From: OC GCP Questions
To: [redacted]
Subject: reporting obligations for non-clinical investigation noncompliance
Date: Thursday, March 30, 2017 7:42:00 AM
Attachments: [redacted]

Good morning –

21 CFR 56.108(2) states any instance of serious or continued non-compliance with the regulations or the requirements determinations by the IRB should be reported. 56.108(1) states unanticipated problems involving risk to subjects. Noncompliance can cause possible risk to subjects.

Per regulatory requirements as outlined in sections of 21 CFR Part 56 (Institutional Review Boards) and 21 CFR 56.108(b) requires that the IRB follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration of:

1. Any unanticipated problems involving risks to human subjects or others;

2. Any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or

3. Any suspension or termination of IRB approval.

(Assuming it is a clinical investigation for an FDA regulated study).

The sponsor of the study also has a responsibility to ensure that the clinical investigator conducts the study in compliance with the applicable regulations. Prior to shipping the study drug to the investigator, the study sponsor is required to obtain the investigator's commitment "to comply with all requirements regarding the obligations of clinical investigators and all other pertinent requirements," including those pertaining to IRB review of his study. See 21 CFR 312.53(c)(1)(vi)(b) and (vii).

Please also note that if a study is exempt from IND/IDE requirements, CFR parts 50/56 still apply.

Additionally, below is the link to a page on FDA web site with instructions of how to report problems to FDA:

www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ReportProblemstoFDA/default.htm

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Wednesday, March 29, 2017 12:41 PM
To: OC GCP Questions
Subject: reporting obligations for non-clinical investigation noncompliance

Good morning,

I am writing to verify that only studies that meet the definition of a *clinical investigation* [of a drug, biologic, device, and whether with an IND/Exempt from IND, and whether with an IDE/Exempt from IDE] would have reporting obligations to the FDA when a (serious/continuing) noncompliance occurs?

If so, please provide the specific regulation citation.

Thank you for the clarification.

Best regards,

[redacted]