

## 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:	<ul style="list-style-type: none"> <li>• pregnant women?</li> </ul>
	<ul style="list-style-type: none"> <li>• children aged five or under?</li> </ul>
	<ul style="list-style-type: none"> <li>• adults who lack the capacity to give informed consent?</li> </ul>
Does the research include medical intervention involving:	<ul style="list-style-type: none"> <li>• investigating a medical device?</li> </ul>
	<ul style="list-style-type: none"> <li>• contraception?</li> </ul>
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: \_\_\_\_\_