Investigational Drug Service

The Tampa General Hospital (TGH) Investigational Drug Service operates as part of the TGH Inpatient Pharmacy. We are located on the 2nd floor of the main hospital in room F220. Research medication is stored separately and securely (locked cabinets or refrigerators/ freezers) within the Inpatient Pharmacy. Temperature within all storage areas are continuously monitored by inhouse wireless system (TempTrack). The Inpatient Pharmacy may only be entered by badge access. The area is also monitored by security cameras.

The IDS staff includes:
J. Michael Hayes, Pharm.D.
Veroniya Winkfield, CPhT
Thi Nguyen, Pharm.D.

IDS staff may be contacted by email researchpharmacy@tgh.org or by calling (813) 844-4996.

IDS general hours are Monday-Friday 0730-1600. Staff may be available at other times as necessary. The TGH Charge Pharmacist may be contacted after normal business hours at (813) 310-0432.

IDS shipping address:
Investigational Drug Service
Tampa General Hospital
Inpatient Pharmacy, Room F223-C
1 Tampa General Circle
Tampa, FL 33606

All drug accountability will be performed using the Vestigo system. TGH IDS will not utilize sponsor provided forms for drug accountability. For more information, please see "Investigational Drug Accountability."

TGH IDS will not save any used or punctured vials, drug packaging, or any patient returned items. IDS will document all returns, and will provide accountability records as requested. For more information please see "Retention of Punctured Vials and Hazardous Materials."

Tampa General Hospital
POLICY & PROCEDURE

__ Organizational _X_ Hospital __ Ambulatory Services __ Departmental

Title: Investigational Drug Accountability		
Original Issue Date: 11/1/2017 Review Date: 6/13/2022 Revision Date: 6/15/2021	**Number: PHRM 117**	**Page:** 1 of 2
Originating Department: Pharmacy	**Approved by**: Kelly Cullen – EVP & Chief Operating Officer	

POLICY:
All investigational drug receiving, dispensing, transferring, disposition and destruction will be documented in the electronic drug accountability record form (eDARF) in Vestigo®.

PROCEDURE:
1. The Investigational Drug Service will maintain electronic Drug Accountability Record Forms (eDARFs) utilizing the Vestigo® system that captures the essential elements as common practice standards:
   Elements for the DARF:
   - Institution Name
   - Investigator Name
   - Protocol Title and Number
   - Agent Name, Strength, and Formulation
   - Dispensing Location
   - Recorder date and name
   - Expiration/ Retest dating if available
   - Transactions (receipts, dispensing, transfers, disposition)
     - Receipt
       - Date, Quantity, Lot Number, expiration/ retest if available
     - Dispensing
       - Subject Information, Date, Quantity, Lot Number, expiration/ retest if available
       - Dosing Information
     - Transfers
       - Date, Quantity, Location
     - Disposition
       - Unused Drug Returns and/or Destruction
     - Lot Number and Quantity on Hand

2. Patient-returned medications will be accounted for and destroyed based on institutional practices as described in "Retention of Punctured Vials and Hazardous Materials" policy. Return / used medication units or packaging shall not be retained for monitor review. Packaging and individual dosage units will be inspected for signs of obvious tampering. This inspection will not include the opening of individual capsules or dosage units that will risk exposure to a hazardous substance. Any obvious signs of tampering will be reported to the sponsor. The medication return should be recorded/ reconciled by the IDS study team. Note: A separate

eDARF for waste will **not** be provided. The eDARF serves as documentation for destruction of used vials, however, a certificate of destruction may be provided upon request.

3. If a study uses more than one supplied agent or more than one strength or formulation of the same agent, each agent will be stored separately and an eDARF will be prepared for each dosage strength, formulation, and lot by a member of the IDS team.

4. Patient specific Vestigo eDARFs may be maintained for each patient by the IDS team in a placebo-controlled trial unless otherwise directed.

5. Receipts, invoices, packing slips and other study documents (such as certificate of analysis) will be kept with the study specific files or pharmacy binders in the IDS pharmacy. Copies of these forms may be scanned to the Vestigo® system.

6. **No sponsor-based forms will be utilized for drug accountability.** Duplicate accountability logs will **not** be maintained by the IDS staff.

7. Drug accountability will only be maintained for the investigational drugs supplied by the sponsor or procured by the pharmacy on behalf of the sponsor for use on the clinical research trial (these are agents provided at no cost to the patient). IDS will not provide lot numbers or expiration dates to sponsors for commercial agents.

