

**Application form for ethical approval of a research project by a**

**University Research Ethics Committee**

The University Research Ethics Committees meet on a weekly basis between September and July each year. All applications must be submitted to your School/Institute Signatory by the end of June or it will not be considered until September. Please see the link below for the calendar of UREC meetings. The normal expectation is that your application will be reviewed in the third week after submission by the School/Institute Signatory. Please note that the School/Institute signatory process aims to take an average of 10 working days:

<http://www.staffnet.manchester.ac.uk/services/rbess/governance/ethics/howtoobtainethicalapprovalfromurecornres/urecmeetingtimetable/>

**Guidance on completing the form**

This form should be completed by the Principal Investigator(s). For student research, the Supervisor must provide guidance to the student on the application and sign off the form.

Guidance can be found by clicking on the links provided with some sections. Additionally, guidance can be found here:

<http://www.staffnet.manchester.ac.uk/services/rbess/governance/ethics/howtoobtainethicalapprovalfromurecornres/>

The form must be completed **succinctly** and in **plain, jargon-free English** so that committee members, who may not be familiar with your academic discipline, are able to understand it.

Applicants are asked to forward all supporting papers in **one document**, preferably in a PDF format. Experience indicates that it is easy for separate documents to get misplaced as they are transferred from one office to another during the review process.

**Submitting the form**

Your form must be submitted to the UREC via your assigned School/Institute Signatory. Please see the link below for a list of current Signatories:

<http://www.staffnet.manchester.ac.uk/services/rbess/governance/ethics/howtoobtainethicalapprovalfromurecornres/listofschoolsignatories/>

**Checklist of documentation to include**

**Please DO NOT include CVs**

|  |
| --- |
|[ ]  **Participant Information Sheet** |
|[ ]  **Consent form** |
|[ ]  **Letters to gatekeepers (i.e. those from whom permission is required such as employer or data custodian) if applicable** |
|[ ]  **Questionnaire (if using)** |
|[ ]  **Interview/focus group schedule (if using)** |
|[ ]  **Any advertisements/flyers/posters to be used** |
|[ ]  **Research Protocol (if applicable)** |

***Please note:*** *The UREC will decide based on the information provided in the form and any approval will relate to this information only. If you have a separate research protocol it* ***must*** *be consistent with the information in the form.*

**Insurance Questions**

**Please answer the following questions. If in doubt, err on the side of caution and answer yes. If you answer yes to any of the questions below then your application, Participant Information Sheet and Consent form will be forwarded to the Insurance Office by the Research Governance, Ethics and Integrity team. For additional guidance for completing the Insurance Questions, please see Appendix 1.**

|  |  |
| --- | --- |
| 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: |  |

**SECTION A – Administrative information**

**\*\* Do you also need to obtain NHS R&D approval?**

**[ ]  Yes [ ]  No**

**\*\*If yes, have you already contacted your** [**University sponsor**](http://www.staffnet.manchester.ac.uk/services/rbess/governance/ethics/guidanceonthenresapplicationsystem/) **regarding NHS R&D approval?**

**[ ]  Yes [ ]  No**

**IMPORTANT: You MUST contact your University sponsor regarding NHS R&D approval PRIOR to submitting a UREC application. Any UREC applications submitted prior to contacting your University sponsor will be returned.**

**1. Title of the research:**

**2. Investigator(s)** *(nb. In the case of postgraduate student applications the supervisor is always the joint investigator):*

|  |  |  |
| --- | --- | --- |
|  | Student | Supervisor/Staff |
| Title |  |  |
| Surname |  |  |
| First name |  |  |
| Post |  |  |
| Qualifications |  |  |
| School/Unit |  |  |
| Contact Address |  |  |
| Email address |  |  |
| Telephone |  |  |

**3. School contact (if applicable): The School/Institute Signatory will receive a copy of the outcome of the ethical review,** *If the School wishes anyone else to receive a copy, the relevant details should be entered here.*

**Name:**

**Post:**

**Email address:**

**4. Is this study, or any part of this study a student project?** Yes/No

 **If Yes what degree is it for?**

**5. Please provide the names and email addresses of any academic staff or students involved, other than those named at 2 above:**

**SECTION B – Details of Project**

**6. When will the data collection take place?**

 **Start date:**

 **End date:**

**7. What is the principal research question?**

**8. What is the academic justification for the research?** *(Must be in language comprehensible to a lay person)*

**9. Give a brief summary of the design and methodology of the planned research. It should be clear exactly what will happen to the research participant, how many times and in what order. Describe any involvement of research participants, participant groups or communities in the design of the research.** *(This section must be completed in language comprehensible to the lay person and should be no longer than half a page*. *If there is a full research proposal or protocol it should be appended to the application, but it does not replace the information given in this section)*

