Joint Research Management Office Standard Operating Procedure for:			
Barts Health/Queen Mary Sponsorship of Research Studies – Process for JRMO staff			
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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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Scope:

This SOP applies to all Barts Health/Queen Mary sponsored research studies where participating sites are in the UK or outside the UK.

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

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 studies: Process for JRMO staff.

For interventional studies (research involving a change in treatment, care or other services made for the purpose of the research) please use SOP 12b Barts Health /Queen Mary Sponsorship of Interventional studies – Process for JRMO Staff.

This study involving experimental use of medical equipment and/or devices please use SOP 9 Sponsorship of Clinical Investigations and other MHRA-regulated Medical Device Studies.

Abbreviations:

Barts Health	Barts Health NHS Trust
CAG	Confidentiality Advisory Group
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
PI	Principal Investigator
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
RMGO	Research Management and Governance Officer
SoECAT	Schedule of Events Cost Attribution Template
TMF	Trial Master File

SOP Text		
	Responsibility	**Activity**
		Early engagement
1.	Governance Team	**Governance Team will guide and support researchers with the 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, the use of appropriate protocol template (SOP 13a Associated Documents 2a, 2b and 3) and local process. The JRMO sponsorship proportionality document (SOP 12b Associated Document 1) is a good guide to help explain the 3 study types. Also, use the study approvals reference table as guidance for the required approvals (SOP 13a Associated Document 1).
		Confirmation of Sponsorship
2.	Assigned Research management and Governance Officer (RMGO) GO/R&D Administrator or delegate	**Upon receipt of a sponsorship submission pack, the assigned RMGO acknowledges receipt.** 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 Research Studies Submission checklist (SOP 13a Associate Document 3), otherwise, the submission is deemed as 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. When submissions are received via research.governance@qmul.ac.uk they will be allocated to a RMGO who will assess sponsor application pack as per JRMO Research Studies Submission checklist (SOP 13a Associated Document 3) and Retrospective data studies guidance document (Associated Document 1), if applicable. The assigned RMGO will set up the study on EDGE and upload the paperwork to the indemnity folder. If no EDGE account is available for the CI notify the Research Information Lead.
3.	Research Information Lead/RMGO	**Create EDGE account for the CI if one does not exist** Ensure EDGE training is provided where required.

	Assigned RM & GO	**Send valid submission/introductory email to CI or delegate and proceed to review the study.** Inform the CI or delegate that you will be the main point of contact. Confirm receipt of a valid submission or request further documents/clarification if incomplete submission. Any concerns about the application should be brought to the attention of the Research Governance and Performance Manager and raised with the relevant Barts Health /Queen Mary expert i.e., GCP and Governance Manager, Information Governance, HTA representative, IT. Where appropriate confirmation or evidence of funding and costing of study by the costing and contracting team is required. Obtain confirmation with Queen Mary pre-award team (Queen Mary via WorkTribe) or Barts Health pre-award team (Barts Health directly by costing officer) on any shortfalls.
4.	Assigned RM & GO	**Undertake sponsorship review of the protocol and study.** Upon receipt of a valid application as per submission checklist (SOP 13a Associated Document 3), the RMGO will update EDGE with all study details and commence sponsorship workflow. Review all documents for completeness and consistency using the JRMO research application review form for Research Studies as a guide if required, ensuring feedback is given to the CI or delegate**.** The JRMO RMGO's review is the primary sponsorship review of documents listed in Associated Document 2 Sponsorship review guidance document for Interventional and Research Studies. If the CI intends to access confidential patient information without consent or by individuals outside the direct care team then the CI should apply to the CAG. RMGO can provide guidance to CI on how to make the application (guidance and process can be found on HRA website). Studies requiring CAG approval, the appropriate Caldicott Guardian will need to sign off the IRAS form appropriately. Review study for high risk/trigger issues (as defined in SOP 23 Associated Document 2 Triaging for research studies risk assessment) then complete a risk assessment if deemed necessary. See SOP 23 Risk Assessment for details on assessment if risk scores. Information governance (IG) requires completion of a pre-screening questionnaire and subsequent Data Protection Impact Assessment (DPIA) where applicable. See SOP 16a Associated Document 2 for full details and procedure. Upon completion of the review, the RMGO will email the research team with their feedback and request further clarification as applicable. Complete the appropriate data fields and workflows on EDGE. Keep EDGE workflow, attributes and documents updated live as the study progresses.

