

Jesse Brown VA Medical Center  
Chicago, Illinois

Memorandum No. 119-11-14  
March 31, 2011

**PROCEDURES FOR THE HANDLING OF INVESTIGATIONAL  
AND CLINICAL TRIAL DRUGS**

1. **PURPOSE:** To establish policy and procedures for the handling and administration of investigational drugs and clinical trial drugs.

2. **POLICY:** It is the policy of the Jesse Brown VA Medical Center (JBVAMC) that all investigational drug studies will be carried out by properly qualified investigators under protocols approved by the Research and Development Committee and the Collaborative (JBVAMC/NU/UIC) Institutional Review Board (UIC-IRB #4). The committees will ensure that maximum safeguards are in place to protect the patient, staff, facility, and the quality of the study.

3. **RESPONSIBILITY:**

a. It is the responsibility of the principal investigator to:

(1) Submit his/her protocol to the appropriate Research and Development Committee and Institutional Review Board for review and approval.

(2) Obtain proper research subject consent for the use of an investigational drug and furnish a copy of the protocol, signed research subject consent, VA Form 10-1086, "Agreement to Participate in Research By or Under the Direction of the Department of Veterans Affairs".

(3) Furnish the Chief, Patient Administration Service, the original copy of the VA Form 10-1086, "Agreement to Participate in Research By or Under the Direction of the Department of Veterans Affairs", for filing in the medical record.

(4) Secure funding for purchase of drugs being used for investigational purposes. Non-formulary medications for investigational use will not be funded by pharmacy service.

(5) Notify the Chief, Pharmacy Service, and the Research and Development Committee when a study involving investigational drugs is started and terminated and to direct in writing the disposition of any remaining drugs.

b. It is the responsibility of the Chief, Pharmacy Service:

(1) To make available to requesting services (i.e. nursing) copies of a completed "Investigational Drug Information Record" as a summary of the basic information regarding investigational drugs for each participating patient's medical record.

(2) To receive, store, and dispense all drugs used under investigative protocols or in clinical stages of evaluation. All protocol procedures will be followed in obtaining investigational drugs. Investigational drugs will be stored separate from other drugs and dispensed only after receipt of the informed consent, VA Form 10-1086, and the properly written order or electronic equivalent of the practitioner authorized to use the drug.

(3) Maintain a file of investigative drug protocols and an investigative drug log for accountability.

#### 4. **DEFINITIONS:**

##### a. Investigational Drugs:

(1) Drugs for which a new drug application has been filed with the Food and Drug Administration (FDA) and which have not been released through the FDA for general use. They are not available for distribution through regular channels of interstate commerce but are ready for human investigation.

(2) Drugs that are available through regular channels of interstate commerce, but may be used in an investigation for purposes other than the approved Food and Drug Administration indication, will be considered investigational.

b. Clinical Trial Drugs: Drugs that are available through regular sources of interstate commerce, but are not formulary approved in the VACHCS.

#### 5. **PROCEDURES:**

##### a. Investigational Drugs:

(1) All investigational drugs as defined in 4.a. may only be administered to research subjects after a written protocol has received prior approval of the appropriate Research and Development Committee (R&D Committee). This does not apply to drugs used within research laboratories on animals.

(2) In the late stages of a drug's investigation the drug may, in certain limited situations, be used as a humanitarian act for specific patients outside the regular protocol. In such cases, these patients must become participants in the research protocol, and an emergency life-threatening situation must necessitate the use of the drug. In such cases, use of an investigational drug, as a humanitarian act should be approved by the Chairpersons of Pharmacy and Therapeutics (P&T) Committee and the IRB. Before granting emergency approval, the chairperson will evaluate the protocol and ensure that the drug has an investigational new drug (IND) number and that the investigator complies with all the requirements of M-2, Part I, Chapter 3, to include obtaining informed consent.

(3) Drugs used to treat patients as part of nation wide cooperative research studies; e.g., National Institute of Health, or VA Cooperative Study Program, must receive prior approval by the R&D Committee; these drugs may be defined in either 4.a. or 4.b.

(4) Cooperative drug research studies at Northwestern Hospital, UIC Hospital, and the JBVAMC must receive prior approval by the R&D Committee when VA patients are participants.

(5) The Institutional Review Boards of Northwestern University (NU) and UIC Hospitals (UIC-IRB #4) will review all proposals for the use of drugs and/or procedures for investigations involving human subjects, whether patients or healthy volunteers. For approval to be obtained, the investigator must prepare a VA Form 1086, "Agreement to Participate in Research By or Under the Direction of the Department of Veterans Affairs" (UIC-IRB #4), which must accompany the research proposal when it is presented to the R&D Committee and the Institutional Review Board of NU or UIC. Approval by both R&D and IRB is required before the study begins and whenever the protocol is changed. It should be written in language, which the subject can be expected to understand and should be as brief as possible while, clearly presenting all the information the research subject needs to make a reasoned decision concerning participation. It must include the following:

(a) The name of the investigation and a general statement as to its purpose, i.e., how it relates to other knowledge and what use may be made of the results obtained.

(b) The procedures to be used, including invasive techniques, restrictions on normal activities or the possibility of receiving inactive material in a double blind trial.

