From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, July 28, 2005 7:33 AM
To: [purged]
Subject: RE: DrugInfo Comment Form FDA/CDER Site - Further Inquiry

Dear Ms. [purged]:

The regulations do not prescribe a date by which the 1572 must be collected.

Bear in mind, however, that the purpose of the form is to assist the sponsor in selecting "only investigators qualified by training and experience as appropriate experts to investigate the drug" (see 21 CFR 312.53(a)) and the form is to be accompanied by the investigator's curriculum vitae (21 CFR 312.53(c)(2)). Presumably the sponsor would need some time to review the investigator's qualifications before the sponsor ships the investigational drug to the investigator (21 CFR 312.53(b)).

I hope this is helpful.

Sincerely,
Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857
Phone: 301/827-3340
Fax: 301/827-1169
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.
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-----Original Message-----
From: [purged]
Sent: Wednesday, July 27, 2005 10:10 AM
To: OC GCP Questions
Subject: RE: DrugInfo Comment Form FDA/CDER Site - Further Inquiry

Dear Ms Hommel,

Thank you for the comprehensive response. If I may just ask further - is there a prescribed date or duration (e.g. 1month before study start) upon which the declaration must be collected in reference to the study start?

Many thanks once again.

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

Your e-mail to CDER DRUGINFO was forwarded to me for a response.

You asked if it was "sufficient" to collect the 1572 and financial disclosure information "prior to study initiation/start". The answer to your question is "yes".

Under 21 CFR 312.53(c)(1), the sponsor is required "...[b]efore permitting an investigator to begin participation in an investigation..." to obtain a signed 1572. Under 21 CFR 312.53(c)(4), the sponsor also has to obtain from each investigator "...[s]ufficient accurate financial information to allow the sponsor to submit complete and accurate certification or disclosure statements required under part 54 [Financial Disclosure by Clinical Investigators] of this chapter."

As for updating the information, the regulation states, "...The investigator shall PROMPTLY update this information if any relevant changes occur in the course of the investigation or for 1 year following completion of the study." [Emphasis added; see 21 CFR 54.4(b).]

Bear in mind that FDA's financial disclosure regulations do not prohibit any financial interests; the regulations simply require that interests of certain types be disclosed or if the financial interests reach certain monetary thresholds.

FDA developed a guidance document, "Financial Disclosure by Clinical Investigators," that may be helpful to you. It can be viewed on FDA's good clinical practice website (http://www.fda.gov/oc/gcp); once at the site, click on "Guidances and Information Sheets, and scroll down the list. Here

also is a direct link to the financial disclosure guidance document: http://www.fda.gov/oc/guidance/financialdis.html . There is also a link to FDA's financial disclosure and other regulations related to clinical trials.

I hope this is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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-----Original Message-----
From: CDER DRUGINFO
Sent: Tuesday, July 19, 2005 10:00 AM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [purged]
Sent: Tuesday, July 19, 2005 5:00 AM
To: druginfo@cder.fda.gov

Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: INQUIRY on FDA1572 and Financial Disclosure Forms for submitted under IND status

Dear Sir/Madam:

I would like to inquire whether there is a required timeframe for collection of FDA 1572 and financial disclosures from Investigators and Sub-investigators prior to site initiation.

Documents signed and collected prior to study initiation/start - would this be sufficient assuming that there is no update on the initially completed documents.

Thank you very much.

Sincerely,
[purged]

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