

Institutional Review Board (IRB)

Section C: Informed Consent

Researchers must obtain the informed consent of participants. In this section you will find the following topics:

- Elements of Informed Consent
- Assent
- Documentation of Informed Consent
- Sample/Draft of an Informed Consent Form

Note: Additional information is given in blue.

Elements of Informed Consent

The basic items of informed consent (Federal Register, V56, June 18, 1991, p. 28016) which should be presented to each subject in sequential order and in language which participants can understand, are as follows:

Notice two important points: (1) in this order and (2) in language participants can understand

1. Research: A statement that the study involves research.
2. Purpose: An explanation of the purposes of the research.
3. Duration: The expected duration of the subject's participation.
4. Description: A description of the procedures to be followed.
5. Procedures: Identification of any procedures which are experimental.
6. Risk/Discomfort: A description of any reasonably foreseeable risks or discomforts to the subject.
7. Benefits: A description of any benefits to the subject or to others which may reasonably be expected from the research.
8. Disclosure: A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
9. Confidentiality: A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
10. Compensation: For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
11. Contact Information: An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
12. Voluntary Participation: A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional elements of informed consent which should be included where appropriate are as follows:

1. Unforeseeable risk: A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
2. Taken Out of the Investigation: Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
3. Additional costs: Any additional costs to the subject that may result from participation in the research.
4. Procedures for Withdrawal: The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. Communicate New Findings: A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
6. Number of Participants Involved: The approximate number of subjects involved in the study.

Assent

For participants less than 18 years of age, the researcher must obtain the informed consent of parents or legal guardian and all reasonable attempts must be made to obtain each participant's assent. Assent is defined as the participant's agreement to participate in the study. You can read more about Assent in [Section B, Item 7](#).

Documentation of Informed Consent

- a. Written Consent: Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.
- b. Except as provided in paragraph (c) of this section, the consent form may be either of the following:
 1. Full, complete written consent: A written consent document that embodies the elements of informed consent. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
 2. Short form stating verbal understanding and consent were given: A short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
- c. Waive written consent: An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Deception: In situations where participants will be deceived, regardless of the type of review, the following must be included and must be presented to participants before they engage in the study:

1. Omit steps 1 and 2 (purpose and description of methodology) substituting a statement, if possible, indicating that full disclosure of the purpose of the study could bias the outcome. Have participants sign the form.
2. Following the study, present participants with a full description of the study and methodology which the participants are to sign.

Sample of Informed Consent Form

The following suggestions are offered as guidelines. The exact language is the decision of the researcher, but keep in mind that the IRB reviewers must determine if the participants will be giving informed consent. The language must be **understood by the participants** at whatever cognitive level they fall. The sequential order of the information on the informed consent form **must follow** that listed under the section on Elements of Informed Consent. The first 12 elements are required if they apply; the last six should be included only if appropriate. Words in parentheses and underlined should be replaced with the required data. The researcher needs to fill in the red sections.

INFORMED CONSENT FORM

Name of Study

Note that this can be a much simpler name than your full title for the study

The purpose of this research is to (fill in purpose). Participation should take approximately (duration of the subjects' participation). As a participant, (you or your child or ward) will be asked to (description of the procedure to be followed).

The only risks include (a description of any reasonably foreseeable risks or discomforts to the subject). The benefits include (a description of any benefits to the subject or to others which may reasonably be expected from the research).

The following alternative procedures may be to your advantage (identify alternative procedures; if none, then this line should be omitted).

All information will be handled in a strictly confidential manner so that no one will be able to identify you when the results are recorded/reported.

(For research involving more than minimal risk, a statement should be included here explaining (1) whether any compensation is available, and (2) whether any medical treatments are available if injury occurs, (3) what they consist of, and (4) where further information can be obtained). Notice all four parts to this.

Please feel free to contact (name(s), title(s), of principal researcher(s) at (telephone number(s) and address(es) if at any time you have any questions, require further information on the research, or have a research related injury. Do **NOT** give out personal information. Give a University phone number and address. You can add a University e-mail address if you would like.

Participation in this test is totally voluntary. Refusal to participate will involve no penalty or loss of benefits or services to which you are otherwise entitled. You may quit at any time without negative consequences (negative consequences should be spelled out, e.g. loss of extra credit, loss of services).

Notice: The following six items should be included only if appropriate:

1. This study may involve risks to the subject or to the embryo or fetus (if the subject is, or may become, pregnant) that are currently unforeseeable. These risks may be (describe risks).
2. Participation may be stopped by the investigator without your consent under the following circumstances: (give details).
3. The following additional costs to you for participation in the study are (give costs).
4. If you should decide to stop your participation in the study the following would occur: (consequences of termination [for example in a drug study]).
5. Should any significant new findings develop during the course of this research that may relate to your willingness to participate in this study, you will be provided with that information.
6. The approximate number of individuals participating in this study is (number). This would be important if the number of participants was small, as in a case study involving 2 or 3 participants.

SEPARATE THE FOLLOWING SECTION. The printed version should have a line drawn across here. You are changing perspective to that of the participant.

I understand the test described above and have been given a copy of the description. I am 18 years of age or older, and I agree to participate.

Signature of participant

Date

ASSENT:

OR the participant is under 18 years of age: **(Minor or one without legal authority)**

I understand what I am being asked to do in this test, and I want to take part.

Signature of child/ward

Date

Parent of Minor or Legal Guardian:

I understand the test described above and have been given a copy of the description. I am the parent or guardian of the above referenced minor and I agree to his/her participation in the test.

Signature of parent or guardian

Date