From: OC GCP Questions
To: [redacted]
Subject: Do Regs Allow RN to be Only Person to Sign Lab Reports?
Date: Tuesday, May 29, 2018 10:34:00 AM
Attachments: [redacted]

Good morning –

As you are probably aware, delegation of specific responsibilities 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). 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

Regarding delegation of study-related tasks, the guidance document states:

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.

The document further states:

The investigator is responsible for conducting studies in accordance with the protocol (see 21 CFR 312.60, Form FDA-1572, 21 CFR 812.43 and 812.100). In some cases a protocol may specify the qualifications of the individuals who are to perform certain protocol-required tasks (e.g., physician, registered nurse), in which case the protocol must be followed even if state law permits individuals with different qualifications to perform the task (see 21 CFR 312.23(a)(6) and 312.40(a)(1)). For example, if the state in which the study site is located permits a nurse practitioner or physician's assistant to perform physical examinations under the supervision of a physician, but the protocol specifies that physical examinations must be done by a physician, a physician must perform such exams

The study tasks assigned to a clinical trial employee should comply with applicable state or local laws.

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

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
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From: [redacted]
Sent: Wednesday, May 23, 2018 2:49 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Do Regs Allow RN to be Only Person to Sign Lab Reports?

Hello,

I hope this message finds you well.

Do current regulations allow a registered nurse to sign lab reports? In this case the lab reports are not signed by a MD, DO, NP, or PA -- only by the RN.

More specifically:

1. Lab results are received by an RN, who is listed in Box 6 on the 1572 and as a coordinator on the delegation log. The RN is delegated to sign lab reports.
2. The RN reviews results, signs in the space designated for "investigator," and files this in the subject's chart.
3. If results are normal, the RN informs the PI via email that results are normal. The PI responds to this email confirming acknowledgement. No additional action is taken.
4. If results are abnormal, the RN informs the PI via email of the out of range values. The PI responds to this email indicating clinical significance. The RN prints and files this correspondence with the lab results in the subject's chart.
5. If results are life threatening, the RN will page or call the PI with results for immediate guidance.

It's not clear if current regulations allow for a RN to be the only person to sign lab reports.

Thank you for your help.

Best,
[redacted]