Joint Research Management Office (JRMO) Standard Operating Procedure (SOP) for:			
Barts Health /Queen Mary Sponsorship of Research 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 a research Study, they are accepting considerable legal and regulatory responsibilities and organisational risks.

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;
- Governance Sponsorship Review; Completed by JRMO team only (Associated document 3)
- Appropriate governance review; (Associated document 4)
- All supporting information being supplied to the regulators for their consideration;
- Defining roles and responsibilities for the duration of the study; (Associated Document 5 and 6)
- 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; Clinicaltrials.gov/ISRCTN guidance document (Associated Document 11)
- 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 Research 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 Research Studies and the documentation necessary for sponsorship review.

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 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, in particular the research Governance team, who work on Barts Health /Queen Mary sponsored Research Studies.

It 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 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. 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.

Abbreviations:

Barts Health	Barts Health NHS Trust
CAG	Confidentiality Advisory Group
CB	Clinical Board
CI	Chief Investigator
EDGE	The research management database used by the JRMO and CRN
GCP	Good Clinical Practice
HRA	Health Research Authority
ICF	Informed Consent Form

IRAS	Integrated Research Application System
JRMO	Joint Research Management Office
NIHR	National Institute for Health Research
NT CRN	North Thames CRN
OID	Organisation Information Document
PI	Principal Investigator
PIS	Patient Information Sheet
QC	Quality Control
Queen Mary	Queen Mary University of London
QMERC	Queen Mary University of London Ethics of Research Committee
REC	Research Ethics Committee
R&D	Research & Development
RM	Research Management
RMGO	Research Management and 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 should be submitted in parallel so that the JRMO can review the consistency across all documents.

Research studies are those that are related to human research where no physical intervention is occurring.

For Barts Health/Queen Mary *single site* sponsored studies the CI should be the Barts Health site's Principal Investigator (PI).

The Health Research Authority and UK policy framework for health and social care research define the Chief Investigator (CI) as:

An individual who is responsible for the conduct of the whole project and is the overall lead researcher for a research project. The named CI should be a researcher who is professionally based in the UK, as they will be:

- able to supervise the research effectively
- readily available to communicate with the Research Ethics Committee (REC) and other review bodies during the application process and where necessary during the conduct of the research.

- <u>For Students Studies</u>

Students should not normally take the role of chief investigator at any level of study, as this function should be undertaken by supervisors or course leaders. Exception is made for an experienced care practitioner or manager undertaking an educational qualification for continuing professional development or a doctoral-level study while employed by a health or social care provider or a university, or for a researcher undertaking a doctoral-level study in receipt of a fellowship.

  - Although non-doctoral students should not be named as the CI, it is expected that the student will complete the application form on behalf of the CI as part of their training. The REC will invite the student to attend the meeting to answer questions about the study and will address all correspondence to the student (copied to the CI). (Supervisors are also encouraged to attend the meeting.) If a

favourable opinion is given by the REC, it is expected that the student will undertake the research under the supervision by the CI.
Relevant SOPs:
This SOP is closely linked with: SOP 1 Research project application SOP 7 Costing and Contracting SOP 10 Confirmation of capacity and capability SOP 11b Barts Health/Queen Mary sponsorship of MHRA-regulated trials: Process for JRMO staff SOP 12b Barts Health /Queen Mary Sponsorship of Interventional studies – Process for JRMO Staff. SOP 13a Barts Health NHS Trust/Queen Mary University of London sponsorship for Research Studies - Process for Researchers SOP 14 Peer Review SOP 15 QM Ethics of Research Committee application and approval procedure SOP 17c Process for Researchers - Amendments for Sponsored studies SOP 18a Project closure: guidance for research staff of Sponsored studies SOP 23 Risk Assessment SOP 38a Use of Computerized Equipment in a research projects SOP 38b Trial Data Management Systems SOP 40 Vendor assessment SOP 45 Essential documentation and Trial Master File (TMF) SOP 46 Site selection, site initiation and site activation

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 (Associated Document 2), the use of appropriate protocol template (Associated Document 1) and local process.
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 Research Studies Submission checklist (Associate Document 2). 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 other will bring the study to the attention of the assigned RMGO who will assess sponsor application pack as per JRMO Research Studies Submission checklist (Associate Document 2).

