

## Informed Consent for Non-English Speakers: Tips for Translation Success

Recruiting of non-English speakers for U.S.-based and global clinical trials is on the rise. As a result of this, foreign language translation has become a critical component of clinical trials management. If done right, translations can play an important role in meeting global product demands. Otherwise, mistakes from poorly done translations can result in product delays, cost overruns, or, even worse, contribute to malpractice or product liability lawsuits.

Are you planning to enroll non-English speaking subjects in a U.S.-based or global clinical trial? If so, you will need to translate informed consent forms (ICF) into the native languages of those individuals to satisfy the requirements of the FDA and/or various directives governing clinical trials in foreign countries.

Based on the practices of leading clinical research companies and its own experience, Global Language Solutions (GLS), a full-service translation company delivering solutions in over 100 languages, offers the following tips for a successful ICF translation:

1. **Know the regulations.** Among different documents given to a research subject, the informed consent form is, arguably, the most important document. Its wording is carefully monitored by the federal government and IRB institutions. According to the Office for Human Research Protection (OHRP), obtaining consent from subjects who do not speak English must be in the language understandable to the subject, and in most cases, be documented in writing.
2. **Readability ensures informed consent.** The consent obtained from subjects who do not understand the information in the ICF means that it was not truly "informed". The *Journal of the American Medical Association* demonstrated in studies in 1995 and 1999 that the number of Spanish speakers who had difficulty understanding written instructions was almost double of the English speakers presented with the same instructions. Readability helps to ensure informed consent. Aim for the recommended 4-8<sup>th</sup> grade reading level of the ICF by using "plain English" and, whenever possible, replacing legalese and scientific terms with simpler terms or by explaining them in the text.
3. **Remain consistent between the original ICF and its translation.** In order to protect the subject's rights, the translated version of the consent must preserve the original document's content and style. This includes everything from font size and footer information to descriptive non-medical terms, if that's what was used in the source document. For example: "high blood pressure" should not be translated as "hypertension".
4. **All words are not created equal.** Use precise translation equivalents for key ICF terminology to avoid critical and costly mistakes. For example: "replacement dose" is not the same as "additional dose" and "study" or "research" does not equal "treatment".
5. **Translators are not lawyers.** Make sure translators don't "play lawyer" and modify key sections of the translated ICF (i.e. Risks, Compensation or other sections). Stick to the wording of the original ICF. Since you may not be familiar with the language the ICF is

being translated to, make sure you communicate this to your translation provider upfront. If you receive pushback from your language service provider, see tip #8.

6. **Me, myself and I.** Make sure that Statement of Consent section is translated in first person (“I”, “me”, “my”), not second person (“you”, “your”), as in the rest of the ICF. We have seen some translations where that very important section of the ICF was incorrectly translated in second person.
7. **Use translation memory (TM) tools.** Translation memory (TM) software analyzes repetitive text in the source documents and then queries a translation memory database to identify previously translated segments. TM tools ensure consistency of terminology, expedite future ICF revisions, and reduce translation costs. These tools should not be confused with Machine Translation (MT) software, which is unusable for ICF translation.
8. **Turn to professionals.** You’ve heard the saying: “Do what you do best and outsource the rest.” Since translation is most likely not your core competency, you’re probably in the market for a professional translation provider. Ensure your vendor has experience in this vertical, understands the regulations and nuances of ICF translation, and can supply a reputable client list with references.



### **About Global Language Solutions**

Global Language Solutions (GLS) is a full-service translation company delivering solutions in over 100 languages to increase its clients’ multicultural and international market share. GLS provides culturally and linguistically accurate document translations, website localization, multilingual typesetting/ graphic design, real-time interpreting, voice-overs, and globalization consulting services. Its clients include public and private companies, convention centers, government agencies, and multinational organizations across a variety of industries. For more information, visit [www.globallanguages.com](http://www.globallanguages.com) or call +1-949-798-1400.