1: Study Set-up and Regulatory Approvals

1.1 Background

The UK Policy Framework for Health and Social Care Research (2017), sets out principles of good practice in the management and conduct of health and social care research in the UK. It is the responsibility of all researchers to ensure that all research, is conducted to the highest ethical standards and with integrity, in line with current guidance and UK legislation[1]. This Policy is applicable to research projects involving NHS staff, NHS premises, NHS data and Social Care research that come under the UK policy Framework for health and social care. For Queen Mary Research of Ethics Committee research please refer to Policy 2b (not involving the NHS).

1.2 Study Set-up

1.2.1 Research Integrity

Research integrity is at the core of the UK policy framework as described in Principle 5 Integrity, Quality and Transparency "Research is designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency" and Principle 18, Integrity of the Care Record, "All information about treatment, care or other services provided as part of the research project and their outcomes is recorded, handled and stored appropriately and in such a way and for such time that it can be understood, where relevant, by others involved in the participant's care and accurately reported, interpreted and verified, while the confidentiality of records of the participants remains protected"

Barts Health and Queen Mary researchers must uphold the highest standards of rigour and integrity when conducting their research work ensuring that they:

- Honestly report data, results, methods and procedures, and publication status;
- Do not fabricate, falsify, or misrepresent data (See JRMO policy 7 on Dissemination and publication; and Policy 8 on Citation);
- Avoid bias in research design, data analysis, data interpretation, and other aspects of research (See JRMO Policy 24 on Misconduct);
- Arrange data management plans from the outset of the research project and throughout the work, within the framework set out by the University data management policy (Policy 11) and Trust data sharing policy (Policy 16);
- Make research findings and methods widely available to other researchers and the public in line with the JRMO dissemination and publication policy (Policy 7); and
- Declare any actual, potential or perceived conflicts of interest relating to research. and seek advice and/or to take steps to resolve them.

1.2.2 Project registration

[1] The Royal College of Physicians (1997, updated 2007) Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects;
The Declaration of Helsinki (2000, amended 2013) Ethical Principles for Medical Research involving Human Subjects;
Governance Arrangements for NHS Research Ethics Committees, (updated 2020);
General Medical Council (1999, updated 2019) Good Medical Practice;
General Data Protection Regulation (2016);
The UK Policy Framework for Health and Social Care Research (2017, updated 2020);
The Medicines for Human Use (Clinical Trials) Regulations (2004).

Research carried out by Barts Health or Queen Mary, either singly or together with external collaborating organisations, must be reviewed and recorded at project registration and arrangements put in place to ensure that oversight is maintained throughout the study. Accurate registration and well-maintained records are an essential enabler of sponsor oversight. Barts Health and Queen Mary are also host sites for research led by other partners including pharmaceutical companies, other NHS Trusts and Universities and have responsibilities to these external sponsors in this regard. Furthermore, it is a requirement of the UK policy framework for health and social care research that organisations maintain an accurate database of all clinical trial activity that involves NHS staff, patients, premises, equipment or facilities.

Accurate registration along with appropriate, proportionate review of all studies and precise record-keeping enables the following:

- Sharing of information across organisations involved in collaborative research or where a researcher holds more than one contract.
- Maintenance of confidentiality and appropriate handling of sensitive information and personal data.
- Monitoring compliance of research with the UK policy framework for health and social care research (2017), Good Clinical Practices standards and all applicable research regulations.

The overall responsibility for maintaining an accurate database of all research studies sponsored by and conducted at either Barts Health or Queen Mary sits with the JRMO. This will include research projects awarded through a successful grant application, projects submitted via the Queen Mary Faculty of Medicine and Dentistry (FMD) and all Barts Health research projects. In some instances, such as research databases and tissue banks, registration of sub-projects falling within a generic approval is delegated to the study teams for record-keeping. Database management includes data entry, verification and data cleansing.

