GENERAL: The Pharmacy Department is responsible for the storage, dispensing, labeling, distribution and destruction of investigational medications for Memorial Healthcare System (MHS) patients and research subjects. Investigational drug refers to any drug or biological drug which is used in a clinical investigation (21CFR312.3). For the purposes of this policy, investigational drugs will be referred to as study drug.

POLICY:
I. Memorial Healthcare System approved outpatient/inpatient investigational drug studies
   A. APPROVAL
      1. Research studies must be approved through an Institutional Review Board (IRB) before they can be conducted on patients within the MHS facilities. Obtaining approval is the responsibility of the principal investigator.

      B. CONSENT
         1. The principal investigator or approved designee is responsible for obtaining proper informed consent prior to the initiation of any study-related procedure in accord with the Office of Human Research (OHR), Standard Operating Procedure 601.1, the reviewing IRB and/or sponsor.
         2. A copy of the signed consent form is to be placed in the patient’s electronic medical record and a copy given to the patient or his/her legally authorized representative. The original should be kept with the regulatory documents (Trial Master File) of the study.
         3. Pharmacy must verify that a fully executed consent has been signed by the patient and/or his/her legally authorized representative, investigator (when required),
assent (when required), and witness (when required) before any study drug can be dispensed from Pharmacy.

4. Pharmacy must notify the MHS IRB office immediately of any situation in which a study drug was dispensed and a fully executed consent was not or could not be obtained.

C. AUTHORIZED DISTRIBUTION

1. Upon receipt of a request for a study drug, the pharmacist will check to determine if the principal investigator or an IRB approved investigator is on the prescription. Pharmacy will not dispense the drug if the investigator has not been approved by the IRB to conduct the study. The prescriber will be notified if this situation arises.

2. Study drugs that are controlled drugs will be handled, secured, and distributed in the same manner as non-study controlled drugs in accordance with all federal, state, local and MHS regulatory requirements.

D. TRAINING/DRUG INFORMATION

1. Training study personnel will be scheduled and supervised by the Investigator and/or his/her designee as per OHR SOP 104: Study Team Training.

2. All study material, not limited to the study protocol, investigator brochure, pharmacy manuals, contact lists and safety letters of all studies will be maintained in password protected electronic files maintained by the OHR.

3. All policies and procedures regarding IDS as related to pharmacy operations will be maintained in electronic shared files.

4. Pharmacy will develop a study drug information sheet for IP as needed to train applicable pharmacy personnel.

5. For non-MHS research protocols a study drug information sheet will be developed to train applicable support staff when the IP is not commercially available.

6. Study drug will have an “INV” prefix attached to the study drug name in the electronic medical record to assist research and support staff.

E. STORAGE

1. The respective site’s central pharmacy will store study drugs in a secure and labeled storage area that is not interspersed among regular pharmacy stock where access can be limited to authorized personnel only.

2. Antineoplastic agents that are study drugs will be stored and handled in compliance with the Chemotherapy and Hazardous Drug Safe Handling Policy (PH-80-05).

3. If the study drug is a controlled substance, it will be kept in a controlled, locked area with access provided only to pharmacists with appropriate authorization.

4. Refrigerated study drugs will be specially labeled when they may require temporary storage with non-investigational drugs.

F. STUDY DRUG TEMPERATURE MONITORING

1. All study medications will be maintained in appropriate storage conditions as specified by the study protocol.
2. Electronic temperature logs for study drugs will be maintained to ensure that the study drug is stored according to study requirements and will be readily available for retrospective review upon request for authorized personnel.
3. For study drug stored onsite, temperature excursions are reported based upon the study protocol specifications.
4. In the event of a temperature excursion described above, the study drug will be quarantined. The study sponsor and Primary Investigator (PI) will be notified as delineated per protocol. Until the sponsor or their designee has provided documentation to the pharmacy that the study drug is acceptable for use, no further study drug will be dispensed.

