

Introduction to IDS

VCU Health Investigational Drug Services (IDS) provides RESEARCH-ONLY pharmacy services and operates two primary locations on Medical College of Virginia (MCV) campus, as well as study dispensing oversight and guidance for satellite pharmacy locations. Please note, satellite pharmacy locations only provide IDS services under the oversight of the Main IDS if *prospectively approved* by IDS to ensure study logistics are feasible. See pharmacy locations at the end of this document for further details.

All IDS staff are licensed by the Virginia Board of Pharmacy, have completed CITI Good Clinical Practice (GCP) and Human Subjects Research (HSR) trainings, and have considerable knowledge managing study drug protocols. VCU Health IDS has facilitated drug services for all types of studies, including government-sponsored, industry and in-house investigator initiated. Our preparation capabilities include most types of sterile and non-sterile compounding, including complex biohazardous and hazardous agent preparations. Lastly, we are able to help design randomization schemes, dispensing logistics and have considerable experience with maintaining trial blinding.

Staff Directory

IDS Manager

Mary Pak, PharmD

mary.pak@vcuhealth.org

IDS Pharmacists

Henly Deutsch, RPh

henly.deutsch@vcuhealth.org

Brittina Powers, PharmD

brittina.powers@vcuhealth.org

Christina Ouellette, PharmD

christina.ouellette@vcuhealth.org

Amalea Huie, PharmD

start date of 3/27/23

amalea.gray@vcuhealth.org

Ghazaleh Mostafaei, PharmD

start date of 3/4/24

ghazaleh.mostafaei@vcuhealth.org

IDS Pharmacy Technicians

Nikima Campbell, BS, CPhT

nikima.campbell@vcuhealth.org

Paty (Mary) Weiss, CPhT

mary.weiss@vcuhealth.org

Princess Johnson, CPhT

princess.johnson1@vcuhealth.org

Zachary Rice, CPhT

start date of 3/5/23

zachary.rice@vcuhealth.org

Due to rotational staff coverage, our group emails are the BEST first method of contact for operational communications:

investigational.drug@vcuhealth.org (For Main IDS or SPP studies)

OR AOP.IDS@vcuhealth.org (For AOP IDS or SP9000 studies)

Emergency ONLY Pager: (804) 628-9000; ask operator to page 9089 (Investigational Pharmacist On-Call)

Latest Updates

The IDS is split between two primary locations, Main IDS and AOP IDS. Please see locations section below for shipping details. Virtual video tours for both our locations are posted [here](#).

- Please ensure that you prospectively communicate requested IDS service location by study and that all applicable regulatory documents including shipping address match or are updated to reflect that request.
- If you are not sure whether the desired location is logistically feasible, please consult with IDS team for a study specific plan based on inventory, preparation, and administration needs.
- Please note: Location and preparation logistics for biohazardous preparations will need special consideration and advanced communication.

VCUMC IDS only accepts REMOTE monitoring visits with access available through Vestigo. See *Scheduling Visits* section below for additional details.

Additional instructions/guidance are available at the end of this guide regarding:

- Self-requesting appointments in Vestigo
- Physical review options when visualization of Investigational Product (IP) is required

Once you log in, Vestigo Verify Training Videos reviewing functionality can be found under the Help Center by searching "video" and watching "Videos for Monitors: How to use Verify." **Additionally, please review Vestigo Help Center for tutorials by topic.**

Due to rotational coverage, we require all primary IDS staff be delegated authority on trials for dispensing related activities at Main IDS and AOP IDS. For any satellite-only trials, we recommend that primary IDS pharmacists be granted access (i.e., IWRS) in case satellite staff are not available and back up assistance is needed.

We strongly recommend that ALL IDS staff have IWRS accounts when applicable per study to prevent potential dispensing delays.

Our IDS SOPs are available as a compressed ZIP file folder by email, upon request.

Key Information for Study Teams & Monitors**Security**

-Restricted access areas with electronic card reader locks, separate keyed drug storage, multiple security cameras

Record Organization

-IDS does not retain physical 3 ring binders and will break down any folders received by shredding contents and saving items not already on file.

