10. Minimising Risk

10.1 Background

All studies carry a definable level of risk and must be adequately managed to ensure that these risks are minimised.

The main risk categories are as follows:

- Regulatory Compliance
- Clinical risk
- Product risk
- Employment risk
- Contractual risk
- Asset risk
- Financial risk
- Reputational risk
- Investigator risk
- Data breach/loss risk

Detailed policies on each of the areas set out below are contained in various sections of this core research management policy document. Reference will be made to each relevant policy.

10.2 Policy

Staff undertaking research in Queen Mary and Barts Health will adhere to national legislation and regulatory frameworks and the relevant Queen Mary and Barts Health research management policies, to ensure that the risks associated with undertaking research are identified, minimised and mitigated.

10.3 Regulatory Compliance

Staff will comply with local and national regulations before commencing any research activity in Queen Mary and Barts Health, ensuring also that their managerial procedures are adhered to. This will include:

- Obtaining external or internal Ethical Approval – See policy number 1
- Obtaining any regulatory approval from the appropriate regulatory body e.g. The Medicinal and Healthcare products Regulatory Agency and Health Research Authority.
- Adherence to Good Clinical Practice and the Declaration of Helsinki when undertaking research.
- Adherence to the published UK policy framework for health and social care research, 2017 for Health and Social Care.
- Compliance with the Human Tissue Act.
- Compliance with GDPR (General Data Protection Regulations)
- Information Governance policies and procedures of Queen Mary and Barts Health and other relevant regulations.

- Adherence to Queen Mary and Barts Health policy and procedures concerning the management of research and development activities in the organisations.

10.4 Clinical Risk

Clinical risk is a generic term that covers a wide range of clinical and related activities. Investigators are required, when undertaking clinical activities as part of their research, to adhere to the appropriate Barts Health and Queen Mary policies and relevant national and local clinical guidelines. Access to these policies is via the Barts Health or Queen Mary's websites. Particular attention should be paid to the following core policies:

- Health and Safety policies of Barts Health and Queen Mary
- Complaints policies of the Barts Health and Queen Mary
- Policies and SOP's relating to specific clinical areas
- Risk Management Strategy & Policy
  Adverse Incidents Policy

10.5 Product Risk

Staff will ensure that the risks associated with the use of experimental products in research are minimised by:

- Adhering to the Indemnity Policy
- Complying with MHRA regulations and adhering to the Safe and secure handling of Medicines (including Advanced Therapies) in clinical trials Policy and the Use of medical devices in research policy.

Ensuring that the value to any patients or volunteer subjects participating in research projects outweighs the personal risks surrounding such participation. This issue should be addressed during the Peer Review Process.

10.6 Employment Risk

Investigators leading research projects, together with other staff who may be involved in the appointment of other staff with a research remit, must adhere to the respective organisational policies on HR arrangements for research-active staff.

10.7 Contractual Risks

To control the risks associated with entering research contracts with external research sponsors and collaborating partner organisations, staff involved in research shall pass the responsibility for all contractual matters relating to research to the Joint Research Management Office or Business Development (QMUL), who will negotiate contract terms, indemnity or insurance, price and arrange for contracts to be signed by an authorised signatory. Failure by staff to adhere to the policies covering agreement with external sponsors of research could be regarded as research misconduct.

10.8 Asset Risk

Queen Mary and Barts Health have, over many years, built up considerable expertise, knowledge and know-how in many scientific fields. This resource, together with the facilities they have at their disposal, constitutes a valuable asset base upon which the organisation's research strategies and plans are developed. All employees involved in research must

ensure that the assets of Queen Mary and Barts Health are protected, in particular those Intellectual Property assets that may have future commercial value. To minimise the risk of external organisations taking unfair advantage of the communication and dissemination activities that are necessary facets of the research process, investigators are required to adhere to the policies set out in Policy 16, Identification and protection of Intellectual Property.

Investigators must contact the Joint Research Management Office before entering any arrangement with external research collaborators or funders.

10.9 Financial risk

Queen Mary and Barts Health must ensure that research is not conducted which could lead to unfunded, unreasonable costs being incurred by either organisation. Commercially funded research must be fully funded and not subsidised in any way by Barts Health or Queen Mary. To minimise financial risks Investigators must ensure that their research is costed and agreed by the JRMO, and adhere to the following policies: Policy 18, Costing research, Policy 19, on externally supported R&D Pricing, and Policy 20, Distribution of research project funds.

10.10 Investigator risk

The investigator and all staff working on a research project must adhere to the approved protocol or agreed schedule of activity to ensure that they are compliant with all regulations concerning research and to ensure that they are fully indemnified. Chief Investigators of CTIMPs are required to attend the mandatory Chief Investigator training courses run by the JRMO and all Chief investigators are required to ensure that their knowledge of the regulatory framework for research is adequate, by undertaking regular training updates in GCP. Where an investigator is made aware of any breaches in compliance with the protocol they must inform the JRMO as per the relevant published JRMO SOPs.

Where a clinical study takes place on a single site, the Chief Investigator and Principle Investigator will be the same person unless there are agreed exceptional circumstances. Chief Investigator and Principle Investigator s must be experienced in the therapeutic area of the study and clinical research. Chief Investigators or Principle Investigators who lack relevant experience in clinical research may still be selected to perform the role of Chief Investigator or Principle Investigator; however, this must be agreed, in writing, by the sponsor, who may appoint an experienced individual to support or mentor the Chief Investigator or Principle Investigator for the duration of the study. This will facilitate the development of the research workforce.

10.11 Reputational risk

The investigator and all staff working on a research project should ensure that their activities do not lead to reputational damage for the Barts Health, Queen Mary or the sponsor organisation. This should be addressed during the internal peer review and any organisational approval process. This risk is mitigated by ensuring that the study is compliant with the UK regulations governing research, the protocol or schedule of activity, policies of each organisation and the JRMO SOPs.

10.12 Responsibility for Minimising Risk concerning Research Activities

The Investigator and all staff working on a research project or programme of research have both individual and collective duties to ensure that studies are conducted in accordance with good academic practice in research, Good Clinical Practice, national regulations and Queen

Mary and Barts Health standing orders and corporate policies. Clinical Board Directors, Faculty Deans of Research, Institute Directors, Heads of Schools, and the Joint Research Management Office are charged with a duty to ensure that staff adhere to this regulatory framework.

10.13 Data breach/loss Risk

The investigator and all staff working on a research project must adhere to Policy 9 Use of Research Participant Information for Research and Policy 16 Barts Health Research Data Sharing to ensure mitigations are in place to reduce any risk of data loss or data accessed by inappropriate staff. Any data leaving the organisation should have a data sharing/transfer agreement in place even if data is fully anonymised. Failure to comply with these policies could amount to Research Misconduct (see Policy 24) which would be investigated as a potential failure to comply with GDPR.

This policy applies to both Barts Health and Queen Mary.