

"Patients/healthy volunteers taking part in a clinical trial should be satisfactorily insured against any injury caused by the trial. The liability of the involved parties (investigators, sponsor/manufacture, hospital/clinics, etc.) must be clearly understood before the start of a trial".

EC GUIDELINES ON GOOD CLINICAL PRACTICE

"The sponsor, whether this be a commercial organisation, university, NHS or other institution, should agree to pay compensation for injury, accident, ill-health or death caused by participation in a research study without regard to proof of negligence and without delay".

RESEARCH ON HEALTHY VOLUNTEERS

LLOYD'S
LLOYD'S OF LONDON

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"CLINICAL TRIALS"



No Fault Compensation Insurance Scheme for Clinical Trials.

DOES YOUR COVER MEET THE CLINICAL TRIALS

COMPENSATION GUIDELINES OR LEGISLATION?

HERE IS A NO FAULT SCHEME THAT DOES

..... The need

The ABPI have spelt it out in guidelines which state: "Compensation should be available to patients/healthy volunteers adversely affected by reason of their involvement in clinical trials or volunteer studies....through a simple procedure...without the need to prove negligence".

- Ethics committees expect it.
- European legislation demands it.
- You will need to make provision for it.

..... The answer

The No Fault Compensation Scheme for Clinical Trials/Volunteer Studies underwritten by Lloyd's Underwriters.

It has the advantage of simplicity, as well as being tailor-made to meet the special circumstances of your particular trials.

..... The Option

The scheme allows for "injured" Research Subjects who do not accept the compensation/arbitration procedures to make Legal Liability claims through the courts in the normal manner.

The Underwriters will indemnify the settlement up to the Indemnity Limit.

..... The Compensation

The level of the compensation payable to the "injured" Research Subject, without the requirement to prove negligence, is decided by the Underwriters and/or an independent lawyer who is an expert in medical related claims. Indemnity is on a "Claims Made" basis (plus legal costs and expenses) any one claim and in total for the period of insurance.



..... The Premium

Separate policies can be arranged for each trial or, to enable cover to be available at the most realistic premium, on an annual basis covering all trials undertaken. The premium is individually calculated on a study of the risk and according to the nature of the trials. Terms will be provided based on a brief questionnaire, to be completed by the applicant accompanied by relevant technical information and the trial protocol(s).

..... The Period

Although the trial concerned may last only a matter of weeks, it is of course, essential that coverage is maintained for as long as the insured considers there is a risk of a claim and/or local legislation demands.

..... Qualifications

The scheme is available for any trial undertaken in countries worldwide. The insured must satisfy Department of Health requirements and recommendations laid down by the ABPI in the United Kingdom or similar guidelines and legislation in other countries.

..... Errors & Omissions/Medical Negligence

If full No Fault Compensation cover is not considered necessary our Scheme Underwriters can consider cover on a Professional Legal Liability basis.

..... Ethics Committee

Full indemnity to ethics committees is automatically provided in respect of their Legal Liability.

..... Extended Discovery Period

In respect of individual trials Underwriters are prepared to provide terms at the outset for an extended discovery period of up to 24 months from expiry of the policy.