

MEDICAL INDEMNITY: ARE YOU COVERED?

This is a summary of the main points contained within *NHS Indemnity Arrangements for clinical negligence claims in the NHS*, issued under cover of HSG 96/48.

It covers NHS indemnity for clinical negligence but not for any other liability such as product liability, employers' liability or liability for NHS trust board members.

NHS bodies are vicariously liable for the negligent acts and Omissions of their employees and should have arrangements for meeting this liability.

WHAT IS CLINICAL NEGLIGENCE?

Clinical negligence is defined as “a breach of duty of care by members of the health care professions employed by NHS bodies or by others consequent on decisions or judgements made by Healthcare Professionals acting in their professional capacity in the course of their employment, and which are admitted as negligent by the employer or are determined as such through the legal process”.

WHO ARE HEALTHCARE PROFESSIONALS?

The term health care professional includes hospital doctors, dentists, nurses, midwives, health visitors, pharmacy practitioners, registered ophthalmic or dispensing opticians (working in a hospital setting), members of professions allied to medicine and dentistry, ambulance personnel, laboratory staff and relevant technicians.

WHO ELSE IS COVERED?

Persons, not employed under a contract of employment and who may or may not be a health care professional, who owe a duty of care to the persons injured.

These include locums; medical academic staff with honorary contracts; students; those conducting clinical trials; charitable volunteers; persons undergoing further professional education, training and examinations; students and staff working on income generation projects.

Where these principles apply, NHS bodies should accept full financial liability where negligent harm has occurred, and not seek to recover their costs from the health care professional involved.

WHO IS NOT COVERED?

NHS Indemnity DOES NOT APPLY to:

Family health service practitioners working under contracts for services, e.g. GPs (including fund holders),

General dental practitioners,

Family dentists,

Pharmacists or optometrists;

Other self-employed health care professionals e.g. independent midwives;

Employees of FHS practices;

Employees of private hospitals;

Local education authorities;

Voluntary Agencies.

Exceptions to the normal cover arrangements are set out in the main document.

CIRCUMSTANCES COVERED

NHS Indemnity covers negligent harm caused to patients or healthy volunteers in the following circumstances:

Whenever they are receiving an established treatment, whether or not in accordance with an agreed guideline or protocol;

Whenever they are receiving a novel or unusual treatment which, in the judgement of the health care professional, is appropriate for that particular patient;

Whenever they are subjects as patients or healthy volunteers of clinical research aimed at benefitting patients now or in the future.

WHEN DOES NHS INDEMNITY APPLY?

NHS Indemnity applies where

- (a) The negligent health care professional was:
 - (i) Working under a contract of employment and the negligence occurred in the course of that employment;
 - (ii) Not working under a contract of employment but was contracted to an NHS body to provide services to persons to whom that NHS body owed a duty of care.
 - (iii) Neither of the above but otherwise owed a duty of care to the persons injured.

WHAT IS COVERED?

Expenses Met

Where negligence is alleged, NHS bodies are responsible for meeting:

The legal and administrative costs of defending the claim or, if appropriate, of reaching a settlement;

The plaintiffs cost, as agreed by the two parties or as awarded by the court;

The damages awarded either as a one-off payment or as a structured settlement.

WHAT IS MY ROLE?

Your role as a clinician is crucial. Unless we have your views and know what you would say at trial about all the relevant factual issues we cannot accurately work out the chances of the claim succeeding. That could increase the risk of paying too much to settle the claim or going to trial and losing.

We need to know:

What you did;

The reasoning behind any decision you made;

What your notes say.

In some claims we may also need you to think through what you would have done in a hypothetical situation. Remember that what you think and know goes without saying and it may well not be the same for someone outside your field. Please explain even the “obvious”.

WHAT ABOUT “GOOD SAMARITAN” ACTS?

There would still appear to be some confusion regarding cover under the scheme for ‘Good Samaritan acts’. Whilst there is no specific mention of these in the scheme Rules, the NHSLA has confirmed that cover will extend to provide indemnity in emergencies, if the act is authorised by the employing trust.

WHAT ABOUT PRIVATE WORK UNDERTAKEN IN THE NHS?

Some consultants undertake private work using trust facilities and occasionally employees. Would the trust be covered in the event of an incident?

As the consultation and any subsequent treatment is being given on a private basis, that is to say the private patient pays the consultant direct, then the **consultant should have his or her own private cover with a defence organisation**. Where possible, we suggest that the trust seeks confirmation of such cover before consenting to the use of premises/employees.

