From: OC GCP Questions
To: [redacted]
Subject: Nurse Practitioner in FDA 1572
Date: Wednesday, February 26, 2014 1:05:53 PM

Good afternoon –

As you reference, The Q&As on the FDA Form 1572 (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf) states that those who should be listed as a sub-investigator (section #6) be anyone who plays a vital role in the conduct of the study, including collecting and/or evaluating data and maintaining study records. From your description, nurse practitioners perform study tasks that rise to that level of importance. Therefore, when nurse practitioners play that level of a role in a clinical study they should be included under section #6 as sub-investigators and listed in section 6.

The regulations require that sponsors choose investigators qualified by training and experience (see 21 CFR 312.53(a)). The regulations also require that investigators commit themselves to personally conduct or supervise the investigation (see 21 CFR 312.53(c)(1)(vi)(c)). FDA's guidance on Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects (available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf) states that, "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."

The delegation of certain study-related tasks to employees would include nurse practitioners. 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

The expectation is that investigators and sub-investigators and well as study staff (nurse practitioners) will be knowledgeable about good clinical practice, including human subject protection, data integrity, recordkeeping, etc.

Only clinical investigators are required to sign the 1572 form. However, if your NPs are functioning as CIs, then they should sign their own 1572. If you are still unclear, you can always ask the sponsor of your study.

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

From: [Redacted]
Sent: Monday, February 24, 2014 2:30 PM
To: OC GCP Questions
Cc: [Redacted]
Subject: Nurse Practitioner in FDA 1572

Dear FDA staff,

I went through the FDA 1572 guideline pdf but I still have a doubt regarding NP's role in clinical research at our institution. Can you please advise us if we can add nurse practitioner, in FDA 1572 Sub-Investigator section, at our Medical Oncology clinic where we will be conducting our phase III clinical trials including NCI ones? If yes then, are NPs required to submit their own FDA 1572 forms?

I appreciate your opinion.

Thanks,
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