From: OC GCP Questions
To: [redacted]
Subject: Data entry question
Date: Thursday, December 03, 2015 6:49:50 AM

Good morning –

I am unaware of any FDA regulation that directly addresses unblinding or blinding. Of course, study sponsors do have a regulatory responsibility to ensure study monitoring (including safety monitoring) and to ensure that bias is minimized. So, this suggests a role for the sponsor in protocol design and implementation to address the issue.

Please see the link below for ICH E-6 -Guideline for Good Clinical Practice.
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

Section 4.7 specifically addresses unblinding. See below

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).

Blinding is usually addressed in the study's investigational plan/protocol. Sponsors use blinding as a means to minimize bias in a study therefore you should ask the sponsor if they approve of the scenario you describe in your email related to blinding and unblinding.

Kind regards,

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

From: [redacted]
Sent: Wednesday, December 02, 2015 1:41 PM
To: OC GCP Questions
Subject: Data entry question

We are conducting a study that involves the need for an unblinded pharmacist to prepare the drug. A study coordinator will be acting as the unblinded pharmacist and would like to know if that same unblinded coordinator could enter data into the eCRF if the data entry is directly from source. The source is completed and signed & dated by a blinded coordinator .

Thank you!
[redacted]