



UNIVERSITY RESEARCH ETHICS COMMITTEE

GENERAL ETHICAL GUIDELINES AND PROCEDURES FOR THE PROPOSAL AND IMPLEMENTATION OF RESEARCH PROJECTS INVOLVING HUMAN PARTICIPANTS

1. PREAMBLE

For all students and staff undertaking research involving human participants within the University, during the preparation of a project/dissertation/thesis proposal, consideration **must** be given to the ethical implications of the research you are intending to carry out. It is the role of the University Research Ethics Committee, and Schools implementing procedures under delegated authority, to ensure that this aspect has been addressed to a satisfactory minimum standard before your research proceeds, and to this end your proposal must be subject to appropriate scrutiny. The intention of these Guidelines is to assist you in this task. Further information and guidance will be provided by your Supervisor and/or the School Research Ethics Officer.

“The term ‘research’ refers to a class of activities designed to develop or contribute to generalizable knowledge. Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference.”

[International Ethical Guidelines for Biomedical Research
Involving Human Subjects (CIOMS, 1993)]

Research involving human participants may consist of:

- observation, or
- physical, chemical or physiological intervention.

It is also of importance to note that research may either create records or use existing records containing biomedical or other information about individuals who may or may not be identifiable from the records or information. Protection of confidentiality, then, immediately becomes a central issue.

Local Research Ethics Committees (LRECs) (established and administered by Health Authorities), Multi-Centre Research Ethics Committees (MRECS) and, possibly in the near future, Local Authority Research Ethics Committees – to which your project, dissertation or thesis proposal may, in appropriate circumstances, need to be submitted - are advised that:

“3.3. [Such committees] should consider the ethical implications of all proposals which involve human subjects, including, for example, questionnaires. All proposals will

belong to one of two categories, therapeutic and non-therapeutic research. Therapeutic research carries the prospect of direct benefit to the research subject. Non-therapeutic research, whilst designed to advance scientific knowledge and therefore be of collective benefit, is not expected to give a direct benefit to the research subject. Non-therapeutic research may involve 'healthy' as well as 'patient' volunteers.

3.4. Where people volunteer to take part in non-therapeutic research, they should know that they cannot expect to derive any direct benefit from that participation. The LREC will therefore want to be satisfied that the risk to which they are submitting themselves can be justified by the expected collective benefit."

[DoH, 1991].

2. THEORETICAL ASPECTS

Before considering the practical aspects of gaining ethical approval, it is important to understand some of the theoretical issues that underlie research ethics in relation to human participants. There are three main approaches that underpin all of our ethical thinking about research.

The first main approach to ethical thinking is the *goal-based approach*. Based on the consequentialist theory, the approach assumes that the researcher should try to produce the greatest possible balance of benefit over disbenefit. A researcher taking this approach would believe that if the intended outcome of the research is worthwhile, then the means of achieving that outcome is worthwhile. This implies that discomfort to one individual may be justified by the consequences for society as a whole. However, even if the research is itself ethical, it is of no use if the outcome is of little value; thus the outcome is as important as the process.

The second approach is *duty-based*. Your duty as a researcher is founded on your own set of moral principles. As a researcher, you will have a duty to yourself and to the individual who is participating in the research. Thus, even if the outcome of the proposed research is for a good cause, if it involves the researcher lying to or deceiving the participants in any way, then this would be regarded as unethical.

The *rights-based approach* takes a similar perspective to the duty-based approach. The rights of the individual are assumed to be all-important, thus a participant's right to refuse must be upheld whatever the consequences for the research. This is based on the idea that we should always follow natural laws and rights. This means that our ethical responsibilities are primarily to the individual and that every human being, including you, should be respected even if this may have some unfortunate consequences.

