From: OC GCP Questions
To:
Subject: Study drug question
Date: Thursday, October 29, 2015 1:15:41 PM

Good afternoon –

FDA regulations are not that specific as to who can dispense investigational product to study subjects.

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 pharmacists. Additionally FDA would expect study staff to follow state and local laws regarding medical licensure and medical practice requirements in addition to sponsor requirements. You would need to contact someone in Michigan to determine state and local laws.

Also, please note that FDA does inspect "drug accountability" records, and the clinical investigator (and the pharmacist, or PI's delegate if applicable) are required to keep appropriate records related to tracking incoming shipments of and dispensing the study drug--e.g., quantities dispensed, to whom, quantities returned by study subjects, quantities returned to the sponsor or destroyed, etc. See 21 CFR 312.61, 312.62(a), and 312.69. Here is a link to all of FDA's regulations for the conduct of clinical trials: www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm.

A FDA guidance document titled, "Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects" (available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf), discusses a clinical investigator's responsibilities when delegating study tasks. This guidance refers back to section 4.1.5 of the ICH E6 guidance on page 3 and includes the following statement:

The investigator should maintain a list of the appropriately qualified persons to whom significant trial-related duties have been delegated. This list should also describe the delegated tasks, identify the training that individuals have received that qualifies them to perform delegated tasks (e.g., can refer to an individual's CV on file), and identify the dates of involvement in the study. An investigator should maintain separate lists for each study conducted by the investigator.

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
Office of the Commissioner, FDA

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.

From: [redacted]
Sent: Thursday, October 29, 2015 10:15 AM
To: OC GCP Questions
Subject: Study drug question

Hello,
I am an Associate Research Coordinator at the [redacted],
and recently there has been a discussion concerning whether or not a licensed pharmacist is required to dispense research study drugs to our research subjects, or if the study drugs can be dispensed by the Principle Investigator or the PI's authorized delegate?
Is there a FDA rule regarding this? If it is a State or local regulation, can you provide contact information for the appropriate governing authority?
Thank you!
[redacted]