Department of Pharmaceutical Care
University of Iowa Hospitals and Clinics

Section	Research
Related Policy	None
Operating procedure	**RES-NP010**

INVESTIGATIONAL DRUG DOCUMENTATION IN VESTIGO

Definitions:

A. **DAR:** Drug accountability record.
B. **Drug accountability:** Drug storage, handling, dispensing and documentation of preparation, return or destruction.
C. **Vestigo:** A 21 CFR Part 11 compliant electronic accountability software application designed specifically for investigational pharmacy use and utilized by the University of Iowa Investigational Drug Service (IDS) pharmacy. Refer to www.mccreadiegroup.com/vestigo/ for additional information.
D. **Certified copy:** A copy of the original information that has been verified, as indicated by a dated signature, as an exact copy, having all the same attributes and information as the original.

Description:

Vestigo is the Drug Accountability Record (DAR) at the University of Iowa for the majority of studies. Some studies may remain on paper at the discretion of the IDS staff (e.g., 24/7 studies).

1. The IDS pharmacy will not keep duplicate records for any trials: sponsor-provided DARs will not be completed.
2. Vestigo meets all FDA and National Cancer Institute (NCI) guidelines for data capture and audit requirements.
3. Monitors will use Vestigo to review DARs electronically: copies of DARs will not be printed, emailed, or mailed to monitors. Access to Vestigo for monitors will be made for the day of their scheduled visits (onsite or remote) during which they may save or email themselves an electronic copy of the DAR.
4. Vestigo will also be used for the following drug accountability or documentation:
   a. Facility level documents
      - Monthly temperature documents
      - Yearly Temperature Device Calibrations
      - Other information pertaining to all studies/IDS operations as defined appropriate by IDS staff (e.g., freezer defrost, part replacement)

   b. Protocol level documents
      - Master patient lists
      - Receipt of shipments
      - Expiry information
      - Patient and investigational drug dispensing information

- Inventory Counts
- Returns
- Destruction
- Monitor Visits
- Pharmacy Manuals and training *
- Protocols
- IRT transaction documents
- Unblinded monitoring letters *
- Preparation worksheets
- Temperature Deviation Documents
- Other pertinent study information as defined appropriate by IDS staff

*Upon implementation of this SOP, any new study added to Vestigo will have these documents included.

5. IDS will maintain a share file unique to each study for storage of electronic documents. These files can be identified by the Principal Investigator as well as the study number. The following documents may be stored in these share files: protocols, investigator brochures and study communications. These files will also be the secondary storage location for wet ink documents that are uploaded to Vestigo.
6. Per 21 CFR Part 11, certified copies of original wet ink signatures including but not limited to shipping documents, investigational drug preparation forms, pharmacy manual acknowledgements, notes to file and other information as defined appropriate by IDS staff will be maintained in Vestigo.
7. Quality checks of the following documents in Vestigo will be performed by IDS staff: shipping documents, expiry memo updates, Interactive Response Technology (IRT) transaction documents and investigational drug preparation forms.
8. Vestigo has a full daily backup that is transferred to a second data center for recovery purposes. Hourly backups of changed data occur throughout the day. Once a month, the full back up is archived for permanent storage. In the event of a Vestigo unscheduled down time, dispensing will be documented within 24 hours of Vestigo coming back online. The documentation will be entered as a late entry, as indicated, depending on the duration of the downtime.