Letter to Editor

INFORMED CONSENT PROCESS

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INTRODUCTION

Informed consent is a continuous process involving three main components – providing relevant information to potential participants, ensuring competence of the individual, ensuring the information is easily comprehended by the participants and assuring voluntariness of participation. Informed voluntary consent protects the individual‘s freedom of choice and respects the individual‘s autonomy. The researcher must obtain voluntary written informed consent from the participants for any biomedical and health research involving human participants. This requirement is based on the principle that competent individuals are entitled to choose freely whether or not to participate or continue to participate in the research.[1]

TYPES OF CONSENT[2]

1. Written informed consent document:

An Informed Consent document is most commonly used to fully inform participants of the study or project. A written informed consent document should contain a signature line for the participants and/ or legally authorized representative (LAR), witness and for the researcher obtaining consent.

2. Oral informed consent:

In cases where all elements of an Informed Consent Document are waived, an oral script may be used to informed participants about key points related to the study (i.e., participation is voluntary). This process should only be proposed if all waiver requirements have been met and justification has been provided to the ethical committee as to why this proposed process meets the waiver criteria.

3. Written parental/ guardian consent document (or parental/ guardian permission):

When someone under the legal age to consent, which is often the age of majority (i.e., child), will be recruited for a project, most commonly consent is sought from the parent or guardian before child assent (if child assent is appropriate for the age group).

4. Oral parental/ guardian consent script:

In cases where all elements of a Parental/ Guardian Consent Document are waived, an oral script may be used to informed ethical committee about key points related to the project.

5. Written assent form:

A Written Assent Form is most commonly used to fully inform children of the project and is most often used for those of a higher maturity, age and psychological

state (i.e. a 16 year old perhaps). Most often, a signature is still required in addition to the Required Elements of Consent. Consent elements should be written at a reading level appropriate to the participants grade level.

6. Waiver of assent:

In some instances, it may be appropriate to waive the use of an assent form. Most often, researchers will still be required to use an oral script with subjects to briefly inform them of key elements. Parental/ guardian consent should be obtained before assent.

7. Oral (verbal) assent form:

A Oral (verbal) Assent form is most commonly used to inform children of the project and is most often used for those of a lower maturity, age and psychological state (i.e., a 7 year old perhaps). A signature may be required in some circumstances, in addition to a witness.

8. Short form:

A Short Form is most commonly used when a majority of the target population would not be able to understand the written consent document (e.g., illiterate, do not speak/read/ write in English) and use of a written translated consent document is not reasonable for the target population. A short form generally contains all the required elements of consent and is used in conjunction with an oral presentation of the required consent elements. The short form and a written summary of what will be presented orally must be approved by the ethical committee and presented orally to the participants in front of a witness. The short form should be signed by the participants and the witness and the summary should be signed by the witness and person obtaining consent (e.g., researcher). The witnesses signature confirms the adequacy of the consent process and to the participant's voluntary consent.

9. Exempt research category:

If the research falls within an exempt research category, it may not require a consent form. However, in most cases the researchers should provide the participants with elements of informed consent that will assist them in making voluntary decisions about whether or not to participate in the research. The final determination of exemption is made by the reviewing body after a complete review of the research protocol, associated measures, the consent process and relevant forms, and after careful consideration of the risks, benefits, confidentiality, voluntariness, and other features of the research. If the researcher selects this as their consent process type, be sure to attach any document with elements of consent you intend to provide the subjects and provide a description of the process you intend to follow.

BASIC ELEMENTS OF INFORMED CONSENT[3]

- Description of Clinical Investigation.
- Risks and Discomforts.
- Benefits.
- Alternative Procedures or Treatments.
- Confidentiality.
- Compensation and Medical Treatment in Event of Injury.
- Contacts.
- Voluntary Participation.

There are 4 components of informed consent including decision capacity,

documentation of consent, disclosure, and competency.[4]

REQUISITES OF INFORMED CONSENT PROCESS

The participant must have the capacity to understand the proposed research, be able to make an informed decision on whether or not to be enrolled and convey her/his decision to the researcher in order to give consent. The consent should be given voluntarily and not be obtained under by force or by offering any undue inducements. In the case of an individual who is not capable of giving voluntary informed consent, the consent of LAR must be obtained. It is mandatory for a researcher to administer consent before initiating any study related procedures involving the participant. It is necessary to maintain privacy and confidentiality of participants at all stages.

ESSENTIAL INFORMATION FOR PROSPECTIVE RESEARCH PARTICIPANTS

Before requesting an individual‘s consent to participate in research, the researcher must provide the individual with detailed information and discuss her/his queries about the research in the language she/he is able to understand. The language should not only be scientifically accurate and simple, but should also be sensitive to the social and cultural context of the participant. The Informed Consent Document (ICD) has two parts – patient/participant information sheet (PIS) and the informed consent form (ICF). Information on known facts about the research, which has relevance to participation, is included in the PIS. This is followed by the ICF in which the participant acknowledges that she/he has understood the information given in the PIS and is volunteering to be included in that research. Adequate time should be given to the participant to read the consent form, if necessary discuss it with family and friends, and seek clarification of her/his doubts from the researchers/research team before deciding to enroll in the research.

RESPONSIBILITY OF RESEARCHERS

The researcher should only use the EC approved version of the consent form, including its local translations. Adequate information necessary for informed consent should be communicated in a language and manner easily understood by prospective participants. In case of differently abled participants, such as individuals with physical, neurological or mental disabilities, appropriate methods should be used to enhance the participants‘ understanding, for example, braille for the visually impaired. There should be no restriction on the participant‘s right to ask questions related to the study or to discuss with family and friends or take time before coming to a decision. The researcher should not give any unjustifiable assurances or influence or intimidate a prospective participant to enroll in the study. The researcher must ensure that the participant is competent and has understood all aspects of the study and that the consent is given voluntarily. Where the participant and/or the LAR are illiterate, an impartial literate person, not connected to the research, should be present throughout the consent process as witness. The researcher should administer a test of

understanding whenever possible for sensitive studies. If need be, the test may be repeated until the participant has really understood the contents. When a participant is willing to participate but not willing to sign or give a thumb impression or cannot do so, then verbal/oral consent may be taken on approval by the EC, in the presence of an impartial witness who should sign and date the consent document. This process can be documented through audio or video recording of the participant, the PI and the impartial witness, all of whom should be seen in the frame. However, verbal/oral consent should only be taken in exceptional circumstances and for specific, justifiable reasons with the approval of the EC. It should not to be practiced routinely reconsent or fresh informed consent of each participant must be taken under circumstances described in section.

REFERENCES

1. https://research-compliance.umich.edu/informed-consent-guideline
2. https://www.swarthmore.edu/institutional-review-board/types-consentassent
3. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent
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