Joint Research Management Office Standard Operating Procedure for:			
Barts Health NHS Trust/Queen Mary University of London sponsorship of MHRA-regulated studies: Process for researchers			
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Signatures:			
Author:	**Marie-Claire Good, Senior GCP and Governance Manager**		
Signature:		**Date**	
Reviewer:	**Rebecca Carroll, Quality Assurance Manager**		
Signature:		**Date:**	
Reviewer:	**Mays Jawad, Research Governance Operations Manager**		
Signature:		**Date:**	

Authorisation:	
Name/Position:	**Coleen Colechin, Senior Operations Manager (Pre-Award)**
Signature:	
Date:	

Background:

When Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary) agree to sponsor a Medicines and Healthcare products Regulatory Agency (MHRA)-regulated study i.e., a clinical trial of an investigational medicinal product (CTIMP) or an advanced therapy investigational medicinal product (ATIMP) they are accepting considerable legal and regulatory responsibilities and organisational risks.

ICH 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 sponsor will be either Barts Health or Queen Mary. Barts Health and Queen Mary will only consider sponsorship for studies where the Chief Investigator (CI) is substantively employed by either organisation. The sponsoring organisation is usually the CI's substantive employer.

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.
- 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.

The Medicines for Human Use (Clinical Trials) Regulations 2004 requires insurance or indemnity for liabilities of the sponsor and investigator.

Purpose:

The purpose of this standard operating procedure (SOP) is to outline the process required for obtaining sponsorship from Barts Health or Queen Mary for CTIMPs and ATIMPs.

This SOP is written:

a. To ensure that Barts Health/Queen Mary research staff are aware of the process for obtaining sponsorship of an MHRA-regulated study; also, the documentation that they need to submit to the Joint Research Management Office (JRMO) so that sponsorship review can be undertaken.

b. To ensure all Barts Health or Queen Mary sponsored CTIMPs have a formal sponsorship agreement in place to comply with the legal requirements of the EU Clinical Trial Directive, the Medicines for Human Use [Clinical Trials] 2004 Statutory Instrument, 1031 and all subsequent amendments, the United Kingdom (UK) policy framework for health and social care research, 2017 and Good Clinical Practice (GCP).

c. To ensure that all Barts Health or Queen Mary sponsored ATIMPs have a formal sponsorship agreement in place to comply with the legal requirements of the EC regulation 1394/2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 in addition to the legal requirements of MHRA-regulated studies.

d. To outline the process undertaken for Barts Health or Queen Mary to agree to act as legal representative of a MHRA-regulated trial on behalf of a sponsor who is based outside of the UK.

Scope:

This SOP is applicable to CI's who wish to have Barts Health or Queen Mary act as sponsor for an MHRA-regulated study and the JRMO staff involved in the process for granting Barts Health or Queen Mary sponsorship.

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

For sponsorship of MHRA-regulated Clinical Investigations, please refer to *SOP 9 Sponsorship of Clinical Investigations and other MHRA-regulated Medical Device Studies*

Abbreviations:	
ATIMP	Advanced Therapy Investigational Medicinal Products
BDU	Business Development Unit
Barts Health	Barts Health NHS Trust
CB	Clinical Board
CI	Chief Investigator
CE	Conformité Européenne
CRE	Clinical Radiation Expert
CRF	Case Report Form
CRN	Clinical Research Network
CRO	Contract Research Organisation
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
CV	Curriculum vitae
DPA	Data Protection Act
DPIA	Data Protection Impact Assessment
EEA	European Economic Area
GCP	Good Clinical Practice
FIH	First in Human
HRA	Health Research Authority
HTA	Human Tissue Authority
IG	Information Governance
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
MPE	Medical Physics Expert
NIHR	National Institute for Health Research
PAF	Portfolio Adoption Form
PI	Principal Investigator
QMI	Queen Mary Innovations
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
RM	Research Management
SOG	Sponsor Oversight Group
SOP	Standard Operating Procedure
TMF	Trial Master File

Definitions:

The UK Statutory Instrument 2004/1031 defines who can act as a CI:

- CI:
  - in relation to a clinical trial conducted at a single study site, the investigator for that site, or
  - in relation to a clinical trial conducted at more than one study site, the authorised health professional, whether or not he is an investigator at any particular site, who takes primary responsibility for the conduct of the study.
- Investigator:
  - In relation to a clinical trial, the authorised health professional responsible for the conduct of that study at a study site, and if the study is conducted by a team of authorised health professionals at a study site, the investigator is the leader responsible for that team.

