From: Toth-Allen, Jean
Sent: Tuesday, August 22, 2006 3:04 PM
To: **[Redacted]**
Subject: RE: investigational drug question/1572

Dear Ms. **[Redacted]**:

Thank you for your inquiry related to transport of investigational product.

The FDA regulations governing pharmaceutical clinical trials (Title 21, Code of Federal Regulations (21 CFR) Part 312), require both study sponsors and clinical investigators to maintain adequate records regarding the receipt, shipment, and any other disposition of investigational product (21 CFR 312.57(a) and 312.62(a) respectively). If, for whatever reason, it becomes necessary to transport investigational product between investigational sites, both sites would need to maintain adequate records with regard to this exchange so that exact investigational product accountability can be ensured at both sites. In addition, such an exchange should only be undertaken with the prior knowledge and agreement of the study sponsor, particularly if there are 2 different clinical investigators involved rather than simply alternate sites where the same clinical investigator is conducting the study. There are no regulations that I know of that would prohibit this, however.

There are a number of reasons why multiple sites may be listed on an individual Form FDA 1572. For example, if the clinical investigator practices at several sites and is conducting the study at each of these sites. Unless one or more of the sites is not properly equipped to conduct the study, this would be an acceptable scenario. On the other hand, it is sometimes seen that a clinical investigator is listed on a 1572 with a number of sub-investigators listed as also participating in the study but who are located at different sites. While sometimes a feasible arrangement, this is not always workable in practice, particularly if some or all of the other sites are geographically distant from the clinical investigator. It is essential that the clinical investigator who signs the 1572 have control over the conduct of the study at the sites included on the form. If he/she signs the 1572, FDA will hold him/her responsible for whatever occurs across the study sites included.

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: Friday, August 18, 2006 4:46 PM
To: OC GCP Questions
Subject: investigational drug question/1572

I am not able to locate anywhere that any regulations exist stating that investigational drug can or can't be transported between sites (ie: main research office to satelite office). With the exception of temperature storage I am trying to see if there are any issues making this an improper action.

This then leads me to the question of what are the FDA thoughts on multiple sites listed on the 1572 for seeing subjects for the trial?
Thanks,

[Redacted]