From: Brown, Sheila (OGCP)
To: [redacted].
Subject: obtaining consent from Non-English speaking subject
Date: Friday, August 05, 2016 3:12:00 PM

Dear [redacted]

21 CFR 50.20 states, in part, "The information that is given to the subject or the representative shall be in language understandable to the subject or the representative."
21 CFR 50.27, Documentation of informed consent states:

> (a) Except as provided in 56.109(c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form.
>
> (b) Except as provided in 56.109(c), the consent form may be either of the following:
>
> (1) A written consent document that embodies the elements of informed consent required by 50.25. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.
>
> (2) 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.

There is no FDA regulatory requirement to use an English consent document for non-English speaking subjects when a translated version is available. There is no FDA regulatory requirement for the person *obtaining* consent to sign either a short or long form, although this may be a requirement of the IRB. You may wish to consult with your IRB regarding this topic.

FDA has two guidance documents that may be helpful: *A Guide to Informed Consent - Information Sheet* www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm

Excerpted below is the section on 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).

From the FDA Information Sheet Guidance, *Institutional Review Boards - 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.

You may also wish to review some of the FDA Bioresearch Monitoring Program Compliance Program Guidance Manuals: *IRBs*; *Sponsors, Contract Research Organizations, and Monitors*; and *Clinical Investigators*, which can be found at http://www.fda.gov/ICECI/ComplianceManuals/CompliancePrograMManual/ucm255614.htm. Each of these documents has a section entitled “Inspectional”, which gives detailed information on what inspectors look for when inspecting each of these groups.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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, August 04, 2016 9:51 AM
To: OC GCP Questions
Subject: obtaining consent from Non-English speaking subject

[redacted]

For this situation, there is a fully translated Spanish consent, a Spanish speaking only family, a translator (serving as witness as well) and the person obtaining consent that does not speak/ understand Spanish. For FDA Inspection purposes, what is the proper way of documenting informed consent, using a fully translated consent document, when the participant and the person obtaining consent do not speak the same language? Does the person obtaining consent also sign the Spanish document or is it necessary to utilize an English consent much like the short form process?

Thank you,

[redacted]

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