

Joint Research Management Office Standard Operating Procedure for:

Confirmation of capacity and capability

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Purpose:	
<p>The purpose of this Standard Operating Procedure (SOP) is to outline the Joint Research Management Office (JRMO) process for assessing and confirming Capacity and Capability (C&C) for Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary) to deliver a study.</p> <p>Confirmation of C&C is the final step in setting up a research study in the NHS or non-NHS site and is confirmed once HRA approval for a study has been received for NHS sites and that the appropriate approvals are in place for non-NHS sites.</p>	
Scope:	
<p>This SOP is applicable to JRMO staff involved in the process of confirming C&C for research involving Barts Health or Queen Mary. This includes research taking place at these sites and research which makes use of resources that Barts Health/Queen Mary is responsible for (such as data or human biological material).</p> <p>Studies such as audits and service evaluations, which are not defined as research, are outside the scope of this SOP.</p>	
Abbreviations:	
Barts Health	Barts Health NHS Trust
C&C	Capacity and Capability
CB	Clinical Board
CD	Clinical Director
CI	Chief Investigator

DSS	Date site selected
GCP	Good Clinical Practice
HRA	Health Research Authority
JRMO	Joint Research Management Office
LIP	Local Information Pack
OID	Organisation Information Document
PI	Principal Investigator
PIC	Participant Identification Centre
Queen Mary	Queen Mary, University of London
RM&GO	Research Management and Governance Officer
SOP	Standard Operating Procedure

Definitions:

Date Site Invited: The date in which the host site receives the study protocol from the sponsor. The protocol must be in the version that the sponsor submitted for regulatory review. The date site invited for studies sponsored and hosted by Barts Health or Queen Mary, should be the date of initial sponsorship submission.

Date Site Selected (DSS): The DSS is the date that the site received HRA Initial Assessment letter. If the study has the final approval from the HRA, then the DSS is the date that the HRA final approval letter is received by the site.

For hosted studies only i.e. non-sponsored hosted studies, the DSS will be the date when the study team confirm that a feasibility was conducted and that they are ready to proceed with study set up. This date would need to be amended if the following took place after this confirmation is received from the site team:

- The date when the final local document pack (including HRA letter) is received by the JRMO;
- The date of receipt of updated documents if there are any pre-C&C amendments submitted after the Local Information Pack (LIP) has been received.

The DSS for studies sponsored and hosted by Barts Health or Queen Mary, should be the date of HRA initial assessment letter or HRA final approval letter.

SOP Text:

	Responsibility	Activity
1.	PI	<p>Confirm participation.</p> <p>The PI will liaise with the study sponsor to confirm that they are interested in taking part in the study and request a copy of the protocol. The date that the site receives the protocol is the official date that the site has been invited to participate in the study.</p> <p>If Barts Health or Queen Mary is the study sponsor then the PI will already have been identified during the sponsorship application (see JRMO SOPs 11a, 12a & 13a).</p>
2.	PI/Study team	<p>Complete feasibility</p> <p>The PI and study team need to complete a feasibility and confirm when there would be resources and staff available to start the set-up process. Ensure there are no competing studies/resources that will impact</p>

		recruitment into the study. Early engagement with support departments at this stage would reduce delays later if any resource issues are identified.
3.	PI and JRMO Research Management and Governance Officer (RM&GO)	<p>Receive local document package.</p> <p>Once the sponsor has obtained either a HRA Initial Assessment letter or HRA Approval Letter, they may submit the study local document pack to the PI and/or JRMO (research.governance@qmul.ac.uk) to formally select Barts Health as a site.</p> <p>In addition to the local study pack, the PI must also:</p> <ul style="list-style-type: none"> • Confirm when the JRMO should start set up following local feasibility outcome. • Provide an optional completed JRMO hosted studies document checklist (See associated document 1) • Provide signed and dated CVs and Good Clinical Practice (GCP) certificates for each member of the study delivery team.* • Provide localised versions of public facing documents such as the patient information sheet, consent form and GP letter. • Clinical Board (CB) for Barts Health sites or Institute Director for Queen Mary site sign off confirmation (see below). • The signed 'no funding form' where there is no funding provided by the sponsor <p><i>* For Medicines and Healthcare products Regulatory Agency regulated studies CVs and GCPs are required for all delivery team but for other studies only CV and GCP of PI is required.</i></p>
4.	JRMO RM&GO or delegate	<p>Create and maintain an EDGE record for the study.</p> <p>Once the study pack is received, check EDGE for existing study record otherwise create a new entry and add the allocated RM&GO to the site level.</p> <p>For studies sponsored by Barts Health or Queen Mary, the same JRMO RM&GO who completed the sponsorship review will also complete the local C&C review. Ensure all study site level details and approval dates on EDGE are kept updated. Upload all the study documents and any approvals to EDGE and also create and save to shared drive (indemnity folder).</p>
5.	JRMO RM&GO	<p>Acknowledge receipt of study and complete 'DSS' on EDGE</p> <p>Within 5 working days of receiving the study pack, the RM&GO will send introductory email and agree a date to start the study set up.</p> <p>For DSS date please see definition section above. Only for Cancer studies, the DSS will be the date of the Cancer RG approval letter.</p>
6.	JRMO RM&GO	<p>Commence review of the LIP</p> <p>At the agreed review date confirm that the submission is valid or request missing documents and any support department approvals.</p> <p>Review the LIP and submitted approvals/documents and raise any queries with the Principal Investigator (PI), Chief Investigator (CI) or sponsor as appropriate.</p>
7.	JRMO RM&GO/PI	<p>Request costing and contract review from the JRMO costing and contracts team</p> <p>For Barts Health sites please contact jrmo-bartshealth@qmul.ac.uk</p>

