Research Ethics

Human Research Ethics Committee (HREC)

Guideline:
Informed Consent in Research

Introduction

Informed consent is the process by which a fully informed competent person voluntarily chooses whether to become a human participant in research. This process involves describing the research to potential participants, what they are being asked to do, what will happen to their data and how it will be managed, and their rights as a participant. The process is ongoing, beginning before consent forms are signed and continuing until the subject is no longer involved in the study. Informed consent requires that participants have a genuine understanding of the research, which involves full disclosure of information about the research to potential subjects including an adequate understanding of the research procedures, the risks and benefits of the research, rights of the subjects and the voluntary nature of participation. The informed consent document, which should include an information sheet for the participant to retain, confirms that people understand exactly what is involved in the study, and what they are to do, and provides protection from liability.

Definition of 'Informed Consent'

Informed Consent is a process by which a person voluntarily opts into a research study and it can only take place after they have been fully informed of all that the study will entail, and all that they will be required to do to become a participant, and are fully aware of what will happen to their data. Consent must be 'freely given, specific, informed and unambiguous'.[1]

[1] See https://www.dataprotection.ie/docs/GDPR/1623.htm and https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/

Capacity to Consent

Capacity means the ability to use and understand information to make a decision, and communicate any decision made. A person lacks capacity if their mind is impaired or disturbed in some way, which means they are unable to make a decision at that time.[2]

A person's capacity to make decisions may be impaired due to one of the following:

- mental health conditions – such as schizophrenia or biopolar disorder
- dementia
- severe learning disabilities
- brain damage – for example, from a stroke or other brain injury
- physical or mental conditions that cause confusion, drowsiness or a loss of consciousness
- intoxication caused by drugs or alcohol misuse

Someone with such an impairment is thought to be unable to make a decision if they cannot:

- understand information about the decision
- remember that information
- use that information to make a decision
- communicate their decision by talking, using sign language or any other mean

As capacity can sometimes change over time, it should be assessed at the time that consent is required. This will usually be done by an appropriately trained and experienced healthcare

[2] 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. Please note that updates on the commencement of the Act can be found at: https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/assisteddecisionmaking/assisted-decision-making.html

professional who is aware of the limitations involved in consenting a person who has any of mental impairments as listed above. If a person lacks the capacity to give consent, a decision about whether they can participate in a research study will need to be made by the healthcare professionals responsible for them. To make that decision, the person's best interests must be considered.

Describing Informed Consent for a Participant

Before a person (participant) with an impairment can agree to participate in a research study, the researcher must ensure that the person has been made aware of the following key points:

1. The Purpose of Research:

The informed consent process must communicate to the participants that the study involves research and it is important to use words such as 'research', 'study', 'investigation', etc. The researcher must state the reasons for the research or the objectives of the research, providing an explanation of the research procedures and specifically identifying experimental procedures.

2. Research Procedures:

It is important to explain tasks and procedures from the participant's perspective, indicating what is expected of him or her and explaining the frequency/duration of procedures. The researcher must provide estimates of the total amount of time individual participants will be involved in the research and the amount of any additional costs or charges for the research procedures. In addition, eligibility criteria should be specified, indicating why the individual is eligible to participate or the criteria used to determine eligibility.

3. Potential Risks of the Research:

The researcher must describe the magnitude and probability of foreseeable risks or discomforts the subject may experience including common risks (inconvenience), soft risks

(embarrassment, limitations on confidentiality) and potentially serious risks (adverse effects), indicating the likelihood of such occurrence. Invasive procedures always involve some uncertainty regarding harmful effects, thus, risks should be explained in terms of the probability of their occurrence. The researcher needs to be aware of the fact that individual perception of the nature of risk varies and she or he may need to determine whether a participant is one who is a risk taker, ignores the risk(s) or has not properly understood the probability of the risk(s). If prospective participants enquire about risks or other aspects of the research, the investigator must supply an explanation.

4. Potential Benefits of the Research:

The researcher must describe the benefits of the research to the participant or others realistically, without overstating them. It is useful to provide the probability that particular beneficial effects will occur, however, remember that possible benefits of the research cannot be promised nor guaranteed. If there are no benefits, this fact should be clearly stated. The terms of any payments used to compensate individuals for their participation and the conditions under which research participants will receive partial payment or no payment at all must be clearly stated on the informed consent form and be in line with the UCD *REC Policy on Expenses & Incentives* (HG2B). It is important to note the benefits of the research to society, science, the profession, etc.

5. Alternatives to Participation:

If alternative procedures or courses of treatment exist that may be available or advantageous to the subject, information should be made available to the participants. Information on what would be viewed as standard treatment(s) for the client's diagnosis and the participant's other options should be provided. When research is non-therapeutic, the alternative may be non-participation.

6. Levels of Confidentiality:

Absolute confidentiality cannot be guaranteed, however, steps should be taken to ensure that the participant's privacy is protected. The researcher must explain to the participants the level of confidentiality of the research data and the measures that will be taken to ensure that confidentiality is maintained. In other words, he or she should provide a description of the steps that will be taken to protect the privacy of the participant and indicate under what circumstances records will be made available and to whom. This discussion may include a description of techniques, such as numeric codes, to be used for identifying data. The researcher should assure subjects that their identity will not be disclosed.