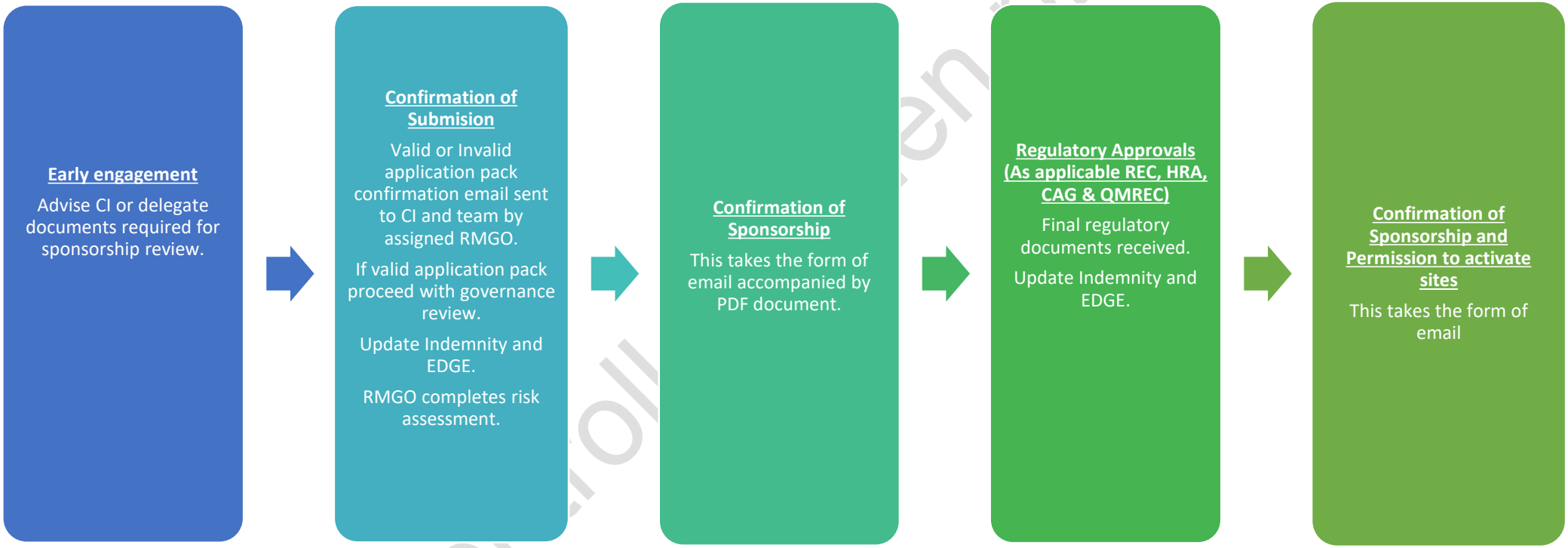
		The assigned RMGO will set up the study on EDGE and upload the paperwork to the indemnity folder. If no EDGE account is available for the CI notify the Research Information Officer.
3.	Research Information Officer	**Create EDGE account for the CI if one does not exist**
4.	Assigned RMGO	**Send valid 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. 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. Check the study has a worktribe reference number, access the worktribe system and confirm that costing has been completed (status) and that there is a matching amount in the funding award letter.
5.	Assigned RMGO	**Undertake sponsorship review and risk assessment of the protocol and study.** Upon receipt of a valid application as per submission checklist (Associated Document 2), the Governance Officer will update EDGE with all study details and commence sponsorship workflow (Associated document 7). Review all documents using**:** The JRMO research application review form for Research Studies, ensuring feedback is given to the CI **or delegate** (see Associated Document 3). The JRMO Governance Officer's review is the primary sponsorship review and includes: • Sponsor agreement and ability to sponsor this project • Assessment of experience and training of CI (through CV and GCP) • Sponsor's ability to insure/ indemnify study • Protocol • IRAS form (If applicable) • CAG form (if applicable) • Favourable scientific peer review • Institute or CB Departmental approval • OID & SoE/SoECAT (If applicable) • CI agreement to Conditions of Sponsorship

