

Section Research

Related Policy None

**Operating procedure RES-NP004**

INVESTIGATIONAL DRUG INTERNAL TRANSPORT  
PROCEDURES FROM THE IDS PHARMACY TO LOCATIONS  
WITHIN THE HOSPITAL

All drugs used in investigational drug studies will be stored and dispensed according to hospital policy and legal requirements. Appropriate records of all investigational drug studies handled by pharmacy will be maintained. This document will describe the procedures related to internal transport of IP for clinical research at the University of Iowa Hospitals and Clinics.

Definitions:

- A. **An investigational product (IP):** 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.
- B. **Investigational drug service (IDS):** a service of the Department of Pharmaceutical Care which provides support to ensure the safety and efficiency of trials at University of Iowa Hospitals and Clinics 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.
- C. **Control:** site to which the investigational product is originally shipped. In the context of this document, the control pharmacy is located on the main campus of the University of Iowa Hospitals and Clinics (IDS Pharmacy).
- D. **On-site Clinic/Patient Care Unit/Pharmacy:** sites away from the control pharmacy that are located within the University of Iowa Hospital and Clinics

RES-NP004

General Procedures:

- A. Investigational products are to be dispensed from the IDS Pharmacy following the site's standard procedures for dispensing and accountability.
- B. The investigational product may be picked up by designated University of Iowa staff members – which may include a nurse, study coordinator, pharmacist, pharmacy technician or other appropriate healthcare professionals.
- C. The transport will occur such that the transporter may walk to the on-site clinic/pharmacy while remaining indoors, therefore preventing any exposure to external temperatures. All internal transport occurs quickly as all locations are within 10 minutes of each other and the IP is directly transported from location to location.
- D. Due to the limited time and exposure, temperature monitoring is not conducted during transport.
- E. A transport/chain of custody form will not be originated by IDS pharmacy staff.

Approved by the Pharmacy Administrative Staff: 7/2022.

Revised:

Reviewed: