Joint Research Management Office Standard Operating Procedure for:

Barts Health /Queen Mary Sponsorship of Interventional studies – Process for JRMO Staff

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Purpose and Scope:

This SOP applies to all Barts Health NHS Trust (Barts Health)/Queen Mary University of London (Queen Mary) sponsored interventional studies where participating sites are in the UK or outside the UK.

This SOP applies to all staff in the Joint Research Management Office (JRMO), and describes the JRMO procedure, in response to receiving a formal sponsorship request from a Chief Investigator (CI) or delegate, for granting sponsorship for an interventional study 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.

Abbreviations:

ARSAC	Administration of Radioactive Substances Advisory Committee
Barts Health	Barts Health NHS Trust
CI	Chief Investigator
GCP	Good Clinical Practice
HRA	Health Research Authority
JRMO	Joint Research Management Office
NIHR	National Institute for Health Research
OID	Organisation Information Document
QMERC	Queen Mary Ethics of Research Committee
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
RMGO	Research Management and Governance Officer
SoE/SoECAT	Schedule of Events/ Schedule of Events Cost Attribution Template

SOP Text		
	Responsibility	**Activity**
		Early engagement
1.	Governance Team	**Governance Team will guide researchers and offer their support in development, design and 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 12a Associated Document 2), the use of appropriate protocol template (SOP 12a Associated Document 1) and local process. The JRMO sponsorship proportionality document (Associated Document 1) is a good guide to help explain the 3 study types.
		Confirmation of Sponsorship
2.	Assigned Research Management and Governance Officer (RMGO)/R&D Administrator or delegated individual	**Upon receipt of a sponsorship submission pack, the assigned RMGO acknowledges receipt.** 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 RMGO who will assess sponsor application pack as per JRMO Interventional Studies Submission checklist (SOP 12a Associated Document 2). Acknowledge receipt of the submission. 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 Interventional Studies submission checklist (SOP 12a Associated Document 2), otherwise, the submission is deemed is 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. The assigned RMGO will set up the study on EDGE and upload the paperwork to the indemnity folder and keep EDGE updated and LIVE throughout review. If no Barts Health/Queen Mary EDGE account is available for the CI, the RMGO will create an EDGE account and notify Research Information Lead that the CI will need EDGE training.
3.	Assigned RMGO	**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 incomplete submission. Seek Good Clinical Practice (GCP) and Governance Managers advice if there is uncertainty regarding whether the study falls under remit of MHRA. Any concerns about the application should be brought to the attention of the Research Governance & Performance Manager and raised with the relevant Barts Health/Queen Mary expert i.e. GCP and Governance Managers, Information Governance, Human Tissue Authority representative, IT.

		Confirmation/Evidence of funding and costing of study by JRMO is mandatory. If the study has funding awarded, then upload the funding award to EDGE and save in indemnity. The study should show as live in worktribe where funding has been awarded and contracts with the funder 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.
4.	Assigned RMGO	**Undertake sponsorship review and risk assessment of the protocol and study.** Upon receipt of a valid application as per submission checklist (SOP 12a Associated Document 2), the RMGO will update EDGE with all study details and commence sponsorship workflow. The JRMO Governance Officer's review is the primary sponsorship review and will be performed in accordance with SOP 13b Associated Document 3 Sponsorship review guidance document for Interventional and Research Studies. Upon completion of the review, the RMGO will email the research team feedback and request further clarification as applicable. For studies that may be adopted on National Institute for Health Research (NIHR) portfolio, advise CI to select 'yes' to question 5b of the IRAS Project Filter. Advise the CI (or delegate) regarding Administration of Radioactive Substances Advisory Committee (ARSAC) preliminary research assessment (PRA) form if study involves the administration of radioactive substances. 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 sponsorship with conditions being granted.
5.	Assigned RMGO	**Support CI/CI team with approvals of the protocol from support departments** 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. Check that all relevant supporting departments are aware of the study and have provided their approval (If applicable).
6.	Costing & Contracts Officer	**Confirm costings & requirement for contracts** Work with the study team to identify all external vendors and the services they will provide. Ensure that each activity in the 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 cost Check for external vendors and agreement for tissues/data sharing. Once satisfied inform the RMGO that the process is completed and send them a copy of the agreed documentation. Advise on appropriateness of contract / Organisation Information Document (OID) for the study. Provide draft mNCA/OID for regulatory submission. The Schedule of Events/ Schedule of Events Cost Attribution Template should be populated by CI team, then submitted via CPMS, and then reviewed by JRMO AcoRD Specialist. Ensure that there are adequate funds to cover the cost of the study and provide confirmation to the assigned RMGO.
7.	Assigned RMGO	**Complete risk assessment** Complete a risk assessment as per SOP 23 Risk Assessment. If the score is medium, then an additional review must be completed the by the Research Governance & Performance Manager and if the score is high then an additional review must be completed by a GCP and Governance manager. Add risk score to EDGE.
8.	Assigned RMGO	**Ensure study is registered on a public database if required** For top 4 IRAS study categories (Clinical Studies), CI or delegate must register the study on a public database such as clinicaltrials.gov or International Standard Randomised Controlled Trial Number. It is the responsibility of the Governance Officer to ensure that the record is "live" otherwise the confirmation of sponsorship cannot be issued. RMGO should facilitate this and work with the study team.
9.	Assigned RMGO	**Finalise the Governance Review & issue Sponsorship with Conditions** Once you have confirmed that all approvals are in place, that appropriate costing is in place and any contracts have been received , finalise the sponsorship review. Review study file and proceed with issuing Sponsorship with Conditions to the CI or delegate as appropriate (Associated Document 2 Sponsorship with conditions email template (Interventional and Research Studies). Insurance Certificate must be issued as part Confirmation of Sponsorship for all Queen Mary Sponsored studies. State that the study can now be submitted for regulatory approval.
10.	Assigned RMGO	**Possible requested changes from regulatory bodies** Any amendments requested by Research Ethics Committee (REC) or Health Research Authority (HRA) during their review should be checked and reviewed

		by assigned RMGO before it is submitted back by the CI to relevant regulatory body.
Once appropriate approvals are received		
11.	Assigned RMGO	**Request all the final HRA Approved documents following regulatory approvals** Once the relevant approvals (REC, HRA, ARSAC and Confidentiality Advisory Group (if applicable)) approvals have been received, the assigned RMGO will request for all the final HRA approved documents as listed on the HRA approval letter. If any contracts are applicable, RMGO must request for the fully executed copies.
Issuing Confirmation of Sponsorship and Permission to Activate Sites		
12.	Assigned RMGO	**Issue confirmation of sponsorship and C&C (confirmation of capacity and capability)** Issue confirmation of sponsorship and permission to activate sites (if applicable) email (Associated document 3). If Barts Health or Queen Mary are also hosting this study, then EDGE Barts health site level entry needs to be completed and site review to be completed. (see SOP 10 Confirmation of Capacity and Capability). Make sure EDGE record and indemnity folder are updated and study documents uploaded.

List of Associated Documents

Associated Document 1	JRMO Sponsorship review proportionality document
Associated Document 2	Sponsorship with conditions email template (Interventional and Research Studies)
Associated Document 3	Confirmation of Sponsorship/Permission to activate sites template email

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	Removal of duplication with associated document
Section 8	Removal of clinical trials.gov guidance in place of hyperlink
Section 9	Removal of the declaration of sponsorship letters
Section 10	Guidance for process of document review following regulatory bodies queries.