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

When Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary) agree to sponsor an Interventional Study, 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 (Associated Document 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 actions and steps undertaken by the Joint Research Management Office (JRMO) before granting sponsorship for Interventional Studies.

This SOP is written:

a. To ensure that Barts Health /Queen Mary JRMO staff are aware of the processes for issuing sponsorship, authorising the IRAS form as sponsor for Interventional Studies, and the documentation necessary for sponsorship review.

b. To ensure all Barts Health/Queen Mary sponsored Interventional 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).

c. To outline the process undertaken for Barts Health /Queen Mary to agree to act as EU legal representative of an Interventional Studies on behalf of a sponsor who is based outside of the European Economic Area (EEA).

Scope:

This SOP applies to all Barts Health /Queen Mary sponsored 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 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 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 trials: Process for JRMO staff.

Abbreviations:

ARSAC	The requirement for Administration of Radioactive Substances Advisory Committee
Barts Health	Barts Health NHS Trust
CI	Chief Investigator
CAG	Confidentiality Advisory Group
CB	Clinical Board
EDGE	The research management database used by the JRMO
EEA	European Economic Area
EU	European Union
GCP	Good Clinical Practice
HRA	Health Research Authority

IRAS	Integrated Research Application System
ISRCTN	International Standard Randomised Controlled Trial Number
JRMO	Joint Research Management Office
NIHR	National Institute for Health Research
OID	Organisation Information Document
PI	Principal Investigator
QC	Quality Control
QMERC	Queen Mary Ethics of Research Committee
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
R&D	Research & Development
RM	Research Management
RMGO	Research Management and Governance Officer
SGO	Senior Governance Officer
SoE/SoECAT	Schedule of Events/ Schedule of Events Cost Attribution Template
TMF	Trial Master File
UK	United Kingdom

Definitions:

Valid submission: This submission should include all documents that will be reviewed by the HRA and REC/CAG or other regulatory body and the forms should be received in parallel so that the JRMO can review the consistency across all documents.

Interventional studies: Research involving a change in treatment, care or other services made for the purpose of the research.

For Barts Health /Queen Mary *single site,* sponsored Interventional Studies the CI should be the Barts Health site's Principal Investigator (PI). For researchers outside Barts Health/Queen Mary organisations who want to acquire sponsorship from Barts Health/Queen Mary, the funding needs to be awarded to Queen Mary/Barts Health as a minimum for the sponsorship request to be considered.

Relevant SOPs:

This SOP is closely linked with:

- SOP 10 Confirmation of Capacity and Capability
- SOP 11b Barts Health/Queen Mary sponsorship of MHRA-regulated trials: Process for JRMO staff
- SOP 13b Barts Health/Queen Mary sponsorship of research studies (JRMO)
- SOP 15 QM Ethics of Research Committee application and approval procedure
- SOP 16a Data protection for research studies
- SOP 23 Risk Assessment

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 what 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 2) is a good guide to help explain the 3 study types.
Confirmation of Sponsorship		
2.	Assigned RMGO/R&D Administrator	**Upon receipt of a sponsorship submission pack, the assigned RMGO acknowledges receipt.** 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. 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). The assigned RMGO will set up the study on EDGE and upload the paperwork to the indemnity folder. If no Barts Health/Queen Mary EDGE account is available for the CI notify the Research Information Lead.
3.	Research Information Lead	**Create EDGE account for the CI if one does not exist** Ensure EDGE training is provided where required.
4.	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 GCP 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 Team Leader and raised with the relevant Barts Health /Queen Mary expert i.e. GCP manager, Information Governance, HTA 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 by accessing the documents via worktribe. The project should show as live in worktribe where funding has been awarded and contracts 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.
5.	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 Governance Officer will update EDGE with all study details and commence sponsorship workflow. Review all documents using the Sponsorship Review for Interventional Studies, ensuring feedback is given to the CI or delegate (Associated Document 1). The JRMO Governance Officer's review is the primary sponsorship review and includes: • Sponsor agreement and ability to sponsor this study • Assessment of experience and training of CI and statistician (through CV and GCP) • Sponsor's ability to insure/ indemnify study • Protocol • IRAS form (If applicable) • Appropriate Peer Review • Institute or CB Departmental approval • Non-Commercial OID & SoECAT (If applicable) • CI agreement to Conditions of Sponsorship (SOP 12a Associated Document 3a & b) • Agreement to delegations to CI • PIS / ICF • The requirement for Administration of Radioactive Substances Advisory Committee (ARSAC) Upon completion of the review, the RM and Governance officer will email the research team feedback and request further clarification as applicable. It is advisable to arrange a meeting with the CI / CI delegate to discuss the study, to seek clarifications and to build a professional relationship. Invite other sections of JRMO as necessary (e.g. costing officer) (Associated Document 3 Early engagement meeting tool). For studies that may be adopted on NIHR portfolio, advise CI to select 'yes' to question 5b of the IRAS Project Filter.

