



Research and Development Forum

Indemnity arrangements within Primary Care – who is responsible for what?

**A paper prepared by the NHS R&D Forum,
Primary Care Working Party**

This paper summarises our current understanding of indemnity arrangements in research, as they apply to PCTs and Primary Care practitioners, including Independent Contractors. It seeks to

- ❑ clarify the current arrangements for indemnity for clinical service providers and for research within primary care
- ❑ explain the additional safeguards that can be put in place through sponsorship arrangements, to secure clear responsibilities and lines of accountability for research
- ❑ highlight potential gaps
- ❑ make specific proposals as to how to close these gaps and minimise risk relating to research in primary care settings.

1. Introduction

The Research Governance Framework requires that insurance or indemnity arrangements for negligent and non-negligent harm are made clear BEFORE a piece of research can commence.

The sponsor's role is to ensure that research responsibilities are clearly and properly identified and allocated to the main parties within a research project from the outset. This includes ensuring that adequate insurance and indemnity arrangements are in place and responsibilities clear. The sponsor is not obliged to provide indemnity for the research it is sponsoring. The sponsor must ensure that the parties to the research (crucially the employer of the Chief Investigator and the care provider) have established that adequate insurance and indemnity arrangements are in place. The Research Ethics Committee is responsible for reviewing the adequacy of these arrangements as part of its scrutiny of the project. The host NHS Trust/PCT must also check that the sponsor has confirmed what arrangements are in place, as part of its role in providing Trust permission for the research to proceed.

The EU regulations governing clinical trials of medicinal products makes it a legal requirement for the sponsor and the lead investigator to ensure that adequate arrangements are in place to address insurance/indemnity for the trial.

By putting in place proper agreements which clearly define and allocate research roles and ensure that research partners accept these roles, there is a reduced risk of anything going wrong, and of the partners in that research being sued inappropriately.

2. Non-commercial clinical research on NHS patients – current arrangements for negligent harm within the NHS

2.1 Negligent harm: Indemnity arrangements within public bodies, especially the NHS, can address only negligent harm. This is the legal liability that arises from the NHS Trust's duty of care towards patients. Where an individual is harmed in the context of R&D, and an individual or group of individuals can be demonstrated to have caused that harm because of their negligence through, for example, not following an agreed procedure according to set policy or protocol, then that would be deemed negligent harm. Therefore if an NHS patient is harmed in the course of research as a result of negligent actions on the part of staff (including those working under Honorary Contracts) then the NHS Trust is liable or vicariously liable. In such cases, the NHS Trust would be responsible for dealing with claims arising against the Trust for the harm caused, according to the details of each individual case (but see below for comments on Independent Contractors).

NHS Trusts in England belong to the Clinical Negligence Scheme for Trusts (CNST), run by the NHS Litigation Authority, which pools the risk of clinical negligence claims. The Trust may subsequently take disciplinary action against the individual responsible for the negligence which caused the harm, (or their employer). To protect themselves in the event of this happening, individual clinicians ensure that they hold personal cover for defending

professional indemnity disciplinary claims (for example through their professional body or organisation such as the MDU/MPS). For researchers not employed by the NHS, their employers are liable for the employee's negligent acts and are responsible for holding adequate professional liability insurance. The sponsor would normally seek written confirmation from research partners, as part of their role in confirming indemnity arrangements

The agreements between research partners clarifying who holds the respective responsibilities for the research, as well as the patient information leaflets, should specify what arrangements are in place covering negligent harm. Such statements should address the responsibilities of the NHS Trust, the employers of any researchers involved in the project and the personal responsibilities of clinicians. (see template for sponsor arrangements in chapter 2 of the R&D Forum's Toolkit for RM&G PCTs).

2.2 Non-commercial research on NHS patients – current arrangements for negligent harm as they affect PCTs and Independent Contractors

PCTs – a PCT, like all NHS Trusts, has a duty of care to its patients. Where research takes place during provision of NHS services, the PCT retains a vicarious liability. The standard NHS indemnity intended to address such liabilities (the CNST) extends to:

- NHS practitioners and staff who are directly employed by the NHS Trust or PCT. This includes those who are directly employed by a PCT as a salaried clinician, or hold an individual (salaried) contract with a Trust, for example as a clinical assistant.
- Non-NHS staff who are operating in the circumstances under which the PCT has vicarious liability for their activities, **provided that:**

The research has been reviewed and permitted by the Trust in accordance with Research Governance procedures

