**From:** OC GCP Questions
**To:** [redacted].
**Subject:** inadvertent unblinding
**Date:** Thursday, January 26, 2017 6:57:00 AM
**Attachments:** [redacted]

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Good morning –

Below is general information regarding monitoring and blinding. Accidental unblinding can compromise the integrity of the study

Generally, the study site monitor and CROs does not need to be aware of study arm assignments in order to fulfill site monitoring responsibilities Although the site monitor and or CRO 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)

If the study is FDA-regulated, you can report the accidental blinding to FDA regulatory project manager of the IND. If you or the sponsor do discuss the situation with FDA, it is best to document all that discussed to ensure the integrity of the study data.

Kind regards,

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**From:** [redacted]
**Sent:** Wednesday, January 25, 2017 8:58 AM
**To:** gcp.questions@fda.gov; OC GCP Questions
**Subject:** inadvertent unblinding

What would be your suggestion for handling of an inadvertent incident which provided information to a CRC who was suppose to be blinded! Besides informing the Sponsor of course.