MessageFrom: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, August 02, 2005 2:50 PM
To: [purged]
Subject: RE: Form FDA 1572s

Dear [purged]:

The sponsor is only required to submit the information on the 1572s to FDA, basically to ensure that the IND is kept up to date.

The example you gave, to correct a misspelling, didn't seem particularly egregious to me, such that it would be a problem during an FDA inspection. The procedure you describe, of retaining all 1572s (correct and incorrect) would be in keeping with GCP, particularly if the procedure is spelled out in your SOPs.

Carolyn

-----Original Message-----
From: [purged]
Sent: Tuesday, August 02, 2005 2:12 PM
To: OC GCP Questions
Subject: RE: Form FDA 1572s

Sure and I apologize, I wasn't sure to which address I should send it to.

I understand we should follow the sponsor's SOPs but they don't go into such detail and the sponsor wants to be compliant if there was an FDA audit.

I was hoping that you could advise that if the sites' files contained all of the 1572s throughout the duration of the study (correct and incorrect ones) and the sponsor only submits the correct ones to the FDA, will that be acceptable to the FDA so essentially what the site has will not match what was submitted.

Thanks,
[purged]

-----Original Message-----
From: Hommel, Carolyn - OC [mailto:Carolyn.Hommel@OC.FDA.GOV]On Behalf Of OC GCP Questions
Sent: Tuesday, August 02, 2005 1:55 PM

To: [purged]
Subject: RE: Form FDA 1572s

Dear [purged]:

By the way, in the future, could you send your questions either to DRUGINFO OR to GCPQuestions, but not to both places? We are very short staffed, and it's a drain on resources for different people to spend time researching the same question submitted to more than one place.

Thank you.
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.

-----Original Message-----
From: CDER DRUGINFO
Sent: Thursday, July 28, 2005 12:48 PM
To: OC GCP Questions
Subject: FW: Form FDA 1572s

Hello-

Would you please repond to the following question?

Thanks

DrugInfo - RC

-----Original Message-----
From: [purged]
Sent: Tuesday, July 26, 2005 2:12 PM
To: DRUGINFO@cder.fda.gov
Subject: Form FDA 1572s

Good afternoon,
I was hoping that you could advise on the following:
If a site generates a Form FDA 1572 that is unacceptable due to a misspelling for example, can the site keep this incorrect form in the regulatory binder or does it have to be destroyed?
The sponsor thought if it was retained in the regulatory binder it would raise a red flag in an audit since the unacceptable versions are not submitted to the FDA.
Thank you for your help.
Kind regards,
[purged]
Effective 28 May 2004, my new contact information will be:
_____
[purged]
_____

"Secure Server" made the following
annotations on 07/26/2005 02:12:14 PM
----------"This e-mail, including attachments, may include confidential and/or proprietary information, and may be used only by the person or entity to which it is addressed. If the reader of this e-mail is not the intended recipient or his or her authorized agent, the reader is hereby notified that any dissemination, distribution or copying of this e-mail is prohibited. If you have received this e-mail in error, please notify the sender by replying to this message and delete this e-mail immediately."
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