AND

Staff involved in undertaking the research hold honorary NHS contracts

- **The PCT's vicarious liability, along with NHS indemnity arrangements provided through the CNST, do NOT extend to Independent Contractors working under a contract for services to a PCT (e.g. GPs, dentists, community pharmacists, optometrists) or their staff.**

NHS indemnity arrangements (CNST) specifically do not extend to Independent Contractors (or their staff) working under contract for services to a PCT. Therefore, the issuing of an NHS honorary contract to this group of practitioners does not bring them under the ambit of NHS indemnity arrangements. NHS indemnity arrangements (CNST) do extend to University staff, which is why in the case of such "third party" researchers, it is necessary to issue honorary contracts to formalise the provision of NHS indemnity as they are operating within the vicarious liability of the NHS Trust.

2.3 Indemnity arrangements for Independent Contractors: Where an Independent Contractor such as a GP, or their practice staff, undertake research as part of their routine clinical services, their personal professional indemnity arrangements provide them with adequate cover for that activity. The contractual arrangements between the PCTs and the Independent Contractors require the latter to hold adequate insurance against liability arising from negligent performance of clinical services. Where Independent Contractors are taking part in research in their role as "part of the organisation providing care", the activity can be interpreted as part of their routine professional practice in delivering clinical services. As such, their existing arrangements for indemnity should be accepted as adequate for any personal liability that may arise from negligent performance.

Examples of clinical activity undertaken within a research study by a clinician on their own patients, where their personal professional indemnity arrangements are deemed appropriate for the purpose of research governance include:

- ❑ Assessing patients against defined inclusion/exclusion criteria
- ❑ Referring or recruiting patients to research
- ❑ Screening patients and taking consent
- ❑ Initiating or undertaking specified tests or investigations that form part of routine clinical practice
- ❑ Delivering clinical interventions within a research project, where those interventions are accepted examples of usual care

Whilst the GP's personal medical defence arrangements are adequate for the clinical services delivered in the context of research to their own patients, the PCT will also wish to check the indemnity arrangements relating to the Chief/Principal Investigator (or their employing organisation). Here the PCT will need to check what indemnity arrangements are in place to address issues arising from the design of the protocol, managing data analysis, interpreting and writing the results, for which Independent Contractors participating in the research as clinicians cannot be held liable.

Where an Independent Contractor is the Chief Principal Investigator or undertaking research on patients outside their routine clinical practice, their personal professional defence arrangements may not extend to cover such research activities. Normally Independent Contractors' indemnity arrangements are geared to provide cover for routine clinical services provided under GMS and additional arrangements will need to be put in place where additional responsibilities for leading research are assumed. In such cases there are three options:

- a) The Independent Contractor could negotiate with their insurer to extend their indemnity arrangements to provide explicit cover for research. The sponsor of the research would need to check that these arrangements were acceptable. In such circumstances, the sponsor would also be concerned to check the arrangements for the quality assurance of the research.
- b) The Independent Contractor could negotiate with the PCT to be the sponsor of the research. The PCT, in taking responsibility for the research, could provide the Independent Contractor with a (salaried) contract as a Clinical Researcher. In this way, the PCT's own duty of care and NHS indemnity arrangements could be extended to the Independent Contractor in relation to their research activity. Such an arrangement would also mean that the funding for the research would also be channelled through and managed by the PCT, or that the PCT was funding the research itself.
- c) The Independent Contractor could negotiate with a University to take responsibility for the research design. The University should then offer the Independent Contractor an academic contract. In this case, the University's Professional Indemnity Insurance would extend to cover the research protocol. If the Independent Contractor's research involved patients, they could be offered an Honorary NHS contract (as a University employee), so that NHS indemnity could be extended to them. The partnership between the Independent Contractor and the University would also mean that the funding for the research should be channelled through and managed by the University. NHS indemnity arrangements or individuals' personal indemnity arrangements would continue to address the clinical services delivered within the research as normal. Either the PCT or the University could sponsor the research.

2.4 Staff employed by Independent Contractors – are defined as NHS staff within the new NHS contract.¹ This means that PCTs do not have to extend Honorary Contracts to practice staff if they are conducting research as part of their NHS practice. However, the PCT may wish to highlight that compliance with research governance is a contractual obligation for such

¹ 'Delivering Investment in General Practice. Implementing the new GMS contract Dec 2003, Annex F3' states 'NHS employee means anyone employed by:

(iii) a person providing services under GMS or GDS contract.

staff as part of the broader obligation to comply with PCTs' corporate risk management arrangements. NHS indemnity (the CNST) currently does not extend to staff employed by Independent Contractors. Independent practitioners' current arrangements for clinical negligence also extend to their practice staff, including when they do research during their NHS clinical practice.

