

Guidance on Oral and Short Form Written Consent

There may be times when it is more appropriate for consent to be presented and obtained orally rather than in written form, particularly if participants have limited proficiency with the English language. In such instances, an investigator may use a **short form written consent** document, stating that the elements of informed consent have been presented **orally** to the subject or the subject's legally authorized representative.

The oral and short form written consent process is designed to provide a mechanism for individuals with limited English language proficiency to participate in human subject research where their lack of proficiency would otherwise be a barrier to their participation.

Participants who have limited English proficiency may be enrolled in research provided that researchers have the resources to communicate effectively during the recruitment process, while obtaining consent, and for the duration of the study. Oral consent **in combination with** short form written consent may be used to obtain a subject's consent.

The use of oral and short form written consent is not intended for use when research is focused on an entire or large population that lacks proficiency with the English language; in these cases, the normal consent process should be used with consent documents translated into the subject population's native language.

Investigator Responsibilities

Investigators must obtain IRB approval for use of the short form written consent process. For new studies, this request should be made when completing the application in Insight.

The investigator must provide the following to the IRB for review:

- A written summary of the information that will be presented orally to participants or their legally authorized representatives.
- The short form document that will be signed by the participant and the person obtaining consent.
- Identification of the individual obtaining consent.
- Confirmation that there will be a witness to the oral presentation of consent (this cannot be the same individual who is obtaining consent). When the person obtaining consent is assisted by a translator, the translator may serve as the witness.
- Confirmation that the witness is fluent in the same language as the potential participant.

The **short form written consent document and written summary of oral presentation** must be translated into the participants' native language.

When this method is used, there must be a **witness** to the oral presentation. Only the short form itself is to be signed by the participant or legally authorized representative. The witness must sign both the short form and a copy of the summary, and the person actually obtaining consent must sign a copy of the summary. The investigator must provide the participant with both a copy of the summary and a copy of the signed short form.