From: OC GCP Questions
To: [redacted]
Subject: 1572 requirements and guidelines
Date: Thursday, January 23, 2014 10:38:12 AM

Good morning,

There is no need to provide an updated 1572 when a new version of the form becomes available. Replace the original signed 1572 need not be revised unless a different clinical investigator is to take over the site, which would require a new commitment to the study via his/her signature on a new form. The study sponsor should be advised of any other changes to the information captured on the form that occur during the course of the study and the sponsor will update FDA in their next progress report for the study.

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: Wednesday, January 22, 2014 1:23 PM
To: OC GCP Questions
Cc: [Redacted]
Subject: 1572 requirements and guidelines

Dear FDA:
I am principal investigator on several clinical drug studies and have been asked by our regulatory people to sign new 1572 forms for three of our studies. I checked the FDA 1572 FAQ webpage:

Information Sheet Guidance
For Sponsors, Clinical Investigators, and IRBs[1]
Frequently Asked Questions
Statement of Investigator (Form FDA 1572)

and noted in section 7 that there are only two instances when it would be necessary for me to sign a new 1572 (when a new protocol or new investigator has been added) and these instances do not apply to any of the three studies for which I am being asked to sign new 1572 forms.

My question is whether I need to sign new 1572 forms for these studies since the FDA has updated the 1572 form since the original forms were signed in 2009-2010. In addition the name of our organization has changed since the original forms were signed. I want to be sure I am following the current guidelines on this before signing.

Thank you for your help with this.

[Redated]