



# Investigational Drug Services

## Main Hospital IDS

UVA Main IDS Pharmacy  
Lane Road | Loading Dock | Rm G541  
Charlottesville, VA 22908  
Phone: 434.982.1048  
Fax: 434.982.2900

### Contacts:

Amy Adams, Pharm.D., CCRP  
APA4N@virginia.edu  
Kara Thornton, Pharm.D., MEd  
KRP4H@virginia.edu  
TraDonna Ownby, CPhT  
TLO7M@virginia.edu  
Sandra Seay, CPhT  
SSS8B@virginia.edu

## Cancer Center IDS

UVA Cancer Center IDS Pharmacy  
1240 Lee Street | Room 4326  
Charlottesville, VA 22903  
Phone: 434.982.5385  
Fax: 434.243.7394

Email: [clpharmacyec4idservices@hscmail.mcc.virginia.edu](mailto:clpharmacyec4idservices@hscmail.mcc.virginia.edu)

### Contacts:

Lauren Benusa, Pharm.D., CCRP  
LC7HV@virginia.edu  
Kyle Luedtke, Pharm.D., BCPS  
KL5RM@virginia.edu  
Jovan Williams, Pharm.D., BCPS  
IJW5G@virginia.edu  
Michele Campolieto, PharmD., BCPS  
MC4BF@virginia.edu  
Sejla Smajic, CPhT  
SS4YN@virginia.edu  
Shanel Tibbs, CPhT  
AST4D@virginia.edu

## 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

### We're on the Web!

<https://www.medicalcenter.virginia.edu/pharmacy/investigational-drug-services>

## Monitor Information

### Drug Accountability

- Vestigo is our exclusive drug accountability source in IDS
- Monitor must bring his/her own laptop to the visit
- 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 Vestigo Implementation as Exclusive IDS DARF Source SOP

### Drug Destruction

- IDS will provide certificates of destruction upon request
- Incineration facility: Ross Incineration Services, 36790 Giles Road, Grafton, OH 44044
- See SOP for Destruction of Disposition of Investigational Drug Products in Investigational Drug Pharmacy

### Site Initiation Disclosure:

- IDS will provide specific documentation of procedures at SIV
- This form will be signed off by sponsor/protocol owner representative
- A copy will be kept on file.

### 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 and a liquid nitrogen tank.
- USP 797 Compliant Clean Rooms
- Biosafety Level 1 & 2 designated compounding area
- Capsule Compounding

### Record Retention and Storage

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



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## UVA Site Initiation Visit Disclosure Form

UVA IRB #: \_\_\_\_\_ Site #: \_\_\_\_\_

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

- Introduction form reviewed with sponsor representative.
- Find the following SOPs on the web at :  
<https://www.medicalcenter.virginia.edu/pharmacy/investigational-drug-services>
  - Pharmacy appointments
  - Drug destruction
  - Vestigo as only DARF
  - Temperature monitoring
  - IP Transport
  - Expiration date management
  - Handling of quarantined IP
  - Any additional SOPs to be forwarded as necessary: \_\_\_\_\_
- All temperature data will be emailed to monitor upon request.
- IDS Pharmacists will be listed on the Delegation Log and any pharmacist involved in the dispensing of the study drug will sign off on UVA training log in the front of the binder.
- Where will Delegation Log be kept (pharmacy or study team)? \_\_\_\_\_
- Investigational Product expiration management description:  
\_\_\_\_\_
- Hazardous designation of study drug is requested at SIV; if undetermined, study drug will be handled as hazardous using standard precautions (i.e. PhaSeal): \_\_\_\_\_

Sponsor Representative Signature: \_\_\_\_\_ Date: \_\_\_\_\_

UVA IDS Pharmacist Signature: \_\_\_\_\_ Date: \_\_\_\_\_

