

Basic Elements of Informed Consent

Remember that informed consent is a process by which the investigator informs potential subjects of all critical aspects of the study, particularly a careful explanation of any risks and of the fact that participation is entirely voluntary and can be refused or terminated by the subject at any time without penalty. The consent form is the main documentation of the informed consent process, but other written or verbal information may also be involved and need IRB review. A major requirement of consent forms and associated materials is that the language must be understandable by potential subjects.

Following are some legally required elements of informed consent:

- a. 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; identification of any procedures which are experimental; and why the subject was asked to participate in the research.
- b. A description of any reasonably foreseeable risks or discomforts to the subject.
- c. A description of any benefits to the subject or to others which may reasonably be expected from the research.
- d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- e. A statement describing the extent if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA, IRB and study sponsor may inspect the records.
- f. 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.
- g. 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. **Usually, this means the phone number of the P.I. and the IRB.**
- h. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

The consent form must contain the *California Human Rights in Medical Studies* (attached).

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