From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, January 15, 2004 2:43 PM
To: [Redacted]
Subject: RE: Reconsenting subjects

Dear Ms. [Redacted],

Your questions to the GCP Questions account, about documenting additional information provided as part of the informed consent process, were forwarded to me for response.

Although we all recognize the importance of informed consent as a continuing process, the focus of the documentation requirements in the regulations is on initial, rather than continuing, informed consent. That being said, we also frequently comment that if something is not documented, then you cannot know that it happened. Thus, if, as the regulations require, you provided a subject with "significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation", it would seem reasonable that there would be some form of documentation that this occurred (e.g., an IRB approved amended consent form or addendum, a notation in the subject's medical records).

It's also important to remember that State law plays an important part in determining what is required in terms of informed consent as well as its documentation. I am not aware of what [Redacted] law says, but it may be worthwhile to check with the IRB on this issue.

As you point out, the ICH guidance recommends that written information be given to the subjects, and this is clearly a good practice. Nevertheless, the ICH E-6 guidance in itself is not enforceable by FDA except where these provisions are also contained within FDA regulations, and as I mentioned above, our regulations do not specifically say how this should be accomplished.

I hope this is helpful.

Sincerely,

Carolyn Hommel
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-----Original Message-----
From: [Redacted]

Sent: Tuesday, January 13, 2004 6:28 PM
To: 'GCPQuestions@OC.FDA.GOV'
Subject: Reconsenting subjects

The answer seems obvious but can you please answer the following question?

Is there any regulation that says subjects must be reconsented when there is new protocol information i.e., safety information, change in schedule of events etc? If the informed consent was not changed and the new information was given to the subject verbally and well documented, would this be acceptable over changing the ICD and having the subject resign it?

Also, ICH guideline 4.8.11 says that "During a subject's participation in the trial, the subject ..... should receive a copy of the signed and dated form updates and a copy of any amendments to the written information provided to subjects." This implies a document must be given to them. What if you provide the information verbally to the subject? What does the get then receive?

Thanks for your input.

[Redacted]