

From: Melvin, Marsha *
Sent: Tuesday, October 27, 2015 1:20 PM
To: [REDACTED]
Subject: RE: Consent of non-English speaking subjects

[REDACTED],

Thank you for your inquiry regarding the use of translators and who may act as a witness when a short form consent is used for an unexpected non-English speaking subject. The pertinent part of the regulations is in 21 CFR 50.27(b)(2), which states:

(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.

I've repeated your questions below and provided responses:

- Am I correct in presuming that a phone interpreter cannot be considered a witness?

The regulations require a witness to the oral presentation but do not specify who may act as a witness. In guidance, FDA has said:

"A witness is required to attest to the adequacy of the consent process and to the subject's voluntary consent. Therefore, the witness must be present during the entire consent interview, not just for signing the documents."

"An impartial third party should witness the entire consent process and sign the consent document." [See "A Guide to Informed Consent - Information Sheet" available at

<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm#nonenglish>.]

The ICH E6 Good Clinical Practice Consolidated Guidance [an FDA recognized guidance available at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf>] states: "By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative."

In order for the phone interpreter to be a witness, he/she must be able to make the attestations identified above and to sign the short form and the summary. FDA accepts electronic signatures (see FDA's guidance "Part 11, Electronic Records' Electronic Signatures – Scope and Application" available at [http://www.fda.gov/regulatoryinformation/guidances/ucm125067 .htm](http://www.fda.gov/regulatoryinformation/guidances/ucm125067.htm) for further information) so it may be possible to have a witness in a remote location who could still sign the consent form.

- [REDACTED] requires an interpreter even when a family member speaks English, if a family member who speaks both languages is present for the consent process involving a phone interpreter, could the family member serve as the witness?

As indicated above, the witness should be an impartial third party. The ICH E6 guidance defines an impartial witness as "A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject."

FDA's formal guidance does not address whether or not a family member may act as a witness but we are aware that some concerns have been raised about whether a family member could be considered impartial.

- Can an interpreter serve as a witness through a video conference such as Skype? If so, what would be considered acceptable methods for signing the consent documents? The study team has asked about a note to file indicating that the consent process was witnessed, I wouldn't think that meets regulatory requirements.

The use of video conferencing may help to address concerns about the remote witness making an attestation to the adequacy of the consent process and to the subject's voluntary consent. I agree that a note to the file indicating that the consent process was witnessed would not meet the regulatory requirements but, as previously indicated, it may be possible to obtain a signature remotely such as by using an electronic signature.

I hope this information helps to address the issues raised. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov.

Best regards,

Marsha Melvin
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: Monday, October 26, 2015 4:31 PM
To: Melvin, Marsha *
Subject: Consent of non-English speaking subjects

Marsha,
I'm hoping you can help me with more difficult questions: At [REDACTED] when study teams consent an unexpected non-English speaking subject, they use the short form method of consent. We have short forms available in a number of different languages. Typically in these cases an interpreter is called and the interpreter signs the short form and summary as the witness. We are hearing from study teams that it is becoming increasingly difficult to get an in person interpreter and they are often required to use phone interpreting services or video conference interpreting. Given that situation, here are my questions:

- Am I correct in presuming that a phone interpreter cannot be considered a witness?
- [REDACTED] requires an interpreter even when a family member speaks English, if a family member who speaks both languages is present for the consent process involving a phone interpreter, could the family member serve as the witness?
- Can an interpreter serve as a witness through a video conference such as Skype? If so, what would be considered acceptable methods for signing the consent documents? The study team has asked about a note to file indicating that the consent process was witnessed, I wouldn't think that meets regulatory requirements.

Thanks in advance for your advice,
[REDACTED]