From: OC GCP Questions
To: [redacted]
Subject: Safety reporting notification
Date: Friday, July 10, 2015 12:03:54 PM

Good morning --

You could potentially be cited for not following your standard operating procedure and protocol requirements for reporting SAEs should a FDA inspection occur at your site. Additionally there are no regulatory requirements as to how SAEs should be reported.

Please see the web link below. There are useful links to adverse event reporting.

Investigational New Drug (IND) Application > Final Rule: Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans

If I have not adequately answered your question, you may consult the Office of Medical Policy at CDEROMP@fda.hhs.gov as they are the experts on AE reporting and developed the FDA guidances.

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, July 08, 2015 3:47 PM
To: OC GCP Questions
Subject: Safety reporting notification

Hello OC GCP,

We would like your guidance on a hypothetical issue we have been discussing recently regarding safety notifications.

As a CRO responsible for SAE processing are we liable for a site not following the instructions on submitting the SAE report? These instructions are generally included in both the protocol and the SAE completion guidelines.

The scenario we have been discussing is that the instructions may instruct the site staff to send a faxed copy of the report to the safety email address provided within 24 hrs of being notified of the event yet the site mistakenly sends the report to the trial site manager. A potential problem may occur when the trial site manager is on vacation and is not monitoring his email during vacation. We are wondering if we would be liable for the site's error? The problem would be most critical if the event was reportable and it caused a delay in notification.

Can you offer any guidance on this issue?

Also, we would like to confirm that there is no regulatory requirement that specifies how a site must submit an SAE report (i.e. fax, email, phone)?

Thanks for your assistance!

Take care,
[redacted]