Consenting of Non-English Speaking Subjects

Presented By:

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Anticipated Non-English Speaking Population

§46.116 - The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

- Translate the full written consent form
- Acceptable to wait until the English version consent form is IRB approved, and then submit translation as a modification.
- Include certificate of translation in IRB submission.
§46.117 (b)(2):
A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
Individuals Involved in the Short Form Process

- Non-English speaking subject
- Translator
- Person obtaining consent
  - Must be authorized by the IRB
  - Can be the translator
- Witness
  - Must be fluent in both English and subject’s language
  - Can be the translator, but cannot be the person obtaining consent.
Conducting the Short Form Process

- Translator will provide an oral presentation of the IRB approved summary, which is the English consent form.
- Person Obtaining Consent should explain the study, answer all questions and ensure subject has adequate time to consider participation.
- Subject presented with the written short form in their language.
  - Being asked to take part in a research study.
  - That the study team should have explained the purpose, procedures, risks, any benefits and cost of taking part.
  - That participation is voluntary and no penalty for declining.
  - Contact information for Principal Investigator and IRB.
Short Form Signature Process

Short Form Document:
- Subject
- Witness

The Written Summary (IRB approved English ICF):
- Person Obtaining Consent
- Witness

Subject should be given a copy of the signed short form and signed written summary.
IRB Submission Process

- Must obtain IRB approval prior to conducting the short form process.
- Submit request as a modification:
  - Include translated short form, with contact information completed.
  - Include certification for translation.
  - Include a description of how the short form process will be carried out.

The IRB approval is for one-time use for the single subject.
Obligations Post Short Form Process

- Certified translations of all documents the participant will be required to complete (such as surveys and questionnaires).
- If the English approved consent form undergoes subsequent modification, certified translations of the consent form in a language understandable to the non-English speaking participant.
- The plan for ensuring that ongoing communication with the participant is in a language understandable to the participant.
Contact Information & Resources

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IRB Short Form Guidance:
https://www.irb.northwestern.edu/process/new-study/informed-consent/short-form-written-consent

IRB Short Form Templates:
https://www.irb.northwestern.edu/templates-forms-sops#short-form-consent

OHRP Short Form Guidance:
http://www.hhs.gov/ohrp/policy/ic-non-e.html

FDA Short Form Guidance:
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm#none