8. Written Pharmacy management approval is required for TGH employees to access Vestigo.

9. Access to Vestigo is limited to only those with a legitimate business need.

10. IDS Pharmacist will create and maintain user access request forms to access Vestigo.

11. Access requests via form supplied by IDS Pharmacist will include at a minimum: TGH user, user's role, user's supervisor or department head, and data owner.

12. Users will be given least privileges required to perform their role in Vestigo.

13. Users will be given access to Vestigo for the least amount of time required to perform their role.

14. User review will be performed on a Monthly/Semi-Annual/Annual schedule.

15. Upon termination, job change, or role change, user access to Vestigo will be immediately revoked.

16. Any user misuse will be reported by IDS Pharmacist to corporate compliance within one business day.

Tampa General Hospital
POLICY & PROCEDURE

__ Organizational _X_ Hospital __ Ambulatory Services __ Departmental

Title: Retention of Punctured Vials and Hazardous Materials

Original Issue Date: 8/01/2018 Review Date: 9/16/2021 Revision Date: 6/1/2019	**Number: PHRM 118**	**Page:** 1 of 1

Originating Department: Pharmacy **Approved by:** David Robbins - Vice President, Professional Services

POLICY:
Investigational new drugs are handled as Hazardous Drugs unless adequate information becomes available to exclude them.[i] All hazardous drug handling will be in accordance with TGH Policy, Hazardous Drug Handling Guidelines.

PROCEDURE:

1. The Investigational Drug Service (IDS) department does not store punctured vials of anti-neoplastics or any investigational products, including packaging, within the pharmacy department. This includes any empty vials or medication returned from prior patient use.

2. These products or packaging will not be retained for sponsor verification of use.

3. All punctured/used vials of anti-neoplastics and used/returned hazardous medications will be discarded in the universal pharmaceutical waste containers immediately after admixture following guidelines created by the Centers for Disease Control, United States Pharmacopoeia (USP) Rule 797, USP 800, and the National Institute for Occupational Safety and Health (NIOSH) Hazardous Alert.

4. IDS will document the receipt of products returned from patients and the destruction of these hazardous substances in accordance with Tampa General Hospital Policy, Investigational Drug Accountability, by use of the Vestigo system. Returned/used medication units or packaging shall not be retained for monitor review.

5.Accountability records will be available upon request.

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[i] Controlling Occupational Exposure to Hazardous Drugs. United States Department of Labor, Occupational Safety and Health Administration. https://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.htm . Accessed Feb 22, 2019.

Tampa General Hospital
POLICY & PROCEDURE

__ Organizational __ Hospital __ Ambulatory Services _X_ Departmental

Title: Disposal / Destruction of Investigational and Study Medications		
Original Issue Date: 10/2006 Review Date: Revision Date: 06/2019	**Number:**	**Page:** 1 of 2
Originating Department: Pharmacy	**Approved by:**	

POLICY:

All investigational/study drugs stored, dispensed, or compounded by TGH pharmacy shall be monitored for expiration dates. The disposal of investigational/study drugs will occur, if approved, will occur as described in this policy.

PROCEDURE:

In the case of drugs expired or nearing expiration/ retest date, IDS Staff will notify the Sponsor promptly of expiring/expired investigational/study drugs.

2. Expired investigational/study drugs will be labeled as "Expired – Do Not Dispense" and segregated from the inventory by a member of the TGH IDS Pharmacy Team.

3. Expired medications must be shipped to or picked up by Sponsor in a timely manner. It is acceptable for Sponsor to request disposal/destruction of expired or unusable drugs by TGH IDS Pharmacy Team.

Disposal/Destruction of Investigational/Study Drugs

4. The PI, study coordinator, or a member of the TGH Office of Clinical Research Regulatory department should notify IDS in writing of impending study close-out.

5. The study monitor should inform IDS in writing of plans for on-site study drug destruction or sponsor destruction.

6. Investigational/study drugs will be stored in the IDS for no longer than 6 months past study closeout date. Medications not picked up by Sponsor or for which shipment has not been arranged, will be destroyed per IDS procedure as outlined below.

