Content Owner: IDS

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Standard Operating Procedure		
DESTRUCTION OR DISPOSITION OF INVESTIGATIONAL DRUG PRODUCTS IN INVESTIGATIONAL DRUG PHARMACY		
Scope: ☒Dept./Unit/Clinic: Investigational Drug Services, Pharmacy ☐Service Line _____ ☐Institutional	**Patient Population:** ☒Neonatal ☒Pediatric ☒Adult ☐Sub-population: _____	**Patient Level of Care:** ☒Ambulatory ☒Acute ☒Intermediate ☒Critical Care ☒Emergency Dept ☒Labor and Delivery ☒Diagnostic/Procedural ☒Peri-operative ☐Other_____
Purpose: *To standardize the UVA Investigational Drug Service (IDS) process of returning investigational product (IP) to the study sponsor as well as outline the process for the destruction of IP's, including all necessary documentation.*		

Background/ Rationale: UVA Investigational Drug Pharmacies provide services for drug-related research protocols and are responsible for overseeing the dispensing, labeling, management of inventory and accounting for study drugs associated with research protocols on-site and at participating sites. The investigational pharmacy staff are to utilize this standard procedure as guidance for the disposition and destruction of investigational agents, which will include any sponsor-provided IP-maintained onsite for use in clinical trials. This guidance also includes any commercially available drugs used in investigational trials that IDS manages. This procedure is conducted in accordance with federal and state regulations, as well as good clinical practice guidelines

Procedure:

1. Unused investigational drug containers
    a. In cases of IP (Investigational Product) expiration, destruction or return of study supplied IP to the sponsor will be completed within 3 business days of expiration and documented in the Vestigo electronic drug accountability system. Refer to UVA IDS Expiration Date Management SOP for details on expiry date procedures.
    b. At the end of a trial, IP will be destroyed or returned to sponsor within 3 business days of the study close out visit with sponsor.
    c. A second IDS staff member or sponsor representative will perform an independent double-check of the items to be returned or destroyed, and will document this as a "witness" in Vestigo.
    d. Certificates of destruction are readily retrievable and will be made available upon request.
    e. If the IP will be returned, the sponsor must provide a prepaid IP shipping label within 3 business days or drug will be destroyed per SOP.

2. Used investigational drug containers
    a. No investigational drug containers will be retained and will be disposed of on the day of use.
    b. Drug product will be disposed of safely following the destruction procedures outlined below.
3. Unused ancillary supplies and supportive care medications
    a. In cases of any expired ancillary supplies, regardless of who purchases, or supportive care drugs purchased by IDS, destruction will be documented in Vestigo.
    b. A second IDS staff member will perform an independent double-check of the items to be destroyed, and will document this as a "witness" in Vestigo.
    c. Certificates of destruction will be made available upon request.
4. Investigational drug returns
    a. All IP patient returns will be documented in Vestigo and subsequently destroyed immediately upon return.
    b. A second IDS staff member will perform an independent double-check of the items to be destroyed, and will document this as a "witness" in Vestigo.
    c. If the patient IP will be returned, the sponsor must provide a prepaid IP shipping label to have on hand and ready to use immediately upon documentation in Vestigo. If no return form is readily available or is sent within 3 business days, we will follow our destruction SOP.
5. Destruction procedures
    a. Full, partially full and empty vials and ampules of all IP supplies must be discarded into a Resource Conservation and Recovery Act (RCRA) pharmaceutical waste bin available at each of IDS pharmacy. All study subject information will be de-identified prior to placing the study drug product into a RCRA container.
    b. When full, the University of Virginia Office of Environmental Health and Safety will pick up the containers and prepare them for shipping to be incinerated.
    c. All waste will be transported to Triumvirate Environmental Services who will then send the material to Ross Incineration Services, 36790 Giles Road, Grafton, OH 44044, a permitted hazardous waste incineration facility.
    d. Once at the site, the transport vehicle, shipping containers, and waste will be weighed on certified truck scales.
    e. The containers will be off-loaded and the waste will be incinerated via RCRA permitted thermal treatment units.
6. Hazardous Medications

    Hazardous IP or IP with unknown hazardous designation will be handled in the same manner as other hazardous medications per UVA policy/procedures as well as local, state and federal regulations applicable to this process.
7. Controlled Substances
    a. All controlled substances that are not returned to sponsor will be destroyed via a controlled substance waste management system, like Cactus Smart Sink, which will render all substances irretrievable and unusable.
    b. This process will be documented in Vestigo and all waste will be witnessed by 2 people both in person and in Vestigo.

Expected Outcomes	Unexpected Outcomes (Escalate)
• IP will be discarded per protocol and per sponsor request	• Any other outcome would be escalated to sponsor

External References:

Joint Commission Standard MM.06.01.05
21 CFR 312.59 – Disposition of unused supply of investigational drug.
21 CFR 312.62(a) – Investigator recordkeeping and record retention.
ICH GCP 4.6.3
ICH GCP 5.14.3
ICH GCP 5.14.4(b,d)

REVISION HISTORY				
Version	Reason (new, cyclical, external)	Relevant Reviewers	Approved By	Date of Approval
10/2003	New			
09/2012	Cyclical			
7/2015	Revised in old format			
9/2015	Revised in old format			
11/2015	Revised in old format			
6/2016	Revised in old format			
7/2016	Revised in old format			
12/2018	Revised in old format			
7/2020	Cyclical	IDS Pharmacists		07/20/20
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02/2022	External	IDS Pharmacists	Michael Neace	02/9/2022
07/2023	Revision	IDS Pharmacists	Michael Neace	07/21/2023
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04/24	Revision	IDS Pharmacists	John Parker, Pharmacy Leadership	04.25.2024