From: OC GCP Questions
To: [redacted]
Subject: RE: Signature and Delegation log question.
Date: Thursday, February 20, 2014 9:39:00 AM

Dear [Redacted]-

Thank you for your question. 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 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 your idea regarding developing a central signature log and combining this with a study specific delegation log with the appropriate individuals at your institution and site, any applicable sponsor and perhaps representatives of the larger disease groups that you are working with.

I hope this information is useful. 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
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [Redacted]
Sent: Friday, February 14, 2014 11:27 AM
To: OC GCP Questions

Subject: Signature and Delegation log question.

I have had a question come up and need some guidance. What are your thoughts on the acceptability of a central signature log (collecting name, signature and initials) combined with a study specific delegation log that lists study personnel name Title/Role, responsibilities, date of responsibilities (both to and from) as well as investigator initials that verify that the listed duties have been delegated. The study specific log would not have a signature and one would need to refer back to the central signature log to match signatures/initials to names. This has come up as we have some larger disease groups that have multiple people on many studies and the feasibility of getting someone to sign 20 different logs.

Any insight you might have would be greatly appreciated.

Thanks,

[Redacted]