From: gcp.questions@fda.hhs.gov
To: [redacted]
Subject: Reregulation of Site-to-Site Transfer of IMP in the USA.
Date: Tuesday, July 08, 2014 9:54:26 AM

Good morning –

Your question was sent to the Center for Drugs (CDER). Please see their response below.

Kind regards,

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

Please refer to 21CFR312.59 in the response.

PART 312 -- INVESTIGATIONAL NEW DRUG APPLICATION

Subpart D--Responsibilities of Sponsors and Investigators
Sec. 312.59 Disposition of unused supply of investigational drug.

The sponsor shall assure the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation 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.

Subpart D--Responsibilities of Sponsors and Investigators
Sec. 312.61 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.

From: [redacted]
Sent: Wednesday, June 25, 2014 11:49 AM
To: OC GCP Questions
Subject: Reregulation of Site-to-Site Transfer of IMP in the USA.
Importance: High

Dear Sir/Madam:

I was hoping you could assist me. I came across this question and I'm unsure what regulations governs Site-to-Site Transfer of Investigational Medicinal Products in Clinical Studies in the US. The situation was that a site was supposed to use the IMP, but once the study didn't continue, the IMP was returned, but they wanted to use the same IMP to be transferred to another site to continue the same study but at a different location. I have mentioned to them the below statement but it came from Annex 13 not specifically a US regulation. The overall question here is what US Regulations govern site to site transfer of IMP?:

FDA/cGMP - Transfer of investigational medicinal products to another trial site. Sending investigational medicinal products from one trial site to another should remain an exception. Such transfers must be regulated by written instructions, and the drugs may have to be relabelled and recertified by a responsible party of the manufacturer (see GMP Guidelines, Annex 13 No. 47).

Best Regards,
[redacted]