

Ethical Approval for Research Involving Human Participants: Guidelines for postgraduate taught students

In carrying out their work researchers inevitably face ethical dilemmas which arise out of competing obligations and conflicts of interest. All research proposals involving data collection involving human participants normally requires prior ethical approval to ensure the safety, rights, dignity and well-being of the participant and those of the researcher. This is why you are required to declare whether or not this applies to your dissertation / project topic and, if so, how these ethical issues are to be addressed. In doing so, you are providing assurance that you have read the guidelines and considered whether your proposed dissertation / project research raises ethical issues which require the attention of the School's ethical committee and /or the University's Senate Committee on the Ethics of Research on Human Beings.

Ethical approval should not be considered as a bureaucratic obstacle; it is a mechanism for ensuring and demonstrating that the design of your research respects the rights of those who are the participants of the research.

Who does this apply to?

All postgraduate taught students (researchers) must secure ethical approval for any research they conduct involving human participants or human data or material before undertaking their research.

Examples of activities for which approval is required include questionnaire and interview based research involving sensitive or confidential issues, telephone interviewing or recording by audio or video tape and contact with participants who are children or considered as potentially vulnerable adults.

How do I obtain Ethical approval?

Application for ethical approval must be made via the relevant School ethics committee (or equivalent) full details of which are produced in the programme handbooks.

Where you will be conducting research involving NHS patients or staff, or working on NHS premises approval must be sought via an NHS Research Ethics Committee. The relevant form can be obtained from the COREC (Central Office for Research Ethics Committee) website:
<http://www.corecform.org.uk>

What happens if I have not applied for or obtained ethical approval?

Failure to follow the School's procedure for ethical approval may leave you and the University open to legal action without the protection of an insurance policy and may result in disciplinary action.

What research does it cover?

All research involving human participants or human data or material must have ethical approval. Research where the information about human participants is publicly and lawfully available e.g. information published in the census, population statistics published by the government, personal letters and diaries etc held in public libraries do not require ethical approval.

Working with children

- You must satisfy yourself that the research you propose to undertake is worthwhile and that the techniques proposed are appropriate.
- You must satisfy yourself that there is a need to involve children and be able to justify this to the committee(s).
- You should ensure that you have familiarised yourself with and comply with the relevant legal position where it is intended to conduct research with children.
- Where your research involves children every effort should be made to gain informed consent from the child and his / her parents (or legal equivalent)
- In certain cases research that involves vulnerable people may require Criminal Records Bureau (CRB) Disclosures. The CRB offers a means to check the background of researchers to ensure that they do not have a history that would make them unsuitable for work involving children.

Working with potentially vulnerable adults

- You must satisfy yourself that the research you propose to undertake is worthwhile and that the techniques proposed are appropriate.
- You must satisfy yourself that there is a need to involve potentially vulnerable adults, e.g. older persons or those with severe learning difficulties and be able to justify this to the committee(s).
- You should ensure that you have familiarised yourself with and comply with the relevant legal position where it is intended to conduct research with potentially vulnerable adults.
- In cases where your research involves vulnerable adults every effort should be made to secure their informed consent. However, in cases where this seems impossible or where the participants are considered not competent to give their consent to the research the issue of honesty and consent may need to be managed via proxies, who should either be those with a duty of care or who can provide disinterested independent approval.
- In certain cases research that involves vulnerable people may require Criminal Records Bureau (CRB) Disclosures. The CRB offers a means to check the background of researchers to ensure that they do not have a history that would make them unsuitable for work involving vulnerable adults.

Recruiting Participants

Participants should enter into the research freely and willingly and know and understand what they are agreeing to when they take part.

- No one should be made to participate in a research study against their will.
- Those recruiting participants should ensure that no undue influence is exerted in order to persuade the participant to take part in the research.

- Participants should be made aware that participation is entirely voluntary; that refusal will attract no sanction, and that they will not be required to give reasons for refusal; that if they agree to participate in the study, they are free to leave the study at any time without being required to give reasons for leaving.
- Wherever possible anonymity and confidentiality should be maintained.
- It is inappropriate to offer volunteers excessive payments which might induce them to participate in a study against their better judgement. Small payments may be made in order to compensate participants for their time and inconvenience. Out-of-pocket expenses may also be met.

There are a variety of ways for recruiting participants:

- mail out
- email
- telephone
- advertisement
- recruitment carried out by third party (e.g. employer, doctor)
- recruitment carried out by researchers
- contact details obtained from public documents (e.g. phone book)
- contact details obtained from private sources (e.g. employee list, membership database)
- participants from a previous study
- snowball (participants suggest other potential participants)
- personal contacts

Information Sheet & Consent Form

Informed consent entails giving as much information as possible about the potential research so that the prospective participants can make an informed decision about their possible involvement. Normally this information should be supplied in written form (information sheet) and signed off (consent form) by the research participant(s). The primary objective is to conduct research openly and without deception.