7. After reconciliation of inventory and verification of accountability logs, investigational/study drugs will be disposed of as follows:

a. FDA approved medications will be disposed of per standard Department of Pharmacy policy (See Department of Pharmacy Policy, "Outdated and Unusable Medications").

b. Investigational/study drugs, used or unused, will be placed in black receptacles, located within the pharmacy. Black receptacles are for incineration. Environmental Services pick up the secured black receptacles and store them for pick up by a contracted incinerator (SteriCycle Specialty Waste Solutions 314-B West Landstreet Road Orlando, FL 32824). All pick-ups are recorded by

TGH. Proof of incineration is received back and kept on file by TGH. Even though proof of incineration is received, it is impossible to determine the exact bin in which a product was destroyed.

8. All investigational/study drug destruction will be documented in the Vestigo System as per PHRM117. A Vestigo generated Certificate of Destruction may be generated upon sponsor request to document the disposal/destruction.

Tampa General Hospital
POLICY & PROCEDURE

__ Organizational __ Hospital __ Ambulatory Services _X_ Departmental

Title: Investigational Drug Service Blinding Plan

Original Issue Date: 07/ 2022 Review Date: Revision Date:	**Number:**	**Page:** 1 of 3
Originating Department: Pharmacy	**Approved by:**	

POLICY:

To ensure the standardization for blinded and unblinded personnel at Tampa General Hospital / University of South Florida in regard to blinded investigational drug studies. The document also outlines the roles and responsibilities for Blinded and Unblinded Personnel.

BLINDED ROLES AND RESPONSIBILITIES:

All site study staff that evaluate the subject, collect or assess clinical safety and efficacy data, and/or make decisions about the subject's care will remain blinded to the treatment the subjects receive at all times.

1. Blinded personnel **will not** perform any activities related to investigational product receipt, inventory, preparation, dispensation or accountability and will not be able to access any unblinding data/documentation.

2. Blinded personnel will administer the products as received from the pharmacy, maintain masking of the study drug if applicable and perform all direct patient care, including assessments and study treatment decisions.

3. Blinded personnel will ensure all other blinded personnel and patients remain blinded during the entire study.

UNBLINDED ROLES AND RESPONSIBILITIES:

All unblinded personnel must be made fully aware that they should not disclose to the subject, blinded study staff, sponsor, and blinded monitors ANY information that will reveal the subject's treatment (unblinded information). Every effort will be taken to limit the number of unblinded staff at the site.

1. Unblinded pharmacy personnel applies to the entire study and are not specific to a subject. Unblinded pharmacy personnel cannot switch to a blinded study role at any point during the study.

2. Unblinded pharmacy personnel may include the following: Unblinded pharmacists including pharmacy residents on rotation, unblinded pharmacy staff including pharmacy technicians - will perform all activities related to investigational product receipt, inventory, storage (including monitoring temperature), preparation, dispensation or accountability and will be able to access any unblinding data/documentation.

3. Unblinded pharmacy personnel will only communicate with unblinded monitors and other unblinded staff identified by the sponsor.

4. Unblinded personnel are responsible for reporting any study issues related to blinding/unblinding to the proper unblinded contacts within each study.

PROCEDURE:

1. The Primary Investigator, Sub-Investigators, Study Nurses, Study Coordinators, and Pharmacists will receive formal training from the Sponsor and the CRA prior to study start up or at the Site Initiation Visit (SIV). These trainings will be documented and maintained in the e-regulatory system at TGH/ USF. The trained site personnel will then train other study, nursing and/or pharmacy staff concerning the procedures used to blind the study drug. All personnel involved in the study will be informed of which site personnel are designated as blinded. Delegation of responsibilities will be documented in Site Signature and Delegation of Authroity log. After the first patient is enrolled at a site, unblinded personnel cannot switch to a blinded role. If a blinded team member switches to an unblinded role, the team member can no longer perform direct patient care tasks

2. The Pharmacy binder, accountability records, and all unblinded study documents will be maintained in the IDS Pharmacy at TGH in a secure, restricted-access location which is accessible with badge entry only code and is available only to the unblinded study personnel 24 hours/day. These records will be maintained only by unblinded personnel who have received study-specific training. Access to unblinded study documents will be restricted to the unblinded pharmacist(s) and unblinded study CRA(s) or sponsor. Only unblinded IDS staff have access to the Vestigo system.

3. Study drug will be stored in the IDS Pharmacy at TGH in a secure, restricted-access location which is accessible by badge access only and is available only to the unblinded study personnel 24 hours/day. It is off-limits to blinded study personnel. The study drug will be stored per the conditions required by the pharmacy manual with continuous temperature monitoring. Temperature records are recorded and stored via the TempTrak system.

