Investigational Drug Service
Huntsman Cancer Hospital
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STANDARD OPERATIONAL PROCEDURE (SOP)
ESTABLISHMENT OF VESTIGO® AS EXCLUSIVE IDS DARF SOURCE

Purpose

This standard operational procedure describes exclusivity of Vestigo® as the DARF source for drug accountability for the Investigational Drug Service (IDS) Program at University of Utah Health

Definitions

A. **DARF:** drug accountability record form
B. **Drug accountability:** Drug storage, handling, dispensing, and documentation of administration, return and/or destruction of the drug.
C. **Investigational drug service:** A function of the Department of Pharmacy and provides support to ensure the safety and efficiency of trials at University of Utah Health that use investigational product(s)/investigational drug(s). Pharmacy personnel that perform investigational drug accountability at UUH satellite locations approved for conducting research protocols are considered an extension of the IDS.
D. **Monitor:** an individual who observes each trial site to ensure that the standardized operation procedures for the trial are being followed, reporting and managing any deviations from the investigation plan as they occur. A monitor may work directly with the sponsor company of a clinical trial, as an independent freelancer or for a contract research organization. Monitors may also do the following functions related to clinical research studies; ensure compliance with the clinical trial protocol, check clinical site activities, make on-site visits, review case report forms and communicates with clinical research coordinators.
E. **Vestigo®:** A 21 CFR Part 11 compliant electronic accountability software application designed specifically for investigational pharmacy use and utilized by University of Utah Heath IDS. Refer to www.mccreadiegroup.com/vestigo/ for additional information.

Description

A. Vestigo® is the exclusive Drug Accountability Record Form (DARF) at University of Utah Investigational Drug Service
    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 use Vestigo® to review DARFs electronically; copies of DARFs will not be printed, emailed or mailed to monitors; access to Vestigo® for monitors will only be made available during on-site monitor visits, during which they may save or email themselves an electronic copy of the DARFs
    4. Vestigo® will also be used for all other drug accountability documentation including:

a. Master patient lists for each study
b. Receipt of shipments
c. Expiration dates of IP
d. Patient and IP dispensing information
e. Inventory counts
f. Returns
g. Destruction
h. Quarantined items
i. Monitor visits