DukeHealth

Policy/Procedure: DUHS Pharmacy IDS - Investigational Drug Service Overview		
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Review Dates: May 2010, February 2016, August 2019, April 2021, August 2022, December 2022; October 2023

Purpose:
This document provides information needed to ensure that clinical trials are carried out safely, effectively, efficiently, and in compliance with all regulations concerning investigational study medications.

Policy Statement:
The Department of Pharmacy is responsible for the control of investigational drugs within Duke University Health System and for Facility Administered Study drugs requiring sterile preparation. The Investigational Drug Services (IDSs) are responsible for establishing study-specific procedures for appropriate drug accountability, billing, procurement, storage, preparation, dispensing, and destruction of investigational drugs within the hospital and clinics. These procedures comply with local, state, and federal requirements and are consistent with Institutional Review Board standards, practice standards of the American Society of Health-System Pharmacists, United States Pharmacopeia, The Joint Commission, and similar institutions across the United States. All IDSs team members are trained in sterile compounding and all sterile products are compounded in areas that meet USP 797 and USP 800 guidelines. All IDSs team members maintain current CITI and GCP certifications.

Level:

☐ **Interdependent** - asterisked [*] items require an order from a health care practitioner licensed to prescribe medical therapy.
☒ **Independent** – no provider order required.

Personnel:
IDSs

Competencies/Skills:
CITI Training Modules
Media fill and Fingertip testing
Annual USP 797 and/or USP 800 Duke required modules

Required Resources:
Per study Protocol

Definitions:
A. Investigational Drug Services (IDSs) includes ICS, IDRP, and IDS
B. ICS: Investigational Chemotherapy Service, located in the Cancer Center Room 4N33
C. IDS: Investigational Drug Service, located in Duke Clinic Room 0101b, Yellow Zone

D. IDRP: Infectious Disease Research Pharmacy, located in Duke Clinic, Clinic 1K

Procedure:

A. DISPENSING

a. Investigational drugs are ordered, received, stored and dispensed for protocols that are approved by the Duke University Health System (DUHS) Institutional Review Board (IRB).

b. Investigational drugs are dispensed subsequent to an order placed in EPIC by an authorized prescriber or designee approved to order study protocol medication. Investigational drugs, that have already been dispensed to study participants, will not be redispensed by IDSs.

c. All orders are processed via the DUHS electronic health record, EPIC. All investigational drug orders are created by IDSs and are used by the study team as part of an EPIC or BEACON order set or treatment plan. The sentence, "Signature indicates that informed consent has been obtained" present on study orders serves as documentation of informed consent. Copies of informed consent forms will not be stored by IDSs.

d. All study drugs are labeled appropriately with EPIC or Vestigo labels to contain the following labeling requirements:

i. Subject name and medical record number
ii. Subject identification number
iii. Name and address of dispensing pharmacy
iv. Name of prescriber
v. eIRB number
vi. Name of Investigational Product or placebo, if blinded
vii. Dose
viii. Patient Instructions/Administration Instructions
ix. Quantity dispensed
x. Date of dispensing and beyond use date/time
xi. Statement "Caution: New Drug – Limited by Federal (orUS) law to investigational use"

e. Before final dispensation, an independent double-check will occur by two personnel, one of which must be a pharmacist, to verify all prescription components are complete and accurate. If study drug preparation occurs outside of IDSs operating hours, a study drug may be dispensed by a pharmacist and a double-check will occur by another pharmacist on the next business day.

f. For Investigational Products (IP) that are controlled substances, 2 IDS team members, one of which must be a pharmacist, will verify inventory both before and after dispensing to confirm accountability. Initials for IDSs team members and date will be documented.

B. STORAGE

a. Investigational drugs are stored separately from standard of care/commercial drugs in an area of limited access and in accordance with USP storage requirements. Study medication bins are clearly labeled with IP name, study title, investigator's name, electronic Institutional Review Board (eIRB) number and other control numbers. IP

that are labeled as a controlled substance are stored in a locked unit inside the IDSs that is limited to the IDS personnel only.

b. The IDSs do not keep or store any used IP, including outer packaging..

