

Joint Research Management Office Standard Operating Procedure for:

## Barts Health /Queen Mary Sponsorship of Research 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 research studies, 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;
- Proportionate Governance Sponsorship Review; Completed by JRMO team only ([SOP 12b Associated Document 2](#) and [SOP 13b Associated Document 1](#))
- 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;
- Dissemination of the results;
- Project 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 Research studies.

At the Joint Research Management office (JRMO), studies are classified into MHRA regulated (See [SOP 11a](#)), Interventional (See [SOP 12a](#)) and Research (this SOP) Studies. A Research study here is defined as any study related to human research where no change to participant care or treatment occurs. A blood test taken for the purpose of the study (so not standard routine care blood tests) is still classed as a research study if it does not change the care the patient receives afterwards.

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 is written:

- a. To ensure that Barts Health/Queen Mary research staff are aware of the process for obtaining sponsorship of research studies including the documentation that they need to submit to the Joint Research management Office (JRMO).
- 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 is applicable to Chief Investigator (CI) or delegate who wish to have Barts Health/Queen Mary act as sponsor for research studies and the 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 is also applicable to non-NHS studies that are to be approved by Queen Mary Ethics of Research Committee (QMREC) (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
CB	Clinical Board
CBS	Central Booking Service
CD	Clinical Director
CI	Chief Investigator
CNST	Clinical Negligence Scheme for Trusts
CRF	Case Report Form

EEA	European Economic Area
EU	European Union
GCP	Good Clinical Practice
HRA	Health Research Authority
IRAS	Integrated Research Application System
JRMO	Joint Research Management Office
NCC	National Coordinating Centre
NIHR	National Institute for Health Research
PI	Principal Investigator
QMI	Queen Mary Innovations
QMERC	Queen Mary University of London Ethics of Research Committee
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
RM	Research Management
RMGO	Research Governance & Management Officer
SOG	Sponsor Oversight Group
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, CI are responsible for the overall conduct of a research study. For a 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 research studies the CI should be the Barts Health site's Principal Investigator (PI), with exception of certain PhD student studies.

For student projects please visit the HRA website for further details- <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/>.

**Relevant SOPs:**

This SOP is closely linked with:

SOP 1	Research Project Application
SOP 7	Costing and Contracting
SOP 10	Confirmation of capacity & capability
SOP 14	Review of Research Including Peer Review and Departmental Authorisation
SOP 15	QM Ethics of Research Committee application and approval procedure
SOP 17c	Process for Researchers - Amendments for Sponsored studies
SOP 18a	Process for Researchers - Study Closure of Sponsored Studies
SOP 23	Risk Assessment
SOP 38a	Use of Computerized Equipment, Software and Systems in Clinical Research
SOP 38b	Study Data Management Systems
SOP 40	Vendor Assessment
SOP 45	Process for Researchers - Essential Documentation including Trial Master Files and for all External Sites and Facilities
SOP 46	Site Selection, Site Initiation and Site Activation

**SOP Text**

	Responsibility	Activity
1.	CI/ CI delegate	<p><b>Work with JRMO Costing Team to obtain an accurate cost for the study.</b></p> <p>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 . Funding should include (but is not limited to):</p> <ul style="list-style-type: none"> <li>• Study set-up,</li> <li>• Study delivery,</li> <li>• Study management and coordination,</li> <li>• Monitoring,</li> <li>• Maintaining and running a GCP compliant database,</li> <li>• Site's supplies and equipment,</li> <li>• Imaging costs (including sample scans), staff and participant travel,</li> <li>• External contractors i.e. labs, sample, handling and storage costs, all subcontractors and outsourced facilitates, Contract Research Office (CRO), statisticians (see <a href="#">SOP 7b Contracting for Interventional and Research Studies</a> and <a href="#">SOP 1 Research project applications</a> for costing questions with prompts),</li> <li>• Archiving.</li> </ul> <p>The CI should complete a Pre Costing Questionnaire <a href="https://webapps2.is.qmul.ac.uk/ecosting/">https://webapps2.is.qmul.ac.uk/ecosting/</a> or email <a href="mailto:jrmo-helpdesk-preaward@qmul.ac.uk">jrmo-helpdesk-preaward@qmul.ac.uk</a> if they do not have a Queen Mary log in to request support from the costing team with the costs.</p> <p>The CI is encouraged to discuss the proposed study with the JRMO Governance Team if they wish to do so.</p> <p>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.</p> <p>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' (<a href="#">SOP 12b Associated Document 7</a>) and get this approved by the head of Institute or Clinical board research director.</p> <p>Before agreeing to any milestones with funders, the CI should discuss their feasibility with 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.</p> <p>Please follow <a href="#">SOP 14 Review of Research Including Peer Review and Departmental Authorisation</a> to obtain grant application and scientific peer review approvals.</p>
2.	CI/ Delegate	<p><b>Write the protocol.</b></p> <p>The CI or delegate must write a protocol using JRMO research studies protocol template that is in line with regulatory requirements (see <a href="#">associated document 2a</a></p>

