

Title: **INVESTIGATIONAL DRUG HANDLING**

1.0 OBJECTIVE:

- 1.1 This SOP describes the methods and policies for:
 - Handling investigational drug
 - Dispensing investigational drug
- 1.2 This procedure applies to investigational drugs used in inpatient and outpatient studies.
- 1.3 This procedure is intended to meet FDA and DHHS regulations, GCP guidelines, state regulations and MCG Health System regulations regarding handling of investigational drugs used in clinical research.

2.0 DEFINITIONS:

- 2.1 Investigational Drug- (1) an agent, not yet approved by the FDA, being considered for commercial marketing or (2) an approved medication being studied for an unlabeled use or population
- 2.2 Placebo- Inactive or inert substance identical in appearance or taste to the study drug.

3.0 RESPONSIBILITIES:

- 3.1 The Principal Investigator (PI) should submit required materials to the Clinical Research Pharmacist when they have decided to initiate a research study involving an investigational drug.
- 3.2 The PI is to ensure that all pharmacy fees are included in the budget for the study and contract (if applicable).
- 3.3 The PI is to inform the study sponsor that the investigational drug must be shipped to the Clinical Research Pharmacy.
- 3.4 The PI is to provide advance notice to the Clinical Research Pharmacy regarding research subject dispensing visits/needs and sponsor/funding agency monitoring visits.
- 3.5 The PI is to ensure that the study prescription or inpatient order is clear and complete.

- 3.6 The PI is to notify the Human Assurance Committee (HAC) and Clinical Research Pharmacy when an outpatient research subject is admitted to the MCG Medical Center or MCG Children's Medical Center.
- 4.0 PROCEDURES FOR STARTING A CLINICAL RESEARCH STUDY INVOLVING THE USE OF MEDICATION
 - 4.1 All medications (drugs or biologics) including placebos used in clinical research studies must be stored and dispensed through the Clinical Research Pharmacy. The Medical College of Georgia Health System, Department of Pharmacy, Clinical Research Pharmacy is responsible for the receipt, dispensing, accountability and record keeping for all research medications used in research studies involving humans on the MCG campus including the Georgia War Veteran's Nursing Home (GWVNH).
 - 4.2 Upon the decision to initiate a clinical research study involving an investigational drug, the Principal Investigator (PI) or designee should send the Clinical Research Pharmacist a copy of the protocol, investigator's brochure (or package insert for approved drugs) and indicate the investigators who are authorized to prescribe study medications (via HAC Form 104). A copy of the HAC Form 104 (drug information sheet, which identifies investigators authorized to prescribe study medication) from the Human Assurance Committee (HAC) submission will be forwarded to the pharmacy by the HAC.
 - 4.2.1. In the event that Chesapeake Research Review, Inc. (CRRI) is the IRB of record for the study, a member of the research team should submit the study protocol and investigator's brochure to the clinical research pharmacist.
 - 4.3 The Clinical Research Pharmacist will review the protocol, investigator's brochure (or package insert for approved drugs) and will send a budget proposal to the site.
 - 4.4 The site must include all pharmacy fees in the budget and contract (if applicable) for the study.
 - 4.5 The site must complete HAC Form 104 (Research Medication Data Sheet) with all submission materials for the study

- 4.6 For studies that require an FDA Form 1572, the Clinical Research Pharmacy should be included on the form as a performance site, with the address below listed:

Medical College of Georgia Hospital Pharmacy
Attention: Clinical Research Pharmacy
1120 Fifteenth Street, BI-2101
Augusta, GA 30912-5600

- 4.7 The study sponsor must be informed that all medications used in clinical research studies are to be shipped directly to the Clinical Research Pharmacy.
- 4.8 The Clinical Research Pharmacist should not be listed as a sub-investigator on the FDA Form 1572.

5.0 PROCEDURES ONCE A STUDY INVOLVING INVESTIGATIONAL DRUG HAS BEEN APPROVED TO START

- 5.1 The Clinical Research Pharmacist will notify the local research team once the investigational drug is received from the sponsor.
- 5.2 The Clinical Research Pharmacy complies with all federal, state, and institutional regulations for labeling, storing, dispensing and accountability of medications involved in clinical research. It also complies with procedures outlined in the study protocol.

6.0 PROCEDURES FOR DISPENSING INVESTIGATIONAL DRUG

- 6.1 The PI or Study Coordinator (SC) is to provide advance notice to the Clinical Research Pharmacy of subject dispensing visits/needs.
- 6.2 An authorized investigator must prescribe study medication (original prescription, copy of inpatient order sheet, or telephone order to MCG pharmacist).
- 6.3 The prescription, or order form, should include the following information:
- 6.3.1 Study Name (Short Title)
Protocol Number
Study Subject ID Number
Patient Full Name (and study initials if applicable)
Patient CPI# (account number)

Allergy Status
Date of Birth
Drug Name, Dosage Form, Route, Frequency/Directions for Use
Quantity to Dispense
Refills (if any)

