

Indemnity for MRC research

The MRC will give sympathetic consideration of claims for any non-negligent harm suffered by an individual as a consequence of their participation in an MRC sponsored study. This does not extend to liability for non-negligent harm arising from conventional treatment where this is part of the trial, nor for any breach in the NHS Lothian's duty of care, nor for any negligence on the part of NHS Lothian employees.

Research sponsors and indemnity

All research conducted within the NHS in Scotland must have a nominated Sponsor. The Sponsor is responsible for ensuring that the proposed research respects the dignity, rights, safety and well-being of participants. NHS bodies must ensure that an appropriate Sponsor, is identified for all the activity which they host.

If an appropriate formal agreement is in place, a Sponsor may devolve responsibility for overseeing particular aspects of quality (e.g. monitoring systems) to another body. Sponsors should ensure that appropriate arrangements for indemnity are in place. The EU Directive should not impact on the usual indemnity arrangements outlined in this leaflet.

Indemnity & Research Ethics Applications

The Research Ethics application form asks specifically about what arrangements are in place to provide compensation for negligence and non-negligence. Negligent indemnity is provided by employer/honorary employer, provided they have approved the activity. If no arrangements for non-negligent indemnity has been made, then write this on the form. Ensure that your patient information sheets make this clear.

Contacts and Information

NHS Lothian - University Hospitals Division, R&D Office

Telephone: 0131 242 3330

Email: R&DOffice@luht.scot.nhs.uk

Edinburgh Research & Innovation (ERI)

Telephone: 0131 650 9090

Email: Research.Innovation@ed.ac.uk

The Medical Research Council (MRC)

For information regarding indemnity issues and MRC, please see the MRC website.

Web: <http://www.mrc.ac.uk>

CNORIS

The CNORIS website has a very good FAQ section as well as general information regarding the CNORIS scheme.

Web: <http://www.cnoris.com>

Chief Scientist Office (CSO)

The CSO website has information on research governance and the role of sponsor.

Web: <http://www.show.scot.nhs.uk/cso/>



Indemnity

University Hospitals Division (UHD) is dedicated to supporting high quality, well governed, service relevant research. Before any research can take place within UHD it is important that appropriate indemnity is in place.

This booklet is designed for all researchers who are concerned about indemnity issues. It provides information on the following:

- NHS indemnity (CNORIS scheme)
 - Clinical academics and non-NHS Lothian staff
 - Medical research
 - Negligent and non-negligent harm
 - Patients and healthy volunteers in research
 - Student research
 - Research involving drugs or medical devices
 - Additional cover
- Indemnity cover for commercial research
- Indemnity cover for MRC funded research
- Research sponsors and indemnity

CNORIS (Clinical Negligence and Other Risks Indemnity Scheme)

CNORIS is a not-for-profit mutual scheme, created by the Scottish Executive in 2000, which provides NHS Health Boards and Special Health Boards in Scotland with indemnity against clinical risk arising from negligence (together with a number of non-clinical risks). The scheme is built around standards of Risk Management which member organisations must adhere to.

Clinical academics and other non-NHS Lothian staff

NHS Lothian is vicariously liable for the actions of staff in the course of their NHS duties. For this purpose, university employed staff, MRC employed staff or other non NHS Lothian employed staff who wish to participate in clinical research which will involve direct access to NHS Lothian patients, should ensure they hold an appropriate honorary contract with the NHS (for more information, contact the R&D Office).

Medical research

Medical research carried out by employees or honorary employees on behalf of the member organisation (i.e. with relevant local R&D Management approval) is included under the scheme. CNORIS only provides such cover if indemnity is not available from other sources.

Any income generation activity (including **commercial research**) is not covered under the CNORIS scheme. Indemnity for commercial research must be sought from other sources (see 'Indemnity for commercial studies')

Negligent and non-negligent harm

CNORIS provides indemnity against clinical negligence in NHS Scotland. It does not provide cover for non-negligence (e.g. harm caused by an unexpected side effect of participating in a study). The NHS is not able to take out commercial insurance against non-negligence. In exceptional circumstances, NHS bodies may consider whether an ex-gratia payment could be offered. However, the NHS cannot make ex-gratia payments for non-negligent harm if a non-NHS body is the research Sponsor.

Research ethics committees are responsible for advising whether the risk of non-negligent harm calls for the nominated research Sponsor to ensure that there are arrangements in place for compensation. The Sponsor must then ensure that such arrangements are made.

Patients and healthy volunteers in research

CNORIS does not provide indemnity against negligence in studies involving healthy volunteers. It is the responsibility of the Chief Investigator to ensure that appropriate provision is in place before such studies take place. This usually will involve making arrangements through the medical defence organisations or, for University employees, through University insurance.

Division staff asked to support such work will be covered by the CNORIS scheme for negligence, provided the study has appropriate Research Ethics committee approval and Local R&D Management approval.

Cover for students involved in research

Students' involvement in research is covered under CNORIS, provided they are under the supervision of a suitable NHS Lothian employee or honorary employee.

Research involving drugs or medical devices

If harm is caused by an unforeseen defect in either a drug or device, the liability rests with the manufacturer of that drug or device, rather than with the NHS body delivering the treatment. However, if such harm could have been predicted, CNORIS indemnity would apply.

Additional cover

Chief Investigators are responsible for obtaining appropriate indemnity cover with a professional defence organisation for any activity that is not covered by CNORIS (or, for University/MRC employees, that which falls out-with University/MRC insurance cover).

Indemnity for commercial research

Researchers involved in commercial research have a duty to ensure that the commercial company sponsoring the study provides full indemnity cover. This must be an NHS Lothian approved document, that adheres to the ABPI (Association of British Pharmaceutical Industries) format, and provides indemnity cover from the Company to NHS Lothian, or indemnity cover from the Company to NHS Lothian and the University of Edinburgh (in the case of University of Edinburgh employees).

Such agreements must be signed on behalf of NHS Lothian by an authorised signatory.

Researchers should contact the R&D Office as early as possible when negotiating their participation in a commercial research study.