From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, October 26, 2005 9:38 AM
To: [purged]
Subject: RE: FDA 1572

Dear [purged]:

The sponsor is supposed to obtain a signed and completed 1572 before permitting an investigator to begin participation in an investigation [see 21 CFR 312.53(c)]. A 1572 should be completed for each study that an investigator is involved in (i.e., the form is study-specific). So, if an investigator has completed a 1572 for protocol "A", and then the same sponsor wants the investigator to also participate in protocol "B", the sponsor must obtain a new 1572 for protocol "B".

The 1572 has two purposes: 1) to provide the sponsor with information about the clinical site and investigator qualifications that will enable the sponsor to establish and document that the investigator is qualified and the site is an appropriate location at which to conduct the study, and 2) to inform the investigator of his/her obligations and obtain the investigator's commitment to follow pertinent FDA regulations (for the study identified in Block #7). The purpose of reporting the title of the protocol and protocol number is to ensure that the study can be correctly identified and that the investigator knows which protocol he/she is supposed to follow.

While a title change for a protocol may not seem like a major change, it may raise other questions:

Is this the same or a different study?
Why was the name changed?
Was it done to correct a typographical error, or for some other reason?
Did the dosage of the study drug change?
Has there been a change in the study's design?
Did the site receive [and follow] the correct study protocol? (etc.)

The sponsor of a study should have appropriate procedures for identifying a protocol, for amending the protocol, and for numbering subsequent versions to ensure that investigators involved in the study can readily identify the most up-to-date version. [If a site has any questions about the protocol that has been provided, they should be raised with the sponsor.]

Having said all of this, I'm not sure you are asking a simple "yes" or "no"

question. Because obtaining a 1572 after the study is over is not in compliance with the regulations, the sites/sponsor might want to document what occurred, along with any steps/corrective actions that are being taken to prevent this from happening in the future.

I hope this answers your question.

Sincerely,
Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
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-----Original Message-----
From: [purged]
Sent: Tuesday, October 25, 2005 2:15 AM
To: Hommel, Carolyn - OC
Subject: FDA 1572

Dear Carolyn,

I got this e-mail from one of my colleagues. Can you advise me on this?

Thanks

[purged]

While finalising all my COV reports I always came across the fact that for most of the close out sites the 1572 forms are not updated with regards to the protocol title change.

My question to you is: Is it necessary to get back to the sites and ask them

to have different 1572 forms completed retrospectively for all the different protocol titles?

Yes or

No

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