From: OC GCP Questions
To: [redacted]
Subject: IMP
Date: Thursday, May 17, 2018 8:33:00 AM
Attachments: [redacted]

Good morning –

This practice would not be considered in line with good clinical practice. The site needs to work with their institutional officials and the sponsor of the studies. The regulations for IMP are as follows.

FDA's regulations regarding sponsor responsibilities for drug accountability include the following:

Sec. 312.57 Recordkeeping and record retention.

(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.

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.

As you can see, the regulations do not specifically state that the sponsor must re-count, re-measure, re-weigh, but the sponsor does need to assure the return of all unused supplies of the drug.

Further insight into FDA's expectations may be gained from FDA's Compliance Program for sponsor inspections, which may be accessed at:
https://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133770.pdf

This document identifies what an FDA investigator is supposed to look at during an FDA inspection of a sponsor. Concerning test article accountability, it includes the following (highlights added):

1.Determine whether the sponsor maintains accounting records for use of the test article including:

a. Names and addresses of clinical investigators receiving test articles (report names and addresses). See 312.57, 511.1(b)(3), and 812.140(b)(2).

b. Shipment date(s), quantity, batch or code mark, or other identification number for test article shipped. See regulations above.

c. Final disposition of the test article. See 312.59, 511.1(b)(7)(ii), and 812.140(b)(2).

d. Final disposition of food-producing animals treated with the test article (511.1(b)(5).

A detailed audit should be performed when serious violations are suspected.

2.Determine whether the sponsor's records are sufficient to reconcile test article usage (compare the amount shipped to the investigators to the amount used and returned or disposed of).

3.Determine whether all unused or reusable supplies of the test article were returned to the sponsor when either the investigator(s) discontinued or completed participation in the clinical investigation, or the

investigation was terminated.

4.If the test article was not returned to the sponsor, describe the method of disposition and determine if adequate records were maintained.

Based on this information, sponsor accounting as you described is desired. Please note, however, that the regulations do allow for the sponsor to authorize alternative disposition of unused supplies of the investigational drug provided the alternative disposition does not expose humans to risks from the drug, see citation above for section 312.59.

I hope this information is helpful.

Kind regards
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U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
Sent: Wednesday, May 16, 2018 2:48 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: IMP

What would be the agency recommendation or expectations for a site's hospital destroying IMP prior to drug accountability because this is their new policy. And they will not allow CRA into their area for drug accountability. The issues becomes no verification of return drug or certificate of drug destruction.