

Joint Research Management Office Standard Operating Procedure for:

Location selection, initiation & activation

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Purpose and Scope:

This standard operating procedure (SOP) outlines the minimum requirements for selecting, initiating, and activating host locations for studies sponsored by Queen Mary University of London (Queen Mary) or Barts Health NHS Trust (Barts Health).

It is mandatory for all trials 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 implemented proportionately to study risk.

Abbreviations:

Barts Health	Barts Health NHS Trust
CI	Coordinating Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
HRA	Health Research Authority
IMP	Investigational Medicinal Product
JRMO	Joint Research Management Office
LIV	Location Initiation Visit
Queen Mary	Queen Mary University of London
SOP	Standard Operating Procedure

SOP Text:		
	Responsibility	Activity
1.	Coordinating Investigator (CI) or delegate	<p>Agree locations with sponsor.</p> <p>Agree the number of locations in the UK and abroad with the Joint Research Management Office (JRMO) Good Clinical Practice (GCP) and Governance Manager during the kick-off and final governance meetings. At the final governance meeting confirm all locations meet the feasibility requirements. The sponsor reserves the right to cap the number of locations. Any changes to the number of countries and national or international locations must be agreed by the sponsor (see SOP 17a: Modifications for sponsored studies).</p>
2.	CI or delegate	<p>Conduct a location selection assessment</p> <p>Define selection criteria before starting assessments, and perform them using Associated Document 1 Local assessment, selection, initiation and activation guidance, recording outcomes using Template 1 Site Selection Report. Repeat this process for any new locations added during the study.</p>
3.	CI or delegate	<p>Conduct due diligence for international locations.</p> <p>Discuss international expansion with the JRMO GCP and Governance Managers and JRMO Contract Managers. Consider indemnity limitations (e.g. Barts Health, can only sponsor studies in the UK). Ensure costs and resourcing for additional indemnity are accounted for (see SOP 7a: Contracting for MHRA Regulated Studies).</p>
4.	CI or delegate	<p>Obtain necessary approvals.</p> <p>Please see SOP 9, SOP 11a, SOP 12a, SOP 13a, and SOP 10 for further details.</p> <p>After sponsor approval of locations and countries, and the study has obtained sponsorship with conditions, obtain national/regional regulatory approvals. For non-UK locations, ensuring the local regulatory requirements are fulfilled.</p>
5.	CI or delegate	<p>Request essential documentation from each location.</p> <p>Minimum requirements:</p> <ul style="list-style-type: none"> • Confirmation of capacity and capability, or local equivalent • Fully signed clinical trial location agreement • Local Investigator's signed CV and GCP certificate • Completed delegation log.
6.	CI or delegate	<p>Prepare the Investigator Location File</p> <p>Set up Investigator Location Files, whether paper or electronic, according to SOP 45 Study Specific Essential File Documentation. It is recommended that files are set up centrally and distributed to locations as part of Location Initiation Visit (LIV).</p>
Location initiation		
7.	CI or delegate	<p>Perform Location Initiation Visit(s).</p> <p>All locations must undergo an LIV prior to activation. The LIV should ensure all locations and study staff are adequately aware of, and trained in:</p> <ul style="list-style-type: none"> • GCP • The protocol

		<ul style="list-style-type: none"> • Study specific SOPs • Source data • Investigator responsibilities. <p>Training must be commensurate and proportionate to the staff member's delegated role(s).</p> <p>LIVs must only be conducted after the trial has received Health Research Authority (HRA) approval (or equivalent) but may be conducted prior to confirmation of sponsorship and permission to activate locations.</p> <p>LIVs should be scheduled as close to location activation as logistically possible. A refresher should be considered if more than 6 weeks have passed since the LIV was conducted.</p> <p>Please see Associated Document 1 Location selection, location initiation and location activation and Associated Document 2: LIV presentation. Ensure all staff sign a LIV attendance log.</p>
8.	CI or delegate	<p>Complete location initiation report.</p> <p>Provide a written report (Associated Document 3: Location initiation report), including actions and documents outstanding, within 2 weeks.</p> <p>Share the initiation report with the CI to ensure CI oversight. The original copy will be stored in the Trial Master File.</p> <p>Resolve any actions arising from the LIV.</p> <p>If applicable, send the initiation follow up letter to non-pharmacy individuals responsible for the Investigational Medicinal Product (IMP).</p>
Post-location initiation		
9.	CI or delegate	<p>Activate location.</p> <p>Use Associated Document 1 Location selection, location initiation and location activation to create minimum location checks to be performed prior to the issuing of the location activation email.</p> <p>The location must not be activated until:</p> <ul style="list-style-type: none"> • HRA approval (or equivalent) is in place. • The signed location agreement and Statement of Activities is completed.* • Confirmation of capability and capacity.* • Any location specific approvals are in place (e.g. ARSAC licence, clinical physics, imaging, pharmacy). • The delegation log has been completed and a copy retained by the coordinating team. • CV(s) and GCP certificate(s) (within the last three years) are held centrally. • Essential documents have been collected by the coordinating centre. • LIV conducted and actions resolved. • Test scans completed as required (SOP 38a: Use of computerised equipment, software and systems in clinical research). • e-Case Report Form (CRF) or CRF training is complete. • IMP / investigational devices have been delivered or are ready to order. <p>*Evidence must be provided to the sponsor.</p>

10.	CI or delegate	<p>Issue the activation email.</p> <p>Send the “Location Activation” email (Template 2: Location activation email template) to the Investigator, pharmacy, monitor, and sponsor. Copy the CI if this has been delegated.</p> <p>Send a copy of each location activation email to: research.governance@qmul.ac.uk.</p>
11.	CI or delegate	<p>File activation documents.</p> <p>For each location, file all activation correspondence and documentation, including:</p> <ul style="list-style-type: none"> • Signed delegation log. • Trial specific training for delegated staff. <p>Update these documents for new staff members as they join.</p>

Change control

This section outlines changes from version **4.0** to version **5.0**

Section changed	Summary and description of changes
Section 7	Extended details on performing Location Initiation Visit
Throughout	Update to terminology in line with ICH E6 R3
Throughout	General administrative changes
Associated Document 1	Merger of previous associated documents 2 and 3 into associated document 1

List of associated documents

Document ref.	Document name
Associated Document 1	Location selection, location initiation and location activation
Associated Document 2	LIV presentation template
Associated Document 3	Location initiation visit report template
Template 1	Location selection assessment and report template
Template 2	Location activation email template