Joint Research Management Office Standard Operating Procedure for:			
Sponsorship of Clinical Investigations and other MHRA-regulated Medical Device Studies			
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Purpose:

The purpose of this standard operating procedure (SOP) is to outline the process required for obtaining sponsorship from Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary) for a Clinical Investigation of a medical device or other MHRA-regulated device study.

This SOP is written:

a. To ensure that Barts Health/Queen Mary research staff and JRMO staff are aware of the process for obtaining sponsorship of an MHRA-regulated device study.
b. To ensure that Barts Health/Queen Mary research staff are aware of the documentation that they need to submit to the Joint Research Management Office (JRMO) to apply for sponsorship.
c. To ensure all Barts Health or Queen Mary sponsored MHRA-regulated device studies have a formal sponsorship agreement in place to comply with the United Kingdom Policy Framework for Health and Social Care Research 2017 and ISO 14155 Good Clinical Practice (GCP).
d. To outline the process undertaken for Barts Health or Queen Mary to agree to act as legal representative of a MHRA-regulated device study on behalf of a sponsor who is based outside of the UK.

e. To describe the process to determine whether the study will fall within the Medical Device Regulations 2002 and therefore require Medicines and Healthcare products Regulatory Agency (MHRA) approval. Studies which do not require MHRA approval should be sponsored according to JRMO SOP 12a/b: Sponsorship of Interventional Studies.

This SOP also describes the procedures that the JRMO must complete in order to issue sponsorship.

Scope:

This SOP is applicable to Chief Investigators (CI) who wish to have Barts Health or Queen Mary act as sponsor for a study that involves experimental use of medical equipment and/or devices. This SOP also applies to the JRMO staff involved in the process for granting Barts Health or Queen Mary sponsorship.

This SOP describes the actions required by the CI to formally request sponsorship and the JRMO procedure for granting sponsorship. This SOP including the review process for sponsorship with conditions and confirmation of sponsorship.

Sections 2-4 of this SOP describe the procedure for assessing whether a study will fall within the Medical Device Regulations 2002. Studies which do not fall within this regulation should be set up according to SOP 11, 12 or 13 as applicable.

This document does not apply to studies led by other organisations where Barts Health or Queen Mary will only act as a host site (see SOP 10 confirmation of capacity and capability).

Abbreviations:

Barts Health	Barts Health NHS Trust
CB	Clinical Board
CI	Chief Investigator
CIP	Clinical Investigation Plan
CRE	Clinical Radiation Expert
CRF	Case Report Form
CTU	Clinical Trials Unit
DPA	Data Protection Act
DPIA	Data Protection Impact Assessment
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HRA	Health Research Authority
IG	Information Governance
ISF	Investigator Site File
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
MPE	Medical Physics Expert
PI	Principal Investigator
QC	Quality Control
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
RM & GO	Research Management & Governance Officer

SOG	Sponsor Oversight Group
SOP	Standard Operating Procedure
TMF	Trial Master File
USADE	Unanticipated Serious Adverse Device Effects

Definitions:

Academic Lead: A member of staff who is responsible for the development of the medical device under study, but who does not have the qualifications, knowledge or experience to act as the CI for the Clinical Investigation.

See associated document 1 *Legal Definitions of Medical Devices* for the definition of *Medical Device*, *Active Implantable Medical Device* and In Vitro *Diagnostic Medical Device*.

Relevant SOPs:

SOP 7a: Contracting for MHRA regulated studies
SOP 10: Confirmation of Capacity and Capability
SOP 12a: Sponsorship of interventional studies: Process for researchers
SOP 12b: Sponsorship of interventional studies: Process for JRMO
SOP 14: Peer Review
SOP 23: Risk Assessment
SOP 28: Monitoring
SOP 38b: Trial Data Management Systems
SOP 38c: Computer System Validation for Interventional and Research studies
SOP 40: Vendor Assessment
SOP 45: Essential Study Documentation
SOP 46: Site selection, initiation and activation
SOP 47: Trial committees

SOP Text:

	Responsibility	Activity
		Study Development Stage
1.	CI/Academic Lead	**Document the development of the medical device.** Researchers who are developing their own medical devices must fully document the development process. The technical file that will ultimately be submitted to the Notified Body in order to obtain approval to UKCA-mark the device and place it on the market must include documentation relating to the pre-clinical development and testing of the device. Creation of the technical file is usually delegated to the manufacture. The technical file must include documents necessary to meet the requirements of EU Directive 93/42/EEC on medical devices, EU Directive 90/385/EEC on active implantable medical devices, or EU Directive 98/79/EC on in vitro diagnostic medical devices as applicable.

