From: OC GCP Questions
To: [redacted]
Subject: Multiple Site Delegation Logs?
Date: Thursday, July 10, 2014 9:59:36 AM

Good morning –

As you state 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 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.

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. Please also remember FDA guidance represents FDA's current thinking on a specific topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.

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

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: Wednesday, July 09, 2014 10:19 AM
To: OC GCP Questions
Subject: Multiple Site Delegation Logs?

Hello,
Although the FDA regulations do not address the subject of the Site Delegation Log (SDL) directly, the Guidance for Industry Investigator Responsibilities was very helpful. I have a few remaining questions I hope you will answer.

Within the site that I work for, the PI believes the SDL is a tool to track protocol training. However, I am hoping you can confirm that this is not the case and that the SDL should be used to track dates of study involvement as approved by the PI. Additionally, would there ever be a reason to have multiple SDLs for a single study? The guidance reads "separate lists for each study," so this leads me to believe it is not optimal. Multiple SDLs for the site have been requested to:
Track staff training on Amendments
Too much time lapse between the SIV and study launch, retraining was necessary
Keep the log tidy due to new/old staff revisions

Any insight you can provide would be greatly appreciated.

Kind regards,
[Redacted]