The JRMO will share activity data with Queen Mary and Barts Health and other collaborating organisations to promote accurate recording and reporting of research activity across all research projects. The JRMO, on behalf of the sponsor, Barts Health or Queen Mary, may use information recorded on the database as a mechanism for undertaking monitoring and/or audits of GCP standards and/or research governance compliance.

It is the responsibility of all researchers to undertake the following steps to ensure that projects are properly registered:

- Comprehensive scientific peer review and institutional review are undertaken (See policy 4);
- Costing is undertaken by the JRMO (see policies 18 & 19);
- Barts Health indemnity or Queen Mary insurance is arranged (see policy 15);
- No disclosure of valuable Intellectual Property has been made (see policy 17);
- Ethical approval is sought from the appropriate Research Ethics Committee, as appropriate;
- HRA approval is obtained, as appropriate;
- MHRA approval is obtained, as appropriate;
- Any further additional regulatory approvals are obtained as required;
- Arrangements for tissue sample consent, storage, transfer and analysis are in place;
- Data storage and data security arrangements are in place (see policies 11 and 16); and
- All project documentation, as per appropriate submission SOPs, is provided to the JRMO.

1.2.3 The Sponsor Organisation

The UK Policy Framework for Health and Social Care Research states that the sponsor is "the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. All health and social care research has a "sponsor". The sponsor is normally expected to be the employer of the Chief Investigator in the case of non-commercial research, or the funder in the case of commercial research.

For health and social care research conducted by researchers at Queen Mary and/ or Barts Health, the following principles apply:

A. The sponsor organisation will, normally, be the Chief Investigator's substantive employer. However, there are some exceptions to this rule, which may relate to funding sources, the grant holder, and the intention to conduct international research. The JRMO can issue sponsorship on behalf of either Queen Mary or Barts Health, as the two institutions share a joint research misconduct policy, but the Chief Investigator must have substantive employment with either Queen Mary or Bart Health, and hold an honorary contract with the other.

B. The sponsor organisation will be either Barts Health or Queen Mary, not joint sponsorship. Additionally, neither Barts Health nor Queen Mary will agree to be a joint sponsor with any external organisation.

C. For prospective Chief Investigators not employed by Barts Health or Queen Mary, sponsorship by Barts Health or Queen Mary will *only* be considered if all of the following apply:

    (a) If the funding has been directly awarded to Barts Health or Queen Mary; and
    (b) An honorary contract is in place with the prospective sponsor organisation (Barts Health or Queen Mary); and
    (c) Written confirmation is obtained from the Chief Investigator's substantive employer's Research & Development department, confirming they have no objections to their staff member acting as Chief Investigator for the study; and
    (d) Written confirmation is obtained from the Chief Investigator's substantive employer's Human Resources department, confirming that any future research misconduct allegation will be investigated as a partnership and that the sponsor's (Barts Health or Queen Mary) recommendations will be actioned; and
    (e) Chief Investigators agree to follow all Queen Mary and Barts Health policies and SOPs regarding research, including the requirement to attend JRMO face-to-face or virtual GCP training.

D. Barts Health and Queen Mary can, under certain circumstances, act as legal representatives within the UK. If this is agreed the study will undergo and adhere to the same policy and procedures that would apply if either Barts Health or Queen Mary were the sponsor.

1.3 Ethics and Other Regulatory Approvals

Before any research activity can commence at Barts Health or Queen Mary, all applicable national and local permissions and approvals must be in place. Researchers must follow national, local and sponsor guidelines and JRMO and local SOPs to ensure appropriate applications are made to the necessary regulatory bodies.

Where a researcher is unclear whether their research requires NHS Research Ethics Committee (REC) or Queen Mary Ethics of Research Committee (QMERC) and/or other local approvals, they must seek clarification from the JRMO. Contact details can be obtained through the JRMO website.

All applications for Sponsorship and external approvals should be applied for following JRMO Procedures. Advice and guidance should be sought from the JRMO, before completion of the required form.

