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Standard Operating Procedure		
RECEIPT AND STORAGE OF 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 general receipt and storage of IP within Investigational Drug Services (IDS) at University of Virginia (UVA) Health*		

The supervision and monitoring of investigational agents are the responsibilities of the primary 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 primary 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 received.

Equipment/Supplies: N/A

Procedure: IP managed by IDS will be received per protocol, and will be stored in compliance with the protocol, local, state, and federal regulations, and practice standards of the American Society of Health-system Pharmacists (ASHP) and The Joint Commission. Additional detail may be found in more specific UVA IDS SOPs, as listed below.

#	Step	Rationale*	Special Considerations*
1	IP will be electronically logged into Vestigo and any other systems (eg, IXRS) as required immediately upon receipt	Inventory documentation must be accurate at all times	All relevant IDS staff (pharmacists and technicians) must be given access to required IXRS systems.
2	IP will be placed into appropriate storage conditions immediately		
3	Shipping/packing slips will be scanned and saved electronically on a shared drive and within Vestigo.		.
4	When applicable, shipping temperature documentation will be completed per instruction sent with the temperature recording device.		Temperature monitoring devices will be discarded following required documentation of shipping conditions unless otherwise clearly marked for the temperature monitoring device to be returned.

**if applicable*

Expected Outcomes	Unexpected Outcomes (Escalate)
• IP will be received and stored per protocol	• Shipping or storage variances – Contact sponsor

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

- 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 – Transporting Investigational Agents from Main Campus IDS Pharmacist to Locations Within the Medical Center
- UVA IDS SOP – Transporting Investigational Agents from Main Campus IDS Pharmacist to Off-Grounds Clinics

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	6/2017
2.0	Update		IDS Pharmacists	1/2020
3.0	Update/Reformat	IDS Pharmacists	Matt Jenkins	10/6/2020
4.0	Cyclical	IDS Pharmacists	Joseph Aloi	10/2024