INVESTIGATIONAL DRUG SERVICE

POLICY AND PROCEDURE

Title: Drug Accountability/Inventory Control	
Policy Number: 6.1	**Version Date:** 02/01/2023

BACKGROUND

IDS uses Vestigo for protocol management and drug accountability. A profile is built in Vestigo at the beginning of each study after the investigational drug is received. Vestigo is used for all aspects of drug accountability which includes drug receipt, dispensing, study participant drug returns, quarantined inventory, lot numbers, expiration dates, cycle counts and documentation of drug return to the sponsor or local drug destruction.

ACCOUNTABILITY RECORDS

Investigational drug accountability records (IDARs) are generated by the system, and sponsors are given access to Vestigo to review accountability records. IDS does not use sponsor-provided manual accountability logs.

DRUG ORDERING

IDS personnel are responsible for ordering drugs and maintaining inventory for all research studies managed by IDS. Initial shipments for industry-sponsored studies are sent automatically by the sponsor once the protocol is approved by the IRB and the notification of award is issued by the Emory Office of Sponsored Programs. Shipments are also automatic for industry-sponsored studies managed by IXRS (interactive voice/web response) systems. IDS is responsible for ordering drugs for all industry-sponsored studies that are not managed by IXRS, for NCI and cooperative group studies, vaccine studies of the Hope Clinic, and investigator-initiated studies. In certain cases, IDS purchases drug from a drug wholesaler and obtains reimbursement from the study grant.

DRUG RECEIPT

Designated IDS technicians receive inventory and document receipt of drugs supplied by sponsors using the checklist, “Receiving Research Drugs from Sponsor”. Upon receiving a shipment for a drug study, IDS personnel inspect the shipment to ensure the contents of the shipment match the shipping invoice and to determine the appropriate storage for the study drug. Inventory requiring refrigerator or freezer storage is immediately placed in the appropriate location prior to entry in Vestigo. The inventory is then entered in Vestigo on the day of receipt or by close of business the following day. Inventory stored at ambient

temperature is placed in the appropriate location for storage and the Vestigo entry is completed.

If the study is industry-sponsored and managed by IXRS, the shipment is registered with the appropriate IXRS system. IDS does not save or maintain the emailed "Shipment Receipt Confirmation" from IXRS. For non-IXRS studies, IDS notifies the sponsor via fax or email, according to instructions on the invoice, that the shipment arrived. In the event that inventory is damaged or a temperature excursion occurred during shipping, IDS personnel place the inventory in the appropriate storage location, quarantine the IP and notify the sponsor as soon as the problem is identified. The damaged inventory is entered in Vestigo, marked as quarantined and is held until further instruction by the sponsor. If a shipment is received without an invoice, IDS personnel complete the "Missing Invoice Form" to document the date and time of arrival. The form is uploaded into Vestigo.

Once all steps are completed and documented on the checklist, the checklist is scanned and uploaded into Vestigo along with the shipping invoice. IDS does not retain the original invoice in the protocol file, but certifies that the invoice is uploaded in Vestigo. An IDS employee scans the document into Vestigo and verifies that the invoice is uploaded before the original is discarded. The original invoice is placed in the IDS secure shredding bin and is destroyed confidentially via the Emory Shredding Services.

IXRS ACCESS

Industry sponsors routinely use IXRS systems to manage study subject enrollments, study visits, inventory shipments and shipment receipts at the site. When an IXRS system is used for a study, the sponsor allows access to study personnel, including IDS staff. For the majority of studies, IDS requests access for the technicians who receive shipments. The technicians are responsible to maintain their accesses, including username and password, and update their passwords as needed. IDS Pharmacists are required to maintain IXRS access only when a study is blinded and IDS Pharmacists are unblinded. In this situation, pharmacists need access to the system for randomization and dispensing purposes, and they are responsible to maintain their accesses, including username and password.

USED VIALS

For studies that involve IV dose preparation, IDS does not retain used vials or any packaging or cartons used for vial storage. Used vials are discarded following the final product check after dose preparation. The vials are placed in the IDS/hospital/clinic Stericycle IV waste bins which are labelled and removed from IDS when full. Stericycle picks up waste bins and processes the contents for destruction via incineration.

