

Joint Clinical Research Board Terms of Reference

Authority

The Joint Clinical Research Board (JCRB) is an established committee within the governance structures of Barts Health NHS Trust and Queen Mary University of London. It is accountable to Barts Health's Group Executive Board (GEB) and to Queen Mary's Senior Executive Team (SET).

The JCRB has no executive powers other than those delegated below in this Terms of Reference (ToR). Its constitution and ToR are set out below and can only be amended substantially with the approval of SET and GEB.

The JCRB is authorised by SET and GEB to oversee legal, regulatory and financial compliance in research and to advise Queen Mary and the Barts Health of any serious transgressions that they need to know about or that cannot be resolved through normal processes, and the actions taken by the JCRB to address these. (This might include dealing with MHRA and other regulatory bodies or suspending studies or initiating action for research misconduct).

Purpose

The purpose of the JCRB is to provide assurance to Barts Health and Queen Mary that our research is being carried out in accordance with:

- Barts Health and Queen Mary strategy and policy.
- Legal and Regulatory requirements.
- Financial regulations.

The JCRB will, from time to time, set R&D activity targets and monitor progress in achieving them.

Scope

The JCRB's remit will cover all clinical research at Barts Health and Queen Mary's Faculty of Medicine and Dentistry with a particular focus on research involving human subjects and tissues.

Reporting

As described above, the JCRB will report to GEB and to SET.

The Barts Health - Queen Mary Joint Research Management Office (JRMO) and JRMO Sponsor Oversight Group (SOG) will provide regular reports on research activities to the JCRB.

The SOG exists to ensure that Senior Management within the JRMO, on behalf of Queen Mary and Barts Health as sponsors of clinical trials, is informed of, manages and where relevant escalates issues relating to the conduct of clinical trials. The group was established in 2014.

Institutes, Clinical Boards and Clinical Trial Units and others will provide regular updates and performance reports to the Board through their respective Directors, on the research activities being undertaken under their auspices.

The approved minutes of the Board will be circulated to GEB and SET for information and widely disseminated throughout the Trust and Queen Mary.

Remit, duties and responsibilities

The JCRB will:

- Provide assurance to the GEB and SET that the research activities of both organisations are carried out in line with current strategies and the published joint policies and to advise on the adequacy of resources and infrastructure to deliver those strategies;
- Provide recommendations to Queen Mary and Barts Health for developing corporate strategic direction or policy changes;
- Oversee the clinical trials portfolio and its balance to ensure delivery of relevant areas of the organisations' strategies;
- Provide oversight of research operations in both organisations, ensuring that adequate structures and processes are in place within Clinical Boards and Institutes; and JRMO to ensure that the highest quality levels of research governance are maintained in undertaking research activities;
- Use the powers delegated to it by Queen Mary and the Barts Health to ensure that both organisations adhere to their obligations under statute and research regulations and ensure that financial probity and adherence to institutional financial regulations is maintained in accounting for research and development funds in both organisations;
- Monitor performance against institutional and national targets and to advise GEB and SET of actions taken to address areas that are not performing adequately;
- Establish sub-committees of the Board, which can be standing or of a limited or fixed duration, to provide operational oversight of specific areas of work or to undertake Board initiated projects that address operational, performance or strategic issues that will impact on joint working arrangements;
- Oversee dealings with MHRA and other regulatory bodies; and
- Where appropriate, suspend non-compliant studies or initiate action for research misconduct (either directly or through a sub-committee).

Frequency of meetings

The Board will normally meet every three to four months but may meet more frequently if required.

Quorum

A quorum shall be 6 members including either the Chair or Deputy Chair, 2 Clinical Board representatives and 2 Institute representatives. This includes people present through telephone links.

Chair's action

The Joint Chairs of the JCRB can make a decision by 'chair's action' after taking advice from the JRMO, the Clinical Director of R&D and/or other relevant parties in circumstances where an issue is escalated and a rapid decision is required on behalf of the sponsor to, for example, protect the safety of patients, ensure integrity of the data, ensure regulatory compliance or to resolve disagreements.

All such decisions must be documented and all documentation and evidence provided to JRMO for filing in the relevant trial files.

All such decisions must also be reported to the next meeting of the Board and be noted in the minutes.

Conflicts of interest

It is important that the integrity of the Board is, and is seen to be, beyond reproach and that conflicts of interest or loyalty are reported and managed. Board members must declare any real or perceived conflicts with any studies under discussion. This includes having any personal role in or involvement with the study being discussed, or any interest in any companies involved in the trial (for example, supplying a drug for the study).

When conflicts arise the individual should absent themselves from the room for the whole discussion relating to the trial.

Membership of JCRB by job title

Group Chief Medical Officer, Barts Health (Joint Chair)
Vice Principal for Health, Queen Mary (Joint Chair)
Clinical Director of R&D
Deputy Clinical Directors of R&D
Director of Research Development, Barts Health
Director of Research Services & Innovation, Queen Mary
COO Faculty of Medicine and Dentistry, Queen Mary
Dean for Research
Clinical Director/ COO of CRN-North Thames
Research Lead Cancer, Barts Health
Research Lead Cardiovascular Clinical Board, Barts Health
Research Lead Children's Health Clinical Board, Barts Health
Research Lead Emergency Care Clinical Board, Barts Health
Research Lead Medicines Clinical Board, Barts Health
Research Lead Surgery Clinical Board, Barts Health
Research Lead Women & Newborn Health Clinical Board, Barts Health
Clinical Support Services, Barts Health
Director Barts Cancer Institute, Queen Mary
Director of Research for Dentistry, Queen Mary
Director Blizard Institute, Queen Mary
Director William Harvey Research Institute, Queen Mary
Director Wolfson Institute of Preventative Medicine & Institute of Population Health Sciences (IPHS), Queen Mary
Director Institute of Health Sciences, Queen Mary
Director of Barts Clinical Research Facility
Director Pragmatic Clinical Trials Unit
Director Barts Clinical Trials Unit

Director of Barts Life Sciences
Group Director of Commercial & Business Development, Barts Health
Leads for Research Nursing and Allied Health Professionals
JRMO Senior Managers
JRMO Secretariat

Others may be invited to attend as necessary.

Reviewed and revised, March 2023.