From: OC GCP Questions
To: [redacted]
Subject: Consent Summary Only in English for Non-English Subject
Date: Wednesday, May 04, 2016 7:27:45 AM
[redacted]

Good morning --

The topic of informed consent for non-English speaking subjects is addressed in two FDA guidance documents. I've excerpted the pertinent information.

From FDA Information Sheet Guidance "Frequently Asked Questions" (available at www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm):

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.

This guidance (link below) addresses Non-English subjects as well.

Guidances > A Guide to Informed Consent - Information Sheet

www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm

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).

Although not clearly stated above, FDA's regulations require that a copy of the IRB approved written summary, of what is to be said to the subject or the representative when the short form is used, be provided to the subject or representative (see 21 CFR 50.27(b)(2)). In previous advice provided, FDA has indicated that a translation of the written summary (or the long consent form, if a written summary has not previously been prepared) be promptly provided to the subject. Many of the clinical investigations regulated by FDA involve ongoing interventions and may involve long-term follow-up. FDA believes that translation of the long form is critically important as a means of providing subjects an ongoing source of information understandable to them.

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 is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Tuesday, May 03, 2016 6:50 PM
To: OC GCP Questions
Subject: Consent Summary Only in English for Non-English Subject

Dear FDA Representative,

I have reviewed the attached response to an email inquiry whereby the responder indicated that it was compliant with FDA regulations to provide a non-English speaking subject with the summary of the consent only in English (i.e., never providing a translated summary to the subject). The email to the FDA noted that the IRB does not require the summary to be translated and provided to the subject at any point. This does not seem to fulfill the intent of the regulation in that the subject cannot read the summary that is provided to them. I have recently come across this myself and informed my client that regardless of the IRB's SOP that allows it, it was not acceptable and not in accordance with the regulation that requires consent to be in the native language. In my opinion, the summary MUST be promptly translated and provided to the subject in order to meet the regulation and in order to ensure the subject is fully informed.

I would like to know for certain whether a translation of the summary is a nice-to-have or whether it is a requirement. In other words, can a clinical investigator receive a 483 observation for improper consent if they have only provided a translated short form along with an English summary (no translated summary) to non-English speaking subjects?

[redacted]

Thank you kindly,

[redacted]

[redacted]

[redacted]

[redacted]