		• Agreement to delegation to CI • PIS / ICF • Questionnaires (confirm validated or not as applicable) • Interview material (if applicable) 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 Confidentiality Advisory Group (CAG). Upon completion of the review, the RM and Governance officer will email the research team feedback separately and request further clarification as applicable. It is advisable to arrange meeting with CI/CI delegate to discuss project, to seek clarifications and to build professional relationship. Invite other sections of JRMO involved in the study if necessary (see Associated Document 12). For studies that may be adopted on the NIHR portfolio, advise the CI/CI delegate regarding PAF (portfolio adoption form) & PAF submission. The appropriate data fields and workflows on EDGE should be completed (See associated document 7).
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: • Tissue Bank Manager • Pathology • Imaging/Radiology • Pharmacy • Clinical Physics 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: • Service cost • Research cost • Service support • Treatment • Excess treatment

		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/Organisation Information Document (OID) for the study. SoE/SoECAT should be completed by CI team and reviewed by JRMO Costing and Contracts Team.
8.	Assigned RMGO	**Complete risk assessment** Complete risk assessment, and if the score is medium or high ensure it is escalated and reviewed by the Research Governance Team Leader/GCP Manager as appropriate. (For guidance refer to SOP 23 Risk Assessment)**.** Add risk score to EDGE as per EDGE Manual (Associated Document 7).
9.	Assigned RMGO	**Finalise the Governance Review & issue Sponsorship with Conditions** (see Associated Document 3, Governance team sponsorship review for Research studies, Associated Document 9, Barts Health sponsorship with conditions letter and Associated Document 8, Queen Mary sponsorship with conditions letter) 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. Proceed with issuing sponsorship with conditions CI or delegate as appropriate. This should be issued as a PDF. Review project file and send (PDF) letters out to CI or delegate as appropriate. State that the project can now be submitted for regulatory approval and provide instructions on how to book a meeting with REC for study review. Insurance certificate must be issued as part confirmation of sponsorship for all Queen Mary sponsored studies. *All projects* which score medium to high on the risk assessment score are to be QC'd by the Senior Governance Officer (SGO) All *CTIMPs* are required to have a QC by the Governance Team Leader.
10.	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 (see Associated Document 7 for guidance on EDGE field completion)
Once REC, HRA and CAG approval is received.		
11.	Assigned RMGO	**Request all the final HRA Approved documents following regulatory approvals** Once REC, HRA, 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		
12.	Assigned RMGO	**Issue confirmation of sponsorship and permission to activate sites (if applicable)** Issue confirmation of sponsorship and permission to activate sites (if applicable) email (see Associated Document 10). Make sure EDGE record (including sponsorship workflow) and indemnity folder are updated and study documents uploaded.
13.	Assigned RMGO	Follow SOP 10 for confirmation of capacity and capability review for Barts Health /Queen Mary site For most NIHR portfolio adopted studies, confirmation of capacity and capability for sites located in North Thames CRN catchment area (including Barts Health) is usually issued by North Thames CRN. For such studies, inform North Thames CRN via email (sss.crnnorththames@nihr.ac.uk) so they can start capacity & capability review. Facilitate by providing information. If Barts Health is the sponsor and also a participating research site, the assigned RMGO may issue confirmation of capacity & capacity (please follow SOP 10 Confirmation of Capacity and Capability for exceptions and scenarios when the RMGO will complete the capacity and capability review). If Queen Mary is participating as a research site, the assigned RMGO will issue confirmation of capacity and capacity for Queen Mary as per SOP 10.

OVERVIEW: Sponsorship Process



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

Associated Document 1	JRMO protocol template for research studies
Associated Document 2	JRMO Research Studies Document Submission checklist
Associated Document 3	Governance team sponsorship review for Research studies
Associated Document 4	JRMO Sponsorship review proportionality document
Associated Document 5	Barts Health Sponsor-CI Agreement (CI) for research studies (not a public document)
Associated Document 6	Queen Mary Sponsor-CI Agreement (CI) for research studies (not a public document)
Associated Document 7	Edge User Guide
Associated Document 8	Queen Mary sponsorship with conditions letter (not a public document)
Associated Document 9	Barts Health sponsorship with conditions letter (not a public document)
Associated Document 10	Confirmation of Sponsorship/Permission to activate sites template email (not a public document)
Associated Document 11	Clinicaltrials.gov guidance document
Associated Document 12	Early Engagement Meeting – Clarification Tool (not mandated but if meeting researcher then useful- see SOP 11)