From: OC GCP Questions
To: [redacted]
Subject: RE: Short Form Consent - Questions on the Main Consent
Date: Thursday, June 12, 2014 5:11:00 PM

Dear [Redacted]-

Thank you for your question. In accordance with the regulations at 21 CFR 50.27(b):

> (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.

From the limited information provided in your question, it is difficult for me to know the circumstances regarding why you are using a short form to obtain consent from a non-English speaking subject vs. using an IRB-approved translation of the long form (e.g., is enrollment of subjects who do not understand English expected or is enrollment of subjects who do not understand English unexpected). Generally, when the study subject population includes non-English speaking subjects and the 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.

If you are using a short form consent document for a non-English speaking subject, I wasn't sure why you are asking who should sign the main consent (in English), which I assume is the long form? The consent form may be **either** a long form or short form. Maybe you are using the English long form to serve as the written summary of what is to be said to the non-English speaking subject? I will assume that you are using the long form in English to serve as the written summary of what is to be said to the subject (i.e., what will be communicated/translated to the subject during the oral presentation/consent process).

FDA's Information Sheet Guidance – A Guide to Informed Consent (found at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm) addresses non-English speaking subjects and states:

> ### 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 [emphasis added]**. 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 [emphasis added]**, 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).

I assume, based on the information in your question that the subject is providing consent for his/her participation in the study, and will sign the short form, as opposed to a legally authorized representative. If the informed consent includes questions such as

"Do you agree to allow your samples to be used for future research?" Yes__ Initials __No__ Initials __, then the person who is providing consent for participation answers such questions (i.e., the subject in your case). It is important to ensure that subjects are given ample opportunity to respond to any such questions and to adequately document their decisions.

Because I may be missing details about your specific scenario that may be important to consider, I recommend you discuss your question directly with your IRB. It should be clear to your IRB what your investigator plans to do regarding obtaining informed consent from non-English speaking subjects. Your IRB should determine that there is sufficient justification to enroll non-English speaking subjects without using a translated long form to document the subject's informed consent.

If your IRB approves a short form consent for non-English speaking subjects, the IRB should decide "where" and "how" the subject documents his/her Yes/No decision regarding questions such as "Do you agree to allow your samples to be used for future research?". Your IRB may also consider whether or not they require documentation from the witness in this case (the purpose of the witness is generally to attest to the voluntariness of the subject's consent and the adequacy of the consent process by ensuring that the information was accurately conveyed and that the subject's questions were answered).

I hope this information is useful. 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. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

---

From: [Redacted]
Sent: Tuesday, June 10, 2014 2:41 PM
To: OC GCP Questions
Subject: Short Form Consent - Questions on the Main Consent

Hello,

I would like to inquire about a specific scenario while using a short form to consent a non-English speaking subject. I understand the general concept of who signs each form (witness- both, subject- short form, research coordinator- main consent). But who should sign the main consent (in English) if there are multiple questions on this form?

For example, some consents ask "Do you agree to allow your samples to be used for future research?" Yes__ Initials __
No__ Initials __.

Who should initial the response to these questions? The interpreter/witness? The subject after the interpreter has explained in the native language? Should the interpreter also initial with the subject to confirm that the patient understood the question?

Please offer guidance on this issue.

Thanks,

[Redacted]