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|  | Procedure Name | Destruction of Medications and Investigational Product |
| | SOP #08 | WVU IDS Pharmacy SOP-08 |
| | Date this Version is Effective | 16 March 2022 |
| | 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. Any protocols put in place by individual studies will be followed.

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) can destroy IP on site after authorization by the study sponsor, and acknowledgement by the sponsor's representative within Vestigo.
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 or to the supplier pending specifics of the study protocol.
 - a. The return or destruction of the unused drug should be recorded on the Drug Accountability Record Form.
4. 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.

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| Container: | Stericycle Model: (R)=Reusable |
| Blue | Non-RCRA Hazardous (R) |

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| 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).
5. 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.
 6. 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