		The requirements of the technical file may vary in third countries.
2.	CI/ Academic Lead, Costing and contract Officer or Research Management & Governance Officer (RM & GO)	**Identify research studies which involve devices and notify the GCP manager.** Researchers may notify the JRMO of upcoming studies involving medical devices, or they may be identified during the JRMO's review processes. If a study involves any of the following, it should be notified the GCP & Governance Manager for consideration: • Medical devices which are being used outside of standard care. • Experimental clinical procedures using equipment or materials that could be classified as medical devices (see AD1 for definition). • Software applications with a medical purpose. There is no need to notify the GCP & Governance Manager of studies which involve devices used as per standard care for their UKCA or CE-marked purpose.
3.	GCP & Governance Manager/RM & GO	**Assess whether the device or software application constitutes a medical device.** If it is not clear whether an item would constitute a medical device, the GCP & Governance Manager should review it against the definition of a medical device (please see *associated document 1 Medical Device Legal Definitions*). The MHRA's *Guidance - Medical device stand-alone software including apps (including IVDMDs)* provides instructions for assessing whether a software application should be considered a medical device. It is available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/717865/Software_flow_chart_Ed_1-05.pdf. If the GCP & Governance Manager is unable to unequivocally confirm whether an item or application will constitute a medical device, they should discuss the study with Research Governance and Performance Manager and Research Governance Operations Manager in the first instance. The Bart's Health Clinical Physics department can be approached for advice. Advice may also be sought from the MHRA via Devices.Regulatory@mhra.gov.uk, but it should be noted that this advice is not legally binding and the manufacturer and sponsor will remain responsible for the classification. If further guidance is required, the GCP & Governance manager may escalate the decision to the Sponsor Oversight Group (SOG).
4.	GCP & Governance Manager/RM & GO	**Confirm whether the proposal will constitute an MHRA-regulated device trial.** There are three types of studies which may require the involvement of the MHRA: **Clinical Investigations -** Studies testing a medical device with the intention to UKCA mark the device, or to amend an existing UKCA mark. The MHRA must always be notified of Clinical Investigations and must issue a Notice of No Objection prior to the commencement of the study.

		Performance Evaluations – Studies testing an in-vitro diagnostic medical device with the intention to UKCA mark the device, or to amend an existing UKCA mark. The MHRA must be notified of Performance Evaluations but does not issue a Notice of No Objection. **Proof of Concept studies –** Studies involving human participants designed to prove that the device works or to demonstrate the mechanism of action. The MHRA must be notified of Proof of Concept studies and must issue a Notice of No Objection if there is an intention to commercialise the product. The MHRA do not need to be notified of studies where: • The device is being used in accordance with its UKCA or CE-mark. • The devices are custom-made and prescribed for individual patients following an approved process (e.g. plaster casts, orthotics). These devices are exempt from requiring a UKCA or CE-mark but the manufacturer must have approval from the MHRA to produce them. • The device is used for a purpose which is not covered by its UKCA or CE-mark but there is no intention to commercialise the product for this purpose **and** the manufacturer are not involved in the study (including providing funding or free devices). The researcher should confirm to the sponsor that they are only using the device for non-commercial research and the device manufacturer are not involved in the study in any way. The MHRA's *Clinical Investigations and Healthcare Establishments* document provides further guidance on when MHRA involvement is required. It is available here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/381068/Clinical_investigations_and_healthcare_establishments.pdf
5.	GCP & Governance manager	Identify the Device Manufacturer and assess their suitability All MHRA-regulated device studies require a device manufacturer who is named on the IRAS form and essential documentation. Neither Barts Health nor Queen Mary can take on the legal responsibility of being a medical device manufacturer. Therefore, an external organisation must be identified as the device manufacturer. The manufacturer must undergo vendor assessment and there must be a contract in place between the sponsor and the manufacturer. See Appendix A for the Barts Health and Queen Mary requirements of any manufacturer that is to be named on a Barts Health or Queen Mary sponsored MHRA-regulated device study.
Funding and Study design Stage		
7.	CI/ Academic Lead, Head of Costing & Contracts, Costing & Contract Officer and GCP & Governance Manager	**Prepare an accurate costing of the study.** The GCP Manager & Head of Costing & Contracts must approve all costings for MHRA-regulated device trials prior to submission to the funding body. It is particularly important ensure that all arrangements for the funding of the study, design of the trial, manufacture of the device, protection of the intellectual property and subsequent commercialisation of the product are appropriate.