- Written information should be supplied to participants making clear that the research is for a student project. It should be written in terms that an ordinary person rather than a specialist in the field can understand i.e. avoid technical jargon. The information provided should be accurate and concise, specific to the proposed research and appropriate for the social and cultural context in which it is being given.
- You must take time over this as it is essential to explain what you are asking participants to do and the possible implications so that they can make an informed decision whether they wish to take part.
- You should consider whether the participant will be able to read the information you provide and consider how to deal with problems of illiteracy or where the participant is not fluent in the language used.

The information sheet should include the following:

1. the name of the researcher(s)
2. an explanation of what you, the researcher, is hoping to achieve by the research
3. what is going to be done by you, the researcher
4. an explanation of the risks, pain or discomfort, if any, that the participant may experience
5. a clear explanation of what the participant is expected to do during the study
6. a statement that the participant is not obliged to take part, and may withdraw at any time
7. a clear statement of payment arrangements for compensation for the participants time and inconvenience and any out-of-pocket expenses
8. consent statement (this can be separate to the information sheet)

Other information can also be included such as:

- a. duration of the study
- b. location of the study
- c. anticipated outcomes in respect of publication of findings

Having understood the above the participant gives their consent to take part in the study by signing a consent form

(www.humanities.manchester.ac.uk/infoforstaffstudents/academicservices/pgteaching/) and is given a copy of both the information sheet and the consent form to keep. Sufficient time must be provided between the request to take part and the signing of the consent form, in order to ensure that the participant has read the information sheet and had the opportunity to ask questions about the research.

- You should be willing to answer any questions put to you by (potential) participants.
- Participants should understand how far they will be afforded anonymity and confidentiality and should be able to reject the use of data-gathering devices such as tape recorders and video cameras.
- You should inform the participant of their rights under any copyright or data protection laws. Where your research is recorded using audio or video recordings you should obtain the appropriate copyright clearances where necessary.
- You have a responsibility to ensure that the physical, social and psychological well-being of the participant is not adversely affected by the research.
- You should clarify whether, and if so, the extent to which the participants are allowed to see transcripts of interviews and notes and to alter the content, to withdraw statements, to provide additional information or to add glosses on interpretations
- Clarification should also be given to participants regarding the degree to which they will be consulted prior to publication. Where possible, participants should be offered feedback on findings, for example in the form of a summary report.
- It is important that participants should not be offered payments in order to persuade them to take part in any research in which they would not ordinarily take part, although reasonable compensation for time and inconvenience and expenses incurred may be made.

- You should take all reasonable steps to ensure that no harm occurs to participants by virtue of their participation in the study.
- Consent is only valid for procedures set out on the information sheet. Should any of the information included on that sheet change during the course of the study, new consent should be sought; participants are free to refuse consent and withdraw from the study if they wish.
- Under certain survey conditions a signed consent form may not be needed e.g. when adult participants are mailed a questionnaire, return of the questionnaire can be considered to indicate consent. However the researcher must provide proof that the participants will be adequately informed of the purpose of the study, the extent of the participant's involvement and how the data will be handled with respect to confidentiality. In the case of a postal survey a copy of an abbreviated information sheet or cover letter should be submitted with the application for ethical approval.

Obligations on researchers

- It is expected that, in addition to the above, you will abide by any guidelines issued by professional bodies to which you belong or which govern research in your area. Where such guidelines conflict with the above, the advice of the School's ethics Committee should be sought.
- Researchers should never present others' work as their own. Nor should they knowingly misrepresent the findings of their research or the work of others. See also plagiarism (<http://www.campus.manchester.ac.uk/staffnet/policies/>)
- Any study should be stopped immediately on request or if the participant shows any sign of distress and should not recommence without the agreement of the participant (or his/her parent or person acting in loco parentis)
- Should you need to use participants for your research obtained via an NHS source, ethical approval must be sought from the Central Office for Research Ethics Committee (<http://www.corec.org.uk>)

Confidentiality of information obtained during research

The confidentiality of information supplied by research participants and the anonymity of respondents must be respected.

