Joint Research Management Office Standard Operating Procedure for:			
Site selection, site initiation & site activation			
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Purpose and Scope:

This standard operating procedure (SOP) outlines the minimum requirements for opening a host site for a study sponsored by Queen Mary University of London (Queen Mary) or Barts Health Trust (Barts Health). It describes the procedure for selecting suitable sites and for conducting site initiation and activation.

This SOP is mandatory for all Barts Health and Queen Mary sponsored clinical trials which are regulated by the Medicines and Healthcare products Regulatory Agency i.e. clinical trials of investigational medicinal products, advanced therapy investigational medicinal products and clinical trials of medical devices which are not approved for use or which are used outside of their approved purpose (Clinical Investigations).

For all other Barts Health and Queen Mary sponsored studies, this SOP should be used as best practice and implemented proportionately in accordance with the risk of the study.

Abbreviations:

Barts Health	Barts Health NHS Trust
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
IMP	Investigational Medicinal Product
JRMO	Joint Research Management Office
PI	Principal Investigator
Queen Mary	Queen Mary University of London
SIV	Site Initiation Visit
SOP	Standard Operating Procedure
TMF	Trial Master File

SOP Text:		
	Responsibility	**Activity**
1.	Chief Investigator (CI) or delegate	**Agree host sites with sponsor during trial set-up.** The number of sites in the UK and abroad must be agreed with the Joint Research Management Office (JRMO) Good Clinical Practice (GCP) and Governance Manager during the kick-off meeting and in the final governance meeting. There must be confirmation at the final governance meeting that all sites meet the feasibility requirements. The sponsor reserves the right to cap the number of sites, depending on the level of resource and on-going compliance of the trial. Once the study has received confirmation of sponsorship, any changes to the number of countries and national or international sites must be agreed by the sponsor *(see SOP 17a: Amendments for sponsored studies*).
2.	CI or delegate	**Conduct a site selection assessment of any prospective sites *(see Associated Document 1 for guidance on how to conduct a site selection assessment and Template 1 Site selection Assessment report template*).** Careful site assessment and selection is the responsibility of the CI, who must ensure that study resources are directed to well-motivated, qualified sites with the potential to recruit eligible participants, generate high quality study data, and conduct the study within the regulations. The CI should define the selection criteria for suitable sites, prior to the start of the selection process. A site selection assessment report should be prepared for each site. See *Template 1*. The above process should be repeated for the selection of all new sites, throughout the study's duration.
3.	CI or delegate	**Conduct due diligence in the selection of international sites and provide the sponsor with this information to enable the sponsor to make an informed decision.** When considering taking a study outside of the UK, the CI must discuss this in detail with the JRMO GCP and Governance Managers and JRMO Contract Managers. The CI should consider the limitation of indemnification of international trials: Barts Health, as an NHS Trust with clinical negligence scheme for trusts indemnification, may only sponsor studies within the UK. Queen Mary as sponsor may consider international studies but additional indemnification could be required for each country, which must be costed and resourced by the CI (see *SOP 7a: Contracting for MHRA Regulated Studies*).
4.	CI or delegate	**Once sites and countries are approved by the sponsor, gain the necessary approvals in each country and then site approval** ***Please see SOP 9, SOP 11a, SOP 12a, SOP 13a, and SOP 10 for full details*** Once the UK sites are approved by the sponsor and the study has obtained sponsorship with conditions, the CI and study team may apply for regulatory approvals. For international studies, once the country has been approved by the sponsor, and when the study has obtained sponsorship with conditions the CI may proceed to gain regulatory approvals in the new countries.

