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Standard Operating Procedure		
MANAGEMENT OF QUARANTINED INVESTIGATIONAL PRODUCT (IP)		
Scope: ☒Dept./Unit/Clinic: Investigational Drug Services, Pharmacy ☐Service Line _____ ☐Institutional	**Patient Population:** ☒Neonatal ☒Pediatric ☒Adult ☐Sub-population: _____	**Patient Level of Care:** ☒Ambulatory ☒Acute ☒Intermediate ☒Critical Care ☒Emergency Dept ☒Labor and Delivery ☒Diagnostic/Procedural ☒Peri-operative ☐Other_____
Purpose: *To ensure and communicate standard processes for moving IP into and out of quarantine within Investigational Drug Services (IDS) at University of Virginia (UVA) Health*		

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

Background/ Rationale: This document outlines the procedures which will be followed at UVA Health IDS when IP is deemed to require quarantine.

Equipment/Supplies: N/A

Procedure: IP will be placed in quarantine when it is deemed potentially unfit for use.

a. Reasons for being potentially unfit for use include, but are not limited to:
    i. Beyond documented expiration/retest date
    ii. Improper storage conditions (ie, temperature excursion)
    iii. Visible damage or contamination
    iv. Product recall
    v. Sponsor/monitor request

#	Step	Rationale*	Special Considerations*
1	Quarantined IP will be physically separated from viable inventory, and clearly labeled as "Quarantined."	Quarantined IP must not be kept with active inventory	Refrigerated or frozen IP in quarantine will be kept at designated temperature only as space allows. If space is needed, quarantined items will be moved to room temperature storage. Sponsors will be notified if quarantined items are to be moved out of designated temperature.
2	Quarantined IP will be removed from active inventory in Vestigo and designated at "In Quarantine."	Inventory documentation must be accurate at all times	
3	Quarantined IP will be returned to active inventory, returned to sponsor, or destroyed only at the discretion of the sponsor.		Reason for quarantine must be fully resolved prior to return to active inventory.
4	Disposition of IP will be documented in Vestigo.		

**if applicable*

Expected Outcomes	Unexpected Outcomes (Escalate)
• IP will be quarantined when necessary pending sponsor resolution	• IP disposition inappropriate – Contact sponsor

Related Documents: *(if applicable: policy, guideline)*

- UVA IDS SOP – Receipt and Storage of Investigational Product (IP)
- UVA IDS SOP – Destruction of Disposition of Investigational Drug Products in Investigational Drug Pharmacy
- UVA IDS SOP – Establishment of Vestigo as Exclusive IDS DARF
- UVA IDS SOP – Out-of-range Temperatures in the Investigational Drug Pharmacy
- UVA IDS SOP – Expiration Date Management of Investigational Drug Product

External References: *(if applicable: regulation, law, certifying body, specialty organization)*

- Joint Commission Standard MM.06.01.05
- 21 CFR 312.59 – Disposition of unused supply of investigational drug.
- 21 CFR 312.62(a) – Investigator recordkeeping and record retention.

- ICH GCP 4.6.3
- ICH GCP 5.14.3
- ICH GCP 5.14.4(b,d)

REVISION HISTORY				
Version	Reason (new, cyclical, external)	Relevant Reviewers	Approved By	Date of Approval
1.0	New		IDS Pharmacists	5/2013
2.0	Cyclical		IDS Pharmacists	11/2016
3.0	Cyclical	IDS Pharmacists	Matt Jenkins	10/6/2020