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I. PURPOSE

This Investigational Drug Service (IDS) SOP describes investigational product (IP) disposal, return, and destruction at all Stanford Health Care (SHC) IDS locations.

II. DEFINITIONS:


- A. Medical Waste: Sharps, biohazardous, pathology, pharmaceutical, or trace chemotherapy waste generated in a health care setting and not regulated by the federal Resource Conservation and Recovery Act (RCRA). (CA HSC 117690)
- B. Hazardous Waste: Any discarded material regulated by RCRA which has been identified by the State as a hazardous waste or meets any of the characteristics established by the State regarding toxicity, flammability, corrosivity, or reactivity. (22 CCR § 66261.3)
- C. Non-RCRA Waste: Any medical waste not defined by SHC as hazardous or controlled substance.
- D. RCRA Waste: Any hazardous or controlled substance waste.

III. MATERIALS & EQUIPMENT REQUIRED


- A. Vestigo®
- B. Non-RCRA Waste Bin
- C. RCRA Waste Bin
- D. Cactus Smart Sink®

IV. PROCEDURE


- A. Waste Disposal and Destruction Information
 - 1. All IP items are disposed of and destroyed in accordance with [SHC Chemical Waste Management Policy](#), [SHC Chemical Waste Management Procedure](#), [California Medical Waste Management Act](#), and [Recovery Act \(RCRA\) of 1976](#).
 - 2. Waste Management Vendors
 - a. RCRA waste utilize RCRA waste bins for hazardous waste disposal and the Cactus Smart Sink® for controlled substance waste disposal.
 - i. Clean Harbors Environmental Services picks up RCRA waste from SHC and transports to a holding facility and ultimately consolidated from transports to an incinerator, where it is appropriately destroyed.
 - 1) Clean Harbors Environmental Services Incineration facility: Clean Harbor Environmental Services, 11600 North Aptus Road, Grantsville, UT 84029
 - b. Non-RCRA waste disposal bins are utilized for medical waste.
 - i. Daniels Environmental Services pickups up non-RCRA waste from SHC and transports to a holding facility and ultimately consolidated from transports to an incinerator, where it is appropriately destroyed.

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- 1) Daniels Environmental Services incineration facility: Daniels Environmental Services, 4144 Therese, Fresno, CA 93725
 - c. Once full, waste bins are closed, secured, and appropriately labeled. SHC Environmental Services (EVS) places full bins in the medical waste accumulation area (designated storage area) where it is picked up by an appropriate vendor.
 - d. Certificates of destruction are not available from either Clean Harbors or Daniels Medical Disposal Service.
- B. Investigational Product Disposal and Destruction**
1. Disposition of IP that accumulate over the duration of a clinical trial may include, but are not limited to:
 - a. Empty, partially full and intact (unopened) investigational agent returns from subjects
 - b. Empty, partially full investigational agent used for compounding finished product
 - c. Partially full or intact expired investigational agents
 - d. Undispensed, in-date investigational agents remaining at study closure
 2. IDS does not retain IP for review by Sponsor
 - a. All used IP:
 - i. IP dispensed to and returned from subjects
 - ii. Empty or partial vial/containers/kits used in compounding or preparing doses
 - iii. Prepared, unadministered IP doses
 - b. All unused IP:
 - i. IP that has expired or beyond their retest date
 - ii. IP which may have remain onsite at enrollment closure or clinical trial closure
 - iii. Damaged vials/containers which have not been used for dispensing
 - c. Labels from packaging, tear-off labels, or ancillary supplies for accountability purposes.
 3. IP that has been dispensed to and returned from subjects
 - a. IDS does not accept IP returned by subjects, unless an exemption by the IDS Director of Pharmacy is made.
 - b. IP return and destruction will solely be documented in Vestigo®.
 - i. Two IDS staff members will perform independent counts to verify the IP quantity returned. The quantity and the number of containers will be counted and recorded.
 - ii. The date of IP return and placed in waste bin for destruction may not be the same as date returned to the site.
 - c. IP returned in unsatisfactory condition (e.g., loose tablets, soiled product bottles) will not be reconciled at IDS discretion.
 - d. IDS will not accept IP or medications from another site/pharmacy to our pharmacy for disposal.

