DukeHealth

Procedure Title: DUHS Pharmacy – IDS Drug Destruction Policy

Document ID: 6184	Revision Number: 5	Status: Published
Origination Date: 05/01/2010	Effective Date: 07/24/2026	

Review Dates: May 2010, April 2016, August 2019, April 2021, August 2022, December 2022, April 2025, June 2026

Applicability:

- ☐ Ambulatory Surgery Center Arringdon
- ☐ Davis Ambulatory Surgery Center (DASC)
- ☐ Duke Health Integrated Practice (DHIP)
- ☐ Duke Health Lake Norman Hospital (DLNH)
- ☐ Duke Health Technology Services (DHTS)
- ☐ Duke HomeCare & Hospice (DHCH)
- ☐ Duke Primary Care (DPC)
- ☒ Duke Regional Hospital (DRH)
- ☒ Duke University Hospital (DUH) (both campuses)
  - ☐ Duke Durham Campus Only
  - ☐ Duke Raleigh Campus Only
- ☐ Patient Revenue Management Organization (PRMO)
- ☐ Population Health Management Office (PHMO)

Purpose:

This policy provides information needed to establish a uniform method for disposal, return, and destruction for investigational products (IP).

The Investigational Drug Service Non-Oncology (IDS) and Oncology Investigational Drug Service (ONC IDS) for Duke University Health System (DUHS) 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.

Biomedical waste from Duke University Hospital is incinerated by Stericycle, Inc. (1-336-578-9800; 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.

Hazardous waste containers are picked up by the Duke OESO Environmental Programs. A contract company (Veoila North America, Creedmoor, NC or Tradebe Environmental Services, Merrilville, IN) transports the containers from Duke Health facilities to their site for subsequent incineration as regulated by the Environmental Protection Agency (EPA).

Controlled Substance Investigational Products (CSIP) are destroyed via reverse distribution by Inmar Healthcare Network, 635 Vine Street, Winston-Salem, NC 27101 (919-208-8387).

Scope:

Pharmacy IDS Non-Oncology
Pharmacy Oncology IDS

Definitions/Acroynms:

A. IDS: Investigational Drug Service Non-Oncology, located in Duke Clinic Room 0010, Green Zone
B. ONC IDS: Oncology Investigational Drug Service, located in Cancer Center Infusion Pharmacy Room 4N33, Duke Cancer Center
C. Vestigo®: An electronic, web-based IP inventory management system used by IDS/ONC IDS.

Procedure:

A. IDS/ONC IDS destroy all IP as hazardous waste unless there is adequate information available about potential toxicity and exposure risks, as recommended by OSHA Guidelines, to exclude them.

B. IDS/ONC IDS maintain complete and accurate destruction documentation of IP via Vestigo®. IDS/ONC IDS do not receive a certification of destruction (COD) from the respective company that carries out destruction (e.g., Stericycle®, OESO).
   a. A Vestigo® generated COD can be obtained from Vestigo®, upon monitor or sponsor request, and is electronically filed in its respective pharmacy file as a permanent study record.
   b. The date of destruction for all IP is the date it is placed in the appropriate disposal container.
   c. Sponsor forms will not be used to document destruction or to duplicate information found within this policy or IDS/ONC IDS internal forms.
      i. An IDS/ONC IDS staff member will only sign a sponsor-provided destruction form if the study monitor or a study team member completes the form in its entirety.
   d. IDS/ONC IDS do not complete destruction in sponsor Interactive Response Technology (IRT) systems unless there is written documentation between the site and sponsor of the agreement to complete IRT functions outside the normal scope of IDS/ONC IDS.

C. DISPENSED AND USED INVESTIGATIONAL PRODUCTS
   a. IDS/ONC IDS do not save or store any used or partially used IP, ancillary supplies, or devices for monitor verification and are destroyed immediately after use according to OESO guidelines.
      i. Documentation of used or partially used IP can be generated as a Vestigo® Drug Accountability Record (DAR). One dispensed line item equals one line item destroyed or otherwise appropriately dispositioned per protocol, sponsor requirements, or site SOP.
   b. All used injectable drug containers will be disposed of in the designated container for vendor destruction after pharmacist product verification.
   c. All packaging material (including bottles, boxes, stickers, and tear-off labels) is considered waste and is appropriately disposed of after use. IDS/ONC IDS do not keep packaging material on site for monitor review.

