From: OC GCP Questions
To: [redacted]
Subject: FDA 1572 Form - Original Signed Copies
Date: Tuesday, April 07, 2015 12:31:43 PM

Good afternoon –

The Form FDA 1572 (the 1572), while an official FDA form, is meant to provide full information about a study site to the study sponsor and to serve as a commitment to compliance with the investigational plan and pertinent regulations by the clinical investigator signing it. There is no requirement that the form be submitted to FDA, though most study sponsors do so, as it is a quick way to provide much of the information required for an IND. As an official agreement between the clinical investigator and the sponsor, as with most such agreements, the sponsor should keep the original form since once signed it represents a contract between the clinical investigator and the sponsor to adhere to the investigational plan and pertinent regulations.

You might find FDA's 1572 form guidance helpful. Please see the link below.
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pd f

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.

Additionally, if it is decided to have a certified copy substitute for the original, it would be desirable to have a "standard operating procedure" (SOP) describing how such copies would be made, verified, and documented. The person who certifies the copy as an accurate and complete representation of the original, having all of the same attributes and information should be the same person who actually made the copy from the original. Certification should be accomplished by having the person who makes the copy, sign or initial and date the copy to indicate it meets the requirements of a certified copy as described above. This should be described in the SOP and can be accomplished by initialing and dating each copy or by initialing and dating a document certifying copies in bulk. Whichever method is used the SOP should describe the procedure. (There are many ways to accomplish this, and the procedures described above are only suggested examples.)

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

Kind regards,

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

From: [redacted]
Sent: Monday, April 06, 2015 7:15 PM
To: OC GCP Questions
Subject: FDA 1572 Form - Original Signed Copies

It is my understanding that a research site should retain the original signed (wet ink) copy of an FDA 1572 form. However, the wet ink copy can be sent to a trial sponsor if the site retains a certified copy. How does a research site certify a copy of an FDA 1572 form?