

INVESTIGATIONAL DRUG POLICY

1. PURPOSE: To establish policy for the receipt, storage, security, dispensing and disposition of unused stock of investigational drugs.

2. POLICY: The Augusta VAMC manages investigational drugs to safeguard the well being of research subjects and follows all Federal rules, regulations and laws regarding controls and safety that pertain to ordinary clinical situations. All investigational drugs will be stored in the Pharmacy and dispensed only when all requirements for their use have been fulfilled.

3. ACTION:

a. Approval

(1) A research protocol involving the proposed use of investigational drugs in a series of patients will be prepared and submitted to the Medical College of Georgia Human Assurance Committee for complete review and recommendations for approval.

(2) The principal investigator or designee will provide the Pharmacy, Lab and other Medical Center departments that may be impacted by the clinical research, with a copy of the drug protocol, an Investigational Drug Information Record, VA Form 10-9012, and the Research Service Outside Service Impact Statement, for signature, prior to submission to the Human Assurance Committee.

(3) The Human Assurance Committee will then submit its recommendations to the VAMC Research and Development Committee for final approval following completion of all needed reviews.

(4) If approved by both of the above committees, Report of Subcommittee on Human Studies, VA Form 10-1223, will be prepared with copies forwarded to the principal investigator and to the Pharmacy Department Chief by the Research Department.

b. Receipt, Storage and Security

(1) Upon approval of the Research and Development Committee, the principal investigator or designee will obtain the investigational drug from the manufacturer and deposit this drug supply in the custody of the Pharmacy Department Manager or designee. Regardless of source, all investigational drugs will be delivered to the pharmacy for receipt, storage and distribution.

(2) Investigational drugs obtained from the Medical College of Georgia will adhere to the protocol procedures and will remain under the control and custody of the pharmacy until the time of dispensing.

(3) The investigational drug will be stored under lock, separate from other drug stocks.

c. **Informed Consent and Prescribing**

(1) The principal investigator or authorized co-investigator will complete the following steps when enrolling a patient into an investigational protocol.

(a) Fully inform the patient concerning the study and planned use of drugs and/or procedures in the investigation, including possible adverse reactions.

(b) Secure consent of patient by witnessed signature or consent of patient's next of kin or guardian by witnessed signature on the Research Consent Form, VA Form 10-1086.

(c) Sign the appropriate Research Consent Form, VA Form 10-1086 and have witness sign.

(d) Provide appropriate education and a copy of Investigational Drug Information Record, VA Form 10-9012, for the patient care staff that will be administering and monitoring the drug for side effects, adverse reactions, etc. The education will include procedures to be taken if a patient experiences adverse effects from the drug, and when and whom to contact to report such effects.

(e) Record on Progress Notes, SF 509, or electronic equivalent, a statement that the requirements in the above paragraphs have been accomplished.

(f) File the original signed consent form in the enrolled patient's medical record and provide a copy of the consent for the patient.

(2) The principal investigator or authorized co-investigator will order the investigational drug for the enrolled patient from Pharmacy on a properly completed Prescription Form, VA Form 10-2577f. The prescription must bear the patient's name, identification number, name of investigational drug, complete directions for use, specific quantities, and must be dated and signed by the principal investigator or authorized co-investigator. A new prescription is required each time the medication is ordered. The principal investigator or authorized co-investigator will provide a copy of the enrolled patient's signed and witnessed VA Research Consent Form, VA Form 10-1086 for Pharmacy at the time the medication is ordered.

(3) The principal investigator will inform the Pharmacy Department Manager and the Research and Development Committee when a study has been terminated, and must direct in writing to Pharmacy Department Manager the disposition of any remaining drug.

d. **Humanitarian use of an Investigational Drug**

(1) Occasionally, it may become necessary to treat a patient with an investigational drug which was received while undergoing treatment at another facility or as a compassionate treatment with an investigational drug as a "last hope." In such cases, the following steps should be taken for humanitarian use of the drug:

(a) The responsible staff practitioner should communicate with the Chairperson, of the Pharmacy and Therapeutics Committee for approval of use of such investigational drug in the

absence of a Research and Development Committee-approved protocol. Initial communication within the facility may be telephonic to expedite patient care.

(b) Approval must also be obtained from the Chairperson of the Human Assurance Committee at the Medical College of Georgia prior to use of such investigational drug in the absence of a Committee-approved protocol.

(c) The practitioner making such request must have an Investigational New Drug (IND) number prior to use of the investigational drug. Requests for approval will be limited to drugs which have been or are being used by well-qualified clinical investigators, and on which reports, or other communications from investigators are available.

(d) Requests submitted for approval will include:

1. Patient's name;
2. Patient's Social Security Number;
3. Name of drug;
4. Diagnosis;
5. Reasons drug is required;
6. Name, ID number, and VA title of VA physician or dentist responsible for therapy;
7. Literature reference source;
8. Authorized source of drug.

(e) Upon receipt and approval of an emergency request for approval to use an investigational drug, the Chairperson, Pharmacy and Therapeutics Committee at the VA facility will instruct the physician, or dentist, under whose supervision the drug is to be used, to fully inform the patient concerning the:

1. Administration of the investigational drug;
2. Reasons for its use;
3. Inconveniences and hazards which can reasonably be expected; and
4. Existence of alternative forms of therapy, other than the use of the investigational drug.

(f) Consent

1. The physician must obtain written consent of the patient, or legal guardian, by a witnessed signature on VA Research Consent Form, VA Form 10-1086.

