From: OC GCP Questions
To: [redacted]
Subject: Change of Principal Investigator
Date: Wednesday, March 29, 2017 11:55:00 AM

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).

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.

Kind regards,

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-----Original Message-----
From: [redacted]
Sent: Wednesday, March 29, 2017 9:48 AM
To: OC GCP Questions
Subject: Change of Principal Investigator

Good day. One of my sites just recently changed PI's. We have updated of the regulatory documents; however, we are not sure how to change the delegation of authority Log.

Should be have the past PI sign off on the new DOA log and start a new DOA log with the PI.

[redacted]