From: OC GCP Questions
To: [redacted]
Subject: RE: Delegation of Authority Log
Date: Thursday, December 04, 2014 10:40:00 AM
Attachments: [redacted]

Dear [Redacted]-

Thank you for your question. As you alluded to, 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'm sorry I couldn't be more helpful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
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Office of Special Medical Programs, Food and Drug Administration

From: [Redacted]
Sent: Wednesday, December 03, 2014 5:10 PM
To: OC GCP Questions
Subject: Delegation of Authority Log

Good evening,
We have a monitor (CRA) who is asking us to list our clinic staff on the DOA but we do not feel that this is required because the staff members are not always assigned to these research subjects and I know according to the 1572 FAQ that hospital/clinical staff do not need to be listed since they have occasional role in the conduct of our research. I also know that the FDA does not regulate DOA logs so what recourse do we have since our policy is not to add these staff members to the logs. Please advise.
[Redacted]