

Name: Clinical Research and Investigational Drugs

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Description: clinical research, investigational drugs

Policy Number: CPM.0152

Origination Date: 09/01/1980

Purpose: To define departmental responsibilities for the safe and accurate handling of investigational drugs.

Policy:

A. The Pharmacy is responsible for the proper procurement storage, labeling, dispensing, record keeping and disposal of investigational drugs where Pharmacy services are provided in accordance with regulations or the requirements of the FDA, TJC, Federal and State Boards of Pharmacy and Froedtert Health.

1. If a Principal Investigator identifies logistical issues in following a protocol that may preclude the use of Pharmacy services, a request may be made for the Principal Investigator to procure and store investigational drugs outside of the pharmacy department. Investigational Drug Service (IDS) pharmacy must be contacted in advance of starting the project for review and approval by Pharmacy leadership.

B. Investigational drugs are defined as any medication or investigational product used for the research question under investigation, as described in the clinical trial protocol, regardless of whether an Investigational New Drug (IND) is required for the medication.

C. All investigational drug protocols must be approved by the IRB before any investigational drug is dispensed.

D. Investigational drugs will only be dispensed to patients enrolled in that drug study and only after informed consent has been completed and verified by a pharmacist.

E. The following items must be on file in the Pharmacy or electronically available for all clinical trials involving investigational drugs prior to dispensing any drugs to patients:

1. Full protocol and all amendments.

2. Investigator's brochure.

3. Pharmacy manual or other supportive materials that outline drug related preparation and procedures, as applicable.

F. Authorization to Order Investigational Drugs

1. Orders written in accordance with CMP.0172 are accepted for investigational drugs, including orders written by study team members and co-signed by the prescribing provider identified as study staff on the IRB application within 48 hours. Orders must clearly indicate the specific protocol, including protocol number, and include any additional information that may be required to properly randomize the patient and/or

prepare treatment. Unclear orders will be clarified by the pharmacist with the prescribing provider or study coordinator prior to processing

2. IDS pharmacy reviews Cancer Therapy Evaluation Program (CTEP) prescribing providers' registration on a monthly basis to ensure prescribing providers have an active CTEP status and therefore are authorized to write orders for cooperative group studies.

#### G. Loaning/Borrowing Investigational Drugs

1. Investigational drugs and other clinical trial medications supplied by the study sponsor may not be loaned or borrowed unless specifically approved by the study sponsor and principal investigator. The loaning or borrowing of study medications must also be authorized by the pharmacist responsible for the provision of investigational drug services at the involved institutions.

#### H. Patient Participation

1. Patients may not participate in more than one drug study at the same time unless specifically approved by both studies.

#### I. Drug Storage

1. Investigational drugs are stored according to conditions specified by the protocol. All investigational drugs are kept locked at all times and accessible only to authorized personnel. Temperature logs are maintained for all storage areas. See Investigational Drug Temperature Monitoring and Temperature Excursion Policy (Attachment A)

#### J. Drug Accountability

1. Investigational drug records will completely and accurately identify all inventory and dispensing activities.

2. Commercial drug records may be tracked in the drug accountability log for an additional fee associated with the process of maintaining a complete and accurate account of inventory and dispensing activities.

#### K. Compassionate and Emergency Use

1. Investigational drugs obtained for a single patient on an emergency use or compassionate use basis will be received by the Pharmacy. Verification of IRB approval and informed patient consent is required prior to dispensing an investigational drug pursuant to a practitioner order for compassionate use.

[See Emergency Use Workflow](#) for documentation required prior to dispensing investigational drugs.

#### L. Investigational Drugs for Non-Froedtert Studies

1. Patients admitted to Froedtert Hospital who are participating in a clinical trial from an outside principal investigator may continue to participate in the trial provided the following:

a. Use will be communicated to outside hospital study staff.

b. All study medications are either FDA approved medications or have been assigned an IND number by the FDA or are IND exempt.

c. Not contraindicated based on patient's condition or concomitant therapy or prohibited by the protocol.

d. Ordered by a Froedtert licensed independent prescriber.

Procedure:

A. Active Study List

1. The list of all active clinical trials involving the IDS is available as a reference for the Pharmacy staff. Information includes protocol name and number, location of drug, supplies, study binder and key study personnel. Additional information is available in the full protocol and investigator's brochure.

B. Protocol and Amendments

1. The principal investigator, Office of Clinical Research and Innovative Care Compliance (OCRICC) or study coordinator will forward a copy or electronic notification utilizing the Institutional Review Board (IRB) PRO number of the protocol and investigator's brochure to the Investigational Drug Service (IDS). Protocol amendments impacting drug therapy must be forwarded to the Pharmacy within a timely manner upon receiving IRB approval.

C. Budget and Invoices

1. Operational costs associated with Pharmacy services must be planned for in the initial stages of protocol development. When appropriate, OCRICC, the primary investigator, or study coordinator will submit studies to the IDS for budgetary review.

2. Upon receipt of the protocol, the IDS will generate a budget based upon the anticipated workload and Pharmacy charges incurred through participation in the clinical trial. See Purchasing, Budgeting, and Billing Standard Operating Procedure for additional details.

3. Invoices reflecting study activity will be forwarded to the principal investigator following initiation/set up on a regular basis throughout the study and upon close out. Studies that lack sufficient funds to support Pharmacy services will be reviewed and approved on a case by case basis and accounted for under Pharmacy community benefit.

D. Informed Consent

1. The principal investigator or his or her designee must obtain an informed consent before enrolling a patient in any investigational drug study, according to federal regulations. Pharmacy will not dispense study medications until informed consent has been obtained.

