Department of Pharmaceutical Care
University of Iowa Hospitals and Clinics

Section	Supply Chain
Related Policy	SUP-002
Operating procedure	**SUP-002~02**

INVESTIGATIONAL PRODUCT DISPOSAL AND DESTRUCTION

Definitions

A. **Hazardous medication :** Any medication identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, and new medications that mimic existing hazardous medications in structure or toxicity.
B. **Investigational drug/product (IP):** A new drug or biological drug that is used in a clinical trial. A medication or dosage form that is not approved by the Food and Drug Administration for use in humans (e.g., not commercially available in the US); this includes non-FDA approved medications that are obtained for individual patients as part of a treatment IND, single-patient use, emergency use, compassionate use, or similar protocol. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous. Investigational drug may also refer to any drug which is FDA approved and is being used under protocol for human research, possibly outside of FDA-approved labeling.
C. **Investigational drug service (IDS):** A service of the Department of Pharmaceutical Care which provides support to ensure the safety and efficiency of trials at University of Iowa Hospitals and Clinics that use investigational product(s)/investigational drug(s). Pharmacy personnel that perform investigational drug accountability at UIHC satellite/IV Admixture locations approved for conducting research protocols are considered an extension of the IDS.
D. **Returned containers:** Containers that have been dispensed for patient use and have been returned to the IDS pharmacy or other satellite pharmacies.
E. **Used containers:** Containers that have been used for admixing or preparing IP to be dispensed for patient use.
F. **Vestigo:** A web-based platform used by the University of Iowa Investigational Drug Service to manage investigational drug products used in studies conducted at the University of Iowa Hospitals and Clinics. It allows tracking of details such as trial status, study team members, patient enrollment, drug dispensing, temperature monitoring, etc.

General procedures:

A. Investigational Product Disposal

a. All empty or partially used containers of returned IP will be disposed of as hazardous medications occurring immediately after use by placing them into the appropriate waste-stream containers for incineration.
    i. Used or partially used vials of antineoplastic or gene therapy (gene-transfer) investigational drugs will be discarded immediately after preparation.
    ii. The IDS pharmacy will not retain or store used vials or containers of IP nor empty boxes previously containing IP for accountability purposes.
    iii. Used vials or containers of IP will be accounted for on the appropriate drug accountability record (DAR) or 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 by placing in the appropriate waste stream container.
    iv. All partial or empty used containers that were administered to the patient will be discarded by nursing at the site of administration.
    v. Sponsor-specific destruction forms will not be utilized to document medication destruction.
    vi. Record of destruction on the DAR or in Vestigo will serve as documentation of disposal.
b. Disposal will occur after documentation of the return is fully completed by two IDS staff members on the DAR or in Vestigo.
c. Expired IP will be held for 60 days from date of expiration for sponsor disposition. At the end of 60 days any remaining expired drug will be destroyed after accountability and documentation of destruction by two IDS staff members is completed.
d. If specifically requested by the Study Sponsor, intact containers of investigational drugs that remain after study closure may be destroyed.
e. IDS will not provide a certificate of destruction for any studies using a paper drug accountability log. A certificate of destruction may be requested for any studies using Vestigo.
f. All disposals of IP (returns, expired, empty, and partials) will have destruction solely notated on the DAR or Vestigo and will also be witnessed by two IDS pharmacy staff, who are indicated as authorized participants in the study, as part of the documentation associated with the disposal.
    i. Each disposal of IP will have an initial IDS staff member indicating destruction on the DAR or Vestigo and a second IDS staff member indicating a witness to the destruction.
    ii. Documentation of both staff members completing destruction of the IP can be provided upon request.

B. Investigational Product Returns by Study Participants to IDS

a. IP that has been dispensed to a study participant and then returned by a study participant will not be returned to the sponsor or held for monitoring by sponsor study personnel.
b. Returned IP from study participants will be counted and documented solely on the DAR or in Vestigo and then disposed of by IDS personnel according to the disposal section of this procedure document.
    i. Sponsor-specific return or destruction forms will not be utilized to document medication destruction.
    ii. IDS personnel are not responsible to document patient compliance.
    iii. IP returned in an unsatisfactory condition (e.g., loose tablets, soiled bottles / product) may not be reconciled at IDS personnel discretion. The inability to reconcile and reason will be documented on the DAR or in Vestigo.

C. Investigational Product Returns to Study Sponsors

a. Intact/Unused containers of investigational drugs shall be returned to the study sponsor at the termination of a study or destroyed at the sponsor's request as stated above.
b. Expired medication stock: Sponsor representatives must physically return the stock to the sponsor or dispose of the stock on site within 60 days after the expiration date, otherwise it will be destroyed as stated above.
c. 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.
d. When study drug is returned to the manufacturer due to expiration, completion of study, drug recall, or when deemed appropriate, documentation will be completed by two IDS staff members and recorded on the DAR or in Vestigo.

D. Expired/Unused IP from NCI

a. For NCI provided IP, any unused /unopened or expired IP will be transferred to another appropriate NCI protocol, returned to the NCI, or destroyed onsite per institutional guidelines following the completion of research IP dosing by the last subject on the protocol. Any returned IP requiring destruction and labeled a Dangerous Good (as noted on shipping documentation) will be destroyed per institutional guidelines. IP requiring return to NCI will be sent back to the NCI within 90 days.

E. Retained Samples of Diluted Investigational Product

a. After admixing the IP, IDS does not collect or store samples of the diluted IP.

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