Informed Consent Checklist

45 CFR §46.116 Basic and Additional Elements of Informed Consent:

☐ A statement that the study involves research
☐ An explanation of the purposes 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
☐ 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 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 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

Additional Elements as Appropriate:

☐ 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), which are currently unforeseeable
☐ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
☐ Any additional costs to the subject that may result from participation in the research
☐ The 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
If an applicable clinical trial per 42 CFR §11 and The Food and Drug Administration Amendments Act of 2007 (FDAAA), Public Law 110-85:

☐ The following exact statement must be included: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.