Human Research Ethics Committee

Further Exploration of the Process of Seeking Informed Consent

HREC Document No: 4

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Introduction

The process of informed consent involves describing the research to potential participants. It is defined as "a process by which an individual voluntarily expresses his or her willingness to participate in a particular trial, after having being informed of all aspects of the study that are relevant to the decision to participate". By *the Harmonisation Guidelines for Good Clinical Practice* (ICH GCP 1996). This 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 often includes an information sheet, confirms that people understand exactly what is involved in the study, and what they are to do, and provides protection from liability. (See below: *Guidelines: UCD Information Sheet/Consent Form*)

Before people agree to participate in the study, the researcher must ensure that the participants are aware of the following information: the purpose of the research, research procedures, potential risks and benefits of the research, alternatives to participation (other procedures or courses of treatment), level of confidentiality (although absolute confidentiality cannot be guaranteed, steps to be taken to ensure that the participant's privacy is protected), disclosure of possible conflict of interest, treatment for research related injury, contact information (details on who to contact for more information about the research), withdrawal (highlighting the voluntary nature of the research and that participants may withdraw at anytime without penalty) and what will happen to the data that is supplied by the participant and how it will be protected.

The Purpose of the 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.

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 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.

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.

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*. It is important to note the benefits of the research to society, science, the profession, etc.

Alternatives to Participation (other procedures or courses of treatment):

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.

Level of Confidentiality (although absolute confidentiality cannot be guaranteed, 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.

It should be noted that 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 must be reported. In rare circumstances, research records may be subpoenaed, in which case confidentiality may not be maintained.

For focused 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 focused group by other participants and they must be informed of this.

Disclosure of Potential Conflict of Interest:

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

Treatment for Research related injury:

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.

Contact Information (details on who to contact for more information about the research).

The researcher should provide the names of people, including the principal investigator, who can answer questions about the research. Student researchers should include the 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.

Non-participation and Withdrawal (highlight the voluntary nature of the research and that participants may withdraw at anytime without penalty):

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 or effects 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.

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 for how long.

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.

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.

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.

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.

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 section on "Ensuring Readability, Assessing Participants Understanding and Time to consider participation" information leaflets must be made child friendly and clearly understandable by the age group to be approached.

Conflict of interest of parent: A separate consent form for the parent and assent form for the child may need to be supplied so that children do not feel pressurised into assenting.

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 will reach the age of consent and the study must have a system in place where they are re-consented and reinformed with age related information.

Mature Minors: A child who is under the age of majority (ie 19) 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.

HREC Information Sheet/Consent Form – Guideline

Please Note: Information Sheets and Consent Forms should be printed on official letterhead paper and pages should be numbered. The HREC recommend that applicants follow the format below for their information sheet and to include additional sections if necessary.

Structure and layout of Information Sheet

1. Introductory statement: include four important elements:
    - Researcher's name and descriptor (Professor, Ms., Mr.)
    - University College Dublin
    - Name of researcher's School
    - The topic and title of the research. If the title of the research is not self-explanatory, it should be replaced with a simplified title.
2. What is this research about?
3. Why are you doing this research?
4. How will the data be used?
5. What will happen if I decide to take part in this research study?
6. How will you protect my privacy?
7. What are the benefits of taking part in this research study?
8. What are the risks of taking part in this research study?
9. Can I change my mind at any stage and withdraw from the study?
10. How will I find out what happens with this project?

Consent Forms – Examples

Please note that these are examples only, some of the details may not be applicable.

Example A: Participant's Consent including elements specific to the study

DECLARATION

I have read this information sheet and have had time to consider whether to take part in this study. I understand that my participation is voluntary (it is my choice) and that I am free to withdraw from the research at any time without disadvantage. I agree to take part in this research.

I understand that, as part of this research project…….
I understand that my name will not be identified…..
I am voluntarily agreeing to....
I agree that the data can be used in the publication of higher degrees, scientific publications…

Name of Participant (in block letters): _____

Signature:_____

Date: / /

Example B: Participant's Consent with option to seek clarification

Please take time to consider whether you want to take part in this research or not. If you have any questions about the research, please telephone me, (name), at (telephone number) or contact me by e-mail: (e-mail address). If you agree to take part in the research, please sign the form below and keep one copy of this agreement for your future reference.

Name of Participant (in block letters) _____

Signature:_____

Date: / /

Example C: Participants' right to communicate with the researcher

If you have any questions regarding your treatment or rights as a participant in this research project, please contact _____at (telephone number) or contact them by e-mail: (e-mail address).

Example D: Participants' Consent to participate with conditions

DECLARATION

I have read this information sheet and have had time to consider whether to take part in this study. I understand that my participation is voluntary (it is my choice) and that I am free to withdraw from the research at any time without disadvantage.

Therefore, I agree to take part in this research *(please tick the box)* ☐

I hereby give permission for the use of the data collected from me using the following methods only: *(please tick the relevant box or boxes you are agreeing to)*

All data collected from me: ☐ De-identified data only: ☐

Personal Details only: ☐ Taped Interview *(audio)*: ☐

Photographs: ☐ Film/Video/DVD ☐

Name of Participant (in block letters):

_____

Signature:_____

Date: / /

Consent/Assent Form for Research Involving Children – Examples

If research involves certain vulnerable populations assent will be required from the participant in addition to consent from the parent or guardian. For further information see Document 6 *Further Exploration of Vulnerable Groups and Deception.*

- The information should be presented at a level that is readily understandable by the participant.
- The declaration should provide a space for the vulnerable individual's name and signature and a space for that of the parent or guardian.
- For example, for research involving children, the following declaration format would be appropriate:

Example E: Parent or Guardian's Consent to allow Child to participate

DECLARATION

Parent or guardian's consent to allow child to participate:
I have read this consent form and discussed it with my child. I have had time to consider whether my child will take part in this study. I understand that his/her participation is voluntary (it is his or her choice) and that we are free to withdraw from the research at any time without disadvantage. I agree that my child may take part in this research.

Name of Parent or Guardian (in block letters):
_____

Signature:_____
Date: / /

Example F: Child's Assent to Participate

DECLARATION

Child's assent to participate:
I have read this consent form and I agree to take part in this research.
Name of Child (in block letters): _____

_____

Signature:_____
Date: / /