

Guidance for Researchers conducting Research with Vulnerable People

This Guidance is for researchers engaged in research involving participants who are or may be vulnerable. It sets out the issues which REC reviewers consider important in reviewing applications for research ethics approval.

The Guidance recognises that research with vulnerable research participants can make an important contribution to improving the lives of vulnerable people. For this reason, vulnerable persons should not be excluded from research because of the challenges involved, rather researchers are encouraged to develop the ethical practices required to include such persons in their research projects. However, it also reflects the concerns which arise in carrying out research with vulnerable participants and the importance of appropriate and proportionate safeguards in this context.

Who are vulnerable research participants?

Vulnerability may be understood as a diminished ability to full safeguard one's own interests in the context of a specific research project. There are different reasons why a person might be considered vulnerable. Reasons may include limited decision-making capacity or limited access to social goods, such as rights, opportunities and powers. Individuals or groups may experience vulnerability to different degrees and at different times, depending on their circumstances.

Some research participants who may be considered vulnerable

- Children and young people
- Adults with a learning disability
- Adults with cognitive impairment
- Older adults
- People with mental illness
- People with serious illness or life-limiting conditions
- People with conditions which may have a social or legal stigma (e.g. addictions/HIV positive)
- People who are in an unequal power relationship with the researcher (e.g. students or staff depending on the context)
- People who are detained or subject to criminal sanction (e.g. prisoners; people on probation).

This is not an exhaustive list. People in these categories will not always be vulnerable and, depending on the nature of the research, the category of vulnerable participant may include participants beyond these categories. For example, where research relates to issues which are potentially distressing or traumatic for the participants, the category of vulnerable participant will be broader than where the research relates to matters which are unlikely to be distressing or traumatic for the participant. This means that the categorisation of research participants as vulnerable must take account of the participant's characteristics, their situation **and** the nature of the research.

In order to obtain university ethical approval for the research, researchers should expect to have additional ethical obligations and specific measures in place in recognition of the vulnerability of research participants.

What should I consider in conducting research with participants who may be vulnerable?

Where research participants may be vulnerable, researchers should pay particular attention to the following issues:

1. Recruitment

Participation in research must always be voluntary. Researchers working with vulnerable research participants should at all times be conscious that a vulnerable participant may feel that s/he does not have a real choice as regards the decision to participate in research. An important role of the ethics approval process is to ensure that appropriate recruitment processes are in place to ensure that the participation in research by vulnerable participants is voluntary.

Researchers should provide information which allows the REC to be confident that vulnerable participants do not feel/have not felt under pressure to participate in the research. This includes:

- Details of the recruitment strategy
 - This should reflect that recruitment is based on free and informed choice and that there is no pressure applied by the researcher or a third party in respect of participation
- Details of the recruitment methods, including provision of any recruitment poster/email etc.
- Precautions taken to avoid any possibility that the participant will feel coerced or pressured into participation
- The provision of clear written assurance that there will be no negative consequence if a person refuses to participate in research
- Clear evidence of ongoing control of recruitment by the researcher and that control has not been handed over to a third party.

2. Language

Documentation should be prepared in appropriate language which is not demeaning for participants or their supporters/family members.

If a study framework is being adopted from another country, researchers should ensure that all terminology/language used is appropriate in an Irish context.

3. Informed Consent

a. Adults with cognitive impairments

The fact that an adult has a cognitive impairment or learning disability does not mean that s/he is unable to consent to research. In many situations, adults with cognitive impairments/learning disabilities will be able to participate in research provided that the necessary information and supports are put in place.

In order to have capacity to consent to participate in research the participant must be able to:

- Understand information about the research
- Retain the information for long enough to reach a decision about whether to participate in the research
- Use and weigh the information so as to decide whether to participate in the research
- Communicate the decision to participate in the research.

