

SPECIMEN ANSWERS TO INSURANCE/INDEMNITY QUESTIONS ON IRAS APPLICATION

Please copy and paste responses into the form as appropriate. Refer any queries to insurance@bath.ac.uk or telephone Simon Holt on 01225 385129

Only use these answers if University of Bath is the research sponsor and it is not a drugs trial

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? Please tick box(es) as applicable.

Check the 2nd box (*Other insurance or indemnity arrangements will apply*) and add:
The University of Bath 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 BATH 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? Please tick box(es) as applicable.

If the University of Bath designed the research then check the 2nd box (*Other insurance or indemnity arrangements will apply*) and add:
The University of Bath holds Professional Indemnity insurance to cover the legal liability of the University as Research Sponsor and/or as the employer of staff engaged in the research, 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?

Check the 2nd box (*Research includes non-NHS sites (give details of insurance/indemnity arrangements for these sites below)*) and add:
The University of Bath's Public Liability and Professional Indemnity insurance policies provide an indemnity to our employees for their potential liability for harm to participants during the conduct of the research.

Again, 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 Bath 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 also 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 (delete as applicable).

Option c) Use where there is a collaborating institution
The University of Bath'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.

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 is rarely used. Refer to Simon Holt if you are required to give an answer. It will probably be a case of simply confirming existing insurance arrangements.

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 – refer to Simon Holt circumstances require you to answer Yes.

RELEVANT DOCUMENTS

Evidence of insurance cover is available to download at www.bath.ac.uk/insurance/liability

Any questions at all should be referred to :-

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