From: OC GCP Questions
To: [redacted]
Subject: Entering Data
Date: Wednesday, December 13, 2017 11:23:00 AM
Attachments: [redacted]

Good morning --

FDA has not provided specific guidance on your question. While an industry sponsor can employee monitors/CRAs for their own studies, such individuals are usually in departments that are independent from those that are responsible for the conduct of the study. We therefore recommend that the CRA not be someone who is participating in the conduct of the study. In the case you describe entering data at. You would want to avoid any appearance of conflict of interest as the conflict may lead to intentional or unintentional bias or errors in the clinical trial and may compromise the well-being of the human research subjects. FDA would also recommend that the sponsor have a specific SOP/policy that addresses this issue.

You should check with your local and national laws and policies to see if there are any requirements related to conflict of interest and clinical trials. The U.S. has regulations related to federally funded studies and ensuring objectivity ("Responsibility of Applicants for Promoting Objectivity in Research for which Funding is Sought" and "Responsible Prospective Contractors" available at www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf).

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Monday, December 11, 2017 9:03 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Entering Data

Hello,

If the sponsor would like to assist a site in entering data, what practices should be implemented to maintain GCP? I was thinking the person entering data on the sponsor side should sign a form that says they attest that all data entered is reflective of the subject medical records, then the site should sign a form attesting they checked the EDC and confirm that the data entered is correct. Then, the person monitoring the data from the sponsor cannot be the same person who entered the data.

Thank you for your guidance!

[redacted]