

	Procedure Name	Destruction of Medications and Investigational Product
	SOP #08	WVU IDS Pharmacy SOP-08
	Date this Version is Effective	01 January 2024
	Responsible for Content	IDS Pharmacy Manager

I. Description

This SOP will describe how to handle and discard Investigational Product (IP) with regards to state and federal regulations.

II. Rationale

This SOP will create a process to allow efficient and safe handling and disposal of IP. Team members will be provided with information and steps to allow them to dispose and handle IP.

III. Procedures

1. WVU Hospitals Investigational Drug Services (IDS) has the resource to destroy IP on site. When possible, authorization by the sponsor's representative within Vestigo will be requested.
2. Qualified site staff (on delegation log) will:
 - a. Verify IP for destruction.
 - b. Document IP preparation for destruction in Vestigo.
 - c. Generate and store a Certificate of Destruction within Vestigo.
3. If dispensed to the nursing unit and not dispensed to the patient, IP must be returned to the pharmacy for destruction.
 - a. The destruction of the unused drug should be recorded on the Drug Accountability Record Form.
4. Used injectable IP dispensed for home use may not be returned to the IDS pharmacy.
 - a. The study coordinator, or other WVUH study personnel will have the returned IP or biohazard sharps container placed in the San-I-Pak machine for autoclave sterilization prior to disposal.
5. All used IP vials and packaging will be destroyed per WVUH standards.
 - a. The above will be reconciled, photographed (upon request of the sponsor), and documented in Vestigo prior to destruction.

b. All pharmaceutical waste will be discarded in color coded containers.

Container:	Stericycle Model: (R)=Reusable
Blue	Non-RCRA Hazardous (R)
Black	RCRA Hazardous (R)
Black Chemo	RCRA Hazardous (R)
Black Corrosive	RCRA Hazardous
Black Oxidizers	RCRA Hazardous
Black Aerosols	RCRA Hazardous
Black PBKC	RCRA Hazardous
Yellow Trace Chemo	RCRA Hazardous
Red Biohazard	RCRA Hazardous

c. Destruction of waste is outsourced to Stericycle Pharmaceutical at Stericycle, Inc. 88 W Airport Industrial Park Road, Parkersburg, WV 26104.

d. Waste is collected by Stericycle weekly from the Cancer Center Infusion Pharmacy, and daily (Monday-Friday) from the main pharmacy IVR (clean and hazardous rooms).

6. Expired IP will be retained for up to 90 days after expiration or until the next monitor visit, whichever is sooner.

a. The sponsor can arrange to maintain expired IP past 90 days with the approval of the IDS manager.

7. Any medication, empty medication bottle, or packaging will not be retained.

a. This includes any of the above returned by the patient to the investigational drug services team. Patient returns will be reconciled, photographed, and documented in Vestigo prior to destruction.

IV. Original Procedure Date and Revisions

16 March 2022, 01 January 2024