The University of Melbourne

Human Research Ethics Committee

GUIDELINES FOR INFORMED CONSENT IN RESEARCH INVOLVING HUMANS

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Researchers are also advised to refer to *The National Statement on Ethical Conduct in Research Involving Humans* which sets out requirements for consent (paragraphs 1.7 to 1.12, 6.9, 14.4, 15.8, 16.13).
http: //www.health.gov.au/nhmrc/publicat/humans/contents/htm

INFORMED CONSENT

1. Overview

The informed consent of participants is a primary requirement in the conduct of research involving humans as participants. The three elements of informed consent (full disclosure, adequate comprehension and voluntary choice) reflect the basic principle of respect for persons.

The Nuremberg Code, developed in 1947 during the criminal war trials of Nazi physicians, was one of the first widely recognised documents to deal with the issue of consent and experimentation with human participants. Subsequent codes, developed mainly for use in biomedical research, incorporate the same principles relating to informed consent.

There are many different forms of research involving humans. Research can have as its focus any one of a broad range of human interests, it can utilise many different forms of data collection and can involve varied types of analysis. Different research traditions will engage with the participants of research in different ways and in different contexts. This has implications for issues relating to gaining informed consent from potential research participants.

Generally, researchers should obtain, in advance, the informed consent of persons being studied, providing information, owning or controlling access to material being studied, or otherwise identified as having interests which might be affected by the research. Whether informed consent will be required, how it will be obtained and how this will be documented will depend on the nature of the project and may be affected by requirements of other codes, laws, and ethics of the community or country in which the research is pursued. Researchers are responsible for identifying and complying with relevant codes of ethics, laws and regulations affecting their projects.

The informed consent process is a dynamic and continuous one. It should be initiated in the project design and, where appropriate, continue through implementation by way of dialogue and negotiation between the researcher and those studied. Participants must be free to withdraw their consent at any time from further involvement with the research.

In most situations consent will be obtained from research participants via a signed consent form. Such documentation of consent is important for proof of compliance and for protecting the parties involved. It should be noted however that it is the process of obtaining informed consent that is most important. Documenting this in some way is only one part of the process.

2. What is informed consent ?

The principle of informed consent is, essentially, an expression of the belief in the need for truthful and respectful exchanges between researchers and the people they study. Studies involving human participants should be based as far as possible on the freely given informed consent of participants. There are three steps in the consent process, giving information, obtaining freely given consent and documenting how consent was obtained. Researchers should be aware that consent in many studies will be a process, not a one off event, and may require negotiation over time. In some research contexts it may be a particularly complex and problematic issue.

Informed consent requires communication between researchers and the participants of research. Communication involves both the provision of information and a capacity for dialogue between researcher and participant. Informed consent requires the communication of information material to a person's willingness to participate such as :

- the aims and purposes of the study

- the anticipated outcomes of the research
- details of what the participant will be required to do
- possible benefits and harms to the participant
- possible benefits and harms of the study
- the right of participants to refuse to participate and to withdraw from the research at any time without being penalised
- the degree of anonymity and confidentiality which may be afforded to participants
- the anticipated use of the data
- details of data collection eg. use of video- or audiotaping, DNA swabs etc
- issues relating to data storage and security
- the identity of funding bodies and sponsors.

Informed consent requires conveying full and understandable information to the participants of research. Information should be presented in a format that is appropriate to the particular subject group and which can be easily understood by them. This may vary according to the particular research context.

In addition to the provision of information to participants, communication between researcher and participants may involve ensuring the capacity for participants to communicate with researchers prior to and for the duration of the research. Participants should be given contact details for the researchers.

It is the responsibility of the investigator to ensure that consent to participate is both informed and freely given by the participants in their research. Participants are free to withdraw from the research at any time without giving reasons or justification for that decision. If any consequences may arise from such withdrawal, advice must be given to participants about these before consent to involvement in research is obtained.

3. Key issues for informed consent

The following are key issues to consider when designing procedures to obtain informed consent and when designing procedures for documenting the informed consent process.

3.1 Invasiveness

Different types of research will have differing levels of invasiveness for the participants. Invasiveness takes different forms. The invasiveness of a surgical procedure is evident, whereas the invasiveness, for the participants, of questionnaire-based or even historical research may not be so apparent. A questionnaire may be an invasive procedure when its content covers areas of sensitivity. Researchers should consider the degree of invasiveness of their research. The more invasive the research the greater care should be taken when designing informed consent procedures and for documenting the informed consent process. Researchers should be explicit in describing the procedures involved in their study so it is apparent to the participants just how invasive the research will be.

3.2 Benefit to participants

Any benefits of the research should be clearly explained to participants, including direct benefits to the participant, possible benefits to the community and benefits to knowledge generally. Researchers should be sensitive not to overstate anticipated benefits, especially those to the participant. They should also take care not to suggest that benefits to knowledge will bring a benefit directly to the participant. In most cases research will have no direct benefit to the research participant.

