Guideline:

Vulnerable Groups in Research

Vulnerable Groups in research are categories of people who are not legally able to provide informed consent due to age or incompetence and include the following:

- Children (under 18);
- Students;
- people who have a language difficulty;
- persons who have an intellectual or mental impairment or neurological condition;
- certain groups of elderly people (with physical or mental impairment);
- persons who are incarcerated;
- people in dependent or unequal relationships (teacher/lecturer-student, therapist-client, employees as participants);
- 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, next of kin, carer, 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 ad litem).
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 of Human Research Ethics Sub Committee.

Assisted Decision Making

A new law has been passed which maximises a person’s right to make their own decisions, with legally recognised supports, whenever possible. The Assisted Decision Making (Capacity) Act 2015 was signed into law on the 30th December 2015. This Act applies to everyone and is relevant to all health and social care services. The Act is about supporting decision-making and maximising a person’s capacity to make decisions. The Act has not commenced yet. ¹

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;

¹ For the latest developments regarding the Assisted Decision Making Act please See https://www.hse.ie/eng/about/who/qid/other-quality-improvementprogrammes/assisteddecisionmaking/assisted-decision-making.html
(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 any discomfort likely to arise. Children should be given sufficient time to consider and reflect on what they are being asked to do before giving their consent. 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 Human Research Ethics Committee will not approve or consent to research that is contrary to the best interests of the child. In all cases where research involves the participation of children, Garda Vetting is required before research can proceed.²

Elderly People (certain groups)

If an elderly participant has impaired vision or hearing they are often not able to consent themselves and may require the assistance of their next of kin or carer. However, if a person is deemed to be incompetent due, to Alzheimer’s disease for example, or other neurological conditions, the researcher must obtain the consent from their next of kin or carer. Although

² Garda Vetting Requirements: The new National Vetting Bureau (Children and Vulnerable Persons) Acts 2012-2016, make it mandatory for people working with children or vulnerable adults to be Garda – vetted. For further information see: http://www.ucd.ie/researchethics/information_for_researchers/gardavetting/
they may not know the wishes of the elderly person regarding participation in research, he or she should try to decide how the person would have decided. They 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. Incompetent elderly people should be treated with dignity and respect by the researcher who should take the time to explain the study verbally regardless of the level of understanding by the elderly person.

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 or Neurological condition
In considering research involving persons with an intellectual or mental impairment or a neurological condition, the Human Research Ethics Committee will weigh the potential benefits of the research against the risk or undue burden to the participants – competent or incompetent. Consent to participate in research by such a person must be acquired from:
(a) the individual who has an intellectual or mental impairment or a neurological condition (e.g. bi-polar disorder, Alzheimer’s disease, severe learning disability) 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 or neurological condition 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 or a neurological condition.

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 they are being accessed through.

People in Dependent or Unequal Relationships (therapist-client, employees as participants, teacher/lecturer-student)
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) **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.

(b) **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.

(c) **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.

**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 and/or the HREC (on behalf of the Registrar). See section above on Persons in Dependent or Unequal Relationships and sections below on Research with Students who are Minors, and Recommendations for Research with Student Population in UCD. 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.

Research with Students who are Minors (where UCD-registered student minors are the subject of the research)

What is a minor?
A minor is defined as someone under the age of 18. It is reasonable to presume that minors under 16 cannot give a proper consent, but that minors between 16 and 18 may sometimes be able to do so and at other times be unable to do so. The latter group (16-18 year olds) is present amongst the cohort of UCD undergraduate students. Overall, the University has an operating presumption that minors between the ages of 16-18 cannot give a valid consent unless investigators, on the basis of accepted ethical principles agreed with the UCD research ethics committee, successfully argue it otherwise.

What can a minor consent to?
The medical profession takes a different approach where consent is required for medical and therapeutic procedures. Patients aged 16 years and over are entitled by law to give their own consent to surgical, medical or dental treatment. However, this entitlement does not apply to other areas such as participation in medical research. Researchers are reminded that in most instances research involving minors in UCD does not involve medical research and is therefore almost certainly non-therapeutic. For this reasons it is imperative that no foreseeable harm might occur to a minor as a result of his/her participating in this kind of research.
Who can consent for a minor?
Participation of minors in research usually requires the consent of their parents or guardians. Parents or guardians are best placed, and have a duty, to make decisions in the best interests of the minor. It is very difficult to argue that allowing minors participate in research is in their best interests.

