## Arranging Insurance for Research Involving Human Subjects

*Details of the insurance cover available are included below as Annex 1.*

*A copy of the Insurance Assessment Form is attached as Annex 2.*

1. Investigators are asked to complete an Insurance Assessment Form designed to identify whether the planned project falls into a lower or higher risk category.

If in doubt about the answer to a particular question, the investigator should err on the side of caution and answer “Yes”.

2. The investigator should submit the competed Form with the project proposal to the appropriate administrative office. *[The Form can be adapted to provide appropriate instructions.]*

3. The administrators should review the Form.

If the answers to all the questions are “No” the project falls into the lower-risk category and insurance cover will be provided automatically, subject to ethics and contractual approval.

If the answer to any of the questions is “Yes” the project falls into the higher risk category and will need to be referred to the Insurance Office before insurance cover can be confirmed. The administrator should forward the Form and a copy of the proposal to the Insurance Office (Lucy.Lynch@manchester.ac.uk) – electronic copies are preferred. Documentation to be provided would normally consist of copies of the protocol, participant information sheets and consent form.

4. The Insurance Office will refer the proposal to the insurers and endeavour to obtain a response within 7 days. Once clearance has been received, the Insurance Office will sign the Form *[possibly electronically]* and return it to the administrative office concerned.

5. The Form (unsigned if lower risk or signed if higher risk) should accompany the proposal to the appropriate ethics committee and a copy be kept with the papers relating to the project.

MARTIN HAMPAR

Insurance Office

**Annex 1 - Insurance for Research Involving Human Subjects**

### Insurance Cover

The University provides insurance for research involving human subjects covering:

harm to participants, normally on a “no-fault” or “non-negligent harm” basis, and

financial loss by participants and participating organisations, on a liability basis.

This cover is available for research sponsored, managed, designed or conducted by, or on behalf of, the University (including research undertaken by students under appropriate supervision). Further details of the cover are provided in Appendix 1, below and a description of the no-fault cover is given in Appendix 2, below.

The insurance cover is subject to approval by an appropriate ethics committee, and approval of any contract terms by the University’s Contracts Office.

#### Research undertaken in the United Kingdom

The insurance provides automatic cover for research undertaken in the United Kingdom that is relatively low risk, but requires that higher-risk projects are reviewed on an individual basis before cover is confirmed (the definition of higher-risk projects is given in Appendix 3, below).

#### Research undertaken overseas

Research undertaken wholly or partially outside the UK (including internet-based research that could include respondents from overseas) is considered to be higher-risk and needs to be approved on a an individual basis before cover is confirmed.

Most overseas countries have specific requirements that insurance for research involving human subjects must comply with specific legal requirements (that may differ from those required in the UK) and/or must be arranged locally. In some countries, it may be possible to obtain a dispensation from a requirement that cover is taken out locally (although this can be a time-consuming process).

Where there is no requirement for specific or local cover, or a where a dispensation has been obtained, the University’s insurance will apply, but only on a legal liability basis.

Otherwise, insurance cover will need to be arranged locally on a case-by-case basis, before the research starts. This can be both time-consuming and expensive. The cover would be designed to meet the specific legal requirements of the jurisdiction concerned (which may or may not include a requirement for no-fault compensation). Alternatively, where research is undertaken with an overseas partner, local insurance can be arranged by the partner organisation.

### Insurance Confirmation Arrangements

The Insurance Assessment Form has been developed to enable proposers/investigators to determine whether a project needs to be referred to the Insurance Office. The proposers/investigators should compete the form (and undertake any actions arising as a result) before the proposal is signed-off by the University or submitted to the NHS NRES or Pan-Man systems. If the project is assessed as being low-risk, there will be no requirement to submit details to the Insurance Office.

Although the Insurance Assessment Form is free-standing, it may be incorporated in other documentation or an on-line system if appropriate.

### Appendix 1 – Insurance Cover for Research Involving Human Subjects

Insurance cover for research involving human subjects is provided under several insurance policies.

* **Clinical Trials** insurance provides no-fault compensation in the case of harm to participants in research involving human subjects.

The limit of liability is £5,000,000 per annum, with an excess of £5,000 per claim.

* **Professional Indemnity** insurance provides cover for financial loss for which the University is legally liable that is sustained by individuals or organisations involved in research involving human subjects.

The limit of liability is £10,000,000 per claim (except £2,000,000 per annum in North America), with an excess of £20,000 per claim.

* **Public Liability** insurance provides liability-only cover for injury or loss for which the University is legally liable, excluding investigations conducted on any person for a medicinal purpose (see Appendix 4 for a fuller definition of the exclusion).

The limit of liability is £50,000,000 per incident, with no annual limit (except for cover of £10,000,000 per year in the USA or Canada). There is no excess.

