

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 directly to the Trust Board and to Queen Mary Senior Executive (QMSE) via the Trust Management Executive (TME) and School of Medicine and Dentistry's Senior Executive Group (SMD-SEG) respectively.

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 with approval of QMSE and the Trust Board

The JCRB is authorised by QMSE and the Trust Board to oversee legal, regulatory and financial compliance in research and to advise QMUL and the Trust of any serious transgressions, that the Board needs 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 the Trust Board and QMUL QMSE that our research is being carried out in accordance with:

- Trust and QMUL 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 QMUL's School of Medicine and Dentistry with a particular focus on research involving human subjects and tissues.

Reporting

As described above, the JCRB will report to the Trust Board via the Clinical Academic Strategy Board and to Queen Mary Senior to Queen Mary Senior Executive (QMSE) via the Medical School's Executive Team (SEG).

The JRMO and JRMO Sponsor Oversight Group¹ will provide regular reports on research activities to the Board through the Director of Research Services.

The Institutes, CAGs and Clinical Trial Units 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 Trust Board and QMSE for information and widely disseminated throughout the Trust and QMUL.

Remit, duties and responsibilities

The JCRB will:

- Provide assurance to the Trust Board and QMSE 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 QMUL and the Trust 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 CAGs 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 QMUL and the Barts Health Board 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 the Trust Board and QMSE 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 on a quarterly basis, but may meet more frequently if required.

¹ The JRMO Sponsor Oversight Group exists to ensure that Senior Management of the Joint Research Management Office (JRMO), on behalf of QMUL and BHT 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.

Quorum

A quorum shall be 6 members including either the Chair or Deputy Chair, 2 CAG representatives and 2 Institute representatives.

Chairman's action

The Chairs of the JCRB can make a decision by chairman's action after taking advice from JRMO, the PI and 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 (eg 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.

Initial membership

Director of Academic Health Sciences	Professor Jo Martin	BH Co-chair
Vice Principal for Health	Professor Steve Thornton	QMUL Co-chair
Joint Director of Clinical R&D	Professor Khalid Khan	BH/QMUL
Deputy Trust Secretary	Sean Collins	BH
Academic Registrar & Council Secretary	Jonathan Morgan	QMUL
COO School of Medicine and Dentistry	Dr Rob Bennett	QMUL
Dean for Research	Professor Mauro Perretti	QMUL
Women's and Children's CAG	Dr Nick Croft	BH/QMUL
Women's and Children's CAG	Professor Shakila Thangaratinam	BH/QMUL
ECAM CAG	Professor Costantino Pitzalis	BH/QMUL
Cancer CAG and Barts Cancer Institute	Professor Nick Lemoine	BH/QMUL
Cardiac CAG	Professor Steffen Petersen	BH/QMUL
CCS CAG	Professor Anju Sahdev	BH
Institute of Dentistry	Professor Mike Curtis	QMUL
Blizard Institute	Professor Graham Hitman	QMUL
Wolfson Institute	Professor Jack Cuzick	QMUL
William Harvey Institute and Cardiovascular	Professor Mark Caulfield	QMUL

BRU		
Nursing and Therapies	Dr Deanna Gibbs	BH
Barts CTU	Professor Peter Sasieni	QMUL
Pragmatic CTU	Professor Sandra Eldridge	QMUL
Director of Research Development	Gerry Leonard	BH
Director of Research Services	Dr Sally Burtles	BH/QMUL
Whitechapel CRC and Whipps Cross CRU	Dr Paul Astin	BH
In Attendance		
Associate Director of Engagement and Diffusion	Neeta Patel	JRMO
Associate Director of CAG Research Development	Jo Morgan	JRMO
Research and Development Manager Post Award	Coleen Colechin	JRMO
Research and Development Manager Governance	Elizabeth Clough	JRMO
Secretary of the JCRB	Nick Good	JRMO

Others may be invited to attend as necessary