

Insurance Guidelines

The University holds insurance policies which cover claims arising from its involvement in clinical trials. The policies are arranged on an annual basis, and it is only in the special circumstances listed in (b) below that it is necessary to seek prior approval from insurers.

The policies are of two types: liability and no-fault. The liability policies cover the University against legal liability claims (ie where the University is at fault). The no-fault policy provides compensation to subjects, regardless of liability, in the event of their suffering a significant and enduring injury (including illness or disease) which, on the balance of probabilities, is attributable to their involvement in the trial.

The following should, however, be noted :

- (a) **The University's policy does not cover medical and dental practitioners while working in a professional capacity.** It is the responsibility of the individuals concerned to obtain medical negligence insurance in their own name through an appropriate medical defence organisation. Any claims alleging negligence against the practitioner should be defended by the appropriate defence organisation but must, also, be brought to the attention of the University's insurers. (Nurses are covered under the University's policies, provided that they are assisting in a trial being undertaken at the University itself, and provided that they only undertake activities which fall within the scope of duties normally expected of nurses. It is assumed that they will have RCN membership).
- (b) Trials involving the following require special consideration and the insurers' prior approval must be sought :
- i. Participants who are pregnant
 - ii. Participants under the age of 5 years
 - iii. Conception or contraception
 - iv. Genetic Engineering Studies not for treatment of disease.
 - v. Substances designed and/or manufactured by the University
- (c) The University's insurers expect clinical trials involving drugs to be conducted in accordance with the Association of the British Pharmaceutical Industry Guidelines. In accordance with these Guidelines, where the trial is sponsored by a pharmaceutical company:
- i. **The company should issue the ABPI standard form of indemnity.** This will indemnify the University against all claims and proceedings brought by subjects arising out of their participation in the trial except where the claim arises from the negligence or wrongful act of the University, or its failure to conduct the study in accordance with the protocol. Such claims would be covered by the University's liability policies.
 - ii. Responsibility for paying compensation should be clarified and reflected in the contractual documentation. This should include an undertaking that **compensation will be offered by the company on a no-fault basis** (ie. regardless of liability) and paid in the event of a subject suffering a significant and enduring injury (including illness or disease) which, on the balance of probabilities, is attributable directly to their involvement in the trial. The amount of any compensation should be appropriate to the nature, severity and persistence of the injury. The offer of compensation must not prevent the subject from alternatively pursuing a claim on the basis of either negligence or strict liability.
- (d) It has been agreed with the University's insurers that the subject's GP will be contacted regarding their suitability for inclusion in a drug trial and for any other clinical trials where the subject's health and medical record is relevant.
- (e) For insurance purposes, it is essential that students acting as investigators are supervised by an employee of the University.

Protocol Submission Proforma: Insurance

The University holds two types of insurance to cover claims arising from its involvement in clinical trials; liability and no-fault. The liability policies cover the University against liability claims (ie where the University is at fault). The no-fault policy is intended to provide compensation to subjects, regardless of liability, in the event of their suffering a significant and enduring injury (including illness or disease) which, on the balance of probabilities, is directly attributable to their involvement in the trial. The University's insurers expect drug trials to be conducted in accordance with the Association of British Pharmaceutical Industry Guidelines. This means that where the trial is sponsored by a pharmaceutical company, that company should issue the standard ABPI form of indemnity and offer no-fault compensation.

Please note that the University's policies do not cover medical and dental practitioners while working in a professional capacity. It is the responsibility of the individual concerned to obtain insurance in their own name through an appropriate medical defence organisation.

The insurers require the following information for each trial :

Trial Number	
Department	
Location of Trial	
Nature of Trial *	
Expected Start Date	
Expected End Date	
Principal Investigator	
Externally Funded?	Yes/No
Name of Sponsor	
ABPI Indemnity/Other Indemnity?	Yes/No
Medical Licence?	Yes/No
Projected/Cumulative Number of Subjects	
Any pregnant research subjects?	Yes/No
Any research subjects under 5 years of age?	Yes/No
Any genetic engineering?	Yes/No
Any own products?	Yes/No
Related to conception or contraception	Yes/No
Brief description of trial in lay terms:	

* Assign to one of the following categories:-

P Pharmaceutical

PS Pharmaceutical, externally funded

NP Non-pharmaceutical

NPS Non-pharmaceutical, externally funded

Q Questionnaire/interview/observation only

Participant Consent Form

The following is based on the wording taken from the model consent form contained in the Association of the British Pharmaceutical Industry Guidelines.

I understand that in the event of my suffering a significant and enduring injury (including illness or disease) as a direct result of my participation in the study, compensation will be paid to me by (insert either the University, or the name of the sponsor where a clinical trial is sponsored by a pharmaceutical company) subject to certain provisos and limitations. The amount of compensation will be appropriate to the nature, severity and persistence of the injury and will, in general terms, be consistent with the amount of damages commonly awarded for similar injury by an English court in cases where the liability has been admitted