(c) Any known risks, inconveniences or side effects that could be expected and measures that will be taken to minimize any hazards or discomforts or, where applicable, a statement that the risks cannot be predicted.

(d) Any benefits that may accrue to the subject as a result of participation in this trial, including therapeutic benefits, payments or recognition.

(e) Any cost to the research subject for participation in the study.

(f) Any alternate courses of action open to the subject, generally another accepted course of therapy or diagnostic procedure, in lieu of participation in the study.

(g) A statement that the subject may withdraw without prejudice at any time from participation.

(h) Statement of Confidentiality of Results, and a VA Form 10-1086, to the Chief, Patient Administration Service.

(i) Information for a contact person the research subject can call if he or she has questions or concerns relating to the study.

(6) When UIC-IRB #4 and the Institutional Review Board and the R&D Committee approve the research study employing an investigational drug, VA Form 10-1223, "Report of the Subcommittee on Human Studies", will be prepared with copies forwarded to the investigator and to the Chief, Pharmacy Service. The original will be placed in the protocol file in the appropriate Research Office. The principal investigator will be responsible for obtaining the investigational drug from the manufacturer and delivering it or having it delivered, with proper identification, in accordance with FDA regulations, to the custody of the Chief, Pharmacy Service.

(7) Pharmacy Service will not dispense investigational drugs until an "Investigational Drug Information Record" has been completed.

(8) If an automated dispensing device is not used in the research area, VA Form 10-2638 must accompany each scheduled II-V investigational drug issued.

(9) Physicians or nursing personnel will not administer investigational drugs until the "Investigational Drug Information Record" if requested has been reviewed by the individual administering the drug.

(10) A copy of the consent form authorizing the use and disclosure of protected health information in accordance to the privacy law, Health Insurance Portability and Accountability Act (HIPAA), is obtained prior to dispensing an investigational drug.

(11) All investigational drug labels will include the following legend "CAUTION - NEW DRUG: LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE."

(12) All investigational controlled substances (Schedule II-V) must be secured under double lock in accordance with VA Handbook 0730.

**b. Research Subject Consent:**

(1) When soliciting a potential research subject for a research project involving an investigational drug, the principal investigator will:

(a) Give the research subject full information concerning the study and the planned use of the drugs and/or procedures in the investigation, including possible adverse reactions.

(b) Secure the consent of the research subject according to the Informed Consent Memorandum No. 11-02.

(c) The physician must also sign the appropriate part of the VA Form 10-1086 and write a statement in the research subject's chart on the Doctor's Progress Notes (SF 509).

(d) File the original VA Form 10-1086, when fully executed, in the research subject's medical record or outpatient treatment folder and a copy of the signed VA Form 10-1086 will be forwarded to the Chief, Pharmacy Service, and the Research and Development Service office.

c. Clinical Trial Drugs: Physicians desiring to carry out a clinical trial of a new drug available through regular channels of interstate commerce and as defined in paragraph 4. (b) must submit an electronic non-formulary drug request and documentation to the facility's Pharmacy and Therapeutics Committee. IRB approval and a written consent of the research subject are required for clinical trial drugs.

d. If, in the professional judgement of the investigator, it is not feasible to get consent, or is contrary to the best interest of the research subject, he must state his reasons for such judgement on SF 509, Doctor's Progress Notes.

e. The wisdom and sound professional judgement of the investigator, professional staff members, R&D Committee and (UIC-IRB #4) Institutional Review Boards of NU or UIC collectively will be used in determining what constitutes risk and potential medical benefit of the use of a particular drug and/or investigational procedure.

f. Investigational and clinical trial drugs will be kept in the pharmacy, separate from other drug stocks and will be dispensed only upon (1) verification of a signed Informed Research Subject Consent by Pharmacy Service (this may be done by telephone only in an emergency), (2) and receipt of a signed prescription or electronic equivalent from the chief investigator or his/her designee. The prescription must be dated, signed and have the research subject's name and ward designation, actual quantities prescribed, and complete directions of use. If an automated dispensing device is not used in the research area, VA Form 10-2638 must accompany each scheduled II-V clinical trial drug issued.

g. Withdrawals of the subject from the study will not affect his/her regular treatment period.

h. The use of pharmacy drug stock to carry out an investigation will not be allowed except for supportive medical therapy. The drugs will be purchased separately with grant or other available research funds and turned over to the Chief, Pharmacy Service.

i. Study budgets should include compensation for personnel and workload costs associated with the JBVAMC Pharmacy Service's participation in the study. Donations from funded research projects can be accepted through the West Side Institute of Science and Education's Pharmacy Reimbursements account.

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j. All drug samples, which are received, should be turned in to the pharmacy for custody and disposal. Drug samples will not be used to treat patients.

k. All controlled substances (Schedule II-V) for clinical trials must be secured under double lock in accordance with VA Handbook 0730.

6. **REFERENCES:** VHA Handbook 1108.4 and VHA Handbook 1200.05



VHA.1200.05.pdf



VHA.1108.04.pdf

7. **RESCISSION:** Rescission date March 31, 2014.

8. **RESPONSIBLE SERVICE:** Pharmacy Service

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**DISTRIBUTION: A**

**X - All Physicians**

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