		Ensure that all of the required costs are included in the study proposal. Please see *SOP 11a associated document 1 Costing MHRA regulated studies guidance* for guidance on the costs that must be included. The JRMO cannot guarantee the approval of any sponsorship application for studies that are considered to have insufficient funds to support the study conduct or 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. Before agreeing to any milestones with funders, the CI should discuss their feasibility with the GCP & Governance Manager. 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 timelines. Studies that will be managed by a clinical trials unit (CTU) or established research centres at Barts Health or Queen Mary should involve the CTU/research centre as early as possible to ensure that their costs are captured in the funding application. The CTU/ research centre should confirm the specific roles and services that it will provide towards the study. If a CTU/research centre will not be involved the CI must be able to demonstrate to the JRMO that they have adequate trial management support, i.e. a dedicated Study Manager, and sufficient experience to deliver the study compliantly. Once funding has been confirmed, the GCP & Governance manager should add the study to EDGE (using study status 'concept' to note early engagement work at this stage).
8.	CI/Academic Lead	**Engage with JRMO Governance Section during the design of the study.** Consider an Early Engagement meeting with the CI, Governance officer, GCP representative and Costing and Contracts Officer (*Associated Document 2 Early engagement meeting - clarification tool)*.
9.	CI and GCP & Governance Manager	**Discuss the assignment of the CI.** The CI in charge of the MHRA-regulated device study must be medically qualified in the appropriate therapeutic area. Therefore, the CI will not always be the same person as the Academic Lead with overall responsibility for the development of the medical device. The CI should discuss their proposal to become CI with the GCP & Governance Manager. The following experience may be considered by the GCP & Governance Manager: • Previous experience as a CI/Principal Investigator (PI) on non-commercial or commercial regulated trials, multi-site/international studies, experience on non-MHRA regulated studies. • Previous regulatory compliance, • Previous experience of working on Clinical Investigations and other MHRA-regulated studies • Previous experience of safety assessments.

		The CI does not necessarily have to be the grant holder, but it is expected that the CI is centrally involved in the CIP writing and development. For new CIs, the JRMO will work with the research team, Clinical Board (CB) or Institute to assess their experience and determine whether additional peer support, training, or study management support is required. Where necessary, the GCP & Governance Manager may escalate to the Research Governance Operations Manager and liaise with the SOG to make this decision. The CI must have a substantive employment contract with either Barts Health or Queen Mary.
10.	CI/Academic Lead	**Allocate an independent named statistician to the study (not the CI or PI).** A named statistician must be allocated to the study for its duration. The statistician must be suitably qualified and experienced, which will be evident from their CV. It is not acceptable for the CI or PI to act as the statistician, but the Academic Lead may be the statistician if suitably qualified. The statistician's role is to give expert advice on the trial at the design phase and throughout. Should there be any amendments that may impact on the statistics or data integrity the statistician should be consulted. It may be necessary to contract an external statistician which will be established during the contract meetings with the JRMO (see SOP 7a Contracting for MHRA regulated studies **).**
11.	Costing and contracting team	**Ensure Queen Mary Innovations or appropriate Barts Health Individual is contacted and involved though contract and IP discussions.** Together they must: • Ensure that a commercialisation plan is implemented. • Ensure that intellectual property is appropriately protected, and ownership is clear.
Sponsorship Stage		
12.	CI	**Write a CIP (Associated document 3) and prepare all applicable document as per Associated Document 4 document submission checklist** The JRMO CIP template (associated document 3) must be used unless a CTU is involved and using their agreed template* or there are exceptional circumstances**. The CI must write a CIP that is in line with regulatory requirements. The JRMO is not responsible for the scientific development of the CIP but will review it against the ISO14155, the Medical Device Regulations, MHRA and Health Research Authority (HRA) requirements. *CTU templates – the use of a CTU template should be agreed with the GCP & Governance Managers prior to commencing writing the CIP and where necessary will be reflected in any agreement or contract in place. If used, it is the CTU's responsibility to ensure the template contains all elements of the JRMO template. ** Examples of exceptional circumstances are instances such as when a CI has recently moved organisation and the approved CIP has already been written on the previous organisations' templates. In such situations it is the CI's responsibility to ensure the template contains all elements of the JRMO template.

