FW: Form FDA 1572sFrom: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, August 02, 2005 1:38 PM
To: [purged]
Subject: RE: Form FDA 1572s

Dear [purged]:

The Form FDA-1572 is supposed to be provided to the sponsor. I would suggest that you follow the sponsor's SOPs with respect to handling and filing these forms.

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
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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, July 26, 2005 2:15 PM
To: GCPQuestions@OC.FDA.GOV
Subject: FW: 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 01:16:09 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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