JRMO Interventional Studies Document Submission checklist for details on supporting departments.
8.	CI	**With the Costing and Contracts team, begin the contract negotiations with external parties where applicable** 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 are kept informed, as QMI or BDU's input may be required. Certain

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		contracts may be expected to be in place prior to HRA, REC and CAG (if applicable) submissions. Contracts must only be signed by Queen Mary / or Barts Health authorised signatories (*see SOP 7 – Costing and Contracting*). 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. A CI with a financial interest in the study results may influence, or be perceived to potentially influence, their interpretation of the results or those of others. Such interests may be financial gain or vested interest, e.g., shares in the product or device supplier, or receipt of funds from a third party with interests in the research output, a commercially funded research associate post or personal relationship with the third party.
Confirmation of Sponsorship		
9.	CI/ Delegate	**Submit a valid sponsorship application pack to the JRMO prior to applying to the HRA, REC, ARSAC or CAG** Once funding has been secured, and all the relevant actions above have been addressed, submit a valid application pack to the JRMO via research.governance@qmul.ac.uk. Use the JRMO Interventional Studies document submission checklist (see Associated Document 2) to ensure the pack is valid. The Sponsor CI agreement should also be signed and submitted (see Associated Document 3a/3b).This submission should include all documents that will be reviewed by the HRA and REC and CAG or other regulatory body. Only when a valid document pack is received will sponsorship review commence.
10.	CI/ Delegate	**Register the study on a public database(s) such as clinicaltrials.gov prior to applying to the HRA, REC or CAG** The registration of research studies on a public database (clinicaltrials.gov/ International Standard Randomised Controlled Study Number (ISRCTN)) is mandatory for the top 4 IRAS study categories (Clinical Studies) and will be a condition in the ethics favourable opinion letter. If the CI or delegate decides to register the study on clinicaltrials.gov, the governance team will support the registration process. It is the researcher's responsibility to ensure that the study is made "live"/published and any queries raised by public database admins are responded in a timely manner, otherwise the study will not receive confirmation of sponsorship. The JRMO encourages to use of ISRCTN until the HRA becomes responsible for this process. It is the CI's or delegate's responsibility to obtain an ISRCTN number and register the study.
11.	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 Research Management & Governance Officer (RM & GO). The JRMO welcomes meetings to discuss the study and clarify any issues that may cause delays in study set up. Once all requirements have been met, the RM & GO will issue 'Sponsorship with conditions' letter.

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12.	CI/ Delegate	**Request sponsor authorisation on the IRAS form. Submit to regulators and inform JRMO of all correspondence with the regulators, including amendments.** Once the sponsorship with conditions letter has been received by 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 NIHR 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. 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 RM & GO, along with all acknowledgement letters and correspondence from the regulators. If a study requires submission of an ARSAC PRA then the CI should also request sponsor signature and submit to the ARSAC Support Unit (along with a copy of the Participation Information Sheet (PIS)) at the same time the study is being submitted to REC.
13.	CI/ Delegate	**Whilst the application is with regulators, begin study specific management set-up including preparation of SOPs, databases and validation, contact participating site / invite sites and facilitate relevant contracts which may be required.** During submission to the regulators, the CI and research team should continue with setting up the study.
14.	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 (C&C). (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.
15.	CI/ delegate	**Send REC, HRA, ARSAC and CAG approvals to the JRMO. Continue with set-up.** Send the JRMO RM & GO all approvals from the regulators and evidence that the conditions of their approvals have been met. If the regulators request

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		amendments to the documents, send revised documents to the RM & GO 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 RM & GO.
16.	CI/ delegate	**Confirmation of Sponsorship and permission to activate sites (if applicable)** Once you have sent the REC and HRA approvals and all final versions of all approved documents, the RM & GO will check that the study has been registered on a public database (If the study belongs to the first 4 categories of IRAS) and issue combined Confirmation of Sponsorship and confirmation of sponsorship e-mail and permission to activate sites (if applicable).
17.	CI	**Confirmation of site Capacity & Capability (C&C)** Study cannot start before confirmation of C&C is received from each site. For Barts Health/Queen Mary sites, C&C will be issued at the same time as Confirmation of Sponsorship in one approval. Please see SOP 10 for Confirmation of Capacity and Capability for other sites.

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List of Associated Documents

Associated Document 1	JRMO protocol template for interventional studies
Associated Document 2	JRMO Interventional Studies Document Submission checklist
Associated Document 3a	Barts Health Sponsor-CI Agreement for interventional studies
Associated Document 3b	Queen Mary Sponsor-CI Agreement for interventional studies
Associated Document 4	Declaration of no cost form

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