G. ACCOUNTABILITY, ORDERING, RECORD KEEPING
1. The appropriately trained pharmacist will follow the guidelines for receipt, distribution, dispensing, labeling, and accountability as outlined in the designated study plan/protocol.
2. For study drugs stored in and/or dispensed from the Pharmacy Department, pharmacy will keep a record of the current study drug inventory and amounts dispensed for each patient.
3. Pharmacy will use the (National Cancer Institute) NCI Drug Accountability Record Form (DARF) (manually or electronically stored) for accountability purposes.
4. If the sponsor requires use of proprietary forms (manual or electronic) the pharmacist or pharmacy designee will attempt to obtain approval from the sponsor to use the NCI DARF.
5. Pharmacy will serve as a designee to place orders as necessary to maintain an adequate inventory.
6. Study drugs will be inventoried on a periodic basis to ensure that accountability records match doses dispensed and current supplies available. All discrepancies will be reconciled.
7. When a study drug does not have an expiration date available, the pharmacist will attempt to obtain an expiration date, or validate that the product is safe for use, from the supplier or sponsor of the study.
8. An electronic entry for a study drug name will be available for entry on patient electronic medical profiles. A generic entry of Investigational Medication is also available for order entry in the event that the ordered medication does not exist in the database. Review of the investigational electronic entries will be performed regularly for any additions.
9. For blinded study drugs, pharmacy will develop a blinding plan as needed.
   a) Cases of breaking the blind will be reported to the MHS IRB, PI and the un-blinded study monitor as required.

H. STUDY DRUG TRANSPORT
1. Study drug will be transported to satellite sites or between hospital campuses from the main Investigational Pharmacy on an as needed patient basis as per Investigational Study Protocol.
2. Pharmacy personnel transferring study drug will if workflow permits, transfer the study drug on the day of therapy. There may be situations in which the study drug will be transferred 1-2 days in advance. Should an early transfer of study drug occur, the study drug will be stored in a secure area under the storage conditions as required by the sponsor.

3. Study drugs will be personally transported by pharmacy personnel and left with satellite pharmacy personnel at the off-campus location. In the case of a transfer to a remote facility within Memorial Healthcare System, the hospital courier will be contacted and study drug will be transferred according to the process outlined in the Memo-To-File Investigational Drug Transfer (See Appendix A) and packaged in order to maintain study storage conditions.

4. All transportation transactions will be documented and signed via a signed Investigational Drug Satellite Pharmacy Transfer Record.

5. Study drug transfer to an external location or other studies will be permitted with approval of sponsor and in accordance with the sponsor.

I. DISPENSING
1. The study drug will be dispensed by the investigational pharmacist or designee and will be identified as an Investigational Drug on the prescription drug label.

2. The patient will be given information about the study drug(s) in either written or verbal form by either the pharmacist or research nurse.

J. ACCOUNTABILITY AND RECORD KEEPING OF STUDY DRUG RETURNS
1. All remaining study drug tablets or capsules (including empty containers) will be returned to the pharmacy if required per study protocol.

2. Upon receipt of drug returns, the pharmacist will conduct a compliance assessment if required per protocol. This will be communicated to the research nurses for arranging intervention as deemed necessary by the study nurse, pharmacist or investigator.

K. FINAL DISPOSITION OF THE STUDY DRUG
1. Unused or expired study drugs will be either returned to the sponsor or destroyed as per the requirements provided by the study sponsor. Whenever necessary, permission to do so (via phone/email/monitor visit) must be obtained from the study monitor prior to returning or destroying the study drug.

2. Un-administered study drug outside of the original container will be returned to the pharmacy to destroy as per the requirements provided by the study sponsor. Whenever necessary, permission to do so (via phone/email/monitor visit) must be obtained from the study monitor prior to destruction.

3. All study drug tablets or capsules (including empty containers) returned will be returned/destroyed as per the guidelines provided by the study sponsor. Whenever necessary, permission to do so (via phone/email/monitor visit) must be obtained from the study monitor prior to returning or destroying the study drug.

4. Partially administered injectables, tablets, oral solutions, repackaged study drug that has been opened (even if not administered), or any dosage form that is
infectious or hazardous will be destroyed at the site of anticipated administration and not returned to pharmacy.

5. An empty original study drug container remaining after dispensing has been completed can be destroyed. When necessary, the remaining empty original container may be saved until the study monitor has authorized destruction.

6. Empty vials, ampules that are considered infectious or hazardous substances which have been opened should not be retained and will be destroyed on-site. Packaging/boxes may be retained for auditing purposes if required by the sponsor.