		<p><a href="#">or 2b if setting up a Research Tissue bank or research database</a>). Care should be taken to ensure that no template wording or guidance remains in the submitted protocol.</p> <p>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.</p>
3.	CI/Delegate	<p><b>Arrange Scientific and Departmental Review of Protocol</b></p> <p>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 <a href="#">SOP 14 – Peer Review</a>).</p> <p>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.</p> <p>Student studies may use supervisor to replace independent scientific reviews.</p>
4.	CI	<p><b>Allocate a statistician to the study</b></p> <p>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 <a href="#">SOP 07b – Contracting for Interventional and Research studies</a>).</p>
5.	CI	<p><b>Discuss the assignment of a new Chief Investigator with the JRMO.</b></p> <p>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).</p> <p>The CI should have the appropriate level of experience to conduct the study.</p>
6.	CI/Delegate	<p><b>Site Feasibility Assessment</b></p> <p>It is the CI's responsibility to undertake a site feasibility assessment (<a href="#">see SOP 46 - site selection, site initiation and site activation</a>) 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.</p> <p><u>If the Research Study is to have international research sites</u></p> <p>Only Queen Mary can sponsor international research, with a Queen Mary substantively employed CI with a legal representative in Europe for EU sites (more details on international only sponsorship see <a href="#">SOP 21</a>). Barts Health (with NHS's Clinical Negligence Scheme for Trusts (CNST) indemnity) cannot sponsor international studies. The CI must notify the JRMO about their plans to open internationally at the beginning. A full justification for international studies and the</p>

		<p>selection of countries must be given prior to sponsorship approval. This will also include information about any contract research organisation (CRO) that will be used to coordinate and secure international regulatory approvals (see <a href="#">SOP 40 – Vendor Assessments</a>). The identification of a national coordinating centre (NCC) may be required in each country to oversee on-going national regulatory compliance (one NCC may cover more than one country). (See <a href="#">SOP 46 Site selection, site initiation and site activation</a>) for more information.</p> <p>All requests for addition of international sites must be reviewed by the JRMO Governance Officer, Post Award Officer and Pre Award Officer with the JRMO. Only once approval is granted can these international sites be added to the study.</p>
7.	CI/Delegate	<p><b>Coordinate approvals of the protocol from support departments</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>• Imaging</li> <li>• Laboratory leads</li> <li>• Pathology</li> <li>• Tissue storage</li> </ul> <p>For contact details please refer to Research Studies submission checklist (<a href="#">Associated Document 3</a>) for contact details.</p>
8.	CI	<p><b>With the Costing and Contracts Manager, begin the contract negotiations with external parties where applicable</b></p> <p>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 <a href="#">SOP 7b – Contracting for Interventional and Research Studies</a>).</p> <p>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.</p> <p>As sponsors, the JRMO must be made explicitly aware of any competing interests that the CI or members of their team may have.</p>
<b>Confirmation of Sponsorship</b>		
9.	CI/Delegate	<p><b>Submit a valid Sponsorship application pack to the JRMO prior to applying to the HRA, REC or CAG</b></p> <p>Once funding has been secured, and all the relevant actions above have been addressed, submit a valid application pack to JRMO via <a href="mailto:research.governance@qmul.ac.uk">research.governance@qmul.ac.uk</a>. Use the JRMO submission checklist (see <a href="#">Associated Document 3</a>) to ensure the pack is valid. This submission should include all documents that will be reviewed by the HRA and REC and CAG or other regulatory body, and should be submitted in parallel so that the JRMO can review the consistency across all documents. The Sponsor CI agreement should also be signed and submitted (see <a href="#">Associated Document 4a and 4b</a>).</p>