-Items such as the protocol, IB, correspondence, packing slips, written procedures, IVRS instructions, dosing worksheets, paper logs, etc. are stored either electronically in Vestigo and/or in a file cabinet in study-specific folders.

-Printed dispensing records are filed together and kept separate from pharmacy site files (PSFs).

-At study close, IDS maintains PSF records. IDS stores its records on site for 6 months, then archives them with Iron Mountain Storage indefinitely (520 East Park Court, Sandston, VA 23150).

-Retrieval requires advanced notice of at least two business days.

-See IDS Record Keeping SOP for further details.

Temperature Records

-Checkpoint/VPx sensors and Viewpoint software are used

-Temperature is measured every 15 minutes, data is saved on secure remote servers

-Email and pager notifications are sent 24/7 to the IDS pharmacist on-call for temperature excursions via an escalating alert pathway

-Temperature documentation includes daily min/max, average, and MKT

-Temperature summaries are uploaded to Vestigo on a monthly basis for monitor review and can be downloaded during remote visits

-Temperature audit logs are reviewed/signed on a daily M-F basis and filed, thus monthly logs uploaded to Vestigo will NOT be signed.

-IDS will NOT maintain separate paper temperature logs or email monthly temperature logs to monitors.

Scheduling Visits

-Monitors must self-request remote pharmacy access appointments in Vestigo, see end of this guide for further details.

-IDS does NOT allow in-person monitoring visits at pharmacy locations.

IDS can coordinate with study team for any in-person monitoring needs, see end of this guide for further details.

-IDS staff will periodically review appointment requests and will accept up to 3 remote monitor visits per location per day.

-Monitoring visits should be requested with advanced notice to ensure a slot is available and that IDS staff have time to review and accept the request.

-Same day access will only be granted for extenuating circumstances.

-For monitors to be able receive login and place appointment requests, IDS requires all monitors to complete our Vestigo E-signature form once per study and email the signed form to the applicable group email, along with the date for initial access and study name to associate the monitor to.

-IDS will grant monitors limited duration access to Vestigo for each visit (typically 24 hours on date requested).

Documentation - Staff Records and Training

-Current signed CVs, GCP, HSR, and licenses are maintained in OnCore CTMS for study coordinator access AND Vestigo for monitor access.

-IDS training logs are available for monitors to download in Vestigo.

-See IDS SOPs for further details on IDS policy surrounding general and study specific trainings including what sponsor training documentation IDS team is able to complete.

-It is against IDS policy to complete duplicative trainings and training documentation.

Chain of Custody

-All pickups and deliveries for dispensed investigational product are documented with receiving study staff signature and date on paper receipts.

-Study coordinators may request to be paged or called when a study medication is ready for pickup.

Drug Accountability

-Vestigo is our SOLE drug accountability source; **it is against policy for IDS to perform transactions in IWRS other than shipping receipt.** Any IDS transactions in IWRS will result in extra charges for time incurred if they cannot be waived or performed by study team

Destruction/Return of IP

- **Effective January 1, 2024 for all NEW studies, IDS will implement a two team member automatic destruction process for all used IP and patient returns.**

Current studies will be given the option to continue with existing handling or update to new handling after their next monitoring visit. **See IDS Destruction SOP for further details.**

Authorizing action in Vestigo: Monitors must authorize unused/expired items for destruction or return to sponsor, if blanket permissions have not been given.

-Once items are authorized in Vestigo by monitor, IDS will proceed with the destruction (or return). If a Certification of Destruction (CoD) is required, the monitor must email IDS to request one.

Vestigo Action Items vs. Comments:

-Monitors may mark items as 'Action Item' in Vestigo but this will require follow up monitor acknowledgement after IDS responds in order to complete the visit.

-'Visit Comments' will display to IDS however IDS is unable to comment in response; if reply is needed please email instead.

