From: OC GCP Questions
To: [redacted]
Subject: Delegation Log
Date: Wednesday, June 27, 2018 9:15:00 AM
Attachments: [redacted]

Good morning –

As you likely know, FDA's regulations related to the conduct of clinical trials do not address site delegation logs or signature logs. When the regulations are silent, sponsors and sites have the flexibility to adopt procedures that make the most sense to them and their existing business practices.

The idea of delegation logs appears in FDA guidance documents. For example, the ICH E6 (R-2) Good Clinical Practice: Consolidated Guidance (which is recognized as official FDA guidance – see http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.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 your question regarding the appropriate time for the CI to sign the delegation log to coincide with new updates with your management or the sponsor of the study.

Kind regards,

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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.

[redacted]

Sent: Wednesday, June 27, 2018 12:33 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Delegation Log

Hi,

I am seeking clarification of the timeliness of signing off on the delegation log. We are receiving quite a few protocol deviations about the timeliness of the PI to sign the delegation log when a new staff member commences study related procedures, after being trained.

For example, a new Sub-I starts on 03Sep2017 and the PI has not signed the delegation log until October.

Is this a breach of GCP, even though the Sub-I is trained and has signed the delegation log prior to performing any study related duties, these instances occur when the PI is at site only 2 days a week which is quite normal practice or on holidays/conferences for example. I thought the delegation log was a tool to capture who has been delegated by the PI and what duties they have been delegated not a tool to document timeliness.

Cheers [redacted]

[redacted]