The position concerning trust personnel depends on the basis of assistance being given. If the trust expects junior doctors, nurses or other employees to assist whilst working in accordance with their contracted terms of employment, then CNST cover would be available for the specific acts of that individual(s). We

anticipate that the trust will be paid by the private consultant in such circumstances to reflect the risk. **If however the private consultant asks an employee to assist and pays that employee direct, no cover is available under the scheme.**

Finally, a point worth mentioning is that it is up to the trust to make sure that the consultant does not write a report on trust headed paper, either following a private consultation or following an NHS consultation where a report is subsequently requested on a private basis. In the event that such reports are written on trust headed paper this can be seen to be ratification by the trust of the consultant's actions. No cover will be available under CNST in such circumstances which would result in exposure to the trust direct.

This is by no means an exhaustive document and therefore it is strongly recommended that the individual clinician should go through their job description and contract in detail to ensure that they are covered by the NHS Indemnity.

Please refer to the detailed document '[NHS Indemnity](http://www.nhs.uk/NHSIndemnity)' available online at:
<http://www.nhs.uk/NHSIndemnity>

When in doubt regarding any aspect of your employment, please clarify in writing with your employer to ensure that NHS Indemnity covers the work you do.

NHS Indemnity

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EXECUTIVE SUMMARY

Introduction

This is a summary of the main points contained within *NHS Indemnity Arrangements for clinical negligence claims in the NHS*, issued under cover of HSG 96/48. The booklet includes a Q&A section covering the applicability of NHS indemnity to common situations and an annex on sponsored trials. It covers NHS indemnity for clinical negligence but not for any other liability such as product liability, employers liability or liability for NHS trust board members.

Clinical Negligence

Clinical negligence is defined as “a breach of duty of care by members of the health care professions employed by NHS bodies or by others consequent on decisions or judgements made by members of those professions acting in their professional capacity in the course of their employment, and which are admitted as negligent by the employer or are determined as such through the legal process”.

The term health care professional includes hospital doctors, dentists, nurses, midwives, health visitors, pharmacy practitioners, registered ophthalmic or dispensing opticians (working in a hospital setting), members of professions allied to medicine and dentistry, ambulance personnel, laboratory staff and relevant technicians.

- (b) persons, not employed under a contract of employment and who may or may not be a health care professional, who owe a duty of care to the persons injured. These include locums; medical academic staff with honorary contracts; students; those conducting clinical trials; charitable volunteers; persons undergoing further professional education, training and examinations; students and staff working on income generation projects.

Where these principles apply, NHS bodies should accept full financial liability where negligent harm has occurred, and not seek to recover their costs from the health care professional involved.

WHO IS NOT COVERED

NHS Indemnity does not apply to family health service practitioners working under contracts for services, eg GPs (including fundholders), general dental practitioners, family dentists, pharmacists or optometrists; other self employed health care professionals eg independent midwives; employees of FHS practices; employees of private hospitals; local education authorities; voluntary agencies. Exceptions to the normal cover arrangements are set out in the main document.

CIRCUMSTANCES COVERED

NHS Indemnity covers negligent harm caused to patients or healthy volunteers in the following circumstances: whenever they are

Main Principles

NHS bodies are vicariously liable for the negligent acts and Omissions of their employees and should have arrangements for meeting this liability.

NHS Indemnity applies where

- (a)** the negligent health care professional was:
 - (i)** working under a contract of employment and the negligence occurred in the course of that employment;
 - (ii)** not working under a contract of employment but was contracted to an NHS body to provide services to persons to whom that NHS body owed a duty of care.
 - (iii)** neither of the above but otherwise owed a duty of care to the persons injured.

receiving an established treatment, whether or not in accordance with an agreed guideline or protocol; whenever they are receiving a novel or unusual treatment which, in the judgement of the health care professional, is appropriate for that particular patient; whenever they are subjects as patients or healthy volunteers of clinical research aimed at benefitting patients now or in the future.

Expenses Met

Where negligence is alleged, NHS bodies are responsible for meeting: the legal and administrative costs of defending the claim or, if appropriate, of reaching a settlement; the plaintiffs costs, as agreed by the two parties or as awarded by the court; the damages awarded either as a one-off payment or as a structured settlement.

Clinical Negligence Definition

1. Clinical negligence is defined as:

“A breach of duty of care by members of the health care professions employed by NHS bodies or by others consequent on decisions or judgements made by members of those professions acting in their professional capacity in the course of employment, and which are admitted as negligent by the employer or are determined as such through the legal process.

2. In this definition “breach of duty of care” has its legal meaning. NHS bodies will need to take legal advice in individual cases, but the general position will be that the following must all apply before liability for negligence exists:

- 2.1 There must have been a duty of care owed to the person treated by the relevant professional(s);

- 2.2 The standard of care appropriate to such duty must not have been attained and therefore the duty breached, whether by action or inaction, advice given or failure to advise;

- 2.3 Such a breach must be demonstrated to have caused the injury and therefore the resulting loss complained about by the patient;

- 2.4 Any loss sustained as a result of the injury and complained about by the person treated must be of a kind that the courts recognize and for which they allow compensation; and

- 2.5 The injury and resulting loss complained about by the person treated must have been reasonably foreseeable as a possible consequence of the breach.

