| Joint Research Management Office Standard Operating Procedure or: | | | |
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| **Barts Health /Queen Mary Sponsorship of Interventional studies – Process for researchers** | | | |
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## Purpose and Scope:

This Standard Operating Procedure (SOP) is applicable to Chief Investigators (CI) or delegate who wish to have Barts Health NHS Trust (Barts Health) /Queen Mary University of London (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. Interventional studies are research studies involving a change in treatment, care or other services made for the purpose of research.

This SOP also applies to non-NHS studies that are to be approved by Queen Mary Ethics of Research Committee (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 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 11a Barts Health/Queen Mary sponsorship of MHRA-regulated trials: Process for Researchers.

## Abbreviations:

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| ARSAC | Administration of Radioactive Substances Advisory Committee |
| Barts Health | Barts Health NHS Trust |
| C&C | Capacity and Capability |
| CAG | Confidentiality Advisory Group |
| CI | Chief Investigator |
| CTU | Clinical Trials Unit |
| HRA | Health Research Authority |
| IRAS | Integrated Research Application System |
| JRMO | Joint Research Management Office |
| NIHR | National Institute for Health Research |
| Queen Mary | Queen Mary University of London |
| REC | Research Ethics Committee |
| RMGO | Research Management & Governance Officer |
| SOP | Standard Operating Procedure |

| SOP Text | | |
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| | Responsibility | Activity |
| 1. | CI/ CI delegate | **Work with the JRMO Costing Team to obtain an accurate cost for the study.**<br><br>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 (See SOP 7a Associated Document 1 JRMO Contract Checklist and SOP 7b Contracting for Interventional and Research Studies). For further best practice guidance please see SOP 11a Associated Document 1 Costing MHRA regulated studies guidance.<br><br>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 with the costs. The CI, together with the Administration of Radioactive Substances Advisory Committee (ACCORD) specialist, should ensure that the ACCORD method is used, and the costs are categorised correctly i.e., research costs, treatment costs, excess treatment costs, service support costs.<br><br>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.<br><br>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.<br><br>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 management support, i.e., a dedicated study manager/study co-ordinator, and sufficient experience to deliver the study compliantly.<br><br>Please follow SOP 14 Review of Research Including Peer Review and Departmental Authorisation to obtain grant application and scientific peer review approvals.<br><br>All studies cost money to deliver, however if the CI wishes to undertake this study at no extra cost then they should complete the Approval for Non-Funded Projects: New Studies (Associated Document 4) and get this approved by the Head of Institute or Clinical Board Research Director.<br><br>Queen Mary insurance will be checked internally by the Research Management Governance Officer (RMGO) and Queen Mary insurance team. |
| 2. | CI/ Delegate | **Write the protocol.**<br><br>The CI or delegate must write a protocol using the JRMO interventional studies protocol template which is in line with regulatory requirements (see Associated |

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| | | Document 1). Care should be taken to ensure that no template wording or guidance remains in the submitted protocol.<br><br>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 (including IRMER / Administration of Radioactive Substances Advisory Committee (ARSAC) reviews)**<br><br>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*).<br><br>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 depending on study design and requirement.**<br><br>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 its duration. The statistician must be suitably qualified, experienced and this person can also be the CI/Principal Investigator of the interventional study.<br><br>Should there be any amendments that may impact on the statistics or data integrity the statistician must be consulted. It may be necessary to contract an external statistician, which will be established during the contract meetings with the JRMO (see SOP 07b – Contracting for Interventional and Research Studies). |
| 5. | CI | **Discuss the assignment of a CI with the JRMO.**<br><br>For Interventional Studies sponsored by Barts Health /Queen Mary, the CI should have a substantive contract with the sponsor (Barts Health/Queen Mary accordingly). If in doubt, please discuss with the JRMO.<br><br>The CI must be medically qualified and ideally work in the therapeutic area.<br><br>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.<br><br>For new CIs, the JRMO will work with the research team, Clinical Board or Institute to assess their experience and determine whether additional peer support, training, or study management support is required. |
| 6. | CI | **Site Feasibility Assessment**<br><br>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, this includes PPI involvement as there a costs to this. A feasibility assessment considers whether the study is logistically possible at each/all site(s). This must be undertaken (and the |

