From: OC GCP Questions
To: [redacted]
Subject: Consent Form Question
Date: Wednesday, February 26, 2014 1:19:39 PM

Good afternoon --

FDA's regulations on informed consent do not specifically address whether informed consent may be obtained over the phone and using faxed consent forms. Following is an excerpt from the regulations identifying the general requirements for informed consent.

§ 50.20 General requirements for informed consent.
Except as provided in §§ 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

As you can see, the regulations require that there be an exchange of information but not the format for the exchange. In guidance, FDA has previously acknowledged a practice similar to what you described. Please see FDA's Information Sheet Guidance "Institutional Review Boards Frequently Asked Questions" (available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm) that includes the following:
35. May informed consent be obtained by telephone from a legally authorized representative?
A verbal approval does not satisfy the 21 CFR 56.109(c) requirement for a signed consent document, as outlined in 21 CFR 50.27(a). However, it is acceptable to send the informed consent document to the legally authorized representative (LAR) by facsimile and conduct the consent interview by telephone when the LAR can read the consent as it is discussed. If the LAR agrees, he/she can sign the consent and return the signed document to the clinical investigator by facsimile.
The guidance acknowledges that there may be situations where an alternative to a face-to-face consent interview may be appropriate for obtaining the subject's or the LAR's consent. An example often provided is when the screening procedures for the clinical investigation require prior activity, such as fasting, that requires consent but does not require a visit to the investigational site.

In general, methods other than a face-to-face consent interview may be acceptable if those methods allow for an adequate exchange of information and documentation, and a method to ensure that the signer of the consent form is the person who plans to enroll as a subject in the clinical investigation. I am not aware that FDA has previously provided guidance on how to verify that the signature is the patient's signature. A site allowing consent to be obtained in this manner should have a procedure in place to address this concern.

Regarding your question about the original signature document, FDA's regulations require the investigational site to maintain the signed and dated consent form (see 21 CFR 312.61(b) for drug and biologic studies and 21 CFR 812.140(a)(3) for device studies). While this is usually the original signature document, a site's procedures could indicate that the faxed copy be maintained and allow the subject to keep the original signed document as his/her copy.
Alternatively, the subject may mail or bring the signed and dated consent form to the clinical site. In these situations, the site would need to ensure that the subject received a copy of the consent form as required by 21 CFR 50.27(a).

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
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [Redacted]
Sent: Tuesday, February 25, 2014 9:24 AM
To: OC GCP Questions
Subject: Consent Form Question

Good Morning,

I received this email address from a Regulatory Project Manager within the FDA as a good place to go for some general questions. Please let me know if there is another place I should be directing this question.

Recent review of DHHS regulations uncovered a section that indicated it was acceptable, after the consent discussion was held with a potential participant, to send the potential participant home with a copy of the consent that they could then sign after considering all of their options and fax (or scan) back to the study team for the consenting individual to then sign. Which in turn would mean there were 2 documents with "original" signatures.

My question is whether or not this would be acceptable per FDA regulations and specifically during an FDA Inspection? I had a hard time finding any clear information that says this process would be acceptable and the regulations do indicate "original" consent. Any insight you have on this topic is greatly appreciated.

Thank you for your time.

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