From: OC GCP Questions
To: [redacted]
Subject: Witness in short form (21 CFR § 50.27(b)(2))
Date: Thursday, May 05, 2016 7:25:36 AM
[redacted]

Good morning –

There is no FDA requirement that the witness needs to speak both English and the subject's language. I can offer you the following information on short form usage.

The regulation on the use of short form written consent documents (See 21 CFR 50.27(b)(2)) actually does not describe the circumstances under which this form of documentation should be used. Specifically, it does not state the condition of using a short form consent when consenting non-English speaking subjects. For your convenience, I include it here:

A short form written consent document stating that the elements of informed consent required by 21 CFR 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 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.

You will note under 21 CFR 56.109(c), IRB review of research, that the IRB shall require documentation of informed consent in accordance with 21 CFR 50.27 (except in certain limited circumstances). The IRB would need to determine if it is more appropriate to utilize the short form for the documentation of informed consent. It should be emphasized that no matter which form is used for the documentation of informed consent, the informed consent process itself should include all the basic elements (See 21 CFR 50.25(a)) and one or more of the additional elements when appropriate (See 21 CFR 50.25(b)). The IRB may also require that additional information be provided if in its judgment, the information would meaningfully add to the protection of the rights and welfare of the subjects (See 21 CFR 56.109(b)). To further emphasize this point I am including a section of the 1981 Preamble to the Informed Consent Regulations:

The fact that a short form is used to document informed consent does not mean that the subject will get less information than if handed a long, detailed written document. When a "short form" is used, the IRB must first approve a written summary of what is to be said, and a witness must be present to attest to the adequacy of the consent process and to the voluntariness of the subject's consent. Section 50.27(b)(2) also requires that a copy of that summary be given to the subject. FDA believes that in many cases an oral presentation and written summary will be an effective method of disclosing necessary information.

Bear in mind also that if the subject speaks another language, the "short form" document and summary would still have to be translated into that language.

It might be helpful to review the guidance document on a Guide to Informed Consent –

Search for FDA Guidance Documents > A Guide to Informed Consent - Information Sheet Please see the section on Non-English Speaking Subjects.

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

Kind regards,

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Office of Good Clinical Practice
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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: Wednesday, May 04, 2016 4:14 PM
To: OC GCP Questions
Subject: Witness in short form (21 CFR § 50.27(b)(2))

Good morning,

We are coming across this question multiple times and would like your input on the matter.

1- When using a short form, a witness is required to sign the document and to attest the consenting process. Does the witness need to speak English **AND** the patient's language ?

Your assistance will be greatly appreciated.

Sincerely,

[redacted]