From: OC GCP Questions
To: [redacted]
Subject: Medical Monitors
Date: Thursday, April 20, 2017 11:26:00 AM
Attachments: [redacted]

Good morning

FDA regulations define sponsor responsibilities (including safety monitoring as well as general monitoring of the clinical investigation). However, the regulations don't contain an explicit requirement for the use of a "medical monitor" during the conduct of clinical trials nor do they define or specify responsibilities of a "medical monitor" per se. Instead, the regulations more broadly address investigator selection. Under 21 CFR 312. 53(a), sponsors must select investigators qualified by training and experience as appropriate experts to investigate the drug. Sponsors have considerable latitude in how they meet their monitoring responsibilities (including the specific selection and qualification of staff --- provided staff are appropriately educated, trained, and experienced to perform their assigned duties).

The Food and Drug Administration's (FDA's) regulations do not contain any specific requirements for qualifications or training of clinical site staff. In general, however, study personnel should be performing only those study functions that are within the scope of their professional license(s). As you know, this varies from jurisdiction to jurisdiction and is regulated by the States.

In order to determine whether a particular individual has the required qualifications, you would need to determine what duties that individual will be assigned, and whether there are any specific State or local requirements necessary to carry out those duties (e.g., licensing, continuing education, certification).

This FDA guidance only states that the CV of the investigator is needed. However the sponsor may require documents that demonstrate other study staff qualifications.

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

22. What is the purpose of Section #2?
Section #2 requires the investigator to attach a curriculum vitae (CV) or other statement of qualifications, showing the education, training and experience that qualifies the investigator as an expert in the clinical investigation of the drug/biologic for the use under investigation. Information identified in this section and attached to the 1572 enables the sponsor to assess an investigator's qualifications.

23. Does the CV or other statement of qualifications need to be updated during a clinical study?
No. FDA regulations do not require a CV or other statement of qualifications to be updated during a clinical study.

24. Are CVs required to be signed and dated?
No. FDA regulations do not require a CV to be signed and dated. The investigator's dated signature on the 1572 is sufficient to attest to the accuracy of the CV or other statement of qualifications submitted with the 1572.

You may also wish to review FDA guidance document on A Risk-Based Approach to Monitoring
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf

Delegation logs are not addressed in the FDA regulations related to the conduct of clinical trials (21 CFR Part 312 for drugs and biologics and Part 812 for medical devices). Such a log is also not specified in the list of essential documents in the ICH good clinical practice (GCP) guidance document (ICH E6), though signature sheets are included there. Appropriate delegation of clinical trial responsibilities is addressed in the FDA guidance regarding clinical investigator responsibility (available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf).

The guidance document states:

It is common practice for investigators to delegate certain study-related tasks to employees, colleagues, or other third parties (individuals or entities not under the direct supervision of the investigator). When tasks are delegated by an investigator, the investigator is responsible for providing adequate supervision of those to whom tasks are delegated. The investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study. The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task.

Though a delegation log 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 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. The clinical investigator is ultimately responsible for the conduct of the study. However, determining if an observed noncompliance resulted from improper delegation of a task is essential to correction of the problem, in the present study or in future studies if the study inspected is already complete. However a site chooses to document those assigned to essential study tasks, it should be updated whenever there is a change in personnel performing any of those tasks. The date on which the designation of the individual was made should be captured, but an ending date would not be necessary. Later addition of a different person for the same task would suffice. If the same study site personnel are assigned essential tasks throughout the life of the study, then no update would be required.

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

Kind regards,

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Office of Good Clinical Practice
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From: [redacted]
Sent: Thursday, April 20, 2017 10:54 AM
To: OC GCP Questions
Subject: Medical Monitors

Good morning,
As a Clinical Research Monitor (6 months into the position), I have a questions regarding Medical Monitors.
I have reviewed CFR and ICH guidelines in regard to the rules surrounding Regulatory Documentation for MMs, but I've come up empty-handed.
When monitoring a site, should we require them to have copies of CVs, licences, FDFs, IAs, etc. for the Medical Monitor, just as we do for the PI/sub-I?
Also, should a MM be added to the Delegation Log?
Thank you for any information.