5.	Costing & Contracts Officer	**Confirm costings & requirement for contracts** Ensure that each activity in the application has been correctly attributed 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 costs Check for external vendors and agreements for tissue/data sharing. Once satisfied inform the RMGO that the process is completed and send them a copy of the agreed documentation. Fully executed agreements do not need to be in place prior to regulatory submission. Advise on appropriateness of Contract/OID for the study. Provide a draft mNCA/ OID for regulatory submission. The SoECAT 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
6.	Assigned RM & GO	**Support CI/CI's team with the necessary support department approvals - Depending on the level of involvement this can be undertaken after the study has been submitted for Regulatory Approvals** 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. Depending on the level of involvement local approvals can be sought once the sponsorship letter has been issued and an application is submitted to the regulatory bodies. Check that all relevant supporting departments are aware of the study and have provided their approval (If applicable). For example: • Tissue Bank Manager • Pathology/Laboratory manager Identify all external vendors and their roles. Liaise with the JRMO Costing and Contact team regarding costs/confirmation of funds and seek advice on contracts/agreements. Depending on the level of involvement and current engagement, completion of contractual arrangements can be undertaken in parallel with regulatory approvals process.
7.	Assigned RM & GO	**Finalise the Governance Review & issue Sponsorship with conditions** Once the RMGO is satisfied that the documentation is complete and that relevant approvals are in place or have been initiated (where it has been confirmed that review and approvals can be undertaken in parallel to regulatory review) finalise the sponsorship review. Proceed with issuing sponsorship with conditions email (AD) and ask the CI or delegate to request sponsor authorisation via IRAS.

		Advise the researcher of the outstanding approvals and contracts that will be required prior to confirmation of sponsorship and/or issuing Confirmation of capacity and capability. Insurance certificate must be issued as part confirmation of sponsorship for all Queen Mary sponsored studies.
Once appropriate approvals are received (REC, HRA and HCRW~~,~~ Administration of Radioactive Substances Advisory Committee (ARSAC), CAG is received.		
8.	Assigned RM & GO	**Request all the final HRA and HCRW Approved documents following regulatory approvals.** Once the relevant approvals REC, HRA and HCRW, and CAG (if applicable) approvals have been received, the assigned RMGO will request for all the final HRA and HCRW approved documents as listed on the HRA and HCRW approval letter. If any contracts are applicable RMGO must request the fully executed copies.
Issuing Confirmation of Sponsorship and Permission to Activate Sites		
9.	Assigned RM & GO	**Issue Confirmation of Capacity and Capability (C&C)** Issue confirmation of sponsorship which is also permission to activate sites (if applicable) email (see SOP 12b Associated Document 3). Complete the EDGE C&C Workflow and Attributes. Ensure supporting department approval are in place and all contracts are executed. If approvals were given more than 6 months ago confirmation of continued approval should be sought. Issue C&C approval for Barts / Queen Mary, if applicable. Once C&C is issued - recruitment may begin.
10.	Assigned RM & GO	**Ensure EDGE and indemnity folder are updated with all relevant details and files are uploaded to EDGE** Update EDGE record and upload application pack on to indemnity folder and EDGE as applicable

List of Associated Documents

Associated Document 1	Retrospective Data studies guidance document
Associated Document 2	Sponsorship review guidance document for Interventional and 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
Throughout	Clarification of delegated activities
Section 5	Triaging of risk assessment completion
Section 7	Removal of sponsorship with conditions letter