From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, October 25, 2005 4:58 PM
To: [purged]
Subject: RE: 1572 question

Dear Ms. [purged]:

An IND can have many different studies/study protocols affiliated with it. The purpose of reporting the title of the protocol and protocol number is to ensure that the study can be identified and that each investigator knows which protocol he/she is supposed to follow.

A 1572 is study-specific. The sponsor is required to obtain a signed 1572 before permitting an investigator to begin participation in an investigation.

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).

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 you receive the correct study protocol? (etc.)

The sponsor of a study should have appropriate procedures for identifying a protocol and 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 you have any questions about the protocol that has been provided, you should raise them with the sponsor.

I hope this answers your question.

Sincerely,
Carolyn Hommel

Consumer Safety Officer
Good Clinical Practice Program
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Office of the Commissioner
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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: [purged]
Sent: Tuesday, October 25, 2005 10:19 AM
To: OC GCP Questions
Subject: Re: 1572 question

What if the title of the protocol changes with the amendment, but the IND number remains the same, does a new 1572 need to be submitted?

OC GCP Questions <GCPQuestions@OC.FDA.GOV> wrote:
Dear Ms. [purged]:

Your e-mail questions submitted on the "DrugInfo Comment Form" were forwarded to me for a response.

You asked if a new 1572 must be completed when a protocol is amended. No; the clinical investigator does not have to "update" the 1572 that he/she previously submitted to the sponsor just to indicate the amendment number for the study protocol.

As you probably know, the sponsor is required to file an amendment to the

IND under 312.30 when certain changes are made, including changes in a protocol (that would significantly affect the safety of subjects, the scope of the investigation, or the scientific quality of the study (21 CFR 312.30(b)), or the addition of a new investigator (21 CFR 312.30(c)). If a new investigator is added, then the sponsor should secure a 1572 from the new investigator. But investigators who have already signed a 1572 for the study do not have to submit a new "updated 1572" every time a protocol is amended.

So, when must a 1572 be updated and signed by the investigator to reflect new or changed information?

If there are changes to information contained on the 1572 (e.g., an IRB address change, the addition of new subinvestigators, discontinuing the use of a clinical lab), the investigator should document the changes and inform the sponsor, so that the sponsor can appropriately update the IND. The 1572 itself does not need to be revised and signed by the investigator.

I hope this is helpful.

Sincerely,

Carolyn Hommel
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-----Original Message-----

From: CDER DRUGINFO
Sent: Sunday, October 23, 2005 12:56 AM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: diane.bolognone@sbcglobal.net [mailto:diane.bolognone@sbcglobal.net]
Sent: Friday, October 21, 2005 11:04 AM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: Please clarify requirements for completing box # 7 on the Form FDA 1572. Do protocol amendments require a new 1572 be completed. Can the protocol #, title, and Amendment # be entered in this box for ease of recognition of why 1572 is updated?