It is widely acknowledged that all research involving human participants must acknowledge and conform to four basic ethical principles. These four basic principles are derived from the approaches outlined above. It is obvious that some of the principles derived from these approaches may be in conflict with one another, and thus some principles rate higher than others in order of importance. The principles are always binding, unless they are in conflict

with other principles, in which case it will be necessary for you to justify why one principle has been chosen over the other. This is the basis of moral reasoning.

The Four Fundamental Ethical Principles

- (i) **Autonomy** – i.e., *respect* for the autonomy of the individual, and protection of persons with impaired or diminished autonomy by the provision of safeguards against harm and abuse. The duty of the researcher is both to recognise the research participants' capacities and perspectives and their right to make choices about whether or not they will take part in any research project. That person should also be treated so as to allow them to act in an autonomous way.
- (ii) **Non-Maleficence** – the researcher is under an obligation not to inflict harm or expose people to unnecessary risk as a result of the research project. This is particularly important when the research participants may have impaired or diminished autonomy.
- (iii) **Beneficence** – the obligation to maximise benefits and minimise harm. This principle obliges the researcher to assist others to pursue their interests. However, there may be conflict between, for example the principle of autonomy (the right to make an informed choice) and beneficence (where part of the study involves non-disclosure to that person as it may do them harm). Paternalism occurs when a researcher acts in the belief that an individual's views should be disregarded since it is in society's interest to do so. If one principle is to be overridden by another, the researcher must be able to justify that decision to the satisfaction of independent scrutiny.
- (iv) **Justice** – the obligation to treat each person in accordance with what is morally right and proper. This principle is concerned with people receiving their due. Equality of opportunity is particularly important here, and is of particular importance when considering inclusion/exclusion criteria.

These guidelines seek to examine these ethical principles in relation to issues which must be carefully addressed and considered by the competent researcher. Research studies are judged ethically on three sets of criteria: ethical principles, ethical rules and scientific criteria. The latter is often neglected, but is important since if a study design is poor or the sample size is insufficient, then the study is not capable of demonstrating anything and consequently could be regarded as unethical.

The four key ethical rules are:

- veracity
- privacy
- confidentiality
- fidelity.

3. PRINCIPLES AND ISSUES

3.1 Respect for Persons

A. Consent

Research carries the attendant potential to:

- (1) cause harm, in the form of actual damage or disadvantage (the practical context);
- (2) ignore the autonomy of the individual (the moral context).

It is, of course, a truism to state that harm cannot be entirely eliminated from the research process, but if we insist that individuals are provided with adequate information and choice about participation, we can at least minimise the possibility of realising either of the above potentials.

Rule 1 of the Nuremberg Code (Rev.1981) emphasises the fundamental importance of consent thus:

“The person involved should have the legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the subject-matter involved as to enable him to make an understanding and enlightened decision.”

This brings the notion of **informed consent** into focus. In law, valid consent may be express or implied. **Express consent** requires an active, affirmative assertion made either orally, in writing or a mixture of both. The notion of **implied consent** rests on an assumption derived from conduct, e.g., the offering of an arm for taking blood pressure. In law, the **minimum** consent requirement is the absence of a negative, i.e., not saying ‘no’. It should be emphasised, however, that, wherever possible, active, informed consent should be sought. Even this can be an imperfect safeguard, which is why independent scrutiny of research proposals is insisted upon by the School, and, where applicable, by Local Research Ethics Committees. The more limited the capacity of the research participant, e.g., young children, or persons with severe mental or behavioural disorders, the more important independent scrutiny becomes. Mere passivity should **not** automatically be assumed to equal consent.

In light of the above, it is recommended by the Central Office for Research Ethics Committees (2003) that, before an individual’s consent is obtained, the researcher should provide the following information in language which that individual is capable of understanding:

- **A statement of the aims of the research.** Sharing aims of research is fundamental to respect the autonomy of the participant.
- **The reason why the participants have been selected** is crucial in order for

individuals to make an informed choice about participation.