The Statutory Instrument distinguishes between "authorised" health professional and health care professional.

- "Authorised" health professionals:
  - Doctor
  - Dentist
  - Nurse
  - Pharmacist

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

First in Human (FIH): For the purpose of this SOP this term is used to describe both FIH/First in man studies. Defined as when an investigational medicinal product (IMP) developed and assessed through in-vitro or animal testing, is tested on human subjects for the first time.

Relevant SOPs:

- SOP 1 Research study application
- SOP 7 Costing and contracts
- SOP 9 Sponsorship of Clinical Investigations and other MHRA-regulated Medical Device Studies
- SOP 10 Confirmation of Capacity and Capability
- SOP 14 Review of research including peer review and departmental authorisation
- SOP 16a Data Protection for Research Studies
- SOP 19 Annual Progress Report
- SOP 21 Sponsorship, management, and oversight of international-only research: MHRA Regulated studies and interventional research
- SOP 23 Risk assessment
- SOP 28 Monitoring
- SOP 38a Use of computerised equipment, software, and systems in clinical research
- SOP 38b Electronic data management systems for MHRA-regulated studies
- SOP 40 Vendor assessment
- SOP 42a IMP management – Barts Health/Queen Mary sponsored studies
- SOP 45 Essential documentation including TMFs for all external sites and facilities
- SOP 46 Site selection, initiation, and activation
- SOP 47 Trial Committees

SOP Text:		
	Responsibility	**Activity**
1.	CI	**Work with the JRMO to obtain an accurate cost for the study.** The CI is responsible for ensuring that their study is accurately and realistically costed in the formative stages to ensure that it has adequate funding to be deliverable, successful, and compliant. The CI should discuss the proposed study with the JRMO GCP and Governance Managers as early as possible, i.e., at the funding application stage so that advice on the resources required in a funding application can be included (See *Associated Document 1 Costing MHRA regulated studies* for further guidance). The JRMO cannot guarantee the approval of any sponsorship application for studies that are considered to have insufficient funds to support the study design or its management. Where the researcher is not substantially employed by Barts Health/Queen Mary but wants these organisations to provide sponsorship, then as a minimum the funding needs to be awarded to Queen Mary/Barts Health for sponsorship request to be considered. 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 and 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 and site approval timelines or protocol design. Studies that will be managed by a clinical trials unit (CTU) or established research centre 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. If a CTU/research centre will not be involved the CI must be able to demonstrate to the JRMO that they have adequate study management support, i.e., a dedicated Study Manager, and sufficient experience to deliver the study compliantly.
2.	CI	**Categorise the study.** If there is any ambiguity as to whether a study is a MHRA-regulated study, the CI should discuss this with the JRMO GCP and Governance Manager. The CI should consider if the study uses any of the following: • Drugs. • Vitamins. • Nutritional supplements. • Food supplements. • Devices that deliver drugs e.g., stents. • Non-CE marked devices • Probiotics. • Imaging tracers. If it is unclear, the JRMO will send a scoping query to the MHRA clinical trials helpline and retain documented evidence to support the MHRA's decision (i.e., the email from the MHRA and version of the protocol sent).

