Office of Human Research Ethics Training Tips

Informed Consent OHRE SOP #28

Informed consent is a process rather than merely a document. Any individual invited to participate in a research study should be given a description of the study that is clear and complete enough for the individual to judge whether she or he wants to participate. The informed consent process should be designed to provide potential subjects with readily understandable information in an amount and timing appropriate to the level of risk in participating. The circumstances of the consent process should minimize the possibility of coercion or undue influence.

- Consent must be obtained from each subject who is legally, mentally, and physically able to provide it unless waived by the IRB.
- Consent should be in writing unless the IRB finds that written documentation of informed consent may be waived.
- Consent forms and other informational documents should be written in simple language so as to be easily understood by persons with no technical background in the field.
- No informed consent, whether oral or written, may include any exculpatory language through which the subject or the subject's authorized 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.
- All subjects will sign a document containing all the elements of informed consent, as specified in the federal regulations and noted below. Some or all of the elements of consent, including signatures, may be waived under certain circumstances.

Required basic elements of informed consent are:

- 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; a description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject 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 subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained; for FDA-regulated studies, the possibility that the Food and Drug Administration may inspect the records must be included;
- For research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available;
- 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;
- 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;
- An explanation of whom to contact to voice concerns or complaints about the research
- Contact information for the IRB to obtain answers to questions about the research; to voice concerns or complaints about the research; to obtain answers to questions about their rights as a research participant; in the event the research staff could not be reached; and in the event the subject wishes to talk to someone other than the research staff.

Additional optional elements of informed consent to be applied as appropriate to the study & potentially required based on the study type:

- A statement that the particular treatment or procedure may involve risks to the subject that are currently unforeseeable. (Include this when the research involves an unapproved drug, device or biological or procedure for which the risks to subjects are not well known.)
- A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus that are currently unforeseeable. (Include this when the research involves pregnant women or women of childbearing potential, and the risks to a fetus of the study drug, device, biologic or procedures involved in the research are not well known.)
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. (Include this when there are anticipated circumstances under which the investigator may terminate participation of a subject.)
- Any additional costs to the subject that may result from participation in the research. (Include this when it is anticipated that subjects may have additional costs.)
- The consequences of a subject's decision to withdraw from the research. (Include this when withdrawal from the research may be associated with risks that are more than minimal.)
- Procedures for orderly termination of participation by the subject. (Include this when the protocol describes such procedures.)
- 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. (Include this, for example, when the research will continue long enough that interim information is likely to be developed during the subject's participation in the research.)
- The approximate number of subjects involved in the study. (Include this, for example, when the research involves more than minimal risk.)

IRB Member & Primary Reviewer Responsibility

- Review the consent form(s) for the study first when you begin your review of an agenda item. This should provide you with a good overview of the study. Then when you review the protocol you will see missing information that should be in the consent and other disconnects.
- ***Do Not Wordsmith a consent!***
  - If the consent meets the regulatory requirements,
  - If it does not misrepresent the research risks,
  - And is not full of jargon or inappropriate reading level, then
  - LEAVE IT ALONE!