Content Owner: IDS Pharmacy
Pharmacist – Investigational Drug Services

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17Oct2024

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 (electronic or paper) will not be completed.
2. IDS interaction with any sponsor Interactive Response Technology (IRT) platforms will be limited to receipt of IP.
    i. For blinded studies, assignment of product *may* be completed by IDS staff. Vial assignment will be completed only when necessary to maintain the blind and only for treatment purposes. This will be reviewed and approved on a protocol-by-protocol basis by IDS Pharmacist if requirements are met.

3. IDS will not complete Electronic Date Capture (EDC) entries.
4. IDS will not sign sponsor forms that duplicate data generated from Vestigo®.
5. Vestigo® meets all FDA and National Cancer Institute (NCI) guidelines for data capture and audit requirements.
6. Monitors may access Vestigo® DARFs electronically during monitor visits.
7. Sponsor employees and sponsor delegates are bound by the confidentiality clause in the contract signed between all sponsors and UVA. Those contracts are managed by UVA School of Medicine Clinical Trials Office.

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
- National Comprehensive Cancer Network investigational drug service consensus recommendations

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
6.0	Cyclical	IDS Pharmacists	Joe Aloi	10/17/2024