-Items requiring destruction will be placed in RCRA hazardous storage containers, which are collected, manifested, and shipped off site for incineration. **See Drug Destruction Memo for further details.**

Please note: all IDS locations and satellites are subject to hours update, depending on operational needs and staffing capacity; please see Holiday Observance Memo for IDS Holiday Closures*

Investigational Drug Services *Primary* Pharmacy Locations

VCU Health Main IDS

Hours: M-F 9:00-5:00 pm

Phone: (804) 828-7901

Fax : (804) 827-0181

Shipping Address

VCU Health Main IDS

1250 E. Marshall St.

Main Hospital, Basement, Room B-300

Richmond, VA 23298

VCU Health Adult Outpatient Pavillon (AOP) IDS

Hours: M-F 9:00-5:00 pm

Phone: (804) 628-7180

Fax : (804) 916-2090

Shipping Address

VCU Health AOP IDS

1001 E. Leigh St.

AOP, 5th Floor, Room 5-182

Richmond, VA 23219

Investigational Drug Services *Satellite* Pharmacy Locations

VCU Health NOW Infusion Pharmacy at Short Pump Pavilion (SPP)

Hours: M-F 7:30-4:00 pm

Phone: (804) 364-6625

Fax: (804) 364-6669

-Staffing coverage by Infusion Pharmacy Team

Shipping Address

VCU Health Short Pump Pavilion Pharmacy, Rm 2600

11958 West Broad Street

Henrico, VA 23233

Staff Directory

Pharmacist

Lauren Knick, PharmD (lauren.knick@vcuhealth.org)

Pharmacy Technicians

Jill Woods, CPhT (jill.woods@vcuhealth.org)

Oksana Sachinskaya, CPhT (oksana.sachinskaya@vcuhealth.org)

VCU Health Stony Point (SP9000) Pharmacy

Hours: M-F 8:30-5:00 pm

Phone: (804) 327-3054

Fax: (804) 327-3067

-Staffing coverage by Infusion Pharmacy Team

Shipping Address

Please contact IDS if needed.

Staff Directory

Pharmacists

Rebecca St. Clair, PharmD

(rebecca.st.clair@vcuhealth.org)

Patrice Norrell, RPh

(patrice.norrell@vcuhealth.org)

VCU Health CCH9 Satellite Pharmacy

Critical Care Hospital Building Room 9-303; Phone: (804) 325-2793*

All shipments and external communications to come through Main IDS/IDS Pharmacist On-Call

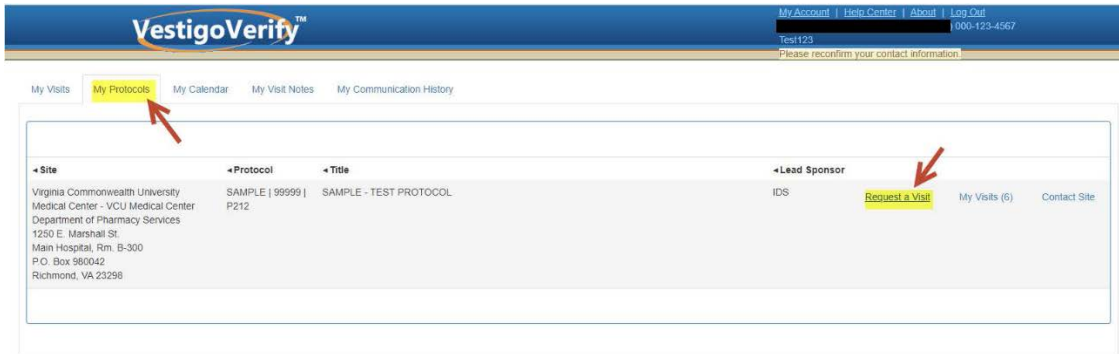
Hours: 24/7 coverage (inpatient ICU satellite)

-Designated for afterhours dispensing for Main IDS when logistics are **prospectively agreed upon**

-Satellite of VCUHS Main Inpatient Pharmacy; rotational staffing by Inpatient Pharmacy Team

