

Checklist

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 are **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,
- 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.

Additional elements may apply, see page 6 for more information

Checklist

Additional Elements that might be Required

Does my Informed Consent Document or 10-1086 include these elements, if applicable

- disclosure that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable **if**
 - ⇒ the risk profile of all research-related interventions is not well-known and the research involves investigational drug or device.
- disclosures 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 **if**
 - ⇒ the research does not exclude women of child bearing potential and pregnant women or the risk profile of all research-related interventions or interactions on embryos and fetuses is not well known or there is reasonable expectation that this research causes risks to fetuses or embryos. (revised 2007)
- disclosures of anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent **if**
 - ⇒ **Narrative question # 8g Is "yes"**: there are anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent
- disclosures additional costs to the participant that may result from participation in the research **if**
 - ⇒ **Narrative question # 14 is "yes"**: there are costs to the participant that may result from participation in the research
- disclosure of consequences of a participant's decision to withdraw from the research **and** disclosure of procedures for orderly termination of participation by the participant **if**
 - ⇒ there are 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 **if**
 - ⇒ significant new finding during the course of the research which may relate to the participant's willingness to continue participation are likely to develop
- disclosure of approximate number of participants (locally or in total) involved in the study **if**
 - ⇒ the approximate number of participants involved in the study (locally and in total) is important to a decision to take part in the research.

Is your study VA? If yes, see next page for additional elements for the 10-1086.

Checklist

VA STUDIES ONLY

In addition to the elements on page 5-6, does my 10-1086 Informed Consent Document also include:

- Financial Costs** paragraph "You will not be charged for any treatments or procedures that are part of this study. However, if you are required to make co-payments for services provided by the VA, or if you receive treatment that is part of your usual medical care, you or your third-party payer (e.g., insurance company) may be billed."
- Contact for Questions** paragraph "See Contact for Questions sections on page 5"
- Injury/Complications** paragraph "According to VA Regulations [38CFR17.85(a)] the medical facility shall provide necessary medical care to a research subject injured as a result of participation in a research project. However, no additional compensation has been set aside. You have not waived any legal rights or released the VA or its agents from liability for negligence by signing this form"
- Statement required for veteran subjects** "If you are a veteran taking part in a research study at the James H. Quillen VAMC, a copy of your signed/dated consent form will be placed in your medical record"
- Statement required if the study involves an investigational drug with an IND** "I have been told that because this study involves articles regulated by the Food and Drug Administration (FDA), the FDA may inspect research identifying me as a subject in this investigation"
- Statement required if the researcher believes that bodily fluids, substances or tissues of a research subject could lead to the development of a commercially valuable product** "I authorize the use of my bodily fluids, substances or tissues for research purposes."
- Confidentiality of Records** Add "ETSU/VA IRB, VA Research and Development Committee, Office of Research oversight (ORO) and Government Accounting Office (GAO), FDA, OHRP-specify drug company or sponsor, if any and specify who in study personnel" to the list of people who will have access to the records.
- Check payment through Austin** Include a statement that the subject's social security number will be required to process the check and that payments will be reported to the IRS and may be counted as income.