Information Sheet

Informed Consent of Subjects Who Do Not Speak English

Enrolling non-English speaking participants may be a requirement for meeting the study objectives or become a mechanism for the researchers to include diverse populations in their studies. FDA and OHRP regulations encourage this as a way to ensure subject selection is equitable (45 CFR Part 46.111[3] and 21 CFR Part 56.111).

Federal guidelines on non-English speakers participating in research focuses mainly on informed consent requirements. Information must be presented "in language understandable to the subject" (45 CFR Part 46.116), and in most cases "informed consent should be documented in writing" (45 CFR Part 46.117).

Food and Drug Administration (FDA) provides more information and guidance regarding the recruitment of non-English speaking participants (P 51-55 of the document):

3. What are some considerations for enrolling non-English speaking subjects?

Prospective subjects who do not understand English may ask or be asked to participate in a clinical trial in locations where English is the predominant language. The investigators and the IRBs that review such research should carefully consider the ethical ramifications of enrolling or excluding prospective subjects when a language barrier may exist between the investigator(s) and some or all of the prospective subjects.

Consistent with the requirement that selection of subjects be equitable (21 CFR 56.111(a)(3)), individuals should not routinely be excluded from participating in research simply because they do not understand English.

When prospective subjects who do not understand English are to be enrolled in a clinical study, IRBs and investigators must ensure that the information given to such prospective subjects or their LARs is in language understandable to the subjects or their LARs (21 CFR 50.20). FDA considers understandable to mean that the information presented to prospective subjects is in a language and at a level they can comprehend, including an explanation of scientific and medical terms.

The IRB must review and approve consent documents (long form or short form with written summary) that are to be used by investigators to document the informed consent of subjects (21 CFR 50.27(a) and 21 CFR 56.111(a)(4) and (5)). When translation and interpretation are needed for written and oral information that is to be presented to subjects, FDA recommends that the IRB review, and if appropriate, approve reasonable procedures for ensuring that the translations will be prepared by a qualified individual or entity, and that interpretation assistance is available.

The Information Sheet also discusses the use of a short form written consent, which can be used when a non-English speaking potential subject unexpectedly arrives at the research site. FDA and OHRP guidance clearly express a preference that the long form be translated, and that the short form is used only in unexpected situations.

What the Regulations Do Not Say

When it comes to non-English speaking research participants, the federal regulations and guidance remain silent on many details. The informed consent document is only one piece of the ongoing consent conversation, and researchers must prepare for the many other instances when non-English speaking subjects need to be provided with new and/or updated study information and ongoing education about their study participation. A&M-SA IRB relies on best practices, and continually learning from researchers, the local community and the research community at large to develop a guideline in the future.

Here are some ways that researchers can ensure non-English speaking participants have all the information they need to make an informed decision to participate in the study:

Interpreters: Having an interpreter available for all study visits helps ensure the non-English speaking participant truly understands the study and his or her role in it.

- An interpreter is different from a translator: A translator converts written content into the reader's native language, while an interpreter explains spoken information in a language understandable to the non-English speaker.
- When working with an interpreter (or translator for that matter), consider inquiring about that person's certifications and credentials. Many states have medical interpreter associations, and The National Board of Certification for Medical Interpreters provides Certified Medical Interpreter (CMI) credentialing.
- You might also ask about your interpreter's experience with clinical research. Most interpreters are familiar with clinical procedures and terminology, but not all interpreters understand the unique differences in clinical research.
- A friend or family member of the subject can serve as an interpreter but use of an impartial interpreter is encouraged over friends and family members. Just like any other interpreter they will need to explain potentially complex terminology in the subject's native language.

- **Documenting Consent with Translated Materials:** This can get tricky, and each organization will need to define the appropriate steps for its researchers.
  - When obtaining signatures on the translated consent document, we suggest following the normal process as required by A&M-SA IRB. For high risk or biomedical studies, a common approach is to have the participant sign the translated long form consent, the principal investigator signs both the English and translated consents, and the witness signs both as well.

- IRBs may choose to modify consent templates to include a signature line for the interpreter if required for the study.

Enrolling non-English speaking subjects can pose additional challenges for researchers and IRBs, but this doesn't mean non-English speaking subjects should be excluded entirely from research. Including a diverse subject population can help confirm that investigational products are safe and effective for the actual populations and subgroups who will use the products. It can also help ensure the risks and benefits of research are equitably shared across all populations who may potentially benefit from the research.

Send your comments, questions and suggestions for this information sheet to irb@tamusa.edu