		The MHRA's opinion as to whether a study is a MHRA-regulated study is final and it is the CI's responsibility to comply with the applicable regulations for MHRA-regulated studies or revise the protocol or grant proposal so that it is no longer classified as a MHRA-regulated study. The JRMO, as sponsor, reserves the right to re-submit a funding proposal or protocols for scoping review by the MHRA, including following revisions to the proposal or amendments to the protocol.
3.	CI	**Write the protocol.** The JRMO protocol template (*Associated document 2*) must be used unless a CTU is involved and using their agreed template* or there are exceptional circumstances**. The CI must write a protocol that is in line with regulatory requirements. The JRMO protocol template contains all the elements that review bodies wish to consider. Care should be taken to ensure that no template wording or guidance remains in the submitted protocol. The JRMO is not responsible for the scientific development of the protocol but will ensure it is compliant with GCP, MHRA, HRA and any other applicable regulatory requirements and guidance. *CTU templates – the use of a CTU template should be agreed with the GCP and Governance Managers prior to commencing writing the protocol 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 protocol 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.
4.	CI	**Send protocol/proposal to JRMO and meet with GCP and Governance Manager and Costing and Contract Manager.** Attend Early Engagement meeting with the JRMO. The CI should send a copy of the protocol to the GCP and Governance Manager and Costing and Contract Manager for review . It may be necessary at this stage to hold an Early Engagement meeting to discuss all the support functions, governance issues, potential study costs or supply of the IMP. Following the meeting the CI is expected to work with the Costing and Contract Manager on their funding applications (see *SOP 07 Costing and contracting*).
5.	Proposed UK / Non-EEA CI	**For non- European Economic Area (EEA) sponsored regulatory studies - formally request that the JRMO be the UK legal representative.** When Barts Health or Queen Mary is requested to act as UK legal representative of a MHRA-regulated study where the main sponsor is outside of the EEA, the JRMO's Sponsor Oversight Group (SOG) will need to agree in principle to act as UK legal representative. The proposed CI/UK Investigator should send a copy of the protocol to the GCP and Governance Manager and Costing and Contract Manager and arrange a meeting with them. The GCP and Governance Manager will liaise with the SOG and report back to the CI/UK Investigator. If the JRMO declines to act as UK legal representative the CI may appeal to the SOG. The Costing and Contract

		Manager will assess costs of planned activities and ensure appropriate reimbursement is in place. The GCP and Governance Manager will assess whether the protocol meets Barts Health or Queen Mary standards as well as UK and EU regulations. If it does not the CI will be required to add any missing information or transfer the protocol onto the JRMO protocol template. Once the JRMO have agreed to act as the UK legal representative, the process is as described in the remainder of this SOP.
6.	CI	**Allocate an independent named statistician to the study (not the CI or PI).** For studies within the remit of this SOP a named statistician must be allocated to the study for the duration of the study. The statistician must be suitably qualified and experienced, which will be evident from their curriculum vitae (CV). It is not acceptable for the CI or PI to act as the statistician. The statistician's role is to give independent and expert advice on the study 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 07 Costing and contracting*).
7.	CI	**Discuss the assignment of a new CI with the JRMO.** If the CI has not previously worked on a Barts Health or Queen Mary sponsored MHRA-regulated study, they should discuss their proposal to become CI with the GCP and Governance Manager. For studies sponsored by Barts Health or Queen Mary, the CI must have a substantive contract with the sponsor (Barts Health or Queen Mary accordingly). The CI must be medically qualified in the therapeutic area and be able to prescribe the IMP. The following experience may be considered by the SOG: • Previous experience as a CI / PI on non-commercial or commercial regulated studies, multi-site / international studies, experience on non-MHRA regulated studies. • Previous GCP and regulatory compliance. • Previous experience of working on MHRA-regulated studies. • Previous experience of safety assessments / pharmacovigilance. The CI does not necessarily have to be the grant holder, but it is expected that the CI is centrally involved in the protocol writing and development. For new CI's, 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.
8.	CI	**Once funding is secured, and the protocol is developed arrange peer review and CB / Institute review of the protocol.** Send the protocol for comprehensive and independent peer review. The peer review includes (but is not limited to) whether the protocol is scientifically sound, understandable, comprehensive, consistent, and compliant with the regulations. (Full peer review guidance is found in *SOP 14 Peer Review*). It is the CI's responsibility to address all peer reviewers' comments (and evidence this) before submitting the study to the JRMO for sponsorship.