**10. How has the scientific quality of the research been assessed?** *(Tick all that apply)*

|  |  |
| --- | --- |
| [ ]  | Internal review (e.g. involving colleagues, academic supervisor) |
| [ ]  | Review within a multi−centre research group |
| [ ]  | Independent external review |
| [ ]  | Review within a commercial company |
| [ ]  | None external to the investigator |
| [ ]  | Other, e.g. in relation to methodological guidelines*(give details below)* |

*If relevant, describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:*

**11.1 Does the research involve the administration of any physically invasive procedures, physical testing or psychological intervention (apart from the administration of standard psychological tests)?**

**[ ]  Yes** **[ ]  No**

**If No, proceed to 11.2 If Yes, please ensure you complete Section F**

**11.2 Does the research involve interviewing participants or focus groups?**

 **[ ]  Yes [ ]  No**

**If No, proceed to 11.3**

**If Yes, please describe briefly how they will be conducted**

**11.3 Does the research involve the administration of questionnaires?**

**[ ]  Yes** **[ ]  No**

**If No, proceed to 11.4**

**If Yes, please describe the process of delivery and collection**

**11.4 Is statistical sampling relevant to this research?**

**[ ]  Yes** **[ ]  No**

**If No, proceed to 11.5**

**If Yes, please answer the following questions:**

 **11.4.1 Has the protocol submitted with this application been the subject of review by a statistician independent of the research team? Select one of the following:**

[ ]  Yes – copy of review enclosed

[ ]  Yes - details of review available from the following individual or organisation (give contact details)

[ ]  No – justify below

**11.4.2 If relevant, specify the statistical experimental design and why it was chosen.**

 **11.5 If you are not using statistical sampling how was the number of participants decided upon?**

**11.6**  **Describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.**

**12.1 What do you consider to be the main ethical issues which may arise with the proposed study?**

**12.2 What steps will be taken to address the issues raised in question 12.1?**

**12.3 What qualifications/experience do the researchers have relevant to the conducting of this research?**

**(For details about requirements for specific types of research, please see** <http://www.staffnet.manchester.ac.uk/services/rbess/governance/ethics/howtoobtainethicalapprovalfromurecornres/requiredtraining/>**)**

**13. Has this or a similar application been previously considered by a Research Ethics Committee in the UK, the European Union or the European Economic Area?**

⭘ Yes

⭘ No

*If Yes give details of each application considered, including:*

**Name of Research Ethics Committee or regulatory authority:
Decision and date taken:
Research ethics committee reference number:**

**SECTION C – Details of participants**

**14. How many participants will be recruited?** *(If there is more than one group, state how many participants will be recruited in each group. For international studies, say how many participants will be recruited in the UK and in total. Please ensure you clearly state the total number of participants)*

**15. Age range of participants:**

**16. What are the principal inclusion criteria for participants?** *(Please justify)*

**17. What are the principal exclusion criteria for participants?** *(Please justify)*

**18.1 Will the participants be from any of the following groups? *(Tick all that apply)***

|  |  |
| --- | --- |
| ***[ ]***  | Adult healthy volunteers (i.e. not under medical care for a condition which is directly relevant to the application) |
| ***[ ]***  | Children under 16 |
| ***[ ]***  | Adults with learning difficulties |
| ***[ ]***  | Adults who have a terminal illness |
| ***[ ]***  | Adults with mental illness (particularly if detained under mental health legislation) |
| ***[ ]***  | Adults with dementia |
| ***[ ]***  | Adults in care homes |
| ***[ ]***  | Adults or children in emergency situations |
| ***[ ]***  | Prisoners |
| ***[ ]***  | Young offenders |
| ***[ ]***  | Those who could be considered to have a particularly dependent relationship with the researcher, e.g. students taught or examined by the researcher. |
| ***[ ]***  | Other vulnerable groups |

***Please note:*** *If an adult participant is not able to give informed consent (eg through mental capacity or is unconscious) or if a prisoner or young offender is involved in health related research ethical review should be undertaken by an appropriate NHS Research Ethics Committee*.

**18.2 If you will be using participants other than healthy volunteers please justify their inclusion:**

**19. How will the potential participants be identified, approached and recruited?** *(Where research participants will be recruited via advertisement, please append a copy to this application)*

**20. Will any research participants be recruited who are involved in existing research or have recently been involved in any research prior to recruitment?**

[ ]  Yes [ ]  No [ ]  Not known

*(If yes, give details and justify their inclusion. If Not known, please state what steps will you take to find out)*

**21. Will individual research participants receive *reimbursement of expenses* or any other *incentives* or *benefits* for taking part in this research?**

[ ]  Yes [ ]  No

*(If yes, indicate how much and on what basis this has been decided)*

**22. What is the expected total duration of participation in the study for each participant?** *For ethnographic research focussing on one or more groups rather than individual participants, indicate the approximate period of time over which research will focus on particular groups*