Absolute confidentiality is not always possible. For example, when the research involves a small number of participants, individuals may be recognizable or if data is recorded using audio, video or photographic records, others may recognize the voice or other features of the participant. In some cases, conditions such as child abuse or criminal activity must be reported to the appropriate authority. In rare circumstances, research records may be subpoenaed, in which case confidentiality may not be maintained.

For **Focus Group interviews** the participants must be informed that they must not disclose the contents of discussion, but that there is a risk of disclosure outside the focus group by other participants and they must be informed of this.

7. Disclosure of Potential Conflict of Interest:

If the research involves any potential conflict of interest, the researcher must inform participants about this situation.

8. Treatment for Research related injury or stress:

Participants must be informed of all contact details of the research and support services either medical or social if injury or an adverse event were to occur during the course of the research, and that appropriate and timely treatment would be made available where required.

9. Non-participation and the right to withdraw:

It is important to emphasize that participation is voluntary and refusing to participate will not involve penalty nor a decrease in benefits to which the participant is otherwise entitled, and that it will not effect their course work or course scores (if students) or affects access to services. The researcher should highlight the fact that the individual may discontinue participation at any time without penalty or loss of benefits. When limitations or risks are involved in withdrawal, for example, harm to individual well-being, these should be clearly explained.

10. What will happen to the data supplied by the participant and how it will be protected:

The researcher must clearly outline what will happen to the data, ie published as part of a higher degree, peer-review publication, will it be used in other studies or stored as part of an archive. If participants quotes are been recorded and might be used by you in your results, the participants need to be informed. The researcher must also ensure that all data be appropriately stored in a secure location within the university and indicate to the participant for how long, of if their data will form part of an archive that may be accessed by other researchers in the future. The nature of storage and management of data must be appropriate to the type of data collected as outlined under GDPR.

As part of the informed consent process, it is important that the researcher ensures that the information sheet/informed consent form are readable, he or she assesses the participant's

understanding of the research and that the subject is given an adequate amount of time in which to consider his or her decision to participate in the research.

11. Ensuring Readability:

Readability is an important part of the consent document process. In order to ensure that a consent document is readable, the information should be presented in simple, straightforward sentences, using only terms that are commonly recognisable and avoiding the use of jargon and technical terms. If a technical term is used, it should be defined in easily understood words. The consent document should be read by a lay person or someone who is not associated with the research in order to identify difficult or confusing elements of the document.

If a participant does not understand the language of the consent document, a translated document must be provided or arrangements made for a qualified interpreter to translate the information for the participant.

12. Assessing Participants' Understanding:

The researcher is responsible for ensuring that prospective subjects understand the extent of their role in the research. This can be accomplished by reading through the consent document with the participants and discussing their participation before they become involved in the research. In doing so, the researcher should answer questions but also ask open-ended, non-directive questions (participants should not be quizzed). It is important to encourage an open exchange of information in which participants ask questions. Participants should be reminded to continue to ask questions throughout the research process and that their willingness should be proactive. Asking questions does not release the researcher from the responsibility of providing the information that subjects need to make their decisions.

13. Time to Consider Participation:

It is important to allow sufficient time for potential subjects to think about their decision to participate in the research, and to discuss this issue with others.

14. Contact Information:

The researcher should provide details on who the participant should contact for more information about the research. It should include the names of people, including the principal investigator, who can answer questions about the research. Student researchers should include their names and University phone numbers of the principal investigator and, where applicable, the name of the research supervisor. In addition, it may be necessary to provide the contact name of a neutral third party who can explain the rights of research participants if the participant has any questions.

Consent from Minors

Where all the above sections need to be included, special consideration must be given to the consenting of minors and the information supplied.

- **Information Leaflet:** In accordance with the sections on Ensuring Readability, Assessing Participants Understanding and Time to Consider Participation outlined above, the information leaflet must be made child friendly and clearly understandable by the age group to be approached.
- **Consent from the Parent/Guardian and Assent from a Child:** A separate consent form for the parents and assent form for the children should be supplied so that children do not feel pressurised into participating and are given the opportunity to opt in or not.
- **Non-participation and Withdrawal:** Special considerations must be given to children who do not agree to participant when in a class and they must not be seen as different or left out during the course of the study so special arrangement must be made and clearly explained in the information leaflet.

- **Re-consenting at age of consent:** Children involved in longitudinal studies who will reach the age of consent during the lifetime of the study must be considered by the researcher who should have a system in place to re-consent and reinform with age related information.

Consent from Mature Minors

A child who is under the age of majority (ie 18) can be described as a mature minor, usually over the age of 16, if they have sufficient intelligence to understand the nature and consequences and the reasonably foreseeable benefits and risks of a study, however as a general rule all childrens parents or guardians must consent and the child must assent to involvement in a study and significant justifications would need to be presented to the ethics committee if this general rule was not to be applied.