From: OC GCP Questions
To: [redacted]
Subject: Research Forms Question
Date: Monday, November 03, 2014 10:43:21 AM

Good morning –

FDA regulations pertaining to recordkeeping practices for clinical trial records are fairly general. The regulations do not specifically address signing or dating of documents by the clinical investigator or study team members. Based on the limited information is your email, it would not be against FDA regulations for infusion RNs to sign a form. That said, when the regulations are silent, sites and institutions can develop their own standard operating procedures for addressing a specific situation or issue.

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
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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.

-----Original Message-----
From: [redacted]
Sent: Friday, October 31, 2014 4:53 PM
To: OC GCP Questions
Subject: Research Forms Question

Hello gcp.questions@fda.hhs.gov,

We are doing a (non-IND/IDE) study where we are randomizing participants to receive an FDA approved medication in addition to their standard of care medication or nothing in addition to their standard of care medication. This medication is administered by the infusion nurses as part of their routine care for these patients. The research staff will provide all required documents and clearly inform the infusion RN if the patient has been randomized to receive the Drug or not receive it.

These infusion RNs are not on the Delegation Log as there are so many of them and they change often. It would be impractical. Also, these RNs can infuse this basic medication as evidenced by their education, experience, and license. They sign off for this medication in the Electronic Med Record per standard practice. We also have them sign on the Research Form indicating that they were the individual who administered the product.

We had an auditor inform us that they cannot sign any "research form" since they are not part of the "research team." There is nothing in the protocol that notes this and the Sponsor had no problem with the infusion nurse signing the form. However, this auditor said it's prohibited by the FDA. I have never heard of such a thing and can find nothing in GCP or the regulations that address this matter. Can you help me with this question?

Thanks again!

[redacted]