From: OC GCP Questions
To: [redacted]
Subject: RE: Question on the use of the short form Informed Consent CFR 50.27(b)(2)
Date: Monday, July 28, 2014 2:02:00 PM

Dear [Redacted]-

Thank you for your question. FDA just recently issued a draft guidance document titled, "Informed Consent Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors" that can be accessed at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf. This is a draft guidance document at this time and FDA is seeking public comment. When finalized, this guidance will supersede the Information Sheets: ''A Guide to Informed Consent'' and ''Frequently Asked Questions'' (only the sections entitled ''Informed Consent Process'' and ''Informed Consent Document Content'') (September 1998, Office of Health Affairs, Food and Drug Administration).

I recommend that you read the draft guidance in its entirety. You may find that this draft guidance helps to addresses your question (see page 30, section V.B.). I also recommend that you discuss the site's consent process for non-English speaking subjects ahead of time with the appropriate IRB(s).

I've listed below a couple of points the draft guidance makes that are important as you assess the consent process to be used by your site for non-English speaking subjects and discuss what you will do with the IRB(s):

- Individuals who do not understand English may ask or be asked to participate in a clinical trial in locations where English is the predominant language. The investigators and the IRBs that review such research should carefully consider the ethical ramifications of enrolling or excluding potential subjects when a language barrier may exist between the investigator(s) and some or all of the potential subjects.

- When the short form is used, the IRB is required to approve a written summary of the information to be presented orally (21 CFR 50.27(b)(2)) and the information presented orally is to be the same quantity and quality of information as when a long form is used.

- For some research, the time frame for subject enrollment may provide sufficient time for the preparation and IRB review of an appropriately translated long form or an appropriately translated short form and written summary. When this is the case, translated consent forms are to be reviewed and approved by the IRB prior to enrollment of the subject.

- In the scenario when enrollment of subjects who do not understand English is unexpected, determine that there is sufficient justification to enroll the subject without using a translated long form to document the subject's informed consent.

- In the scenario when enrollment of subjects who do not understand English is unexpected, take additional actions following subject enrollment such as:
    - After the subject has been enrolled in the research, the investigator takes the following additional actions:
        - (1) If a subject was enrolled in the research without waiting for a translated long form (which served as the written summary) to be reviewed and approved by the IRB, and if the investigator did not consult with the IRB chairperson (or designee) prior to enrollment of the subject who does not understand English, the investigator should promptly notify the IRB chairperson (or designee) that such a subject was enrolled.

        - (2) For FDA-regulated research, the investigator must promptly obtain a translated copy of the IRB-approved English version of the long form, which served as the written summary. The investigator promptly submits it to the IRB for review and approval. Once the translated long form/written summary is approved by the IRB, the investigator provides it to the subject as soon as possible. FDA considers this step essential to the requirement that informed consent be documented by the use of a written consent document and that the subject be provided a copy (21 CFR 50.27). Many of the clinical investigations regulated by FDA involve ongoing interventions and may involve long-term follow-up. FDA believes that translation of the long form is critically important as a means of providing subjects an ongoing source of information understandable to them.

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

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Office of Special Medical Programs, Food and Drug Administration

From: [Redacted]
Sent: Wednesday, July 23, 2014 6:06 PM
To: OC GCP Questions
Subject: Question on the use of the short form Informed Consent CFR 50.27(b)(2)

I have a question regarding the use of the short form written consent in a clinical trial.

I have an investigator site that has a large diverse patient population where up to 25 languages are possible. It is not feasible to have the IRB approved ICF translated into 25 languages for the purposes of the clinical trial. The site proposed using the short form for non-english speaking subjects according to the following procedure:

1) Short form will be written in the language understandable to the subject or legally authorized representative and approved by the IRB. The summary document will be the IRB approved **English** version of the Informed Consent Form.

2) With the use of an interpreter, the Overall PI or person authorized to obtain informed consent will explain the research in detail using an IRB approved written summary (i.e. the IRB-approved English language consent document). The role of the interpreter is to translate the discussion between the Overall PI or person authorized to obtain informed consent and the subject (or legally authorized representative).

3) The subject (or legal authorized representative) will sign the Short Form, in the language he or she understands, to indicate his or her willingness to participate in the research.

4) The witness/interpreter will sign the short form and the IRB approved written summary (i.e. IRB approved version of English ICF).

5) The PI or person administering consent will sign the IRB approved summary (i.e. The IRB approved english ICF).

6) the subject will receive a signed and dated copy of both the summary document and short form.

My question is; Is it acceptable that the the summary document, (in this case a full IRB approved **English** ICF) is used rather than a summary document in the language understandable to the subject?

Thank you,

[Redacted]