- 3** This booklet is concerned with NHS indemnity for clinical negligence and does not cover indemnity for any other liability such as product liability, employers liability or liability for NHS trust board members.
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* The NHS (Clinical Negligence Scheme) Regulations 1996, which established the Clinical Negligence Scheme for Trusts, defines clinical negligence in terms of ‘...a liability in tort owed by a member to a third party in respect of or consequent upon personal injury or loss arising out of or in connection with any breach of a duty of care owed by that body to any person in connection with the diagnosis of any illness, or the care or treatment of any patient, in consequence of any act or omission to act on the part of a person employed or engaged by a member in connection with any relevant function of that member’.

Other Terms

NHS Indemnity

- 4.** Throughout this guidance:

4.1 The terms “an NHS body” and “NHS bodies” include Health Authorities, Special Health Authorities and NHS Trusts but excludes all GP practices whether fundholding or not, general dental practices, pharmacies and opticians’ practices

4.2 The term “health care professional” includes:

Doctors, dentists, nurses, midwives, health visitors, hospital pharmacy practitioners, registered ophthalmic or registered dispensing opticians working in a hospital setting, members of professions supplementary to medicine and dentistry, ambulance personnel, laboratory staff and relevant technicians.

Principles

- 5.** NHS bodies are legally liable for the negligent acts and omissions of their employees (the principle of vicarious liability), and should have arrangements for meeting this liability. NHS Indemnity applies where:

5.1 the negligent health care professional was working under a contract of employment

(as opposed to a contract for services) and the negligence

occurred in the course of that employment; or

5.2 the negligent health care professional, although not working under a contract of employment, was contracted to an NHS body to provide

services to persons to whom that NHS body owed a duty of care.

- 6.** Where the principles outlined in paragraph 5 apply, NHS bodies should accept full financial liability where negligent harm has occurred. They should not seek to recover their costs either in part or in full from the health care professional concerned or from any indemnities they may have. NHS bodies may carry this risk entirely or spread it through membership of the Clinical Negligence Scheme for Trusts (CNST - see EL(95)40).

Who is Covered

- 7.** NHS Indemnity covers the actions of staff in the course of their NHS employment. It also covers people in certain other categories whenever the NHS body owes a duty of care to the person harmed, including, for example, locums, medical academic staff with honorary contracts, students, those conducting clinical trials, charitable volunteers and people undergoing further professional education, training and examinations. This includes staff working on income generation projects. GPs or dentists who are directly employed by Health Authorities, eg as Public Health doctors (including port medical officers and medical inspectors of immigrants at UK air/sea ports), are covered.

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- 8.** Examples of the applicability of NHS Indemnity to common situations are set out in question and answer format in Annex A.

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Who is not Covered

- 9.** NHS Indemnity does not apply to general medical and dental practitioners working under contracts for services. General practitioners, including GP fundholders, are responsible for making their own indemnity arrangements, as are other self-employed health care professionals such as independent midwives. Neither does NHS Indemnity apply to employees of general practices, whether fundholding or not, or to employees of private hospitals (even

when treating NHS patients) local education authorities or voluntary agencies.

10. Examples of circumstances in which independent practitioners or staff who normally work for private employers are covered by NHS Indemnity are given in Annex A. The NHS Executive advises independent practitioners to check their own indemnity position.

11. Examples of circumstances in which NHS employees are not covered by NHS Indemnity are also given in Annex A.

Circumstances Covered

12. NHS bodies owe a duty of care to healthy volunteers or patients treated or undergoing tests which they administer. NHS Indemnity covers negligent harm caused to these people in the following circumstances:

12.1 whenever they are receiving an established treatment, whether or not in accordance with an agreed guideline or protocol;

12.2 whenever they are receiving a novel or unusual treatment which in the clinical judgement of the health care professional is appropriate for the particular patient;

12.3 whenever they are subjects of clinical research aimed at benefiting patients now or in the future, whether as patients or as healthy volunteers. (Special arrangements, including the availability of no-fault indemnity apply where research is sponsored by pharmaceutical companies. See Annex B.)

Expenses Met

13. Where negligence is alleged NHS bodies are responsible for meeting:

13.1 the legal and administrative costs of defending the claim and if appropriate, of reaching a settlement, including the cost of any mediation;

13.2 where appropriate, plaintiffs costs, either as agreed between the

parties or as awarded by a court of law;

- 13.3** the damages agreed or awarded, whether as a one-off payment or a structured settlement.

