



Investigational Drug Services

Main Hospital IDS

UVA Main IDS Pharmacy
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Cancer Center IDS

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Scheduling Visits

- Appointments should be made at least 2 weeks in advance if possible and will not be allowed with less than 3 business days advance notice
- See Pharmacy Appointments SOP

Monitor Information

Drug Accountability

- Vestigo is our exclusive drug accountability source in IDS
- IDS will grant monitors access to Vestigo the day prior to their visit. You will receive an email with login information.
- "Check off" transactions that were reviewed in the monitor review section of Vestigo.
- Document which items are authorized for destruction or return to sponsor
- After the visit, the Vestigo session will be closed and your account will be deactivated until your next visit.
- See Vestigo Protocol Reviewer Guide for further information
- See 'Establishment of Vestigo as exclusive IDS DARF source' SOP for accountability documentation details
- IDS Interaction with IRT platforms is limited. See SOP for details.

Drug Destruction

- IDS will provide certificates of destruction upon request
- UVA approved third party vendor will be used for incineration of IP.
- See SOP for Destruction of Disposition of Investigational Drug

Site Initiation Disclosure:

- IDS will provide specific documentation of procedures at SIV

Temperature Records

- Temperatures are recorded every 15 minutes using the Hampshire device
- Staff receive alerts through email, pager, and telephone
- Temperature records will be emailed to the monitor for the requested date range
- Temperature documentation includes daily max/min and daily average
- Further detail will be provided in the event of an excursion

Equipment

- Calibrated temperature devices include Room Temperature, Refrigeration (2-8°C), Freezers including -20°C and -80°C
- USP 797 and 800 Compliant Clean Rooms
- Biosafety Level 1 & 2 designated compounding area
- Capsule Compounding

Record Retention and Storage

- UVA IDS maintains all physical closed records on site for up to 1 year.
- After 1 year, all physical files are transferred to a UVA contracted off-site facility,
- Electronic and physical records are maintained until authorization to destroy has been obtained from the protocol owner/sponsor.





UVA Site Initiation Visit Disclosure Form

The information below on this form is being provided to the sponsor at the site initiation visit to establish a clear understanding of the University of Virginia Investigational Drug Service's key policies and procedures.

- Form provided to sponsor representative.
- Find the following SOPs on the web at :
<https://www.medicalcenter.virginia.edu/pharmacy/investigational-drug-services/information-for-monitors-sponsors/>
 - Pharmacy appointments
 - Drug destruction
 - Vestigo as only DARF
 - Temperature monitoring
 - IP Transport
 - Expiration date management
 - Handling of quarantined IP
 - Any additional SOPs can be requested and will be forwarded as necessary
- All temperature data will be available to monitor in Vestigo or available upon request.
- IDS Pharmacists may be listed on the Delegation Log and any pharmacist involved in the dispensing of the study drug will sign off on UVA training log.
- Hazardous designation of study drug is requested at SIV; if undetermined, study drug will be handled as hazardous using standard precautions (i.e. CSTD).