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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:

At the beginning of each consent form: a statement of *key information* that a reasonable person would want to have in order to understand the reasons why one might or might not want to participate in the research.

Basic elements of informed consent *(must be included in all informed consent forms):*

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.

i. One of the following statements about any identifiable private information or identifiable biospecimens:

- A statement that identifiers must be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative,

  OR

- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional elements of informed consent if applicable:

a. 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) that are currently unforeseeable.

b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent.

c. Any additional costs to the subject that may result from participation in the research.

d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

e. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.

f. The approximate number of subjects involved in the study.

g. A statement that the subject's biospecimens (even if identifiers are removed)

may be used for commercial profit and whether the subject will or will not share in this commercial profit.

h. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

i. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

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