

# Checklist for Informed Consent

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Research informed consent must include the following required elements to be approved by the IRB, or request a waiver or alteration of 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 **purpose** 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
- Explanation of how **confidentiality of records** identifying the participant will be maintained
- Explanation of appropriate **alternative procedures or courses of treatment**, if any, that might be advantageous to the participant
- Contact information** for the research team to ask questions, withdraw, or report a research related injury or adverse event.
- Contact information** for someone independent of the research team to answer to questions about the research, participants’ rights,

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- Must use ETSU IRB contact information paragraph to satisfy this requirement. Refer to IRB consent template for appropriate language.
  
- Explanation that participation is **voluntary and that refusal to participate will involve no penalty or loss of benefits** to which the participant is otherwise entitled,
  
- Statement that the participant **may discontinue participation at any time without penalty or loss of benefits** to which the participant is otherwise entitled.
  
- 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 if applicable:**

- Disclosure of anticipated circumstances under which the participant's **participation may be terminated by the investigator** without regard to the participant's consent
  
- 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
  
- Disclosure of additional **costs to the participant** that may result from participation in the research

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- Disclosure 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
- Disclosure that the particular treatment or procedure **may involve risks to the participant which are currently unforeseeable**
- 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
- 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
- A statement regarding whether **clinically relevant research results**, including individual research results, will be disclosed to subjects, and if so, under what conditions. This provision is intended to pertain to all clinically relevant research results, including general or aggregate research findings and individual research results.
- 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.**