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Claims Management Principles

- 14.** NHS bodies should take the essential decisions on the handling of claims of clinical negligence against their staff, using professional defence organizations or others as their agents and advisers as appropriate.

Financial Support Arrangements

- 15.** Details of the Clinical Negligence Scheme for Trusts (CNST) were announced in EL(95)40 on 29 March 1995.
- 16.** All financial arrangements in respect of clinical negligence costs for NHS bodies have been reviewed and guidance on transitional arrangements (for funding clinical accidents which happened before 1 April 1995), was issued on 27 November 1995 under cover of FDL(95)56. FDL(96)36 provided further guidance on a number of detailed questions.

AnnexA

Questions and Answers on NHS Indemnity

Below are replies to some of the questions most commonly asked about NHS Indemnity.

1. Who is covered by NHS Indemnity?

NHS bodies are liable at law for the negligent acts and omissions of their staff in the course of their NHS employment: Under NHS Indemnity, NHS bodies take direct responsibility for costs and damages arising from clinical negligence where they (as employers) are vicariously liable for the acts and omissions of their health care professional staff.

2. Would health care professionals opting to work under contracts for services rather than as employees of the NHS be covered?

Where an NHS body is responsible for *providing* care to patients NHS Indemnity will apply whether the health care professional involved is an employee or not. For example a doctor working under a contract for services with an NHS Trust would be covered because the Trust has responsibility for the care of its patients. A consultant undertaking contracted NHS work in a private hospital would also be covered.

3. Does this include clinical academics and research workers?

NHS bodies are vicariously liable for the work done by university medical staff and other research workers (eg employees of the MRC) under their honorary contracts, but not for pre-clinical or other work in the university.

4. Are GP practices covered?

GPs, whether fundholders or not [and who are not employed by Health Authorities as public health doctors], are independent practitioners and therefore they and their employed staff are not covered by NHS indemnity.

5. Is a hospital doctor doing a GP locum covered?

This would not be the responsibility of the NHS body since it would be outside the contract of employment. The hospital doctor and the general practitioners concerned should ensure that there is appropriate professional liability cover.

6. Is a GP seeing a patient in hospital covered?

A GP providing medical care to patients in hospital under a contractual arrangement, eg where the GP was employed as a clinical assistant, will be covered by NHS Indemnity, as will a GP who provides services in NHS hospitals under staff fund contracts (known as “bed funds”). Where there is no such contractual arrangement, and the NHS body provides facilities for patient(s) who continue to be the clinical responsibility of the GP, the GP would be responsible and professional liability cover would be appropriate. However, junior medical staff, nurses or members of the professions supplementary to medicine involved in the care of a GP’s patients in NHS hospitals under their contract of employment would be covered.

7. Are GP trainees working in general practice covered?

In general practice the responsibility for training and for paying the salary of a GP trainee rests with the trainer. While the trainee is receiving a salary in general practice it is advisable that

both the trainee and the trainer, and indeed other members of the practice, should have appropriate professional liability cover as NHS indemnity will not apply.

8. Are NHS employees working under contracts with GP fundholders covered?

If their employing NHS body has agreed a contract to provide services to a GP fundholding practice's patients, NHS employees will be working under the terms of their contracts of employment and NHS Indemnity will cover them. If NHS employees themselves contract with GP fundholders (or any other independent body) to do work outside their NHS contract of employment they should ensure that they have separate indemnity cover.

9. Is academic General Practice covered?

The Department has no plans to extend NHS Indemnity to academic departments of general practice. In respect of general medical services, Health Authorities' payments of fees and allowances include an element for expenses, of which medical defence subscriptions are a part.

10. Is private work in NHS hospitals covered by NHS Indemnity?

NHS bodies will not be responsible for a health care professional's private practice, even in an NHS hospital. However, where junior medical staff, nurses or members of professions supplementary to medicine are involved in the care of private patients in NHS hospitals, they would normally be doing so as part of their NHS contract, and would therefore be covered. It remains advisable that health professionals who might be involved in work outside the scope of his or her NHS employment should have professional liability cover.

11. Is Category 2 work covered?

Category 2 work (eg reports for insurance companies) is by definition not undertaken for the employing NHS body and is therefore not covered by NHS Indemnity. Unless the work is carried out on behalf of the employing

NHS body, professional liability cover would be needed.

12. Are disciplinary proceedings of statutory bodies covered?

NHS bodies are not financially responsible for the defence of staff involved in disciplinary proceedings conducted by statutory bodies such as the GMC (doctors), UKCC (nurses and midwives), GDC (dentists) CPSM (professions supplementary to medicine) and RPSGB (pharmacists). It is the responsibility of the practitioner concerned to take out professional liability cover against such an eventuality.

