From: OC GCP Questions
To: [redacted]
Subject: Informed Consent Guidance on Long/Short Forms for Non-English Speaking Subjects
Date: Thursday, May 12, 2016 11:38:52 AM

Good afternoon --

It appears that investigators at your site(s) are following an SOP that is acceptable to the IRB regarding the informed consent process the investigator follows when he/she encounters a potential subject that does not understand English. It appears that the process followed is irrespective of whether the encounter with a non-English speaking subject is unexpected, or whether the investigator anticipates ahead of time, based on the potential subject population in a given geographic region, that the study will enroll non-English speakers (i.e., expected).

The FDA regulations at 21 CFR 50.20 (general requirements for informed consent) state that no investigator may involve a human being as a subject in research covered by the regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. The regulations also say that an investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence and that the information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

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 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 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).

If your site(s) are located in a geographic region of the country where the investigator expects that non-English speaking subjects may present for potential enrollment in research, the investigator and IRB should discuss how to proactively prepare for this (e.g., prepare a translated consent form in the language(s) upfront to be used when a non-English speaking subject is encountered).

FDA's regulations on informed consent do not use or define the terms "impartial witness" or "independent witness". The regulations require a witness when a "short form" written consent document is used, see 21 CFR 50.27(b)(2), which states:

A short form written consent document stating that the elements of informed consent required by 50.25 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.

Ideally, the witness should be someone who has no vested interest in whether the subject enrolls in the study. The expectation that the witness will be impartial is to assure that the witness will be able to attest that the subject enrolled in the study voluntarily.

If a witness is related to the subject, it may also be difficult for the witness to be objective (for example, if the subject's son believes that the only way for his mother to get appropriate care is for her to enroll in the study). In addition, the relative may not have sufficient knowledge about the study to be able to say whether the information conveyed during the consent process is accurate and complete and that the subject's questions were fully answered.

As for who might serve as an "impartial third party not otherwise connected with the clinical investigation," that role could possibly be filled by a hospital's "patient advocate," or a hospital staff member who does not work directly for the clinical investigator.

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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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: Thursday, May 12, 2016 12:37 AM
To: OC GCP Questions
Subject: Informed Consent Guidance on Long/Short Forms for Non-English Speaking Subjects

Hello,

I need some clarifications regarding the ICF Long and Short Forms Here's the situation: The site (academic setting) is in California with own local IRB. But the IRB of record is a Central IRB (CIRB). Justification for use of CIRB is in place as approved by the site's local IRB.

- The site is anticipating non-English speaking subjects per their application to the IRB. However, there could be several languages that may not be anticipated. The site indicated to the Central IRB that a qualified interpreter may orally present the informed consent information using the CIRB approved English version to the subjects, then the subject's Experimental Bill of Rights (also serves as the site's short form) will be given that is translated in their spoken language. The central IRB instructed the site that for non-English speaking subjects whose native language is not anticipated, the CIRB will allow oral translation, however, a witness should be available to document that the subject was properly consented. The site ended up consenting 4 non-English speaking subjects (Cantonese, Vietnamese, and Burmese) using the process as outlined.

  Is this acceptable practice? What is FDA's definition and/or expectation of a witness? Can the Study Coordinator (involved in the study but not the person obtaining consent) be a witness or does it have to be an impartial witness such as the interpreter?

- The site has readily available translated versions of the HIPAA and Bill of Rights (BoR) in various languages previously approved by its local IRB. The translated BoR also serves as the site's "short form." The site has specific guidelines in place on consenting process using the BoR as a short form for non-English speaking subjects.

  Is this acceptable practice? Should the site submit the translated HIPAA form and BoR to the CIRB for review/approval along with the site's process? Can the site use the BoR as a short-form as well?

I look forward to hearing back from you.

Regards,