- **A statement as to what is involved.** Many people are concerned as to what the research actually involves in practical terms for them. Does it involve visits or treatment? Will it mean school absences? How painful or distressing could the experience be?
- **The researcher's background.** In building a relationship of trust and mutual respect, it is important that participants are told of the skill and experience of the researcher and their experience in this particular field. For inexperienced researchers they will need to know the supervision arrangements that are in place.
- **What happens if I do not take part?** Participants must be reassured that any treatment/services/benefits, etc., to which they are entitled will not suffer if they do not take part, and that they can withdraw from the study at any time, without giving a reason.
- **Clear explanation of difficult terminology.** Most lay people do not understand common scientific terms, and may be apprehensive about them, or of revealing their lack of understanding. Without understanding, consent and assent are not valid.
- **What happens if something goes wrong?** Participants will want to know what arrangements may be made to compensate them in perhaps the unlikely event of something going wrong, which happens as a consequence of the research. Considerations of justice and equity would underpin the duty to discuss compensation arrangements.
- **Form and content.** Information must be presented in a form which is comprehensible to the research participant (or, say, parents of participating children). People vary enormously in their ability to assimilate different types or amounts of information. Whilst information sheets should contain the basic information, which a reasonable person might want to have to make a choice about participation, it is also clear that some people have different needs. It might be reasonable to suggest that information provided should be tailored to the participant in question.
- **How much information?** There are no specific legal criteria as to how much information is required for a research project. For treatment, the legal criterion is that the person should understand in broad terms the nature and purpose of the procedure and the material risks which are involved. Perhaps the best advice is that it would now be expected that the amount of information is enough for a reasonable participant to make the decision in hand. Clearly, this would involve a duty to warn of **risks** which a reasonable person might want to know in order to weigh risks and benefits.

In providing the above information, care should be taken to:

- give the prospective participant full opportunity and encouragement to ask questions;

- exclude the possibility of unjustified deception, undue influence and intimidation;
- seek consent only after a sufficient opportunity has been provided to consider whether or not to participate;
- as a general rule, but subject to exceptions, e.g., questionnaires , obtain from each prospective participant a signed form as evidence of consent;
- renew the consent if there are material changes in the conditions or procedures of the research.

Such details should usually be provided as an information sheet, which the participant signs and dates, thus requiring an ACTIVE response from the participant.

B. Confidentiality

Researchers will need to show clear evidence that:

- (i) personal information will be kept confidential;
- (ii) data will be secured against unauthorised access;
- (iii) no individual will be identifiable from the published result without his/her explicit consent;
- (iv) all data from which an individual is identifiable will be destroyed when no longer required. In certain circumstances the researcher may wish/need to retain such data beyond completion (particularly for external scrutiny purposes). Here, all relevant persons (particularly the research participant) must be made aware of the reasons for retention, and the circumstances where disclosure might occur. Written consent will be required.

Written permissions and the general principles of confidentiality also apply in relation to the medical records of deceased persons. Permission must, therefore, be sought from the LREC.

DoH Guidance to LRECs (1991) provides further important detail:

“3.12. Epidemiological research through studies of medical records can be extremely valuable. Patients are however entitled to regard their medical records as confidential to the NHS and should in principle be asked if they consent to their own records being released to researchers. However, there will be occasions when a researcher would find it difficult or impossible to obtain consent from every individual and the LREC will need to be satisfied that the value of such a project outweighs, in the public interest, the principle that individual consent should be obtained. When a patient has previously indicated that he or she would not want their records released, then this request should be respected.

3.13. The LREC will need to be assured that this kind of research will be conducted in accordance with current codes of practice and data protection legislation. Wherever possible, consent should also be sought from the health professional responsible for the relevant aspect of

the subject's care. Once information has been obtained from the records no approach should be made to the patient concerned without the agreement of the health professional currently responsible for their care."