When dispensing the vials in Vestigo, the pharmacist enters the vials as a return and processes them for destruction. A technician then witnesses the destruction and documents it in Vestigo. Monitors can obtain the destruction documentation on the drug accountability log by clicking the box "Include Subject and Inventory Returns" when pulling up the IDAR.

SUBJECT RETURNS

During subject visits for studies involving outpatient medications, research coordinators count the amount of drug returned from the study participant to assess compliance. At the end of the visit, the coordinator returns the used study drug bottle or package and any remaining study drug to IDS for processing. For most studies, IDS receives the returns from the study coordinator, an employee counts the returns and documents the return in Vestigo. A second IDS employee double checks the count and processes the return for destruction. For certain studies, subject drug returns are received from the study coordinator, counted, documented in Vestigo and held for monitor review. Once reviewed, they are removed from Vestigo and are returned to the sponsor or destroyed locally per monitor instruction.

CYCLE COUNTS

IDS conducts cycle counts of all investigational drugs on a monthly basis. During the cycle count process, IDS technicians ensure drug balances are correct and check for expired or expiring inventory. Any cycle count discrepancies are brought to the attention of the pharmacist for clarification and correction, if needed.

EXPIRED INVENTORY PROCESSING

Investigational drugs supplied by sponsors are marked in Vestigo with an actual expiration date, with a retest date or an expiration date "unknown." To manage expired drugs, IDS personnel access the "Expired or soon to expire inventory" report in Vestigo on a monthly basis. All expired drugs are marked and processed each month. Drugs are either held for monitor review or destroyed locally according to the sponsor's requirements. For drugs with a retest date, IDS enters the retest date as the expiration date in Vestigo and contacts the sponsor to determine if the date is extended.

Non-hazardous study drugs supplied by the Pharmaceutical Management Branch (PMB) for studies sponsored by the National Cancer Institute are returned to PMB within 90 days after expiration. For hazardous drugs supplied by PMB, IDS must submit a request for authorization to destroy drug locally and maintain the authorization in Vestigo.

UNKNOWN EXPIRATION DATES

For certain studies, sponsors provide inventory with a lot #, but no expiration date. Vestigo tracks all lot numbers, expiration dates and has the capability of tracking "unknown" expiration entries and retest dates. The majority of industry-sponsored studies are managed by an IXRS system which maintains expiration dates and quarantines inventory when it nears the expiration. When IDS receives investigational product (IP) for IXRS studies with no expiration date on the invoice or IP label, the IDS technician checks IXRS to see if the expiration date is listed in the system. If so, the technician enters the correct expiration date in Vestigo and uploads the notification from IXRS to Vestigo with the shipment documentation. If the IXRS system does not list the expiration date, IDS contacts the sponsor for the information. The IDS technician may enter the inventory in Vestigo with an "unknown" expiration date, but only as a temporary measure until the sponsor provides dates.

If IDS receives inventory from a sponsor that is not managed by an IXRS system, IDS contacts the sponsor for the actual expiration date or retest date.

For studies of the National Cancer Institute (NCI), IDS receives inventory from the Pharmaceutical Management Branch (PMB). If inventory is received with no expiration date, the IDS technician checks the CTEP website to see if an expiration date is provided. If there is no established expiration date, the IDS technician enters a 3-month expiration and retest date per PMB instruction, beginning from the date of shipment receipt in IDS. The technician checks the PMB website every month to determine if there are any notifications of expiring inventory. The PMB will send out stock recovery letters within 30-60 days of the IP reaching its expiration date. In addition, the PMB posts notifications of expiring inventory on the CTEP website, https://ctep.cancer.gov. The IDS technician enters the actual expiration date or the retest date assigned by the PMB.

IDS routinely checks the UNKNOWN expiration date report in Vestigo and obtains actual expiration or retest dates for any inventory listed in the report. IDS pharmacists do not dispense inventory marked with an UNKNOWN expiration date, but ensure that the actual expiration date is obtained before dispensing.

References: Georgia Board of Pharmacy Rules 480-16-.03 to .04; 480-33-.06.

Prior Versions: 2/24/2014, 3/27/2017, 1/30/2020, 3/02/2020, 6/15/2020, 8/01/2020, 2/01/2022