



Institutional Review Board

Consent Short Form Guidance

What are short forms?

A short form is a written document stating that the elements of informed consent required by 45 CFR 46.116 have been presented to and understood by the subject or the subject's legally authorized representative.

When can a short form be used?

A short form may be used when the majority of subjects in a study are English speakers, but there are a portion of the subjects who will not be able to understand the consent form written in English. A short form can be used in these instances to obtain consent ensuring equal access for potential participants.

If the majority of the anticipated subjects to be enrolled do not speak English or will be unable to understand the consent form written in English, the consent form must be translated into a language understandable to the subjects. When a translator assists the person obtaining consent, the translator may serve as a witness. The subject must be given copies of the short form document and the summary.

How to use short forms

A short form may be used in conjunction with an oral presentation of the consent information required by 45 CFR 46.116. A summary of what will be said to the subject or representative must be approved by the IRB and then presented orally to the subject or representative in front of a witness.

A copy of the short form and a copy of the summary must be given to the subject or representative.

Required signatures for short forms

1. Short Form - Subject/Representative and the Witness
2. Copy of Summary - Witness and Person obtaining consent

What must be approved by the IRB?

1. Justification for the use of short forms.
2. A summary of what will be presented to the subject or representative.
3. Text of short form, or assurance that University of Minnesota IRB Short Forms will be used.

These forms cannot be used as a substitute for a translated consent form when the primary population of a study will be non-English speakers. In that instance, fully translated consent forms should be provided for IRB review with an English Language Version.