Instructions for Self-Requesting Remote Visit Appointments within Vestigo

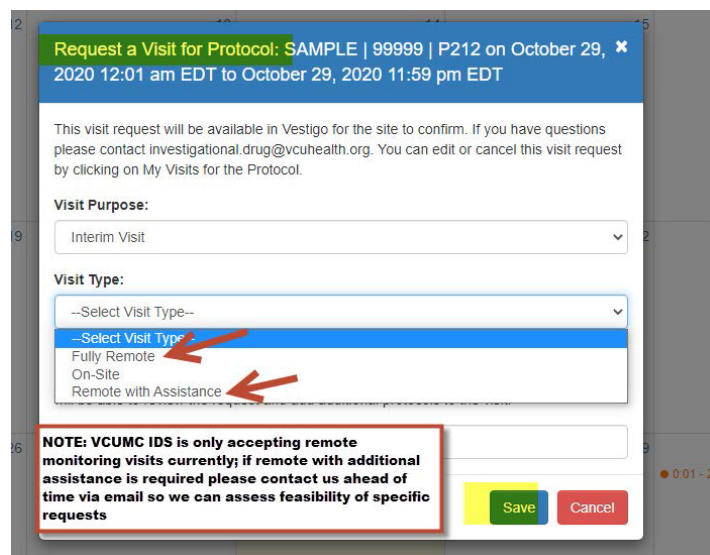
Vestigo allows monitors to request monitoring visits, once associated on the protocol by IDS Team.
See screenshot below detailing how to create a request:



In order to request an appointment in Vestigo:

- You must already have or be granted a Vestigo login
- IDS staff must have already received your signed Vestigo E-signature form (to be completed *per study*; available in Vestigo facility documents or by email)
- IDS staff must have already received communication notifying that monitor will serve in unblinded CRA role for that specific protocol so we can associate you as a monitor for that study in Vestigo

Please note, VCUMC IDS is ONLY accepting remote monitoring visits at this time. We periodically review appointment requests and will accept up to 3 monitor visits per day per facility location. Monitoring visits should be requested with advanced notice to ensure a slot is available and that IDS staff have time to review and accept the request. VCUMC IDS typically grants protocol access for a 24 hour period.



Investigational Product Hand-off Process for Physical Review at In-Person Monitoring Visits

Please note, because Investigational Pharmacy locations are VCU Health System restricted access areas, IDS does NOT allow in-person study or monitoring visits. Virtual video tours for both our locations are posted [here](#).

In-person visits can occur on VCU Campus property, which allows IDS to coordinate with study team for any in-person needs.

- **With advanced notice to IDS, the study coordinator can check out quarantined product and subject returns (current studies only; studies initiated after 1Jan2024 will have automatic destruction of subject returns and used IP) from IDS for physical review by monitor.** Please note, study coordinator or other study team member must facilitate pick up and return from IDS to the location of the monitor.
- IDS requires returned and quarantined IP to be reviewed, processed/authorized in Vestigo by monitor at time of check out and at least quarterly.
 - **IDS will NOT continue to hold the return or quarantined item on our shelf after monitor review (for example until end of study), in order to prevent storage capacity issues.** Per our Destruction SOP, IDS will proceed with destruction if no response/resolution within 90 days of routine accountability.
- Product hand-off details including date and time of check out/return, and name of study coordinator it was handed off to will be documented on our internal IDS Chain of Custody Hand-Off Log
- **All product must be returned to IDS by the study coordinator for final disposition documentation on the study's Accountability Log in Vestigo.**

IDS would like to share the following additional details regarding return and destruction:

- **If reviewing and authorizing for onsite destruction by IDS staff** (quarantined IP, subject returns – excluding new studies, and/or remaining inventory at close-out): **Monitor must mark each item as authorized for destruction in Vestigo and product must be returned to IDS for destruction completion.** IDS can email a Vestigo generated Certificate of Destruction if sent an email request after the destruction action is completed.
- **If reviewing and authorizing for return to depot** (quarantined IP, subject returns, and/or remaining inventory at close-out): **Monitor must mark each item as authorized for return to sponsor in Vestigo; product must be returned to IDS along with prepaid label and packaging materials.** The return shipment will be finalized/packaged by IDS (including removal of patient labels), with send out recorded by IDS in Vestigo and picked up from IDS area.