

Elements of Informed Consent

General Requirements

- Consent documents must be in ***a language understandable to participants*** or representatives.
- There may be ***no exculpatory language*** through which participants or representatives are made to 1) waive or appear to waive any legal rights or 2) release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Basic Required Elements of Informed Consent

In seeking informed consent, the following information must be provided to each participant:

- A statement that the ***study involves research***, an explanation of the ***purposes of the research*** and the ***expected duration*** of the participant's participation, a description of the ***procedures*** to be followed, and identification of any ***procedures which are experimental***;
- A description of any ***reasonably foreseeable risks or discomforts*** to the participant;
- A description of any ***benefits*** to the participant or to others which may reasonably be expected from the research;
- A disclosure of appropriate ***alternative procedures or courses of treatment***, if any, that might be advantageous to the participant;
- A statement describing the extent, if any, to which ***confidentiality of records*** identifying the participant will be maintained. If study is FDA regulated, add statement that the FDA may inspect the records;
- ***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;
- An explanation of ***whom to contact in the case of a research-related injury*** to the participant;
- ***Contact information for the research team*** for answers to pertinent questions about the research and ***contact information for someone independent of the research team*** for questions, concerns or input and for answers about ***research participants' rights; and***
- A statement that ***participation is voluntary***, and that ***participant may refuse or discontinue participation*** at any time refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.

Additional Elements of Informed Consent

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

- The ***approximate number of participants*** involved in the study;
- A statement that the particular treatment or procedure may involve ***risks to the participant*** (or to the embryo or fetus, if the participant is or may become pregnant) which are ***currently unforeseeable***;
- A statement that ***significant new findings*** developed during the course of the research which may relate to the participant's willingness to continue participation ***will be provided to the participant***;
- Anticipated circumstances under which the ***participant's participation may be terminated by the investigator*** without regard to the participant's consent;
- Any ***additional costs to the participant*** that may result from participation in the research and the ***amount and schedule of payments***; and
- The ***consequences of a participant's decision to withdraw*** from the research and ***procedures for orderly termination of participation*** by the participant.