

STANDARD OPERATIONAL PROCEDURE (SOP) DISPOSAL, RETURN, AND DESTRUCTION OF INVESTIGATIONAL PRODUCT

Purpose

- A. This policy describes the specific procedures relating to disposal, return, destruction of investigational product for the Investigational Drug Service (IDS) Pharmacy at University of Utah Health (U of U Health) and all associated pharmacy satellites. This SOP replaces previous SOPs on this topic as of June 1, 2018.

Definitions

- A. **CFR:** code of federal regulations
- B. **Hazardous drug:** Any drug identified as causing cancer, teratogenic effects, developmental impairment, reproductive toxicity, organ toxicity, or genotoxicity at low doses in humans or animals. This includes any new drug that is similar to an existing hazardous drug in chemical structure or spectrum of toxicity. Refer to Appendix A in the **Policy: Safe Handling of Hazardous Drugs: Overview and General Procedures** for a list of hazardous agents that may require safe handling precautions.
- C. **Investigational new drug application (IND):** An Investigational New Drug Application (IND) is a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans.
- D. **Investigational drug:** A new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous for purposes of this part. Any drug which has not received FDA approval for use in humans. Also refers to any drug, which is FDA approved and is being used under protocol for human research, possibly outside of FDA approved labeling.
- E. **Investigational drug service:** A function of the Department of Pharmacy and provides support to ensure the safety and efficiency of trials at University of Utah Health that use investigational product(s)/investigational drug(s). Pharmacy personnel that perform investigational drug accountability at UUH satellite locations approved for conducting research protocols are considered an extension of the IDS.
- F. **Investigational product (IP):** A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
- G. **Returned containers:** containers that have been dispensed for patient use and have been returned to the IDS pharmacy or other satellite pharmacies
- H. **Site initiation visit (SIV):** a meeting during which protocol training is provided for all delegated study personnel prior to the study site enrolling patients into a clinical trial.
- I. **Used containers:** containers that have been used for admixing or preparing IP to be dispensed for patient use

- J. **Vestigo®**: A 21 CFR Part 11 compliant electronic accountability software application designed specifically for investigational pharmacy use and utilized by University of Utah Health IDS. Refer to www.mccreadiegroup.com/vestigo/ for additional information.

Description

A. Disposal Information

1. All investigational product items are disposed and destroyed in accordance with 40 CFR 261 (EPA), U of U Health **Medication Waste Disposal Policy**, U of U Health **Waste Handling/Separation Policy**, U of U Health **Storage, Labeling, and Discarding Requirements for Drug Products policy**, U of U Health **Medication & Medical Waste Process** document and the Resource Conservation and Recovery Act (RCRA) of 1976.
2. All investigational product items will be disposed and destroyed through U of U Health Environmental Services Department.
 - a. U of U Health holds three contracts for handling its medical/hazardous waste stream:
 - i. Waste Management for regulated medical waste disposal
 - ii. Clean Harbors for RCRA waste disposal
 - iii. Medical Disposal Services for chemo waste disposal
 - iv. Regular trash/solid waste is disposed of as municipal solid waste and landfilled.
 - b. Black RCRA rigid chemo/hazardous waste containers are claimed by Clean Harbors, who ensures hazardous materials are over-packed into special hazardous waste drums.
 - i. These black waste containers are picked up from U of U Health and transported by Clean Harbors to a holding facility and ultimately consolidated for transport to an incinerator, where it is appropriately destroyed.
 - A. Holding Facility Location:
2205 Red Butte Rd. Building # 590
Salt Lake City, UT 84103
 - B. Incinerator Location:
90 North W.
North Salt Lake, UT 84054
 - C. Clean Harbor's EPA ID is #UTD 981552177.
 - c. Yellow rigid chemo/hazardous waste containers are claimed by Medical Disposal Services.
 - i. These yellow waste containers are picked up from UUH and transported by Medical Disposal Services to a holding facility and ultimately consolidated for transport to an incinerator, where it is appropriately destroyed.
 - A. Holding Facility Location:
2500 S Decker Lake Blvd #12
West Valley City, UT 84119
 - B. Incinerator Location:
7505 State Highway 65
Anahuac TX, 77514
 - d. Certificates of destruction are not available from either Waste Management, Clean Harbors, or Medical Disposal Services.

- e. Documentation of IP destruction will occur and be maintained solely in Vestigo®.
- f. Documentation in Vestigo® of destruction of IP will serve as the certificate of destruction.