4. After a patient has been consented, evaluated and confirmed to meet all study criteria and the site is ready to initiate study treatment, the unblinded pharmacy personnel will follow sponsor provided direction to retrieve treatment assignment and document assignment in Vestigo.

5. If preparation is necessary, study drug will be prepared in the IDS Pharmacy at TGH in a secure, restricted-access location which is accessible by badge access only and is available only to the unblinded study personnel 24 hours/day. Appropriate time will be allowed before dispensing all IP so as not to break the blind. The area will not be accessible to blinded personnel. Blinded study drug will be labeled by IDS personnel with appropriate label that contains information that will not break blind. For example:

"Drug X or Placebo" or Drug X 10, 20 or 50mg tabs". The IP label will be generated from the EMR or Vestigo system as appropriate.

6. The IDS pharmacist will not be blinded, and will mask the IV infusion bag / syringe if necessary with the cover provided by the sponsor, seal the cover, and apply a blinded label to the cover so that the identification of the study drug solution will not be seen by the blinded study staff or study patients.

- Unblinded personnel will prepare the study drug products.
- Unblinded personnel will perform the blinding of the infusion bag / syringe with masking covers, if necessary.
- Unblinded personnel will generate the blinded label and apply it to the bag or syringe to cover prior to dispensation.

7. If blinded investigational drug requires transportation, IDS or other study personnel will deliver the product while maintaining proper temperature storage conditions.

8. If IV infusion bags need to be blinded with masking covers, the unblinded pharmacist will do so and seal the bag before it leaves the pharmacy for administration. The IV bag, infusion start and stop date, infusion start and stop time, interruptions, and completion are all to be recorded in the electronic medical record (EMR) by the blinded staff who are administering the IV infusion. Documentation from the EMR is retrievable and can be accessed by blinded study staff and/or sponsor representative, as needed. Information in the EMR will not divulge any information so as to break the blind. Masking bag covers will NOT be removed at any time, for any reason and IV bags will be disposed of in the hazardous bins. Oral agents can be returned to the IDS pharmacy for destruction.

9. The personnel who administered the infusion / syringe / oral product will destroy blinded investigational product following site's SOP for destruction and applicable TGH procedures.

10. No unblinding information will be forwarded via email, hardcopy, or verbally communicated to any blinded personnel (including blinded site personnel or blinded sponsor members). All communications will be reviewed for unblinding information by the relevant unblinded personnel sending the communication prior to it being shared with staff outside of unblinded team. All emails will be labeled "Warning unblinded content" in the subject line. Verbal communication between the blinded and unblinded personnel will be kept to a minimum.

11. Unblinded pharmacy staff will report any unblinding events to the appropriate contacts identified by the sponsor, following the sponsor's procedures for reporting.

12. Requests to unblind any doses will not be facilitated by the IDS Team. These requests should be directed to sponsor or medical monitor.

Investigational Drug Service

Standard Products Utilized by Tampa General Hospital Investigational Drug Service

IV Pump

BD Alaris PC Guardrails Unit, Model 8015 and BD Alaris Pump Module, Model 8100

IV Tubing

Filtered: Alaris Pump Module set Low Sorbing 0.2 Micron Filter (1.72 sq. in Low Protein Binding) Roller, Pinch Clamp(s) 1 SmartSite needle-free valve(s) 6" (below pumping segment) from 2-piece Male Luer Lock. Non- DEHP, latex free. 115 inches in length, 26mL priming volume. Fluid Path Sterile. Ref# 10010454

Non-filtered: Alaris pump module infusion set, 2 check valves, needle-free valves at 88 inches and 6 inches from 2-Piece Male Luer Lock, 120 inches in length, 25 ml priming volume. Non-DEHP, latex free. Fluid path sterile. Ref# 11607704

IV Bags

B Braun: Partial Additive Bags (0.9% Sodium chloride, D5W, etc). 50mL, 100mL. Does not contain latex, PVC or DEHP.

B Braun: Excel IV bags (0.9% Sodium chloride, D5W, etc) 250, 500, 1000mL. Does not contain latex, PVC or DEHP.

Baxter: Viaflex plastic containers (0.9% Sodium chloride, D5W, etc) 50, 100, 250, 500, 1000mL. Product contains PVC.

Empty Container

SECURE Empty EVA container. Does not contain latex or DEHP. Various sizes available.

Syringes

Coviden (Monoject) syringes with luer lock tip. 1, 3, 6, 12, 20, 30 and 60mL.

