From: OC GCP Questions
To: [redacted]
Subject: Study question
Date: Tuesday, May 29, 2018 11:30:00 AM
Attachments: [redacted]

Good morning –

Question # 1 - FDA's regulations do not specifically address an investigator delegating tasks in a clinical trial; however, FDA's "Guidance for Industry: Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects" (available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf) may assist you. This guidance includes the following statements:

"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 investigator is responsible for conducting studies in accordance with the protocol (see 21 CFR 312.60, Form FDA-1572, 21 CFR 812.43 and 812.100). In some cases a protocol may specify the qualifications of the individuals who are to perform certain protocol-required tasks (e.g., physician, registered nurse), in which case the protocol must be followed even if state law permits individuals with different qualifications to perform the task (see 21 CFR 312.23(a)(6) and 312.40(a)(1))."

The clinical investigator has the ultimate responsibility of overseeing the conduct of the trial and abiding by FDA regulations as required by law.

The guidance document on the Form FDA 1572 (the 1572) (see www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf) states, anyone who performs a task essential to the conduct of the clinical trial should be listed as a sub-investigator on the 1572. Question 33 addresses study coordinators. See below.

Generally, a research coordinator has a greater role in performing critical study functions and making direct and significant contributions to the data. For example, a research coordinator often recruits subjects, collects and evaluates study data, and maintains study records. Therefore, the research coordinator should usually be listed in Section #6 of the 1572.

The sponsor along with the clinical investigator and in some cases the protocol should outline the study coordinator's role in the clinical investigation. The study coordinators role as well as other institutional employees role in administrating investigational product should be aligned with the institutions policies and procedures.

With regard to the Study Coordinator - I can think of few circumstances in which a study coordinator would not have an integral role in the conduct of a study. Whether the study coordinator needs to be present during the investigational product (IP) dispensing would be up to the sponsor and/or the clinical investigator and the nature of the IP.

Question # 2 - FDA's regulations place responsibility for control and accountability of supplies of the investigational drug on the sponsor (see 21 CFR 312.57(a), 312.58(b), and 312.59) and the clinical investigator (see 312.61, 312.62, and 312.69):

Sec. 312.57 Record keeping and record retention.

(a) A sponsor shall maintain adequate records showing the receipt, shipment, or other disposition of the investigational drug. These records are required to include, as appropriate, the name of the investigator to whom the drug is shipped, and the date, quantity, and batch or code mark of each such shipment.

Sec. 312.58(b) Controlled substances. If an investigational new drug is a substance listed in any schedule of the Controlled Substances Act (21 U.S.C. 801; 21 CFR part 1308), records concerning shipment, delivery, receipt, and disposition of the drug, which are required to be kept under this part or other applicable parts of this chapter shall, upon the request of a properly authorized employee of the Drug Enforcement Administration of the U.S. Department of Justice, be made available by the investigator or sponsor to whom the request is made, for inspection and copying. In addition, the sponsor shall assure that adequate precautions are taken, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

Sec. 312.59 Disposition of unused supply of investigational drug.

The sponsor shall assure the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated. The sponsor may authorize alternative disposition of unused supplies of the investigational drug provided this alternative disposition does not expose humans to risks from the drug. The sponsor shall maintain written records of any disposition of the drug in accordance with 312.57.

Sec. 312.61 Control of the investigational drug.

An investigator shall administer the drug only to subjects under the investigator's personal supervision or under the supervision of a subinvestigator responsible to the investigator. The investigator shall not supply the investigational drug to any person not authorized under this part to receive it.

Sec. 312.62 Investigator record keeping and record retention.

(a) Disposition of drug. An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 312.59.

Sec. 312.69 Handling of controlled substances.

If the investigational drug is subject to the Controlled Substances Act, the investigator shall take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

While the regulations do not require locked cabinets for investigational drugs that are NOT controlled substances, the investigator is nevertheless still required to maintain control of the investigational drug and if the IP is locked, the clinical investigator will decide who has control of the key and who should have access to the IP.

Kind regards,

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U.S. FOOD & DRUG ADMINISTRATION

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or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Friday, May 25, 2018 1:32 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Study question

Good evening,

I have a general question regarding the role of a study coordinator during an ongoing clinical study

Does the study coordinator need to be present during the administration of study drugs ?

If the task of dispensing and administering is delegated to "non study" staff within the organization in which the study is being performed, does the study coordinator need to be present to observe and record data?

If study medications are stored in locked refrigerator, who is responsible for holding key, unlocking the refrigerator and retrieving medication?

Thank you very much for your time,
[redacted]