Joint Research Management Office Standard Operating Procedure for:			
Site selection, site initiation & site activation			
SOP Number:	**46**	Version Number:	**3.0**
Effective Date:	**24th May 2021**	Review Date:	**24th May 2024**

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Purpose:

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.

The purpose of this SOP is to ensure that:

- All essential documentation including, but not limited to, approved protocol, study specific SOPs, and required approvals are in place prior to the start of the study at a site.
- All staff members at each site are aware of their responsibilities, the sponsor processes, and SOPs.
- The site team has had appropriate Good Clinical Practice (GCP) training which is current and documented.
- The delegation log is completed before any study related activities are performed and that all individuals are authorised by the Principal Investigator (PI) to undertake such tasks.
- The pharmacy (and/or individuals responsible for the Investigational Medicinal Product (IMP) at site) are provided with notification to proceed with ordering IMP (if applicable), and that procedures for receipt, dispensing, destruction, and accountability are documented.
- To ensure that the contact details for the site, sponsor, and coordination team are up to date and correct, and that the site and pharmacy know how to contact the sponsor.

Scope:
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 (MHRA) i.e. clinical trials of investigational medicinal products (CTIMPs), advanced therapy investigational medicinal products (ATIMPs) 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:	
ARSAC	Administration of Radioactive Substances Advisory Committee
ATIMP	Advanced Therapy Investigational Medicinal Products
Barts Health	Barts Health NHS Trust
CI	Chief Investigator
CNST	Clinical Negligence Scheme for Trusts
CRF	Case Report Form
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HRA	Health Research Authority
IMP	Investigational Medicinal Product
ISF	Investigator Site File
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
Queen Mary	Queen Mary University of London
SIV	Site Initiation Visit
SOP	Standard Operating Procedure
TMF	Trial Master File

Definitions:

- Site activation: The point at which the Chief Investigator (CI) confirms that the site can start recruiting. No participant can be identified or approached prior to this point.
- Site Selection assessment – this is also commonly known as site feasibility assessment, for the purpose of this SOP and to tie into Clinical investigation terminology site selection assessment will be used

Relevant SOPs:	
• SOP 7	Costing and contracting
• SOP 10	Conformation of Capacity and Capability
• SOP 11a	Barts Health/Queen Mary sponsorship of MHRA-regulated trials (Researchers)
• SOP 12a	Barts Health/Queen Mary sponsorship of interventional studies (Researchers)
• SOP 13a	Barts Health /Queen Mary sponsorship of research studies (Researchers)
• SOP 17a	Amendments for sponsored studies (JRMO)
• SOP 21	Sponsorship management and oversight of international-only research Regulated studies
• SOP 38a	Use of computerised equipment in research projects
• SOP 45	Essential documentation including trial master files (TMF)

SOP Text:		
	Responsibility	**Activity**
1.	CI or delegate	**Agree host sites with sponsor during study set-up.** The number of sites in the UK and abroad must be agreed with the Joint Research Management Office (JRMO) GCP and Governance Manager during the kick-off meeting and in the final governance meeting. The sponsor reserves the right to cap the number of sites, depending on the level of resource and on-going compliance of the study. 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 (CNST) 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 7: Costing and contracting*).
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 11a, SOP 12a, SOP 13a, SOP 21 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 PI's signed CV and GCP certificate • Completed delegation log
6.	CI or delegate	**Set up Investigator Site file as per *SOP 45 Study Specific Essential File Documentation*** It is advised that the Investigator Site File (ISF) 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 study activities begin. SIVs must only be conducted after the study has received Health Research Authority (HRA) approval, but may be conducted prior to the sponsor issuing the confirmation of sponsorship with 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 study 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 IMP.
9.	CI or delegate	**File all site initiations/actions and correspondence in the TMF.**

Post-site initiation		
10.	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: • HRA 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. Administration of Radioactive Substances Advisory Committee (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 (if applicable; e.g. MRI), 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.
11.	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. The site activation email is not an approval for all centres to commence recruitment, but is site specific. An individual site activation email must be sent.
12.	CI or delegate	**File all site activation correspondence in the TMF.** This will include a copy of the signed delegation log for each site which requires the PI to ensure that study specific training is provided to the study team (including new members as they join). For study specific training templates see *SOP 45: Study Specific Essential File Documentation*.

Change control

This section outlines changes from version **1.0** to version **2.0**

Section changed	Summary and description of changes
All	General administrative changes throughout

List of appendices

Appendix ref.	Appendix name
Appendix A	Site activation email 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

The JRMO would like to acknowledge the Centre for Experimental Cancer Medicine for their templates which have been used and incorporated to create this SOP.

Appendix A Site Activation Email template

SUBJECT: (Insert trial acronym) Clinical Trial Opening Notification

Dear Study Team,

Trial name:

PI:

IRAS reference:

REC reference:

EudraCT:

The above trial is now open to recruitment at (Insert NHS Trust).

Current versions:

Protocol: (version and date)

IB / SmPC: (version and date)

Diary Card (where applicable): (version and date)

CRFs: (version and date)

Patient Information Sheet: (version and date)

Consent sheet: (version and date)

GP letter: (version and date)

Pharmacy manual: (version and date)

If you require any additional information, please contact (state name and contact details).

Kind regards

(Insert name)

(Insert job title)

(Insert contact details)