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| | | protocol adapted to include feedback from sites and collaborators) before the study is approved by the sponsor and regulators.<br>The JRMO must approve the study expanding internationally and any issues will be escalated to the Sponsor Oversight Group as per the JRMO's escalation policy. |
| 7. | CI | **Coordinate approvals of the protocol from support departments**<br><br>At the design stage, the CI or delegate should obtain input into the protocol from each support department. The support department's 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**<br><br>Where Queen Mary Innovation, JRMO International Team or the Business Development Unit staff have been involved in the contract negotiations, the CI must ensure that the JRMO are kept informed of these discussions. Certain contracts may be expected to be in place prior to HRA, REC and Confidentiality Advisory Group (CAG) (if applicable) submissions. Contracts must only be signed by Queen Mary or Barts Health authorised signatories (see SOP 7b – Contracting for Interventional and Research Studies).<br><br>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. |
| 9. | CI/ Delegate | **Register the study on a public database(s) such as clinicaltrials.gov prior to applying to the HRA, REC or CAG**<br><br>The registration of research studies on a public database (clinicaltrials.gov/ International Standard Randomised Controlled Study Number) is mandatory for the top 4 Integrated Research Application System (IRAS) study categories (Clinical Studies) and will be a condition in the ethics favourable opinion letter. Please contact research.governance@qmul.ac.uk to request an account is set up but the researcher will need to complete all fields in order for the study to be "live"/published by the time confirmation of sponsorship is issued. |
| **Application for JRMO Sponsorship** | | |
| 10. | CI/ Delegate | **Submit a valid sponsorship application pack to the JRMO prior to applying to the HRA, REC, ARSAC or CAG**<br><br>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.<br><br>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 (This includes submitting a completed Data Protection Impact Assessment checklist. See SOP 16a Data protection for research studies for further details) |

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| 11. | CI/ Delegate | **Revise documents to incorporate feedback (and answer any questions) from the JRMO.**<br>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. Updated documents without clear tracked changes or comments included will not be reviewed and may hold up the approval process. The JRMO welcomes meetings to discuss the study and clarify any issues that may cause delays in study set up.<br><br>Once all requirements have been met and any support department approvals obtained, the RMGO will issue 'Sponsorship with conditions' email. |
| 12. | CI/ Delegate | **Request sponsor authorisation on the IRAS form. Submit to regulators and inform JRMO of all correspondence with the regulators, including amendments.**<br><br>Once the sponsorship with conditions email 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.<br><br>To apply for National Institute for Health Research (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.<br><br>The CI or delegate should submit to the HRA, REC and CAG application (if applicable) in parallel to avoid delays.<br><br>Once submitted to HRA, REC and/or CAG any comments/queries should be forwarded to the JRMO for information.<br><br>If the regulators request amendments to the documents, revised documents should be sent 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. |
| 13. | CI/ Delegate | **During submission to the regulators, the CI and research team should continue with setting up the study.**<br><br>Whilst the application is with regulators, begin study specific management set-up including preparation of SOPs, setting up a Trial Master File, validation of all databases and e-systems, contact participating site / invite sites and facilitate relevant contracts which may be required. |
| 14. | CI/ Delegate | **Send local document pack to sites once HRA initial assessment letter has been received.**<br><br>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*) |

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| | | 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 RMGO. Continue with set-up.**<br><br>Send the RMGO all approvals from the regulators, alongside evidence that the conditions of their approvals have been met and all approved versions of the finalised study documents. |
| 16. | CI/ delegate | **Confirmation of Sponsorship and permission to activate sites (if applicable)**<br><br>Once you have sent the REC and HRA approvals and all final versions of all approved documents, the RMGO will check these and that registration of the study is complete (as applicable) and issue the confirmation of sponsorship e-mail and permission to activate sites (if applicable). |
| 17. | CI | **Confirmation of site C&C**<br><br>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. |

## List of Associated Documents

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| 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 | Approval for Non-Funded Projects: New Studies |

## Change Control

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| 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 1 | Confirmation Queen Mary insurance checked by the RMGO |
| Section 9 | Registering on a public database prior to application for JRMO sponsorship |
| Associated Document 4 | Change of document name for clarity |