- You should not give unrealistic guarantees of confidentiality and anonymity, where given such guarantees must be honoured, unless there are clear and overriding reasons to do otherwise, for example in relation to the abuse of children. You should be aware that legal challenge may preclude the honouring of such a guarantee. Passing on confidential information without the express permission of the participant should not be undertaken lightly and legal and professional advice should be sought immediately if this is contemplated.
- Appropriate measures should be taken to store research data in a secure manner. You should be aware of your obligations under the Data Protection Act. Where appropriate and

practicable, methods for preserving anonymity should be used including the removal of identifiers, the use of pseudonyms and other technical means for breaking the link between data and identifiable individuals.

- Data and results obtained from the research should only be used in the way(s) for which consent has been given. Informed consent is the most important part of the Data Protection rules for researchers.

What happens if I want to publish the research?

- You must tell the proposed participant in advance if you have any intention of publishing the results of the study.
- You must explain the extent to which, if at all, any identifying information about the participant will appear in the publication.
- If identifying information about the participant is intended to be published you must obtain and keep specific written agreement from the participant.
- Preferably these issues should be addressed on the initial information sheet that is issued before participant gives their consent.

Informing research participants of results of research

It is appropriate for research participants to be able to receive feedback on research they have been involved in, where this is possible. You should consider the issue of informing the participants of the results of the research or where they may be able to get access to this information (although participants may not be able to be given their individual results).

Whilst these guidelines are not exhaustive, they indicate a set of obligations to which researchers should normally adhere. Responsibility for both interpretation and compliance rests with the researcher.

Further sources of information

Source of information / act	URL
Economic and Research Council (ESRC)	http://www.esrc.ac.uk
Arts, Humanities Research Council (AHRC)	http://www.ahrc.ac.uk/images/4_94629.doc
British Sociological Association	http://www.britisoc.co.uk/new_site/index.php
Association of Social Anthropologists	http://www.theasa.org/
Political Studies Association	http://www.psa.ac.uk/
Criminal Records Bureau (CRB)	http://www.disclosure.gov.uk
Central Office for Research Ethics Committee – COREC (NHS)	http://ww.corec.org.uk
The Human Rights Act (1988)	http://www.hmsa.gov.uk/acts/acts1988/19980042.htm

Data Protection Act (1988)	http://www.opsi.gov.uk/ACTS/acts1998/19980029.htm http://www.informationcommissioner.gov.uk/
UK Copyright Act (1988)	http://www.opsi.gov.uk/acts/acts1988/Ukpga_19880048_en_1.htm
Race Relations Act (1976)	http://www.homeoffice.gov.uk/documents/204501/
Race relations (Amendment) Act 2000	http://www.opsi.gov.uk/ACTS/acts2000/20000034.htm
Disability Discrimination Act (1995)	http://www.opsi.gov.uk/acts/acts1995/1995050.htm
Freedom of Information Act (2000)	http://www.opsi.gov.uk/ACTS/acts2000/20000036.htm http://www.informationcommissioner.gov.uk/
Communications Act (2003)	http://www.opsi.gov.uk/acts/acts2003/20030021.htm
University of Manchester Code of Practice for Dealing with Allegations of Misconduct in Research Disability Discrimination Act Policy Equality & Diversity Policy Freedom of Information Act Policy Health & Safety Policy Harassment, Discrimination & Bullying Policy Intellectual Property Policy (guidance on) Plagiarism and other forms of academic malpractice	http://www.campus.manchester.ac.uk/staffnet/policies/
University's data protection policy	www.campus.manchester.ac.uk/recordsmanagement/dataprotection/

University Contact: Dr Timothy Stibbs, Secretary to the Senate Committee on the Ethics of Research on Human Beings (Email: timothy.stibbs@manchester.ac.uk)

Glossary of Definitions:

Consent – the voluntary agreement of a person or group, based on adequate knowledge and understanding of relevant material, to participate in research. Informed consent is one possible result of the informed choice process, the other possible result is refusal.

Confidentiality – the obligations of persons to whom private information has been given is not to use the information for any purpose other than that for which it is given.

Deception – this occurs when research participants have essential information withheld and / or initially misled about procedures and purposes, including studies where participants are deliberately given misleading info about the purposes of the study.

Ethics – the study of morals and values; that is, the study of right & wrong, justice and injustice, virtue and vice, good and bad and related concepts and principles.

Ethical / Unethical – right or morally acceptable / wrong or morally unacceptable.

Harm – that which adversely affects the interests or welfare of an individual or a group

Research – this involves systematic investigation to establish facts, principles and knowledge.

Research participant – living individual (or group of living individuals) about whom a researcher conducting research obtains data through intervention or interaction with the person or identifiable private information.

Risk – the function of the magnitude of a harm and the probability of its occurrence

Voluntary – free of coercion, duress or undue inducement.

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