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## Research: Investigational Drugs- AD.0156

### PURPOSE

The purpose of this policy is to assure regulatory and operational compliance and efficient management and security of the receipt, storage, dispensing, returns, disposal, and maintenance of investigational drugs. It is intended that this investigational drug policy be consistent with Food and Drug Administration (FDA) federal regulations, the Common Rule, HIPAA, and good clinical practice, each as amended from time to time. Our policies guide our practices and ensure that we place people at the heart of all we do to deliver the best outcomes and safest care.

### APPLICABILITY

This policy applies to Lakeland Regional Health's **Workforce** and personnel engaged in research.

### POLICY

- I. The Investigational Drug Service (**IDS**) oversees the duties of medication acquisition, storage, preparation, dispensing, and disposal; documentation of accountability; and recordkeeping as required by Good Clinical Practices (GCP), the Code of Federal Regulations (**CFR**), and applicable state laws. In accordance with FDA and **TJC**, the pharmacy department is responsible for drug receipt, storage, accountability and preparation.

### PROCEDURE

- I. **Study Initiation**
  - A. Prior to opening a study, each **ID** is reviewed to determine the appropriate receipt, storage, preparation, dispensing, return, disposal, and transportation requirements. The IDS facilitates the provision of information that outlines preparation and pertinent dispensing information. Suggested information to be included:
    - 1. Medication designation;

2. Common synonyms (i.e., names used in prescribing);
3. Labeling;
4. Dosage forms and strength;
5. Pharmacology;
6. Pharmacokinetics;
7. Usual dosage range;
8. Dosage schedule;
9. Preparation information;
10. Route of administration;
11. Storage information;
12. Dispensing information;
13. Administration instructions;
14. Appropriate monitoring;
15. Expected therapeutic effect;
16. Expected and potential adverse events;
17. Potential toxicity prevention and treatment regimens;
18. Symptoms of toxicity and their treatment;
19. Drug-drug and drug-food interactions;
20. Contraindications;
21. Handling precautions;
22. Names and telephone numbers of **PI** and authorized sub-investigators; and/or
23. Disposal methods for unused doses.

- B. Cerner entries for all drug doses reflected in the study are created prior to study initiation. Entries include pop-up information that directs the pharmacist to the necessary protocol information on Share Point.
- C. If the drug is an FDA approved drug and in the Multum database, Cerner will provide a system alert for dose calculations and limits, allergy checks, drug–laboratory and drug-drug interaction checks.
- D. Protocols requiring supportive care should be based on standard hospital guidelines and the LRH formulary.
- E. Checklists or study-specific reference sheets may be created to ensure consistent processes.
- F. Development of drug information templates for commercially available and investigational drugs by pharmacy specialists are recommended. The pharmacist who develops the information template for a particular agent becomes the resource person for that agent.

## II. Inventory Maintenance

- A. The purpose of inventory maintenance is to:
  1. Account for each dose received, dispensed, disposed, transferred, or returned.
  2. Maintain adequate levels of study medication for the duration of the trial.
- B. Drug inventory maintenance documentation is accomplished by the use of **DARFs**. An electronic inventory system is also permitted when available. The inventory accountability method will be protocol specific.
- C. Electronic or paper DARFs include the following:
  1. Investigator name;
  2. Investigative site name;
  3. Protocol number;
  4. Protocol title;
  5. Medication name, strength, formulation;
  6. Transaction type;
  7. Drug Received (date, quantity, lot number/medication kit ID);
  8. Dispensed (subject info, date, quantity, lot # /medication kit ID);
  9. Un-dispensed disposition;
  10. Transfer;
  11. Return;
  12. Unused;
  13. Disposal/destruction; and
  14. Recorder's initials and date.
- D. Events recorded on DARFs will be on the day the event occurred.
- E. The investigator retains records for two (2) years after a marketing application is approved (for the investigated indication) or, if an application is not filed or not approved, for two (2) years after the investigation is discontinued and the FDA is notified.

## III. Expiration Dating

- A. The sponsor is responsible for providing expiration dates.
- B. IDs are included in the routine process for checking expiration dating.

## IV. Prospective Audits

Periodic audits ensure that a study is being conducted in an appropriate manner and follows federal and state laws, sponsor requirements, and institutional policies and procedures. Audits include reviewing medication accountability, shipment, transfer, destruction, return forms, physical inventory, expiration dating, storage, and security.

## V. Safe Handling

Each ID will be assessed for the potential of being a hazardous agent.

