

FAQ's for informed consent



Informed consent is more than just a signature on a form; it is a process of information exchange. In addition to reading and signing the informed consent document, participant recruitment materials, verbal instructions, and question/answer sessions are ways the Principal Investigator assures the participant has an understanding of what was being asked. Institutional Review Boards (IRBs), clinical investigators, and research sponsors all share responsibility for ensuring that the informed consent process is adequate. Thus, rather than an endpoint, the consent document should be the basis for a meaningful exchange between the investigator and the participant.

The clinical investigator is responsible for ensuring that informed consent is obtained from each research participant before that participant participates in the research study. Food and Drug Administration (FDA) does not require the investigator to personally conduct the consent interview. The investigator remains ultimately responsible, even when delegating the task of obtaining informed consent to another individual knowledgeable about the research.

Q Is “informed consent” different in research?

A Informed consent is a regulatory requirement that says a research participant must be given complete information about the study before they can agree to take part. Participants must understand all of the information before they agree to be in the study. A participant must receive and understand the following information:

- The study involves research of an unproven drug or device
- The purpose of the research
- How long the study will take
- What will happen in the study and which parts of the study are experimental
- Possible risks or discomforts
- Possible benefits
- Other procedures or treatments that you might want to consider instead of the treatment being studied
- Regulatory Officials may look at study records but the records will be kept private
- Whether any medical treatments are available if you are hurt, what those treatments are, where they can be found, and who will pay for the treatment
- The person to contact with questions about the study, your rights, or if you get hurt
- You can quit at any time

Q Is getting the participant to sign a consent document all that is required by the regulations?

A No. The consent document is a written summary of the information that should be provided to the participant. Many clinical investigators use the consent document as a guide for the verbal explanation of the study. The participant's signature provides documentation of agreement to participate in a study, but is only one part of the consent process. The entire informed consent process involves giving a participant adequate information concerning the study, providing adequate opportunity for the participant to consider all options, responding to the participant's questions, ensuring the participant has comprehended the information, obtaining the participant's voluntary agreement to participate, and continuing to provide information as the participant or situation requires. To be effective, the process should provide ample opportunity for the investigator and the participant to exchange information and ask questions.

Q Who should be present when the informed consent interview is conducted?

A FDA does not require a third person to witness the consent interview unless the participant or representative is not given the opportunity to read the consent document before it is signed. The person who conducts the consent interview should be knowledgeable about the study and able to answer questions. FDA does not specify who this individual should be. Some sponsors and some IRBs require the clinical investigator to personally conduct the consent interview. However, if someone other than the clinical investigator conducts the interview and obtains consent, this responsibility should be formally delegated by the clinical investigator and the person so delegated should have received appropriate training to perform this activity.

Q How do you obtain informed consent from someone who speaks and understands English but cannot read?

A Illiterate persons who understand English may have the consent read to them and “make their mark,” if appropriate under applicable state law. Requirements for signature of a witness to the consent process and signature of the person conducting consent interview must be followed, if a “short form” is used. Clinical investigators should be cautious when enrolling participants who may not truly understand what they have agreed to do. The IRB should consider illiterate persons as likely to be vulnerable to coercion and undue influence and should determine that appropriate additional safeguards are in place when enrollment of such persons is anticipated.

Q Are there alternatives to obtaining informed consent from a participant?

A The regulations generally require that the investigator obtain informed consent from participants. Investigators also may obtain informed consent from a legally authorized representative of the participant. FDA recognizes that a durable power of attorney might suffice as identifying a legally authorized representative under some state and local laws. For example, a participant might have designated an individual to provide consent with regard to health care decisions through a durable power of attorney and have specified that the individual also has the power to make decisions on entry into research. FDA defers to state and local laws regarding who is a legally authorized representative. Therefore, the IRB should assure that the consent procedures comply with state and local laws, including assurance that the law applies to obtaining informed consent for participants participating in research as well as for patients who require health care decisions.”

Q When should study participants be informed of changes in the study?

A Participants who are presently enrolled and actively participating in the study should be informed of the changes if it might relate to the participants’ willingness to continue participation in the study. FDA does not require reobtaining consent if the participant has completed active participation in the study, of participants who are still actively participating when the change will not affect participation, for example when the change will be implemented only for newly enrolled participants or if the change was minor not affecting risk.