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Avoiding Linguistic Landmines: Translating Informed Consent Forms Accurately

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Over 34 million foreign-born people live in the United States, mostly from countries where English is not the primary language.[1] In fact, over 30 percent of the residents in counties such as Queens (New York), Miami-Dade (Florida), and San Francisco (California) were born overseas.[1] For many of these people to participate in clinical trials, informed consent forms (ICFs) must be translated into their native languages. With the increasing globalization of clinical trials, the requirement for informed consent translations can only increase.

ICFs are highly technical medical, legal and regulatory documents. Doctors and lawyers spend days getting the wording exactly right. Imagine their trepidation when the document goes out for translation. Translation errors can confuse or offend potential subjects. They can also strengthen potential liability claims with missing, unclear or even false information. The following guidelines will help ensure successful translations:

- **Ensure readability.** FDA regulations and ICH guidelines both require that "information that is given to the subject or the representative shall be in language understandable to the subject or the representative."[2,3] The percentage of primary-Spanish speakers who have difficulty understanding instructions written in English is almost double that of primary-English speakers presented with the same instructions.[4]
- **Know your audience.** Languages such as Spanish, German, French and Portuguese have dialects that require separate translations. For example, Mexican Spanish is not the same as Puerto Rican Spanish or Castilian Spanish. In addition to differences in the use of common words, there are differences in medical terminology. For example, medical professionals in Spanish-speaking countries use the term "constantes vitales" for "vital signs." Potential subjects from Spain and South America would likely understand this term. However, most potential subjects from Mexico and Central America would not understand the term "constantes vitales" but would understand the literal translation "signos vitales."
- **Be precise.** Use precise translation equivalents for key terminology. For example: "replacement dose" is not the same as "additional dose"; "study" or "research" is not "treatment."
- **Be consistent.** Do not translate plain language into medical terminology. For example, do not translate "high blood sugar" into the Spanish "hiperglucemia". Use the equivalent non-medical phrase "nivel alto de azúcar en la sangre" instead. In addition, be consistent in terms of format, e.g., font size and use of white space.
- **Do not play lawyer.** Translators are seldom lawyers, and never the lawyers that drafted the original informed consent form. Stick to the wording in the original.
- **You talking to me?** The Statement of Consent section at the end of the document must be translated in first person ("I", "me", "my"), not second person

("you", "your'), as in the rest of the ICF. This rule seems obvious, but is broken fairly often.

- **Use translation memory tools.** Translation memory (TM) software compares text in source documents to a database of previously translated segments. TM tools ensure consistency of terminology, expedite future revisions, and reduce translation costs. These tools should not be confused with automated machine translation (MT) software, found at popular website portals such as Google, which is unusable for informed consent form translation.
- **Control quality.** Use systematic quality control processes that include more than one translator. Do not task the same person with translating, proofing and editing the ICF. Although roughly double the cost, consider making back (reverse) translations. For example, translate an ICF written in English to Spanish, have a completely separate team translate the document back to English, and then compare the result to the original to identify problem areas.
- **Hire professionals.** Whether you hire full-time employees, freelancers or translation firms, make sure your translators are qualified. The translators you want to hire have most or all of the following qualifications:
  - Native fluency in the target language and dialect
  - A linguistics degree from a major university or language school
  - Experience translating informed consent forms, or at least medical documents
  - Understanding of applicable laws and regulations
  - Access to up-to-date word processing and translation memory software
  - A reliable quality control process
  - Certification by the American Translators Association or equivalent foreign translators association
  - Reputable references

References

1. 2000 U.S. Decennial Census
2. 45 CFR 46.116
3. ICH Subpart B Section 50.20
4. "Health Literacy among Medicare Enrollees in a Managed Care Organization", Julie Gazmararian, et al., Journal of the American Medical Association, 1999. 281: 545-551

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