9.	CI	**Site feasibility assessment.** It is the CI's responsibility to undertake a site feasibility assessment (*see SOP 46 Site selection, site initiation and site activation*) at the early stage of the study design to ensure that the study design and protocol are practicable. A feasibility assessment considers whether the study is logistically possible at each site(s). This must be undertaken (and the protocol adapted to include feedback from site(s) and collaborators where applicable) before the site is approved by the sponsor and regulators (i.e., prior to being listed on an Integrated Research Application System (IRAS) form). If the MHRA-regulated study is to have international research sites please see *SOP 21 Sponsorship, management, and oversight of international-only research: MHRA Regulated studies and interventional research* for further details. The CI should discuss plans to include international sites with the GCP and Governance Manager. The GCP and Governance Manager must approve the study expanding internationally on behalf of the JRMO. When an agreement cannot be reached the discussion will be escalated to the SOG. The JRMO reserves the right to refuse expansion.
10.	CI	**Coordinate approvals of the protocol from support departments.** At the design stage, the CI should obtain input into the protocol from each support department. The support departments' risk assessments and feedback should be included in the protocol development and their costs included in funding requests. The following support departments may be included: • Imaging, Clinical Radiation Expert (CRE), Medical Physics Expert (MPE), • Laboratory leads, to include where relevant Human Tissue Authority (HTA) approval. • Clinical Trials Pharmacist approval (*see SOP 42a IMP management: Barts Health/Queen Mary sponsored studies*) • Clinical physics' risk assessment • Medical photography • Information governance (IG): complete pre-screening questionnaire (*See SOP 16a AD 2 for full details and procedure*) and submit to IG/ Data Protection Act (DPA) team (bartshealth.infogov@nhs.net or data-protection@qmul.ac.uk as applicable) to 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.
11.	CI	**With the Costing and Contract Manager begin the contract negotiations with external parties.** Where Queen Mary Innovation (QMI) or the Business Development Unit (BDU) staff have been involved in the contract negotiations, the CI must ensure that the JRMO is informed, as QMI or BDU's input will be required during subsequent meetings and negotiations. Certain contracts may be expected to be in place prior to HRA, REC and MHRA submissions e.g., non-disclosure agreements with the IMP supply company / device manufacturer if the company's confidential information is required for REC or MHRA submissions. Contracts must only be signed by Queen Mary or Barts Health authorised signatories (*see SOP 7 Costing and Contracting*).

		The CI must disclose all conflicts of interest that may exist when professional judgment concerning the patients' welfare, or the validity of research data may be influenced by a secondary interest. A CI with a financial interest in the study results may influence, or be perceived to potentially influence, their interpretation of the results or those of others. Such interests may be financial gain or vested interest, e.g., shares in the IMP or device supplier, or receipt of funds from a third party with interests in the research output e.g., a commercially funded research associate post or personal relationship with the third party. It is of particular importance to disclose any CI conflict of interest as the CI is delegated the role of sponsor's pharmacovigilance medical assessor, where independent judgement is paramount to patient safety. As sponsor, the JRMO must be made explicitly aware of any competing interests that the CI or members of their team may have.
Sponsorship with conditions and confirmation of Sponsorship		
12.	CI or delegate	**Submit a valid sponsorship application pack to the JRMO and register the study on a public database(s) – this must be reviewed and approved by JRMO prior to applying to the HRA / REC or competent authority (MHRA in the UK).** Once funding has been secured, and all the relevant actions above have been addressed, submit a valid submission pack to JRMO via research.governance@gmul.ac.uk Use the 'JRMO submission checklist' (*see Associated Document 3*) to ensure the pack is valid. This submission should include all documents that will be reviewed by the HRA, REC, MHRA or other regulatory body, and should be submitted as one submission package to the JRMO so that the JRMO can review the consistency across all documents. Failure to send all documents together in one pack will mean submission is invalid and the study will not be reviewed until all documents are submitted to the JRMO which will cause a delay in the sponsorship review and approval process. To apply for NIHR CRN support you should select 'yes' to question 5b of the IRAS Project Filter. Key information from your IRAS submissions will then be shared with the NIHR CRN and used to assess eligibility. It is the CI's responsibility to register the study on a public website and if needed an International Standard Randomised Controlled Trial Number (ISRCTN) number or register on the ClinicalTrials.gov website.
13.	CI or delegate	**Revise documents to incorporate feedback (and answer any questions) from the JRMO.** To avoid delays in sponsorship review and approval, please answer any questions the JRMO may have and return tracked-changed documents incorporating any feedback from the Research Management (RM) and Governance Officer and GCP and Governance Manager. The JRMO welcomes meetings to discuss areas of concern with the research team.
14.	CI and research team	**Attend the Kick-off meeting with the JRMO.** The JRMO will invite the CI and coordination team to attend the Kick-off meeting. This meeting can take place at any time between receipt of valid submission by the JRMO and 'sponsorship with conditions. The purpose of this meeting is to ensure that all stakeholders in the JRMO and the CI's team are aware of: • the key information about the study

