

# Information for members

I-04-63

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Vice-Chancellors and Principals, Pro Vice-Chancellors (Research), University Registrars and Secretaries, Directors of Human Resources, Deans/Heads of Medicine, Pharmacy, Health Sciences and Biosciences

## Action

For information

## Attachment(s)

Responsibilities, liabilities and risk management in clinical trials of medicines (I-04-63(a))

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## Clinical trials of medicines

### Executive Summary

On 1 May 2004, new regulations came into force, changing the legal framework for clinical trials on medicinal products. This I-Note informs members of the implications of these regulations.

The attachment to this I-Note explains how Universities UK and the Department of Health expect the responsibilities, liabilities and risk management in publicly funded trials of medicines to be managed.

### Overview of the implications of the new regulations

The Medicines for Human Use (Clinical Trials) Regulations 2004 came into force on 1 May 2004. These regulations implement the EU Clinical Trials Directive 2001/20, and may accessed at the following web address:

[www.legislation.hmso.gov.uk/si/si2004/20041031.htm](http://www.legislation.hmso.gov.uk/si/si2004/20041031.htm)

Following detailed discussion, Universities UK and the Department of Health wish to reassure universities and NHS bodies that the regulations do not change the underlying allocation of responsibilities and potential liabilities in collaborative academic trials.

We are clear that universities will be able to continue clinical trials with confidence. Universities already have insurance cover for negligent harm. There will be no need for universities to take non-negligent cover unless, as is currently the case, ethics committees identify a specific need for such cover.

For their part, NHS bodies will continue to take on liability for clinical negligence that harms individuals towards whom the NHS has a duty of care. The current policy of NHS Indemnity for clinical trials conducted with NHS permission still applies.

The new regulations clarify specific legal duties of sponsors, investigators and others in clinical trials of medicines, based on internationally agreed principles.

Chief Executive **Baroness Warwick**



Universities UK

The regulations do not alter other responsibilities and potential liabilities, as the attached paper explains.

The legislation should not be seen as a cause for alarm. Rather, it is a useful reminder of the need for continuing high standards in clinical research governance, to protect individuals and ensure reliable findings.

Institutions are encouraged to disseminate the attached paper to all those with responsibilities for the management of clinical trials of medicines.

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## Responsibilities, liabilities and risk management in clinical trials of medicines

### Introduction

1. This note summarises how the Department of Health and Universities UK expect responsibilities, liabilities and risks to be managed in publicly funded clinical trials involving medicines. It confirms the approach NHS bodies and universities are expected to take to claims for personal injury in clinical research.
2. From 2004, EU Member States have to implement the Clinical Trials Directive<sup>1</sup>. The Directive specifies it is without prejudice to the civil and criminal liability of the sponsor or the investigator. The UK Regulations<sup>2</sup> do not change the civil liabilities of the NHS, universities or others undertaking clinical trials under the legislation.
3. Claims for death or personal injury from clinical research are infrequent. The Government and Universities UK expect implementation of the Directive and NHS research governance to reduce further the risk of claims resulting in liabilities for the NHS, universities and public funders of clinical trials.

### Key points

4. The Directive requires insurance or indemnity for liabilities of the sponsor and investigator. It does not change existing liabilities.
5. NHS bodies remain liable for clinical negligence and other negligent harm to individuals covered by their duty of care.
6. Institutions employing researchers remain liable for negligent harm caused by the design of studies they initiate.
7. Producers continue to have strict liability for faulty medicines.
8. The UK Regulations do not require no-fault compensation. Ethics committees will continue to consider the need for it case by case.

### Clinical negligence and NHS indemnity<sup>3</sup> in clinical research

9. Under the UK Regulations, an *investigator* is a registered doctor, dentist, nurse or pharmacist responsible for the conduct of a clinical trial at a trial site. The Regulations

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<sup>1</sup> Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

<sup>2</sup> The Medicines for Human Use (Clinical Trials) Regulations 2004 were made on 31 March 2004, under the European Communities Act 1972. They came into effect on 1 May 2004.

