From: OC GCP Questions
To: [redacted]
Subject: Delegation of Responsibility log
Date: Wednesday, October 17, 2018 8:32:11 AM
Attachments: [redacted]

Good morning –

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 https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.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.

Please also see FDA’s 1572 guidance
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

V. SECTION #4: NAME AND ADDRESS OF CLINICAL LABORATORY FACILITIES TO BE USED IN THIS STUDY

28. What qualifies as a clinical laboratory facility for Section #4?
Section #4 is intended to identify clinical laboratories or testing facilities directly contributing to or supporting the clinical study (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an IND.

If the MRI and/or PET scan sites are making a significant contribution to the clinical study, then they may need to be listed on the 1572 and may need to be listed on the delegation log. Please consult your clinical investigator, who has ultimate responsibility of overseeing the study at your site and/or the sponsor.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee 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.

From: [redacted]
Sent: Wednesday, October 17, 2018 4:52 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Delegation of Responsibility log

Hi,

I have a question related to the Delegation of Responsibility log.
During the studys conduct we are making MRI and PET tests in an external center.
I would like to ask you that should MRI and PET center staff be enered to the delegation of resposibility log if, they are not our staff?

Regards,

[redacted]