Informed Consent (IC)
Part 4: Non-English Speaking Subjects

Translation

• Process of translating words or text from one language into another
• Should be done by a certified translator fluent in subject's native language and in English

Interpreter

• Person who translates the words that someone is speaking into a different language
• Unless the person obtaining consent is fluent in the patient's language
• Preferable to have someone independent of the subject
• Provide interpreter with the consent document(s) ahead of time for their review, if possible
Expected Enrollment

- PI expects non-English speaking patients to be screened or enrolled
- Must have translation and IRB approval of the long form consent document is required
- DO NOT USE THE SHORT FORM PROCESS

Unexpected Enrollment – Short Form Process

- Federal regulations allow use of short form in participant’s native language after approval by IRB
- Short form states that 8 required elements of IC document have been presented orally
- Written summary used by investigator and interpreter

Short Form Process

21 CFR 50.27, 46 CFR 46.117
Signatures on the Consent Documents
“Short Form” Process

• Short form, IRB approved
  • Signed by subject
  • Signed by witness/translator
• English version, IRB approved
  • Signed by investigator
  • Signed by witness/translator