From: OC GCP Questions
To: [redacted]
Subject: ICF Short Form
Date: Friday, August 29, 2014 12:32:10 PM

Good afternoon –

Speaking from an FDA standpoint, FDA has a general guidance on informed consent, "A Guide to Informed Consent - Information Sheet Guidance for Institutional Review Boards and Clinical Investigators" (available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm), that includes some information on translating consent forms:

Non-English Speaking Subjects
To meet the requirements of 21 CFR 50.20, the informed consent document should be in language understandable to the subject (or authorized representative). When the consent interview is conducted in English, the consent document should be in English. When the study subject population includes non-English speaking people or the clinical investigator or the IRB anticipates that the consent interviews will be conducted in a language other than English, the IRB should require a translated consent document to be prepared and assure that the translation is accurate. As required by 21 CFR 50.27, a copy of the consent document must be given to each subject. In the case of non-English speaking subjects, this would be the translated document. While a translator may be helpful in facilitating conversation with a non-English speaking subject, routine ad hoc translation of the consent document should not be substituted for a written translation.

If a non-English speaking subject is unexpectedly encountered, investigators will not have a written translation of the consent document and must rely on oral translation. Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented, the subject's consent will not truly be informed and may not be legally effective. ***If investigators enroll subjects without an IRB approved written translation, a "short form" written consent document, in a language the subject understands, should be used to document that the elements of informed consent required by 21 CFR 50.25 were presented orally. The required signatures on a short form are stated in 21 CFR 50.27(b)(2). [*****Emphasis added]**

Additionally we just issued a *draft* guidance on informed consent. Please see the link below. http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf Enrolling non-English speaking subjects is addressed starting on page 30.

There is no FDA requirement that the translators be certified.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hh.gov should you have additional quesitons.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather

From: [redacted]
Sent: Thursday, August 28, 2014 4:25 PM
To: OC GCP Questions
Subject: ICF Short Form

Hi,

I have a question regarding use of the short form for non-English speaking subjects. Is it acceptable for an institution to, as a rule, use a short form instead of translating the ICF? Further, the short form does not state anything about the study itself, it is a generic form that states the ICF was discussed/translated for the subject by a translator. And additionally, I was told that the translators do not have to be "certified" translators, that the institute will allow a family member to translate if they can speak and understand both languages in question.

What is FDA's point of view?

Thanks.

[redacted]