

## STANDARD OPERATIONAL PROCEDURE (SOP) TRANSPORT OF MEDICATIONS WITH TEMPERATURE AND HUMIDITY MONITORING

### Purpose

This standard operational procedure is intended to establish a mechanism whereby medications that must be maintained at a specific temperature and humidity can be safely transported to another location either for study participant use or administration

### Definitions

- A. **Ambient temperature gel pack:** A gel-filled pack which has been maintained at room temperature (15°C to 25°C).
- B. **Data logger:** A device used for transport which records minimum and maximum temperature readings (in Celsius) and high and low relative humidity (in percentage); and can indicate when ranges for temperature and/or humidity are not maintained during transport; this device records information which can be reviewed at completion of transport, and later downloaded/saved for reporting purposes
- C. **Frozen gel pack:** A gel-filled pack which has been maintained in a freezer (-25°C to -10°C).
- D. **Investigational drug:** A new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous for purposes of this part. Any drug which has not received FDA approval for use in humans. Also refers to any drug, which is FDA approved and is being used under protocol for human research, possibly outside of FDA approved labeling.
- E. **Investigational drug service:** A function of the Department of Pharmacy and provides support to ensure the safety and efficiency of trials at University of Utah Health that use investigational product(s)/investigational drug(s). Pharmacy personnel that perform investigational drug accountability at UUH satellite locations approved for conducting research protocols are considered an extension of the IDS.
- F. **Investigational product (IP):** A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
- G. **Protocol:** A study plan in which all clinical trials are based. The plan is designed to safeguard the health of the enrolled patients as well as answer specific research questions such as clinical efficacy in the treatment of a particular disease state.
- H. **Refrigerated gel pack:** a gel-filled pack which has been maintained in a refrigerator (2°C to 8°C). A refrigerated gel pack will be flexible if the gel inside is not frozen.
- I. **Research Staff:** Individual(s) involved in clinical investigation. This includes the study coordinator, principal investigator, study monitor, study sponsor

- J. **Satellite:** A UUH facility that that is not physically adjoined or connected to the University of Utah Hospital or the Huntsman Cancer Hospital that performs drug accountability for IP.
- K. **Transporter:** The individual completing the transport (physical movement of investigational medication from one location to another), can be a member of the research team or an employee of a courier service
- L. **Transport Case:** An insulated cooler fitted with a data logger, and gel packs.

## Implementation

For products requiring transport at a specific temperature and or humidity, the IDS will use a transport case to measure temperature and or humidity during transport to ensure investigational product integrity and to protect the investigational product from exposure to improper conditions

- A. Use of the transportation case
  - 1. Ambient temperature product
    - a. Indoor transport – use of the transport case is not necessary unless otherwise requested by the study sponsor; use of the transport case may be used for product which is sensitive to temperature variations
    - b. Outdoor transport – use of the transport case is required whenever outdoor temperatures are below 15°C (59F) or above 25°C (77F) during the expected transportation time
  - 2. Refrigerated product
    - a. Indoor transport – use of the transport case is required if travel time is over 5 minutes
    - b. Outdoor transport – use of the transport case is required at ALL times
    - c. The transport case can be used if transportation time is less than 4 hours
    - d. If transport time is to be more than 4 hours, than another transport container must be used (such as a foam shipper).
  - 3. Frozen product
    - a. The transport case should always be used for outdoor or indoor transport
    - b. The transport case can be used only if transportation time is to be less than 30 minutes
    - c. If transport time is to be more than 30 minutes, than another transport container must be used (such as a foam shipper).
- B. Packing medications into the case:
  - 1. Temperature-specific considerations
    - a. Ambient temperature items: place at least one ROOM TEMPERATURE gel pack(s) in the bottom of the case. After IP and data logger has been added to the transport case, one or more ROOM TEMPERATURE gel pack(s) placed on top of the IP packed into the case; the gel pack should help maintain temperature and provide padding for the medication;
    - b. Refrigerated items: place at least one FROZEN gel pack in the bottom of the case, followed by one or more REFRIGERATED gel pack(s) into the transport case to cover the entire bottom of case. Ideally this first step should be done at least 5 minutes prior to adding IP into the transport case; after IP and data logger has been added to the transport case, one or more REFRIGERATED gel pack(s) and at least one FROZEN gel pack should be placed on top of the IP packed into the case

