

Research, Indemnity and GP Practices – Advice Sheet

Independent Contractors

NHS indemnity for clinical negligence does not cover independent contractors or the staff they employ. Medical Defence Organisations (MDOs) provide cover for clinical negligence for GP practices. Independent contractors must check their professional and practice indemnity extends to cover research activities. (Department of Health 2005)

Where Independent Contractors are taking part in research in their role as the ‘organisation providing care’, the activity can be interpreted as part of their routine professional practice in delivering clinical services. Professional indemnity will normally provide adequate cover for research procedures which are equivalent to services normally offered by the practitioner to their NHS patients, for example.

- 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 normal care within their clinical practice

(NHS R&D Forum 2005, NHS Health Research Authority 2017)

When acting as a Participant Identification Centre (PIC) or as a Spoke practice in a Hub and Spoke model, the General Practice’s liability will be limited to following the protocol on initial selection of patients and also maintaining confidentiality of the selected patients until they have consented to participate in the research.

Where an Independent Contractor is the Chief Investigator, Principal Investigator or undertaking research with patients outside their routine clinical practice or from another GP practice (in the role of a hub in a hub and spoke model for research), they should discuss with their MDO whether they need to take out any additional cover, prior to commencing a research study. (NHS R&D Forum 2005, NHS Health Research Authority 2017)

Research Sponsor

The research sponsor ensures that appropriate 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. (NHS R&D Forum 2005)

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. Pharmaceutical companies organise clinical trial agreements with individual GP 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). (NHS R&D Forum 2005)

References

Department of Health (December 2005) *Research in the NHS: indemnity arrangements*. Gateway reference: 5957

NHS R&D Forum (January 2005) *Indemnity arrangements within Primary Care – who is responsible for what?*

NHS Health Research Authority (January 2017) *Standard Operating Procedures for Research Ethics Committees – Version 7.2 page 282-4*

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This advice sheet has been developed from the published information available in March 2017.