

Policy/Procedure: DUHS Pharmacy - IDS Drug Destruction Policy		
Document ID:6184	Revision Number: 3	Status: Published
Origination Date: 05/01/2010		Effective Date: 12/14/2022
Entity: <input type="checkbox"/> AHS <input type="checkbox"/> DHCH <input type="checkbox"/> DHTS <input type="checkbox"/> DPC <input checked="" type="checkbox"/> DRAH <input checked="" type="checkbox"/> DRH <input checked="" type="checkbox"/> DUH <input type="checkbox"/> PDC <input type="checkbox"/> PHMO <input type="checkbox"/> SOM		

Review Dates: May 2010, April 2016, August 2019, April 2021, August 2022, December 2022

Purpose:

This policy provides information needed to establish a uniform method on handling and destruction of used, returned, unused, expired, and controlled substance investigational products.

Policy Statement:

- A. The Investigational Drug Services IDSs of Duke University Hospital Pharmacy follow the guidelines of the Chemical Waste Management Policy and Safe Handling of Hazardous Drugs found in the Duke University Hospital Safety Manual and administered by the Occupational and Environmental Safety Office (OESO) and the guidelines recommended by the Duke Occupational Health and Safety Division of the OESO.
- B. The Duke IDSs maintain complete and accurate documentation of investigational product (IP) destruction. Destruction records are available to study monitors upon request and are part of the permanent study record. Sponsor forms will not be used to document destruction or to duplicate information found in this policy. IDSs will not complete IP destruction in sponsor Interactive Response Technology (IRT) systems.
- C. The Department of Pharmacy complies with the following [Duke University Safety Manual](#) guidelines relating to the safe handling and disposal of hazardous drugs
 - a. [Hazardous Drug Policy](#)
 - b. [Chemical Waste Management](#)
 - c. [Hazard Communication](#)
- D. The Department of Pharmacy destroys all investigational drugs as hazardous unless there is adequate information available about potential toxicity and exposure risks to subjects and employees to exclude them, as recommended by OSHA guidelines.
- E. Biomedical waste from Duke University Hospital is incinerated by Stericycle, Inc. (1-336-578-8900; or 1-800-MED-WASTE, option 2), located at 1168 Porter Avenue, Haw River, NC 27258. The North Carolina Department of Environment and Natural Resources (NCDENR) issued Stericycle a Solid Waste Permit Number (#01-02-1) on September 15, 2003.
- F. Hazardous waste containers are picked up by Duke's OESO-Environmental Programs. A contract company (Veolia North America, Creedmoor, NC or Tradebe Environmental Services, Merrillville IN) transports the containers from Duke University Hospital to their site for subsequent incineration as regulated by the environmental protection agency (EPA).
- G. Investigational controlled substances are destroyed via reverse distribution by Inmar Healthcare Network, 635 Vine Street, Winston-Salem, NC 27101. (919-208-8387).

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- H. The IDSs does not receive a certificate of destruction from the respective company that carries out destruction. A certificate of destruction can be obtained via Vestigo. The date IP is placed in the appropriate bin is considered the date of destruction for all IDS records.

Level:

- ☐ **Interdependent** - asterisked [*] items require an order from a health care practitioner licensed to prescribe medical therapy.
☒ **Independent** – no provider order required.

Personnel:

IDS
ICS
IDRP

Competencies/Skills:

NONE

Required Resources:

- A. ASHP Guidelines on Handling Hazardous Drugs. Am. J. Health Syst Pharm 2006; 63: 1172 - 1191.
B. [OSHA Standards on Hazardous Drugs](#)
C. [NIOSH Alert](#): Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. Atlanta, GA: Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH); 2004. DHSS (NIOSH) publication 2004-165. [Update by CDC](#).