3.3 Risk and Risk Management

There is frequently a degree of risk in research. The key point for informed consent processes is that the risk is identified to the participant and that the researchers' plans for risk management are explained.

In some cases, the risk of participating in research is apparent. In other research issues of risk are more subtle. Risk does not mean the same thing to all people. The participants in the research may perceive the risks involved differently to the researcher. It is therefore the responsibility of the researcher to consider fully the types and levels of risk for participants in their research and include this information in the informed consent procedures and documentation.

3.4 Limits to confidentiality

As part of the informed consent process participants in research should be told how their data is to be collected, stored and analysed and who will have access to it. Participants should be advised of any limits to the confidentiality of their data. The following examples illustrate some of these limitations:

- small subject populations - participants could be recognised, even though names are not used
- mandatory reporting - researchers are obliged to report suspected child abuse if they belong to mandated professions - (Children and Young Person's Act 1989 Victoria, S 67 protection of information)
- duty of care to a third party - researchers may report a participant's information if harm to another may occur
- subpoena - researchers may be required to hand over their data to police or a court if subpoenaed.

3.5 Funded or sponsored research

As more and more research is funded and more researchers undertake consultancies for organisations there may be contractual obligations which may impact on the researcher-participant relationship, especially with regard to confidentiality. For example, issues relating to ownership of and access to raw data need to be clarified and potential participants informed of these. Details of what access the researchers may be given to personal records and details of participants in an organisation should be explained to potential participants. Details of content and format of any reports and findings being made available to funding bodies or sponsors should also be made clear to participants. Participants need to be advised that the research is being funded and to be told the name of the sponsoring body.

The researcher needs to consider how these relationships will impact on the procedures for obtaining and documenting informed consent.

3.6 Informed consent and minors

When researchers wish to involve children or minors in research studies, a number of issues arise which need special care. In law a "minor" refers to anyone under the age of 18 years. While generally minors do not have the legal capacity to give consent, ethically the basic principles of providing information suitable to the participant's level of understanding, and gaining the agreement of the participant still generally apply. When research involves minors, however, the consent procedure is made more complex by the need to obtain the informed consent of the minor's parent(s) or legal guardian.

A number of distinctions can be made in working with minors which help to clarify some of the issues. One distinction that can be made is between children (minors who lack the maturity to make a decision about being involved in research) and young people (minors who may have the maturity to make such a decision). Another distinction can be made between "informed consent" which is sought from parents or guardians, and "assent" which is sought from the young person. The understanding in this distinction is that informed consent is sought from an appropriate person who is legally

capable of giving informed consent for the young person or child. The assent of the young person is also sought, which still involves a process of the provision of relevant and appropriate information and agreement.

In some research circumstances it is clearly understood that the research cannot proceed without the assent (and implied cooperation) of the minor (eg: studies in psychology or teaching involving young people). In other fields this is not the case, and in some circumstances research may proceed on the basis of the informed consent of the parent(s) or guardian (eg. invasive medical research involving children).

In general, if a young person is a potential participant in a research project, informed consent must be obtained from both the young person and his or her parents or legal guardians. This will usually involve both parents and minor documenting their consent (assent) by signing a consent form. This needs to be carefully considered and the involvement of the minor should be appropriate to his or her age and capacity to understand the nature of the research.

The complexity of the issues surrounding consent and the participation of minors will vary greatly depending on the nature of the project and the ages of the participants. Care must be taken that information about the project is provided for both the minor and the parent, in language that is appropriate to each of these groups. In some cases, especially with younger minors, this may involve very different presentations of information to adults and minors. For example, drawings for the minors and written information for the parents.

It is important to respect the privacy of young people and children. Obtaining parental consent is a general requirement of research on young people up to the age of 18 years, but the consent process does not remove the need to protect the privacy of the minors involved. For example, if a researcher wanted to study the effectiveness of school counsellors by interviewing some student clients the research design should protect the confidentiality of the counsellor - client relationship while obtaining parental consent.

Not all minors have parents or guardians, or it may not be possible or safe to obtain consent from a parent or guardian (for example, research with homeless youth, or research with young victims of incest). In these situations obtaining informed consent from a parent or guardian may be waived after the relevant ethics committee has satisfied itself that a waiver is necessary based an assessment of the safety issues for the minor or the impossibility of obtaining parental/guardian consent. In such circumstances researchers should consider whether consent can be sought from another appropriate adult in proximity to the minor (eg. social worker) to provide confirmation of the consent process.

In addition, researchers may need to obtain permission from schools, Department of Education or other organisations where the participants are being recruited.

