From: OC GCP Questions
To: [redacted]
Subject: Informed Consent Translations
Date: Tuesday, March 10, 2015 12:55:46 PM

Good afternoon –

FDA has some guidance documents that may be helpful to you in understanding FDA's current thinking on these regulatory requirements. FDA's Information Sheets Guidance - Frequently Asked Questions (see http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm) discusses translation of informed consent forms in question 51 (copied here for reference):

51. Must informed consent documents be translated into the written language native to study subjects who do not understand English?
The signed informed consent document is the written record of the consent interview. Study subjects are given a copy of the consent to be used as a reference document to reinforce their understanding of the study and, if desired, to consult with their physician or family members about the study.

In order to meet the requirements of 21 CFR 50.20, the consent document must be in language understandable to the subject. When the prospective subject is fluent in English, and the consent interview is conducted in English, the consent document should be in English. However, when the study subject population includes non-English speaking people so that the clinical investigator or the IRB anticipates that the consent interviews are likely to be conducted in a language other than English, the IRB should assure that a translated consent form is prepared and that the translation is accurate.

A consultant may be utilized to assure that the translation is correct. A copy of the translated consent document must be given to each appropriate subject. While a translator may be used to facilitate conversation with the subject, routine ad hoc translation of the consent document may not be substituted for a written translation.

Also see FDA Information Sheets: "A Guide to Informed Consent Documents" and "Informed Consent and the Clinical Investigator"

The FDA Information Sheet Guidance, Guide to Informed Consent (see http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm) addresses when non-English speaking subjects are anticipated to be enrolled (i.e., expected) and when non-English speaking subjects are unexpectedly encountered (i.e., unexpected) copied here for reference.
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).

While FDA's regulations do not specify who is qualified to orally translate information for the subject during study visits, we are aware that some IRBs prohibit using a family member or friend of the subject in this capacity and prefer an impartial translator. FDA regulations do not require the translator be certified. FDA recommends that the IRB review, and if appropriate, approve procedures for ensuring that the translations will be prepared by a qualified individual or entity. The determination of what party is appropriately qualified to translate the informed consent document and the actual process to review and obtain the translated version is left to the individual IRBs to determine. I would recommend that you not only have appropriate procedures in place for doing so, but also maintain sufficient records of the actual process including whether a back translation is required.

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

Kind regards,

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From: [redacted]
Sent: Monday, March 09, 2015 2:49 PM
To: OC GCP Questions
Subject: Informed Consent Translations

Hi: When conducting a study under an IND, is it a requirement that the (English) informed consent be translated to another language by a certified translator? If so, is a back translation also required? Thank you.

Kind regards,
[redacted]