Definitions:

- A. Investigational Drug Services (IDSs) includes ICS, IDRP, and IDS
B. ICS: Investigational Chemotherapy Service, located inside the Cancer Center Infusion Pharmacy Room 4N33 Duke Cancer Center
C. IDS: Investigational Drug Service, located in Duke Clinic Room 0101b, Yellow Zone
D. IDRP: Infectious Disease Research Pharmacy, located in Duke Clinic, Clinic 1K
E. Vestigo: The IDSs account for all study medications using an electronic, web-based investigational drug inventory management system called Vestigo. Vestigo is 21CFR part 11 compliant and defaults to the NCI Drug Accountability Record/Form (DAR/DARF). All drug transfers, receipts, dispenses, subject returns, and the destruction of investigational products are recorded in Vestigo.

Procedure:

- A. Used Investigational Products
a. The IDSs do not save or store any used investigational products (IP).

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- b. All empty and partially used vials are not saved for monitor verification and are destroyed immediately after use according to OESO guidelines. Used injectable drug containers will be disposed of in the designated container for vendor destruction after pharmacist product verification.
- c. All preparation details are recorded and available for monitor review. See Investigational Drug Services Overview Policy.
- d. All packaging material (including bottles, boxes, stickers, and tear-off labels) is considered waste and is disposed of appropriately after use. No packaging material is kept on site for monitor review.

B. Returns

- a. Any Investigational Product (IP) dispensed to a subject and returned to IDSs for accountability will be double – counted by the study team member and an IDSs team member, recorded in Vestigo, and destroyed. Subject returns of an empty container (zero), that has a specific container number will be documented in Vestigo. Bulk dispenses with a zero balance returned that do not have a specific container number will not be recorded in Vestigo. If the study team is keeping the subject's non-hazardous IP returns for monitor review, then it is their responsibility to maintain returns/destruction documentation.
- b. Sponsor Interactive Response Technology (IRT) will be utilized for documenting shipment receipt and IP assignment if applicable. The IDSs will not complete IRT accountability or any other IRT functions that are already recorded in the Vestigo DAR.
- c. Any remaining IP in IV bags or oral syringes/containers that have been administered to subjects are considered biohazardous and are disposed of on the floor or clinic area. The IDSs do not accept returns of used bags, syringes, or containers that have been in contact with a subject.

C. Unused or Expired Investigational Product

- a. Expired IP is disposed of immediately in appropriate waste containers unless otherwise requested by the sponsor. IDSs will reach out if the expiration date of the IP is not defined. Study IP will be quarantined in Vestigo and at the physical location until the Sponsor provides documentation of extended use by date or approves destruction. The IDSs will only hold IP that needs to be returned to the sponsor for 60 days after which will be destroyed per this SOP.
- b. Any IP which is recalled, or damaged and needs to be returned to the sponsor will be completed during a scheduled monitoring visit unless otherwise instructed by the sponsor in writing; written documentation will be filed with the study records. These products will be placed into a bag and quarantined.
- c. Destruction of unused or expired IP that is performed on site is recorded in Vestigo. Vestigo certificates of destruction include the study protocol, investigator's name, study title, study product name, quantity per container, number of containers destroyed, date of destruction and manufacturer, lot number, expiration date (when available), and reason for destruction. Vestigo certificates of destruction are available for monitor and sponsor review upon request. A

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separate sponsor destruction form will not be completed by the IDSs. An IDSs team member will sign a sponsor destruction form if completed by the study monitor.

D. Controlled Substances

- a. Controlled investigational medications (CI-CIV) requiring on-site destruction are destroyed with two witnesses and recorded on the Vestigo DAR or are destroyed via reverse distribution by Inmar Healthcare Network, 635 Vine Street, Winston-Salem, NC 27101. (919-208-8387).

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Citations: N/A

Authoritative Source: DUH Pharmacy Senior Management Group/Investigational Drug Service

Original Policy Date: 05/2010

Revised Dates: 04/2016, 08/2019

Review Dates: 04/2021, 08/2022, 12/2022

Additional References:

NONE

Associated Policies:

[DUH Pharmacy IDS - Investigational Drug Service Overview](#)

Attachment Names:

NONE