3.7 Situations where the capacity for fully informed consent is reduced

There are circumstances where participants in research may not be able to give informed consent or where this may be compromised. This can occur for several reasons. One is that the individual does not have the capacity to give fully informed consent (for example, unconscious). A second is where an individual is capable of giving consent but has difficulties in understanding the information provided by the researcher (for example, the researcher and the potential participant do not speak the same language, the participant may be illiterate). Thirdly, external circumstances may affect how participants will make a choice (eg. research on prisoners - inmates may feel obliged to participate).

Some research situations where capacity to consent could be impaired are those where participants are:

- psychologically or cognitively impaired
- unconscious or critically ill
- prisoners or wards of state

- recipients of pensions or benefits
- in a dependent relationship with the researcher, for example, student/teacher, patient/doctor, client/professional
- in commercial or political contexts where independent action may be impaired (for example, a coercive political influence may inhibit free choice)
- in contexts where cultural or language differences affect how information is understood.

These situations do not remove the requirements for fully informed consent. Researchers are encouraged to explore all available options and develop creative solutions to obtaining informed consent and its documentation. This may involve the use of guardians, witnesses, deferred documentation or researcher statements.

Where a participant lacks competence to consent, a person with lawful authority to decide for that participant must be provided with that information and exercise that choice.

Consent to participate in research must not be subject to any coercion, influence or inducement which could impair its voluntary nature.

Dependent relationships

Special care should be taken when recruiting participants who may be in a dependent relationship (doctor/patient, student/lecturer, pupil/teacher, professional/client), with any of the researchers, or, who are in other ways vulnerable (ill, frail aged, wards of state, prisoners). Researchers need to ensure that participants consent freely and do not feel obliged or in any way pressured to be involved in the research. The researchers need to take steps to help ensure participants do not feel under any obligation to take part in a project. It may be appropriate to have a third party undertake the recruitment for the study. Participants must be advised that their decision to be involved, or not, will have no consequences for their relationship with the researcher regarding any service or treatment they might be receiving, at that time or in the future.

3.9 Research in other institutions

When participants in a study are related to another institution, such as a school, community organisation, or commercial enterprise, the approval of the institution may be required before potential participants can be approached. Researchers are responsible for obtaining appropriate approvals. In some cases this may involve negotiations with the institution's human research ethics committee. This is especially true in hospitals, nursing homes and other medical institutions. In some cases, ethics approval from one properly constituted human research ethics committee may be accepted by another institutional ethics committee, but this is not always the case, and researchers will need to clarify this.

3.10 Research in hostile environments

Sometimes informing institutions or powerful bodies of the intention to carry out research may preclude the research from going ahead. In these circumstances permission from the hostile institution may not be required by the ethics committee. Such situations need to be explained to the ethics committee for its assessment.

Release from the obligation to obtain consent from a governing body does not equate to a waiver of the need to obtain consent from the participants in the research. The hostile environment may raise some particular issues in the area of consent, particularly if the participant may be at risk because of their participation in the research, for example, loss of employment. Researchers need to consider the additional ethical issues involved in carrying out research in hostile environments, especially questions of how consent is to be documented in situations where written consent may compromise the participant's confidentiality.

3.11 Research on hostile subjects

In some situations, research involving human participants may be investigative in nature, and the participant may be entirely hostile to the researcher's aims in the study. This would be the case, for example, if a researcher's work is seeking to expose or investigate improper practice in some field. In these cases, informed consent of the participants may be unobtainable, yet a researcher may consider that the research itself is ethically driven and a significant area for study. In such a circumstance, the researcher may believe that the principles of informed consent should not fully apply. In a case such as this, the researcher will have to write to the committee explaining why the study is significant, and why it is not possible to seek the consent of the participant. In addition the researcher must outline for the committee the likely outcomes of the study and risks to the participant. The committee will decide on such research on a case by case basis.

3.12 Deception in research

Deception in research is generally not accepted as ethical practice, however, some research designs may involve a degree of deception. Researchers should consider seriously whether deception in a research design is necessary, and whether or not the information sought can be obtained another way.

In research involving degrees of deception a range of strategies can be undertaken to obtain consent, for example, partial or *post hoc* consent. Sometimes consent based on partial or somewhat misleading information can be used in research where a level of deception is necessary. For example, in research into the effects of background music on learning skills, participants may be informed only that the research is into learning skills rather than on the effects of background music, as full knowledge of the research design would invalidate the research. Where deception is involved all participants should be given full information about the study on completion of the project, as well as be invited to participate in a debriefing session to discuss the issues relating to deception in the research and how they felt about being involved in such research.

4. When informed consent is not required

In some circumstances the ethics committees may agree that informed consent will not be needed from participants in a particular research project. Those circumstances include:

- research based on writings or documents in the public domain
- observational studies where individuals are not identified in the research (for example observational studies in public places)
- the case notes or reflections on practice of a qualified professional, written up for publication. This needs to be done is such a way that the participants are not identifiable.

