A76 Insurance/indemnity to meet potential legal liabilities

A76-1 What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research?

This question relates to the responsibilities of the Research Sponsor.

Where the University is the Research Sponsor and has not delegated any of its Sponsorship duties to any other party the answer shown below should be correct.

If any sponsorship responsibilities (e.g. for research participant safety or data security) have been delegated to other parties by the University; please contact the Insurance Officer for advice on how to answer this question.

Check the 2nd box (Other insurance or indemnity arrangements will apply) and add:

The University of Bristol has arranged Public Liability insurance to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from management of the research by the University.

This does not in any way affect an NHS Trust’s responsibility for any clinical negligence on the part of its staff (including the Trust’s responsibility for University of Bristol employees acting in connection with their NHS honorary appointments). (Delete this 2nd paragraph if not applicable e.g. if your research takes place on University premises and/or involves no clinical intervention by the NHS).

A76-2 What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research?

This question relates to the responsibilities of the protocol author. Where the protocol is owned by the University, please use the specimen answer below. If not, the organisation responsible for the protocol should answer this question.

If the University of Bristol designed the protocol then check the 2nd box (Other insurance or indemnity arrangements will apply) and add:
The University of Bristol holds Professional Negligence insurance to cover the legal liability of the University, for harm to participants arising from the design of the research, where the research protocol was designed by the University.

A76-3 What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

This question relates to the liabilities of those carrying out the research intervention.

This is difficult as in many cases the intervention may be carried out by a number of different parties, some University employees or students, some not, or by University employees undertaking clinical duties as part of an NHS honorary contract.

Separating these different strands may be complex. In most cases, the answer below should be sufficient but if in any doubt, please contact the Insurance Office for advice.

Check the 2nd box (Research includes non-NHS sites (give details of insurance/indemnity arrangements for these sites below) and add:

The University of Bristol’s Public Liability insurance policy provides an indemnity to our employees for their potential liability for harm to participants during the conduct of the research.

This does not in any way affect an NHS Trust’s responsibility for any clinical negligence on the part of its staff (including a Trust’s responsibility for University of Bristol employees acting in connection with their NHS honorary appointments).

(Delete this 2nd paragraph if not applicable e.g. if your research takes place on University premises and/or involves no clinical intervention by the NHS).

Option a) Use for clinical research within NHS Hospital Trusts. Add: Professor X/Doctor Y/Nurse Z/Student A holds an honorary appointment with # NHS Hospital Trust giving him/her the protection of the NHS indemnity scheme.

Option b) Use for clinical research outside an NHS Hospital Trust (including Primary Care). Add: Professor X/Doctor Y has the protection of medical malpractice indemnity with MDU/MPS/DDU/DDS (delete as applicable).

Option c) Use where there is a collaborating institution

The University of Bristol’s insurance policies do not provide an indemnity to collaborators or Site Management Organisations (delete as applicable). As Research Sponsor we will ensure as far as reasonably practicable at the outset of the study that collaborators/SMOs (delete as applicable) hold appropriate legal liability insurance.

The committee are referred to the attached letter from the University’s Insurance Officer confirming details of our current insurance, including the limits of indemnity.

A76-4 What arrangements will be made for insurance and/or indemnity to meet any potential legal liability for harm to participants arising from any aspect of the research?
This question seems intended to pick up any aspects of the research that may cause harm to participants other than arising from the design, management or conduct of the trial.

Circumstances will vary but it would appear the question is concerned with circumstances where other parties or factors could be involved e.g. manufacturers of products or equipment being tested or being used as part of a clinical intervention.

Where such circumstances exist, please contact the Insurance Officer for advice. Otherwise, please state:

The committee are referred to the attached letter from the University’s Insurance Officer confirming details of our current insurance, including the limits of indemnity.

**A77 Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?**

ALWAYS ANSWER "NO" TO THIS QUESTION OR CONTACT THIS INSURANCE OFFICER FOR ADVICE. Always contact the Insurance Officer for advice in respect of a drug trial.