From: OC GCP Questions
To: [redacted]
Subject: Nurses/non nurses distributing study drug
Date: Monday, February 03, 2014 11:46:38 AM

Good morning –

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."*

It also 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.*

The delegation of certain study-related tasks to employees would include clinical research coordinators.

The expectation is that investigators and sub-investigators and well as study staff (research coordinators) will be knowledgeable about good clinical practice, including human subject protection, data integrity, recordkeeping, etc. Note that sponsors have discretion in determining what qualifications will be needed to conduct a study and may identify in the protocol a required frequency of GCP training, in which case the investigator, sub-investigators and study staff would be expected to meet that frequency of training in order to comply with the sponsors requirements. Every effort should be made to train the investigational sites.

The mixing of medication is not solely performed by pharmacists. For example, nurses mix medication frequently before delivery. However, any task outlined in the protocol would be subject to applicable state or local laws as required for licensed medical professional staff.

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: Friday, January 31, 2014 1:52 PM
To: OC GCP Questions
Subject: Nurses/non nurses distributing study drug

Good Afternoon,
I have a question on what qualifications a clinical research coordinator should have in order to dispense study drug and if they are ever permitted to MIX study drug prior to administration. I have heard that the mixing is done and I am truly surprised. I thought that only a licensed pharmacist could do that.
Thank you,
[Redacted]