Policy Title: FHFMH, FMFH, FMLH, FWBH Pharmacy Investigational Drug Service Product Disposition and Destruction Policy	**Last Review Date:** 03/28/2024
Policy Number: 5482	**Next Review Date:** 03/28/2027

Full Policy Title: FHFMH, FMFH, FMLH, FWBH Pharmacy Investigational Drug Service Product Disposition and Destruction Policy

Origination Date: 03/30/2016
Key Words: PHRM.IDS.103
Supersedes: PHRM.IDS.103

Applies to:
☐ Health system with no exclusions

Or the entities checked below -

Hospitals	Physician Practices	ASCs	Other
☐ FCH ☒ FHFMH ☒ FMFH ☒ FMLH ☒ FWBH	☐ CP ☐ NEMG	☐ DTSSC ☐ FSC ☐ MFASC ☐ WBSC	☐ ACO ☐ CIN ☐ Exceedent ☐ FH Home Infusion ☐ FH Pharmacy Solutions ☐ Inception Health ☐ Workforce Health ☐ _____

A. Purpose

1. To provide uniform methodology on handling of Investigational Product (IP) after it has been dispensed and/or returned to Froedtert Pharmacy Department to meet the Code of Federal Regulations (CFR) requirements.

B. Definitions

1. **Pharmacy Summary** - a study specific document that is prepared and maintained by the Lead IDS Pharmacist using information from, including but not limited to: the study protocol, pharmacy manual, site initiation meeting, etc. Pharmacy summaries provide protocol-specific information that the pharmacy must perform for adherence to the protocol.

C. Equipment

1. N/A

D. Policy Statement(s)

1. Froedtert Pharmacy Department maintains accurate and complete drug accountability records, including accountability of patient returned medication and final disposition of IP.
2. Froedtert Pharmacy Department is responsible for destruction and documentation of IP returned from subjects.
3. Returns will not be saved for monitor review.
4. Syringes will not be accepted as returns from subjects.
5. Sponsor supplied destruction forms will not be used for individual subject returned IP.
6. Only waiver requests due to drug integrity or patient safety concerns will be considered for approval by Pharmacy manager. An additional fee will be incurred for storage of subject returned medication bottles.

E. Procedure

Froedtert Pharmacy Responsibilities

1. Document all vials used for the preparation of IP as destroyed onsite on the accountability log upon usage.
2. Document IP dispensed in pre-filled syringes as destroyed onsite on the accountability log upon dispense.
3. IP returned from subjects
   a. Verification of subject returned IP will be independently completed by two Pharmacy Department staff members. For electronic documentation of returns, one staff member will document returns on the accountability log and a second staff member will document destruction. Pharmacy Department staff will document the date returned by the subject on the accountability log and documentation will occur within 3 business days of receipt by Froedtert Pharmacy Department.
   b. Complete documentation at the time of destruction.
   c. Document the disposition of the study medication on the accountability log including:
      i. date,
      ii. lot/kit/bottle number,
      iii. quantity of the returned IP destroyed onsite, and
      iv. the name and signature of Pharmacy Department staff.
4. Onsite destruction will consist of placing the IP in the appropriate waste bin per the FH Pharmacy Pharmaceutical Waste Policy. Pharmaceutical waste is disposed and processed by Clean Harbors®, http://www.cleanharbors.com, 309 American Circle, El Dorado, AR 71730. Waste manifests are maintained on site for three years. An internal certificate of destruction will be provided upon request by the sponsor.

5. Final Disposition (Return or Destruction) of unused or expired IP
    a. If return to the sponsor is required per the study protocol, instructions on the return procedures, if available, will be included in the Pharmacy Summary.
    b. If the sponsor is unwilling or unable to accept unused or expired IP, Froedtert Pharmacy Department will dispose of the unused IP per the FH Pharmacy Pharmaceutical Waste Policy. The cost incurred will be charged to the study account.
    c. Unused or expired IP that are either returned to the sponsor or destroyed onsite, will be documented by Froedtert Pharmacy Department on the accountability record.
    d. If the sponsor requests utilization of a destruction form, Froedtert Pharmacy Department will request the monitor to complete the form when expired or unused drug IP is returned to the depot or destroyed on site. Otherwise, all final IP dispositions will be documented on the accountability log by Froedtert Pharmacy Department. An internal certificate of destruction will be provided upon request by the sponsor.

F. Related Policies

1. FHFMH, FMFH, FMLH, FWBH Pharmacy Clinical Research and Investigational Drugs Policy
2. FHFMH, FMFH, FMLH, FWBH Pharmacy Investigational Drug Vestigo Accountability and Inventory Management Policy
3. Pharmacy Pharmaceutical Waste Policy

G. Reference(s)

1. Food and Drug Administration, Department of Health and Human Services. 21 CFR 312.59. Disposition of unused supply of investigational drug. https://www.ecfr.gov/current/title-21/part-312/section-312.59
2. Food and Drug Administration, Department of Health and Human Services. 21 CFR 312.57. Recordkeeping and record retention. https://www.ecfr.gov/current/title-21/part-312/section-312.57
3. Food and Drug Administration, Department of Health and Human Services. 21 CFR 312.62. Investigator recordkeeping and record retention. https://www.ecfr.gov/current/title-21/part-312/section-312.62

H. Attachment(s)

1. N/A