**23. What is the potential benefit to research participants?**

**24. Will any benefit or assistance, which the participant would normally have access to, be withheld as part of the research?**

[ ]  Yes [ ]  No

*(If yes, give details and justification)*

**SECTION D – Consent**

**25.1 Will informed consent be obtained from the research participants?**

[ ]  Yes [ ]  No

*If Yes, give details of how consent will be obtained. Give details of your experience in taking consent and of any particular steps to provide information to participants before the study takes place eg information sheet, videos, interactive material.*

*If participants are recruited from any of the potentially vulnerable groups listed in Question 19.1, give details of extra steps taken to assure their protection. Describe any arrangements to be made for obtaining consent from a legal representative.*

*If consent is not to be obtained, please explain why not.*

**25.2 Will a signed record of consent be obtained?**

[ ]  Yes [ ]  No

*If not, please explain why not. Please append any* [*consent forms*](http://documents.manchester.ac.uk/display.aspx?DocID=19044) *to this application.*

**26. How long will the participant have to decide whether to take part in the research? (***If less than 24 hours please justify***)**

**27. What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters etc.)***

**SECTION E – RISKS AND SAFEGUARDS**

**28. Activities to be undertaken (***This should be in the form of a brief list, such as answering a questionnaire, being interviewed***)**

**29. Where will the research/data collection take place?**

**30.1 What are the potential adverse effects, risks or hazards for research participants, including potential for pain, discomfort, distress, inconvenience or changes to lifestyle for research participants? Are they any greater than those that would arise from normal social interaction?**

**30.2 Could individual or group interviews/questionnaires raise any topics or issues that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could take place during the study (e.g. in the application of screening tests for drugs)?**

[ ]  Yes [ ]  No

***If yes, provide your distress policy/give details of procedures in place to deal with these issues:***

**30.3 What precautions have been taken to minimise or mitigate the risks identified above?**

**31.1 What is the potential for adverse effects, risks or hazards, pain, discomfort, distress, or inconvenience to the researchers themselves? *(If any)***

**31.2 What precautions have been taken to minimise or mitigate the risks identified above?** (*If the research means working alone in a location which is not public, semi-public or otherwise risk-free, please describe your lone worker policy or append a copy*)

**32. The University will automatically provide indemnity and/or compensation for most approved studies, but you should complete the Insurance Section on page 1 of this form and consult the** **University Procurement Office** **if necessary. If another body or institution is providing insurance or indemnity please provide details below.**

**33. Please confirm that any adverse event requiring a radical change of method or design, or even abandonment of the research, will be reported to the Committee.**

**SECTION F – MEDICAL INTERVENTION**

**This section need only be completed by applicants whose project involves any form of medical or other therapeutic intervention or any physically invasive procedures, physical testing or psychological intervention (apart from the administration of standard psychological tests) (i.e. you answered ‘Yes’ to question 12.1)**

**34. Drugs and other substances to be administered (if applicable)**

*Indicate status, eg full product licence, CTC, CTX. Attach: evidence of status of any unlicensed product; and Martindales Phamacopoeia details for licensed products*

DRUG STATUS DOSAGE/FREQUENCY/ROUTE

 **35. Procedures to be undertaken**

 *Details of any invasive procedures, and any samples or measurements to be taken. and/or any psychological tests etc. What is the experience of those administering the procedures?*

**36. Will any procedures which are normally undertaken be withheld?**

**37.1 Will the research participants’ General Practitioner be informed that they are taking part in the study?**

[ ]  Yes [ ]  No

*If No, explain why not*

**37.2 If you answered yes to question 37.1, will permission be sought from the research participants to inform their GP before this is done?**

[ ]  Yes [ ]  No

*If No, explain why not*

**38. What are the criteria for electively stopping research prematurely?**

**SECTION G – Data protection and confidentiality**

**39.1. Will the research involve any of the following activities at any stage (including identification of potential research participants)?** *(Tick all that apply)*

Storage of personal data on any of the following:

|  |  |
| --- | --- |
| [ ]  | Storage of personal data on manual files |
| [ ]  | Storage of personal data on laptops or other personal computers |
| [ ]  | Storage of personal data on University computers |
| [ ]  | Storage of personal data on NHS computers |
| [ ]  | Storage of personal data on private company computers |
| [ ]  | Use of audio/visual recording devices |
| [ ]  | Use of personal addresses, postcodes, faxes, e-mails or telephone numbers |
| [ ]  | Electronic transfer by magnetic or optical media, e-mail or computer networks |
| [ ]  | Examination of medical records by those outside the NHS, or within the NHS by those who would not normally have access |
| [ ]  | Sharing of data with other organisations |
| [ ]  | Export of data outside the European Union |
| [ ]  | Publication of direct quotations from respondents |
| [ ]  | Publication of data that might allow identification of individuals |

