

Insurance and Indemnity

This Guidance has been based, with minor adaptations, on a document written by the R&D Department of Sheffield Teaching Hospitals NHS Foundation Trust.

Their generous assistance in giving us permission to use their work in this way is hereby gratefully acknowledged

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This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	1 st October 2010	
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1 Indemnity

Indemnity is a contractual arrangement whereby parties agree to provide compensation for any losses suffered by another party. Indemnity specifies that the insured should not collect more than the actual cash value of a loss but should be restored to approximately the same financial position as existed before the loss.

2 Non Indemnity

While indemnity cover provides compensation against the actual costs incurred, non-indemnity cover would simply pay a predetermined fixed amount of compensation on occurrence of a claim, regardless of the costs incurred. Non-indemnity insurance is a type of insurance where the insured and insurer agree on the amount that the insurance company will pay if something happens to you – for example: life insurance or disability insurance.

3 Insurance

Insurance is a promise of reimbursement in the case of loss; paid to people or companies so concerned about hazards that they have made prepayments to an insurance company. In order to indemnify another against a specified loss, the party providing the form of indemnity may arrange an insurance policy to cover potential losses.

4 Liability Insurance

Liability Insurance is designed to protect an individual or organisation in the event of being sued by a member of the public or by an employee. The concept of liability insurance is that if the insured causes a member of the public or a company any damage and they sue due to negligence, liability insurance will cover the cost of compensation to the third party. There are various different types of liability insurance:

Public liability insurance covers an organisation e.g. an NHS Trust in the event that a member of the public is injured and the accident is deemed to be the organisations' fault - a direct result of the organisation's actions or those of its employees. For example, a public liability claim could arise if a visitor to Trust premises walked into the hospital and fell over on a wet floor, where there was no visible sign of warning.

Employers liability insurance applies where injury is caused to an employee by the actions of the employer or its other employees.

Product liability insurance covers a business in the event that any goods supplied cause injury, illness, loss or damage to a member of the public. For example, if a drug manufacturer fails to take all reasonable steps to update medical professionals on potential adverse effects and a consumer has an adverse reaction causing long term injury, the third party could sue.

Personal/Investigator Professional indemnity insurance covers an investigator in the event that they are sued by a patient/organisation who claims that they have suffered a loss as a result of professional negligence or breach of duty. NHS indemnity pays for the financial consequences of negligence which occurs in NHS hospitals however it does not include private practice, 'Good Samaritan' acts or other work undertaken outside the NHS contract. In addition, it does not provide assistance with GMC or disciplinary hearings or any criminal charges that result from clinical practice in the NHS. Investigators should ensure they have up to date professional indemnity cover in place from an appropriate body e.g. Medical Defence Union.

5 Clinical Negligence

The medical profession has what is called a "duty of care" towards their patients, i.e. a duty to ensure that their patients receive proper treatment, in the proper manner. All researchers are accountable for their own practice and for promoting the safety and welfare of participants in any research. If a research participant is the victim of medical negligence, incompetence or carelessness i.e. clinical negligence they may be entitled to claim compensation for injuries suffered.

6 NHS Indemnity

Any research carried out by a Trust employee with the knowledge and permission of the employing organisation will be subject to NHS indemnity. NHS indemnity provides indemnity against clinical risk arising from negligence through the Clinical Negligence Scheme for Trusts (CNST). In this context clinical negligence is defined as "a breach of duty of care by members of the health professions employed by NHS bodies". NHS indemnity covers NHS staff, medical academic staff with honorary contracts and colleagues working on a study under their direct supervision. This is one reason for the necessity to keep a delegation log for each research project. If there is negligent harm NHS bodies will accept full financial liability. This means that any civil claim brought by a patient injured due to the alleged negligent act or omission of the researcher or those acting on their behalf will be settled by the employing organisation.

Negligent harm is covered by NHS indemnity for all healthy volunteers or patient clinical trials, whether they involve medicines or not as long as

there is appropriate approvals for the study to take place within the specific NHS organisation.

7 Commercial Research

Researchers involved in commercial research have a duty to ensure that the commercial company sponsoring the study provides full indemnity cover. Companies should provide a document that adheres to the ABPI (Association of British Pharmaceutical Industries) format and provide indemnity cover from the Company to the Trust in the event of injury caused to a patient attributable to participation in the trial. Whatever arrangements are in place must be communicated to potential research participants during the consent process and a full explanation should be included in the patient information sheet.