Researchers should ensure that:

- The participant is provided with appropriate and accessible information together with appropriate props/additional materials so as to ensure that the participant is able to give informed consent to the research. This information should be provided to the REC.
- The participant is given ample time to understand the research and the consequences of participation and to discuss the research with their chosen support person toward helping them to make their decision.
- The participant is facilitated in asking questions about the research and the consequences of participation.
- The participant is facilitated in having a trusted person chosen by the participant available as a supporter during the decision about whether to participate in the research. Information about the structures and processes put in place toward ensuring informed consent should be provided to the REC.

b. Children

In line with the *Guidance for Developing Ethical Research Projects Involving Children* (2012) provided by the Department of Youth and Community Affairs, a child is defined as a person under the age of 18 years.

This clearly states that parental and/or guardian informed consent is required in respect of research participation by a child (under the age of 18 years). Good practice also requires that the child agrees to participate in the research.

Information in respect of the research should be provided to parents/guardian to the child in an appropriate and accessible manner so as to ensure that consent is properly informed. This includes the provision of child-friendly information sheets, consent forms and assent forms appropriate for the age and maturity of the child. Samples of this information should be provided to the REC.

4. Additional Requirements pertaining to children who are research participants

- All researchers working with child participants must comply with the UCC Child Protection policy and Garda vetting requirements.

Further detail on these is available at

https://www.ucc.ie/en/media/support/ocla/policies/UCC_Child_Protection_Policy_5April2018-Final.pdf and

<https://www.ucc.ie/en/media/studyatucc/undergrads/downloadabledocumentssection/UCCStudentVettingPolicyandProcedure.pdf>.

Students for whom Garda vetting is required should contact studentgardavetting@ucc.ie for information and to initiate the vetting process.

Staff for whom Garda vetting is required should contact the University Liaison person Sylvia Curran at s.curran@ucc.ie to initiate the vetting process.

- In UCC, research involving children and other vulnerable persons / groups requires a data protection impact assessment to be undertaken. For further information, see:

<https://www.ucc.ie/en/gdpr/procedures/dataprotectionimpactassessmentprocedure/>

- In recognition of the vulnerability of a child in research contexts, good practice is that a researcher and a child should not be alone together (another person that the child trusts should be present or very close by) and that if for reasons of confidentiality, the researcher and child are alone together (e.g. in an office / child's home) the room has to have an open door or visual access.

5. Carrying out the Research

The research must be carried out in an appropriate way which takes account of the nature of the vulnerability of the research participants and evidence of this needs to be provided to the REC. This may require some or all of the following steps to be taken:

6. All Vulnerable Participants

- Research process must be structured in a way which is not too onerous for participants
- Appropriate breaks and rest periods must be factored into the research process
- Appropriate props and/or materials should be used and advice may be obtained from vulnerable persons' representatives / advocates as to the suitability of these

- The researcher should be alert for any signs of trauma or discomfort on the part of the vulnerable research participant to act accordingly
- The researcher should put in place the procedures and practices needed to prioritise the safety, welfare and rights of vulnerable persons when carrying out their research and detail these in their applications to the REC.
- Depending on the circumstances, vulnerable participant may wish to have a trusted supporter within them during the research. This may be especially important for young children or adults with cognitive impairments. Structures should be in place to ensure that research participants are facilitated in having a trusted supporter present.
- Research Project Advisory Panels / Steering Groups, which include advocates / service users / vulnerable persons / vulnerable persons' representatives can usefully guide and advise researchers. Researchers should always indicate the structures / practices adopted in their REC applications.

7. De-briefing/Supports

It is especially important where the research relates to topics which may be traumatic or distressing that vulnerable participants are afforded appropriate and effective opportunity for de-briefing after the research has been concluded. Details of de-briefing mechanisms should be provided to the REC.

Vulnerable participants should be provided with access to appropriate supports with the level of support offered being proportionate with respect to the extent to which the research is likely to be traumatic or distressing for participants.

8. Research Benefit

Just as researchers should seek to minimise the risks of participation in research for vulnerable persons, they should seek to maximise the benefits of their participation in the research and not compound persons' vulnerability, by taking the following into consideration:

- Being sure that the participation of vulnerable persons is essential to the particular research project
- Undertaking a costs benefits analysis for the research participants when the research is being planned
- Being realistic about the benefits likely to result from the research for participants, but also doing their utmost to ensure participants do benefit
- Careful and sensitive research reporting
- Putting in place accessible modes of research dissemination for the benefit of vulnerable participants.