<sup>3</sup> DH guidance to the NHS on NHS Indemnity and clinical negligence is available at [www.dh.gov.uk](http://www.dh.gov.uk).

do not transfer vicarious liability from NHS bodies to universities or public funders. NHS bodies' duty of care applies both:

- i) when a health care professional employed by the NHS body is negligent in the course of their employment; and
  - ii) when the negligent health care professional was contracted to an NHS body to provide services to people to whom the NHS body owed a duty of care.
10. In either case, if there is negligent harm, NHS bodies will accept full financial liability. They are not expected to recover costs from the health care professional. *NHS Indemnity* is the understanding that NHS bodies will provide for these liabilities. NHS bodies may carry this risk themselves, or spread it through the Clinical Negligence Scheme for Trusts. The CNST provides unlimited cover for this risk.
  11. If there is negligent harm during a clinical trial when the NHS body owes a duty of care to the person harmed<sup>4</sup>, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial<sup>5 6</sup>.
  12. From April 2004, research-active NHS bodies have to comply with a controls assurance standard for research governance, and to report compliance as part of NHS-wide arrangements for clinical and financial risk management. If a clinical trial involves an NHS body's employees or otherwise affects its duty of care, its permission is required before the trial commences at that site<sup>7</sup>. These arrangements reduce the risk (to the NHS and to university employers of medical academic staff) of unauthorised clinical research resulting in unexpected liabilities.

### Research liabilities

13. When staff design and initiate a clinical trial in the course of their employment, their employer has vicarious liability for their actions.
14. Universities are expected to insure against the risk of claims against the university or its staff relating to clinical trials they<sup>8</sup> design and undertake in their university employment. This insurance mainly operates for claims arising from the authorship of the protocol.
15. Full and proper independent expert scientific review should demonstrate that all reasonable care was taken in designing the protocol, reducing the risk of liability.
16. Under the UK Regulations, there is a legal requirement for ethical review, providing a mechanism to ensure that the trial design respects the dignity, rights, safety and well-being of participants. Ethical review also ensures the information provided when seeking consent is sufficient to convey an understanding of the risks. In addition, the process leading to a Clinical Trial Authorisation should provide an assurance that the

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<sup>4</sup> The person may be a patient or a healthy volunteer.

<sup>5</sup> This applies both to publicly funded clinical trials and contract research.

<sup>6</sup> Independent practitioners are expected to arrange their own insurance or indemnity. NHS Indemnity covers them only when they are directly employed or engaged by an NHS body to provide services to people to whom the body owes a duty of care.

<sup>7</sup> DH guidance to the NHS on permission for R&D is available at [www.dh.gov.uk](http://www.dh.gov.uk).

<sup>8</sup> or anyone acting on the university's behalf

protocol takes account of known risks associated with the medicines under investigation. It also confirms there are arrangements allocating or delegating all the legal responsibilities relating to the initiation and management of the trial, and to pharmacovigilance.

### **Product liability**

17. Under the Consumer Protection Act 1987, when a defect in a medicinal product causes harm, a manufacturer is strictly liable. It is no defence for the manufacturer to show he took reasonable care<sup>9</sup>. This strict liability may apply if an NHS body or university manufactures the product, as part of a research programme.
18. The NHS Litigation Authority's risk pooling scheme covers NHS bodies' product liability<sup>10</sup>. NHS bodies may ask to be indemnified if they are required to manufacture or supply products in circumstances that would make them liable. Pharmaceutical companies may provide a warranty when supplying products that will not be altered.
19. Under the UK Regulations, *investigational medicinal products* have to be supplied and packaged according to Good Manufacturing Practice, reducing the risk of product liability.

### **Non-negligent harm**

20. The EU Directive does not require no-fault compensation. It requires insurance or indemnity covering liabilities of the sponsor and investigator<sup>11</sup>. This refers to cover for legal liability, such as liability for negligence, under the Consumer Protection Act, or in contract. No-fault compensation is compensation when there is no legal liability.
21. The UK Regulations make ethics committees 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 in each trial whether it is acceptable to seek consent without no-fault compensation, given the risks.
22. As sponsors, pharmaceutical companies normally offer a standard form of commitment about compensation<sup>12</sup>. In effect, it offers no-fault compensation in case of personal injury resulting from clinical research. It excludes harm caused by the negligence of an NHS body, its staff or agents. It applies when the study is conducted according to the protocol, and the sponsor is notified and has control of any offer of compensation.

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<sup>9</sup> The manufacturer may be able to rely on the "development risks" defence in section 4(1)(e) of the Act, particularly where the product is at the early stages of research.

<sup>10</sup> There are exemptions regarding income generation activities.

<sup>11</sup> Under the UK Regulations, NHS indemnity and risk-pooling arrangements meet this requirement for NHS sponsors or NHS investigators.

<sup>12</sup> The ABPI's Clinical Trial Compensation Guidelines recommend the assurance ABPI members provide, without legal commitment through the investigator to the ethics committee.



23. Universities initiating similar studies may have clinical trials insurance that offers both negligence cover and no-fault compensation for personal injury arising from the design of the study. This insurance also normally excludes clinical negligence for which NHS bodies are liable.
24. NHS Indemnity does not offer no-fault compensation. Public bodies, including DH, the MRC and NHS bodies, are unable to agree in advance to pay compensation for non-negligent harm. They are able to consider an ex-gratia payment in the case of a claim.