From: OC GCP Questions
To: [redacted]
Subject: Delegation Log Question
Date: Wednesday, April 18, 2018 11:17:00 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.

As far as I am aware, personnel changes to the DOA log do not have to be approved by an IRB unless it is written in the IRB SOPs. 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.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Tuesday, April 17, 2018 3:13 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Delegation Log Question

Hello,

I have a quick question for you about adding personnel to study delegation logs, related to the IRB approval of any personnel changes that occur over the life of a study. Do you have guidance about when the delegation log should be signed?

For example, we have heard each of the following statements:

- Personnel changes should be approved by the IRB prior to any changes on the delegation log itself
- Personnel changes should be submitted to the IRB before edits to the DoA log, but IRB approval does not have to be granted yet
- The DoA is the source of truth, and as long as study personnel are added in a reasonable amount of time (what is reasonable?) the DoA log can be signed before any IRB submissions/ approvals of said personnel changes

How do you like to see dates line up for any study personnel changes? Any guidance you can share would be very welcome.

Thanks!
[redacted]

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