2. The physician may proceed to administer an investigational drug for therapeutic purposes without obtaining consent when the following conditions exist:

- a. If the patient is unable to give consent;
- b. A life-threatening situation exists, and it is believed that the patient's only chance for survival is the administration of this drug; and/or
- c. The treating physician determines the obtaining of consent from the patient's representative could result in a delay, which would increase the hazards to the life or health of the patient.

3. A dated and signed progress note documenting this decision to proceed must be written by the responsible physician.

4. If time permits, reasonable attempts should be made to contact the patient's representative to obtain consent. If time does not permit, or if the representative is not available, such individual should be contacted as promptly as possible to explain what action has been taken, the indications for the action, and the outcome.

5. The signature of the Chief of Staff is required on VA Form 10-1086 in cases where the administration of an investigational drug is based upon an implied consent.

6. Full documentation in the medical record of proper informed consent will be performed in accordance with the requirements of M-2, Part I, Chapter 23.

(g) A preliminary report will be made to the local Pharmacy and Therapeutics Committee on results of use of the drug within 90 days of beginning of tests or therapy. A final summary report will be made upon completion of diagnosis or treatment as applicable. All documentation of use of drugs obtained for humanitarian or compassionate use will be the same as other drugs as outlined in M-2, Part VII, Chapter 6, Paragraph 6.03

e. **Dispensing and Administration of Investigational Drugs**

(1) Investigational drugs will not be given to patients by a registered nurse until the nurse has read the approved information sheet, VA Form 10-9012.

(2) A Nurse, physician, or dentist will not prescribe or dispense any drug to a patient that has not been obtained from the Medical Center pharmacy.

(3) The Pharmacy Service must ensure that investigational drugs are not dispensed without the following on file:

- a. Approved Protocol
- b. Signed informed consent form
- c. VA Form 10-9012 (Investigational Drug Information Record)

(4) The Pharmacy Service maintains an investigational drug log of each drug that includes the following information:

- (a) Name of drug;
- (b) Manufacturer or other source;
- (c) Date of receipt of the drug;
- (d) Quantity received;
- (e) Expiration date, if any;
- (f) Lot or control number;
- (g) Lot or control number;
- (h) Date protocol approved;
- (i) Name of investigator(s) authorized to sign prescriptions;
- (j) All entries will be initialed by dispensing Pharmacist;

(5) The final entry in the record of each drug will be the date on which use is discontinued, the quantity remaining, and the action taken to dispose of the balance.

(6) The drug will be labeled properly to include the following legend in capital letters, **"CAUTION-NEW DRUG: LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE"** and such other auxiliary cautions or warning labels as may be indicated.

(7) For each research subject, the Pharmacy Service maintains the following information in the Investigational Drug Log:

- (a) Name of the patient receiving the prescription;
- (b) Serial number of the prescription;
- (c) Quantity dispensed;
- (d) Balance remaining after the transaction;
- (e) All entries will be initialed by the dispensing pharmacist.

f. Disposition of Unused Investigational Drug

(1) It will be the responsibility of the principal investigator to inform the Research Pharmacist via the Chief, Pharmacy Service, and the R&D Committee in writing when a study has been completed or terminated. The principal Investigator must direct in writing the disposition of any remaining drug (i.e, return to manufacturer or destruction by appropriate means.)

(2) Unused investigational drug that remains after a study is completed or terminated will be disposed of in one of the following ways:

(a) At the sponsor 's request, any unused investigational drug will be returned to the sponsor and so documented.

(b) All other unused investigational drug will be boxed and marked for destruction, following usual pharmacy protocol

g. Use of Drugs for Unapproved Indications

(1) A physician may use a marketed drug in a manner not approved by the FDA without obtaining an IND if it is given for therapeutic rather than investigational purposes.

(2) The Chief of Staff and/or Medical Center Director may apply more stringent controls regarding such drug usage.

4. REFERENCES: M-2, Part VII, Chapter 6;M-2 Part 1, Chapter 3, Paragraph 3.04 and 3.05 M-3, Parts I, II and III.

5. RESPONSIBILITY:

a. The principal investigator is responsible for obtaining all required reviews and all approvals, including final approval to begin the research study, from the Research Department and the Research and Development Committee. The principal investigator is responsible for obtaining the investigational drug from the manufacturer and delivering it to the custody of the Pharmacy Department Manager. The principal investigator will be responsible for furnishing the Pharmacy Department a copy of the approved investigational drug protocol and complete copy of Investigational Drug Information Record, VA Form 10-9012. The principal investigator or his designee will also be responsible for securing the informed written signed and witnessed consent of each patient subject on VA Form 10-1086 and providing a copy of the signed consent form to the Pharmacy Department Manager.

b. The Pharmacy Department Manager or designee is responsible for the custody, security, dispensing, and receipt of all investigational drugs, which have been authorized for use.

December 22, 2004

MCPM 509-04-114/07

c. The Associate Medical Center Director for Patient/Nursing Services is responsible for ensuring that no investigational drug is administered by the nursing staff until adequate information is made available by the principal investigator and the Pharmacy Department Manager.

6. RESCISSIONS: Medical Center Policy memorandum 509-01-147/07, Investigational Drug Policy dated June 1, 2001.

7. RECERTIFICATION: This memorandum will be recertified on or before the last working day of December 2009.

/s/ Thomas W. Kiernan for
James F. Trusley III
Director, Augusta VA Medical Center