E. Department Procedure

1. The IDS will prepare a departmental summary for all studies requiring inpatient general staff participation. The following information will be included:

- a. Principal investigator(s) and Clinical Coordinator.
- b. Type of study.
- c. Drug information including dose, route, frequency, adverse effects, medications to avoid, incompatibilities.
- d. Order processing, computer entry.
- e. Dose preparations, cautions, special handling and labeling.
- f. Record keeping requirements.
- g. Drug and supply storage.

#### F. Study Binder/File

1. A study binder or file is prepared for each study involving investigational drugs managed by IDS. The study binder will include a departmental summary, the latest version of the study protocol, and other study specific documents. Previous versions of the protocol and all versions of the Investigators Brochure (IB) are available for review electronically through the eIRB system.

#### G. Staff Orientation and Education

1. The study binder and procedures are reviewed on a group or individual basis with Pharmacy staff, as necessary, to highlight dose preparation, documentation and all other related procedures in which general Pharmacy staff may be involved.

2. IDS staff training will be documented for each active study. Training will be facilitated by self-review of the IDS pharmacy summary and any other training materials required by the sponsor. Pharmacy staff (including IDS) is responsible to refer to the summary at the time of drug preparation and dispensing. As protocols are amended, these investigational drug summaries are updated to ensure the staff is trained on the most recent version of the protocol.

#### H. Ordering of Study Drug

1. IDS pharmacy will follow protocol specific investigational drug inventory ordering procedures (i.e the physician name used in ordering cooperative group supplied agents will be the investigator registered as the physician of record). The PI or the designated physician's name will be documented on the accountability log when applicable and referenced when ordering investigational agents. In the event of a change in designated ordering PI the cancer center clinical trials office will notify IDS pharmacy through an email communication.

#### I. Perpetual Inventory

1. A perpetual inventory reflecting shipments received and doses dispensed will be maintained for all investigational drugs on a study basis and stored within the study binder or electronically, as applicable.

a. The IDS should be notified immediately of any discrepancies involving study medications.

b. In the event that any discrepancy is unable to be resolved by the IDS, the sponsor will be informed as soon as possible. All discrepancies are noted on the drug accountability log forms.

#### J. Blinded Studies - Breaking Code

1. A mechanism is established for each protocol involving blinded supplies to break the blind and reveal the identity of the study drug in the event it becomes necessary.

2. If requested to break the blind, the pharmacist must refer to the study protocol for the specific procedures to follow. Only the principal investigator is authorized to request to break the blind.

#### K. Drug Storage

1. All investigational drugs and supplies are kept locked at all times. Investigational drug supplies are stored in clearly labeled, designated areas separate from standard Pharmacy stock.

#### L. Temperature Monitoring

1. Continuous temperature logs track temperatures for the primary freezer, refrigerators and for drugs stored at room temperature in the Pharmacy.

2. See policy AD33.001 for Investigational Drug Temperature Monitoring and Temperature Excursions.

#### M. Drug Labeling

1. Investigational drugs dispensed from the Pharmacy will be labeled to facilitate safe use without compromising the blinding to the study, if applicable.

2. Investigational drug labels for sterile products will include:

a. Protocol name and number.

b. Investigational product name versus placebo, if blinded.

c. Patient name or initials.

d. Prep time and date.

e. Expiration time and date.

f. The expiration dating for any IV admixture containing an investigational agent will be based on information contained in the protocol.

g. Initials of the person preparing the sterile product.

h. Initials of the pharmacist checking the sterile product.

i. As required by Federal Regulations, the statement, "Caution: New Drug Limited by Federal (or United States) law to investigational use."

## N. Drug Preparation

1. Institutional Standards will be followed for drug preparation, unless specifically prohibited by the sponsor. Any exceptions will be reviewed and included in the pharmacy summary.

## O. Record Retention

1. Copies of all investigational study records are kept for the period of time designated by federal law. See Investigational Drug Record Retention Standard Operating Procedure

## P. Disposition and Destruction of Investigational Medications

1. Used vials will be documented and destroyed on site upon usage. Patient returned medication bottles will be documented and destroyed upon return to IDS pharmacy. See Investigational Drug Disposition and Destruction Policy.

## Q. Patient's Own Investigational Drugs

1. Investigational medications for patients enrolled in clinical trials through outside investigators will be handled as the patient's own medications. (See Policy CL07.000-Patient Supplied Medications and Other Medications from an Outside Source.) The pharmacist should work with the Froedtert physician to obtain pertinent protocol information including drug information, contraindications and possible adverse effects. The PI must be notified that the patient has been admitted. A copy of the informed consent form should be obtained by the PI and placed in the patient's chart.

## R. Remote Monitoring

1. Remote monitoring by studies may be requested. Monitoring requiring submission of accountability logs, temperature logs, or other study-related material is made available to study monitors not on site for an additional fee. This fee is included in the initial budget proposal.

## S. Biosafety Level 2 (BSL-2) Agents

1. See Investigational Drug Biosafety Level 2 (BSL2) policy for policy and procedure related to appropriate and safe handling of BSL-2 products.

## T. Prescriptions for oral agents

1. Printed prescriptions generated for dispensing of investigational agents must have a signature from a physician or transcribed with pharmacist signature.

Related Policies: [Investigational Drug Biosafety Level 2 \(BSL2\)](#)  
[Investigational Drug Disposition and Destruction](#)  
[Investigational Drug Record Retention Standard Operating Procedure](#)  
[Investigational Drug Service Purchasing, Budgeting and Billing SOP](#)  
[Investigational Drug Temperature Monitoring and Temperature Excursion](#)

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