From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, March 07, 2006 4:44 PM
To: **[Redacted]**
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. **[Redacted]**:

Your questions that were submitted on the "DrugInfo Comment Form FDA/CDER Site" was forwarded to my office for a response.

You asked: "Could you tell me what the FDA position is on the storage and dispensing of medication as part of a clinical trial? Can a clinical trial coordinating center store the study drugs on-site in a locked cabinet or must the drug be dispensed to patients by a pharmacy? Is it allowable for study coordinators (non medical)to dispense the medication directly to patients? Could you tell me which written guidelines provide the details about what is acceptable (FDA,GCP,ICH, etc)?"

Controlled substances are required to be stored 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." See 21 CFR 312.69.

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:

"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." [See 21 CFR 312.61.]

"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 the disposition of the unused supplies of the drug under §312.59." [See 21 CFR 312.62(a).]

Certainly, limiting access to the investigational drug products is in keeping with good clinical practice. Because the regulations are fairly general, however, study sites and sponsors have the flexibility to develop their own procedures for handling, storing, and dispensing the investigational drugs.

You also asked if non-medical personnel may dispense medication to study subjects. FDA regulations are silent with respect to identifying the study personnel who should perform specific trial-related duties. Having said that, I wish to point out that sponsors are responsible for selecting investigators who are qualified by training and experience as appropriate experts to investigate the drug. The corollary to that idea is that study personnel who are assisting the investigator in carrying out the study should be performing only those study functions that are within the scope of their professional licenses. Generally, medical licenses are regulated by the States, and thus, may vary from jurisdiction to jurisdiction. If there are questions regarding the study functions that a particular individual is eligible to perform, we should suggest that he/she consult the professional licensing authority. In addition,

it would probably be a good idea to check the protocol and/or with the sponsor of the study, as the sponsor may have specified in the protocol that certain duties be carried out by specific study personnel.

The ICH E-6, "Good Clinical Practice: Consolidated Guideline," includes some general guidance about handling the investigational product at the study site (section 4.6), the investigator's qualifications and delegation of duties (sections 4.1, and 4.2), compliance with the protocol (section 4.5), and the sponsor's role in supplying and handling the investigational product(s) (section 5.14). However, as I stated earlier, because the regulations are fairly general, study sites and sponsors have discretion in developing their own (more specific) procedures for handling, storing, and dispensing the investigational drugs.

I hope this is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather 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.

-----Original Message-----
From: **[Redacted]**
Sent: Thursday, February 16, 2006 5:19 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: **[Redacted]**

E-Mail: **[Redacted]**

Comments: Hello:

Could you tell me what the FDA position is on the storage and dispensing of medication as part of a clinical trial? Can a clinical trial coordinating

center store the study drugs on-site in a locked cabinet or must the drug be dispensed to patients by a pharmacy? Is it allowable for study coordinators (non medical)to dispense the medication directly to patients? Could you tell me which written guidelines provide the details about what is acceptable (FDA,GCP,ICH, etc)? I appreciate any help that you can provide.

Thanks,
[Redacted]