From: OC GCP Questions
To: [redacted]
Subject: Questions about FDA Good Clinical Practice
Date: Thursday, April 27, 2017 6:25:00 AM
Attachments: [redacted]

Good morning –

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 .

An 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.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Wednesday, April 26, 2017 9:38 PM
To: OC GCP Questions
Subject: Questions about FDA Good Clinical Practice

Hello,

I am writing to inquire about compliance with FDA Good Clinical Practice Guidelines, Clinical Trials Guidelines and CFR Title 21 as relates to an investigational drug service (IDS).

The IDS scope of service is to manage investigational drugs used in clinical trials; provide for procurement of study drug and necessary materials for compounding study drug or placebo, inventory accountability, handling, storage, and dispensation. This would be done in accordance with IRB approved protocols for research activities.

My situation is that I am a licensed pharmacist in [redacted] where I work at the [redacted] Prior to this all of my work with IRB and investigational drugs was done as a pharmacist under the operation of a hospital pharmacy.

I have the following questions regarding the IDS as described above in an academic setting.

1) Does there need to be a licensed pharmacy entity for which the licensed pharmacist will operate under to:

a) procure study drug and manage inventory?

b) package and label drugs for dispensation?

c) compound study drug from raw chemical?

Any reference to supporting documentation is greatly appreciated.

I look forward to your response, or referral to a different office if more appropriate.

Sincerely,
[redacted]

[redacted]

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