D. PARTICIPANT RETURNS OF INVESTIGATIONAL PRODUCTS
   a. **IDS** does not document participant returns or their destruction.
      i. IDS does not accept participant returns. Participant returns are the responsibility of the study team in addition to their disposal and documentation.
      ii. Study teams may utilize IDS waste bins for final disposal of IP. Documentation of disposal is not provided by IDS or maintained in pharmacy study records.
      iii. Any remaining IP in IV bags or in syringes/containers that has been administed to study participants are considered biohazardous and disposed of per institutional policy.
   b. **ONC IDS** does document specific participant returns and their destruction in Vestigo®.
      i. Documentation of the returns are in Vestigo and is reviewed by two ONC IDS staff members. Participant returns are immediately discarded after second verification and destroyed per OESO guidelines.
      ii. Participant returns of an empty container, that has a specific container number, will be documented in Vestigo®.
      iii. Bulk dispenses (without container numbers) will be documented in Vestigo® with the total number of product as the return (e.g., total number of tablets or capsules).
      iv. Any participant self-administered injectable IP will not be accepted back to ONC IDS. These should be discarded in a participant's sharps container.
      v. ONC IDS will document if a bottle is returned of oral liquid IP (e.g., 1 bottle). If the sponsor would like the weight of bottles measured for liquid IP, a scale needs to be provided by the sponsor with specific instructions on how to document a return weight.

vi. If the study team is retaining the participant's non-hazardous returns for monitor review, then it is the study team's responsibility to maintain return/destruction documentation.
vii. Study teams are responsible for leading the investigation of any discrepancies between Vestigo® records, participant diaries, and EPIC notes.

E. UNUSED AND EXPIRED INVESTIGATIONAL PRODUCTS
   a. IDS/ONC IDS will request clarification of expiration dates from the sponsor if not clearly defined.
   b. Expired or unused IP will be disposed of on site in appropriate waste containers 60 days after the expiration date, study close out visit (COV), or quarantine date, whichever occurs first.
      i. IP will be quarantined in Vestigo® and at the physical location under appropriate temperature conditions until the sponsor provides documentation of an expiration extension (retest date) or approves destruction.
      ii. IDS/ONC IDS will attempt to contact the sponsor or its acting representative a minimum of two times before IP expire to establish a disposition process. Upon completion of site reconciliation and final documentation, and in the absence of sponsor direction following these documented attempts, IP may be destroyed on site without monitor review and verification.
      iii. Destruction of unused or expired IP that is performed on site is recorded then witnessed by a secondary IDS/ONC IDS staff member in Vestigo®.
   c. IDS/ONC IDS will retain IP requiring return to the sponsor for 60 days, after which it will be destroyed.
      i. IP requiring return to the sponsor will be handled during a scheduled monitoring visit unless otherwise instructed by the sponsor in writing.
      ii. Written documentation about the return will be filed with the pharmacy study records, recorded then witnessed by a secondary IDS/ONC IDS staff member as a Send Back to Sponsor within Vestigo®, and physically separated from active inventory.
      iii. It is the responsibility of the sponsor to provide the site with a shipping label/postage for IP that are being returned to the sponsor.
      iv. If the sponsor requires special handling (e.g., temperature controlled) for returns, the sponsor must provide all shipping and temperature monitoring materials.

F. CONTROLLED SUBSTANCE INVESTIGATIONAL PRODUCTS (CSIP)
   a. **IDS** procedures for CSIP (C-I to C-VI)
      i. IDS does not save or store any used or partially used CSIP for monitor verification and are destroyed immediately after use according to OESO guidelines (e.g., Stericycle®, CsRx® service container).
      ii. Documentation of used or partially used CSIP for dispensing can be generated as a Vestigo® DAR. One dispensed line item equals one line item destroyed or otherwise appropriately dispositioned per protocol, sponsor requirements, or site SOP.
      iii. Expired/unused CSIP supplied by the sponsor must be returned to the sponsor. It is the responsibility of the sponsor or their acting representative to facilitate this process and to ensure compliance with state and federal laws and regulations.
      iv. Expired/unused CSIP procured by IDS on behalf of the sponsor may be returned utilizing a reverse distributor or destroyed on site according to OESO guidelines.
      v. IDS does not save, store, or document any participant returns that are CSIP. This is the responsilibty of the study team.
   b. **ONC IDS** procedures for CSIP (C-I to C-VI)
      i. ONC IDS does not save or store any used or partially used CSIP for monitor verification and are destroyed immediately after use according to OESO guidelines (e.g., Stericycle®, CsRx® service container).
      ii. Documentation of used or partially used CSIP for dispensing can be generated as a Vestigo® DAR. One dispensed line item equals one line item destroyed or otherwise appropriately dispositioned per protocol, sponsor requirements, or site SOP.

iii. Expired/unused CSIP must be returned to the sponsor. It is the responsibility of the sponsor or their acting representative to facilitate this process and to ensure compliance with state and federal laws and regulations.
iv. ONC IDS does not save, store, or document any participant returns that are CSIP. This is the responsilibty of the study team.

References:
ASHP Guidelines on Handling Hazardous Drugs. Am. J. Helath Syst Pharm 2018; 75(24):1996-2031

Occupational Safety and Health Administration (OSHA) Standards on Hazardous Drugs

NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2004-165, 2004 Sep:1-50. Updated by CDC.

NIOSH [2024]. NIOSH List of Hazardous Drugs in Healthcare Settings, 2024. Cincinnati, OH: U.S. Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2025-103 (Supersedes 2016-161). Updated by CDC.

Associated Policies:
DUHS Pharmacy – IDS Overview

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