

Elements of Informed Consent

Elements of Informed Consent, Requirements and Guidelines for Consent Forms

Informed consent is a process of communicating to the subject the purpose, risks, benefits, and voluntary nature of a specific study.

The consent form documents that the communication process took place. The consent form must contain all of the required "elements" of informed consent. The "sample consent form" should be used as a guide for writing a consent form. Rules and regulations are subject to change and revision. Standards for consent documents change over time. The investigator should be prepared to revise and update consent forms at the request of the Institutional Review Board (IRB).

The consent form should be written in lay terms; jargon and technical language should be avoided. If that language cannot be avoided, the terms should be defined parenthetically so that subjects can make an informed decision. The IRB recommends that researchers write the consent forms using simple declarative sentences, avoid technical language, and have the final draft of the consent form reviewed by a person unfamiliar with the research to test for comprehension, prior to submitting it for review. Foreign language versions should be prepared for research with subjects whose English is limited.

Elements of Informed Consent that must appear in the consent form: (Federal Policy 46.116-111)

1. A statement that this is research, an explanation of the purpose of the research and the expected duration of the subject's participation, (including an estimate of the total amount of the subjects' time involved in participation), a description of the procedures to be followed, and identification of any procedures which are experimental. The reason for the subjects' selection.
2. A description of any reasonably foreseeable risks or discomforts to the subject (including psychological risks such as stress, invasion of privacy etc.).
3. A description of any benefits to the subject or others that may reasonably be expected from the research. If there is no benefit to participation to the individual subject, an honest declaration of that fact must be included in the text of the context form.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject. If any standard treatment is withheld as a result of participation, the subject must be informed.
5. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights. A name and telephone number should be included. (If the researcher is a student, the advisor's name and telephone number must be included on the form.)
6. A statement that participation is voluntary, the subject may refuse to participate, and may discontinue participation at any time without penalty or loss of benefits to which he/she is otherwise entitled. The consequences of a subject's decision to withdraw from the research, if any, and procedures for an orderly termination of participation by the subject, should be included. Generally, use of friends, co-workers or clients makes voluntary participation impossible.

7. A statement describing the extent to which confidentiality of records identifying the subject will be maintained. If data obtained will be made available to any person or organization other than the subject, the investigator, and the investigator's staff, or become part of a permanent record maintained in the subject's name, the purposes of the disclosure, and the nature of the information to be furnished must be described. If audio or video tape recording, photographs, or movies will be taken, they should be described. The duration of time they will be retained before erasure or destruction should be specified. Use of such data for other purposes, including educational purposes, must be disclosed and permission obtained in a special portion of the consent form. Video or audio recording also requires separate consent in a special portion of the consent form.
8. An offer to the subject of a copy of the consent form.
9. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent, i.e., when in the investigator's opinion, it would be detrimental to the subject to continue.
10. Space for signature and date. (If applicable there should be a separate signature for permission to video-tape or audio-tape interviews.)
11. Space provided to document oral or written consent of minors. Parental consent for minors is required. However, the minor must also consent in writing if possible. If the child cannot provide written consent, oral consent is sufficient but must be documented by a witness whose signature is obtained. Mere failure to object should not be construed as consent.
12. If a subject will receive compensation or if there is an inducement or reward for participation, specific information concerning the terms of disbursement must be clearly described on the consent form, including consequences of subject's early withdrawal.
13. If there is the possibility of injury as a result of the research, information as to the medical treatment and compensation available should be included. (Note: if the research involves any invasive procedures, a "Health and Biological Sciences" application for approval form should be completed in lieu of the "Social Sciences Form.")

Tips for completing consent form:

- Write the form in second person "You", e.g., "You are invited to participate in a research project conducted by..." Avoid language like "you have been told..." or "you understand..." Numerous language and coercion pitfalls result when using those phrases;
- Define or explain research terms such as "randomization" (like "the flip of a coin"), "double-blind" ("neither the researcher or the subject will know");
- Quantities for blood drawing should be listed in lay term equivalents, not milliliters (teaspoon equivalents);
- Headings for paragraphs are helpful and make the form easier to read;
- Typeface should be a comfortable-readable size; avoid fine print. The form may not fit on to one page; additional pages are acceptable as long as they are essential.