## VI. Storage

- A. The IDS determines and documents appropriate storage conditions for the ID.
- B. Access to IDs is restricted to essential personnel.
- C. IDs are stored in a designated, secure area separate from non-Investigational Drugs according to the manufacturer's instructions.
- D. The ID storage cabinet is located in the south hallway of the pharmacy. The IV room pharmacist retains the key to this cabinet.
- E. If the same drug is used for more than one protocol, there must be a separate storage area and DARF for each protocol.
- F. A separate drug inventory record is maintained for each protocol, strength and/or dosage of drug used.

## VII. Temperature Monitoring and Reporting

- A. Storage temperature monitoring is accomplished by using the Temptrack continuous monitoring system. Temperature ranges and excursions are consistent with **USP** definitions for storage conditions. The monitoring system alerts with a pop-up on the pharmacy IV, Central and Day Shift Technician Team Lead Computer if a temperature goes out of range. Engineering is notified to correct the problem.
- B. If a temperature excursion occurs, IDs are quarantined, and study sponsors are notified. A sponsor may require the unused study medication be returned to the sponsor or designee or locally destroyed with permission per LRH policy. The sponsor is provided, upon request, with copies of the final medication accountability log and record of destruction.

## VIII. Returns and Disposal

- A. Patient-returned hazardous medications are disposed of or returned to the sponsor immediately upon reconciliation.
- B. When returning drugs to the sponsor, package drugs securely to prevent breakage, and double bag to minimize risk to couriers.
- C. The Standard procedure for disposal of hazardous medication is followed. See [Recommended Disposal of IVs and Pharmaceutical Waste](#).
- D. Returns may occur when:
  - 1. The agent is no longer required because the study is completed or discontinued, and the agent cannot be transferred to another protocol;
  - 2. The agent is outdated; or
  - 3. The agent is damaged or unfit for use.
  - 4. Double-check quantities and lot numbers before shipping returns.

## IX. Destruction

- A. The DARF will include the following information for ID destruction:
  - 1. Trial name;
  - 2. Investigator name;
  - 3. Investigator Address;
  - 4. Drug name;
  - 5. Package description (eg. vials, kits, bottles, blister cards);
  - 6. Lot number;
  - 7. Quantity of packages destroyed (vials, kits, bottles, blister cards);
  - 8. Package number(s) if applicable;
  - 9. Reason for destruction;
  - 10. Method and location of destruction (incineration);
  - 11. Date of destruction or date sent for destruction; and
  - 12. Name, title and signature of person confirming destruction.
- B. Unused, partly used and empty containers should be returned to the pharmacy. Do not store with ID not yet dispensed. Study specific personnel will evaluate and determine appropriate next steps for the returned ID.
- C. ID Destruction SOP; See [Recommended Disposal of IVs and Pharmaceutical Waste](#).

#### X. Protocol Information

- A. Protocol information is available to essential pharmacy personnel at time of prescribing.
- B. This information includes the most current **IRB**-approved versions of the protocol, **IB**, pharmacy manual, and safety data sheets are available for reference when verifying orders and dispensing medications. This information is available electronically on Share Point. In addition, paper copies are stored in the ID cabinet.

#### XI. Training of Pharmacy

- A. All pharmacy staff involved in ID activities receive standardized training on the ID Policy and on how to access protocol information documents.
- B. All pharmacy staff who will have involvement in a specific protocol will receive protocol specific training.
- C. Documentation of training will be made on a standard attestation form, unless protocol specific records are available.

#### XII. List of Authorized Prescribers

The IDS maintains a list of authorized prescribers for each protocol. This information is provided at the time of order verification with a Cerner PharmNet pop-up.

#### XIII. Protocol-Specific Medication Order Sets

- A. Standardized order sets improve compliance with recommended processes of care

and promote patient safety. Independent review by the PI or designee occurs prior to activation of the order set. The following should be included in the order set when applicable:

1. Protocol title and study number;
2. PI name and contact information;
3. Protocol-defined dose calculations (e.g., weight to be used, BSA and AUC formula) or dose-rounding requirements;
4. Dose modifications;
5. Supportive care medications, including pre-medications and hydration;
6. Baseline laboratory parameters on the day of treatment;
7. Drug interactions, food requirements, venous access device requirements, research-specific procedures, and instructions the treatment nurse should provide to the patient;
8. Monitoring parameters before and after administration; and/or
9. Date and time of the order and signature of the authorized prescriber.

#### XIV. Clinical Decision Support for ID Ordering

- A. CPOE with **CDSSs** help reduce medication-related errors. Decision support should be protocol-specific.
- B. Research order sets are inactivated when the study is complete.

