These definitions have been created by the University of Cambridge insurance manager to assist University of Cambridge researchers involved in research on humans. More detailed explanations can be found on NHS websites & on the NHS Ethics Committee application form. This guidance is not concerned with the arrangements for pharmaceutical company research studies.

(* denotes a separate definition elsewhere in this guidance)

Insurance Office webpage = http://www.admin.cam.ac.uk/offices/insurance/

**Sponsor** means 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 “jointly sponsored” as when the University jointly sponsors with the Addenbrookes Trust. Or “solely sponsored” where only one organisation acts as sponsor. The University’s Research Services Division and Addenbrookes Research & 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&D early and establish who is acting as sponsor.

**Funder(s)** - means 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 & Development offices deal with funding matters.

**Negligent Harm** – standard liability at law where the person alleging injury must prove that the other party has been negligent in observing their duties at law. The party being sued can defend themselves by showing that they have taken all reasonable precautions to avoid injury to the person or property of another.

**Non-Negligent Harm** – compensation provided where only the likelihood of fault needs to be shown. In this case it is not necessary for the injured party to prove negligence; they must simply show that on the balance of probability injury was caused by the other party. In the case of a clinical trial subject bringing a claim it would only be necessary for the subject to show that their health had deteriorated during the period of the trial. Where cover is bought on a non-negligent harm basis the cover includes the option for the claimant to sue on a negligent harm basis rather than asking for compensation; so it can be stated that cover is in place for both negligent harm and non-negligent harm on the application for NHS Ethics Committee approval.

**Protocol Risks** – risks associated with the Design of Protocol. The designer of the Protocol is usually a qualified medical practitioner. For pharmaceutical company sponsored drug trials, the pharmaceutical company acts as sponsor and arranges ABPI (Association of the British Pharmaceutical Industry) standard insurance to cover these
risks, regardless of the employment status of the protocol designer. However for other studies the substantive employer of the protocol writer is responsible for providing insurance for the Design of Protocol. Whether the research is jointly or solely sponsored by the University; University employed Principal Investigators (PIs) are responsible for arranging insurance for Design of Protocol, for each study, with the University insurance office.

**Treatment Risks** – risks associated with the clinical execution of the protocol. Insurance/Indemnity cover is provided EITHER 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 for solely sponsored University research, insurance can be arranged under the University’s Clinical Trials block policy*; in this case researchers must make specific arrangements for each study, with the University insurance office.

**Equipment & Site 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 office.

**NHS Indemnity** – 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 risks* but where there is joint sponsorship, the scheme does provide honorary contract staff with cover for treatment risks.

**(University) Clinical Trials Insurance** – commercial insurance for research on humans which is not early phase drug company research. This insurance is available on negligent or non-negligent harm basis via the University insurance office. Cover is only available where the Principal Investigator (PI) is a University employee or where the University is Sponsor.

Cover under the policy excludes the treatment risks* of physicians, surgeons and dentists. In the event of a claim, once a settlement has been agreed and made to the injured research subject, the insurer may look to recover proportionate costs from physicians, surgeons and dentists for their negligent treatment of the claimant. Perceived flaws in the design of protocol* would always be covered and would not be the subject of recovery from the designer. (see MDU membership note for action to be taken by medically qualified staff to protect themselves in respect of treatment risks*).

There are some trials that insurers would be reluctant or totally opposed to insuring, examples would be early phase drug trials where ABPI cover should be provided by the drug company and studies involving children under five. However completion and return of a simple checklist, (blank checklist on the insurance office webpage), to the University insurance office will gain an answer about whether insurance would be
available for the proposed study and the likely costs. Research which is excluded under the block policy will always be referred to insurers for a decision on whether the policy can be extended to cover the planned research.

The premium for the block policy covers the cost of insuring non-hazardous (insurers definition) studies, however where insurers perceive a risk (for example, where a drug is being used in a novel way or a PET scan is being done) there is an additional cost which must be met by the research study.

**Medical Defence Union membership** – 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. 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.

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). 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. Members should not rely on this brief guidance note but should check their status and cover with their MDU.

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.

*Insurance Office webpage* = http://www.admin.cam.ac.uk/offices/insurance/