13. Are clinical trials covered?

In the case of negligent harm, health care professionals undertaking clinical trials or studies on volunteers, whether healthy or patients, in the course of their NHS employment are covered by NHS Indemnity. Similarly, for a trial not involving medicines, the NHS body would take financial responsibility unless the trial were covered by such other indemnity as may have been agreed between the NHS body and those responsible for the trial. In any case, NHS bodies should ensure that they are informed of clinical trials in which their staff are taking part in their NHS employment and that these trials have the required Research Ethics Committee approval. For non-negligent harm, see question 16 below.

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14. Is harm resulting from a fault in the drug/equipment covered?

Where harm is caused due to a fault in the manufacture of a drug or piece of equipment then, under the terms of the Consumer Protection Act 1987, it is no defence for the producer to show that he exercised reasonable care. Under normal circumstances, therefore, NHS indemnity would not apply unless there was a question whether the health care professional either knew or should reasonably have known that the drug/equipment was faulty but continued to use it. Strict liability could apply if the drug/equipment had been manufactured by an NHS body itself, for example a prototype as part of a research programme.

15. Are Local Research Ethics Committees (LRECs) covered?

Under the Department's guidelines an LREC is appointed by the Health

Authority to provide independent advice to NHS bodies within its area on the ethics of research proposals. The Health Authority should take financial responsibility for members' acts and omissions in the course of performance of their duties as LREC members.

16. Is there liability for non-negligent harm?

Apart from liability for defective products, legal liability does not arise where a person is harmed but no one has acted negligently. An example of this would be unexpected side-effects of drugs during clinical trials. In exceptional circumstances (and within the delegated limit of £50,000) NHS bodies may consider whether an ex-gratia payment

could be offered. NHS bodies may not offer advance indemnities or take out commercial insurance for non-negligent harm.

17. What arrangements can non-MIS bodies make for non-negligent harm?

Arrangements will depend on the status of the non-NHS body. Arrangements for clinical trials sponsored by the pharmaceutical industry are set out in Annex B. Other independent sector sponsors of clinical research involving NHS patients (eg universities and medical research charities) may also make arrangements to indemnify research subjects for non-negligent harm. Public sector research funding bodies such as the Medical Research Council (MRC) may not offer advance indemnities nor take out commercial insurance for non-negligent harm. The MRC offers the assurance that it will give sympathetic consideration to claims in respect of non-negligent harm arising from an MRC funded trial. NHS bodies should not make ex-gratia payments for non-negligent harm where research is sponsored by a non-NHS body.

18 Would health care professionals be covered if they were working other than in accordance with the duties of their post?

Health care professionals would be covered by NHS Indemnity for actions in the course of NHS employment, and this should be interpreted liberally. For work not covered in this way health care professionals may have a civil, or even, in extreme circumstances, criminal liability for their actions.

19.

Are health care professionals attending accident victims (“Good Samaritan” acts) covered?

“Good Samaritan” acts are not part of the health care professional’s work for the employing body. Medical defence organizations are willing to provide low-cost cover against the (unusual) event of anyone performing such an act being sued for negligence. Ambulance services can, with the agreement of staff, include an additional term in the individual employee contracts to the effect that the member of staff is expected to provide assistance in any emergency outside of duty hours where it is appropriate to do so.

20. Are NHS staff in public health medicine or in community health services doing work for local authorities covered? Are occupational physicians covered?

Staff working in public health medicine, clinical medical officers or therapists carrying out

local authority functions under their NHS contract would be acting in the course of their NHS employment. They will therefore be covered by NHS Indemnity. The same principle applies to occupational physicians employed by NHS bodies.

21. Are NHS staff working for other agencies, eg the Prison Service, covered?

In general, NHS bodies are not financially responsible for the acts of NHS staff when they are working on an individual contractual basis for other agencies. (Conversely, they are responsible where, for example, a Ministry of Defence doctor works in an NHS hospital.) Either the non-NHS body commissioning the work would be responsible, or the health care professional should have separate indemnity cover. However, NHS Indemnity should cover work for which the NHS body pays the health care professional a fee, such as domiciliary visits, and family planning services.

22. Are former NHS staff covered?

NHS Indemnity will cover staff who have subsequently left the Service (eg on retirement) provided the liability arose in respect of acts or omissions in the course of their NHS employment, regardless of when the claim was notified. NHS bodies may seek the co-operation of former staff in providing statements in the defence of a case.

23. Are NHS staff offering services to voluntary bodies such as the Red Cross or hospices covered?

The NHS body would **be** responsible for the actions of its staff only if it were contractually responsible for the clinical staffing of the voluntary body. If not, the staff concerned may wish to ensure that they have separate indemnity cover.

