Use of The Short Form

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Basics of the Short Form

• Who?
• What?
• When?
• Where?
• Why?
What?

The short form is a written consent document for participants who do not speak English.
Who?

- **Obtaining Consent**
  - PI/Study Staff
  - Translator
  - Witness

- **Giving Consent**
  - Participant or Legally Authorized Representative (LAR)
When?

• The participant or LAR does not speak/understand English; and
• The participant or LAR speaks only a language(s) that was not anticipated in the study population or location; and
• An appropriately translated consent form in the participant’s language has not been approved by the IRB; and
• There is not adequate time for preparation and IRB review and approval of a translated consent form
The short form IS NOT intended for studies in which it is expected that study recruitment will include a large number of persons who do not speak English.
Why?

- Respect for persons
- Beneficence
- Justice
How?

• Oral Translation of the English language consent form is presented
• There must be a translator
• There must be a witness to the oral presentation
• The IRB must receive all foreign language versions of the short form document as a condition of approval
Where …do I sign?

- Participant
- Study Staff
- Witness
- Translator
Questions?