



Human Research Ethics Committee

Further Exploration of Vulnerable Groups

HREC Document No: 6

Approved by the UCD Research Ethics Committee on February 28th 2008

Vulnerable Groups are categories of people who are not legally able to provide informed consent due to age or incompetence. Children, students, people who have a language difficulty, persons who have an intellectual or mental impairment, certain groups of elderly people, persons who are incarcerated, and people in dependent or unequal relationships (teacher/lecturer-student, therapist-client, employees as participants) are also viewed as vulnerable groups. Other groups might also be included in this category depending on the nature and context of the research.

Research that involves vulnerable groups may require a proxy (parent, guardian or legal representative) to provide consent. However, in such situations researchers should provide an appropriate explanation of the research to each participant and obtain his or her assent to participate, in addition to the appropriate permission gained from a legally authorised person.

Researchers should note:

1. A proxy signature, in itself, will not perfect an improperly formed consent by a member of a vulnerable sub-group (i.e. except for guardians at law).
2. Securing a proxy signature may, however, help to demonstrate that the researcher is not attempting to take advantage of a vulnerable person.
- 3 The more vulnerable the subject is, the greater is the degree of caution and prudence, which should be exercised by a Researcher.
4. There may be cases where it might be preferable for a researcher to exclude a particular person from the research if consent would rely on a proxy. If a researcher is in doubt on this point it is recommended that advice initially be sought from the Head of School or Research Group or from a colleague who has

experience in dealing with the vulnerable group in question and if necessary from the Chairperson or Academic Secretary of Human Research Ethics Sub Committee.

Children

Research involving children (under the age of 18) should only be conducted where the:

- (a) research will contribute to the health and well being of children;
- (b) information required can only be provided by children;
- (c) research method is appropriate for children;
- (d) research conditions provide for the safety (physical, emotional and psychological) of the children.
- (e) all requirements under child protection legislation and procedure are in place and observed

In order to justify the involvement of children in your research, the specific benefits the child will encounter must be documented. Consent to a child's participation in research must be acquired from:

- (a) the parents or guardian of the child
- (b) the child, if he or she is able to comprehend aspects of the research (age seven and older) and is competent to make this decision.

Consent should be secured from parents before children are invited to participate in the research. A separate assent form should be developed for the child, tailored to his/her understanding and should include reasonable descriptions of discomfort. Refusal of the child to participate in the research must be respected even in situations where the parent or guardian has given their approval. The UCD Research Ethics Committee will not approve or consent to research that is contrary to the best interests of the child.

Students

The status of student is viewed as rendering individuals vulnerable with regard to research. If the study proposes to involve students formal approval will be required from the Head of School or the Registrar. See further details below in section on Persons in Dependent or Unequal Relationships. In the case of certain unequal relationships such as that of teacher/lecturer- student, the student may feel constrained from refusing to become a research subject. In such cases researchers should seek advice before approaching the students. Such advice should be sought initially from the researcher's Head of School.

Persons who have a language difficulty or impairment

If research involves people who have a limited understanding of the English language, the research should provide a consent form in English and one in a language understandable by the participants. In some cases, an explanation of the translations and the assistance of a translator may be beneficial. In addition, where there is a concern that potential subjects may have difficulty with written comprehension of information the researcher must ensure that information is provided in an accessible format. Alternatively, in situations where there is a concern regarding the accessibility of written information (either due to a learning difficulty or familiarity with the English language) an oral presentation of informed consent information may be presented in conjunction with a short accessible written consent document, which states that elements of the consent have been presented orally. In this situation the researcher should maintain a written summary of the oral presentation. The participants should sign the consent form in the presence of a witness to the oral presentation. Participants must be provided with copies of the short form document and the summary of the oral presentation.

Persons who have an intellectual or mental impairment

In considering research involving persons with an intellectual or mental impairment the UCD Ethics Committee will weigh the potential benefits of the research against the risk or undue burden to the participants. Consent to participate in research by a person who has an intellectual or mental impairment must be acquired from:

- (a) the individual who has an intellectual or mental impairment when he or she is of sufficient competence, or in cases where the impairment is temporary or recurring, when the impairment does not prevent him/her from giving or refusing consent; or, if this is not possible, from

- (b) the individual's guardian or legal representative.

In the case where a proxy gives consent the study must be explained to the participant themselves. Refusal of an individual who has an intellectual or mental impairment must be respected. The UCD Research Ethics Committee will not approve or consent to research that is contrary to the best interests of an individual who has an intellectual or mental impairment.

Certain groups of elderly people

If an elderly participant has impaired vision or hearing they are often able to consent themselves. However, if a person is deemed to be incompetent due, for example, to Alzheimer's disease or other brain disease, the researcher must obtain the consent of a proxy. Although the proxy may not know the wishes of the subject regarding participation in research, he or she should try to decide how the person would have decided. The proxy should discuss the decision with family members and/or the medical

staff caring for the person. Even if the participant has been deemed incompetent, he or she should be considered competent to refuse to participate.

Persons who are incarcerated (prisoners or residents in 24 hour nursing facilities)

People who are incarcerated are rendered vulnerable by their dependent and unequal relationship with the institution.

People in dependent or unequal relationships (teacher/lecturer-student, therapist-client, employees as participants)

With regard to research, persons in dependent or unequal relationships are those in which an unequal or asymmetrical relationship is evident. The selection of such participants should be completed in a way that is free from coercion. Subjects should not feel that refusal to participate may result in some disadvantage or penalty. Participants should not be selected solely on the basis of convenience; all ways of recruiting participants should be examined. Some relationships are potentially problematic in terms of informed consent; therefore, extra consideration may be needed to accommodate these situations. If prospective research subjects are subordinates, students, or dependent on the researcher in another way researchers should take steps to protect participants from any adverse consequences relating to refusal to participate or withdrawal from participation.

(a) Teacher/lecturer-student

When a teacher wants to include her/his students in a research study, she or he must not assume that everyone will want to participate in the study. Students must be assured that their grades will not be affected by participation or non-participation. Even

when there is no identified risk in the research, students or other participants have the right to refuse to be involved. If participation in research is a course requirement, students should be given the choice of an equitable alternative.

(b) Therapist-client

If research involves individuals who are in a therapist-client relationship with the researcher (or similar service provision arrangement), it is important to make a distinction between the treatment or service and the research involvement and measures must be taken to ensure that the subject's decision to consent is not determined by the professional's influence. In addition declining to take part in the research should not prejudice an individual's access to the treatment or services.

(c) Employees as participants.

Employees, whether colleagues or subordinates should not feel coerced into participation or put in a situation in which they may perceive disadvantage or retribution for refusal to participate in research. In order to avoid such coercion, it is better to recruit subjects via advertisements or a third party.