From: OC GCP Questions
To: [redacted]
Subject: Original documents for IND submission
Date: Tuesday, May 20, 2014 9:04:12 AM

Good morning –

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: [redactedo
Sent: Thursday, May 15, 2014 2:40 PM
To: OC GCP Questions
Subject: Original documents for IND submission

Which documents are “required” to be submitted as part of the IND application to the FDA with original ink signatures? Do you require original ink signatures for 1572’s, Financial Disclosure’s, protocol signature pages, etc. or can those be maintained at the investigator sites, with copies provided to the sponsor for the TMF?