From: OC GCP Questions
To: [redacted]
Subject: Breaking the Double Blind Study due to fatal SAE
Date: Friday, March 20, 2015 9:24:16 AM

Good morning –

I cannot specifically answer your question since all studies are different. However below is general information regarding monitoring and blinding.

Generally, the study site monitor does not need to be aware of study arm assignments in order to fulfill site monitoring responsibilities. Although the site monitor does not have a role in study outcome assessment, he/she will be interacting with the site staff. There is the potential that information may unintentionally be revealed that could break the blind for study staff. In order to avoid such a possibility, individuals whose roles do not require knowledge of study arm assignments should be kept blinded. If a monitor discovers findings where unblinding may be needed, he/she should contact the sponsor who would determine how to proceed with those findings while maintaining the study's integrity.

The ICH E-6 Good Clinical Practice Consolidated Guidance, an FDA official guidance, addresses Randomization Procedures and Unblinding in Section 4.7

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

4.7 Randomization Procedures and Unblinding

The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product(s).

You may also want to ask the Center for Drugs (CDER) at druginfo@fda.hhs.gov

I hope this information is helpful. Please contact us again at gcp.question@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Wednesday, March 18, 2015 5:18 PM
To: OC GCP Questions
Subject: Breaking the Double Blind Study due to fatal SAE

Hi- Could you please help me in determing what steps to take in breaking a double blind study due to a fatal SAE? I am writing SOP on this subject and would appreciate any help. Thanks so

much!