From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, February 23, 2006 2:58 PM
To: [Redacted]
Subject: RE: Question regard a subject re-entering study

Dear [Redacted], In looking at your question, below, I do have 2 questions:

assuming this was a blinded study, is anyone concerned that the blind is now broken for this patient, and
is there a compelling reason to consider the patient a "continuing" patient, rather than a new patient?

I can't answer those questions. If you decide to move forward as you've suggested, I would be very sure that the case history documents what was done before the withdrawal, the withdrawal itself, and what was done afterwards to include the subject in the study. I would also encourage you to contact the review division at FDA responsible for the study to see whether the data from this subject would be able to be included in the IND or not. I have two contacts who may be helpful: Dottie Pease (Dorothy.Pease@FDA.HHS.gov) and Karen Jones (Karen.Jones@FDA.HHS.gov).

I'm sorry that I can't be more helpful.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
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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.

-----Original Message-----
From: [Redacted]
Sent: Thursday, February 16, 2006 11:31 AM
To: OC GCP Questions
Subject: Question regard a subject re-entering study

To whom it may concern:

We are [Redacted] and a client has posed a situation to the IRB.

A subject was enrolled in a [Redacted] study – [Redacted]. The study involved 2 arms, one of which was the standard of care [Redacted]. And the other included the study drug in the [Redacted].

The patient entered the hospital and when it was determined that the subject would move forward with the standard of care [at the hospital, the PI noted in the source documentation that the subject was withdrawn from the study. This decision was made because the hospital was not listed on the 1572, not on the

research consent form, not approved by the IRB and the hospital had not waived jurisdiction to the central IRB.

It turns out the subject was in the standard of care [Redacted] arm of the study. This is what they received in the hospital as a part of their treatment. It was the [Redacted] that they would have received if they had continued on the study.

The investigator would like to know if the subject can 'continue' in the study (for data purposes), although in the source documentation it was noted that the subject was withdrawn and one of the [Redacted] (that would be a part of the protocol) was done in a non-IRB approved facility. At this point, even if all the below changes were done - if would be after the fact. They have permission from the sponsor to continue and are seeking a waiver of jurisdiction from the hospital to allow the central IRB to be the IRB of record on this study.

The investigator would:

- Revise the 1572
- The consent would be revised to include the hospital (IRB would approve)
- The subject would be re-consented; and
- All IRB requirements for approving a site where a research procedure is taking place will be met.

The question is would it be possible for the subject to continuing in the study even though he/she was withdrawn (as noted on the source documentation - yet still in the IVRS) and one of the [Redacted] was done at a facility that at the time was not listed on the 1572 and not IRB approved (also not listed on the consent)?

Please feel free to call for any clarification of this situation. I appreciate your time in this matter.

Thank you,
[Redacted]