What is the researcher’s duty with respect to a minor?
The researcher has a duty to consider the best interests of the participant, more particularly when that participant is a minor. Should a researcher know or suspect on reasonable grounds that a consent obtained from a minor’s parent or guardian is not in the best interests of the minor, the researcher should not pursue the research on that minor, as the consent obtained is likely to be of little value or protection. For the researcher, it is of primary importance to anticipate whether there is any possibility of harm occurring to a minor as a result of participating in their research. The University expects researchers to address this issue fully and with great care in their research proposals, and when conducting the research itself, to be very careful to ensure no harm does come to the minor.

What is the University’s duty with respect to a minor?
Within the University community, researchers are often interested in investigating their students and student life. The researcher is reminded that the University is a community of scholars and as such it must not condone or approve anything that is oppressive or damaging to its own students, who are part of that community.

When can minors consent to be research participants?
Some minors, particularly university students themselves, may well be able (i.e., have sufficient capacity at law) to consent to non-therapeutic research because they are capable of understanding the nature and likely consequences of the research and in fact have done so. It is the duty of the researcher, on an individual case-by-individual case basis, to ensure that a
minor has in fact the proper understanding of what she or he is consenting to. This is an important issue for all research but is even more important with research involving minors because there is a greater need to protect their best interests.

What must you include in your research application for participants who are minors?

- Provide a justification and rationale for the inclusion of the students who are minors in the research they wish to undertake;
- Show evidence that the information being sought from the research cannot be obtained by alternative, less intrusive means than the research proposed;
- Show evidence that the steps taken to inform minors of the purpose of the research demonstrate that minors are capable of understanding the nature and consequences of the research they are being asked to participate in;
- Show evidence that consent by the minor to participate in the research has been obtained based on a full understanding of the nature and consequences of the research they are being asked to participate in;
- Describe the steps taken and the methods employed to protect the interests of the minor;
- Describe the steps taken and the methods employed to ensure no foreseeable harm comes to the minor.

The HREC will consider each application for research ethics approval of research involving minors on a case-by-case basis in line with its policy of facilitating ethical research while protecting research subjects, research staff and the reputation of the university.

Recommendations for Research with Student Population in UCD

Students are currently included as a vulnerable population in all Research Ethics Committee and Human Research Ethics Committee documentation. However it is recognised that it may be
more appropriate to consider this group as requiring additional consideration in the research process rather than as vulnerable per se.

There are a number of reasons why students may require additional consideration as participants in research.

Key issues are:

- the potential for undue influence, or
- unintentional pressure to participate where research is being conducted by staff members who have an existing relationship with the student. This can include lecturers but also postgraduate students who are tutors or demonstrators in their respective Schools.

In addition, consideration is required to:

- ensure that the quality of students’ experience of their time at UCD is not negatively affected by multiple requests to participate in research.
- ensure that researchers consider the fact that sourcing student participants as a result of their availability may mean that they are more exposed to invitations to take part in research as a result of being a ‘captive audience’.

Given these different issues it is important that researchers consider the extent to which these issues apply in their study.

It is possible to identify a number of situations where research with students may fall under the low risk study review process for ethics approval.

For example these studies are considered to be low risk studies and exempt from a full review:
• where students are conducting research with their peers (i.e. students at the same stage of study, so there is no existing unequal relationship), and

• the topic and methodology of the study does not fall under the criteria of sensitive topics, or invasive procedures, and

• the study does not raise any other ethical dilemma (e.g. unequal power relations).

In addition, in recognition of the existing exemption categories, the following is also considered as low risk and exempt from a full review:

• research using anonymous student data that would fall under the label of ‘standard educational assessment or practices’ (e.g. including student performance and feedback data). Please note that in this situation, researchers will be required to inform participants in advance that the information may be used for research purposes.

In all of the above situations researchers should limit participation to students aged 18 years and over, should follow the existing procedures for the low risk study review submission which includes a request to access students for research and makes provision to indicate a requirement for campus-wide surveys via the University Student Survey Board (USSB).