

*Office for Protection from Research Risks*

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## Tips on Informed Consent

The process of obtaining informed consent must comply with the requirements of [45 CFR 46.116](#). The documentation of informed consent must comply with [45 CFR 46.117](#). The following comments may help in the development of an approach and proposed language by investigators for obtaining consent and its approval by IRBs:

- Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language" (i.e., understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.
- Use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Use of scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool, not as a legal instrument.
- **Describe the overall experience that will be encountered.** Explain the research activity and how it is experimental (e.g., a new drug, extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues). Inform the human subjects of the reasonably foreseeable harms, discomforts, inconvenience, and risks that are associated with the research activity. If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are re-contacted or newly contacted.
- **Describe the benefits that subjects may reasonably expect to encounter.** There may be none, other than a sense of helping the public at large. If payment is given to defray the incurred expense for participation, it must not be coercive in amount or method of distribution.
- **Describe any alternatives to participating in the research project.** For example, in drug studies the medication(s) may be available through their family physician or clinic without the need to volunteer for the research activity.

- **The regulations insist that the subjects be told the extent to which their personally identifiable private information will be held in confidence.** For example, some studies require disclosure of information to other parties. Some studies are inherently in need of a Certificate of Confidentiality, which protects the investigator from involuntary release (e.g., subpoena) of the names or other identifying characteristics of research subjects. The IRB is responsible for ensuring that risks are minimized to the fullest extent possible, and for determining that any remaining risks warrant the involvement of human subjects, so the IRB will determine the level of adequate requirements for confidentiality.
- **If research-related injury (i.e., physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk (see [45 CFR 46.102\[g\]](#)), an explanation must be given of whatever voluntary compensation and treatment will be provided.** Note that the regulations do not limit injury to “physical injury.” This is a common misinterpretation.
- **The regulations prohibit waiving or appearing to waive any legal rights of subjects.** Therefore, for example, consent language must be carefully selected that deals with what the institution is *voluntarily* willing to do under circumstances, such as providing for compensation beyond the provision of immediate or therapeutic intervention in response to a research-related injury. In short, subjects should not be given the impression that they have agreed not to and are without recourse to seek satisfaction beyond the institution’s *voluntarily* chosen limits.
- **The regulations provide for the identification of contact persons who would be knowledgeable to answer questions from subjects about the *research, rights as a research subject, and research-related injuries*. These three areas must be explicitly stated and addressed in the consent process and documentation.** Furthermore, a single person is not likely to be appropriate to answer questions in all areas. This is because of potential conflicts of interest or the appearance of such. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects or research-related injuries (where applicable) may best be referred to those not on the research team. These questions could be addressed to the IRB, an ombudsman, an ethics committee, or other informed administrative body. Therefore, each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas.
- **The statement regarding voluntary participation and the right to withdraw at any time can be taken almost verbatim from the regulations ([45 CFR 46.116\[a\]\[8\]](#)).** It is important not to overlook the need to point out that no penalty or loss of benefits will occur as a result of *both* not participating or withdrawing at any time. It is equally important to alert potential subjects to any foreseeable consequences to them should they unilaterally withdraw while dependent on some intervention to maintain normal function.