C. ACCOUNTABILITY AND RECORD KEEPING

a. IDSs account for all provided study medications using an electronic, web-based investigational drug inventory management system called Vestigo. Vestigo is 21CFR part 11 compliant and defaults to the NCI Drug Accountability Record/Form (DAR/DARF) or IDS form. Both are updated by Vestigo as needed to be in compliance. All drug transfers, receipts, dispenses, and destructions and disposals are recorded in Vestigo. No sponsor-specific forms will be utilized – including label pages and destruction forms.

b. Vestigo Accountability Records contain the following information:

i. Name of Institution
ii. Protocol and IRB number
iii. Protocol title
iv. Principle Investigator
v. Agent name, dosage form, and strength
vi. Storage area
vii. Date drug received or dispensed
viii. Net ID of the IDSs team member who received or dispensed drug
ix. Subject initials and ID number
x. Dose
xi. Quantity dispensed or received
xii. Balance
xiii. Kit or item number, if applicable
xiv. Lot number and expiration/retest date
xv. Destruction
xvi. Quarantine

c. Sponsor supported Interactive Response Technology (IRT) will only be utilized for shipment receipt. The IDSs will not complete IRT accountability or any other IRT functions that are already recorded in the Vestigo DAR.

d. IDSs will only account for agents that are provided to the IDSs by the Sponsor. IDSs will not document accountability of lot numbers for commercial agents billed to the sponsor.

e. IDS does not accept IP returns.

f. ICS does accept oral IP returns. Any oral IP dispensed to a subject that is returned to ICS for accountability will be recorded in Vestigo and immediately destroyed per local method of destruction. Subject returns of an empty container (zero), that has a specific container number will be documented in Vestigo.

g. Vials, labels, and boxes used for IV preparations are not saved for monitor verification and are destroyed immediately after use. IDSs will not create a separate destruction log for these items.

h. Unused IP that requires disposal (expired, study closed, damaged, etc.) are destroyed in accordance with requirements of the principal investigator, the sponsor and applicable OSHA and EPA regulations. For expired or damaged IP, or if the sponsor has closed and the sponsor has not contacted IDSs or IDSs are not able to contact the Sponsor and the Sponsor has not monitored the study for more than 60 days, the IP will be destroyed per

IDS SOP. Destruction is recorded in Vestigo. For more information, see IDSs Drug Destruction Policy.

i. IDSs are responsible for maintaining a study file containing the following information for each study protocol. All parts indicated as necessary will be prepared and stored in a study notebook (physical or electronic) prior to study initiation:

File Section:	Contents:
Drug Accountability Records	DAR/DARF for each drug/dosage-form including package size/strength, lot number, expiration date/temperature, and storage location Note: IDSs and PIs do not sign a printed copy of the DARF
Master Subject Log	Record of all subjects enrolled and dispensed IP in the study
Protocol	Previous protocol versions are kept electronically.
Drug Information	Only information relevant to the preparation and dispensing of IP is kept in the study file.
Pharmacy Procedures	Study-specific pharmacy procedures that outline the necessary steps to prepare and dispense the study medication.
Shipping and Receiving	Receipt and disposition documents for IP shipments

j. Study specific binders or files are maintained in all pharmacy areas where study drugs are stored. This binder/file contains a copy of Pharmacy procedures, DARF, and other necessary documents. All investigational pharmacy records are consolidated and stored in accordance with regulatory requirements of study materials at close-out.

k. Any changes to documents maintained in the study file will follow Good Clinical Practice (GCP) guidelines. Any changes or corrections will have a single line strikethrough through the change with the date and initials of the person making the change.

l. Upon closure of a study, drug accountability records, receipts, and other relevant dispensing documentation are maintained on site at Duke University Hospital for a minimum of 6 months. After the 6-month period, files are moved to off-site institutional archives. Requests for retrieval of archived pharmacy records must occur at least 2-3 business days before the date of review. Retrieval of archived pharmacy records may take additional time. The current policy does not mark these records for destruction at any future time.

