UKCRC Registered Clinical Trials Units

Research Insurance: Frequently Asked Questions

UK CLINICAL RESEARCH COLLABORATION

igniting our potential

Research Insurance: Frequently Asked Questions

This guide was produced by the UKCRC Registered CTUs Network Insurance Task and Finish Group to assist staff within its registered CTUs with specific insurance related issues affecting the delivery of clinical trials. This document provides clarification in some of the key areas in which questions are raised. The advice contained is to be used as a guide and must not replace legal advice from your sponsoring institution, if you are in any doubts concerning the operation of these arrangements you should check with your insurance/indemnity provider.

1. *Who is responsible for insurance in relation to clinical trials?*

The Sponsor is responsible for the initiation, and management and for the financing of that clinical trial [or for arranging that another takes on these duties].

This includes ensuring that there is an appropriate insurance and / or indemnity in place at all Sites for any research participant who might suffer harm from their participation in the trial, and ensuring that those collaborating with the Sponsor also have appropriate insurance/indemnity for fulfilling this role.

2. *Why is it taking ages to negotiate the insurance and indemnity bit of the site agreement for my study?*

The contract negotiations need to ensure that there is complete clarity on which party is responsible for each element of the research activity.

The Site Agreement will ensure that:

- adequate insurance/indemnity arrangements are in place to protect the interests of the research participants;
- delegation and division of responsibilities are clear to ensure that there is an equitable mechanism to achieve financial recovery for the Sponsor in those cases where a Sponsor-responsibility has arisen from the negligence or statutory breach of another collaborating party — e.g. from not correctly implementing a requirement of the research protocol — and where this has directly led to, or exacerbated, any harm suffered by a research participant;
- provisions unconnected with cover for any potential physical harm to research participants are in place, including those connected with ensuring the confidentiality of any medical records accessed in connection with the trial.

The different insurance/ indemnity provision in place for different types of organisation — NHS trusts/foundation trusts, Health Boards, GP consortia, other collaborating universities — can result in extensive negotiations.

3. *Who has to insure members of Data Monitoring Committee ('DMC') or Trial Steering Committees ('TSC') on our trials?*

The Sponsor should ensure that appropriate insurance is in place to cover the members of the DMEC or TSC (and other similar committees). There are two main options:

1. The Sponsor's insurance provides cover for DMC or TSC members while they are fulfilling this role;
2. The Sponsor is unable to provide insurance cover and requires the DMEC's employer to provide cover.

If there is any doubt, the position should be checked with the provider of the indemnification/insurance. Specific guidance on this issue is available.

4. What are the different kinds of cover that relate to research?

Relevant insurances/indemnity arrangements to be referenced in any site/ collaborator agreement include:

- **Clinical Trials** insurance, as mentioned above, arranged in the name of the sponsor, to provide cover for any claim arising from harm suffered by a research participant.
- **Public Liability** insurance for any non-clinical harm which might rise from participating in the trial: e.g. from falling-over and being injured on loose flooring tiles at the trial site.
- **Professional Liability/ Professional Indemnity / Errors & Omissions** insurance [essentially the same covers, different names]; for any claim for damages which might arise from a breach of professional duty, e.g. following a release of confidential medical information accessed for reasons connected with the clinical trial.

NHS organisations will be covered by their national indemnity schemes. If there are any gaps in the cover offered by these organisations then Foundation Trusts are empowered to arrange commercial insurance to supplement the cover available.

5. What does 'no fault cover' mean? Can we offer it?

Ordinarily, legal liability insurances provide compensation to those suffering harm which has arisen from an act or omission of the insured for which there is a liability at law; usually arising from the tort [legal wrong] of negligence, or through failing to comply with legislation on the statute-book. Which is to say, normally insurance covers liabilities that arise because you have done something wrong that you could be sued for.

In certain circumstances, this may place an inappropriate potential burden on those volunteering as research participants, (particularly so in the case of healthy volunteers) as they would need to establish fault in order to make a successful claim.

In such cases it is usually appropriate for a broader provision through so-called No Fault/ Non Negligent Harm provision, where they only need to establish a direct,

causal link between the participation in the trial and any harm suffered for a valid claim to be made.

A specific clinical trials insurance policy may contain a no Fault/ Non Negligence provision.

Individual organisations may wish to consider carefully those circumstances where it is appropriate to provide a no Fault undertaking. Possibly particularly so where research involves very limited departure from standard medical treatment, and where the relevant NHS Clinical Negligence Scheme operates in respect of harm which may be suffered following negligence. The conclusion may be reached that No Fault cover is unlikely to be sought by the considering ethics committee, and that to offer it could leave the sponsor inappropriately exposed for a potential No Fault claim. The would be particularly so in circumstances where it would be difficult to determine if any harm arose from the clinical intervention, or from the research-participation.

For information, NHS clinical negligence schemes, as their title suggests, ordinarily provide for those occasions where there is established fault — i.e. a negligent act or omission — and do not allow for any commitment to grant a `No Fault' undertaking in advance of any harm being suffered; a commitment which might be sought from an ethics committee considering the trial. There is, however, some provision for post-event, *ad hoc, ex gratia,* consideration of a No Fault payment.