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- e. IDS is not responsible for documenting patient compliance.
 - 4. Unused IP that has expired
 - a. Monthly expired IP reviews will be conducted to identify expired IP
 - i. Expired IP will be physically separated (bagged and/or relocated) from other drug inventory and clearly marked as quarantined.
 - ii. IP that expired will be held for 30 days from date of quarantine.
 - iii. IDS staff will contact the sponsor for an IP disposition plan. If there is no response from the sponsor after two contact attempts, then IDS will destroy intact, expired IP at the end of the 30 days.
 - iv. IP that has a new retest date provided within the 30 days will be released from quarantine and placed back in the inventory stock. The new retest date will be updated in Vestigo®. The IP will be considered expired if an extension is not provided by the sponsor.
 - 5. Unused IP which has remain onsite at enrollment closure or clinical trial closure
 - a. Following the last treatment dose, the sponsor shall work with IDS to close out the study.
 - i. Cycle counts will be conducted monthly throughout the duration of the study to confirm the quantity on hand is consistent with the drug accountability log. All discrepancies will be reconciled and resolved before the study close out.
 - ii. IDS staff will contact the sponsor for a close out IP disposition plan.
 - iii. Intact, in-date IP will be held for 30 days from the date of the initial request.
 - iv. If there is no response from the sponsor after two contact attempts, then IDS will destroy intact, in-date IP at the end of the 30 days.
 - v. If the sponsor requests return of IP, then the sponsor must provide appropriate shipping materials and proper billing and labeling. The IP will be destroyed if IDS does not receive shipping materials within 30 days.
 - 6. Documentation
 - a. IP return and destruction will solely be documented in Vestigo®. Sponsor destruction forms or electronic systems are not used to document IP destruction.
 - b. For used IP, an IDS staff member will record the return followed by another IDS staff member to record its destruction. Both staff members will witness the destruction.
 - c. For unused IP, an IDS staff member will document the final destruction which is witnessed by a second IDS staff member.
 - d. Destruction of IP in Vestigo® will serve as the certificate of destruction (COD). Study teams or unblinded study monitors may request CODs generated from Vestigo®.
- C. Retained Samples of Investigational Product
- 1. After admixing the IP, IDS does not collect or store samples of the diluted IP.
 - 2. IDS does not retain samples from packaged products.

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V. COMPLIANCE:

- A. All workforce members including employees, contracted staff, students, volunteers, credentialed medical staff, and individuals representing or engaging in the practice at Stanford Medicine Health Care (SHC) are responsible for ensuring that individuals comply with this procedure.
- B. Violations of this procedure will be reported to the Department Manager and any other appropriate department as determined by the Department Manager or in accordance with SHC policy. Violations will be investigated to determine the nature, extent, and potential risk to SHC. Workforce members who violate this procedure will be subject to the appropriate disciplinary action up to and including termination.

VI. RELATED DOCUMENTS/PROCEDURES:

- A. [SHC Investigational Drug and Biologics Policy](#)
- B. [Establishment of Vestigo® as Exclusive IDS DARF Source](#)
- C. [Chemical Waste Management Policy](#)
- D. [Chemical Waste Management Procedure](#)
- E. [Antineoplastic and Hazardous Drug Handling Program](#)

VII. DOCUMENT INFORMATION:

- A. Original Document
 - 1. Author/Date: 12/2021, Danielle Thanh Pharm.D., Investigational Drug Service Pharmacist
- B. Stored in: Pharmacy Manual
- C. Review and Renewal Requirements:
 - 1. This procedure will be reviewed and/or revised every three years or as required by change of law or practice.
- D. Review and Revision History:
 - 1. 12/2021 Samit Patel Pharm.D., Pharmacy Compliance Coordinator, IDS; Elyse MacDonald, Pharm.D., Director of Pharmacy, IDS
 - 2. 5/2023 Zoe Ngo Pharm.D., Pharmacy Compliance Coordinator, IDS; Elyse MacDonald, Pharm.D., Director of Pharmacy, IDS
- E. Approvals:
 - 1. 12/2021 Janjri Desai, PharmD, MBA - Director of Pharmacy, Quality
 - 2. 06/2023 Jamie Kuo, PharmD, Director of Pharmacy-Quality

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