12. Clinical trial compensation

12.1 Background

Clinical trials and other research studies undertaken by employees of Queen Mary or Barts Health may be undertaken at the instigation of commercial organisations or non-commercial external funders, or they may be unfunded. Where trials are funded by a company, it is accepted practice for the company to offer compensation to patients or healthy subjects who participate, if they are harmed through some fault of the manufacturer or for other reasons not attributable to the negligence of the investigator. In such circumstances, the offer of compensation will be made according to a standard procedure of independent evaluation.

At present, a trial subject who suffers harm as a result of participation in a non-company-funded (e.g. charity-supported) or unfunded study will only be entitled to compensation if they can prove negligence on the part of the investigator or the clinical staff or the manufacturer of a product used. They must, therefore, prove not only the existence of fault but who or what was at fault.

It is generally thought that where a subject is harmed as a result of participation in a trial, the prospect of compensation should not depend on whether the trial happens to be company-sponsored or if there is evidence of negligence.

This document sets out Queen Mary and Barts Health's policy concerning compensation payments. It sets out applicable criteria and procedures for making compensation payments to those subjects injured in non-company sponsored trials for which there is no alternative equivalent compensation available, or in company-sponsored trials where an injury results from the negligence or other fault of the investigators.

12.2 The Policy

For the purpose of this policy, Trial Subject means:

a) A patient, that is, an individual, whose participation in a piece of research derives from either:
   - Having sought or accepted medical care within Barts Health primarily for the treatment of a condition, the investigation of which is the subject of the clinical trial.
   - Having been selected from the general population because of known or suspected abnormality

b) A healthy volunteer, i.e. an individual, who is generally healthy and does not suffer from the condition expected to be modified by the trial intervention.

c) A child in utero - a child subsequently born alive whose mother was a trial subject while the child was in utero.

All research studies must first be submitted to and approved by an appropriate ethics committee or other relevant ethics committee and the JRMO. Failure to obtain such approval, or disregard of any conditions for approval, would be a breach of the investigator's

terms of employment within Queen Mary or Barts Health. Further, the investigator could bear personal responsibility for any harm resulting to a patient.

12.3 Coverage

Queen Mary or Barts Health will pay compensation to trial subjects suffering a bodily injury in accordance with this policy.

Compensation will be paid when, on the balance of probabilities, the injury was attributable to the administration of a medicinal product or device under trial, or any clinical trial intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the patient in the trial.

Where a trial design includes pregnant women, the principles of compensation under these Guidelines will apply to injuries caused to a mother or her child in utero. However, since strict criteria are laid down by the Health Research Authority (HRA) for the exclusion of pregnant women from clinical trials in general, compensation will be paid in the event of injury to a child in utero only where the mother's participation in such an excluding trial has been non-negligent on her part.

Compensation will not be paid for temporary minor pain or discomfort.

Where there is an adverse reaction to a medicinal product or device under trial and injury is caused by a procedure adopted to deal with the adverse reaction, compensation will be paid for such injury as if it was caused directly by the medicinal product or device under trial.

Neither the fact that the adverse reaction causing the injury was foreseeable or predictable nor the fact that the trial subject has freely consented (whether in writing or otherwise) to participate in the trial, should exclude a trial subject from consideration for compensation under this policy although compensation may be abated or excluded in the light of the factors described below in section 12.4.

This policy applies to injury caused to patients and healthy volunteers partaking in clinical trials involving unlicensed medicinal products or devices who are not protected by a similar policy offered by any external sponsor of the trial.

Compensation will also be paid for an injury caused by licensed or non-licensed products administered to the trial subject for the purpose of comparison with the product under trial.

12.4 Limitations

Compensation will not be paid:

- For the failure of a medicinal product, device, technique or procedure to benefit a patient
- To patient receiving placebo in consideration of its failure to provide a therapeutic benefit
- To the extent that the injury has arisen (or it should be abated as the case may be):
    - Through the wrongful act of default or a third party for whom Queen Mary or Barts Health is not responsible (for example, a patient's own doctor); or
    - Through contributory negligence by the trial subject.

The maximum amount of compensation payable under this policy will be the maximum ex gratia payment permitted by Queen Mary's insurance policy or, in the case of Barts Health, The Department of Health national insurance provisions.

The undertaking given by Queen Mary and Barts Health extends to injury arising (at whatever time) from all administrations, clinical interventions or procedures occurring during the trial but not to treatment extended beyond the end of the trial at the instigation of the investigator. The use of unlicensed products beyond the trial period or on a named patient basis is wholly the responsibility of the treating doctor. Doctors should notify their protection society of their use of unlicensed products.

12.5 Investigators Liability

Where the cause of an adverse reaction or injury is attributed wholly or partly to a significant departure from the protocol as approved by the HRA and Queen Mary or Barts Health, either organisation, in respect of its liability to compensate the trial subject, shall be entitled to claim indemnity to the appropriate extent from the investigator(s) responsible. For this reason, investigators are required to maintain appropriate professional indemnity insurance.

12.6 Assessment of Compensation

Subject always to any overriding financial limitations imposed on Queen Mary or Barts Health, the amount of compensation should be appropriate to the nature, severity and persistence of the injury and should in general terms be consistent with the quantum of damages commonly awarded for similar injuries by an English court in cases where legal liability is admitted.

Compensation may be abated, or in certain circumstances excluded, in the light of the following factors:

a) The seriousness of the disease or condition being treated.
b) The risks and benefits of established treatments.
c) The known or suspected risks and benefits of the trial medicine or device.
d) The information and warning given to the patient as to (a) – (c) above, in the knowledge of which he or she has given consent.

Where Queen Mary or Barts Health have agreed in principle to compensation being paid but the amount offered under clause 12.4 is not acceptable to the trial subject, the question may, if the trial subject agrees, be submitted for the decision of an independent arbitrator accepted by both parties, and failing such appointment, to be appointed by the President of the Law Society.

12.7 Procedure and Claims

An investigator undertaking a non-company sponsored trial should make it clear to participating trial subjects that the trial is being conducted in accordance with either Barts Health or Queen Mary policy.

The management of claims will be decided on a case by case basis, between Queen Mary and Barts Health, with due regard to the employment status of the investigator, any contractual arrangements with external funders, honorary contract considerations and insurance coverage. Once an agreement has been reached, and where it is possible, one organisation will conduct the procedures involved in examining and settling claims.

Claims under this policy should be made by the trial subject to Barts Health for patient-based studies, or the most appropriate organisation in the case of patient volunteer studies, setting out details of the nature and background of the claim and are conditional upon the trial subject providing, on request, an authority for Barts Health or Queen Mary to review any medical records relevant to the claim. Queen Mary or Barts Health should consider the claim expeditiously.

Trial subjects should be required to accept that any payment made under the policy is in full settlement of their claims.

The fact that Queen Mary or Barts Health has agreed to abide by this policy does not affect the right of a trial subject to pursue a legal remedy in respect of injury alleged to have been suffered as a result of participation. Nevertheless, it is hoped that by adopting this policy the organisations will be seen to deal fairly with trial subjects and will avoid litigation with its attendant expense, publicity and uncertain outcome.

Where relevant, the basic principles and procedures described in Barts Health's Policy for the handling of Clinical Negligence and Personal Injury Claims will apply to this clinical trials compensation policy except where the procedures conflict, in which case the wording of this clinical trials compensation policy will take precedence.

In providing financial compensation in accordance with this policy Queen Mary and Barts Health accept the need for an expeditious settlement and will make every effort to complete the necessary investigations as a matter of urgency.

This policy applies to both Barts Health and Queen Mary.