Investigational Drug Service
Emory University School of Medicine

IDS Summary for Sponsors

The Investigational Drug Service (IDS) is an integral part of the research process at Emory University. University policy requires that investigators who conduct drug studies use IDS for the management and dispensing of research drugs. To accommodate investigators throughout the system, IDS maintains three pharmacy locations. The primary site is at Emory University Clinic (EUC), with satellite locations at the Hope Clinic and Emory University Hospital (EUH).

Protocol Management/Drug Accountability

All studies in IDS are entered into Vestigo, IDS protocol management software. The system maintains all pharmacy-related study documentation which includes protocol and drug information, all inventory records, patient profiles, randomization assignments, and dispensing and patient return information. Vestigo is used to document drug receipt from the study sponsor or other source, drug dispensing, patient returns and drug return to the sponsor or local drug destruction. The system is fully HIPAA compliant. Investigational drug accountability records (IDARs) are generated by the system and available to sponsors as needed. Study monitors are given temporary and read-only access to Vestigo during site visits. The IDS does not use sponsor-provided manual accountability logs.

Drug Storage

All investigational drugs are stored according to manufacturers' guidelines. The investigational drug label indicates the appropriate temperature range for storage, whether ambient, refrigerated or frozen. IDS maintains refrigerator units for 2 – 8 degrees C storage and freezer units for - 20 and -80 degrees C storage. For ambient storage, IDS maintains shelving units in the EUH and Hope Clinic locations which are marked and designated for drug storage by protocol. IDS maintains a carousel for ambient storage in the EUC location. A narcotic cabinet is available in the EUC and EUH locations for storage of narcotics and other controlled drugs used in investigational drug studies.

Temperature Monitoring

To insure that investigational drugs are stored at the appropriate temperature, IDS utilizes Verisolutions, a continual temperature monitoring system. Sensors are placed in each IDS storage location to monitor ambient temperature and humidity, and refrigerator and freezer temperatures. Temperature ranges for each monitored storage area are indicated below.

Storage Area/Unit	**Normal Range**
Ambient	15 to 25 degrees C
Refrigerators	2 to 8 degrees C
-20 Freezers	-15 to -25 degrees C
-80 Freezers	-70 to -90 degrees C

The Verisolutions system notifies IDS personnel via email and text if a unit goes out of range. If an

excursion occurs, IDS personnel notify sponsors and quarantine IP until it is cleared for use or replaced by the sponsor. Verisolutions completes a calibration process of each probe on an annual basis and provides calibration certificates to IDS. Temperature logs and Calibration Certificates are maintained in Vestigo for monitor review.

All clinic and hospital buildings at Emory have power outlets that are connected to a 5.25 AMP converter for emergency power. All refrigerator and freezer units in IDS are connected to emergency power. In case of a power outage, the emergency system is activated and power is uninterrupted. The system for each building is maintained and checked monthly by Facilities Management.

Limited Access

Only IDS personnel carry keys and have routine access to IDS locations. Due to confidentiality agreements between Emory University and study sponsors, only IDS personnel are allowed to enter the investigational drug storage areas. During routine industry-sponsored monitor visits, IDS personnel pull inventory from the storage locations into the IDS monitor area for the monitor to inspect. All records specific to each study are maintained in the protocol file or Vestigo, and are available for the monitor to review. Copies of all records are available as requested. This includes all drug accountability documentation, temperature logs, documentation of equipment calibration and any other records specific to the conduct of the study.

Delegation of Authority/Training

The Director or designee signature serves as the representative signature for IDS on the sponsor's delegation of authority log. All IDS pharmacists are trained on each protocol at the beginning of the study. Training involves a review of the sponsor provided materials which can include the study protocol, investigator brochure, pharmacy manual, study inventory, and study-specific drug preparation guidelines. Training of pharmacists is documented on the Training Log which is maintained in the Regulatory section of the IDS protocol file or in Vestigo. In addition, IDS conducts and documents retraining of pharmacists if protocol changes related to drug dosing occur and/or if variances occur.

IXRS Access

The majority of industry-sponsored studies involve the use of an Interactive Web Response System (IWRS or IXRS). The IDS role related to IXRS for most studies is to receive shipments and acknowledge them in the system. IDS technicians receive and process all shipments and maintain access to multiple IXRS systems. For double-blind studies in which IDS pharmacists are unblinded, pharmacists access the IXRS system to obtain patient treatment assignments. At study initiation, IXRS access is requested for specific IDS employees.

Transport

IDS personnel use the IDS Chain of Custody (COC) form when study doses are transported via local courier. The form is used to document the protocol#, delivery location, date and time of pickup and delivery, and name and # of the driver. The recipient of the package signs the form and faxes it to IDS to verify that the package was received. In addition, prior to sending a package via commercial courier, IDS confirms with the research coordinator that study personnel are available to receive it. All study doses sent via commercial courier are placed in a container for transport which is sealed with a tamper evident seal. If the package should contain controlled substances,

the outside package will bear no indication of content.

Record retention

Following study closure, any remaining paper records from the protocol file are scanned and uploaded into Vestigo. All pharmacy records are maintained electronically in Vestigo and are available at any time for inspection.

Scheduling a Monitor Visit

IDS accomodates monitor visits on a daily basis. After scheduling a site visit with the study team, monitors are asked to schedule a visit with IDS by clicking the Monitor Calendar on the IDS website**.** Due to COVID-19, IDS is not routinely conducting onsite monitor visits. IDS provides remote access to Vestigo all day on the date of the scheduled visit. The monitor receives an email from Vestigo with login information on the day of the visit. For questions about scheduling monitor visits, email tracy.t.obert@emory.edu

Drug Destruction or Return to Sponsor

Study drug inventory that is processed to be returned to the sponsor or destroyed locally includes expired Investigational Product (IP), patient returns, used vials, damaged IP (i.e. from temperature excursion) and all IP remaining at study closure.

For Winship studies and for any studies others involving hazardous drugs, used vials, patient returns, expired inventory and damaged IP are not held for monitor inspection, but are processed immediately for destruction. Patient returns are received from the study coordinator, counted by two IDS employees and processed in Vestigo for destruction. A destruction certificate is generated in Vestigo, and all certificates are available for monitor review. Non-hazardous drugs can also be destroyed locally per the sponsor's instruction.

Local destruction

Non-controlled, bulk pharmaceutical waste can be destroyed rather than returned to the sponsor. IDS personnel process the destruction in Vestigo which generates a certificate of destruction. Personnel from the Emory University Environmental Health and Safety Office (EHSO) pick up drugs for destruction along with the certificate of destruction. The Chemical Disposal Facility processes all chemical waste for incineration. The destruction certificate is maintained in Vestigo and is available for monitor review.

Shipping Address:

Emory Clinic shipping address (primary location):
Investigational Drug Service
Emory University Clinic
Building A, Suite 1200
1365 Clifton Road, NE
Atlanta, GA 30322