

Guidance - General Requirements for Informed Consent

45 CFR 46.116 [OHRP] 21 CFR 50.25 [FDA]

Except as provided elsewhere, no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

45 CFR 46.116 (a) Basic elements of informed consent:

Study involves research; study description	(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
Reasonably foreseeable risks	(2) A description of any reasonably foreseeable risks or discomforts to the subject
Benefits	(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
Alternative procedures or treatment	(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
Confidentiality of records	(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; <i>[FDA regulated research only: "and that notes the possibility that the Food and Drug Administration may inspect the records"]</i>
Compensation and treatment for injury	(6) 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;
Contact information	(7) 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; and
Voluntary participation	(8) 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.

45 CFR 46.116(b); 21 CFR 50.25(b) **Additional elements** of informed consent.

When appropriate, one or more of the following elements of information shall also be provided to each subject:

Risks which are currently unforeseeable	(1) 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;
Investigator may terminate participation	(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
Additional costs	(3) Any additional costs to the subject that may result from participation in the research;
Consequences of subject's withdrawal	(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
Significant new findings	(5) 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; and
Number of subjects	(6) The approximate number of subjects involved in the study.
Clinical trial registration	FDA (<i>applicable clinical trials</i>): A statement that a description of the trial will be available on http://www.ClinicalTrials.gov