From: OC GCP Questions
To: [redacted]
Subject: RE: Clinical Site GCP questions
Date: Monday, February 13, 2017 1:02:00 PM
Attachments: [redacted]

[redacted]

Thanks for your inquiry. Please see below for our response.

1. As you state, 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 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.

   Additionally, FDA has a guidance titled, "Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects," (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm187772.pdf) which describes on page 3 responsibilities including that 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.

   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.

   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 officials at your site and/or the sponsor company, and follow any relevant SOPs.

2. FDA Regulations under 21 CFR 312 (Investigational New Drug Applications) and 21 CFR 812 (Investigational Device Exemptions) do not specifically address this issue.

   The ICH E6: Good Clinical Practice: Consolidated Guidance (www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf), which is official guidance recognized by FDA, addresses storage temperatures in the following manner:

Section 5.13.2 The sponsor should determine, for the investigational product(s), acceptable storage temperatures, storage conditions (e.g., protection from light), storage times, reconstitution fluids and procedures, and devices for product infusion, if any. The sponsor should inform all involved parties (e.g., monitors, investigators, pharmacists, storage managers) of these determinations.

Section 5.14.3 The sponsor should ensure that written procedures include instructions that the investigator/institution should follow for the handling and storage of investigational product(s) for the trial and documentation thereof. The procedures should address adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subjects, and return of unused investigational product(s) to the sponsor (or alternative disposition if authorized by the sponsor and in compliance with the applicable regulatory requirement(s)).

The manufacturer/sponsor of the investigational product generally determines (via controlled studies) the appropriate storage conditions for the investigational product. The study protocol usually states the conditions/controls under which the investigational product should be stored in an effort to preserve the quality, strength, purity and identity of the product. Again I recommend you discuss how to address this issue with the appropriate officials at your site and/or the sponsor company, and follow any relevant SOPs.

I hope this information is helpful to you. Please contact us again at gcp.questions@fda.hhs.gov should you have additional GCP/HSP questions.

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From: [redacted]
Sent: Thursday, February 09, 2017 3:19 AM
To: OC GCP Questions
Subject: Clinical Site GCP questions

Hello,

I have two clinical investigator site related questions:

1) I know a Delegation Log is not a federal requirement however our company chooses to use in practice. Regulations discuss significant trial related duties that are delegated should be listed. We have studies that are at sites that may have 20 Sub I's etc. Do they all need to be on a delegation log or can the head of that group be listed and take accountability. Additionally site keep CV/training/qualification for all employees. (site state they

cannot always know which staff member may conduct certain test etc, however regardless the "head"who is listed on delegation would always review the test/results, etc.

2) if drug is to be stored frozen and sites keep drug in freezers with a thermometer that they monitor once or twice daily via a log, does the freezer and or thermometer need to be calibrated? How often and what suffices as documentation of calibration?

Thank you so much for you input.

Best,

[redacted]