Where practice staff wish to lead a piece of research they should consider the advice set out in section 2 above.

2.5 Universities – hold professional liability insurance to cover the activities of their employed staff. Where a Trust agrees to host research that has been written by a University researcher and where the University is the employer of the Chief/Principal Investigator, the University will remain liable for the protocol design. However, regardless of this, health and social care bodies remain responsible for the care of their patients when they participate in research. The Trust will retain its duty of care towards the patient if the patient makes a claim as a result of harm that may have arisen from the research and which may be attributable to negligence. Where such harm may be attributable to negligence in the research design or the conduct of the researcher employed by the University, the University may subsequently be counter-sued by the Trust for the element of a claim that may be attributed to the research employer's area of responsibility (i.e. not any aspect of the claim that relates to clinical patient care).

3. Non-negligent harm

Indemnities cover legal liabilities, whereas non-negligent harm (commonly known as no-fault) raises the possibility of whether compensation becomes payable because of a moral or ethical obligation. Non-negligent harm arises where an individual has been harmed in the context of R&D, through no fault of an individual or institution involved in the research and even though all the correct policies and procedures have been followed.

It is the role of ethics committees to decide whether or not a study can go ahead without a scheme of compensation for harm caused where there is no negligence. The sponsor, along with the parties to the research, should consider whether or not the research presents sufficient risk to merit indemnity for non-negligent harm. NHS indemnity arrangements do not extend to non-negligent harm and NHS bodies cannot purchase commercial insurance for this purpose. NHS bodies, including PCTs cannot give advance undertaking to pay compensation when there is no negligence attributable to their vicarious liability. Organisations such as University bodies normally purchase professional indemnity cover for non-negligent harm but anecdotal evidence suggests that it is becoming increasingly difficult and financially prohibitive for universities to purchase professional indemnity insurance for clinical research.

The agreements between research partners clarifying who holds the respective responsibilities for the research, as well as the patient information leaflets, should specify whether there are arrangements in place for non-negligent harm (provision of insurance/indemnity for non-negligent harm is not a requirement and its provision needs only to be considered, and then only for research involving clinical interventions). Where there are no arrangements in place for non-negligent harm, or where such arrangements are limited to consideration of ex-gratia payments, this should be clearly stated in the agreements between the research partners and in patient information leaflets.

4. Commercial research

Pharmaceutical companies act as sponsor of their own research and are expected to hold adequate insurance cover to indemnify the research, covering negligent and non-negligent harm. Currently, pharmaceutical companies organise clinical trial agreements with individual practices. In this way, independent contractors and their staff are covered by the company's indemnity for any research activity, with the clinicians' professional insurance cover operating alongside this to cover them for any claims relating to clinical negligence (i.e. activity not attributable to the research). PCTs should be presented with confirmation of the indemnity arrangements provided by commercial companies as part of the R&D procedures for approving research

5. Private patients

Where patients are recruited to a commercial trial as private patients, then the trial agreement must be with the practice only, with explicit publicity provided to clarify that the NHS is not participating in the trial and is therefore not responsible for the research or any aspect of related patient care. The ethics committee and the sponsor must satisfy themselves that the study documentation provides adequate information so that the patient can understand the private nature of the study, the implications of this to them and that all indemnities will be provided by the commercial company (often on a self-insuring basis).

6. Further action being undertaken by the Department of Health

Marc Taylor on behalf of the Department of Health, has indicated that work is currently being undertaken in four areas:

- a connected statement of the way NHS Indemnity applies to R&D;
- a standard form of words for NHS bodies to use in an exchange of letters giving permission for R&D - this would spell out how NHS indemnity applies to the study and may remove the need for other forms of contract for the purpose of establishing indemnity;
- a statement and examples to clarify the position with NHS Indemnity when PCTs wish to facilitate studies initiated by another NHS body or its non-commercial partners and GPs' professional insurance would not cover one or more of the research team;
- a statement and examples to clarify the position with NHS Indemnity when PCTs wish to sponsor studies which are initiated by GPs but are not conducted in a setting covered by the GPs' professional insurance.

Colleagues are invited to provide further real-life examples of cases involving research which illustrate potential gaps in provision of indemnity, which the Department of Health should consider. Please send them to Stella Barclay Stella.Barclay@dh.gsi.gov.uk.

Rhian Hughes
January 2005