From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, October 14, 2005 4:51 PM
To: [purged]
Subject: RE: Form FDA 1572

Dear Ms. [purged]:

Your question about the Form FDA 1572 (1572) was forwarded to me for a response. You asked where the original form should be stored.

FDA's regulations at 21 CFR 312.53 state, "Before permitting an investigator to begin participation in an investigation, the sponsor shall obtain the following: (1) a signed investigator statement (Form FDA-1572)..." While the regulations do not specifically state where the 1572 should be stored, I would interpret this to mean that the original, signed form should be provided to the sponsor, and a copy maintained at the study site.

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: Thursday, October 13, 2005 4:49 PM
To: gcpquestions@oc.fda.gov
Subject: Form FDA 1572

To whom it may concern:

Where should the original signed 1572 (or any updated original signature 1572) be kept? In the Investigator Regulatory Document Binder at the study site or at the sponsor in the Trial Master File?

Thanks.

[purged]