Joint Research Management Office Standard Operating Procedure for:			
Review of Clinical Research including Scientific and Departmental Review			
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Purpose:

As per Queen Mary University of London (Queen Mary) and Barts Health NHS Trust (Barts Health) Research Management Policies, the responsible management - Institute or School (within the Faculty of Medicine & Dentistry (FMD) at Queen Mary) or Clinical Board (CB) (at Barts Health) - must ensure that research being undertaken under the auspices of their clinical area, is appropriately reviewed.

To ensure the effectiveness of the review process, this Standard Operating Procedure (SOP) outlines the responsibilities of (a) the researcher; (b) the CB Director of Research or delegated Specialty Clinical Leads for Barts Health; the Institute Directors for Queen Mary; (c) and the Joint Research Management Office (JRMO). It should be our collegiate aim to ensure that research undertaken by Queen Mary and Barts Health researchers is of the highest quality and world-class standard.

This SOP ensures that all the necessary reviews are conducted at the appropriate stages of planning and preparation of clinical research to ensure that the sponsor, regulators, and researchers have a high quality, scientifically robust and clear research protocol and that research teams are adequately resourced to deliver.

This SOP details the various aspects of review that may be relevant for any given clinical study, including the processes for obtaining grant application authorisation, scientific peer review, departmental approval and capacity and capability approval for research studies conducted by or within Queen Mary and Barts Health.

NOTE: The 'review' described in this SOP is in addition and separate to Sponsorship review, as conducted by the JRMO and described in *SOP 11a Sponsorship of MHRA Regulated studies*, *SOP 12a Sponsorship of Interventional Studies* and *SOP 13a Sponsorship of Research Studies*. This SOP does not relate to regulatory body approvals or ethics approvals required for research (please see related relevant SOPs list below). When using the word 'review', this SOP refers to internal departmental approvals to proceed and internal/external scientific peer review.

Scope:

This SOP applies to all researchers wishing to perform clinical research at, or under the auspices of, Barts Health or Queen Mary (FMD); the departments responsible for the Review Committee process; and JRMO staff, where applicable. This applies to Queen Mary and Barts Health sponsored and hosted studies.

Abbreviations:

Barts Health	Barts Health NHS Trust
CB	Clinical Board
CI	Chief Investigator
HRA	Health Research Authority
JRMO	Joint Research Management Office
PI	Principal Investigator
Queen Mary	Queen Mary University of London
FMD	Faculty of Medicine & Dentistry
SOP	Standard Operating Procedure

Definitions:

Scientific Peer Review:

"A judgement on a piece of scientific or other professional work by others working in the same area" [Oxford Advanced Learner's Dictionary]

Relevant SOPs:

SOP 11a: Barts Health/Queen Mary Sponsorship of MHRA Regulated Studies Process for researchers

SOP 12a: Barts Health /Queen Mary Sponsorship of Interventional studies – Process for researchers

SOP 13a: Barts Health /Queen Mary Sponsorship of Research Studies – Process for researchers

SOP Text:		
	Responsibility	**Activity**
Responsibilities of: Queen Mary (Institute Director) or Barts Health (CB Clinical Director/ Director of Research or delegated Speciality Clinical Leads)		
1.	Institute Director or CB Clinical Director, Director of Research, or delegated speciality Clinical Leads	**Establish and maintain an appropriate research review system or Review Committee**. The Queen Mary (Institute Director) or Barts Health (CB Clinical Director or Director of Research or delegated Speciality Clinical Leads) should determine an appropriate system for organising, checking, and coordinating reviews that is facilitated by individuals with relevant skills and expertise and reflective of the departmental research output. For further information about the detailed aspects of various reviews see *AD1 Review of Clinical Research - Guidance Document*. Guidance on the constitution and membership of review groups, timelines for review, principles of independence and declaring conflicts of interest can be found in *AD2 Template Terms of Reference*. The agreed system/structure put in place should be recorded in a formal Terms of Reference document (see *AD2 Template Terms of Reference*) and the finalised version submitted to and agreed with the JRMO (specifically the Research Governance Operations Manager). Review Committees can modify their structure or Terms of Reference by formal request. All documentation pertaining to the review system should be stored as per Queen Mary and Barts Health retention policies.
2.	Reviewer /Committee Members	**Conduct reviews in compliance with this SOP and Review Committee Terms of Reference.** The following reviews should be conducted of clinical studies that are *sponsored by Barts Health or Queen Mary.* Reviews should be conducted to assess the detail of the research outlined at grant application stage, to review the quality of the study protocol and its scientific rigour and to consider the resource and capacity implications of the research activity for the department and the wider institution. *1.* Departmental authorisation at grant application stage: for the purpose of this SOP, this is defined as a review of the grant application form and its contents (if grant application is submitted); confirmation the department is happy to support the research to take place; that the research question is valid; that the financing is comprehensive and appropriate and that the study fits with the departmental strategy. This authorisation includes agreement to underwrite any undeclared costs. *Important note: For those applications that have been given authorisations via the Worktribe system, those approvals are sufficient, and duplication is not necessary.* 2. Scientific peer review: If scientific review has taken place as part of the funding body review or as part of a funder's national open competition for research funds, this does not need to be

