Standard Operating Practice: On-site Destruction and Returns

EFFECTIVE JANUARY 1st, 2012

For medication returns, the investigational pharmacy will adhere to a consistent policy of NOT storing returned investigational products that have been consumed, either partially or completely and/or have expired. Medication returns will be documented in the respective protocol binder in the condition that they have been returned in:

a). Empty vials or bottles
b). Partial return (with quantity)
c). Expired return
d). Full return (from satellite pharmacy)

The quantity returned will be documented in the protocol binder as a “return for destruction”. The quantity to be destroyed and the method of destruction will also be clearly delineated in the protocol binder respective of the study.

Please see below the specific criteria for each return:

a). Empty vials/bottles/blister packs: Once the empty vials/bottles/blister packs have been documented as “returned” by the pharmacy technician or the investigational pharmacist, the bottles will be ultimately destroyed. If the item must be kept on site, the returned bottles will be kept on site for up to 4 weeks. If not processed by a drug monitor within that time frame, they will be disposed off on-site and will be documented as such in the respective protocol binder. No empty vials containing solution product for intravenous, subcutaneous, or intramuscular administration will be stored for any protocol.

The ultimate disposition of empty bottles policy will go into effect for studies that commence operation starting September 1st, 2011 and thereafter.

b). Partial return (with quantity): Partial returns of investigational capsules or tablets housed in bottles will be kept on site for up to 4 weeks. If not processed by a drug monitor within that time frame, they will be disposed off on-site and will be documented as such in the respective protocol binder. Any antineoplastic or other hazardous materials must adhere to HazMat policies on disposal of the aforementioned products and/or NIOSH standards. No vials containing chemotherapeutic solution product for intravenous, subcutaneous, or intramuscular administration will be stored for any protocol.**

If the partial returns are controlled substances, two pharmacists must sign with full name (not initials) for the destruction of the medication.

**Exception: Non-chemotherapy solutions (intact, sealed vials, partial patient returns or expired items) may be stored in the investigational pharmacy for up to 4 weeks, after which they will be destroyed if the study monitor fails to process the return)
c). **Expired returns:** Upon recognition of “soon-to-be expired” investigational drug products, the pharmacist will e-mail the respective study drug monitor and the Primary Investigator (PI) regarding the upcoming expiration date of the study product. The pharmacy will hold the expired products for **up to 4 weeks**, after which they will be destroyed if the study monitor fails to pick up the return or provide the necessary accommodation.

d). **Full return from satellite pharmacy:** Only in the event that a sealed, unexpired investigational drug product/bottle is returned to the main investigational pharmacy because it was never dispensed to the patient due to reasons such as- cancellation/patient no-show, study trial closure or patient discontinuation, can the product be returned back to the investigational drug pharmacy inventory.

*Any antineoplastic or other hazardous materials must adhere to HazMat policies on disposal and/or the NIOSH standards.*