13.	CI	**Obtain scientific peer review and Clinical Board/ Institute approval** The study must undergo independent expert scientific peer review and must also be reviewed by the applicable CB or Institute within Barts Health/Queen Mary. The CI must address the comments raised by both reviews and incorporate the changes or explain why they are not being incorporated into the study documents before submitting them to the JRMO for sponsorship. See JRMO SOP 14: *Review of Research Including Peer Review and Departmental Authorisation* for further information.
14.	CI	**Complete site feasibility assessments** Each research site must be identified and confirmed as suitable so that they can be listed on the Clinical Investigation Plan and IRAS application form. The feasibility assessment involves confirming that the site has a suitable patient population, suitable facilities and trained experienced research staff. It is the CI's responsibility to undertake a site feasibility assessment (*see SOP 46 Site selection, site initiation and site activation)* CVs and evidence of appropriate training must be collected from the PI at each research site.
15.	CI	**Obtain approval from Clinical Physics and other support departments.** Clinical physics must approve all research studies involving medical devices. Guidance on the approval process is available on the *Clinical Physics Support for Research* section of the JRMO website or from research.clinicalphysics@nhs.net . Other support department approvals may be required depending on the CIP, for example: • Studies involving medical imaging will require imaging approval and studies using ionising radiation will require Clinical Radiation Expert (CRE), Medical Physics Expert (MPE) review. • Studies using Barts Health laboratories will require pathology approval. • Studies that involve medicinal products will require sponsor pharmacy approval. See the sponsorship submission checklist (associated document 4) for guidance on obtaining support department approvals.
16.	CI	**Apply for sponsorship** Using the document submission checklist (associated document 4), the CI should prepare a valid sponsorship application pack and submit it to research.governance@qmul.ac.uk. Failure to send all documents together in one pack to the JRMO may cause a delay in the sponsorship review and approval process. The CI is responsible for registering the study on a publicly accessible database.

17.	Assigned RM & GO (Research Governance and Performance Manager may assume this role if allocated the study) Research Management & Governance Officer	**Upon receipt of a sponsorship submission, assess whether the sponsorship application pack is valid using the valid submission checklist (Associated document 4) and ensure the study is registered accordingly on EDGE using the relevant attributes and workflows as per EDGE Manual. Proceed with sponsorship review.** Respond to researcher as soon as possible (maximum 5 working days) upon receiving the submission. The response should confirm receipt of a valid submission or reject the submission due to mandatory documents being missing (SOP 11b Associated Document 3 Valid submission email and Associated Document 4 Invalid submission email). Use of the flowchart when responding to the researcher is recommended. Provide the research team with guidance and signpost additional support if needed. The date of sponsorship submission is the date the JRMO receives a complete valid submission application. The JRMO's clock will not start until a valid submission is received. The RM & GO's review is the primary sponsorship review and includes the protocol, IRAS form, and all documents that are submitted to the REC, HRA and the MHRA for approval. Ensure the relevant clinical physics representative and other support department(s) are aware of the study and have access to all up-to-date documentation. Information governance (IG) requires completion of a pre-screening questionnaire (See SOP 16a AD 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.
18.	GCP and Governance Manager	**Undertake sponsorship review and risk assessment of the protocol and trial** Review all study documentation in tandem with the assigned RM & GO Officer. Send all comments to the assigned RM & GO who will feed back to the researcher. Follow JRMO SOP 23 *Risk Assessment*. The risk assessment must be completed and signed prior to Sponsorship with Conditions being issued and must be revised prior to the start of the study. Ensure that the study has been added to JRMO clinical trials spreadsheet and SOG meeting documents. Allocate a JRMO Clinical Trial Monitor to the study. Invite the CI to forthcoming CI training and ensure that the research team are aware of the approvals process i.e. how it differs from non-MHRA regulated trials including final sponsorship and the sponsor greenlight process.

