

The Consent Process

1. A Process - not a form

Since subjects retain the right to withdraw from a study, consent is an ongoing process. It starts well before any forms are signed and continues until the subject's participation is complete.

The informed consent process is different from the consent form. It involves meeting with a potential subject, finding out whether he or she is capable of giving consent, and discussing the purpose, risks, and benefits of participation. The consent form formalizes the agreement to participate and should be designed to document the process. Obtaining informed consent is not just giving a prospective subject a consent form and getting it signed.

INFORMATION TO BE INCLUDED IN THE CONSENT DOCUMENT
(adapted from 45CFR.46.116)

- A statement that the study involves research;
- An explanation of the purpose of the research, an invitation to participate and explanation of why the participant was selected, and the expected duration of the participant's participation;
-