8 Non-negligent or no-fault indemnity

No-fault indemnity cover provides compensation where there is no legal liability. NHS liability insurance provides indemnity against clinical negligence. It does not provide cover where there is no negligence, e.g. for harm caused by an unexpected side effect of participating in a study.

The Medicines for Human Use (Clinical trials) Regulations 2004 does not require no-fault compensation. It requires insurance or indemnity covering liabilities of the sponsor and investigator.

The NHS is not able to take out commercial insurance against non-negligent harm and therefore NHS indemnity does not offer no fault compensation. In exceptional circumstances NHS bodies may consider whether an ex-gratia payment could be offered. However the NHS can not make an ex-gratia payment for non-negligent harm if a non-NHS body is the research Sponsor.

For commercial trials, the commercial company when acting as Sponsor must provide non-negligent/no fault indemnity according to the Association of the British Pharmaceutical Industry (ABPI) Guidelines.

For trials where a commercial company has made a donation of drugs or other financial support to the study the company may, in some circumstances, provide non-negligent indemnity. As part of the process of the approval process it is essential to establish whether or not this is the case and ensure that the commercial company provides the appropriate documentation. If the company declines to provide non-negligent indemnity, usual NHS arrangements will apply.

Other independent sector sponsors of research involving patients for example universities and medical research charities may make arrangements to indemnify research subjects from non-negligent harm. Public funded bodies such as the MRC are unable to take out research

insurance however the MRC offers assurance that it will consider claims for on-negligent harm arising from MRC funded trials.

9 Harm as a result of a fault in drug or equipment

Where there is harm as a result of a fault in drug or equipment, liability would lie with the manufacturer and therefore NHS indemnity would not apply. NHS indemnity may apply if the investigator continued to use a drug or equipment if they knew that the drug/equipment was faulty. NHS liability may apply if the drug/equipment had been manufactured by the NHS body itself for example as part of research.

10 Off label and unlicensed medicines

The use of medicines which have no Marketing Authorisation (MA) or which are used outside the terms of their MA (referred to as “off label”) is provided for in the Medicines Act. It is not illegal to prescribe, dispense or administer off label and unlicensed medicines.

If an investigator uses a medicine that is not within the strict terms of the MA the investigator is responsible for negligent and non-negligent harm to the patient. When using unlicensed or off label medicines the investigator must demonstrate that there is sufficient knowledge, information or experience to show they are acting in the best interest of the patients. Failure to do so could result in a claim of negligence should a patient be harmed.

If a licensed medicine is used for an unlicensed indication i.e. in breach of the terms of its Product Licence the manufacturer is only likely to be found liable if harm results from a defect in the product.

The Sponsor of a trial using an unlicensed medication or a licensed medication outside the strict terms of its MA is responsible either for ensuring that the manufacturer’s Product Liability insurance will apply to protect trial participants, or for arranging specific cover.

11 Research Ethics Committees Approval

Ethics committees are responsible for considering provision for indemnity or compensation in the event of injury or death attributable to the clinical trial and any insurance or indemnity to cover the liability of the investigator or sponsor. It is for the ethics committee to consider whether it is acceptable to seek consent without no fault compensation given the risks for a particular trial.

12 Honorary Contracts

An NHS Trust is liable for the actions of staff in the course of their NHS duties. NHS indemnity for clinical negligence can also cover negligence by staff on honorary contracts and others conducting research with NHS permission, if the NHS organisation has a duty of care to the person harmed. For this purpose university or other externally employed staff who wish to participate in clinical research which will involve direct access to patients should ensure that they hold an appropriate honorary contract with the relevant Trust.

13 University Insurance

A university will have arranged liability insurance to provide cover in the event of harm to third parties resulting from negligent acts, and this will cover the acts of university employees carried out in the course of their employment. It follows that university employees must have explicit authorisation from their employers to carry out any research.

The university's normal insurance arrangements will automatically provide cover for injuries arising out of most university activities, but special rules apply in the case of medically related activities, and vary from University to University. Where a University has liability in respect of a clinical trial, separate insurance may be arranged and individual notification may be necessary.

14 Cover notes and policy documents

Any organisation that will place reliance on another party's insurance in relation to a research project should, in checking the cover, see full policy details, not merely a 'cover note' or policy schedule. This is to ensure that the policy does not contain exclusions that would render the offered cover void. This is particularly important in relation to clinical trials of investigational medicinal products.