From: OC GCP Questions
To: [redacted]
Subject: RE: Verbal Remote Consent
Date: Thursday, February 06, 2020 11:24:00 AM
Attachments: [redacted]

Dear [redacted],

It is not clear from the limited information provided who instructed you to obtain consent over the phone and then document it on the informed consent form (e.g., IRB? Sponsor?). Who is documenting what on the consent form? It isn't clear if the observational study consent form will provide the patient with any information about the interventional study, or in what way the 2 studies may be related (or if they are related).

FDA's regulations do not currently provide a specific option for verbal consent. FDA's regulations do allow a waiver of *documentation* of informed consent for minimal risk studies under 21 CFR 56.109(c)(1):

> An IRB shall require documentation of informed consent in accordance with §50.27 of this chapter, except as follows:
>
> (1) The IRB may, for some or all subjects, waive the requirement that the subject, or the subject's legally authorized representative, sign a written consent form if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context;…
>
> 56.109(d) In cases where the documentation requirement is waived under paragraph (c)(1) of this section, the IRB may require the investigator to provide subjects with a written statement regarding the research.

The complete regulation can be found at https://www.ecfr.gov/cgi-bin/text-idx?SID=80c3fec60cf5b826ec5e2975ad90cefa&mc=true&node=pt21.1.56&rgn=div5#se21.1.56_1109

FDA's draft Informed Consent Information Sheet guidance, which can be found at https://www.fda.gov/media/88915/download , gives an option for obtaining informed consent orally by phone, using a faxed/emailed copy of the consent form to guide the discussion, as quoted below:

> 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 or is the legally authorized representative of the subject. For example, the consent form may be sent to the subject or the subject's legally authorized representative by facsimile or e-mail, and the consent interview may then be conducted by telephone when the subject or subject's legally authorized representative can read the consent form during the discussion. After the consent discussion, the subject or the

subject's legally authorized representative can sign and date the consent form and return the document to the clinical investigator by facsimile, scanning the consent form and returning it through a secure e-mail account, or by posting it to a secure internet address. Alternatively, the subject may bring the signed and dated consent form to his/her next visit to the clinical site or mail it to the clinical investigator. The signed document should be filed with the subject's case history. See 21 CFR 312.62(b) and 812.140(a)(3). In addition, the person signing the consent form must receive a copy of the consent form (21 CFR 50.27(a)). Although FDA regulations do not require the subject's copy to be a signed copy, FDA recommends that a copy of the signed consent form be provided.

FDA's guidance, *IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects*, which can be found at https://www.fda.gov/media/106587/download provides the following information:

> In light of the Cures Act amendment to the FD&C Act…, FDA intends to revise its informed consent regulations to add this waiver or alteration under appropriate human subject protection safeguards to the two existing exceptions from informed consent (i.e., in life-threatening situations and for emergency research). However, until FDA promulgates these regulations, we do not intend to object to an IRB approving a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in 21 CFR 50.25, or waiving the requirements to obtain informed consent when the IRB finds and documents that:
>
> 1. The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;
> 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
> 3. The clinical investigation could not practicably be carried out without the waiver or alteration; and
> 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
>
> FDA does not intend to object to a sponsor initiating, or an investigator conducting, a minimal risk clinical investigation for which an IRB waives or alters the informed consent requirements as described above.

We recommend that you discuss the informed consent process with your IRB and study sponsor to determine the process best suited to your situation.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcpquestions@fda.hhs.gov .

Best regards,

Sheila

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This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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: Friday, January 31, 2020 11:45 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Verbal Remote Consent

Dear Food and Drug Administration,

We have a study with minimal risk and we are instructed that we can obtain consent from the patient verbally over the phone and then document this on the informed consent form. Is there any issue to obtain verbal consent in a clinical study? This is an observational study where the patient may be eligible for an interventional study with a separate consent. I haven't seen much about this in the regulations.

Thank you!

Kind Regards,

[redacted]