From: OC GCP Questions
To: [redacted]
Subject: Investigational drug storage.
Date: Wednesday, April 19, 2017 7:28:00 AM
Attachments: [redacted]

Good morning –

n reference to your question concerning investigational drugs, only controlled substances are required by FDA regulation 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.

Kind regards,

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

From: [redacted]
Sent: Monday, April 17, 2017 4:23 PM
To: OC GCP Questions
Subject: Investigational drug storage.

Hello,
I was hoping to clarify some concerns our IDS staff have concerning the storage and access of medications and what authorized personnel means. Does a segregated area of investigational drugs that are in the

lockedpharmacy (limited access to pharmacists and pharmacy technicians ONLY) suffice as limited access?

And is a locked pharmacy considered "limited authorized personnel"?

(c) Only personnel authorized by supervisory personnel shall enter those areas of the buildings and facilities designated as limited-access areas.
(d) Labels and other labeling materials for each different drug product, strength, dosage form, or quantity of contents shall be stored separately with suitable identification. Access to the storage area shall be limited to authorized personnel.

Thank you ,
sincerely,

[redacted]

[redacted]