From: OC GCP Questions
To: [redacted]
Subject: Monitor assistance with completing study tracking logs
Date: Monday, April 14, 2014 2:00:28 PM

Good afternoon –

I believe FDA would expect the monitor of a study to be as independent as possible. However "tracking logs" are not specifically addressed in FDA regulations. If the monitor is going to assist with completing the tracking logs, the site should develop standard operating procedures that address this task in case this situation might be addressed in a FDA inspection.

It would be helpful for you to review FDA's new guidance on A Risk Based Approach to Monitoring. Please see the link below.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf

As stated above, delegation "tracking" logs are not addressed in the FDA regulations related to the conduct of clinical trials (21 CFR Part 312 for drugs and biologics and Part 812 for medical devices). Such a checklist is also not specified in the list of essential documents in the ICH good clinical practice (GCP) guidance document (ICH E6), though signature sheets are included.
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

Appropriate delegation of clinical trial responsibilities is addressed in the FDA guidance regarding clinical investigator responsibility (available at
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf
).

The guidance document states:

It is common practice for investigators to delegate certain study-related tasks to employees, colleagues, or other third parties (individuals or entities not under the direct supervision of the investigator). When tasks are delegated by an investigator, the investigator is responsible for providing adequate supervision of those to whom tasks are delegated. The investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study. The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task.

Though a delegation log or checklist is not required, it is commonly used at clinical sites to document who is assigned essential study tasks. While an FDA investigator would not routinely request to see such a log/checklist during a bioresearch monitoring (BIMO) inspection of a site, since it is not a regulatory requirement, he/she may request documentation of who performed which task during a study, particularly when regulatory noncompliance is observed. The clinical investigator is ultimately responsible for the conduct of the study. However, determining if an observed noncompliance resulted from improper delegation of a task is essential to correction of the problem, in the present study or in future studies if the study inspected is already complete. However a site chooses to document those assigned to essential study tasks, it should be updated whenever there is a change in personnel performing any of those tasks. The date on which the designation of the individual was made should be captured, but an ending date would not be necessary. Later addition of a different person for the same task would suffice. If the same study site personnel are assigned essential tasks throughout the life of the study, than no update would be required.

Again, please note when the regulations are silent sponsors, sites, and institutions are free to develop their own standard operating procedures to address a specific issue or situation as you describe in your email.

I hope this information is helpful. Please contact us again at gcp.questions@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, April 11, 2014 2:55 PM
To: OC GCP Questions
Subject: Monitor assistance with completing study tracking logs

To whom it may concern:
Recently an article appeared in a popular Journal read by many Sponsors and Study Monitors. The article was a reprint from "Good Clinical Practice: A Question & Answer Reference Guide" from [redacted] . In the article an FDA warning letter was referenced [redacted]
The article
stated that FDA cited the site ***for allowing the CRA to complete some of the required logs and then provide them to the site for review and signature*** and that FDA ***indicated that only properly delegated site staff should complete the site's required documentation and CRFs.***

The wording in the warning letter was slightly different however; it stated
that forms containing study data should not be completed by study monitors or other personnel outside of the site study
team. Only clinical investigators and appropriately delegated members of the site study team should complete forms with study data.

The Journal article and [redacted] Q&A guide raised concerns by Study Monitors; specifically, it is common practice for Monitors to prepopulate "tracking logs" with basic information to ensure accurate reporting. A good example would be a training log. The monitor prepopulates the log with the names of Study Staff and type of training they are required to complete. The Study Coordinator would complete the log with date of training, trainer, obtain signatures etc. This type of "tracking log" may be required by the study, but is does not contain "source data"; it is just used a tools for both the site and monitor to ensure the protocol is adhered to and to summarize information in an organized fashion.

Could you please confirm that FDA does not object to monitors assisting sites in this manner and that the warning letter was not addressing this practice?
Thank you in advance.
[Redacted]