		Complete the "JRMO GCP Manager Checklist – Part 1" workflow on EDGE.
19.	RM & GO	**Collate the feedback and return to the researcher.** The assigned RM & GO should collate the comments provided by the GCP & Governance Manager with their own comments. These should be fed back to the researcher as a single response to the submission.
20.	GCP & Governance Manager/RM & GO	**Organise the JRMO "kick-off" meeting (Associated document 5 Guidance for GCP and Governance section staff)** The purpose of the kick-off meeting is to ensure that all stakeholders within the research team, JRMO and manufacturer are aware of: • The key information about the study • The roles and responsibilities of each party involved in the study • The requirements that must be met for 'sponsorship with conditions' to be issued It is mandatory that the following individuals attend the kick-off meeting: • CI • JRMO GCP & Governance • JRMO Costing & Contracts officer • Clinical Physics representative • Representative from the device manufacturer Other research team members, JRMO staff and manufacturer staff are encouraged to attend. The Contracts & Costings Officer is responsible for creating the contract checklist and sending a draft to the CI for confirmation that all contracts have been identified. For meeting guidance see SOP 11b Associated Document 1 Guidance for GCP and Governance section The CI – Sponsor agreement (Associated Documents 6 & 7) should be discussed and signed during the kick-off meeting.
22.	GCP & Governance Manager	**Complete vendor assessments for all vendors used in the study.** JRMO SOP 40 *Vendor Assessment* should be followed. The level of assessment should be risk adapted. Where Barts Health or Queen Mary are procuring UKCA/ CE-marked devices or equipment, a proportionate assessment can take place. Where Barts Health or Queen Mary are engaging a device manufacturer to produce new devices for use in an MHRA-regulated study, a full assessment must take place. Where Barts Health or Queen Mary are producing their own devices in-house, it may be necessary to complete vendor assessments of the suppliers of materials used to construct the devices.
23.	Costing and Contract Officer	**Put contracts in place with funder and manufacturer. Confirm cost attribution is correct.**

		The primary funding agreement and the contract with the device manufacturer must be executed before sponsorship with conditions is issued. All other contracts may be executed while the trial is under review by the review bodies. The completed contracts checklist should be circulated once the necessary contracts have been executed. Ensure that each activity in the HRA application has been correctly allocated according to the National Institute for Health Research (NIHR) guidelines (i.e., Attributing the costs of health and social care research (AcoRD)) as either: •Service costs •Research costs •Service supports •Treatment costs •Excess Treatment costs Once satisfied, inform the RM & GO that the process is completed and send them a copy of the agreed documentation.
24.	Contract & costing officer	**Ensure that appropriate insurance or indemnity is in place** Where equipment or devices are being used outside of their UKCA or CE-marked purposes, the original manufacturer's indemnity will not cover the use of the device or equipment. The JRMO must arrange for additional insurance cover where required. Where contracting a device manufacturer to produce new medical devices, the JRMO must confirm that the manufacturer holds appropriate manufacturing indemnity to cover harm caused by participants or users caused by manufacturing errors.
25.	RM & GO/GCP and Governance Manager	**Finalise sponsorship review.** The GCP & Governance Manager will confirm in writing once all of items on the GCP Manager's checklist (Associated document 8) have been completed and any other actions from the Kick-off meeting have been completed. Ensure that all feedback has been actioned. Complete the 'Governance Team Sponsorship Review' form (associated document 9) and update EDGE. Save all documentation and correspondence in the 'Indemnity' electronic file. When satisfied, ask the Research Governance and Performance Manager to complete a Quality Control (QC) cross check.
26.	Research Governance and Performance Manager or delegate	**Complete QC Cross check** Undertake a quality control check of the documentation and approvals. Once satisfied sign the 'Governance team sponsorship review' form as evidence of the sponsor's QC check. If this task is delegated to a RM & GO, it must be performed by someone other than the RM & GO who undertook the sponsorship review.
27.	RM & GO	**Issue Sponsorship with Conditions Letter** Use associated documents 10a or 10b to compose the letter. The letter should be issued as a PDF. The letter should be sent to the CI, study team contact and the manufacturer's contact using email templates associated document 11.