#### XV. Receiving Inventory

- A. Inventory will be received by the Director of Pharmacy or designee.
- B. Drug shipments are typically sent in insulated boxes with temperature monitor recorders. The boxes contain an instruction sheet on how to read out the temperature records and to whom they have to be sent. The receipt of medication and any temperature deviations must be reported to the study sponsor.
- C. Upon receipt of shipment the receiver will:
  1. Check the amount and condition of the drug;
  2. Check for appropriate language in the label;
  3. Check drug expiration date;
  4. Confirm temperature monitor readings;
  5. Sign the receipt of shipment form;
  6. File the site binder;
  7. Complete the DARF; and
  8. Acknowledge receipt of shipment.
- D. Contact the sponsor or monitor ASAP if there is a problem with the shipment and quarantine the shipment until resolution is obtained.
- E. The following Packing List information will be recorded on the study drug DARF:

1. Date received;
  2. Lot number;
  3. Package description;
  4. Quantity;
  5. Comments; and
  6. Date/verified initials.
- F. Receipt will be documented on the appropriate DARF.
- G. Additional protocol specific inventory receipt instructions (temperature monitoring, documentation, etc.) will be included in the study binder.
- H. The process for inventory reorders will be protocol specific.
- I. It is important not to overstock. It is recommended to limit inventory orders to an eight (8) week supply at one time.

#### **XVI. Order Review and Verification**

- A. IDs are high-risk medications and must be reviewed in the context of the protocol and patient treatment assignment (i.e., treatment arm and dose). The patient profile should be reviewed each time a new order is received.
- B. Double checks are vital to the preparation and dispensing process. Investigational medications require verification by a second pharmacist prior to dispensing. The verification process is documented on the physical product and on the DARF.
- C. Pharmacists will ensure that the ID is prescribed and dispensed according to LRH policy (e.g., [Chemotherapy Administration- CL.0064](#)).
- D. Prior to dispensing IDs, the order verification pharmacist will verify that:
1. The patient is enrolled in an approved protocol;
  2. IRB approval has been received;
  3. The patient has signed the appropriate consent forms; and
  4. The order was initiated by an authorized prescriber.
- E. ID orders, including medications, dosages, calculations, routes, and schedules, are checked against the protocol. Height, weight, date of birth, and BSA should be included on the orders.
- F. The pharmacist dispensing the ID will verify the BSA (for chemotherapy), dosage calculations, treatment plan, and any other pertinent information provided by the verifying pharmacist.

#### **XVII. Dispensing**

- A. The dispensing pharmacist will check the finished product and verify amount used to reconstitute/withdrawn/added to the bag, number of tablets, capsules or volume dispensed.
- B. The final product should be checked by at least two (2) people (pharmacist and pharmacist/nurse/prescriber). The pharmacist checking the final product ensures

that all required checks have been completed prior to dispensing.

C. For all dispensed doses of ID the following will be captured on the DARF:

1. Patient ID;
2. Lot number (if applicable);
3. Bottle/package # (if applicable);
4. Amount dispensed;
5. Date; and
6. Discrepancies (if applicable).

#### **XVIII. Randomization**

For studies that require the pharmacist to perform patient randomization, the process steps will be provided in the study binder. This process may require completing a patient worksheet, obtaining patient assignment by phone, documentation of treatment assignment, etc.

#### **XIX. Informed Consent Verification**

Prior to dispensing any ID, pharmacists verify that a patient has consented to participate in the clinical trial - by direct observation of the consent document or through communication with study team personnel.

#### **XX. Labeling**

- A. Consider whether the medication will be dispensed in the sponsor-provided container or repackaged.
- B. For IDs that are provided in bulk containers, labels will be created prior to study initiation that are to be used for providing the product in unit-dose format.
- C. For oral medications dispensed to out-patients, the following information will be included:
  1. Name, address, and phone number of the dispensing location;
  2. Name and strength of the medication in the container;
  3. Instructions for dosing; and
  4. Quantity dispensed.
- D. Containers and packaging for Investigational new drugs must include the following language: "Caution: New drug—Limited by federal or United States law to investigational use."
- E. Computer labels will be checked for accuracy by the dispensing pharmacist.

#### **XXI. Dispensing IDs for Single- or Double-Blind Studies**

- A. In a single-blind trial, the ID can be unblinded and used to perform patient randomization. Pharmacists should obtain the necessary randomization information from the sponsor or study staff. Caution should be taken during communication of subject information to blinded individuals to not disclose treatment arm or randomization information. Dispensing should be carried out so that the ID appears

identical regardless of treatment assignment.

- B. Double-blinded dispensing procedures may differ in that the ID may also be blinded to the treatment assignment. The ID is typically provided with patient-specific supplies or individual kits containing either active drug or matching placebo. In this case, the checking process includes verifying patient ID or kit numbers.

