Informed Consent Checklist

To fulfill federal requirements for informed consent, the consent document should address the elements listed below. The Basic Elements are required of all consent forms. Information on the Additional Elements should be included as applicable.

Basic Elements

_____ A statement that the study involves research
_____ An explanation of the purpose of the research
_____ The expected duration of the subject's participation
_____ A description of the procedures to be followed
_____ Identification of any procedures which are experimental
_____ A description of any reasonably foreseeable risks or discomforts to the subject. *Note that potential risks may be physical, psychological, social, legal, or economic.* ***Any risks that may be irreversible should be clearly labeled as such.***
_____ A description of any potential benefits to the subject or to others. *Benefits may pertain to the individual subject as well as to society. Benefits may take the form of increased knowledge, improved safety, technological advances, and better health.*
_____ 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 will be maintained
_____ 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 for answers regarding the following:
a) questions about the research and research subjects' rights
b) questions about subjects' rights
c) 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.

Additional Elements

As applicable, the consent also must provide the following additional elements:

_____ A description of standard care for the condition under study and how the proposed investigational treatment or procedure differs from standard care
_____ A statement that the particular treatment or procedure may involve risks to the subject
_____ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
_____ Additional costs to the subject that may result from participation in the research
_____ Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
_____ 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
_____ The approximate number of subjects involved in the study
_____ Notification that the sponsor, oversight agencies and FDA (as applicable) may inspect identifiable records to verify the accuracy of the information collected