From: OC GCP Questions
To: [redacted]
Subject: GCP Question regarding a delegation log
Date: Monday, March 16, 2015 11:04:41 AM

Good morning --

Thank you for your question. FDA's regulations related to the conduct of clinical trials do not address site delegation logs. When the regulations are silent, investigators, sites, sponsors, institutions and IRBs have the flexibility to adopt procedures that make the most sense to them and their existing business practices, as long as applicable regulatory requirements are met.

The idea of delegation logs appears in some FDA guidance documents. For example, the ICH E6 Good Clinical Practice: Consolidated Guidance (which is recognized as official FDA guidance – see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf) states in section 4.1.5:

4.1.5 The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

The ICH E6 GCP guidance also mentions having a signature sheet on file to document signatures and initials of all persons authorized to make entries and/or corrections on CRFs (see section 8.3.24).

Another FDA guidance document titled, "Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects" (available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf), discusses a clinical investigator's responsibilities when delegating study tasks. This guidance refers back to section 4.1.5 of the ICH E6 guidance on page 3 and includes the following statement:

The investigator should maintain a list of the appropriately qualified persons to whom significant trial-related duties have been delegated. This list should also describe the delegated tasks, identify the training that individuals have received that qualifies them to perform delegated tasks (e.g., can refer to an individual's CV on file), and identify the dates of involvement in the study. An investigator should maintain separate lists for each study conducted by the investigator.

We are aware that delegation logs are commonly used at clinical sites to document who is assigned essential study tasks and to help ensure and document the proper conduct of a clinical trial.

Because sponsors and sites have the flexibility to adopt procedures that make the most sense to them and their existing business practices, I recommend you discuss how to address this issue with the appropriate intuitional officials at your site, and then further discuss it with the appropriate representatives at the sponsor company.

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

-----Original Message-----

From: [redacted]
Sent: Monday, March 16, 2015 6:45 AM
To: OC GCP Questions
Subject: GCP Question regarding a delegation log

Good evening,

For one of our site in our study, the PI will leave the study because of his disease.
New PI will take over the responsibility of the former PI during his absence.
New PI decided to delegate his significant tasks to the same qualified persons to whom the former PI has delegated.
(The delegated tasks will be also same as the former PI.)
In this case, will the new PI need to remake a Delegation Log?
If the new PI make "Note to File" to explain his decision instead of a Delegation Log, is it acceptable?

Thank you.

[redacted]