

Department of Pharmaceutical Care
University of Iowa Hospitals and Clinics

Section	Investigational Drugs
Related Policy	RES-001
Operating procedure	RES-001~01

INVESTIGATIONAL DRUG DISPENSING PROCEDURES

Definitions:

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" and investigational product 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.

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 Hospitals and Clinics (UIHC) that use investigational product(s)/investigational drug(s). Pharmacy personnel who are not specifically part of the IDS and who perform investigational drug dispensing and accountability at other UIHC locations approved for conducting research protocols are considered an extension of the IDS.

Human drug studies at UIHC are approved by the Pharmacy and Therapeutics Subcommittee and University of Iowa IRB-01 Biomedical.

General procedures:

Any investigational product, whether intended for administration to inpatient or an outpatient, is dispensed through UIHC's electronic medical record (Epic Willow Ambulatory) only upon the receipt and review of a prescription signed by an authorized prescriber in compliance with applicable legal, institutional and professional standards. Investigational products intended to be administered at UIHC must also have a valid inpatient or clinic medication order in Epic. Verbal orders for investigational drugs are not routinely allowed; all requests for verbal orders must be directed to an Investigational Drug Service pharmacist. Prescriptions and/or orders for medications assigned by an Interactive Response Technology (IRT) system must be accompanied by a copy of the IRT assignment at the time the prescription is presented to IDS. **NO PRESCRIPTION FOR AN INVESTIGATIONAL PRODUCT IS REFILLABLE.**

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1. Authorized prescribers' names can be obtained from HawkIRB as members of the research team, or a list of authorized prescribers may be provided by the Principal Investigator (PI). If a prescription signed by an unauthorized prescriber is received by the pharmacy, it is the responsibility of the pharmacist to notify the prescribing physician that he/she is not authorized to prescribe the investigational product. This should be done without divulging the name of the primary investigator (PI), as the study may be confidential. The Pharmacy may notify the investigator of requests for study drug by unauthorized prescribers to allow for necessary communication between the two providers.
2. If the quantity or other information required for order processing is not designated on a prescription, the pharmacist who receives the prescription will contact the authorized prescriber to determine the amount to be dispensed. This information is to be documented on the prescription. For oral IP, if the quantity to be dispensed is not outlined in the protocol, the dispensing pharmacy staff will dispense the minimum sufficient quantity using intact bottles. Counting out the dose will only be done if required by the sponsor/protocol and approved by IDS.
3. IDS uses paper accountability forms developed internally to record IP receipt, dispensing, transfers and disposal. IDS will not use study provided accountability forms. All accountability forms will contain the following elements: Institution Name, Primary Investigator (PI) Name, Protocol Title and Number, IP name, strength and formulation, dispensing location, recorder initials, date, lot number and quantity on hand. Each dosage form and lot must have a separate form (see below for National Cancer Institute (NCI) requirements). Each entry must be completely filled out in black ink. The format of these drug accountability records will be tailored to the individual study depending on the protocol and the needs of the investigators. Sponsor worksheets will require the approval of IDS prior to use. Redacted copies (with personal health information or PHI removed) will be available to monitors for review. IDS will not upload/add information to any third-party platforms.
4. The NCI drug accountability forms must be used to record receipt, use and disposition of all drugs for studies which are sponsored by the National Cancer Institute. Accountability logs are not lot specific, multiple lots of the same drug and strength will be traced on the same form in accordance with NCI Policy and Guidelines. Each entry must be completely filled out.
5. Drug accountability will be maintained only for the IP supplied by the sponsor or procured by IDS as study supply on behalf of the sponsor or investigator for use on the clinical research trial. IDS will not provide accountability, lot number or expiration dates to sponsors for non-study-supplied commercial agents or standard of care medications. Accountability will not be maintained for ancillary supplies such as syringes, IV bags or tubing.
6. Under no circumstances shall any IP bearing the label "Investigational Drug: Limited by Federal Law to Investigational Use" be used as regular pharmacy stock.
7. Documentation errors made on the prescription, drug accountability record, or any other study document must be corrected by placing a single line through the incorrect information along with the staff member's initials and the date the

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correction was made. **White out or similar correcting products may NOT be used on any study documentation.**

8. The sponsor is required to provide IDS with an expiration or re-test date for the IP upon request. This can be labeled on the container or equivalent documentation. Not receiving an expiration or re-test date in a timely manner could result in the IP being placed into quarantine and this may result in unavailability of the IP to patients.
9. All IP administered or dispensed to a UIHC patient must contain a UIHC label that complies with Iowa Board of Pharmacy requirements.
 - A. The pharmacist must verify the identity of the patient when dispensing directly to a patient.
 - B. Only the directions should be discussed when dispensing the investigational drug. Questions should be directed to the study coordinator or investigator. The word "investigation" should be avoided.
 - C. Products intended to be administered to hospital inpatients or clinic subjects will be labeled in a manner consistent with similar non-study drug products.
 - D. All drugs dispensed from an investigational drug study supply must be labeled with the federal caution auxiliary label.

<p style="text-align: center;">CAUTION: New Drug- Limited by Federal law to investigational use</p>
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10. Investigational drug study protocols are confidential. Requests to review them by non-pharmacy personnel should be referred to IDS.
11. Prescriptions for investigational drug studies will be filed separately from non-investigational drug prescriptions.
 - A. Upon dispensing the investigational drug, the prescription will be placed in the investigational prescription bin.
 - B. All prescriptions will be filed by the Investigational Drug Service in IDS pharmacy 02184 PFP and will be retained for 2 years. Prescriptions older than 2 years will be maintained in off-site storage.