**School of Arts, Languages and Cultures - Research Ethics**

**Frequently asked questions**

**What are Research Ethics?**

Research Ethics is a world-wide set of principles governing the way any research involving interaction between the researcher and other humans or data relating to humans is designed, managed and conducted.

Research ethics has its origins in the medical world and the testing of new medicines and new techniques on patients and healthy volunteers (and in some cases forced subjects). Thus, some of the fundamental statements on research ethics, such as the Helsinki Declaration, originate from medical organisations. However, the same principles are now applied more widely to all human and social sciences where interaction with individuals or with defined groups, or confidential information about individuals, is involved.

What are the principles of Research Ethics?

Nowadays the principles of research ethics are grouped under the headings of Autonomy, Beneficence, Non-maleficence, Confidentiality and Integrity.

Autonomy

* because the participant must be free to take part in the research without coercion or penalty for not taking part;
* because the participant must be free to withdraw at any time without giving a reason and without a threat of any adverse effect.

Beneficence

* because the research must be worthwhile in itself and have beneficial effects that outweigh any risks; it follows that the methodology must be sound so that positive results will be yielded.

Non-maleficence

* because any possible harm must be avoided or mitigated by robust precautions

Confidentiality

* because the right of the participant and his/her personal data to remain unknown to all but the research team must be respected (unless the participant agrees otherwise).

Integrity

* because the researcher must be open about any gains he or she makes from the research.

**What is ethical approval?**

Research Ethics Committees are responsible for reviewing ethics applications in order to ensure that adequate consideration has been given to the ethical aspects of a research project thus reducing the potential for harm and upset to the participants.

An ethics committee will assess whether the research you propose can be considered ethical, i.e.

* Whether the research is justified, i.e. whether it is likely to add to the existing knowledge base;
* Whether it is of sufficient standard - including whether the researchers are qualified to carry out the roles proposed in the research proposal;
* Whether the risk it poses to participants is outweighed by the potential benefits of the research;
* Whether the research appears to comply with all statutory and other guidance;
* Whether data management and handling appears to comply with the relevant legislation (Data Protection Act 1998) and guidance (e.g. Research Governance Framework, NHS Code of Practice on Confidentiality; NHS Care Records Guarantee);
* Whether financial arrangements appear sound - it would be unethical to start research that may not be completed because insufficient funds were available.

**Does my project require ethical approval?**

It is up to staff, and research students in conjunction with their supervisors, to make an initial assessment of how their project potentially involves ethical considerations, and to consider whether or not to make an application for ethical approval.

The key principle here is that all research projects conducted by University staff or students that involve human participants in a way that might harm, disturb or upset them (however slight the possibility) or where they can be deemed to be in a vulnerable or disadvantageous situation, must receive approval from a recognised research ethics committee or a designated screening panel using an agreed Template at School level. No work on a research project that involves ethical issues can take place until pre-screening has been fully completed and, if required, formal ethical approval has been obtained.

If your research does involve contact with human participants, you must consider whether your research project complies with the SALC Ethics Template. The template allows the School of Arts, Languages and Cultures (SALC) to approve research that carries low risks for researchers and research participants. Research that presents low risk is defined as research that takes place in stable urban and rural environments, and that

* Engages with healthy adults;
* Engages with healthy children and young people under 16 years in a professional setting accredited to work with children and young people, such as a cultural institution, school or youth club, and *only* when the child/young person is accompanied by a parent/carer or professional with a duty of care. All participants must be able to give informed consent;
* Follows standard procedures and research methods relevant to its discipline;
* Does not require research participants to provide personal and sensitive information likely to lead to significant levels of distress (where the research topics are either not contentious or sensitive at all, or where a reasonable person would agree the topic is of legitimate interest and may result in distress in *rare* instances);

The Template adheres to accepted principles of informed consent and University regulations on data management and IT security.

**What is meant by ‘informed consent’?**

This means people able to give informed consent fully and freely. You must consider whether or not your research participants might be defined ‘vulnerable’ or ‘dependent’ according to the definitions below (provided by UREC). If the level of vulnerability or dependence is such that research participants cannot give informed consent fully and freely, your research will need to go forward to UREC for approval.

Vulnerable subjects are individuals whose willingness to volunteer may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior or powerful members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

Dependent subjects are those who cannot give informed consent because of limited autonomy, such as children and the mentally ill.

**What happens if my research does not comply with the SALC Ethics Template?**

If your research project does not comply with the template, then a University of Manchester Research Ethics Committee (UREC) ethical approval form must be completed and referred to UREC for approval. The SALC Research Ethics panel can offer guidance and support in preparing your application.

Research that **must** be reviewed by UREC includes research that involves the following:

a) Any form of physical risk or serious inconvenience to the subject or to any third party;

b) The administration of drugs or use of invasive or semi-invasive procedures;

c) Any risk of psychological damage or distress to the subject (or the subject’s family);

d) Privileged access to the subjects’ clinical records, or that may incur the risk of the disclosure of sensitive information about the subject disclosed by persons taking part in the investigation;

e) Participants deemed to be vulnerable or dependent or otherwise have an unequal relationship with the researcher;

f) The deception of research participants;

g) The use of tissue from living subjects (subject to the Human Tissue Act 2004)

i) Cadavers of or tissue from the recently dead, other than bequeathed cadavers and tissue obtained in the normal course of necropsy (subject to the Human Tissue Act 2004).

This is not an exhaustive list and if you have any doubts about whether you should seek advice.

In addition to the above, if your project involves a likelihood of danger to you above and beyond risks normally associated with research in your discipline you may be advised to apply for approval from UREC.

It is also vital that when completing your the application form for ethical approval that both you and your supervisor have read and understood the Full Application Guidance Notes and the general University Ethics Committee Guidelines (see useful links).

No work on a research project that involves ethical issues can take place until pre-screening has been fully completed and, if required, formal ethical approval has been obtained.

**Does every project involving human subjects require a full ethical review?**

As a general rule projects do not usually need to be submitted to UREC if they involve course evaluation, evaluation of teaching methods, the audit of secondary analysis of existing datasets, archives or other publicly available documents such as service evaluation, market research or research into public opinion rather than the collection of new primary data involving interaction with human subjects.

**Applying to the University Research Ethics Committee**

If you have initially established that your project requires ethical approval from the University Research Ethics Committee you will need to complete a UREC ethical approval form.

The form and guidelines must be read carefully and the questions answered fully. The form is, however, designed to cover many different types of research project so some of the questions may seem more relevant than others.

If you are a postgraduate student, you and your supervisor are jointly responsible for completing the form.

On submission you will have the choice of review by the first available committee or wait for the committee which specialises in your subject area, which could take 6 weeks.

**What are the issues that I need to consider in preparing an application?**

Each research project will have its own ethical implications but in general you will need to consider the following factors:

* Does the research have clear objectives?
* Is the methodology sound?
* Have you sought advice on research design?
* If it is quantitative research what statistical advice have you sought?
* If it is qualitative research is the design appropriate?
* Has the application been prepared in understandable English, free of jargon and terms that may not be understood by the intelligent layperson?
* There must no element of coercion in the recruitment of volunteers. Adverts and invitations to participate must be drawn up in neutral terms and potential participants cannot be approached directly by the researcher and asked for an immediate answer
* All participants must give informed consent, which means providing an information sheet (generally in a standardised format) and asking for written consent.
* If consent is to be obtained in possibly difficult or complex situations, the researcher should show that they have experience in administering consent
* Participants must be able to withdraw at any time without giving a reason and with an assurance that it will not effect any benefit, service etc which you or the organisation hosting the research might be offering
* Any compensation, financial or otherwise, must be related to expenses incurred and time taken up and not be seen as an incentive to take a risk. Modest prize draws are, however, permissible
* There should be an assurance that there will be some sort of outcome to the research, preferably as a publication. In this respect a dissertation or thesis, even if not publicly available, counts
* Any conflicts of interest should be declared.

**What supporting papers will be needed?**

The Committee will want to see the following documents:

* Any research protocol (this will only be relevant to the more complex projects)
* Any advert of letter of invitation to participate
* A participant information sheet (known as a PIS for short)
* A consent form
* Any questionnaires or research tool being administered
* A schedule (i.e. a list of topics) to be discussed at any interview or focus group
* Ground rules for any meetings or focus groups
* Any consent letters from third parties involved

Not every application will need all these documents. For instance, the return of a questionnaire does not always need a consent form, since the return itself implies consent, but the implied consent should be set out in the information sheet.

**What happens at the Research Ethics Committee meeting?**

After submission to the University Ethics Review Committee, you will be told the date of the meeting. It is also quite usual to invite you to meet the committee at a given time. This will be an opportunity to clarify uncertain points or agree amendments. If you are a postgraduate student, it is important that your supervisor(s) make to time to attend as well since they are formally responsible for the management of the research and may be in a better position to answer questions.

After the meeting you will be sent a letter which may: confirm ethical approval, give conditional approval, or give an unfavourable opinion and ask for a revised submission.

**What happens if I do not get ethical approval?**

It is contrary to University policy to collect data for a research project which requires ethical approval without having first obtained that approval. A number of consequences flow from this:

* Conducting research without proper ethical approval could be construed as misconduct in research
* The University cannot protect you against any consequences, financial or otherwise
* An aggrieved participant could seek legal redress and you would have a weaker defence if the research did not have ethical approval