7. Authorized destruction of any study drug or container will take place as dictated by the hospital waste protocol and documented in the accountability records. If permission is required and obtained, it will be documented as such in the accountability logs.
   a) Destruction of IP can be documented in a Memo-To-File and given to the study monitor if the sponsor requires.

8. Drug returns should be arranged by the study sponsor and prepared for shipping by the designated monitor.

9. Study drug destruction will comply with all local, state and federal laws.

L. CHARGES FOR STUDY DRUGS

1. Subjects will not be charged for study drugs with the exception of expanded access study drug under an IND when permitted by the FDA.

M. RECORDS RETENTION

1. Upon closure of studies, original pharmacy source documents will be transferred to the Office of Human Research. The Office of Human Research will determine duration of retention and destruction of those documents in accordance with contracts or regulatory requirements.

2. Electronic copies of original pharmacy source documents may be retained by pharmacy for research performed by non-employed MHS investigators for an unspecified duration but will be maintained in a secure electronic shared drive.

II. PROCEDURES FOR PATIENTS ADMITTED ON STUDY DRUG FROM HOME

A. Prior to starting a study drug supplied from home by a patient, the admitting provider or designee is responsible for contacting the study principal investigator or their designee, to communicate the patient’s hospital admission. The provider and principal investigator, or their designee, must evaluate for appropriateness, and if no contraindication exists, approve continuation of the study drug.

B. In those instances in which an approved study drug is ordered to continue upon patient admission into an MHS hospital, pertinent information relating to the trial is to be obtained from the patient and/or admitting physician, when available. This includes the protocol name or number and the contact information of the principal investigator or their designee for the trial.

C. An effort should be made to obtain a copy of the informed consent to place in the electronic medical record. In the event a copy is not available, acknowledgment that the patient has signed an informed consent should be documented in the medical record.
D. Once approval is obtained from the principal investigator, the principal investigator's name, location, and telephone number should be clearly documented in the patient's electronic medical chart, along with an emergency contact.

E. The prescribing physician or designee is responsible for notifying the pharmacy of the study drug and the IRB of the inpatient admission.

F. Once approved for use, study drug supply will be turned in to pharmacy for review, labeling and dispensing.

G. An investigational medication electronic entry will be used by the provider to denote that the medication is for investigational use and that it is approved for inpatient dispensing within the electronic medical record.

H. Study drug approved for use during hospitalization may be stored in an automated dispensing cabinet or patient medication box and should be returned to the patient at discharge.

I. Study drug that is not approved for administration to the patient during admission should be sent home with a family member if this option is available. Otherwise, the study drug should be placed in a Valuables Envelope until discharge as per policy PH-20-04.

J. Study drug not retrieved by the patient at discharge will be handled by pharmacy to ensure appropriate disposition and/or return to the study sponsor or principal investigator and/or designee.

III. REPORTING MEDICATION ERRORS FOR INVESTIGATIONAL DRUGS

A. Medication errors as defined by the MHS policy PH 100-01 will be reported as stated in such policy.

B. Medication errors reaching the patient will be reported to the study coordinator, principal investigator and sponsor in accordance with the study requirements.

IV. References:


B. Medication Management In: Comprehensive accreditation manual for hospitals. Oakbrook Terrace, IL; Joint Commission; 2012: MM.06.01.05.01-04.


D. Memorial Healthcare System, Office of Human Research; Investigator Standard Operating Procedures:

1. 104 SOP Study Team Training
2. 303 SOP Investigator Brochure & Investigational Plan
3. 503 SOP Documentation and Records Retention
4. 601.1 SOP Obtaining and Documenting Informed Consent/Assent

E. Memorial Healthcare System, Department of Pharmacy Policy No PH-20-04: Medications and Medication delivery devices brought into the hospital.

F. Antineoplastic agents that are study drugs will be stored and handled in compliance with the Chemotherapy and Hazardous Drug Safe Handling Policy (PH-80-05).

V. Appendix A. Investigational Drug Transfer Memo-To-File
VI.

VII. Appendix C. Pharmacy Drug Accountability Record

Appendix D. Medication Errors Policy

PH-100-01 Medication Errors.pdf

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2019oral_agent_accountability.pdf