From: OC GCP Questions
To: [redacted]
Subject: Monitor assistance with completing study tracking logs
Date: Friday, May 02, 2014 12:25:21 PM

Good afternoon --

I am unclear as to what was discussed during this conference as I did not attend. However, nothing in what you list seems problematic. We have often talked about issues with "prefilling" fields but what you describe appears not to be a problem.

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

Kind regards,

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

From: [redacted]
Sent: Friday, May 02, 2014 9:59 AM
To: OC GCP Questions
Subject: RE: Monitor assistance with completing study tracking logs

I understand a BIMO representative addressed this issue recently at the ACRP conference in San Antonio and I think there is ongoing confusion.

1) Sponsors create generic logs of various types for sites to use to both enter study data and track/collection of information in one place. An example of the latter might be a log to track ancillary study materials; binders, (Non IP) materials used during the trial etc. These items may vary by site and the generic log might not capture all the information that would allow the site to best capture/track it. Therefore with Sponsor & Monitor assistance the logs are modified to improve the way the information is collected (columns are added/rearranged etc). While the monitor does not enter data on the log, they may add a column or enter a description of an item that will be received so it is consistent from site to site. I do not believe FDA finds this practice objectionable as it is designed to improve the quality of information tracked.
2) Some logs specifically have a column for Monitors to check that they have confirmed the data by entering the corresponding number they found in the source. I do not believe FDA finds this practice objectionable either however if the blanket statement is made that "monitors may never enter anything on study logs" then this is confusing.
3) In order to avoid protocol deviations, a monitor will often "prepopulate" a study log with info to ensure nothing is missed. This is not "data" but rather identifiers; i.e. the monitor might enter the name of every staff person required to be trained on a protocol specific method on the training log as a reminder to the trainer. The trainer then fills in the date of training, signs

that it was completed etc. Again, if the blanket statement is made that only the site may enter data on logs then the training log used in this manner is obsolete.

Could you please comment on the above.
Thank you