		State that the study can now be submitted for regulatory approval and provide instructions on how to book a meeting with REC for study review.
28.	CI	**Submit IRAS applications to the MHRA and HRA.** Submission to the MHRA and HRA/REC are both made via IRAS. The two submissions are separate but should be made in parallel in order to avoid delays. Once sponsorship with conditions has been issued, the CI may request electronic signatures on the IRAS forms. Note that any change to the IRAS forms following signature (other than to enter the REC reference) will cause the signature to become invalid and the form will need to be resigned. The email to enter for sponsor signature is research.governance@qmul.ac.uk. REC review must be booked as part of the submission to the HRA. The REC booking system is accessed via the IRAS Submission tab. Once submitted to the review bodies, send copies of the final (clean and signed) versions of the documents, including all forms generated within IRAS, to the RM & GO. Where the review bodies request amendments to the documents, send the revised documents to the GCP & Governance Manager 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.
29.	CI	**Continue setting up the study while awaiting regulatory approval.** While some actions may only be completed once regulatory approvals are in place, others can be completed while awaiting regulatory approval, such as: • Setting up the trial master file (TMF) and investigator site files (ISF) (see SOP 45 Study Specific Essential documentation. • Designing the Case Report Forms. CRFs should be reviewed by the Clinical Trial Monitor and approved by the CI and statistician (see SOP 38c Data Management Systems). • Commencing database design and validation, and design and validation of any associated computer programs (see SOP 38b Trial data management systems). • Developing study specific SOPs (e.g., randomisation, unblinding) . • Progressing contract negotiations. • Preparing the site initiation training (see SOP 46 Site selection, site initiation and site activation). • Preparing trial committee charters. (For guidance and template charters see SOP 47 Trial Committees). • Preparing the monitoring plan with the GCP & Governance Manager. (For a template monitoring plan see SOP 28 Monitoring). • Recruiting / assigning trial specific research posts e.g. research nurse / study coordinators.

Once REC/MHRA approval is received		
30.	CI	**Send local document pack to sites once HRA Initial Assessment Letter has been received.** Once the HRA initial document package has been received, the CI should send the local document package to participating sites so that they can begin assessing Capacity and Capability (see SOP 46 Site selection, site initiation and site activation). The final, approved documents should also be sent to the JRMO.
31.	Contracts and Costings Officer	**Ensure that all contracts have been executed.** All contracts with vendors and partners must be fully executed before the study can commence. The contracts and costing checklist is used to identify the status of all study contracts. Once all contracts have been executed, the Costings & Contracts Officer should send the contract checklist to the CI to review and sign.
32.	GCP & Governance Manager	**Schedule and hold the Final Governance meeting.** Once informed by the RM & GO that HRA and MHRA approvals have been received, the GCP and Governance Manager should schedule and hold the final Governance meeting. The purpose of the final Governance meeting is for the sponsor to identify all outstanding items before the GCP and Governance Manager can issue Confirmation of Sponsorship. This meeting must take place after the REC and MHRA have approved the study. The CI must be present for the meeting to take place. Representatives of the device manufacturer are encouraged to attend. The 'final governance meeting report' (*Associated Document 12*) should be used as an agenda and circulated before the meeting so that the CI and team can prepare. Any actions or items outstanding identified in the meeting should be followed up to resolution. Ensure the Sponsor-CI agreement is discussed and re-signed. (*See associated documents 6 and 7*)
33.	Costing and Contracts Officer	**Finalise the Contracts Checklist.** Following the Final Governance meeting the 'costing and contracts checklist' should be finalised and sent to the CI for signature (see *SOP 7a Costings for MHRA regulated studies*). The JRMO RM and GO cannot issue Confirmation of sponsorship until the 'Contracts checklist' has been signed by the CI and returned to the Costing and Contracts Manager.

