4. Review of research including peer review

4.1 Purpose

The purpose of this Policy is to ensure that Barts Health and Queen Mary have a peer review process that is robust and rigorous, but also appropriate and proportionate to the type, scope and nature of any given clinical research study. The UK Policy Framework for Health and Social Care states that it is the sponsor's responsibility to have adequate peer review systems in place, proportionate to the research activity.

Scientific peer review is the process of assessing the quality of a research proposal or study protocol for its academic and clinical relevance, appropriate design and methodologies and scientific rigour. Research conducted under the auspices of, or on the premises of, Queen Mary and Barts Health should always strive to be of the highest quality and integrity.

In addition to scientific review, Review Committees must be established by Clinical Boards (Barts Health) and Institutes (Queen Mary) and they are responsible for conducting several other components of a review (see below). These reviews should be initiated before, or alongside, the submission of an application to the Joint Research Management Office (JRMO) for sponsorship, regulatory approvals or research site approval. The Review Committee that leads the review of any given study should be appointed by the Clinical Board or Institute within which the Chief Investigator holds substantive employment, though this may not necessarily be the place where the research is proposed to take place (the research site).

Accountability for and oversight of the scientific peer-review process and resource and capacity assessment will remain with the Institute Director (Queen Mary) or the Clinical Board Director of Research /or delegated Specialty Clinical Leads (Barts Health).

Responsibility to obtain the approval from the appropriate Review Committee lies with the Chief Investigator and failure to so do, or falsely claiming that this is in place, may constitute research misconduct (see *Policy 24: Research Misconduct*).

4.2 Scope

This policy applies to all staff and students at Queen Mary (primarily School of Medicine & Dentistry) and Barts Health, who are conducting clinical research, and external staff using Barts Health or Queen Mary as a research site for their clinical research. Note: for students of Universities other than Queen Mary, primary responsibility for the quality of the research lies with the educational institution issuing the qualification.

For the purposes of this policy, the term 'review' can refer to various aspects of the review process, including scientific peer review of the quality of the research protocol, the relative merits of the research, feasibility and likelihood of successful delivery, resource and capacity assessment.

4.3 Aspects of Review

For clinical research involving human participants, each Clinical Board, Institute or School must ensure that the following aspects are reviewed for every study before confirming

approval or support to conduct the research within their jurisdiction. (Note: this is not an exhaustive list and more information is given in SOP 14 and Associated Documents):

- Departmental approval of funding – should include details of the grant application; availability of sufficient funds and confirmation of departmental capacity to underwrite any unexpected costs or shortfalls.

- Confirmation of appropriateness of the scientific peer review – if a scientific review has occurred as part of the grant application to a funder listed as a member of the *Association of Medical Research Charities (*AMRC), this is sufficient. If scientific peer reviewers have been identified through other means, the Review Committee should confirm the suitability of the chosen reviewer(s) to appraise the study, taking into consideration their degree of independence.[1] Subsequently, the Review Committee needs to consider the reviewers' comments and whether, if necessary, they have been suitably addressed by the Chief Investigator. The amount and independence of the scientific peer review should comply with JRMO SOP 14.

- Reputational risk to the organisation – assess perceived risks to the sponsor organisation, and if appropriate the proposed research sites delivering the study, with regards to:
  (i) highly sensitive, controversial or security-sensitive topics;
  (ii) Chief Investigator and study team experience and expertise (specifically concerning institutional risk, as opposed to the appropriateness of the team to deliver the study);
  (iii) the likelihood of successful delivery and completion (considering previous audits if applicable);
  (iv) past performance of Chief Investigator and study team, including registration and reporting of previous studies; and
  (v) potential conflicts of interest and mitigations.

- Protocol review – assess the risks and benefits, departmental strategic fit, practicalities and feasibility.

- Training and expertise of the researchers – assess the appropriateness of the Chief Investigator and study team to coordinate, deliver, monitor and oversee the research study.

- Capacity and Capability departmental approval – this is a resource and capacity review by the department conducted when Queen Mary and/or Barts Health is also a research site in the study. To assess the availability of adequate resources, including departmental capacity and infrastructure to ensure the research is conducted and completed.

4.4 Establishing Review Committees

The Institute Director (Queen Mary) or the Clinical Board Director of Research /or delegated Specialty Clinical Leads (Barts Health) should:

- Identify individuals that will be responsible for reviewing research proposals for studies to be conducted in their areas;

- Adopt specific terms of reference (advice on the content of these and a template guide can be obtained from the JRMO);
- Ensure that the responsibilities of researchers and the Review Committee are explicitly recorded;
- Outline appropriate appeals, complaints and escalation process; and
- Ensure the procedures of the Review Committee align with the standard operating procedures of the JRMO, and publicise relevant JRMO SOPs to researchers in their area.

In establishing the Review Committee, a Chair (and Deputy) should be appointed, with consideration given to that individual's experience, expertise and capacity. Adequate administrative support is essential to the success, function and effectiveness of a Review Committee and so it is advised that specific work time allocation for the position of Secretary is given in a suitable role.

Additional guidance on establishing Review Committees is available from the JRMO in SOP 14 and Associated Documents.

4.5 Review Committee Composition

The Review Committee must be comprised of individuals that have a sufficient range of knowledge, expertise and experience to address all the relevant criteria being reviewed.

In undertaking reviews regarding resource and capacity, reviewers should be able to address the practicalities of conducting a specific study within the organisation, its cost, impact and the capacity of the department or research group to deliver the project. Furthermore, it should consider the impact on routine clinical caseloads for research-related services and clinical departments inputting to the research such as Radiology, Pathology, Pharmacy, Lung Function and Clinical Physics.

The Review Committee should assess the scientific peer-review process and the suitability of the selected scientific peer reviewers. Scientific peer review should be carried out by individuals who are independent of the research;[1] qualified to make a judgment about the scientific quality, relevance and probity of the research; and the clarity of the protocol.

4.6 Review Committee Process

The Chair of each local Review Committee, or their designated deputy, should ensure that staff and students are aware of the following: a) how to submit research for approval, including contact details for queries and assistance; b) the frequency and dates of meetings; c) the expected review time for applications; d) outcome dissemination procedure; e) appeals, complaints and escalation procedure; and f) any other special arrangements that may apply.

4.7 Review Committee Reporting

The Review Committee is expected to keep up-to-date and accurate records of the applications submitted for approval. The JRMO reserve the right to request access to records and reports at any given stage, including the option to audit.

[1] A guide on who can act as an 'independent' scientific peer reviewer, as proportionate to the type and nature of a research study can be found in the SOP 14 AD1 Review of Research Guidance document.

This policy applies to both Queen Mary and Barts Health.