Data Protection

The consent form will need to include a statement that the data obtained will be held securely only for the time necessary to complete the project. Data should not be stored on computers or discs to which unauthorised persons may have access. This needs to be carefully considered when using the computer at home. Questionnaires should not be returned to home addresses, as participants may interpret this as meaning that data will also be stored at home, and therefore not be secure. Thus, confidential information returned by post to the researcher should be sent to the University address.

Regard should also be had to the Principles of Data Protection as laid down in the Data Protection Act 1998, viz:

1. *Personal data shall be processed fairly and lawfully, and, in particular, shall not be processed unless*
 - (a) *at least one of the conditions in Schedule 2 is met, and*
 - (b) *in the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met.*
2. *Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.*
3. *Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed.*
4. *Personal data shall be accurate and, where necessary, kept up to date.*
5. *Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.*
6. *Personal data shall be processed in accordance with the rights of data subjects under this Act.*
7. *Appropriate technical and organizational measures shall be taken against unauthorized or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.*
8. *Personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.*

Once your research has been completed, confidential data relating to participants should normally be destroyed and assurances should be given to this effect. However, in certain instances, there may be legal requirements concerning the length of time during which data must be retained and you may need to give careful consideration to this. Further, if

your project/dissertation, etc., forms the basis of a published research paper, authors may be asked by publishers to provide the raw data at any time within a prescribed period (e.g., 5 years in the case of *The Lancet*).

Issues may arise concerning the ownership of the data. As a general principle, data contained in a project/dissertation/thesis submitted in partial or total fulfilment of a degree award of the University belongs to the student; however, in some cases, especially where a student conducts research as part of a team which also includes members of University staff, they may be required to assign intellectual property rights to the University.

3.2 Beneficence (Maximise benefits and minimise harm)

Two general groups require initial consideration:

3.2.1 Healthy Volunteers

It is unlikely that healthy volunteers will benefit directly from the research undertaken. They may, therefore, be more difficult to recruit. In relation to such volunteers, the following points should be noted:

- there must be no pressure to volunteer, e.g., arising from some obligation;
- recruitment should be public, i.e., by appeal to a cohort, rather than by individual, private recruitment;
- the term 'healthy' requires specific definition for the purposes of the study.

You may be seeking to conduct research involving participants who are members of professional groups. Members of professional groups are known in the sense that their names appear in a public register. It is considered that it is the responsibility of the researcher to acknowledge the source of the name and address of such members in a covering letter which should accompany any questionnaire, and, further, that the researcher has the responsibility of distinguishing the personal opinion of the professional participant from institutional policy and, particularly, to protect the professional participant's confidentiality. Permission should, therefore, be sought from the relevant institution or authority to seek and release information. Professional body guidelines on this matter should be consulted where relevant.

3.2.2 Patients

A patient may be defined as an individual who:

"has sought or accepted medical care" or

"has been selected from the general population because of known or suspected abnormality".

[Royal College of Physicians, 1990]

Although the points raised in 3.2.1. also refer here, there are further matters to consider, e.g.:

- a patient's ability to consider the implications may be impaired;
- patients are dependent on health practitioners – a sense of obligation might, therefore, be present, and such a conflict of interest may need to be considered when formulating the proposal.

3.2.3 Special Groups

The third basic ethical principle relates to **Justice** which refers to the ethical obligation to treat each person in accordance with what is morally right and proper, and to give each person what is due to him or her.

*“In the ethics of research involving human subjects the principles refer primarily to **Distributive Justice**, which requires the equitable distribution of both the burdens and benefits of participation in research. Differences in distribution of benefits and burdens is justifiable only if they are based on morally relevant distinctions between persons; one such distinction is vulnerability. “Vulnerability” refers to a substantial incapacity to protect one’s own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. Accordingly, special provisions must be made for the protection of the rights and welfare of vulnerable persons.”*

[CIOMS, 1993].

Over and above any general considerations arising, special groups may, and in some instances must, require further attention. The competence of individuals within these special groups to assess risk, and therefore to give informed consent, is the main issue here.

