**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Destruction of Study Drug
**Date:** Thursday, November 05, 2015 6:43:08 AM

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Good morning --

FDA's regulations on records about disposition of the investigational drug state, "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."

312.59 states -- 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 are very general to allow sponsors and study sites the necessary flexibility to account for the supplies of investigational product that were received, administered, returned, and the final disposition (e.g., destruction) of any unused investigational articles. Please note that the records maintained at the site need to be adequate to show "disposition of the drug, including dates, quantity, and use by subjects.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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



**From:** [redacted]
**Sent:** Wednesday, November 04, 2015 4:06 PM
**To:** OC GCP Questions
**Subject:** Destruction of Study Drug

Hello, hope you're doing well.

I have a question. Is there a specific guideline to be followed for research sites on the destruction of study medication on site?

Regards,

[redacted]