B. Investigational Product Disposal

1. IDS does not store empty or used product containers, labels from packaging / containers, tear-off labels, or ancillary supplies for accountability purposes.
2. All empty or partially used containers of IP are to be treated as hazardous substances with disposal occurring immediately after use into the chemotherapy waste-stream containers.
 - a. Storage of used or partially used vials of antineoplastic or gene therapy (gene- transfer) investigational drugs will not occur in the IDS Pharmacy due to health concerns and risk of exposure of staff to residual hazardous materials.
 - b. The IDS pharmacy will not retain or store used vials or containers of IP for accountability purposes.
 - c. Used vials or containers of IP will be accounted for in the appropriate drug accountability records in Vestigo® and then disposed of immediately in a manner that is in accordance with local, state, and federal requirements for disposal of medication waste.
 - d. Sponsor-specific destruction forms or electronic systems are not utilized to document medication destruction.
 - e. Assignment of the vial or container of IP in Vestigo® will serve as documentation of destruction.
3. All returned containers of IP are to be treated as hazardous substances with disposal occurring only after documentation of the return is fully completed in Vestigo®. Disposal will occur as soon as possible in accordance with local, state, and federal requirements for disposal of medication waste.
4. Expired IP is to be treated as hazardous substances with final disposal occurring 30 days past the expiration date.
5. IND-sponsored trials: IP that expires will be held for 30 days from date of expiration for sponsor disposition. At the end of the 30 days, any remaining expired drug will be destroyed.
6. IND-exempt trials: IP may be destroyed once it reaches the expiration date unless a specific request is made to hold the product for disposition. If a request is made to hold the product, the product supplier has 30 days from date of expiration to determine disposition otherwise IP will be destroyed. The request to hold a product for an IND- exempt trial must be in writing and must come PRIOR to the expiration date being reached.
7. Destruction for all expired medications will be documented in the IDS accountability system, Vestigo®, and a certificate of destruction regarding the disposal may be generated upon request.
8. All disposals of IP (returns, expired, empty, and partials) will have destruction solely notated in Vestigo® and will also be witnessed as part of the documentation associated with disposal.
 - a. Each disposal of IP will have an initial user indicating destruction in Vestigo® and a separate independent user indicating a witness to the destruction in Vestigo®. Two independent individuals will view the IP when it is disposed and marked as destroyed in Vestigo®.

- b. Both the initial user and the witness user documentation can be generated upon request.

C. Investigational Product Returns by Study Participants to IDS

1. IP that has been dispensed to a study participant and then returned by a study participant will not be returned to the sponsor.
2. Returned IP from study participants will be counted and documented solely in Vestigo® and then disposed by IDS personnel according to the disposal section of this procedure document.
 - a. Sponsor-specific return forms or electronic systems (eg, interactive response technology) are not used to document medication destruction.
 - b. IDS personnel are not responsible to document patient compliance.
 - c. IP returned in an unsatisfactory condition (eg, loose tablets, soiled bottles / product) may not be reconciled at IDS personnel discretion.
3. When patients return study medication at their ambulatory visits, the following steps should be completed:
 - a. Clinical Research Coordinator (CRC) should obtain the returned study medication from the patient.
 - b. The CRC will return the IP to the IDS during the patient's clinic visit.
 - c. When the CRC returns the medication to the IDS, the following may occur:
 - i. If requested by the PI, the CRC will make an in-person verbal request for the IDS pharmacy personnel to complete a "real-time" return count.
 - A. The CRC will need to wait for IDS pharmacy personnel to complete this count.
 - B. IDS personnel will complete the "real-time" return count using appropriate drug handling requirements as specified in institutional policy.
 - C. Once the return count is completed, IDS personnel will verbally tell the CRC the return count and will document the return in Vestigo® by the end of the business day.
 - ii. If an immediate return count is not needed or requested, the CRC may place the IP being returned into one of the designated return bins.
 - A. IDS pharmacy personnel empty this return bin once daily.
 - B. Return counts on returned IP will be completed and documented in Vestigo® within 5 business days from when the IP was placed in the return bin.

D. Investigational Product Returns to Study Sponsors

1. Intact, unused containers of investigational drugs may be returned to the study sponsor at the termination of a study or destroyed at the sponsor's request.
2. Expired medication stock: Sponsor representatives must provide appropriate shipping materials within 30 days after the expiration date, otherwise the IP will be destroyed as stated above.
3. If specific materials are required for the return of the medications, it is the responsibility of the sponsor/supplier to provide those items. The sponsor/supplier will be responsible for the cost of shipment and all related materials.
4. When study drug is returned to the manufacturer due to expired drug, completion of study, drug recall, or when deemed appropriate, the following information will be recorded in Vestigo®:
 - a. Date (month/day/year)

- b. Study Name and IP
- c. Lot number
- d. Quantity returned
- e. Ending balance
- f. Initials of pharmacy personnel returning drug
- g. Name of person or manufacturer to who drug was returned

E. Retained Samples of Investigational Product

- 1. After admixing the IP, IDS does not collect or store samples of the diluted IP.
- 2. IDS not retain samples from packaged products.

F. Destruction of Intact Containers of Investigational Drugs

- 1. If specifically requested by the Study Sponsor, intact containers of investigational drugs that have expired or that remain after study closure may be destroyed through the chemotherapy and hazardous substances waste stream. Documentation of the Sponsor's request for destruction as well as additional details will include drug name and strength, dosage form, lot number, quantity, protocol number, and date of destruction and will occur solely in Vestigo®. Sponsor-specific return forms or electronic systems (eg, interactive response technology) are not used by IDS personnel to document IP destruction.
- 2. Following the last investigational treatment dose, the sponsor shall work with IDS to closeout investigational pharmacy services for the study. If there is no response from the sponsor after multiple contact attempts, then IDS will destroy intact, unused IP per our processes described above. IDS will also discard any intact, unused IP following 6 months of the last treatment dose of IP.

Owner: IDS Manager

Last updated: 02/01/2021

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