From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, April 04, 2003 2:18 PM
To: [Redacted]
Subject: RE: faxing consents

[Redacted], You are not a pain; I do appreciate the further clarification. I think that in many respects, the answer depends upon what your Institutional Review Board (IRB) thinks about the idea. If the purpose of faxing the signed form is to initiate some study related things, then the process ought to be described to the IRB as well as the reason for it, and they should make a decision about it. Another way to approach this would be to have the study consent form, as you've described, the conversation, questions/answers, and allow the subject to take the form home to talk with family; at the same time, the subject could be provided with another (IRB approved) form that would be limited to certain tests or other procedures that may need to be initiated before the full study consent form is signed and returned. I'm not sure what these procedures would be because in most cases, it would seem to me that the patient/subject would need to return anyway to give blood, get xrays, take other tests, or whatever the case might be; it is one reason why I think that it's important for the IRB to look at the rationale. As long as there is sufficient opportunity to discuss the protocol and ask questions and assuming that the subject will have the written consent form, the IRB may consider that there is sufficient justification to allow the form to be faxed back to the investigator or study nurse. I hope this helps.

Bonnie

Bonnie M. Lee

Associate Director for Human Subject Protection Policy

Good Clinical Practice Program, HF-34, FDA

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.

-----Original Message-----
From: [Redacted]
Sent: Wednesday, April 02, 2003 4:00 PM
To: OC GCP Questions
Subject: RE: faxing consents

Bonnie,

Thank you for your insight. To clarify, the investigator isn't necessarily the person signing the consent, but it is usually a nurse or someone who is there during the consent process who is explaining the consent. The signature is just to attest that the process took place, not the accuracy of the process. I think what is happening in this scenario (and why faxing enters into it) is that these are cancer patients who have probably just been given a devastating diagnosis. The investigator or nurse explains the consent, then asks the potential subjects to take the document home, talk with family and friends, call with questions, etc. The consent form is not signed at that first visit. What then happens is that the subject might call and say they want to participate and make an appointment. They will bring the signed consent with them to their appointment, but what I think the investigator is asking is the appropriateness of relying on a faxed consent to begin some

study-related tests before the subject comes in and gives the signed physical consent document over to the investigator. Does this help?

Sorry to be a pain,

[Redacted]

-----Original Message-----
From: OC GCP Questions [mailto:GCPQuestions@OC.FDA.GOV]
Sent: Wednesday, April 02, 2003 3:50 PM
To: [Redacted]
Subject: RE: faxing consents

Dear [Redacted],

Unless you are using a "short" form, which few people do, there is no FDA requirement for the investigator to sign the consent form. If you are using a "short" form then there is a requirement for a witness, but that is a witness attesting to the adequacy of the verbal presentation of information. Thus, it sounds as though the PI is making this far more complex than needed. First, why wouldn't the subject be asked to either sign the consent after the discussion of the study and the question/answer period (before leaving the site) or when the subject returned to the site. I don't understand why a fax would enter into this at all. Perhaps with more information I could be more helpful. Also, if you are going to require the signature of the investigator or sub-investigator then it is important to indicate what that signature means. Is it attesting to the adequacy of the informed consent process? just the subject's signature? something else? You don't want multiple forms, the danger of losing forms and having no documentation, or the danger of having different versions of them. I encourage you to consider simplicity, rather than the scenarios you have described. I hope this is helpful.

Sincerely,

Bonnie

Bonnie M. Lee

Associate Director for Human Subject Protection Policy

Good Clinical Practice Program, HF-34, FDA

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.

-----Original Message-----
From: [Redacted]
Sent: Friday, March 21, 2003 8:04 AM
To: OC GCP Questions
Subject: faxing consents

You have been so helpful in the past that I'm hoping you'll be able to answer a question regarding the faxing of consents. Here is what the PI proposes below. Would this be acceptable to the FDA?

The subject takes the informed consent home after a discussion of the study, the consent form, and all questions related to the trial. The subject signs the consent form and faxes it to the nurse at the site. The nurse orders prestudy tests to be performed. When the subject returns to the clinic, the subject re-signs the faxed consent form in the presence of the investigator or sub-investigator who also then signs it on this later date. Study tests may be performed after the subject has signed the consent and faxed it in, but before all parties, i.e. investigator or sub-investigator, sign the consent form. This process is all documented either in the nurse's note or the doctors dictation.

Here is what we have advised in the past, although I don't necessarily agree with the consenter signing the consent prior to the subject doing so:

The consenter should sign and date the original consent after discussing the consent with the patient as that was the actual date of conducting the consent. Thus the patient would take home with them an original consent with the consenter's signature on it. If the subject then chose to sign it, what got faxed back would have BOTH signatures on it. At the next visit, the subject would be asked to bring the original back so that the consenter could attach the faxed copy to the original (in case there is any question in the future about the differences in dates for the consenter/subject's signature) and file. Thus the consenter would not sign the faxed version (unless it would be a second signature acknowledging receipt) but would sign the original immediately following the consent discussion with the patient, not upon receipt of the fax.

Presumably "study tests" and/or treatment should not be performed until the signed original is returned by the subject. What about providing a stamped- self addressed envelope for subject to return original? Next clinic visit should be fine, but what happens if he forgets and/or loses it?

I apologize for the length of this e-mail and truly appreciate any guidance you can provide.

[Redacted]