		Advise the CI (or delegate) regarding 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. Any concerns about the application should be brought to the attention of the Research Governance Team Leader and raised with the relevant Barts Health/Queen Mary expert i.e., IG, HTA representative, IT.
6.	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). For example: • Caldicott Guardian * • Tissue Bank Manager • Pathology • Imaging/Radiology** • Pharmacy • Clinical Physics • Lung function • CRF *Studies requiring CAG approval, the appropriate Caldicott Guardian will need to sign off the IRAS form appropriately. Contact with the CAT (Confidentiality Advisory Team) will also needs to be made and the application submitted within 24 hours, otherwise the submission is deemed invalid and will be cancelled by CAG. ** Radiology department will also need to review and sign the ARSAC PRA form created in IRAS. Sign off from Clinical Research Expert (CRE) and Medical Physics Expert (MPE) is also required (Part B, section 3 of IRAS). Identify all external vendors and their roles & inform the JRMO Costing and Contact team. Liaise with JRMO Costing and Contact team regarding costs/confirmation of funds and seek advice on contracts/agreements.
7.	Costing & Contracts Officer	**Confirm costings & requirement for contracts** Ensure that each activity in the HRA application has been correctly allocated according to the NIHR guidelines (Attributing the costs of health and social care research - AcoRD) as either: • Research cost • Service support cost • Treatment cost Check for external vendors and agreement for tissues/data transfer. Once satisfied inform the RMGO that the process is completed and send them a copy of the agreed documentation.

		Advise on appropriateness of contract / OID for the study. SoECAT should be completed by CI team and reviewed by JRMO Costing and Contracts Team.
8.	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 Governance Team leader and if the score his high then an additional review must be completed by a GCP manager. Add risk score to EDGE as per EDGE Manual
9.	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 ISRCTN. It is the responsibility of the Governance Officer to ensure that the record is "live" otherwise the confirmation of sponsorship cannot be issued. RMGO/ R&D administrator should facilitate it (see Associated Document 4 Clinicaltrials.gov guidance document).
10.	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 finalised, finalise the sponsorship review. Review study file and proceed with issuing Sponsorship with Conditions to the CI or delegate as appropriate (Associated Document 5 Sponsorship with conditions email template (Interventional and Research Studies), Associated Document 6a Queen Mary Declaration of Sponsorship letter (Interventional and Research Studies) and Associated Document 6b Barts Health Declaration of Sponsorship letter (Interventional and Research Studies)). This should be issued as a PDF. 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 and advise the researcher to book the study for a review via the online booking system.
11.	Assigned RMGO	**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
Once appropriate approvals are received (REC, HRA ARSAC, CAG) is received.		
12.	Assigned RMGO	**Request all the final HRA Approved documents following regulatory approvals** Once the relevant approvals (REC, HRA, ARSAC and CAG (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		
13.	Assigned RMGO	**Issue confirmation of sponsorship and combined C&C (confirmation of capacity and capability)** Issue confirmation of sponsorship and permission to activate sites (if applicable) email. If Barts Health or Queen Mary are also hosting this study then AAC review form will need to be completed along with the EDGE entries associated with the C&C (see SOP 10 Confirmation of Capacity and Capability). Supporting department approval does not need to be acquired again unless the study has been in set up for 6 months then confirmation of continued approval should be sought). Combine Confirmation of sponsorship and C&C in one approval, after this is issues then the recruitment may begin . Make sure EDGE record and indemnity folder are updated and study documents uploaded.

List of Associated Documents

Associated Document 1	JRMO Governance Team Sponsorship Review for interventional studies
Associated Document 2	JRMO Sponsorship review proportionality document
Associated Document 3	Early engagement meeting tool
Associated Document 4	Clinicaltrials.gov guidance document
Associated Document 5	Sponsorship with conditions email template (Interventional and Research Studies)
Associated Document 6a	Queen Mary Declaration of Sponsorship letter (Interventional and Research Studies)
Associated Document 6b	Barts Health Declaration of Sponsorship letter (Interventional and research studies)
Associated Document 7	Confirmation of Sponsorship/Permission to activate sites template email