From: OC GCP Questions
To: [redacted]
Subject: Requirement of original document from Investigator Site
Date: Tuesday, May 27, 2014 1:32:55 PM

Good afternoon --

I received the following information from the Center for Drugs (CDER). They receive the IND applications.

FDA requires the original "ink on paper" handwritten signature be submitted for paper submissions. However, submitting exact reproductions of the original "ink on paper" handwritten signature is also acceptable. The sponsor needs to retain the original signed signature for inspection/audit purposes. This is also applicable to NDAs, ANDAs, supplements, annual reports, and forms.

Kind regards,

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

From: [Redacted]
Sent: Monday, May 26, 2014 8:59 AM
To: OC GCP Questions
Subject: Requirement of original document from Investigator Site

Dear Sir/Madam,
Kindly let me know if FDA recommends to collect the original documents (1572, FDF etc) from Investigator's site, leaving the photocopy for investigator file OR a scan copy would be sufficient for Trial Master at Sponsor/CRO. Thanks in advance for your response.
Regards,
[Redacted]