BD syringes with luer lock tip. 1,3,5, 10, 20, 30 and 60mL.

Needles

B-D Precision Glide needles. Various gauges and lengths available.

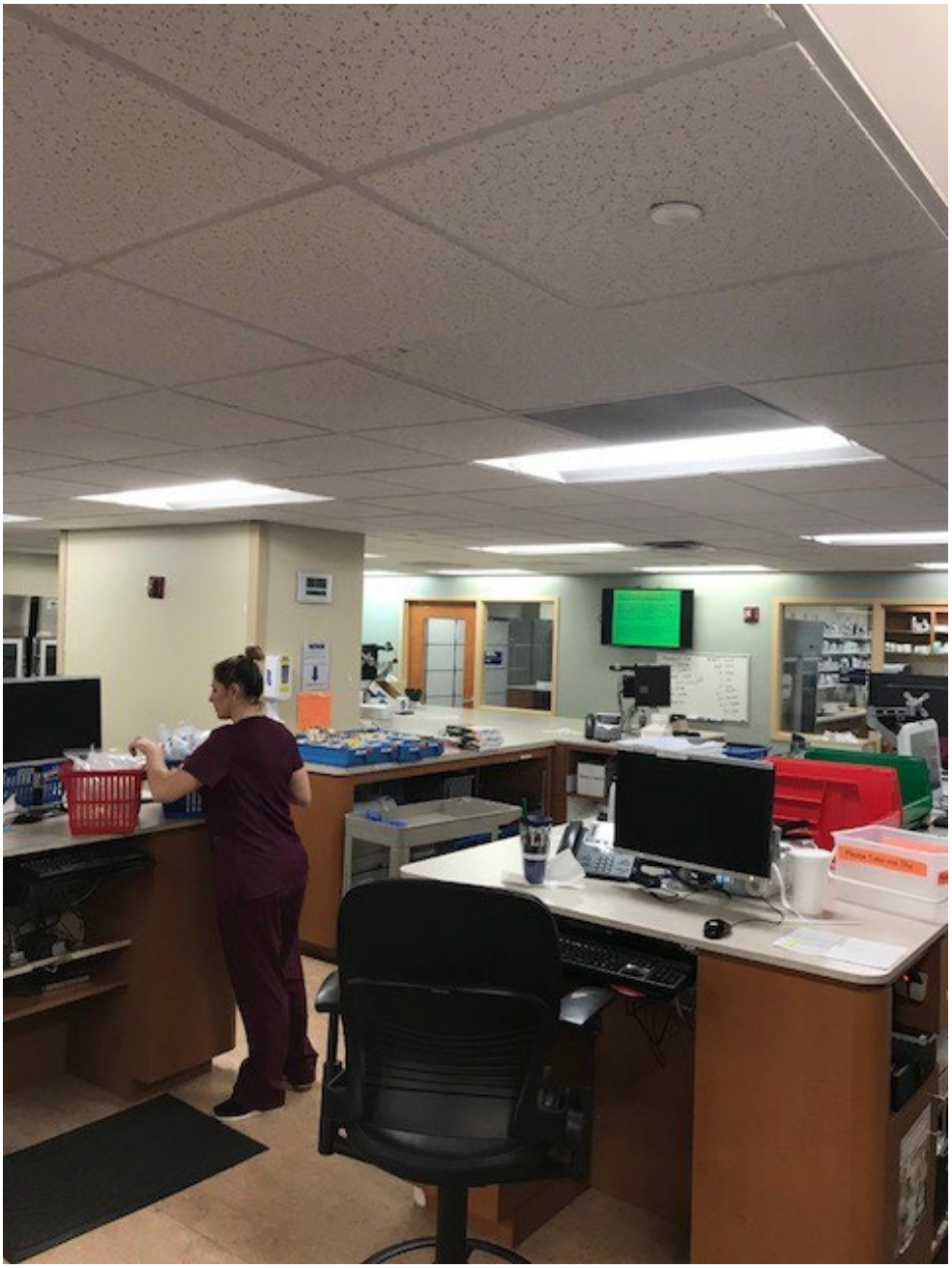
0.2 micron disk filter

B.Braun 0.2 micron non pyrogenic filter. Ref# 415002

Main entrance to the Inpatient Pharmacy. It is located on the second floor of Tampa General Hospital, room F222E

Badge access is required for pharmacy entry.

The Inpatient Pharmacy also has a window with bullet proof glass and a telephone to speak to a member of the staff without providing any access.

