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Standard Operating Procedure		
ESTABLISHMENT OF VESTIGO® AS EXCLUSIVE IDS DARF SOURCE		
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 establish single-source drug accountability records for IDS at 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: Drug Accountability Records Forms (DARF) are required inventory documentation for investigational product (IP).

Equipment/Supplies: Vestigo® (McCreadie Group, Inc)

Procedure:

A: Vestigo® is the exclusive DARF at UVA Health IDS.

1. IDS will not keep duplicate records for any trials; sponsor-provided DARFs will not be completed.
2. Vestigo® meets all FDA and National Cancer Institute (NCI) guidelines for data capture and audit requirements.
3. Monitors may access Vestigo® DARFs electronically during monitor visits.

B. Vestigo records that are kept electronically are readily accessible per regulatory requirement until sponsor determines study documents may be destroyed.

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

- Joint Commission Standard MM.06.01.05
- 21 CFR 312.62(a) – Investigator recordkeeping and record retention.
- ASHP Guidelines on Clinical Drug Research

REVISION HISTORY				
Version	Reason (new, cyclical, external)	Relevant Reviewers	Approved By	Date of Approval
1.0	New		IDS Pharmacists	6/2010
2.0			IDS Pharmacists	9/2012
3.0			IDS Pharmacists	11/2016
4.0			IDS Pharmacists	2/2017
5.0	Cyclical	IDS Pharmacists	Matt Jenkins	10/6/2020