From: OC GCP Questions
To: [redacted]
Subject: signature of person obtaining consent when consent discussion occurs by phone
Date: Friday, May 06, 2016 11:27:39 AM

Good morning --

FDA's regulations on informed consent do not specifically address whether informed consent may be obtained over the phone. However this situation is mentioned in guidance (See below).When the regulations are silent IRBs, institutions, and sites have the flexibility to develop their own standard operating procedures (SOPs) for handling certain situations. From the brief information in your email it appears that the scenario you describe may not conflict with the general FDA regulations on informed consent. It is important to have a detailed SOP and to follow the SOP with documentation.

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 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.

Please see two draft guidances that might be helpful to you. Please note that both these guidances are still out for public comment and have not been finalized. Phone consents are discussed in both documents.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM436811.pdf

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf

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
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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: Thursday, May 05, 2016 4:42 PM
To: OC GCP Questions
Subject: signature of person obtaining consent when consent discussion occurs by phone

Good afternoon,

A Principal Investigator overseen by our IRB has a prospective subject who would like a family member to be present during the consent discussion, but the family member is only available after the site's office hours; the consent discussion will need to occur by phone from the subject's home. Our IRB adopts the GCP provision whereby consent forms are signed by both the subject and the person obtaining informed consent. Here, the subject does not have access to a fax or scanner at home, so the signed consent cannot be sent for signature by the person obtaining consent on the same day. We are trying to determine an approach that would allow for signatures by both the subject and the person obtaining consent while satisfying ALCOA principles. Would it be acceptable for the study record to indicate the date/time/participants of the consent discussion, then allow the person who conducted the consent discussion to sign the consent form once the subject can bring it back in with a current dated signature and note to the effect of "on previous date [MM/DD/YYYY] I conducted a consent discussion with the subject" ?

Thank you for your consideration of this inquiry.

Kind regards,

[redacted]