JRMO SOP 14
Associated Document 1

Review of Clinical Research
Guidance Document

These guidelines are to be used in conjunction with SOP 14 on Review of Clinical Research including Scientific and Departmental Review of Clinical Research

Contents

A. GUIDANCE ON FORMAT AND MEMBERSHIP OF REVIEW COMMITTEES

The purpose of this guidance is not to be a prescriptive, mandatory set of rules, rather a set of guidelines to be interpreted at departmental level in a manner that suits the localised governance and clinical arrangements. It is for staff in each Clinical Board, Institute / School to establish the most appropriate model that is fit for purpose and suits the needs of their research, researchers and facilities.

Accountability for the review and resource and capacity review will remain with the Institute Director (Queen Mary) or the Clinical Board Clinical Director, Director of Research or delegated Specialty Clinical Leads (Barts Health) and that individual or department lead should identify a process suitable to the department, considering:

- Volume of research performed by and within the department
- Type of research
    - Clinical trials, CTIMPs, student studies
    - Hosted vs Sponsored
    - Commercially sponsored vs non-commercially sponsored

Based on this assessment the department can decide if they will:

- form a Review Committee, to meet and discuss proposed studies
- designate one or more individual(s) to conduct reviews

It is essential that the Review Committee membership represent a range of expertise to address all the relevant criteria. Review Committees should not only seek assurances about a study's scientific quality but also consider the impact on routine clinical work and related services such as Pathology, Pharmacy, Clinical Physics, Lung Function and Radiology. Potential issues should be identified and addressed at the outset.

A procedure and/or Review Committee Terms of Reference should be created for whichever system is chosen (see *AD2 Template Terms of Reference for Review Committees*). The Terms of Reference should outline:

- Chair or lead, and Deputy
- List of members (either of a Committee or of those delegated to conduct review)
- Submission process and required documents
- What will be reviewed
- Timelines of meetings or turnaround times of reviewers
- Decision options
- Details of how the review outcome will be disseminated, and/ or escalated
- Appeals, complaints and resubmission process
- Details of how the review outcome will be recorded and stored

Once created, the procedure/Terms of Reference document should be submitted to the JRMO Research Governance Operations Manager or delegated other, who will review to ensure this aligns with JRMO policy and SOP. Once agreed the procedure/ Terms of Reference should be passed to all members of the Review Committee. Departments should conduct annual assessments of its reviews and these should be available to the JRMO on request.

Upon request and on behalf of the School, Institute and Clinical Board, the JRMO can advertise procedures for the Review Committee on the JRMO website and when there are changes, in the R&D News Bulletin.

B. REVIEW TYPES

There are four distinct elements to the review of a research study:

I. Departmental approval to apply for a grant
II. Scientific peer review
III. CI Departmental Authorisation
IV. Capacity & Capability at Site Level

I. Departmental approval to apply for a grant

This review establishes the resource, financial implications and strategic fit of the research activity. This authorisation includes agreement to underwrite any undeclared or unforeseen costs. For Queen Mary studies costed via Worktribe system this authorisation process is automated through the system and additional approval is not necessary.

The review should include, but is not limited to the following;

- review of grant application form (if applicable)
- confirmation the department is supportive of the research;
- assessment of the validity of the research question;
- confirmation the proposed financing is comprehensive and appropriate;
- checking that JRMO costings have been submitted;
- confirmation the study fits with the departmental strategy;
- agreement to underwrite any undeclared or unforeseen costs (for Barts Health this requires approval of both the clinical lead and speciality manager / divisional manager).

II. Scientific Peer Review

Under the UK Policy Framework for Health and Social Care all studies must be subjected to an independent review by experts in the relevant field. It is the responsibility of the Review Committee or designee to ensure that appropriate scientific peer review has occurred. If scientific review has taken place as part of the study's funding body review or as part of a funder's national open competition for funding (please refer to *list of AMRC members via https://www.amrc.org.uk/*), this does not need to be repeated.

However in circumstances where the funder is also the drug or device manufacturer, an assessment should be made regarding the impartiality and independence of that review. Where the Review Committee cannot be confident of the independence of the scientific review undertaken by the funder, the researcher or Review Committee must organise additional scientific review.

Wherever possible, the scientific reviewers should be independent and objective and declare all potential conflicts of interest such as financial relationships with the study team/PI/CI.

All researchers and departments should strive to achieve *best practice,* where scientific review is conducted by **two independent reviewers who are not affiliated to the proposed study or the sponsor organisation**; however detailed below is a chart representing proportionate review by study type:

REGULATED STUDIES *Research that requires MHRA approval*	**INTERVENTIONAL STUDIES** *Research involving a change in treatment, care or other service, made for the purpose of the research*	**RESEARCH STUDIES** *Research with human participants involving no change to participant care or treatment*
- Both reviewers must be *independent of the work* proposed - and also *independent of the sponsor organisation* (not employed by the sponsor when this is Barts Health or Queen Mary).	- Both reviewers should be *independent of the work* proposed, however for educational projects, the internal reviewer can be the supervisor. - Ideally both reviewers should be *independent of the sponsor organisation*; however one external and one internal reviewer also acceptable.	Both reviewers can be internal (employed by the sponsor organisation), one of which can be a student's supervisor (educational projects only); one of which must be independent of the work proposed.

