From: OC GCP Questions
To: [redacted]
Subject: Draft or unused versions of 1572s in Investigator Site File
Date: Thursday, October 08, 2015 6:19:03 AM

Good morning ---

Please see the guidance document (below) on the 1572 form.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

The sponsor should obtain the original signed document for the 1572. Per the instructions on the 1572 form, the clinical investigator is instructed to:

5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

All study documents should be kept until the study has been completed per the sponsor's instructions. If an inspection occurs during an on-going clinical study the FDA investigator will compare the source (original) data with the information on the site's completed case report forms.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Wednesday, October 07, 2015 1:49 PM
To: OC GCP Questions
Subject: Draft or unused versions of 1572s in Investigator Site File

To Whom It May Concern,

If a site completes a 1572, that is fully signed, but then makes an update to staffing and revises the 1572, does the first 1572 have to be discarded?

Is there a guidance on draft 1572s being maintained in the investigator site files?

Warm Regards,
[redacted]