The following groups may be identified:

(a) Children (both under 16 and in the 16-18 category)

Older, ‘Gillick competent’ children (i.e., those children who, although under 16, are deemed to have sufficient understanding to give consent in their own right) should be selected before younger children.

Competence involves:

- The ability to understand information;
- The belief that the information applies to one’s self;
- The ability to retain, ask questions about and reflect upon the information long enough to make a decision.

The following principles should be applied:

- *children should not be involved in research that might equally well be carried out with adults;*
- *the purpose of the research is to obtain knowledge relevant to the health or social needs of children;*
- *a parent or legal guardian or other person with parental responsibility of each child has given proxy consent;*
- *the consent or assent of each child has been obtained to the extent of the child's capabilities;*
- *the child's refusal to participate in the research must always be respected unless, where relevant, according to the research protocol, the child would receive therapy for which there is no medically acceptable alternative;*
- *the risk presented by interventions is low and commensurate with the importance of the knowledge gained;*
- *(where relevant) interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child-subject as any available alternative.*

[CIOMS (1993)]

Further guidance in relation to the conduct of research involving children may be obtained at www.doh.gov.uk. The Central Office for Research Ethics Committees (www.corec.org.uk) has also issued helpful advice (2003).

(b). Persons with Mental or Behavioural Disorders

Where individuals are not capable of giving adequately informed consent, the researcher should ensure that:

- *such persons will not be participants of research that might equally well be carried out on persons in full possession of their mental faculties;*
- *the purpose of the research is to obtain knowledge relevant to the particular health needs of persons with mental or behavioural disorders;*
- *the consent of each participant has been obtained to the extent of that participant's capabilities, and a prospective participant's refusal to participate in non-clinical research is always respected;*
- *in the case of incompetent participants, informed consent is obtained from duly authorised persons;*
- *the degree of risk attached to interventions that are not intended to benefit the*

individual participant are low and commensurate with the importance of the knowledge to be gained;

- *interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual participant as any alternative.*

[CIOMS (1993)]

(c) The Elderly

Particular care should be taken if the person is living in long-stay accommodation, in hospital or in a residential home.

(d). Persons with Learning Difficulties

(e). Pregnant Women (including during the postpartum period)

(f). Others: other vulnerable groups might include people to whom the researcher owed a duty of care, where there is a real or potential conflict of interest or, possibly, where participants might feel that receipt of services may be dependent on participation in the study (e.g., asylum seekers, refugees).

3.2.4 The Risks

Before becoming involved in any research endeavour, potential risks need demonstrably to be weighed against the benefits, i.e., a **risk/benefit analysis** needs to be conducted. Normally, for the purposes of undertaking a project/ dissertation/thesis within the School, you should not consider any design which goes beyond a minimal risk.

Essentially, minimal risks are those which can be ignored; i.e., the risk itself is trivial and/or the chance of it arising is remote.

3.2.5. Deception

As a general rule, participants should know beforehand that they are participating in a study and being asked to give their consent. Some studies may include an aspect about which the participant is not fully informed (for example, a placebo treatment may be used, in which case informing the participant would invalidate the research). This procedure must first be deemed acceptable by a Research Ethics Committee before being applied, and you will need to be able to justify its use to the Committee. There are also concerns regarding withholding of treatment in order to maintain a control group. Opinion has grown increasingly against this practice, and it is suggested that you consider another type of design. Otherwise, the justification for the use of a control group must be highlighted and justified in the research proposal.

3.2.6 Notification of Study Participation

If a study originates in a hospital or other health institution, the participant's GP and Consultant should be informed of the study. This usually takes the form of an

explanatory letter with the request that if the GP has any concerns, you should be contacted regarding them by a certain date. In some cases the Consultant may be the more appropriate person to contact.

