From: OC GCP Questions
To: [redacted]
Subject: Shipping investigational agent?
Date: Tuesday, March 07, 2017 11:05:00 AM

Good morning --

FDA regulations do not specifically address the issue you have described below. FDA regulations for investigational drug studies reference the need for control and accountability of the investigational product and that investigators should only receive the investigational products if they are participating in the study (i.e. the sponsor obtains a signed investigator statement (FDA Form-1572). I have cut and pasted some relevant regulations for you below.

Under 21 CFR 312.59--Disposition of unused supply of investigational drugs, FDA regulations state--The sponsor shall assure the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigations 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.

When FDA inspects a sponsor, FDA's field investigator will verify the sponsor's records pertaining to drug accountability, per 21 CFR 312.57(a):

(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.

(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.

Under 21 CFR 312.61--Control of the investigational drug, FDA regulations state--An investigator shall administer the drug only to subjects under the investigator's personal supervision or under the supervision of a sub investigator. The investigator shall not supply the investigational drug to any person not authorized under this part to receive it.

FDA experience is that only the CI of record can receive the investigational product (must be shipped to him/her at the specific site address). All this being said, the disposition (shipment) of the drug should be outlined in the protocol or the Investigator Brochure. Also, please contact your study sponsor for specific questions regarding shipment. [Emphasis added]

There is some guidance that is available for your review that references essential documents for the conduct of a clinical trial. The list is available within FDA's recognized guidance, the International Conference on Harmonization (ICH) guidance E6: Good Clinical Practice, available through the following web link: www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf. Additionally, you could also review the inspectional information section contained within the Compliance Program Guidance Manuals (CPGM). CPGMs are used to direct FDAs field personnel on the conduct of inspectional and investigational activities. These documents are available through the following web link: www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm160670.htm.

Kind regards,

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Office of Good Clinical Practice

Office of the Commissioner, 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.

-----Original Message-----
From: [redacted]
Sent: Tuesday, March 07, 2017 5:21 AM
To: OC GCP Questions
Subject: Shipping investigational agent?

Hello

Does the FDA have formal policy regarding the shipment of investigational agents directly to study participants residences?

I'm aware that state laws would need to be nuanced. I'm simply wondering if it is permissible from a FDA/GCP perspective. The agents would range from cytotoxic agents to small molecule, etc. No viral vectors, etc.

A courier service would be used which would allow temp control as well as temp tracking logs.

Please let me know your feedback.

Sincerely,

[redacted]

[redacted]