5.	CI or delegate	**Request all site essential documentation from individual sites.** As a minimum request the following documents from each site: • Confirmation of capacity and capability or equivalent • Fully signed clinical trial site agreement • Copy of the Principal Investigator (PI) I's signed CV and GCP certificate • Completed delegation log
6.	CI or delegate	**Set up Investigator Site file as per SOP 45 (Essential documentation)** It is advised that the Investigator Site File are set up centrally and distributed to sites as part of Site Initiation Visit (SIV).
		Site initiation
7.	CI or delegate	**Perform site SIV at each site, train site staff, resolve all issues, and complete reports.** All sites must undergo a SIV prior to the CI activating the site to start the study (site activation). The aim of the SIV is to ensure that all sites and study staff are adequately aware of GCP, and trained in the protocol, study specific SOPs, source data and PI responsibilities before trial activities begin. SIVs must only be conducted after the trial has received Health Research Authority approval but may be conducted prior to the sponsor issuing confirmation of sponsorship and permission to activate sites. SIVs should be scheduled as close to site activation as logistically possible to ensure that training remains fresh in the mind of all site staff at the start of the trial. A refresher should be considered if the SIV was conducted more than 6 weeks prior to activation. Please see *Associated Document 2: Site Initiation and minimum requirements guidance*, *Associated Document 3: Site activation checklist* and *Associated Document 4: SIV presentation*. The person delegated to perform the SIV must ensure that all trial staff attending the SIV will sign a site initiation attendance log. A written report (*Associated Document 5: Site initiation report*) including actions and documents outstanding should be issued to the site within 2 weeks of the visit.
8.	CI or delegate	**Complete site initiation report along with actions and send to site.** If the SIV report has been delegated to a person other than the CI, provide a copy of the initiation report to the CI to ensure CI oversight. The original copy of the initiation report will be stored in the Trial Master File (TMF). Resolve any actions that arose from the SIV. This may include the monitor providing copies of any documentation required by the CI to their TMF, or sponsor oversight file in the JRMO. It may also be necessary to send the initiation follow up letter to non-pharmacy individuals responsible for the Investigational Medicinal Product (IMP).
		Post-site initiation
9.	CI or delegate	**Activate site in accordance with *Associated Document 1: Site selection and assessment guidance*.**

		Use *Associated Document 1* to create minimum site checks to be performed prior to the issuing of the site activation email. The site should not be activated until: • Health Research Authority Approval is in place. • The sponsor has received the signed site agreement and Statement of Activities. • The sponsor has received confirmation of capability and capacity • Any additional site approvals are in place at the site (e.g. ARSAC licence, clinical physics, imaging and pharmacy approval). • The delegation log has been completed and a copy retained by the coordinating team. • The research team's CV(s) and GCP training certificate(s) (within the last two years) are retained by the coordinating team. • All other essential documents have been collected by the coordinating centre. • SIV has been conducted, report sent, and all additional actions completed. • Test scans have been performed, and the quality and transfer has been deemed acceptable (*SOP 38a: Use of computerised equipment, software and systems in clinical research*). • Site has received e-Case Report Form (CRF) or CRF training, which should include clear guidelines as to when the CRF should be completed, how this is checked and monitored by the coordinating team and CI, and how problems are escalated. • IMP / investigational devices have been delivered to site, or the site is ready to order IMP for when it is required.
10.	CI or delegate	**Notify sites of their activation by email.** Once initiations are complete and follow up actions are addressed (if applicable), issue the site with a "Site Activation" email. Where possible, *Appendix A: Site activation email template* should be used. This should be sent to the PI, pharmacy, monitor, and sponsor. The CI should be copied into this correspondence if this task has been delegated by them. The sponsor should be informed of the activation of each site by sending a copy of the email to: research.governance@qmul.ac.uk.
11.	CI or delegate	**File all site activation correspondence and documentation in the TMF.** This will include a copy of the signed delegation log for each site which requires the PI to ensure that trial specific training is provided to the trial team (including new members as they join). For trial specific training templates see *SOP 45: Essential documentation including TMFs and files for all external sites and facilities*.

Change control

This section outlines changes from version **3.0** to version **4.0**

Section changed	Summary and description of changes
All	General administrative changes throughout
Section 1	Requirements to confirm at the final governance meeting that all sites meet the feasibility requirements.
Template 2	Appendix converted to template

List of associated documents

Document ref.	Document name
Associated Document 1	Site assessment and selection Guidance
Associated Document 2	Site Initiation and minimum requirements guidance
Associated Document 3	Site activation checklist
Associated Document 4	SIV presentation template
Associated Document 5	Site initiation visit report template
Template 1	Site selection assessment and report template
Template 2	Site activation email template