3.2.7 Requirements of Professional Bodies

Even if ethical clearance is obtained from the relevant bodies outlined above, the researcher is not necessarily absolved from a duty of care. The general and continuing duty of care may also be subject to guidelines and rules of conduct laid down in the Codes of Practice/Ethics laid down by professional and/or statutory bodies. Care should be taken to consult the relevant documents, in addition to the general guidelines given above.

4. THE RESEARCH PROPOSAL

RESEARCH PARTICIPANT INFORMATION SHEET CHECKLIST

This checklist has been prepared to assist researchers in the design.

1. The information sheet should be printed on appropriately headed paper.
2. A name and contact number should be given. The name and contact details of the research supervisor should be given where appropriate.
3. The project should be given a simplified title if there is any likelihood that the full title will confuse the research participants involved.
4. The information sheet should not be too long.
5. The purpose of the project and the fact that it is a research project should be explained in plain, concise English. The nature of the project and all technical terms and abbreviations should also be clearly explained. It should be made clear whether the research is therapeutic or non-therapeutic, where relevant. A translation should be provided where needed.
6. When undertaking a randomised trial, an explanation of randomisation should be given along with an explanation of how the participants are assigned and in what proportions to the control and intervention groups.
7. Where relevant, the alternative forms of diagnosis and treatment being assessed should be explained clearly, including the expected benefits to the participants and/or others.
8. Any serious risks and possible side-effects and discomforts should be clearly indicated.
9. The length of the trial or study, any extra attendances and procedures involved, and the nature of the drug or devices being tested should all be explained.
10. A careful explanation, with assurances, should be given if the project involves withholding effective treatment for a short time.
11. It should be made clear that involvement in a research project is entirely voluntary.
12. The right to withdraw at any time from the project without influencing current or future treatments (where relevant) should be made clear.
13. A statement should be made assuring participants of the confidentiality of data and the protection of identity when publishing results unless their consent is obtained.
14. Participants must be informed if an organisation sponsoring the research requires access to their notes to verify or cross-check data. They should also be assured that access will only be given to this specific information.
15. A clear statement should be made offering refund of expenses such as travel costs. Where payments to healthy volunteers are being made, it should be stated that these may be liable to tax.
16. Clear information about indemnity arrangements should be given.
17. Participants should be informed if participation in a study might affect health-related insurance.
18. The participant's permission should be sought, where relevant, to contact his/her GP about his/her involvement in the trial/study.
19. The investigator should indicate if he/she is receiving any funding in the form of personal payment.
20. Clear information about complaints procedures should be given.
21. An approval statement from the relevant ethics committee should be included.
22. Any participant involved in research which could harm a foetus should be advised of this and be given advice about contraception.

MODEL CONSENT FORM

<p>The participant should complete the whole of this sheet him/herself</p>		
	<p><i>Please tick the appropriate box</i></p>	
	<p>YES</p>	<p>NO</p>
<p>Have you read the Research Participant Information Sheet?</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Have you had an opportunity to ask questions and discuss this study?</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Have you received satisfactory answers to all your questions?</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Who have you spoken to?</p>		
<p>Do you understand that you will not be referred to by name in any report concerning the study?</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Do you understand that you are free to withdraw from the study:</p>		
<ul style="list-style-type: none"> • at any time 	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • without having to give a reason for withdrawing? 	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • (where relevant, adapt if necessary) without affecting your future care? 	<input type="checkbox"/>	<input type="checkbox"/>
<p>(Where relevant) I agree to my interview being recorded.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>(Where relevant) I agree to the use of non-attributable direct quotes when the study is written up or published.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Do you agree to take part in this study?</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Signature of Research Participant:</p>		
<p>Date:</p>		
<p>Name in capitals:</p>		
<p><u>Witness statement</u></p>		
<p>I am satisfied that the above-named has given informed consent.</p>		
<p>Witnessed by:</p>		
<p>Date:</p>		
<p>Name in capitals:</p>		