STANDARD OPERATING PROCEDURES (SOPs): DESTRUCTION OR DISPOSITION OF INVESTIGATIONAL DRUG PRODUCTS IN INVESTIGATIONAL DRUG PHARMACY

Policy: The investigational pharmacy provides service for drug-related research protocols and is responsible for overseeing the dispensing, labeling, management of inventory and accounting for study drugs associated with research protocols on-site and at participating sites. The investigational pharmacy staff is to utilize a standard procedure for disposition and destruction of investigational agents, which will include any sponsor-provided, IDS-maintained drug product for use in a clinical trial, even those agents that are commercially available. This procedure is to be conducted in accordance with federal and state regulations, as well as good clinical practice guidelines.

Procedure:

A. Destruction or disposition of investigational products

1. Unused investigational drug containers
    a. In cases of drug expiration or end of trial, with sponsor approval destruction will be documented in Vestigo, UVA's electronic drug accountability system, where a certificate of destruction is retrievable. Destruction will be witnessed by a second IDS staff member or sponsor representative and certificates of destruction will be made available upon request. If the drug product will be returned, the sponsor must provide a prepaid shipping label.
2. Used investigational drug containers
    a. Main IDS: Hazardous investigational drug containers will not be retained and will be disposed of on the day of use. Non-hazardous investigation drug containers may be retained if sufficient space is available. Drug product will be disposed of safely following the procedures listed below.
    b. Cancer Center IDS: All investigational drug containers will not be retained and will be disposed of on the day of use. Drug product will be disposed of safely following the procedures listed below.
3. Investigational drug returns
    a. Main IDS: All investigational drug returns will be documented in Vestigo and saved for monitor review unless approval was given to destroy at study startup.

b. Cancer Center IDS: All investigational drug returns will be documented in Vestigo and immediately destroyed or returned to the sponsor after documentation. If the drug product will be destroyed, it will be disposed of safely following the procedures listed below. If the drug product will be returned, the sponsor must provide a prepaid shipping label.

4. Destruction procedures
   a. Full, partially full and empty vials and ampules of all Investigational drug supplies must be discarded into the white 5-gallon, screw top hazardous waste container. All subject information will be de-identified prior to placing the study drug product in the white waste containers. When full, the University of Virginia Office of Environmental Health and Safety will pick up the containers and prepare them for shipping to be incinerated.
   b. All waste will be transported to Triumvirate Environmental Services who will then send the material to Ross Incineration Services, 36790 Giles Road, Grafton, OH 44044, a permitted hazardous waste incineration facility.
   c. Once at the site, the transport vehicle, shipping containers, and waste will be weighed on certified truck scales. The containers will be off-loaded and the waste will be incinerated via RCRA permitted thermal treatment units.

Applicable Regulations & Guidelines:

Joint Commission Standard MM.06.01.05
21 CFR 312.59 – Disposition of unused supply of investigational drug.
21 CFR 312.62(a) – Investigator recordkeeping and record retention.
ICH GCP 4.6.3
ICH GCP 5.14.3
ICH GCP 5.14.4(b,d)

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