From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, May 17, 2006 5:17 PM
To: **[Redacted]**
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. **[Redacted]**:

It certainly would be in keeping with Good Clinical Practice to sign any addenda related to the form, but there is no specific regulatory requirement to do so. You might also consider making sure any addenda are stapled to the form, so that it is clear which 1572 a particular page pertains to.

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 14-B17
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.

-----Original Message-----
From: **[Redacted]**
Sent: Wednesday, May 17, 2006 4:49 PM
To: OC GCP Questions
Cc: CDER DRUG INFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site
Importance: High

I was asking about an attached addendum (i.e when too much ifnormation too much information to fit into designated box) to the 1572. Does that need to be signed?

-----Original Message-----
From: Hommel, Carolyn - OC [mailto:carolyn.hommel@fda.hhs.gov] On Behalf Of OC GCP Questions
Sent: Wednesday, May 17, 2006 4:46 PM
To: **[Redacted]**
Cc: CDER DRUG INFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. **[Redacted]**:

Your inquiry was forwarded to my office for a response. You asked if an investigator is required to sign and date a new 1572 just to add a

laboratory.

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
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 14-B17
Rockville, MD 20857

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-----Original Message-----
From: **[Redacted]**

Sent: Thursday, May 11, 2006 2:45 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: **[Redacted]**

E-Mail: **[Redacted]**

Comments: Is it a requirement or preference of the FDA to have addendums to the FDA Form 1572 be signed/dated by the Investigator. I am inquiring because we have an unsigned/dated addendum where the site added a laboratory. I am under the assumption the addendum would need to be signed/dated or else anyone can do an addendum without having to update or re-do a 1572. i.e. for addition of sub-investigators. Can you please provide me your guidelines/preferences?

Thanks
[Redacted]