6. *Why is it important to ensure that any clinical trials insurances have terms and conditions which are broadly consistent with those in any preceding insurance?*

Clinical trials insurance is ordinarily provided on a claims-made basis [rather than claims occurring]: that is, the insurance needs to be operating at the time at which a claim is made, and irrespective of how far before that the event giving rise to that claim actually occurred. For this reason alone, it is particularly important that any changes to the annual clinical trials insurance have adequate 'retroactive dates' in order to cater for any long-tail claims which may have been incurred but not [yet] been reported to the insured, and in turn to the insurer (so called 'Incurred But Not Reported' ('IBNR') claims).

7. *If a clinical trial-specific insurance is arranged, how best can allowance be made for any claims which might be made beyond the end of the trial [being mindful that such cover will be written upon a claims made basis].*

Care is needed when considering the likely period over which a claim might possibly be made. The usual period of legal limitation in the UK is, broadly, three years from the `date of knowledge' for claims arising from death or personal injury following negligence*. However, consideration needs to be given to the age, and/or mental capacity of the research participants, to determine if it is possible that the `date of knowledge' may be held to start some period beyond the end of the trial. *In extremis*, it may be possible for a claim to be made by a minor up to their 21st birthday, as three years beyond their reaching of legal majority.

A view may also need to be taken on the likelihood of any harm arising from the IMP

administered in the trial not becoming apparent until some years after that trial. Cover can usually be purchased to allow for a pre-determined extended reporting period ('ERP') beyond the trial and the period of insurance cover in order to allow for any long-tail claims.

*note though, that no time limit for making a claim is specified in the standard Association of the British Pharmaceutical Industry (ABPI) No Fault compensation wording, with this, theoretically, being open-ended.

International Clinical Trials

8. *What insurance do I need in country x?*

For European Community countries, this will depend upon the practical implementation of the European Commission Clinical Trials Directive (2003/94/EC), and the country-specific regulations — including those for the placement of insurance — in the country/ies in question.

In order to determine the insurance requirements for any given country, you should liaise with:

- other UK organisations which have undertaken research in that country;
- the local collaborator to establish their understanding of the practical implementation of the requirements in that country;
- your usual clinical trials insurance provider to establish if and how your normal annually-arranged insurance may need to be supplemented with a `locally-arranged' cover [a database such as that provided through Axco Insurance Services may be available through your usual clinical trials insurer/ insurance broker].

The principal points to be considered for country-specific insurance are:

- Requirements differ between countries [and occasionally, in practice, between different ethics committees in different regions of the same country];
- requirements as to which party/ies arrange insurance may differ — the Sponsor may be required to take out insurance to cover all collaborating parties, which in turn can have a bearing on contract terms within any collaboration (e.g. such requirements may proscribe any rights of recovery/ subrogation rights between the collaborating parties);
- 'in-country paper' may be required (see below);
- The value of required insurance limits varies between countries.

9. *If we are Sponsor and we have a partner who is the coordinating centre in country x (and taking on Sponsor duties in country x), and our partner is taking out insurance for the trial, does my institution need insurance as well?*

This will depend on the legal requirements in the collaborating country; for instance, does its legislation and practical implementation of the CT directive allow for rights of recovery/ subrogation. If it does, then it is possible that any annually arranged `umbrella' CT insurance held by the Sponsor — that which can apply to cover all

clinical trials sponsored by the insured — and other liability insurances arranged [Public Liability/ Professional Indemnity/ Professional Liability in particular] should operate to provide an appropriate indemnity for any potential liability exposure.

When dealing with the requirements of a jurisdiction which is unfamiliar, it is essential to have a clear understanding of the likely practical implications of what is being implemented. It can often be helpful to ask… "What experience of such arrangements does our collaborator have," and "have we exhausted all sources of knowledge internally in our institution, for similar circumstances which have arisen before in a different clinical department."

Much will also depend upon the contract between the Sponsor and coordinating centre, and the extent to which defined responsibilities and indemnities are introduced [where such a division and delegation is possible in the country in question].

10. What does 'I need in-country paper' mean? How do I get it?

The insurance regulations of a particular country can require that certain insurances be arranged with an insurer based-in, or with representation in that country. This is often the case with clinical trials insurances where it can be a legal requirement that they meet given requirements such as defined policy limits and `reporting periods'.

Where the level of insurance required by law in a country is lower than a Sponsor would normally put in place in the UK, the Sponsor might be sensible to consider putting in place a higher level of insurance than is legally required.

Once you have met the requirements for insurance 'in-country' it may be possible to supplement the level of cover by recourse to your institution's existing clinical trials cover. This, however, is a complex area, and there is little by way of a common approach.

11. We are participating in a trial with a Sponsor in a different country — does this make any difference to the insurance arrangements?

Yes, to the extent that it will be the Sponsor as the party responsible for arranging the clinical trial insurance. The collaborator is likely to be concerned to ensure that the overseas sponsor maintains adequate clinical trials insurance, or an acceptable alternative form of indemnity, and that any site agreement and division of responsibilities proposed by the Sponsor are consistent with the usual arrangements entered-into in the UK.