- 6.4 A copy of the research subject's signed informed consent document must be submitted to the Clinical Research Pharmacy before the study drug is dispensed.
- 6.4.1 If additional consents (e.g. study amendment, extension or new risks) are signed during study participation, a copy of the new consent should be provided to the Clinical Research Pharmacy at the time of the visit when consent is obtained.
- 6.5 Dispensing of drugs to research subjects is limited to a licensed pharmacist, physician, or dentist. Once the Clinical Research Pharmacist has dispensed study medication, a research team member may (act as an agent and) give the medication to the subject, or licensed individuals may administer the medication to the subject.
- 6.6 In the event that a research subject misses an appointment and the investigational medication has been dispensed to the possession of the research team member, the medication must be returned to the Clinical Research Pharmacy immediately.
- 6.7 When a research subject returns used or unused study drug (packets, bottles, tablets, capsules, etc.) the items must be returned to the Clinical Research Pharmacy immediately.
- 6.8 In the event that investigational medication will be dispensed from satellite locations off the MCG campus the Clinical Research Pharmacist will work with the research team to develop individualized procedures that ensure all federal, state, and institutional regulations and policies are adhered to.
- 7.0 PROCEDURES WHEN AN "OUTPATIENT" RESEARCH SUBJECT IS ADMITTED TO THE MCG MEDICAL CENTER WITH AN "OUTPATIENT" SUPPLY OF STUDY MEDICATION
- 7.1 When an outpatient research subject is admitted to the MCG Medical Center the PI or designee must notify the Human Assurance Committee (HAC) and Clinical Research Pharmacy of the admission.

- 7.2 The admitting physician shall notify the PI of the patient's admission, and determine whether the patient should be continued on the investigational drug.
- 7.3 If the investigational drug 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 Clinical Research Pharmacy.
- 7.4 If the patient is enrolled in a study at another institution and is to continue the research protocol while at the MCG Hospitals, the admitting physician shall contact the HAC Chairman (721-2991) to obtain approval for the study as required by federal regulations.
 - 7.4.1 The admitting physician or the clinical research pharmacist must obtain a copy of the investigational drug data sheet and a copy of the informed consent document from the other institution.

8.0 PROCEDURES FOR BREAKING THE BLIND

- 8.1 In the event that the blind must be broken for an investigational drug the PI should notify the Clinical Research Pharmacy immediately.
 - 8.1.2 In the event that an emergency occurs such that the sponsor contacts the Clinical Research Pharmacy before contacting the PI, the Clinical Research Pharmacy will contact the PI immediately.
- 8.2 Blinding information will be maintained in a secure environment in the Clinical Research Pharmacy while a study is open (if applicable). The Clinical Research Pharmacist will ensure that the researcher has the need and authority to break the blind (e.g., approval from the study medical monitor, confirmation of "study data lock" for local investigator-initiated trial) before authorizing the blind to be broken.

9.0 PROCEDURES FOR MONITORING VISITS

- 9.1 The Clinical Research Pharmacy must be included in sponsor/funding agency monitoring visits.

- 9.2 The PI or SC must provide advance notice to the Clinical Research Pharmacy regarding sponsor/funding agency monitoring visits. This procedure also applies to site selection visits.

10.0 PROCEDURES FOR STUDY CLOSEOUT

- 10.1 The PI or SC must provide advance notice to the Clinical Research Pharmacy regarding planned closeout visits and activities.
- 10.2 Unused study medication and subject returns will be shipped back to the sponsor at the conclusion of the study at the sponsor or researcher's expense, unless arrangements have been made for local disposal. The sponsor should provide a courier account number for the shipment to be charged to them.
- 10.3 Copies of drug accountability documentation (dispensing logs, shipment receipts etc.) will be made for the sponsor and/or PI's regulatory files at closeout upon request. Copies will be made of pertinent case report form (CRF) documents, such as drug label pages, for the pharmacy files and the original CRF pages returned to the PI.
- 10.4 The Clinical Research Pharmacy maintains archived records of pharmacy procedures, correspondence, original drug dispensing/accountability records, and pharmacy copies of consent documents and label pages for all closed research studies for the time period required by the FDA and/or ICH guidelines. Because the protocol and investigator brochures are maintained in the PI's regulatory files, these are not archived by the pharmacy. The Clinical Research Pharmacy also maintains archival copies of temperature monitoring records.
- 10.5 The PI should include a "Note to File" in their archived study files indicating that study drug accountability records are archived and available through the MCG Clinical Research Pharmacy.
- 10.6 Because FDA auditors expect to see original documents on a site visit, the Clinical Research Pharmacy does not permit original drug accountability forms to be removed (unless instructed to do so by the sponsor on their letterhead in a document explaining why the documents must be removed and where/how they will be stored.)

11.0 PROCEDURES FOR VETERANS AFFAIR MEDICAL CENTER (VA)
PATIENTS

- 11.1 All medications provided to patients at the VA will be dispensed by the VA Hospital Pharmacy. If the study stock is maintained at the MCG Clinical Research Pharmacy, a subject-specific supply will be transferred to the VA Pharmacy for final labeling and dispensing.
- 11.2 A member of the research team must submit a copy of the signed VA informed consent document and prescription to the MCG Clinical Research Pharmacy before the drug will be transferred.
- 11.2 It is the research team's responsibility to contact the VA Pharmacy to make arrangements for the transfer and notify the MCG Clinical Research Pharmacy.
- 11.3 When a VA research subject returns used or unused study drug (packets, bottles, tablets, capsules, etc.) from a study coordinated through the MCG Clinical Research Pharmacy, the study coordinator must return these items to the Clinical Research Pharmacy immediately.