Cover under these insurance policies is available for research sponsored, managed, designed or conducted by or on behalf of the University.

### Appendix 2 – No-fault Cover

No-fault cover provides for the payment of compensation (and associated costs) to research subjects who suffer a physical or mental injury as a result of their participation.

The insurance policy specifies arrangements for determining the level of compensation offered. The claimant has to establish that injury has occurred as a result of the research, but does not have to establish liability.

Any decision under the no-fault arrangements is binding on the insurers but not on the claimant. If the claimant does not accept the no-fault compensation offer the cover reverts to legal liability. In this case the claimant would have to establish both that an injury has occurred and that the University is liable.

The no-fault process is subject to a confidentiality clause. Any information disclosed by the parties at the no-fault hearing cannot be relied upon if the matter reverts to a legal liability claim.

In the case of a claim for no-fault compensation there is no question of a claim against individuals. In the case of a legal liability claim, the University’s insurance will cover staff and students acting in the course of their duties/studies, and members of University ethics committees carrying out their duties.

### Appendix 3 – Higher-Risk Research

The Clinical Trials insurers identify certain research to be “higher risk” as follows:

research:

* involving “first into man” use of a medicinal product

research involving vulnerable groups, specifically:

* pregnant women
* children aged five or under
* adults who lack the capacity to give informed consent

research that involves:

* medical devices
* contraception

research carried out by other organisations where the University is required by contract to provide Clinical Trials insurance cover.

### Appendix 4 – Medicinal Purpose

Under the University’s insurance cover, the term “medicinal purpose” is taken to mean:

* treating or preventing disease
* diagnosing disease or ascertaining the existence, degree of, or extent of a physiological or psychological condition
* assisting with or altering in any way the process of conception or investigating or participating in methods of contraception
* inducing anaesthesia

otherwise preventing or interfering with the normal operation of a physiological or psychological function in order to improve health or wellbeing.

Research Involving Human Subjects



## Insurance Assessment Form

The University provides insurance cover in respect of research involving human subjects undertaken in the United Kingdom for:

* harm to participants, on a “no-fault” or “non-negligent harm” basis, and
* financial loss by participants and participating organisations, on a legal liability basis.

The University also provides insurance cover in respect of research involving human subjects undertaken abroad that does not have a medical content, on a legal liability basis.

Special arrangements are normally required for research involving human subjects undertaken abroad that has a medical content.

For these purposes, medical content means:

* treating or preventing disease
* diagnosing disease or ascertaining the existence, degree of, or extent of a physiological or psychological condition
* assisting with or altering in any way the process of conception or investigating or participating in methods of contraception
* inducing anaesthesia
* otherwise preventing or interfering with the normal operation of a physiological or psychological function in order to improve health or wellbeing
* testing medicinal products or devices, or
* taking tissue or blood samples.

The insurance cover is available for research sponsored, managed, designed or conducted by, or on behalf of, the University (including research undertaken by students under supervision). For further details, visit <http://www.campus.manchester.ac.uk/insurance/professional-activities/humansubjects>.

If you answer “No” to all the questions below, you may assume that cover will be provided by the University, subject to approval of the research by an appropriate ethics committee, registration of final ethics approval with the University Ethics Office and approval of any contract terms by the University Contracts Office.

If you answer “Yes” to any of the questions the proposal will need to be considered by the Insurers as part of the review process by the Research Office. If insurance cover is confirmed you will be provided with a copy of this form signed by the Insurance Office. Cover will be subject to approval and registration as above.

If you have any doubts about whether the answer to a question should be “Yes” or “No”, answer “Yes”.

|  |  |
| --- | --- |
| Title of Research: |  |
| Principal investigator: |  |
| School: |  |

|  |  |  |
| --- | --- | --- |
| Question | | Yes/No |
| If any part of the research, or use of the protocol, is to be carried out outside the UK (including internet-based research that could include respondents from abroad), does it have a medical content? | |  |
| Does the research involve “first into man” use of a medicinal product? | |  |
| Do the research subjects deliberately include: | * pregnant women? |  |
|  | * children aged five or under? |  |
|  | * adults who lack the capacity to give informed consent? |  |
| Does the research include medical intervention involving: | * investigating a medical device? |  |
|  | * contraception? |  |
| Is the research to be carried out by other organisations where the University is required by contract to provide insurance cover for the research if it proceeds? | |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Signed (PI): |  | Date: |  |

This form should accompany the proposal when it is submitted to the Research Office for review.

|  |  |  |  |
| --- | --- | --- | --- |
| Insurance Office approval (not required if all answers above are ‘No’) | | | |
| Signed: |  | Date: |  |