From: OC GCP Questions
To: [redacted]
Subject: Ending people on delegation log
Date: Tuesday, September 05, 2017 10:17:00 AM
Attachments: [redacted]

Good morning –

Delegation 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 log 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 there. Appropriate delegation of clinical trial responsibilities is addressed in the FDA guidance regarding clinical investigator responsibility (available at 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 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 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, then no update would be required.

When the regulations are silent, sites can develop their own standard operating procedures (SOPs) for handling specific situations. If a person is listed on the log but never performed study tasks I don't think training is required. A note to file explaining why the person was not trained might be helpful.

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: Saturday, September 02, 2017 1:47 PM
To: OC GCP Questions
Subject: Ending people on delegation log

Good Afternoon,

I am curious what the rule of thumb is for the end date of staff on a delegation log that have never performed study tasks?

If they never performed tasks does training of the protocol and relevant tasks still need to be completed?

Thank you,

[redacted]