Human Research Ethics Training Tips

The Basics of Short Form Consent for Non-English Speakers

General Requirements for All Informed Consent:

1. Must be prospectively obtained from the subject or legally authorized representative of the subject.
2. Information must be conveyed in understandable language.
3. Subjects must be given sufficient opportunity to consider whether they want to participate.
4. Consent must be given without coercion or undue influence.
5. Subjects must not be made to give up legal rights or given the impression they are asked to do so.
6. Consent documents written in non-technical language that can be understood by the proposed participant population consistent with their education level, familiarity with research, and cultural views.
7. Rule of thumb is approximately a 6th-8th grade level.
8. Avoid medical jargon.
9. Clear that participation is voluntary.
10. Does not include any language waiving or appearing to waive participants' rights.
11. Ads, fliers, letters and brochures are part of the consent process and require IRB review and approval.

Research Consent for Non-English Speakers:

1. Translation expected:
    a. if a significant number of participants (e.g., >10%) with limited English proficiency **or**
    b. if study conducted internationally.
2. Consent document (and all other materials) in a language understandable to the subject; translated documents require IRB approval.
3. Describe in the IRB application if study will translate documents or use short form consent
4. Required: Certification of Translation or back-translation by Certified translator

    Case by case exceptions in rare CIRCUMSTANCES:

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

Short Form Consent Process:

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

2. Oral Presentation of Informed Consent Information is Allowed in Conjunction with:
    a. Short Form Written Consent Document
    b. Written Summary of what is presented orally
    c. A Witness is required
    d. Subject must be given copies of the Short Form & the Summary
3. May be used when potential subjects doesn't speak English and not enough time to translate documents into native language.
4. The oral presentation & the short form must be in language understandable to the subject.
5. The IRB-approved English language informed consent document may serve as the summary.
6. 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 both the Summary and the Short Form documents.