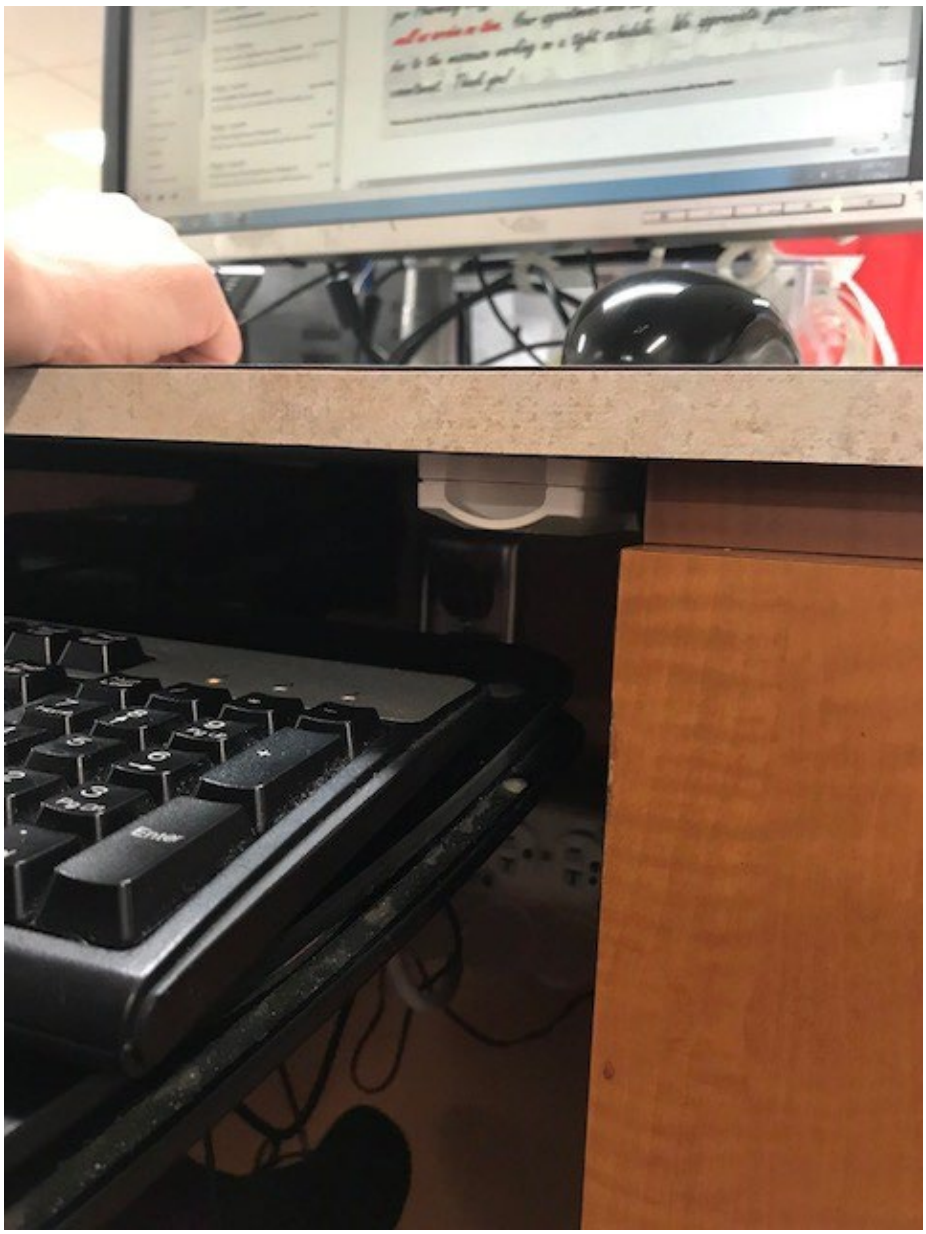


Inside the main area of the Inpatient Pharmacy.

Rolling shelf storage for room temperature medications. The front cover pulls down and is kept locked when not in use.

This room is specifically for IDS use and contains 3 refrigerators, one -20 C freezer and one -80 C freezer. The units are all locked when not in use.

IDS utilizes the TGH USP 797 clean room for sterile product / IV preparation. This located in the main Inpatient Pharmacy.



Panic buttons are located at various workstations throughout the Pharmacy. Tampa General Security is immediately notified and they in turn notify the police. Response is immediate.