		Only when a valid document pack is received will sponsorship review commence.
10.	CI/Delegate	<p><b>Revise documents to incorporate feedback (and answer any questions) from the JRMO.</b></p> <p>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 &amp; Governance Officer (RM &amp; GO). The JRMO welcomes meetings to discuss areas of concern with the research team.</p> <p>Once all requirements have been met the RM &amp; GO will issue 'sponsorship with conditions' letter.</p>
11.	CI/Delegate	<p><b>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.</b></p> <p>Once the sponsorship with conditions letter has been received by the CI or delegate, they should request <a href="mailto:research.governance@qmul.ac.uk">research.governance@qmul.ac.uk</a> 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.</p> <p>A Portfolio Application Form (PAF) is no longer required to apply for NIHR Clinical Research Network (CRN) support. 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.</p> <p>For Research Tissue Bank/Research Database studies authorisation request of IRAS form to be sent to Tissue Bank Manager (Katie Ersapah <a href="mailto:k.ersapah@nhs.net">k.ersapah@nhs.net</a>) or the Information Governance/Data Protection Officer where appropriate (<a href="mailto:bartshealth.infogov@nhs.net">bartshealth.infogov@nhs.net</a>).</p> <p>The CI or delegate should submit to the HRA, REC and CAG application (if applicable) in parallel to avoid delays.</p> <p>Once the application has been booked into the Central Booking Service (<a href="https://www.hra.nhs.uk/about-us/committees-and-services/online-booking-service/">https://www.hra.nhs.uk/about-us/committees-and-services/online-booking-service/</a>), a confirmation email will be sent to the CI, who must forward this to the <a href="mailto:research.governance@qmul.ac.uk">research.governance@qmul.ac.uk</a>.</p> <p>Once submitted to HRA, REC and CAG send copies of the documents (including all forms generated within IRAS) to the RM &amp; GO, along with all acknowledgement letters and correspondence from the regulators.</p>
12.	CI	<p><b>Whilst the application is with regulators, begin study specific management set-up including preparation of SOPs, database validation, and facilitate contract negotiations.</b></p> <p>During submission to the regulators, the CI and research team should continue with setting up the study, including:</p> <ul style="list-style-type: none"> <li>• Setting up Tissue/data access committee(s).</li> <li>• Setting up the study master file (TMF) and investigator site files (ISF).</li> </ul>

		<p>(see <a href="#">SOP 45 – Essential documentation and Study Master File (TMF)</a>)</p> <ul style="list-style-type: none"> <li>• Designing the Case Report Forms (CRF). This needs to be reviewed and approved by the CI and statistician. (see <a href="#">SOPs 38a – Computerised Equipment in Clinical Research</a> and <a href="#">38b – Trial data management systems</a>)</li> <li>• Commencing database design and validation, and design and validation of any associated computer programs (see <a href="#">SOP 38b – Trial data management systems</a>)</li> <li>• Sending a copy of the protocol to the statistician to ensure the CRF matches the protocol.</li> <li>• Drafting study specific SOPs (e.g. plan for multi-site studies).</li> <li>• Progressing contract negotiations if applicable</li> <li>• Preparing the site initiation training. (For a template PowerPoint see <a href="#">SOP 46 – Site selection, site initiation and site activation</a>)</li> <li>• Preparing study committee charters. (For guidance and template charters see <a href="#">SOP 47 – Study Committees</a>)</li> <li>• Recruiting / assigning study specific research posts e.g. research nurse / study coordinators.</li> <li>• Attending the REC meeting to answer any questions raised by the committee (so that their decision can be made during the meeting).</li> </ul>
13.	CI/Delegate	<p><b>Send local document pack to sites once HRA Initial Assessment Letter has been received.</b></p> <p>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 <a href="#">SOP 46 – Site selection, site initiation and site activation</a>)</p> <p>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.</p>
14.	CI/Delegate	<p><b>Send REC, HRA and CAG approvals to the JRMO. Continue with set-up.</b></p> <p>Send the JRMO RM &amp; GO 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 RM &amp; 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 &amp; GO.</p>
15.	CI/ delegate	<p><b>Confirmation of Sponsorship and permission to activate sites (if applicable)</b></p> <p>Once you have sent the REC, CAG and HRA approvals and all final versions of all approved documents, the RM &amp; GO will issue combined confirmation of sponsorship email and permission to activate sites (if applicable).</p>
16.	CI	<p><b>Confirmation of Capacity and Capability (C&amp;C)</b></p> <p>Study cannot start before confirmation of C&amp;C is received from each site. For Barts Health/Queen Mary sites, C&amp;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.</p>



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

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