24. Do NHS bodies provide cover for locums?

NHS bodies take financial responsibility for the acts and omissions of a locum health care professional, whether "internal" or provided by an external agency, doing the work of a colleague who would be covered.

25. What are the arrangements for staff employed by one trust working in another.

This depends on the contractual arrangements. If the work is being done as part of a formal agreement between the trusts, then the staff involved will be acting within their normal NHS duties and, unless the agreement states otherwise, the employing trust will be liable. The NHS Executive does not recommend the use of ad hoc arrangements, eg a doctor, in one trust asking

a doctor in another to provide an informal second opinion, unless there is an

between the trusts as to which of them will accept liability for the “visiting” doctor in such circumstances.

26. Me private sector rotations for hospital staff covered?

The medical staff of independent hospitals are responsible for their own professional liability cover, subject to the requirements of the hospital managers. If NHS staff in the training grades work in independent hospitals as part of their NHS training, they would be covered by NHS Indemnity, provided that such work was covered by an NHS contract of employment.

27. Are voluntary workers covered?

Where volunteers work in NHS bodies, they are covered by NHS Indemnity. NHS managers should be aware of all voluntary activity going on in their organizations and should wherever possible confirm volunteers’ indemnity position in writing.

28. Are students covered?

NHS Indemnity applies where students are working under the supervision of NHS employees. This should be made clear in the agreement between the NHS body and the student’s educational body. This will apply to students of all the health care professions and to school students on, for example, work experience placements. Students working in NHS premises, under supervision of medical academic staff employed by universities holding honorary contracts, are also covered. Students who spend time in a primary care setting will only be covered if this is part of an NHS contract. Potential students making preliminary visits and school placements should be adequately supervised and should not become involved in any clinical work. Therefore, no clinical negligence should arise on their part.

In the unlikely event of a school making a negligent choice of work placement for a pupil to work in the NHS, then the school, and not NHS indemnity, should pick up the legal responsibility for the actions of that pupil. The contractual arrangement between the NHS and the school should make this clear.

29. Are health care professionals undergoing on-the-job training covered?

Where an NHS body’s staff are providing on-the-job training (eg refresher or skills updating courses) for health care professionals, the trainees are covered by NHS Indemnity whether they are normally employed by the NHS or not.

30. Are Independent midwives covered?

Independent midwives are self-employed practitioners. In common with all other health care professionals working outside the NHS, they are responsible for making their own indemnity arrangements.

31. Are overseas doctors who have come to the UK temporarily, perhaps to demonstrate a new technique, covered?

The NHS body which has invited the overseas doctor will owe a duty of care to the patients on whom the technique is demonstrated and so NHS indemnity will apply. NHS bodies, therefore, need to make sure that they are kept informed of any such demonstration visits which are proposed and of the nature of the technique to be demonstrated. Where visiting clinicians are not formally registered as students, or are

not employees, an honorary contract should be arranged.

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32. Are staff who are qualified in another member state of the European Union covered?

Staff qualified in another member state of the European Union, and who are undertaking an adaptation period in accordance with EEC directive 89/48EEC and the European Communities (Recognition of Professional Qualifications) Regulations 1991 which implements EEC Directive 89/48/EEC) and EEC Directive 92/51/EEC, must be treated in a manner consistent with their qualified status in another member state, and should be covered.

Indemnity for Clinical Studies

Sponsored by Pharmaceutical companies

Section One

1. Clinical research involving the administration of drugs to patients or non-patient human volunteers is frequently undertaken under the auspices of Health Authorities or NHS Trusts.
2. When the study is sponsored by a pharmaceutical company, issues of liability and indemnity may arise in case of injury associated with administration of the drug or other aspects of the conduct of the trial.
3. When the study is not sponsored by a company but has been independently organised by clinicians, the NHS body will carry full legal liability for claims in negligence arising from harm to subjects in the study.
4. The guidance in Section 2 and the Appendix has three purposes:
 - to ensure that NHS bodies enter into appropriate agreements which will provide indemnity against claims and proceedings arising from company-sponsored clinical studies;
 - to ensure that NHS bodies, where appropriate, use a standard form of agreement (Appendix) which has been drawn up in consultation with the Association of the British Pharmaceutical Industry (ABPI);
 - to advise Local Research Ethics Committees (LRECs) of the standard form of agreement.

