From: OC GCP Questions
To: [redacted].
Subject: Delegation Log
Date: Monday, May 15, 2017 9:55:00 AM
Attachments: [redacted]

Good morning –

There is no yes or no answer to your question based on the roles the endoscopy RNs place would be significant. However, I can offer you the following information.

FDA's 1572 Form guidance
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf states --

32. Should research nurses, other nurses, residents, fellows, office staff, or other hospital staff be listed in Section #6?
Hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make a direct and significant contribution to the clinical data, do not need to be listed individually. It is not necessary to include in this section a person with only an occasional role in the conduct of the research, e.g., an on-call physician who temporarily dealt with a possible adverse effect or a temporary substitute for any research staff (see ICH E3, Section 6) (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073113.pdf).

So if the OR nurses are not listed on the 1572 form, they may not need to be listed on the delegation log.

That said 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.

In this guidance, FDA addresses appropriate delegation of study tasks (see Section III.A.1); I pasted another excerpt below:

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. Appropriate delegation is primarily an issue for tasks considered to be clinical or medical in nature, such as evaluating study subjects to assess clinical response to an investigational therapy (e.g., global assessment scales, vital signs) or providing medical care to subjects during the course of the study. Most clinical/medical tasks require formal medical training and may also have licensing or certification requirements. Licensing requirements may vary by jurisdiction (e.g., states, countries). Investigators should take such qualifications/licensing requirements into account when considering delegation of specific tasks. In all cases, a qualified physician (or dentist) should be responsible for all trial-related medical (or dental) decisions and care.

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.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, May 11, 2017 11:22 PM
To: OC GCP Questions
Subject: Delegation Log

Hello again,

I would like to get your thoughts on one more item. This study in question is being conducted in a hospital setting in an Endoscopy procedure suite. Therefore, there are other personnel in the room assisting with the investigational procedure. All of the research site staff have been listed on the delegation log and study specific training documented. However, the OR nurses have received study specific training which has also been documented but did not sign the delegation log. Site's rationale is that what the OR nurses are doing is standard of care and therefore don't need to be on the log.

My thought is that is they received study specific training so I would expect to see them on the delegation log because they are part of using the experimental device.

My question is what would and FDA inspector's expectations be?

Thanks,
[redacted]

[redacted]