# Guidance -
# Short Form Consent Process

Federal regulations permit the use of a short form consent process (45 CFR 46.117(b)(2)) with the prior approval of the IRB. IRB approval is granted on a protocol-specific basis, for use with participants who are non-English speaking or other specific circumstances where the participant may understand but have problems signing. The IRB considers the study complexity and the amount and duration of participant involvement when determining if using the short form consent process is appropriate and can be approved.

## What to submit to the IRB for approval?

1) *Intention to use the short form consent process.* This should be provided in the "consent" section of the study application and protocol, where the Principal Investigator must agree to follow the procedures specified in the study application and protocol for use of the short form consent process.

2) *Summary Form (Modified consent form):*
Modified to have a signature line and text added on the last page beneath the Person Obtaining Consent section, as follows:

*The following witness line is to be signed only if the consent is provided as a summary form and accompanied by short form consent.*

_____ _____

*Signature of Witness* *Date*

3) *If HIPAA applies: Request an "Alteration of HIPAA Authorization":*
This should be provided in the "HIPAA" section of the study application. The alteration means that when using the Short Form Consent Process, neither the participant nor their LAR should sign the HIPAA Authorization (whether there is a separate HIPAA Authorization or one embedded in the Summary Form.

## Witnesses - Who are they and what do they do?

The short form consent process requires the assistance and the presence of a *witness*.

- *Who can be the witness?*
  - A person who attests to the oral presentation.
  - The witness may be staff, or other person.
- *Before starting the consent process* verify who will serve as a witness.

## Signature Requirements

If the participant agrees to take part in the study, the following signatures are required:

*Short Form must be signed and dated by:*

i) Participant, or the participant's legally authorized representative [LAR]; ii) Witness

*Summary Form must be signed and dated by:*

i) Person obtaining consent; ii) Witness

**HIPAA** - no signature: When using the Short Form Consent Process, neither the participant nor their LAR should sign the HIPAA Authorization (whether there is a separate HIPAA Authorization or one embedded in the Summary Form.
These documents do not contain study specific information, but state what will be explained to the participant about the specific study (e.g. purpose, procedures, duration, risks, benefits, alternatives [if any] confidentiality of information, compensation [if any] for research-related injuries, and that participation is voluntary).