At a minimum the scientific peer reviewer should be asked to comment on the points below (*AD2 Scientific Peer Review template* can be used):

- Does the research have a worthwhile hypothesis or research question? Can that question be answered by the proposed methods?
- Are the stated objectives clear?
- Is the methodology clear?
- Has a robust literature review and rationale been provided?
- Is there justification for sample size?
- Is the sample representative of the target population?
- Is the proposed data analysis described clearly?
- What are the arrangements for study management, including the formation of a project steering group?
- Are the outcomes of the study clearly stated and appropriate for the study aims and objectives?
- Is the timescale realistic? Are the objectives likely to be met?

Further to scientific review, it is the responsibility of the researcher to make adjustments to the study protocol based on the reviewer's comments and suggestions, or to provide justification if these are not implemented. The complete set of comments and declarations should be submitted to the departmental Review Committee or designee, who have a responsibility to consider the comments and decide whether they have been suitably addressed.

Confidentiality Concerns regarding External Reviews

All study synopses, outlines or protocols sent for review should be clearly marked as confidential. Protocols and project outlines that are sent to external organisations outside of Barts Health or Queen Mary should only be sent once an agreement has been received that the reviewer is willing to carry out the review, and that documents will be viewed in confidence. If there are any concerns

surrounding intellectual property or pending patents, advice regarding confidentiality agreements should be sought from the JRMO or Queen Mary Innovation Ltd before disseminating any documentation. For IP issues emerging see *Policy 17 Identification and protection of Intellectual Property.*

III. CI Departmental Authorisation

In order to conduct this element, the study protocol should be reviewed in full. Considerations that concern the departmental authorisation include (but are not limited to):

- Has the study been costed by the JRMO? If departmental authorisation of the financing has not yet been issued at grant application stage (because the study is at least partially internally funded and not been approved through Worktribe), a full assessment of the costs and whether the funds are sufficient should be conducted. By issuing departmental authorisation of the study, the signatory accepts that any unforeseen shortfalls in costs for the study will be met by the department. This step is automatically completed for studies costed through Worktribe.
- Does the protocol give a clear description of the practical way in which the study will be conducted?
- Is the research proposal clearly described?
- Is there the potential for reputational risk to the sponsor organisation?
- Are there any potential conflicts of interest?

Note; If the CI department is also the proposed research site, the same Review Committee can go on to conduct the Capacity & Capability approval at research site (IV below).

IV. Capacity & Capability at research site

This is a review of resource and capacity on behalf of Barts Health and/or Queen Mary where either institution is a research site in a proposed study. For the list of approved authorised signatories, please contact the JRMO Governance team (research.governance@qmul.ac.uk). Any individual or Review Committee performing this review should consider the points below:

- Can the research study be delivered successfully (recruiting to target and protocol compliance) at this site?
- Is the study team appropriate to run the study?
- Is the study team appropriately resourced?
- Does the PI have sufficient time to lead this study? (considering work plan and existing commitments)
- Does the team have capacity to run this study (staff and facilities)? Is the team overcommitted?
- Are there existing studies that would directly conflict with recruitment to this study (are there competing studies)? Is there a recruitment plan for conflicting studies if necessary?
- Is the financing appropriate and sufficient?
- Is the Clinical Board / Institute being asked to underwrite any unforeseen costs? Has this been agreed?

- Does the study fit with the Clinical Board/ Institute research strategy?

Associated Document 4 Review Form can be used for this review should reviewers find this useful.

C. PROPORTIONALITY OF REVIEW

Internally funded ('own account') research - It is important that own account and internally funded research is subject to a thorough review, including independent scientific review, in order to ensure that Barts Health and Queen Mary can demonstrate that all its research meets the required standards of quality, probity, financial transparency and that the CI's department has sufficient funds to cover all the costs associated with the study.

Student research - Some student research studies are short-term and have minimal resource implications and should be treated proportionately, with the emphasis on general appropriateness, feasibility and the impact on the institution, service delivery and participants. Review Committees may wish to consider a fast track form of review for these studies to ensure there is no unnecessary delay in commencement and inform JRMO of any relevant deadlines.

Research in small sub-specialties or small departments - Researchers working in small sub-specialties or small departments where there are limited numbers of people and challenges in providing a degree of independence, may need to submit their research for external review. However, researchers must ensure that their ideas are adequately protected (see note on *Confidentiality Concerns regarding External Reviews* in the Scientific Peer Review section above) and ensure the comments of the external reviewer are made available to the Review Committee and JRMO.

Independence in scientific peer review – best practice and a proportionality table have been included in this document to illustrate the appropriateness of reviewer and the degree of independence, across the landscape of research projects, including MHRA-regulated studies and student studies.