The Chief Investigator has overall responsibility for ensuring that the research meets the standards stipulated by the HRA, REC and the sponsor. For Barts Health and Queen Mary sponsored studies the Chief Investigator will be asked to sign a Sponsor to Chief Investigator agreement outlining their duties and responsibilities, as Chief Investigator. This includes (but is not limited to):

- Compliance with requirements to protect the rights, health & safety, privacy and dignity of research participants;
- Notification of changes to the protocol or supporting documentation to regulatory bodies and other interested parties;
- Maintaining high standards of record keeping;
- Ensuring participants have given fully informed consent (see JRMO Consent Policy 3);
- Ensuring that research is assessed following the JRMO Peer Review Policy 4;
- Ensuring full accountability for all study supplies (including trial medication, clinical equipment and devices);
- Ensuring the investigator and study team are appropriately trained in the protocol and the applicable regulations (for example, GCP and UK Policy Framework for Health and Social Care Research);
- Notification of annual reports to required bodies; and
- Agreement to register the clinical trial on a public website and to disseminate results.

For Barts Health and Queen Mary MHRA regulated sponsored studies where Barts Health or Queen Mary is the only site the Chief Investigator and Principle Investigator will be the same person. This will apply unless clear justification is given for a deviation from this policy.

1.3.1 Training

All staff engaged in delivering Barts Health and Queen Mary led studies must complete mandatory GCP training, regardless of the type of study or sponsor. The Chief Investigator and lead team (See SOP 34a Researcher training for full definitions) working on Barts Health/Queen Mary sponsored studies are required to attend JRMO training.

Staff delivering studies that are sponsored by external parties' such as commercial companies or NHS Trusts or Universities other than Barts Health or Queen Mary, may complete any GCP training that meets the sponsor's requirements (NIHR training provision is advised).

A 2 yearly GCP refresher course is mandated for all staff working on MHRA regulated studies and is recommended as best practice for all other study types.

1.3.2 Monitoring Progress

Investigators must update the JRMO during the active stage of a project ensuring that the office is provided with annual reports and safety reports, and is notified of project delays and

halts, changes in project details such as amendments to protocols or other study documentation, changes to vendors or suppliers or when additional contracts with third parties are required. as directed by the relevant JRMO SOPs.

Official documents relating to a project, such as amendments to a protocol or study documentation must be sent to the JRMO as soon as possible and following sponsor and/ or JRMO procedures. Investigators must notify the JRMO at the close of a project and provide all the required closure documentation, (for example, end of trial notifications, publications and archiving arrangements) as set out in the relevant JRMO SOPs

1.3.3 Externally Sponsored Studies

Principal Investigators leading studies at Barts Health or Queen Mary, where the Sponsor and study Chief Investigator are external, must ensure that they obtain a complete study pack from the Sponsor that contains the appropriate regulatory approvals and study information. Local confirmation of capacity and capability issued by the JRMO must also be in place before commencing any study.

For all externally sponsored studies one of the following must be in place:

- A Site agreement between Barts Health or Queen Mary and the study Sponsor, using the UK model template agreement where possible is mandatory; or
- Organisational Information document (or current HRA equivalent)

These agreements will cover data protection and confidentiality, material transfer agreements and intellectual property management arrangements.

REC/ HRA approval should not be viewed as an automatic license to begin a research project. Investigators must ensure they have all the appropriate contractual agreements in place, any additional regulatory approvals and any local Barts Health or Queen Mary approvals, in particular, final JRMO confirmation of sponsorship and local confirmation of capacity and capability (as applicable) before a study can commence.

Failure to obtain the appropriate regulatory approvals and JRMO approval constitutes research misconduct and may result in formal disciplinary action being taken.

The JRMO retains the right to monitor and audit studies to ensure that all research conducted at Barts Health and Queen Mary has JRMO and the required regulatory approvals and is being delivered according to the approved protocol.

This policy applies to Barts Health and Queen Mary as indicated.