IOWA HEALTH CARE

Department of Pharmaceutical Care Policy and Procedure Manual

TITLE			REFERENCE NUMBER
Investigational Drug External Transport Procedures Between Network Locations			RES-004-01
SITES AFFECTED ☒ MCU ☐ MCD ☐ MCNL ☒ MCB ☐ Offsite Locations	**LICENSE** ☒ Hospital License ☒ Retail License	**REVIEW CYCLE** ☐ 1 year ☒ 3 year	**CATEGORY** ☐ Policy ☒ Standard Operating Procedure (SOP)
REVIEW DATE(S):			**DATE CREATED:** 08/25/2026
REVISION DATE(S):			
OVERSIGHT AUTHORITY: Approved by the Associate Chief Pharmacy Officer(s) and Chief Pharmacy Officer			

Definitions:

1. **Investigational product** (IP) is defined as a new drug or biological drug that is used in a clinical trial. It is a medication or dosage form that is not approved by the Food and Drug Administration for use in humans (e.g., not commercially available in the US); this includes non-FDA approved medications that are obtained for individual patients as part of a treatment IND, single-patient use, emergency use, compassionate use, or similar protocol. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous. Investigational drug may also refer to any drug which is FDA approved and is being used under protocol for human research, possibly outside of FDA approved labeling.
2. **Investigational drug service (IDS)** is a service of the Department of Pharmaceutical Care which provides support to ensure the safety and efficiency of trials at University of Iowa Health Care that use investigational product(s). Pharmacy personnel that perform investigational drug dispensing and accountability at UIHC satellite/IV Admixture/Holden Cancer Center locations approved for conducting research protocols are considered an extension of the IDS.
3. **Control (shipping location)**: site to which the investigational product is originally shipped directly from the sponsor.
4. **Receiving Location**: Secondary location that is receiving the IP via courier from the Control/Shipping Location

Standard Operating Procedure:
Purpose: To describe the procedures related to external transport of IP for clinical research at University of Iowa Health Care.

1. IDS and Mission Cancer + Blood research pharmacy's preference is to have the sponsor ship IP directly to **each** site.

   Investigational product will be transferred and transported between University of Iowa Health Care network locations when the sponsor will not allow for IP to be shipped to multiple locations directly and the following items have been met:

a. Approval from the study sponsor

b. Receiving Site is trained and delegated (SIV has taken place)

c. Protocol that uses the Investigational Product has been authorized to conduct IRB approved clinical research at the satellite location.

d. If transferring the study drug requires a protocol waiver per sponsor requirements, one must be obtained by the study coordinator prior to transferring the IP.

2. **CARE AND VISIT MANAGEMENT**

   a. It is the responsibility of the study coordinator to do the following:

      i. Identify when a patient will need to have IP dispensed at a satellite location

      ii. Contact the IDS pharmacy via email (idspharmacy@team.uiowa.edu) ,Julie Suiter (jsuiter@missioncancer.com) and Allison Knutson (aknutson@missioncancer.com) a minimum of 3 business days prior to when the IP needs dispensed for patient use with the following information included in the email:

         1. IRB number and study name
         2. Subject number and patient initials
         3. Investigational product name
         4. Location of satellite where IP will be dispensed
         5. Date and time of patient appointment that IP is to be dispensed for patient use

   b. The medication orders should be entered and pended at least 24 hours prior to the scheduled treatment visit.

   c. Required lab results must be available by 09:00 AM the day prior to the scheduled patient visit.

   d. IDS pharmacy must receive patient-specific vial or kit assignments, where applicable, prior to 09:00 AM the day prior to the patient scheduled visit.

   e. All medications will be prepared by the pharmacy staff at the receiving site. Any preparation forms will be completed by the receiving site and provided to the IDS pharmacy within 24 hours.

   f. Any IRT assignments will be maintained in the IDS Pharmacy study files.

3. **INVENTORY AND TRANSPORT**

   a. Frozen IP and medications for blinded studies (pharmacy unblinded, study staff blinded) will not be shipped to remote network locations.

   b. IP will be labeled when transported so that it is easily identifiable as to which study it corresponds to.

   c. IP will be transported by an authorized courier or representative of the pharmacy or UIHC study staff.

   d. IP must be transported in a manner that maintains the integrity of the IP and protects the transporter from exposure.

      i. The shipping site will ensure the integrity of any study medication that is shipped to the receiving site.

ii. Cytotoxic and hazardous medications must be double-bagged prior to placing in the shipper to protect from leaks, breaks and spills.

iii. The shipping site will package the drug appropriately to minimize the risk of damage in a temperature validated/qualified shipper with a temperature logger. Shippers will be conditioned as appropriate for the shipping temperature of the study medication.

e. University of Iowa Health Care will not be responsible for covering the costs of shipping supplies or courier service.

f. The shipping site will generate an Inventory Sent Document that will list the protocol name, drug sent, lot number, expiration date and amount. Staff receiving the IP at the receiving site will immediately unpack the shipment, place the drug in appropriate storage conditions and will sign the Inventory Sent Document and send to the shipping site staff along with the temperature logger download upon receipt of the shipment. These documents will be maintained in the control site pharmacy study files.

g. Any temperature excursion occurring during transport will be noted on the Inventory Sent document by the receiving location and the study team and sponsor will be notified and the IP will only be dispensed upon approval for use from the sponsor or other authorized individual.

h. Any inventory transported to a satellite location should not be returned to the control site. The satellite site should document usage, destruction, and/or returns on that site's accountability logs.

References: None

Related Policies & Procedures:

1. RES-004 - Investigational Drug External Transport Procedures Between Network Locations

Appendices (if applicable): None