

## Appendix A: Clinical Trials Insurance Terminology

Funder(s)	<p>The organisation(s) providing funding for the study through contracts, grants or donations to an authorised member of either the employing and/or care organisation. External funders rarely act as sponsor*, the main exception being pharmaceutical companies who make special arrangements for insurance and are not the subject of this guidance. The University's Research Services Division and Addenbrookes Research &amp; Development offices deal with funding matters.</p>
Medical Defence Union membership	<p>Membership confers certain rights and access to services including a helpdesk. Membership categories are determined by the type and level of work undertaken by the member, as declared to the MDU.</p> <p>A member engaged in private work will pay increased fees so that he can have the protection of commercial professional indemnity insurance often called medical malpractice cover. All non-NHS work counts as private work. Work exclusively for GP practices and the University is classified as private work.</p> <p>The Medical Malpractice insurance provided by the MDU covers the professional advice and treatment given by named medical practitioners. However, it does not provide insurance for designing research protocols (for this, PIs must ensure University Clinical Trials insurance is in place).</p> <p>To have the benefit of this medical malpractice cover the medical professional must have registered for it with the MDU and must be named on the MDU's block insurance policy. Listing on the policy provides insurance cover for the named individual but not for their staff (i.e. other medical practitioners or nurses assisting the named individual). MDU members enrolled only as NHS doctors do not have automatic medical malpractice insurance with the MDU, so where they are engaged in non-NHS work they should advise the MDU in writing and ensure that they have appropriate insurance.</p> <p>Members should not rely on this brief guidance note but should check their status and cover with their MDU.</p> <p><b>The University's terms of employment state that medical malpractice insurance is not provided by the University for employees, and medical staff are required to join a medical defence union at an appropriate level.</b></p>
NHS Indemnity	<p>A discretionary scheme for the settlement of NHS patient claims. Generally claims are investigated on the basis of negligent harm. However the scheme is not bound to settle only on a negligent harm basis and can exercise its discretion and make goodwill gestures. Full and Honorary contract employees of an NHS Trust rely on this scheme for protection, where their work is carried out under the auspices of the NHS. For staff with only honorary contracts, the scheme does not provide cover for design of protocol</p>

	risks but where there is joint sponsorship, the scheme does provide honorary contract staff with cover for treatment risks.
Pharmaceutical Company Drug Trials	Insurers will not cover early phase drug trails. Such studies must have Association of British Pharmaceutical Industry standard insurance and this should be provided by the drug company who are commissioning the drug trial.
Site and Equipment Risks	Risks associated with the site and equipment used in the execution of the protocol. These risks should be insured by the responsible party (NHS, University, Product Manufacturing Company, GP surgery etc) depending on where the research is to be carried out and the equipment to be used. These matters can be discussed with the University Insurance Section.
Sponsor	<p>The organisation taking primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. The Sponsor may, but does not have to be, the main Funder*. Studies can be:</p> <ul style="list-style-type: none"> <li>▪ “jointly sponsored” as when the University jointly sponsors with the Addenbrookes Trust; or</li> <li>▪ “solely sponsored” where only one organisation acts as sponsor.</li> </ul> <p>The University’s Research Services Division and Addenbrookes Research &amp; Development offices deal with sponsorship matters. Certainty of sponsor is required by the insurance office before insurance can be arranged, researchers should therefore contact RSD and R&amp;D early and establish who is acting as sponsor.</p>
Treatment Risks	<p>Risks associated with the clinical execution of the protocol. Insurance/Indemnity cover is provided either:</p> <ul style="list-style-type: none"> <li>▪ under the NHS indemnity scheme for jointly sponsored studies- for this the research staff must have honorary contracts with the NHS partner to the research; or</li> <li>▪ for solely sponsored University research, the researchers must make the sponsorship status clear when arranging cover with the University Insurance Section.</li> </ul>