## XXII. Reporting Unanticipated Problems, Adverse Events, and Protocol Deviations

Patients should be monitored for adverse events during protocol treatment. Monitoring may include a review of laboratory data, concomitant medications, and self-reported complaints. Medication-related protocol deviations should be reported in accordance with protocol requirements and reporting guidelines.

## XXIII. Pharmacy Technician's Role

- A. LRH will establish minimum qualifications and competencies for technicians working with IDs.
- B. Duties may include:
  1. Assist with ID Preparation (involves more complex calculations);
  2. Assist with dispensing oral IDs by generating labels and preparing the prescriptions;
  3. Assist in documenting inventory, lot numbers, expiration dates, retest dates, agent receipt, dispensing, disposition, and returns;
  4. Maintain temperature monitoring logs;
  5. In the event of equipment malfunction, help coordinate transfer of IDs to functioning equipment and follow up with appropriate documentation;
  6. Manage return or disposal of temperature-recording devices sent by study sponsors;
  7. Help maintain inventory levels of IDs and non-study inventory for clinical trials;
  8. Ensure that medications are returned and accounted for as required by study sponsors or at study closure.
  9. Ensure that received medications are checked in accurately and damaged inventory is addressed with the provider;
  10. Maintain orderly inventory, separating like inventory or multiple strengths and formulations within the same clinical trial;
  11. Assist with correspondence and hosting of on-site monitoring visits;
  12. Review inventory and pharmacy records prior to any scheduled audit visits; and/or to
  13. Assist with organizing the study binder.

## XXIV. Expanded Access

- A. Expanded access, is the use of an investigational medication (IND agent) outside of

a clinical trial for the sole purpose of patient treatment. This access is limited to patients with a serious or immediately life-threatening disease or condition who have exhausted commercial treatment options or have no comparable or satisfactory alternatives (i.e., clinical trials).

- B. Verify FDA and Local IRB Approval for Use of the Medication Through Non-Emergency Expanded Access.
- C. Expanded access protocols are approved by the FDA and IRB prior to treatment. Documentation of approval and the current protocol and consent are readily accessible during ID handling and preparation.
- D. Verify FDA Approval and Local IRB Notification for Use of the Medication Through Emergency Expanded Access.
- E. FDA regulations permit emergency use of an ID without informed consent where the investigator and an independent physician who is not otherwise participating in the clinical investigation certify to the appropriateness of the request (21 CFR 50.23(a)-(c)). When an investigational agent is being used under the emergency-use mechanism (21 CFR 312.310d), FDA approval must be obtained (verbal approval permitted). Treatment may begin without prior IRB approval or patient consent, provided the IRB is notified of the emergency treatment within five (5) working days of treatment (21 CFR 50.23(c)). IRB acknowledgment should be requested and maintained for IDS pharmacy records. Subsequent request to use the same agent will require full IRB approval.

#### XXV. Using Patient's Own ID

- A. It is often quite time consuming to get the required information if a patient comes in with a study drug from an outside institution. To ensure quality of care (as well as study requirements) the processes listed below should occur as soon as possible.
- B. Ensure that the investigator is aware of the hospitalization and determine if the study drug should be continued, tapered off or stopped.
- C. When a patient participating in an outpatient drug study either at LRH or another institution is admitted, the following process shall be followed:
  - 1. The admitting physician shall notify the PI of the patient's admission, and determine whether the patient should be continued on the study medication.
  - 2. If the patient enrolled in a study at another institution is to continue the research protocol while at LRH, the admitting physician shall contact the LRH IRB Committee Chairman to obtain approval for the study as required by federal regulations.
  - 3. The admitting physician or clinical pharmacist must obtain a copy of the investigational drug data sheet and a copy of the informed consent documentation from the other institution.
  - 4. If the ID is continued after admission, the admitting physician shall document in the medical record the name of the PI, and write a complete order for the use of the "patient's own investigational medication" including drug, dose, and regimen. The medication will be stored in and dispensed

from the Pharmacy. The LRH policy for Patient's Own Medication will be followed. (See: [Medication: General Principles](#)).

## DEFINITIONS

**CDSS:** Clinical decision support systems

**CFR:** Code of Federal Regulations

**DARF:** Drug Accountability Record Form

**IB:** Investigators Brochure

**ID:** Investigational Drug

**IDS:** Investigational Drug Service

**IRB:** Institutional Review Board

**NCI:** National Cancer Institute

**PI:** Principle Investigator

**TJC:** The Joint Commission

**USP:** United States Pharmacopeia

**Workforce:** All LRH employees, volunteers, trainees/students, contractors, and medical staff.

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## Approval Signatures

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