Section Two

1. A wide variety of clinical studies involving experimental or investigational use of drugs is carried out within NHS bodies. This includes studies in patients (clinical trials) and studies in healthy human volunteers. They may involve administration of a totally new (unlicensed) drug (active substance or ~NAS') or the administration of an established (licensed) drug by a novel route, for a new therapeutic indication, or in a novel formulation or combination.
2. Detailed guidance on the design, conduct, and ethical implications of clinical studies is given in:

HSG(91)5: Local Research Ethics Committees (with accompanying booklet).
NHS Executive: 1991;

Guidelines for Medical Experiments in non-Patient Human Volunteers

ABPI:1988, amended 1990;

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Research Involving Patients, Royal College of Physicians of London:

1990;

Guidelines in the Practice of Ethics Committees in Medical Research,

2nd edition; Royal College of Physicians of London: 1990;

Clinical Trial Compensation Guidelines ABPI: 1991

3. The Medicines Act 1968 provides the regulatory framework for clinical studies involving administration of drugs to patients. Drugs which are used in a sponsored* clinical study in patients will be the subject of either a product licence (PL), a clinical trial certificate (CTC), or clinical trial exemption (CTh) which is held by the company as appropriate. A non-sponsored study conducted independently by a practitioner must be notified to the Licensing Authority under the Doctors and Dentists Exemption (DDX) scheme. Studies in healthy volunteers are not subject to regulation under the Medicines Act and do not require a CTC, Cm, or DDX. Further particulars of these arrangements are provided in Medicines Act leaflet *M₁₁ 30: A guide to the provisions affecting doctors and dentists* (DHSS: 1985).

4. Participants in a clinical study may suffer adverse effects due to the drug or clinical procedures. The appendix to this annex is a model form of agreement between the company sponsoring a study and the NHS body involved, which indemnifies the authority or trust against claims and proceedings arising from the study. The model agreement has been drawn up in consultation with the Association of the British Pharmaceutical Industry (ABPI).
5. This form of indemnity will not normally apply to clinical studies which are not directly sponsored by the company providing the product for research, but have been independently organised by clinicians. In this case, the NHS body will normally carry full legal liability for any claims in negligence arising from harm to subjects in the study.
6. The NHS body will also carry full legal liability for any claims in negligence (or compensation under the indemnity will be abated) where there has been significant non-adherence to the agreed protocol or there has been negligence on the part of an NHS employee, for example, by failing to deal adequately with an adverse drug reaction.
7. The form of indemnity may not be readily accepted by sponsoring companies outside the UK or who are not members of the ABPI. NHS bodies should, as part of their risk management, consider the value of indemnities which are offered and consider whether companies should have alternative arrangements in place.

*A sponsored study may be defined as one carried out under arrangements made by or on behalf of the company who manufactured the product, the company responsible for its composition, or the company selling or supplying the product.

NHS Indemnity Several health authorities and trusts have independently developed forms of indemnity agreement. However, difficulties have arisen when different authorities have required varying terms of indemnity and this has, on occasion, impeded the progress of clinical research within the NHS. Particular difficulties may arise in large multi-centre trials involving many NHS bodies when it is clearly desirable to have standardised terms of indemnity to provide equal protection to all participants in the study.

9. Responsibility for deciding whether a particular company-sponsored research proposal should proceed within the NHS rests with the Health Authority or Trust within which the research would take place, after consideration of ethical, clinical, managerial, financial, resource, and legal liability issues. The NHS body is responsible for securing an appropriate indemnity agreement and should maintain a register of all clinical studies undertaken under its auspices with an indication whether it is a company-sponsored study and, if so, with confirmation that an indemnity agreement is in place. If for any reason it is considered that the model form of indemnity is not appropriate or that amendments are required, the NHS body involved should seek legal advice on the form or amendments proposed.
10. Even when the model form of indemnity is agreed, the NHS body should satisfy itself that the company sponsoring the study is substantial and reputable and has appropriate arrangements in place (for example insurance cover) to support the indemnity. The NHS body will carry full liability for any claims in negligence if the indemnity is not honoured and there is not supporting insurance.
11. Where a clinical study includes patients or subjects within several NHS bodies, for example in a multi-centre clinical trial, it is necessary for each Authority or Trust to complete an appropriate indemnity agreement with the sponsoring company.
12. Where independent practitioners, such as general medical practitioners, are engaged in clinical studies, Health Authorities should seek to ensure that such studies are the subject of an appropriate indemnity agreement. It is good practice for the GP to notify the Health Authority of his participation in any clinical study.
13. Clinical investigators should ensure that details of any proposed research study are lodged with the appropriate NHS body and should not commence company-sponsored research unless an indemnity agreement is in place.
14. Local Research Ethics Committees (LREC5) provide independent advice to NHS and other bodies and to clinical researchers on the ethics of proposed research projects that involve human subjects [TISG(91)5]. Clinical investigators should not commence any research project involving patients or human volunteers without LREC agreement. Acceptance of the ABPI guidelines and the terms of the model indemnity agreement should normally

be a condition of LREC approval of any pharmaceutical company sponsored project.