		Inform the GCP and Governance Manager and RM & GO in writing once the 'costing and contracts checklist' is complete. Ensure all checklists and contracts are saved electronically in EDGE and any wet ink signature copies filed within the sponsor oversight files.
34.	GCP & Governance Manager	**Send GCP managers agreement to proceed.** Once all actions for Final Governance meeting have been completed, and the "GCP managers Checklist part 2" workflow has been completed on EDGE and an email confirming GCP manager's approval to the assigned RM & GO.
	Issuing Confirmation of Sponsorship	
35.	Assigned RM & GO	**Upon receipt of all approvals and documentation and receipt of GCP manager's agreement to proceed, issue confirmation of sponsorship (*Associated Document 13*)** Once MHRA, HRA and REC approvals are received (including documented evidence that their conditions of approval have been met) the RM and Governance Officer can proceed to issue confirmation of sponsorship once: • All approvals and associate documents submitted to HRA, REC and MHRA have been received (signed and final version) as listed in the HRA and REC approvals. This includes a signed protocol. All documents are saved in the Sponsor Oversight File, in the study specific electronic folder and EDGE. • Clinical physics final approval has been issued. • The 'Costing and contracts checklist' has been received from the Contract Manager and saved in the sponsor file. • The 'governance team sponsorship review' form (*Associated Document 9*) has been fully completed and filed in the study file**.** • The GCP manager has sent GCP manager agreement to proceed. Save evidence that all actions above are completed in indemnity.
36.	Assigned RM & GO and Governance Officer	**File Documentation** Update EDGE to indicate that the study is open. Set up the electronic sponsor oversight file and notify the JRMO Clinical Trials Monitor once complete.
37.	JRMO Clinical Trial Monitor	**Set up electronic sponsor oversight file, schedule first monitoring visit according to monitoring plan, set annual report reminders on ReDA.** • File Confirmation of sponsorship • Create a ReDA record for the study • Ensure that all annual report reminders are set before they are due, update ReDA with Annual Progress Report (APR) and end of trial reminders (for date on IRAS from). (See SOP 19 Annual Progress Report) • Add study to Monitoring tracker and complete with relevant reminders • Ensure EDGE MHRA-regulated device dossier attribute and JRMO MHRA Risk Assessment attributes are up to date • Obtain relevant documents for the sponsor oversight file from the RM and Governance Officer.

Site approval and activation		
38.	CI	**Activate sites and commence the study.** Complete the site activation procedure to activate the research sites. See JRMO SOP 46: *Site selection, site initiation and site activation*. Only sites which have confirmed Capacity and Capability may be activated. See SOP 10 *Confirmation of Capacity and Capability* for more information.
39.	RM & GO	**Ensure SOP 10 (Confirmation of Capacity and Capability) is followed for local site approval.**

Change control

This is a new SOP.

List of appendices

Appendix ref	Document name
Appendix A	Barts Health/Queen Mary Manufacturers Requirements

List of associated documents

Document ref.	Document name
Associated document 1	Legal Definitions of Medical Devices
Associated document 2	Early Engagement Meeting Clarification Tool
Associated document 3	Clinical Investigation Plan template
Associated document 4	JRMO document submission checklist
Associated document 5	Clinical Investigations Guidance for GCP and Governance section staff
Associated document 6	Sponsor CI agreement (Barts Health)
Associated document 7	Sponsor CI agreement (Queen Mary)
Associated document 8	GCP Managers checklist
Associated document 9	Governance team sponsorship review for Clinical Investigations
Associated document 10a	Barts Health Medical Devices sponsorship with conditions letter
Associated document 10b	Queen Mary Medical Devices sponsorship with conditions letter
Associated document 11	Sponsorship with conditions email template
Associated document 12	Final governance meeting report
Associated document 13	Sponsors Confirmation of sponsorship email

Appendix A:

Barts Health/Queen Mary Manufacturers Requirements

- Willingness to be named as the Device Manufacturer on the MHRA application form and to assist with the completion of the IRAS form.
- Capability and willingness to produce the supporting documents required for the MHRA application.
- Capability and willingness to input into the development of the Clinical Investigation Plan (CIP).
- Adequate insurance to cover all study related activities that the manufacturer is responsible for.
- Compliance with ISO 14155.
- Compliant with General Data Protection Regulation (GDPR) and the Data Protection Act (DPA) 2018.
- Agreement that the sponsor will own the data generated by the trial.
- Provision of experimental devices – including calibration, repair, sterilisation, user support etc. where required. If the manufacturer owns the patent for the device and will benefit from the study, the device must be provided free of charge.
- Capability and willingness to manage device safety reporting in accordance with ISO14155 and MHRA requirements. This includes Unanticipated Serious Adverse Device Effects (USADE) and Device Deficiencies.
- Understands that Barts Health and Queen Mary will only comply with UK regulations (e.g. not FDA standards).