From: Toth-Allen, Jean
Sent: Thursday, March 16, 2006 11:22 AM
To: **[Redacted]**
Subject: RE: Storage of clinical trial medication

Dear Mr. **[Redacted]**:

Thank you for your inquiry regarding storage of investigational drugs.

Regulations regarding the conduct of studies with investigational drugs require that both the sponsor and clinical investigator ensure "proper control" of the investigational product. FDA has interpreted that to mean that the investigator needs to be able to demonstrate that only the investigator and/or appropriately delegated study personnel can have access to the investigational product and administer it to study participants and only study participants. However, when a hospital pharmacy maintains and dispenses investigational products, these products will, by necessity, be stored with other products, both marketed and investigational. Keeping them secure and available only to appropriate study personnel is what is essential, not necessarily keeping them separated. However, for investigational products that are controlled substances, regulations (312.69) go further and specifically require storage 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."

The ICH GCP guidance, available at http://www.fda.gov/cder/guidance/959fnl.pdf, also states, under the section on Supplying and Handling Investigational Product(s) - 5.14 - the following:

5.14.3 - "The sponsor should ensure that written procedures include instructions that the investigator/institution should follow for the handling and storage of investigational product(s) for the trial and documentation thereof. The procedures should address adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subjects, and return of unused investigational product(s)..."

This would say that sponsors could and should spell out any restrictions they deem necessary for their products that might go beyond general security and control.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA

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.

From: **[Redacted]**
Sent: Wednesday, March 15, 2006 2:45 PM

To: OC GCP Questions
Subject: Storage of clinical trial medication

I am trying to find out where it is stated that a clinical trial site is required to keep study drugs separate from the other medications in the office. My employer/doctor is asking me where that is stated and i need to be able to give that to him.
[Redacted]