- c. Frozen items: place at least three FROZEN gel packs into case (one across bottom, one on either side of case) at least 10 minutes prior to adding investigational product into the transport case; additionally one or more FROZEN gel packs should be placed on top of the IP packed into the case. When placing investigational product inside the transport case ensure it is surrounded by frozen packs on three sides
    - d. ALL gel packs and IP product should have a single foam liner placed in-between them for appropriate temperature and packing insulation.
  - 2. When placing medication into the case, ensure that the medication is secure enough for transport (bubble padding may be used if needed).
  - 3. Fill out the Investigational Product Transportation and Monitoring Form and then close the transport case (zippered with zip tie placed or taped shut).
    - a. The form should be placed into a sealed plastic bag and placed on the top of the final layer of gel packs.
- C. IDS personnel responsibilities
  - 1. For IP that must be transported, print out an Investigational Product Transportation and Monitoring Form, begin filling out the form and begin to prepare a transportation case
  - 2. After verification is complete and product is ready for dispense, confirm the proper temperature for the product (refrigerated, frozen, room temperature) and that the transport case is prepared prior to use and packed appropriately (see above)
  - 3. At the time the medication is placed into the transport case, fill out the required portions of the Investigational Product Transportation and Monitoring Form (see below for further details)
    - a. Arrange transport of the investigational product to its intended destination, see **Policy: Investigational Drug Service Transport** for details.
- D. Transporter responsibilities
  - 1. Sign for the Investigational Medication Pick-up Log when picking up the transport case from the IDS pharmacy
  - 2. Physically transport the transport case to the intended location and wait for the data logger to be queried and information recorded on the Investigational Product Transportation and Monitoring Form by the receiving staff if possible
  - 3. Return the transport case, data logger and all packing materials to the IDS pharmacy upon the next scheduled pick-up at the IDS pharmacy
    - a. If the transport case is lost and cannot be returned to IDS, the cost will be charged to the transporting group
    - b. If the case is returned damaged, any parts that must be replaced (such as a damaged data logger, or missing gel packs) will be charged to the transporting group
- E. Upon arrival at the intended location
  - 1. The IP should be removed from the transport case upon arrival, but may remain in the case if it is not ready to be provided to patient or dispensed.
  - 2. When the transport case is opened and IP removed, the recipient should first stop the data logger, and then review information on the data logger display and record the following information
    - a. Name and signature of who removed IP from transport case
    - b. Presence of alarm indicating temperature excursion
    - c. Transport temperature and humidity ranges (min/max, high/low)
    - d. Indication if product within appropriate range(s) during transport

3. The completed transport form should be emailed to the IDS. The group receiving the IP may keep the original; the emailed copy should be filed in IDS electronic records
    - a. Completed forms should be emailed to [investigational.pharmacy@hci.utah.edu](mailto:investigational.pharmacy@hci.utah.edu); faxed forms are accepted, although it is strongly preferred that forms are emailed
  4. Have the transporter return the transport case, data logger and all packing materials to the IDS Pharmacy during their next scheduled IDS pick-up
- F. Use of the Investigational Product Transportation and Monitoring Form
1. One Investigational Product Transportation and Monitoring Form may be completed for multiple products being transported ONLY if the following occurs
    - a. the temperature and humidity ranges required for transport are IDENTICAL for all products being bundled in the transport case AND
    - b. all the bundled products are being delivered to the SAME location
  2. The completed Investigational Product Transportation and Monitoring Form should contain:
    - a. Location transported from
    - b. Location transported to
    - c. IRB number and study short name
    - d. Product name, strength, formulation
    - e. Lot number(s) of product
    - f. Quantity being transported
    - g. Required temperature and required humidity range
    - h. Identification number of transport case used
    - i. Identification number of data logger used
    - j. Name and signature of who prepared transport case
    - k. Name and signature of who removed IP from transport case
    - l. Presence of alarm indicating temperature excursion
    - m. Transport temperature and humidity ranges (min/max, high/low)
    - n. Indication if product within appropriate range(s) during transport

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