From: Breen Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, March 29, 2005 10:02 AM
To: [pagerd]
Subject: RE: Drugfoto Comment Form FDA/CDER Site

Dear [pagerd],

Your inquiry was forwarded to our office for a direct reply. It is a good idea to keep a copy of the signed 1572 form somewhere in your study records although the regulations do not state/mandate where this copy could be retained. In the ICH E6 Good Clinical Practice Consolidated Guidance (see http://www.fda.gov/cder/guidance/959fbst.pdf), section 8.2.6 notes that copies of signed agreements between involved parties (e.g., the investigator/institution and the sponsor) should be retained by the investigator or the institution/study site. Copies of clinical records (like the 1572) can be retained at the study site in any number of ways; where/how the copy is retained is a matter of site preference. For example, the copy could be retained in files that contain only study specific records, or as you note, in a binder that is kept with the pharmacist that contains all of the protocols/protocol amendments. (The original 1572 form must be signed by the clinical investigator and provided to the sponsor. The sponsor is expected to preserve the original 1572 form.)

I hope this information is helpful to you.

Sincerely,

Patricia M. Breen Block
Special Assistant to the Director
Good Clinical Practice Programs
OHRC/Office of the Commissioner
301-827-3340

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: Friday, March 25, 2005 1:50 AM
To: OC GCP Questions
Subject: FW: Drugfoto Comment Form FDA/CDER Site

-----Original Message-----
From: [pagerd]
Sent: Thursday, March 24, 2005 2:41 PM
To: druginfo@cder.fda.gov
Subject: Drugfoto Comment Form FDA/CDER Site

Name: [pagerd]

E-Mail: [pagerd]

Comments: Good afternoon.
As an Investigational Drug Pharmacist [pagerd],I'm taking care of clinical research protocols. Do I need to keep a copy of the 1572 form in Pharmacy binder. Is this FDA or JACHO requirement?
thank you very much for your attention

Sincerely,
[pagerd]