From: OC GCP Questions
To: [redacted]
Subject: FDA Warning Letter Issued to a Clinical Investigator in France
Date: Monday, August 10, 2015 12:27:17 PM

Good morning –

This answer (below) is from CDER's Office of Scientific Investigations (OSI). If you have additional questions related to your inquiry, you may email OSI directly at CDEROSIPMTrack@fda.hhs.gov.

Kind regards,

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

Hi all,

See below for OSI's response to this inquiry.

As you know, a sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND regulations must be met, including the requirement to obtain a signed Form FDA 1572 (1572). Signing the 1572 constitutes the clinical investigator's commitment to conduct the clinical studies in compliance with FDA regulations, including applicable provisions in 21 CFR parts 50, 56, and 312. As such, violation(s) of FDA regulations may result in the issuance of a warning letter, and may result in regulatory action against a foreign clinical investigator.

If a clinical study is conducted outside of the U.S. and is not conducted under an IND, then a clinical investigator is not required to sign a 1572. However, the sponsor must ensure that the study complies with 21 CFR 312.120 if the sponsor intends to submit the study to FDA. In such cases, it is unlikely that FDA would issue a warning letter to the clinical investigator.

From: [redacted]
Sent: Thursday, July 23, 2015 4:18 PM
To: OC GCP Questions
Subject: FDA Warning Letter Issued to a Clinical Investigator in France

Hello GCP Questions Group,

The FDA has recently issued a warning letter to a clinical investigator in France. Can the

FDA take regulatory action against a foreign clinical investigator?

- Is it correct that in order to issue a warning letter to a foreign clinical investigator, the trial must have been conducted under an IND and a Form 1572 signed by the clinical investigator?
- Would it be possible to issue a warning letter in case the trial has not been conducted under an IND and a Form 1572 not signed?
- The warning letter states that: Failure to address the violations noted above adequately and promptly may result in regulatory action without further notice.

Kind regards,

[redacted]