The Basics of Short Form Consent for Non-English Speakers

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Informed Consent General Requirements

- Prospectively obtained from the subject or legally authorized representative (LAR).
- Conveyed in understandable language.
- Subjects have sufficient opportunity to consider if they want to participate.
- Consent given without coercion or undue influence.
- Subjects can not appear to give up legal rights or appear to be give the impression they are being asked to do so.

Consent Document Preparation

- Use non-technical language understandable to the proposed population.
- Rule of thumb is a 6th-8th grade level.
- Avoid medical jargon.
- Clear that participation is voluntary
- No language waiving or appearing to waive participants' rights
- Ads, fliers, letters, emails and brochures are considered part of the consent process and require IRB review and approval.

Research Consent for Non-English Speakers

- If expect a significant number of participants (e.g., >10%) with limited English proficiency or
  - if study conducted internationally, translation is required.
- All translated documents require IRB approval
- Required: Certification of Translation or back-translation
- Describe in the IRB application whether will translate documents or use short form consent

Research Consent for Non-English Speakers

- Required certified translator
- Case by Case Exception:
  - If non-certified translator, provide documentation of credentials/expertise
  - For example, a statement attesting to translator's proficiency in English and the other language (native born, etc.)
  - For translated documents, if not a certified translator, provide an independent "back translation"

Short Form Consent Process

- Participants with limited English proficiency may be enrolled if the researcher has resources to communicate effectively:
  - During recruitment process
  - While obtaining consent
  - For the duration of the study

Short Form Consent Process contined

- Oral Presentation of Informed Consent Information Allowed in Conjunction with:
  - Short Form Written Consent Document
  - Written Summary of what is presented Orally
  - A Witness is required
  - Subject must be given copies of the Short Form & the Summary

Short Form Consent Process

- Used when potential subjects don't speak English and not enough time to translate documents into native language.
- Both oral presentation and short form must be in language understandable to the subject.
- The IRB-approved English language informed consent document may serve as the summary.
- The Witness is fluent in both English and the language of the subject.

At the Time of Consent

- The Short Form should be signed by the subject.
- The Summary is signed by the person obtaining consent as authorized under the protocol.
- The Short Form and the Summary are signed by the Witness.
- When the person obtaining consent is assisted by a translator, the translator may serve as the Witness.
- The subject receives copies of the Summary and the Short Form documents.

QUESTIONS?