		• the requirements for 'sponsorship with conditions' to be issued • the contracts and agreements that need to be put in place • the actions that must be completed once the study has been submitted for regulatory approval. It is mandatory for the CI to attend the Kick-off meeting and it is recommended that the Study Coordinator or Manager also attends. If a CTU has been engaged with the study a representative from the CTU should also be invited to attend. The 'CI-Sponsor agreement' will be discussed and ideally signed during this meeting.
15.	CI or delegate	**Request sponsor (i.e., JRMO) authorisation on the IRAS form. Submit to regulators and inform JRMO of all correspondence with the regulators, including amendments.** Unless otherwise agreed between the JRMO and CI the admin contact in IRAS should be the sponsor representative. Once the 'sponsorship with conditions' letter has been received by the CI, they should request research.governance@qmul.ac.uk for sponsor representative electronic authorisation of the IRAS form via the IRAS authorisation tab. The CI should email the RM and Governance Officer once this is complete so that they can coordinate the approvals. Any changes to the IRAS form (other than adding the REC number) will invalidate the CI and sponsor authorisations on the IRAS forms. Therefore, only request sponsor authorisation when the IRAS forms have been finalised. The CI or delegate should submit the HRA, REC and MHRA applications in parallel to avoid delays. It is the CI's responsibility to ensure all fees are paid as per current MHRA guidelines (please see MHRA website for details). Once the application has been booked into the Central Booking Service (https://www.hra.nhs.uk/about-us/committees-and-services/online-booking-service/) a confirmation email will be sent to the CI, who must forward this to the research.governance@qmul.ac.uk. Once submitted to HRA, REC and the MHRA, send copies of the final (clean and signed) versions of the documents (including all forms generated within IRAS) to the RM and Governance Officer. Please note that where the HRA, REC or MHRA request amendments to the documents, send the revised documents to the GCP and 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.
16.	CI	**Whilst the application is with the regulators, continue study specific management set-up including preparation of SOPs, databases, and facilitate contract negotiations.** During submission to the regulators, the CI and research team should continue with setting up the study, including: • Setting up the trial master file (TMF) and investigator site files (ISF) (*see SOP 45 Essential documentation and TMF*).

		• Commencing database design and validation, and design and validation of any associated computer programs (*see SOP 38a Use of computerised equipment in research studies*). • Designing the Case Report Files. This needs to be reviewed and approved by the CI and statistician (*see SOP 38b Trial data management systems*). • Sending a copy of the protocol to the statistician to ensure the CRF matches the protocol. • Drafting study specific SOPs (e.g., randomisation, unblinding, IMP management plan for multi-site studies). • Progressing contract negotiations. • Preparing the site initiation training. (For a PowerPoint presentation template *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 and Governance Manager. (For a template monitoring plan *see SOP 28 Monitoring*). • Recruiting / assigning study specific research posts e.g., research nurse / study coordinators. • Attending the REC meeting to answer any questions raised by the committee (so that their decision can be made during the meeting).
17.	CI or delegate	**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*).
18.	CI or delegate	**Send REC, MHRA and HRA approvals to the JRMO. Continue with NHS set-up.** Send the JRMO RM and Governance Officer all approvals from the regulators and evidence that the conditions of their approvals have been met. The approved versions of the finalised study documents should be submitted to the RM and Governance Officer, including the final protocol signed by the CI and statistician.
19.	CI and Research team	**Prepare for and attend the Final Governance meeting with the JRMO.** When REC and MHRA approvals have been sent to the JRMO, the GCP and Governance Manager will schedule the 'Final Governance meeting'. The purpose of the 'Final Governance meeting' is for the sponsor to identify all items outstanding before the GCP and Governance Manager can issue the sponsor confirmation of sponsorship and to permission activate sites. This meeting can occur before or after HRA approval but must be after the REC and MHRA have approved the study. The CI must be present for the meeting to take place. Other members of the JRMO or study team are welcome to join the meeting e.g., Costing and Contracts Manager, research nurse, data manager, and statistician as part of study specific training, CTU (if applicable) and clinical physics expert (if a Clinical Investigation). Attendance will be recorded.

