From: OC GCP Questions
To: [redacted]
Subject: ICF Translations
Date: Thursday, September 10, 2015 6:47:04 AM

Good morning --

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.

FDA's regulations require that the IRB must review and approve all English and non-English language versions of any consent documents (long form or short form with written summary) that are to be used by investigators to document the informed consent of subjects (21 CFR 50.27(a) and 21 CFR 56.111(a)(4)-(5)). When reviewing proposed informed consent procedures involving translation of written and oral information that is to be presented to subjects, 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.

FDA notes that informed consent should be viewed as an ongoing process throughout the course of a subject's involvement in the research. Therefore, FDA recommends that whenever subjects who do not understand English are involved in research, appropriate interpreter services be made available throughout the course of the research.

I am not sure what you mean by Spanish translation certificates. Otherwise it appears from the limited information in your email your processes appear acceptable. However it is recommended that you have a standard operating procedure in place for consenting non-English speaking subjects.

Please see the guidance document on a Guide to Informed Consent specifically the section on Non-English Speaking Subjects.

Search for FDA Guidance Documents > A Guide to Informed Consent - Information Sheet

Please also see the new *draft* guidance on informed consent. While not for implementation yet as the public comments are still being reviewed, it reflects FDA's current thinking on this topic. Please see section V. Part B starting on page 30.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf

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

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: Wednesday, September 09, 2015 2:01 PM
To: OC GCP Questions
Subject: ICF Translations

Hello-
I hope that you are doing well today! I have a question regarding FDA requirements for translation of ICFs and proper documentation sites must have.
I am a CRA and have a site that enrolls Spanish and English speaking subjects. The site does have a Spanish translator listed on the Delegation of Duties log, that is present during the ICF process when the Spanish speaking subjects are being consented by the English speaking study coordinator. The site does document the ICF process and that the translator was present during the ICF process. Is this sufficient?
The site does have Spanish translation certificates from the IRB that approved the Spanish ICFs and has this documentation as well.
Is there any other documentation required?

Thank you!

[redacted]