15. Indemnity

15.1 Background

Clinical Trials and other research studies undertaken by Barts Health NHS Trust or Queen Mary University of London carry an element of risk for research subjects. The principal objective of the Joint Clinical Trial Compensation Policy (12 above) is to ensure that where subjects suffer harm as a result of participation in a study, they will be compensated – if, of course, the circumstances under which the subject was harmed, meets the criteria set out in the policy. The objective of this policy is to set out the indemnities that are required to be in place for the Compensation Policy to come into force.

15.2 Policy

(a) Commercially Sponsored Trials

All organisations in the UK are required to ensure that before any trial sponsored by a commercial organisation (pharmaceutical company, devices company) commences, confirmation of Indemnity is reviewed and accepted by the JRMO. This is captured within the Liabilities and Indemnity clause of the appropriate standard ABPI Agreement which is Section 5 of the mCTA (Model Clinical Trial Agreement) and is submitted with the Research Ethics Application by the Study Sponsor. This legally binding agreement provides indemnity for both trial subjects, and Barts Health NHS Trust or Queen Mary University of London, ensuring that if harm is caused by the product under investigation, or because of deficiencies in the trial protocol, the subject will be compensated (see Policy 12 above) and Barts Health NHS Trust or Queen Mary University of London indemnified from liability to pay the claim.

(b) Non-commercially Sponsored Trials

Where a trial is sponsored by either Queen Mary University of London or Barts Health NHS Trust they, as the sponsor, will be responsible for the design of the study protocol and the conduct of the study and will provide the following indemnities dependant on the scope of the study. These include but are not limited to the following:

- A commercial company that is providing support, such as finance, contributing free drugs or devices etc. will be indemnified by the sponsor against any claims made by a participant in the study.

- Where an unlicensed product is used beyond the trial period, on a named patient basis, or for humanitarian purposes, the sponsor is not liable, and the responsibility is wholly that of the treating doctor. Doctors are required to maintain adequate and appropriate professional Indemnity Insurance and notify their protection society and the appropriate regulatory body if they intend to use unlicensed products.

- A company supplying products for a research study will reciprocate with its own indemnity to the sponsor for any manufacturing defect of the product it supplies ensuring that adequate insurance is in place to cover this liability, evidence of which should be provided on request from the sponsor (product liability cover).

15.3 Negligence

Organisations are required to indemnify research subjects and some funding organisations from claims arising from the negligent acts of their employees. Where an ethics application is required and before submission to the NHS or Queen Mary Ethics Committee, investigators are required to submit the Ethics Application Form and Protocol/Project Specification to the JRMO for review. The Office will issue a Provisional Letter of Sponsorship, which includes terms under which indemnity would be issued. Once Ethics Approval has been given for a study, the Office will issue a Final Letter of Sponsorship, which incorporates confirmation of Indemnity.

Where Queen Mary University of London is the legal sponsor, they offer “no-fault” Indemnity to the subject for any harm caused by participation in a trial. “No-fault” indemnification means the subject does not need to seek legal redress in court to prove harm. The claim would be made directly to the sponsor who will submit it to their insurer to settle. Queen Mary would indemnity any partner organisations against claims made against the study by any subject. The partner organisation will reciprocate by indemnifying the sponsor against negligence.

Where Barts Health NHS Trust is the legal sponsor, their indemnity is covered through NHS Resolution and that only covers Barts Health staff and patients. Where Investigators from other organisations are conducting a study on Queen Mary or Barts Health premises, a letter of Indemnity from the sponsoring organisation must be submitted to the JRMO and Ethics Committee. Investigators must continue to inform the Office and Ethics Committee(s) of changes to the Protocol/Project Specification so that Indemnity cover is maintained. Failure to inform the Office and/or the Ethics Committee(s) of the intention to conduct a study will be viewed as a breach of an Investigator’s contract of employment and investigators could have personal liability for any harm resulting to a patient or claims made by a funder (see Policy 12 above).

15.4 Health and Safety

Staff involved in Research and Development activities are bound by all published Health and Safety Regulations, as set out in Queen Mary or Barts Health policies on Health and Safety at work.

15.5 Insurance

Queen Mary secures insurance for its research liabilities from a commercial insurance company. Whilst most of its liabilities are covered, exclusions within the policy may require additional insurance cover to be purchased. Expert reviews of individual cases, plus annual audits undertaken by the JRMO, enable the JRMO to bring to the attention of Queen Mary’s Insurance Purchasing Officer any instances where additional coverage may need to be purchased from an external insurer.

Barts Health insures its liabilities through the NHS Litigation Authority’s liabilities to third parties’ scheme.

This policy applies to both Barts Health NHS Trust and Queen Mary University of London.