

Standard Operating Procedure		
<i>Expiration date management of investigational drug product</i>		
Scope: <input checked="" type="checkbox"/> Dept./Unit/Clinic _____ <input type="checkbox"/> Service Line _____ <input type="checkbox"/> Institutional	Patient Population: <input checked="" type="checkbox"/> Neonatal <input checked="" type="checkbox"/> Pediatric <input checked="" type="checkbox"/> Adult <input type="checkbox"/> Sub-population: _____ _____	Patient Level of Care: <input checked="" type="checkbox"/> Ambulatory <input checked="" type="checkbox"/> Acute <input checked="" type="checkbox"/> Intermediate <input checked="" type="checkbox"/> Critical Care <input checked="" type="checkbox"/> Emergency Dept <input checked="" type="checkbox"/> Labor and Delivery <input checked="" type="checkbox"/> Diagnostic/Procedural <input checked="" type="checkbox"/> Peri-operative <input type="checkbox"/> Other _____
Purpose: <i>To ensure standard procedures regarding dispensing IP that is not expired or beyond its re-test date</i>		

Background/ Rationale: The supervision and monitoring of investigational agents are the responsibilities of the principle investigators, sponsors, co-operative research groups and/or their designee(s). The Department of Pharmacy’s Investigational Drug Service (IDS) staff are to function as stewards on behalf of the principle investigator to maintain inventory, storage conditions, accountability, recordkeeping and other monitoring functions as deemed necessary to uphold the sanctity and safety of human research at the University of Virginia Health System. IDS is responsible for establishing standard procedures for the appropriate control of investigational drugs and biologics used in human subject research. Standard procedures for the control of investigational agents comply with local, state and federal regulations and requirements and are consistent with IRB standards, and practice standards of ASHP and The Joint Commission.

Equipment/Supplies: Vestigo

Procedure:

- A. Receipt of investigational drug product with known expiration
 - a. Upon receipt, IDS staff will electronically load inventory into Vestigo, the site’s electronic drug accountability system, with expiration date.
 - b. Inventory will be pulled onto an automatically generated report to alert staff to drug product with an approaching expiration or re-check date within 45 days. IDS staff is to review this report at least weekly, and document any action taken.
 - c. IDS staff will quarantine inventory as necessary based on expected duration of use (i.e. 30 days from known expiration date for outpatient administration dispensed every month, day of expiration for immediate use IV drugs, etc).
 - d. Notification of an extended expiry date should be provided by the Sponsor in written format.
 - e. If a sponsor has an alternate procedure for managing expirations, IDS must be made aware of this process before the study begins.

- B. Receipt of investigational drug product with known ‘re-test’ date
 - a. ‘Re-test’ dates are dates identified by the drug manufacturer as the date by which new stability data should be generated. Stability of the drug product is not to be assumed suitable for use beyond this date, unless the sponsor provides certification to support an extended date.
 - b. IDS staff will treat investigational drug product with ‘re-test’ dates in the same manner as known expiration date drug product and will follow the steps for its management as described above in Section A of this document.
- C. Receipt of investigational drug product with unknown expiration
 - a. Upon receipt, IDS pharmacy staff will reach out to the drug supplier, manufacturer, and/or sponsor for any of the following:
 - i. Expiration date
 - ii. Re-test date
 - iii. Confirmation in writing that the drug product is suitable for use and a date for when follow-up contact should be made. The date given will be treated as a ‘re-test’ date in Vestigo and actioned upon as outlined in Section B of this document.
 - iv. Sponsors who have an established process for proper management of expired drug without an assigned expiration will have an exception to the above process. The sponsor must be responsible for communicating any upcoming expiration to UVA IDS Pharmacy.
- D. Until the investigational pharmacy receives adequate information as described above, the inventory in question will be quarantined and unavailable for use. IDS staff will notify local PI and no dispensations may be made until reconciled.
- E. IDS will continue to monitor expiration and retest dates by continually reviewing and addressing the ‘Expired or Soon to Expire’ inventory report in Vestigo.
- F. IDS will monitor and address Unknown Expiration Dates in Vestigo by generating the appropriate report in Vestigo monthly.

Expected Outcomes	Unexpected Outcomes (Escalate)
<ul style="list-style-type: none"> • Expired IP will not be dispensed 	<ul style="list-style-type: none"> • Expired IP is dispensed – escalate to sponsor

External References:

- Code of Virginia § 54.1-2400
- 21 CFR 50 – Protection of human subjects.
- 21 CFR 312.57(a) – Recordkeeping and record retention.
- 21 CFR 312.61 – Control of the investigational drug.
- 21 CFR 312.62(a) – Investigator recordkeeping and record retention.
- ICH GCP 4.63 – Investigational Product(s)
- ICH GCP 5.145 – Supplying and Handling Investigational Product(s)

REVISION HISTORY				
Version	Reason (new, cyclical, external)	Relevant Reviewers	Approved By (Area leadership & PCC)	Date of Approval
8/2016	New	IDS Pharmacists		8/2016
7/2023	Cyclical	IDS Pharmacists	Michael Neace	8/2023
04/23	Revision	IDS Pharmacists	Pharmacy Leadership	04/2023