		<p>For Queen Mary site, please contact jrmo-helpdesk-preaward@qmul.ac.uk</p> <p>To initiate the costings and contracts review forward the following to the above applicable team:</p> <ul style="list-style-type: none"> • Study Protocol • Schedule of Events Cost Attribution Template and Site agreement (Organisation Information Document (OID) OR Model Non-Commercial Agreement) for non-commercial studies (see SOP 8 Site agreement for clinical trials). • Model Clinical Trial Agreement for commercially sponsored studies). • Participant Identification Centre (PIC) site agreement for PIC sites.
8.	JRMO Costing and Contracts Officer/ JRMO RM&GO	<p>Review the costings and contracts.</p> <p>For all hosted studies, the JRMO Costing and contracts team will:</p> <p>(a) Review the budget and negotiate the contract.</p> <p>(b) Raise any queries with the sponsor’s representative/PI (or PI delegate)</p> <p>(c) Notify the assigned once the review has been completed.</p> <p>For Queen Mary sponsored studies, confirmation of agreement(s) can occur at sponsorship stage. (For more information see JRMO SOP 7a and 7b costing and contracting and SOP 8 Site agreements for clinical trials).</p> <p>Where there is no funding affiliated to a study, the RM&GO will review the ‘no funding form’ and ensure it is signed off by the Clinical Director (CD) /Institute Director. In this instance the OID should be signed off the by RM&GO as delegated by the Research Governance Operations Manager.</p>
9.	PI/ Peer Review/CD	<p>Arrange CB approval / Queen Mary sign off/ CD sign off.</p> <p>The study must be reviewed by the appropriate Queen Mary/Barts Health signatory (as per agreed signatory list saved in the shared drive). Please follow SOP 14 for the local review requirements and template forms, although authorisation via email confirmation will suffice.</p>
10.	PI/ Support department/RM&GO	<p>Arrange for support department sign off.</p> <p>All support departments must confirm they have the appropriate resources and capacity to support the study – please refer to associated document 1 study checklist for support department contacts. Forward all approvals to the RM&GO.</p>
11.	JRMO RM&GO	<p>Complete C&C review</p> <p>Finalise the C&C review.</p> <p>Ensure EDGE entry is complete (See EDGE manual). Upload all necessary documents including the final document set to EDGE.</p> <p>Note reason for any delays on EDGE.</p> <p>Request Barts Health trust authorisation from Research Governance and Performance Manager or Research Governance Operations Manager.</p> <p>Save all documents and communication in the Indemnity folder in the shared drive.</p>
12.	Research Governance and Performance	<p>Confirm Barts Health trust authorisation for the study.</p>

	Manager / Research Governance Operations Manager	Confirm that the JRMO RM&GO has completed the C&C review. Ensure that all approvals have been uploaded to EDGE and that EDGE data is up to date prior to granting authorisation.
13.	JRMO RM&GO	<p>Send confirmation of C&C to the PI, copying their study team, JRMO costing/contracts team, JRMO generic mailbox, support departments, CI and sponsor.</p> <p>The Barts Health confirmation of C&C email (Associated Document 2) should be sent with the signed contract and/or HRA OID.</p> <p>Update the indemnity folder with the latest document set and essential communication.</p> <p>Update EDGE as follows:</p> <ul style="list-style-type: none"> • Date site confirmed by sponsor • Date site confirmed <p>For non-clinical trials (not the first 4 IRAS categories), please amend the site status to 'open' and insert the 'open to recruitment date'.</p>
14.	PI	<p>Notify the sponsor that everything is in place for Barts Health/Queen Mary to open the study.</p> <p>The sponsor will usually reply by giving the PI confirmation to commence research activity, or will give a date that the study may begin.</p> <p>The study team should update EDGE as follows:</p> <ul style="list-style-type: none"> • Study status (site set up to 'open') • Site Initiation Visit date • Open to recruitment date • All recruitment data • Any reason(s) for delays to recruitment
15.	PI	<p>Request additional C&C assessments for new locations within Barts Health.</p> <p>Occasionally, a study which is already open may expand into another Barts Health location. Note that only one PI can be listed for Barts Health at any one time so the other site can only have a sub investigator delegated by the PI any of the required site activities.</p> <p>The PI should request JRMO permission to expand the study to the new local site via Research.Governance@qmul.ac.uk. The email request should include the:</p> <ul style="list-style-type: none"> • the name of the local co-Investigator • CVs and GCP certificates for new site staff • Departmental approval for the new location • Clinical Service Support department approval(s) for the new location
16.	JRMO RM&GO	<p>Complete additional C&C assessments for new locations within Barts Health.</p> <p>Assess and confirm the capacity and capability of the new location to conduct the study. Update EDGE with the details of the new location and the outcome of the capacity and capability assessment.</p> <p>Confirm continued CC with the additional sites within Barts Health to the PI, CI and support departments.</p>

Change control

Section changed	Summary and description of changes
Definitions	Clarification on date site selected
Section 3	Clarification on CV and GCP requirements
Section 3	Hosted checklist optional not mandated
Throughout	Updates to correct email addresses
Associated Documents	Removal of Local C&C review template (CRN-template)
Associated Documents	New confirmation of C&C email template
Templates	Removal of Initial contact email template

List of associated documents

Document ref.	Document name
Associated document 1	JRMO hosted studies submission checklist
Associated document 2	Barts Health confirmation of capacity and capability email template