# Standard Operating Procedure

## Establishment of Vestigo® as Exclusive IDS DARF Source

### Scope:
- Dept./Unit/Clinic: Investigational Drug Services, Pharmacy
- Service Line: Investigational Drug Services, Pharmacy
- 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.
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Always refer to the official online version. Printed copies are for temporary reference only.