Checklist for Informed Consent

Required Elements
Does my Informed Consent Document or 10-1086 include?

☐ Disclosure that the study involves research (the word “research” must be present in the sentence)

☐ An explanation of the purposes of the research

☐ An explanation of the expected duration of the participant’s participation

☐ A description of the procedures to be followed

☐ Identification of any procedures that is experimental

☐ Description of any reasonably foreseeable risks or discomforts to the participants

☐ Description of any benefits to the participants or to others which may reasonably be expected from the research

☐ Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant

☐ Disclosure to which confidentiality of records identifying the participant will be maintained

☐ For ETSU studies deemed more than minimal risk: Include ETSU compensation paragraph, the second sentence must state, “ETSU makes no commitment to pay for any other medical treatment” instead of “ETSU will not pay for any other medical treatment”

☐ Contact information for answers to questions about the research,

☐ Contact information for answers to pertinent questions about the participants’ rights
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☐ Contact information in the event of a research-related injury to the participant

☐ In contact information section, the following sentence is included, “If you have any questions or concerns about the research and want to talk to someone independent of the research team or you can’t reach the study staff, you may call an IRB Coordinator at 423/439-6055 or 423/439/6002.”

☐ Disclosure that participation is voluntary,

☐ Disclosure that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled,

☐ Disclosure that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

☐ For studies subject to the 2018 Common Rule, a statement that identifiers might 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 researcher for future research studies without additional informed consent from the participant or legally authorized representative, if this might be possibility; or a statement that the participant’s information or specimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements that might be Required:

☐ Disclosure that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable UNLESS the risk profile of all research-related interventions is well-known and the research involves no investigational drugs or devices.
Disclosure that the particular treatment or procedure may involve risks to the embryo or fetus, if the participant is or may become pregnant, which are currently unforeseeable UNLESS the research excludes women of child bearing potential and pregnant women or the risk profile of all research-related interventions or interactions on embryos and fetuses is foreseeable and risks are described in the ICD or there is no reasonable expectation that this research causes risks to fetuses or embryos.

Disclosure of anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent UNLESS there are no anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent.

Disclosure of additional costs to the participant that may result from participation in the research UNLESS there are no costs to the participant that may result from participation in the research.

Disclosure of the consequences of a participant’s decision to withdraw from the research and disclosure of procedures for orderly termination of participation by the participant UNLESS there are no adverse consequences (physical, social, economic, legal, or psychological) of a participant’s decision to withdraw from the research.

Disclosure 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 UNLESS significant new finding during the course of the research which may relate to the participant’s willingness to continue participation are unlikely.

Disclosure of approximate number of participants (locally or in total) involved in the study UNLESS the approximate number of participants involved in the study (locally and in total) is not important to a decision to take part in the research.
☐ For studies subject to the 2018 Common Rule, disclosure of a statement that biospecimens, even if identifiers are removed, may be used for commercial profit and whether the participant will or will not share in this commercial profit UNLESS the study does not involve the collection of biospecimens.

☐ For studies subject to the 2018 Common Rule, disclosure of a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions UNLESS there will be no clinically relevant research results. This provision is intended to pertain to all clinically relevant research results, including general or aggregate research findings and individual research results.

☐ For studies subject to the 2018 Common Rule, disclosure of a statement about 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) UNLESS the study does not involve the collection of biospecimens OR the study will not include any whole genome sequencing.”

Is your study VA? If yes, see VA10-1086 template for additional VA specific required elements.