		The 'final governance meeting report' (*SOP 11b Associated Document 9*) should be used as an agenda. Following the meeting the Final Governance meeting report must be completed by the GCP and Governance Manager and distributed to the study team. Any actions or items outstanding identified in the meeting should be emailed to the CI and followed up to resolution. The CI should be able to demonstrate that they have existing TMF and SOPs/systems in place (*see SOP 45 Essential documentation and TMF*). If needed a JRMO monitor will review the TMF prior to confirmation of sponsorship. The 'CI-Sponsor agreement' will be discussed and ideally re-signed during this meeting.
20.	CI	**Sign the Costing and Contract checklist and complete all items outstanding in the Final Governance meeting report.** Following the Final Governance meeting, the GCP and Governance Manager will send the Sponsor-CI agreement (SOP 11b Associated Document 10a/b) and the final governance meeting report (SOP 11b *Associated Document 6*). It is the CI's responsibility to complete all actions identified in this report and send evidence to the GCP and Governance Manager. Once all contracts are fully executed, the Costing and Contract Manager will send the CI the 'Contracts Checklist.' This must be signed and returned to the JRMO before confirmation of sponsorship is given.
21.	CI	**Receive the confirmation of sponsorship from the GCP and Governance Manager.** Following all relevant checks and Governance agreement, the GCP and Governance Manager will send the CI an email giving the confirmation of sponsorship. Recruitment of sites can then begin in accordance with *SOP 46 Site selection, site initiation, and site activation*. **NB:** The NHS Confirmation of Capacity and Capability does NOT give permission to begin recruiting to the study. **The CI must receive the 'Confirmation of Sponsorship' email to activate sites (see below) and NHS Confirmation of Capacity and Capability before recruiting any participants.**
22.	CI	**Ensure SOP 10 (Confirmation of Capacity and Capability) is followed for local (Barts Health and/or Queen Mary) site approval.** NB: Permission to activate sites is a separate document to local site approval.
		First in Human Studies
23.	CI	**Identify a FIH study** It is important to identify and inform all involved parties if the planned study will be a FIH. The GCP manager must be informed immediately if a study is suspected to be a FIH. Not all FIH can be sponsored by Queen Mary and/or Barts Health so early engagement is vital.

24.	CI	**All FIH studies will be assessed on a case-by-case basis.** Factors that will be assessed include: • Risk of IMP • IMP Pharmacology • Design of study • Study population • Manufacture agreement • Reason why manufacture cannot sponsor • Comments from Independent scientific reviewers • Proposed delivery location/facilities of study
25.	CI	**Final decision to sponsor a FIH study will be taken by the SOG.** The GCP and Governance manager will present the study to the SOG who will review the risks involved and confirm ability to sponsor the study.
26.	CI	**In order for Barts Health or Queen Mary to consider sponsoring FIH studies this SOP and additional points below must be adhered to:** • Additional requirements: Use delivery department/facility that is phase I accredited or can evidence that they meet the standards outlined. • CI should be an experienced CTIMP/ATIMP CI preferably with early phase experience. • Study coordination team should be experienced in CTIMPS/ATIMPs and preferable early phase studies. • The group should be established groups like a CTU, who are able to evidence written procedures and processes. • The statistician should have early phase clinical trials experience or be able to evidence other appropriate experience or mentor or supervision. • Liaise with the JRMO Pre-award team to ensure team appropriate contract is in place to evidence agreement, publication in favour of Queen Mary/Barts Health. • Obtain written agreement from organisation insurance team or representative that this study is covered.

Change control

This section outlines changes from version to version

Section changed	Summary and description of changes
Section 23 to 26	Clarification on FIM sponsorship requirements.
Whole document	Administrative updates throughout
New Associated Documents	Costing MHRA regulated studies guidance

List of appendices

There are no appendices for this SOP.

List of associated documents

Document ref.	Document name
Associated Document 1	Costing MHRA regulated studies guidance
Associated Document 2	Protocol Template for MHRA regulated studies
Associated Document 3	JRMO document submission checklist