5. Process of obtaining informed consent

The informed consent process requires the full disclosure of all information relating to the study by the researcher to the participant so that the participant can make informed decisions about whether to take part or not. In the case of continuing research the informed consent of the participant is not simply obtained at a moment in time, eg. by the signing of a form, rather it is part of an on-going process between researcher and participant as the research progresses.

As a general principle full disclosure of all relevant information is to be made to the participant but in some circumstances (use of deception) this may not be the case (see Section 3.12 above).

Consent is usually obtained from participants in writing by use of an information sheet and a consent form. Participants are given written information about the study, disclosing all information that will be necessary for them to make an informed decision concerning participation. In addition to written

information the researcher will usually take time to explain the study to the participant and to answer any queries or concerns the participant may have. Depending on the intrusiveness and complexity of the study potential participants should be given time to think about the study before they agree to participate. Potential participants should be encouraged to discuss the projects with others before they decided to participate.

When an individual agrees to participate he or she is asked to sign a consent form which identifies the study and outlines the researcher's and participant's understanding of what they are agreeing to. Appendices 1 and 2 provide details of the information that researchers are required to include in the plain language statement for participants and the consent forms. Even if participants have signed a consent form they may withdraw from the study at any time without explanation.

6. Ways of documenting informed consent

There is a range of procedures for documenting informed consent. It should be stressed that the *documentation* of informed consent is no substitute for the *process* of informed consent.

The consent documents have two functions for both the University and the researcher. They define the parameters of the research for both the researcher and the participant and they provide written evidence for the University of the consent procedures that are being used and that the research is being conducted ethically. The University has ethical obligation to ensure that research is being conducted according to accepted guidelines. In the event of a dispute the written documentation could assist researchers in verifying that their research was carried out according to the approved ethics protocol.

Researchers are encouraged to explore the different means through which informed consent can be documented to ensure that mechanisms of documenting informed consent are culturally appropriate to the research context. Possible ways of documenting informed consent include:

- use of a consent form – the signed document is a written acknowledgment of consent to participate by the participant;
- documentation of consent provided by a witness to the procedure of informed consent (taped or written);
- taped verbal consent of the participant;
- delayed witnessing of verbal consent - the tape is transcribed by a third party who "witnesses" that consent was obtained by the researcher, the tape is then destroyed to protect the participant's identity;
- verbal consent where it is culturally inappropriate to request documentation of consent;
- a signed *researcher statement* of the process of informed consent. This may be used where it is culturally inappropriate to request documentation of consent; or for telephone interviews when it is not possible and/or appropriate to sign consent forms. A researcher statement requires the researcher to provide a personally signed checklist which lists the steps of the consent process, as a record that informed consent was obtained;
- where an interview is recorded and transcribed, and the participant is asked to check and sign the transcription, the signature on the transcription can be used as documentation of consent to the procedure.

7. When should consent be witnessed?

It is considered that having a witness to the consent process is a protection to both the investigator and the participant in the research. Researchers should consider whether it is appropriate to have the consent process witnessed by a third party for any particular study. Where research is of a

particularly intrusive nature or where the participants are considered vulnerable it may be appropriate to have a third party witness.

It may not be necessary or appropriate to have a witness in the following circumstances:

- it can be assumed that the participant has consented to the process (such as voluntary completion and return of a questionnaire);
- the procedure involved is indisputably low risk, and not personally sensitive to participants;
- it is 'unsafe' for participants to identify themselves (because, for example, they are supplying legally sensitive material);
- it is impracticable. In this case investigators should explain why it is considered impracticable.

What must a witness do?

A witness may either:

- be present during the process of explanation of the intended procedure and the agreement of the participant, and thereby witness the procedure of obtaining informed consent; or
- witness the signing of a consent form.

The higher the risk to the participant the more appropriate it is for a witness to be present during the process of consent. The principle also applies to the subject population; the more vulnerable a subject population, the more important it will be for a third party to be present for the process of consent.

For projects involving high risk, or where highly vulnerable subject populations are involved, it is useful to consider participants being given an opportunity to have a friend or family member present with them during the process of consent.

Who is an appropriate witness?

The investigator should not perform both functions of recruitment and witnessing. Wherever possible the witness must be independent of the investigator and the research team. If participants have a friend or family member present it may be appropriate for that person to act as witness.

4. When documentation of informed consent is not required

There may be circumstances where informed consent is required, however documentation of informed consent may not be required. Documentation of the informed consent process is not required in the following circumstances:

- where participation in the research explicitly denotes consent, for example, where participants have voluntarily completed and returned an anonymous questionnaire in circumstances where there is no pressure to do so;
- some interview situations where the interviewee is in a more powerful position than the researcher and can freely choose to participate or not, for example, interviews with politicians about public matters.