From: OC GCP Questions
To: [redacted]
Subject: Requirement to notify deviations to IRB/Local regulatory agency
Date: Friday, January 17, 2014 9:58:45 AM

Good morning –

In the ICH -6 Guidance on Good Clinical Practice you can read and review how non-compliance can be discovered and handled throughout this guidance in investigator responsibilities, auditing, and specifically non-compliance in section 5.20.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

It appears that not using the proper investigational product would be considered non-compliance and should be reported to the reviewing EC and the sponsor.

Kind regards,

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

From: [Redacted]
Sent: Thursday, January 16, 2014 8:48 PM
To: OC GCP Questions
Subject: Requirement to notify deviations to IRB/Local regulatory agency

Dear GCP Team:
Probably I haven't ask questions this year, therefore first at all best wishes for this new year.

Basically, I would like to ask you the international regulation under we should be based to request sites to ensure deviations regarding misuse of study supplies to be reported to both IRB and local regulatory agency.

Case: Site used in one study a commercial product that belongs to another study for the indication, etc, etc but this marketed product was exclusively brought for another study.

Regards

[Redacted]