D. SITE BLINDING PLAN

a. The Principal Investigator delegates the responsibility of managing the Investigational Product per protocol to the IDSs. IDSs will not sign or complete Sponsor specific blinding plans and thereby acknowledge the responsibilities as listed below are followed to protect the blind.

i. IDSs pharmacy areas are limited and controlled-access facilities – only unblinded IDSs pharmacy staff have access to the pharmacy and Investigational Product
ii. Pharmacy office equipment (i.e. fax machines, printers, computers) and Vestigo are secure and accessible only by unblinded pharmacy staff or designated unblinded coordinators
iii. IDSs staff are trained and understand the importance of written and verbal communication in a blinded manner with the blinded team members
iv. IV study drug, once prepared, will be covered with a blinding bag (when necessary) that shields the viewer fromidentifying the color of the IV. Labeling on the outside of this blinding bag will be a duplicate label that is on the IP bag.

E. TRANSPORT, TRANSFER, AND CHAIN OF CUSTODY
   a. The IDSs define TRANSPORT as the following:
      i. Transport: the process of relocating prepared or unprepared investigational product from one physical address to another. Transported IP has left or is brought to the Duke University Hospital campus (i.e., transport to Duke Wake County Campus). If the study drug is refrigerated or frozen, the IP is transported with cooling blocks and the transport is documented in Vestigo.
         1. Agents that are transported to an external satellite will be sent via a traceable courier (FedEx, UPS, or Contracted, licensed courier), at appropriate storage conditions, with verification of the delivery. Satellite locations will be required to use an electronic drug accountability system or a paper form provided by IDSs to document IP accountability. At the completion of the study, a copy of the drug accountability records will be returned from the external satellite to IDSs along with any remaining IP.
         2. IDSs will use sponsor-provided containers if supplied or appropriate containers from the site for study drug transport. IDSs will supply freezer or cold packs as needed to keep study drug at desired temperature.
         3. When transport is less than or equal to 60 minutes temperature will not be monitored.
         4. The packaging slip will include the storage location for the IP that is being transported. In addition, the zip-top bag that contains the IP will have the identical information as the packing slip including lot number, expiration, quantity, storage location and the applicable protocol affixed to the bag. Upon receipt, the receiving location will review and document the receipt.

   b. The IDSs define TRANSFER as the following:
      i. Transfer: the action of prepared or unprepared IP being passed from one person or place to another within the same physical address (Duke University Hospital). Transferred IP does not leave the main campus where it was stored

or prepared, has a transfer time of <15 minutes, and does not require temperature regulation/recording during the period of transfer.

c. SHIPMENT OF IP DIRECT TO SUBJECTS:
    i. When shipping investigational products to subjects these guidelines are followed:
        1. Appropriate shipping containers and supplies are used to maintain the integrity of the IP.
        2. Ship using a traceable courier (i.e., FedEx, UPS). The traceable courier will be set up to notify the IDSs personnel if there is a shipment delay and when delivery occurs.
        3. Require recipient to sign for the package
        4. The study team is responsible for contacting the subject to ensure the package was received and that the subject has no questions.
d. FACILITY CHAIN OF CUSTODY:
    i. Study drugs, that are picked up from the investigational drug service by a study team member or are transported by a designated courier, are documented on a Chain of Custody Form.
    ii. Copies of the Chain of Custody Form will not be placed in each study file.
    iii. For study drugs that are a controlled substance, a separate Chain of Custody Form will be used where there is a documentation review/count by both IDSs and the study team member picking up the drug.

F. TRAINING AND DELEGATION OF AUTHORITY (DOA)
a. All IDSs team members complete Collaborative Institutional Training Initiative (CITI) Good Clinical Practice (GCP) and Research Involving Vulnerable Subjects training courses as required by the Duke HRPP policy.
b. All IDSs team members review the study protocol, pharmacy manual, and other relevant training materials and have the opportunity to ask questions before performing any study-related IP preparation or dispensing activities for that protocol. Documentation of training is available for review and is maintained by the IDSs or study team regulatory coordinators and will be documented in Vestigo, if applicable.
c. The IDSs will not complete pre-recorded or on-line training modules. If an in-person or virtual meeting training is required, an IDSs study lead or designated alternate will be designated to attend the required training. Documentation of all training is available for review and is maintained by the IDSs or regulatory coordinators in most cases and will be documented in Vestigo, if applicable.
d. IDS will have the lead pharmacist sign the sponsor's DOA (being delegated by the PI) and remaining IDS staff will be listed on IDS' internal DOA.
e. All ICS staff members will be documented on the DOA by each study team's regulatory staff.
f. Hospital pharmacy staff that perform study preparation and/or dispensing are trained by the IDSs before study activities begin. Hospital pharmacy staff do not sign sponsor or IDS DOAs or training logs as they are performing their duties as hired to do by the Department of Pharmacy.
g. Training will only be recorded for changes to the protocol or pharmacy manual that are relevant to pharmacy.

