INVESTIGATIONAL DRUG SERVICE

POLICY AND PROCEDURE

Title: Destruction of Investigational Product (IP)		
Policy Number: 6.2		**Version Date:** 02/01/2023

DESTRUCTION PROCESS

Non-controlled, bulk pharmaceutical waste can be destroyed through the Emory Environmental Health and Safety Office, rather than returned to the sponsor. To destroy IP, an IDS employee signs the inventory out of Vestigo to document destruction and the date of destruction. A second employee verifies the IP description and quantity to be destroyed and witnesses the destruction in Vestigo. Vestigo automatically generates a certificate of destruction (COD) from the system which can be downloaded as a pdf file. The certificate is printed and a copy is sent with the IP.

Personnel from the Environmental Health and Safety Office (EHSO) pick up drugs for destruction each week. The Chemical Disposal Facility turns waste over to an outside contractor for incineration.

Heritage Thermal Services
1250 Saint George St. East Liverpool, OH
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CONTROLLED DRUGS

Controlled substances will be destroyed rather than returned to the sponsor. IDS uses the Rx Destroyer system to destroy controlled drugs. All controlled drugs to be destroyed are placed in the Rx Destroyer container which neutralizes medications on contact. The system is compliant with DEA regulations. IDS maintains an inventory of Rx Destroyer containers in the narcotic cabinet. Once the container is filled, it is removed from IDS and placed in the Stericycle waste stream.

EMPTY/USED VIALS

All used vials containing investigational drugs are placed in the ChemoSafety bucket following dose preparation. Full buckets are labelled using the UN3291 Regulated Medical Waste label and picked up in IDS by Emory Healthcare Facilities Management who contracts with Stericycle, Inc. to destroy via incineration.

Documentation of destruction occurs in Vestigo when the IDS pharmacist dispenses the vial(s). The vials are marked for destruction and the destruction is documented on the IDAR. An IDS technician witnesses the destruction, and the witness is also documented on the IDAR for monitor review.

References:

21 CFR 312.59 & .62; Drug Enforcement Agency Pharmacist's Manual at http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/

Investigational Drug Service Best Practice Standards; 2014; Hematology/Oncology Pharmacy Association

Prior Versions: 2/24/2014, 3/24/2017, 10/23/2018, 1/30/2020, 3/2/2020, 2/1/2022