Annex B: Appendix

FORM OF INDEMNITY FOR CLINICAL STUDIES

To: [Name and address of sponsoring company] (“the Sponsor”)

From: [Name and address of Health Authority/Health Board/NHS Trust] (“the Authority”)

Re: Clinical Study No [] with [name of product]

1. It is proposed that the Authority should agree to participate in the above sponsored study (“the Study”) involving [patients of the Authority] [non-patient volunteers] (“the Subjects”) to be conducted by [name of investigator(s)] (“the Investigator”) in accordance with the protocol annexed, as amended from time to time with the agreement of the Sponsor and the Investigator (“the Protocol”). The Sponsor confirms that it is a term of its agreement with the Investigator that the Investigator shall obtain all necessary approvals of the applicable Local Research Ethics Committee and shall resolve with the Authority any issues of a revenue nature.
2. The Authority agrees to participate by allowing the Study to be undertaken on its premises utilising such facilities, personnel and equipment as the Investigator may reasonably need for the purpose of the Study.
3. In consideration of such participation by the Authority, and subject to paragraph 4 below, the Sponsor indemnifies and holds harmless the Authority and its employees and agents against all claims and proceedings (to include any settlements or ex-gratia payments made with the

consent of the parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise):

- (a) by or on behalf of Subjects taking part in the Study (or their dependants) against the Authority or any of its employees or agents for personal injury (including death) to Subjects arising out of or relating to the administration of the product(s) under investigation or any clinical intervention or procedure provided for or required by the Protocol to which the Subjects would not have been exposed but for their participation in the Study.

- (b) by the Authority, its employees or agents or by or on behalf of a Subject for a declaration concerning the treatment of a Subject who has suffered such personal injury.

4. The above indemnity by the Sponsor shall not apply to any such claim or proceeding:

- 4.1** to the extent that such personal injury (including death) is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Authority, its employees or agents;
- 4.2** to the extent that such personal injury (including death) is caused by the failure of the Authority, its employees, or agents to conduct the Study in accordance with the Protocol;
- 4.3** unless as soon as reasonably practicable following receipt of notice of such claim or proceeding, the Authority shall have notified the Sponsor in writing of it and shall, upon the Sponsor's request, and at the Sponsor's cost, have permitted the Sponsor to have full care and control of the claim or proceeding using legal representation of its own choosing;
- 4.4** if the Authority, its employees, or agents shall have made any admission in respect of such claim or proceeding or taken any action relating to such claim or proceeding prejudicial to the defence of it without the written consent of the Sponsor such consent not to be unreasonably withheld provided that this condition shall not be treated as breached by any statement properly made by the Authority, its employees or agents in connection with the operation of the Authority's internal complaint procedures, accident reporting procedures or disciplinary procedures or where such statement is required by law.
- 5.** The Sponsor shall keep the Authority and its legal advisers fully informed of the progress of any such claim or proceeding, will consult fully with the Authority on the nature of any defence to be advanced and will not settle any such claim or proceeding without the written approval of the Authority (such approval not to be unreasonably withheld).
- 6.** Without prejudice to the provisions of paragraph 4.3 above, the Authority will use its reasonable endeavours to inform the Sponsor promptly of any circumstances reasonably thought likely to give rise to any such claim or proceeding of which it is directly aware and shall keep the Sponsor reasonably informed of developments in relation to any such claim or proceeding even where the Authority decides not to make a claim under this indemnity. Likewise, the Sponsor shall use its reasonable endeavours to inform the Authority of any such circumstances and shall keep the Authority reasonably informed of developments in relation to any such claim or proceeding made or brought against the Sponsor alone.
- 7.** The Authority and the Sponsor will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of Subjects (or their dependants) or concerning such a declaration as is referred to in paragraph 3(b) above.

8. Without prejudice to the foregoing if injury is suffered by a Subject while participating in the Study, the Sponsor agrees to operate in good faith the Guidelines published in 1991 by The Association of the British Pharmaceutical Industry and entitled "Clinical Trial Compensation Guidelines" (where the Subject is a patient) and the Guidelines published in 1988 by the same Association and entitled "Guidelines for Medical Experiments in non-patient Human Volunteers" (where the Subject is not a patient) and shall request the Investigator to make clear to the Subjects that the Study is being conducted subject to the applicable Association Guidelines.

9. For the purpose of this indemnity, the expression "agents" shall be deemed to include without limitation any nurse or other health professional providing services to the Authority under a contract for services or otherwise and any person carrying out work for the Authority under such a contract connected with such of the Authority's facilities and equipment as are made available for the Study under paragraph 2 above.

10. This indemnity shall be governed by and construed in accordance with English/Scottish* law.

SIGNED on behalf of the Health Authority!

Health Board/NHS Trust

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Chief Executive/

District General Manager

SIGNED on behalf of the Company

.....

Dated

* Delete as appropriate