**39.2 Please provide details of how you plan to store and protect the study data as stated in 39.1 above.**

**40. What measures have been put in place to ensure confidentiality of personal data? Give details of what encryption or other anonymisation procedures will be used and at what stage?** *Note: the* [*University requires*](http://documents.manchester.ac.uk/display.aspx?DocID=14914) *all personal data stored electronically to be held on wholly managed University servers or to be encrypted.*

**41. Where will the analysis of the data from the study take place and by whom will it be undertaken?**

**42.1 Who will control and act as the custodian for the data?** *Note: for a student project this must be a supervisor or a permanent member of staff*

**42.2 Who will have access to the data and where are they based?**

**42.3 Will the data be stored for use in future studies? If yes, has this been addressed in the consent process?**

**43. For how long will the data from the study be stored?**

Years

 *Note: the University requires non-medical data to be held for a minimum of 5 years and medical data to be held for a minimum of 10 years after the completion of the research. Some funding bodies require storage for longer periods.*

**44. What arrangements are in place to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?**

**45. What arrangements are in place for monitoring the conduct of the research by parties other than the researcher?**

 **Will a data monitoring committee be convened?**

[ ]  Yes

[ ]  Not relevant

**SECTION H – Conflict of Interest**

**46.1 Will individual *researchers* receive any personal payment over and above normal salary and reimbursement of expenses for undertaking this research?**

[ ]  Yes [ ]  No

*If Yes, indicate how much and on what basis this has been decided:*

**46.2 Does the principal researcher or any other investigator/collaborator have any direct personal involvement (e.g. financial, share-holding, personal relationship etc.) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?**

[ ]  Yes [ ]  No

If Yes, give details:

**47. Will the host organisation or the researcher’s department(s) or institution(s) receive any payment of benefits in excess of the costs of undertaking the research?**

[ ]  Yes [ ]  No

*If Yes, give details:*

**SECTION I - Reporting Arrangements**

**48. How is it intended the results of the study will be reported and disseminated?** *(Tick as appropriate)*

|  |  |
| --- | --- |
| [ ]  | Peer reviewed academic journals  |
| [ ]  | Book or contribution to a book |
| [ ]  | Other published outlets e.g. ESRC or Cochrane Review,  |
| [ ]  | Thesis/dissertation |
| [ ]  | Conference presentation |
| [ ]  | Internal report |
| [ ]  | Other e.g. deposition in University Library |

**49. How will the results of research be made available to research participants and communities from which they are drawn?**

|  |  |
| --- | --- |
| [ ]  | Presentation to participants or relevant community groups |
| [ ]  | Written feedback to research participants |
| [ ]  | Other e.g. videos, interactive website |

**50.1 Will dissemination allow identification of individual participants?**

[ ]  Yes [ ]  No

If No, proceed to 51

If Yes, indicate how these individuals’ consent will be obtained:

**50.2 Will dissemination involve publication of extended direct quotations from identified participants and/or distribution of audiovisual media in which identified participants play leading roles?**

[ ] Yes [ ]  No

If No, proceed to 51

If Yes, indicate how the participants’ possible Intellectual Property or Performance Rights in these outputs will be negotiated. Where relevant, attach a model of the release form that will be used.

**50.3 Are special arrangements needed to provide indemnity and/or compensation in the event of a claim by, or on behalf of, participants on grounds such as libel, breach of confidence and infringement of Intellectual Property or Performance Rights?**

**SECTION J – Funding and sponsorship**

**51. Has external funding for the research been secured?**

[ ]  Yes [ ]  No

If Yes, give details of funding organisation(s) and amount secured and duration:

**Organisation:**

**UK contact:**

**Amount (£):**

**Duration: Months**

**52. Name of organisation which will act as Sponsor for the research, if other than the University:**

***Note****: the University will normally act as Sponsor (ie responsible for the design, management and conduct of the research project by University staff and/or students), but in some cases of externally commissioned research the funder will be the Sponsor. If this is the case please provide details)*

**SECTION K – Confirmation of Application**

***Note: Student applications must also be signed by their supervisor***

**Signature(s) of applicant(s):**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_**

**SIGNATURE (Name in italics is sufficient) DATE**

**--------------------------------------------------------------**

**NAME AND POST OF APPLICANT (PLEASE PRINT)**

**Signature of supervisor (if applicable):**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_**

**SIGNATURE (Electronic signature is required) DATE**

**--------------------------------------------------------------**

**NAME AND POST OF SUPERVISOR (PLEASE PRINT)**

**Please note: Once complete, please submit this application form and ALL supporting documentation to your signatory for review. Please DO NOT send directly to** **Research.Ethics@manchester.ac.uk** **or your application will be returned to you.**

**Appendix 1**

## 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.