From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, October 02, 2003 11:24 AM
To: [redacted]
Cc: CDER DRUGINFO
Subject: RE: FDA Comments

Dear [redacted]:

Your questions on whether original 1572s, CVs, and financial disclosure forms need to be submitted to FDA was forwarded to me for a response.

The 1572 itself is not required to be submitted to FDA, although some of the information contained in the form must be submitted. In practice, sponsors commonly submit the 1572 to the IND as an efficient means to provide the information required under 21 CFR 312.23(a)(6)(iii)(b):

(b) The name and address and a statement of the qualifications (curriculum vitae or other statement of qualifications) of each investigator, and the name of each subinvestigator (e.g., research fellow, resident) working under the supervision of the investigator; the name and address of the research facilities to be used; and the name and address of each reviewing Institutional Review Board.

The purpose of submitting the CV or other statement of qualifications of the clinical investigator with the protocol is to assist the sponsor in determining and documenting that selected investigators are "qualified by training and experience as appropriate experts to investigate the drug." [See 21 CFR 312.52(a).]

With respect to financial disclosure forms, the sponsor is required to submit to FDA either a certification attesting to the absence of disclosable financial interests and arrangements, using Form 3454, or a disclosure statement describing the disclosable financial interests and arrangements, using Form 3455. Since these forms must be signed and dated by the chief financial officer or other responsible corporate official or representative of the applicant, it would make sense to submit the originals of the financial disclosure forms. [See 21 CFR 54.4(a)(1)].

FDA issued guidance on financial disclosure in March 2001. You may view the guidance on FDA's website at the following URL:
http://www.fda.gov/oc/guidance/financialdis.html

Also, you may access all of FDA's regulations pertaining to clinical investigations by visiting FDA's website at http://www.fda.gov/oc/gcp . Under the center column heading, "Regulations," click on "Good Clinical Practice/Clinical Trials Regulations".

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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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: Wednesday, October 01, 2003 9:02 AM
To: druginfo@cder.fda.gov
Subject: FDA Comments

Name: [redacted]

E-Mail: [redacted]

Comments: Please can I obtain clarification on the FDA 1572 form and related documents with regard to an IND submission:
Are the original or copies of the FDA 1572 forms required for the submission.
Is the original or copies of Investigator signed CV required to be submitted and are the CV's of all the Co-investigators also required.
Please confirm also if the financial disclosure forms for the investigator and the co-investigators are required (also confirm if these should be copies or originals).

Thank you