		repeated. Scientific reviewers should, wherever possible, be independent and objective and should always declare all potential conflicts of interest such as financial relationships with the study team/Principal Investigator (PI)/Chief Investigator (CI). Please see AD1 and AD3 for further guidance 3. CI Departmental Authorisation: Review of the quality of the study protocol, including reputational risk, and of resource and capacity implications for the CI's department and sponsor organisation. 4. *NOTE: Step 4 is applicable to sponsored studies only when Queen Mary/ Barts Health is also a named research site. Step 4 is the only review stage applicable to hosted studies that are externally sponsored (because Steps 1-3 are the responsibility of the sponsor organisation):* Capacity and Capability Review: a review of resource and capacity at local site (as per Health Research Authority (HRA) requirements). See SOP 10 for full details.
3.	Peer Review /Committee Chair or designee	**Feedback and decisions notified to CI and JRMO** *NOTE: not applicable to the authorisations given via Worktribe.* Compile a written report of recommendations and the outcome of review(s). This should be sent in writing to the researcher (see *AD4 Review Form* for template). Retain a copy in the department for records. Ensure JRMO Governance team is informed of the decision and forward a copy of the review, either directly to JRMO or via researcher. If the researcher is required to make changes to the proposal the process should be clearly outlined, and the revised versions checked and confirmed. If the researcher wishes to appeal any decision made by the Review Committee or designee, the agreed Terms of Reference should stipulate the process.
Responsibilities of: CI		
4.	CI/ PI or delegate	**Prepare and submit all relevant documentation to the Chair/Administrator of the Review Committee or delegate reviewer as per CB/Institute procedure.** Submit the appropriate paperwork to the Review Committee/designee for review and approval. For a list of Queen Mary / Barts Health authorisers please contact the JRMO Governance team (research.governance@qmul.ac.uk). Refer to a specific Review Committee for their own documents/process for submission. See *AD1 Review of Clinical Research Guidance* document for further information about the various elements of review.
5.	CI/PI or delegate	**Obtain the appropriate reviews** Ensure all the required reviews are submitted (if not completed) prior to submission of the study to JRMO for sponsorship review.

6.	CI/PI or delegate	**Submit signed review documentation to JRMO Research Governance team** The relevant review outcome forms and supporting documentation from the Review Committee are required to complete sponsorship or local capacity and capability review for the study. Researchers must submit a copy of the Review Committee's approval and all relevant correspondence to the Research Governance e-mail address (research.governance@qmul.ac.uk), clearly labelled 'departmental review'.
7.	CI/PI or delegate	**Modifications made during or further to confirmation of sponsorship** For substantial amendments to an approved study that could have an impact on the original peer review approvals, documentation should be re-submitted to the Review Committee for reassessment.
Responsibilities of: JRMO		
8.	JRMO Research Governance Operations Manager, Research Governance & Performance Manager or delegated other	**The JRMO will review and maintain a list of signatories and agreed committee terms of reference.** An up-to-date list of authorisers/committees will be maintained and shared on request.
9.	JRMO Research Governance Operations Manager/ Research Governance & Performance Manager	**Support Review Committees to establish their systems and processes to meet this SOP** Advice and support can be offered to ensure the processes of the Review Committee are aligned with the JRMO SOPs. The JRMO can also support in providing templates, examples of good practice and advising on aspects of the review and evidential requirements.
10.	JRMO Research Management & Governance Officers	**Receive and confirm receipt of review documentation** On receiving the evidence of reviews from Review Committee or CI, to confirm receipt and include in the submission for sponsorship document pack that is to be reviewed.
11.	JRMO Research Management & Governance Officers	**Complete Sponsorship or Confirmation of Capacity and Capability Review** Review all study submissions for sponsorship and Capacity and Capability approval received via research.governance@qmul.ac.uk

Change control

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

Section changed	Summary and description of changes
All	Removal of flow charts

List of appendices

There are no appendices for this SOP

List of associated documents

Document ref.	Document name
Associated Document 1	Review of Clinical Research - Guidance document
Associated Document 2	Template Terms of Reference for Review Committees
Associated Document 3	Scientific Peer Review template
Associated Document 4	Review Form