G. MONITORING

a. Monitoring visits occur as: Remote only with Vestigo access; Remote with a phone call or Web-Ex, Zoom, or Microsoft Teams component.
b. The IDSs will meet, virtually with monitors for pre-site qualification visits (SQV), site initiation visits (SIV), close-out visits, and interim monitoring visits (IMV) as required by the study protocol. The IDSs will also be available to meet for audits as requested.
c. If an in-person visit is requested and approved, visits will consist of IP review for up to 15 minutes. Monitors are not permitted in the pharmacy beyond this timeframe.
    i. If a longer monitoring sessionis requested and approved, the Sponsor may be subject to an additional monitoring fee.
d. The maximum number of visits scheduled on a daily basis will depend upon the time needed for each visit and the IDSs will determine the maximum number of visits allowed daily basaed on subject workload and staffing. This includes SIVs, SQVs, IMVs, and audits, and is not dependent on if the visits are remote or in-person.
e. All pharmacy monitoring must be booked through the booking website which explains current monitoring services offered and availability for each service.
    i. IDS Booking Link: https://outlook.office365.com/owa/calendar/IDSPharmacyDukeUniversityHospital1@ProdDuke.onmicrosoft.com/bookings/
    ii. ICS Booking Link: https://outlook.office365.com/owa/calendar/ICSPharmacy@ProdDuke.onmicrosoft.com/bookings/
f. All appointments must be scheduled at least 10 days in advance; last minute requests may limit the ability to accommodate a visit. Unscheduled visits are not permitted.
g. The sponsor will agree to ensure that the monitor will be well-versed in the protocol and has a thorough understanding of study-related pharmacy requirements.
h. Temperature monitoring logs and calibration certificates will be made available for review in Vestigo. Refer to the IDSs Temperature Monitoring SOP for more details.
i. The IDSs will maintain Curriculum Vitaes (CV) and licenses for all team members and will be made available upon request.These will not be stored in individual study files. CVs are updated every 2 years at a minimum.
j. IDSs source documents will be kept in the study-specific files and Vestigo within the IDSs pharmacies.
k. The expectationis that monitors will download necessary documents with each monitoring visit and file documents in such a way to ensure availability to future monitors. Documents are available in Vestigo for monitoring. All documents required for the visit should be requested when the appointment is made to ensure availability.
l. Due to the volume of studies and types of visits (as described above), monitors will be limited to one scheduled monitoring visit every 60 days.
    i. If more frequesnt monitoring visits are requested and approved, the Sponsors may be subject to an additional monitoring fee.
m. Regulatory documents are not maintained within the IDSs pharmacies. All regulatory-related documents will be reviewed with the appropriate site regulatory personnel. It is not the responsibility of the IDSs to make an appointment for the study monitor with the regulatory team or study coodinators.

n. The IDSs do not have the ability to schedule EMR (EPIC) access for moniroting visits. This will need to be requested form the study team.

H. CONTACT INFORMATION:

a. Investigational Chemotherapy Service (ICS)
Room 4N33 Duke Cancer Center
20 Duke Medicine Circle
Durham, NC 27710
Phone: (919)-668-0657
Fax: (919)-668-3895
Email: Pharmacy-ICS@duke.edu

b. Infectious Disease Research Pharmacy (IDRP)
Duke Clinic 1K, Room 1346
40 Duke Medicine Circle
Durham, NC 27710

c. Duke Investigational Drug Service (IDS)
Room 0101b, Yellow Zone
200 Trent Drive, Duke Clinics
Durham, NC 27710
Phone: (919)-684-3543
Fax: (919)-681-2740
Email: IDS.Pharmacy@Duke.edu

REFERENCES

Citations: N/A

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Additional References:
NONE

Associated Policies:
DUHS Pharmacy IDS - Temperature Monitoring
DUHS Pharmacy - IDS Drug Destruction Policy
DUHS Pharmacy - IDS Purchase of Investigational Agents for Use in Clinical Trials

Attachment Names:
NONE