Department of Pharmacy Services

STANDARD OPERATING PROCEDURES (SOPs): ESTABLISHMENT OF VESTIGO® AS EXCLUSIVE IDS DARF SOURCE

Policy: Investigational Drug Services (IDS) at the University of Virginia Health System (UVAHS) is responsible for establishing standard procedures for the appropriate control of investigational drugs and biologics used in human subject research, including establishment of a drug accountability system. 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 the American Society of Health-system Pharmacists (ASHP) and The Joint Commission.

Procedure:

A. Vestigo® is the exclusive Drug Accountability Record Form (DARF) at UVAHS 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 both while the study is open and when the study is closed.

Applicable Regulations & Guidelines:

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

Implemented: 06/2010
Revised: 09/2012, 11/2016, 2/2017