

**LOUIS STOKES CLEVELAND
VA MEDICAL CENTER**
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MEDICAL CENTER POLICY 119-019
November 5, 2004

INVESTIGATIONAL DRUGS FOR PATIENT USE

1. **PURPOSE.** To establish the necessary guidelines and procedures that must be followed when prescribing or administering investigational drugs within VAMC Cleveland.

2. **POLICY.** It is Medical Center Policy to adhere to all FDA and VHA regulations concerning prescribing, dispensing, administering, and disposing of investigational drugs.

3. DEFINITIONS

a. **Investigational drugs:** An investigational drug is defined by one of the following: (i.) a drug in any of the clinical stages of evaluation which has not been released by the FDA for general use or cleared for sale in interstate commerce; (ii.) any commercially available drug proposed for a new use; (iii.) any commercially available drug proposed for a new dosage form or method of administration; (iv.) a commercially available drug which contains a new component such as an excipient or coating; (v.) a new combination of two or more commercially available drugs; or (vi.) a combination of commercially available drugs in new proportions.

b. **Emergency Use.** The use of an investigational drug or biological product for a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval.

c. **Compassionate Use.** "Compassionate Use" is often meant to refer to the emergency use situations discussed above. The term does not appear in FDA guidance relating to investigational drugs.

4. PROCEDURES

a. Investigators

(1) Physicians, dentists, and others desiring to employ investigational drugs or study drugs must submit a proposed protocol to the Research and Development Committee (R&D), the Institutional Review Board (IRB) and the Pharmacy and Therapeutics (P&T) Committee for review and approval. Upon approval the investigator will receive a signed and dated VA 10-1223, Report of Subcommittee on Human Studies. A copy of this report must be filed in Pharmacy Service to provide approving authority for stocking and issuing of the drug item.

(2) The principal investigator will then be responsible for furnishing the Chief, Pharmacy Service with the following:

- (a) A copy of the approved research protocol.
 - (b) Pertinent information about the investigational drug, including a completed Investigational Drug Record, VA Form 10-9012. The 10-9012 must also include names of all physicians that he/she has designated as an approved authority for writing prescriptions for the drug.
 - (c) Supplies of all investigational drugs required for the study.
 - (d) Prompt notification of the discontinuance of the study.
 - (e) The name and telephone number of a physician familiar with the drug.
- (3) The principal investigator will:
- (a) Fully inform the patient concerning the administration of the investigational drug; to include all inconveniences and hazards reasonably expected; the existence of alternative forms of therapy, and the possible effects upon his/her health.
 - (b) Obtain consent of the patient, or legally authorized representative, by his/her signature on the currently approved version of the VA IRB Consent Form 10-1086. A copy of the signed VA Form 10-1086 will be filed in the patient's case history records and the principal investigator will retain the original for at least five years after the study is completed.
 - (c) Record a statement in the patient's CPRS chart that subparagraphs (2)(a) and (2)(b) have been accomplished
 - (d) Adhere to all provisions regarding the protection of human rights and safety during clinical investigations.
 - (e) Maintain:
 - [i] Current curriculum vitae (CV),
 - [ii] Protocol of the study,
 - [iii] Clinical Investigator's Brochure (CIB) or package insert,

- [iv] Records of receipt and disposition of drugs,
 - [v] List of any co-investigators with their curriculum vitae,
 - [vi] Certification that all physicians, dentists, and/or nurses responsible in the study have appropriate valid licenses for the duration of the investigation, and
 - [vii] Case histories with particular documentation on evidence of drug effects. Emphasis is on toxicity and possible untoward happenings. All adverse effects are reportable, even if the investigator considers that the event is not related to the drug. All adverse effects shall be reported immediately to Pharmacy Service and the IRB in the manner defined by the protocol.
 - [viii] R&D, IRB and P&T Committee letters of approval.
- (f) Enter a copy of the signed 10-9012 into the patient's medical record.
- (4) Emergency use-- investigational drugs will be approved by the IRB prior to initiation of therapy. In an emergency situation, where the patient is in a life-threatening or severely debilitating status for which standard FDA approved treatment is not available and intervention is required before the IRB can convene, the investigator may use the investigational drug. However, they must report this use to the IRB within five (5) working days. Subsequent use of the investigational drug in another patient cannot commence until the IRB has reviewed the protocol and consent form. Any data generated from emergency use cannot be counted as research, nor can it be used to support research.
- b. **Pharmacy Service.** Once the P&T Committee has approved the project, they will provide a notice to the principal investigator, research pharmacist and to the IRB office. All investigational drugs will be stored under lock and key and dispensed by Pharmacy Service. The custody, control, and dispensing of all investigational drugs will be the responsibility of the Chief, Pharmacy Service, and will be in accordance with the provisions of M-2, Part VII, Chapter 6.
- (1) Investigational drugs will be dispensed only in response to prescriptions written by a physician or dentist specifically authorized in writing as a principal or secondary investigator or his/her authorized designee as documented on VA Form 10-9012. Pharmacy Service will be required to maintain a record of all primary investigators and authorized designees.
- (2) Any prescription for investigational drugs must be dated, bear the patient's name,

ward designation, social security number, drug name, quantities prescribed, complete directions for use, and the signature of an authorized prescriber.

(3) A complete record of each investigational drug will be maintained in a log and will include the following information:

- (a) Name of drug,
- (b) Manufacturer or other source,
- (c) Amount and date received,
- (d) Expiration date, if any,
- (e) Lot or control number,
- (f) Prescription number and date prescription was dispensed,
- (g) Patient's name,
- (h) Amount dispensed, and
- (i) Name of prescribing physician or dentist.

(4) The final entry in the record for each drug will be the date on which its use is discontinued or the date on which the drug becomes available for procurement through normal trade channels and is therefore no longer subject to controls applicable to drugs in the clinical stages of evaluation.

(5) Disposition of the remaining drug supplies at the conclusion of the study will be in accordance with protocol procedures.

(6) Pharmacy Service will be responsible for preparing and making available to the using service (nursing stations, clinics) summaries of basic information regarding the specific drug to be administered.

(7) Pharmacy Service is required to maintain a copy of the authorization document (VA Form 10-9012) that designates the principal investigator and secondary investigator(s) for each investigational drug maintained in the pharmacy.

(8) Pharmacy Service must maintain all copies of investigational transactions for five (5) years following the termination of a study.

(9) Pharmacy Service must maintain a record of all personnel involved in the preparation of cytotoxic agents for twenty (20) years.

c. **Administration of Drugs:** The administration of all investigational drugs to patients will be the responsibility of a physician, registered nurse (RN), or licensed practical nurse (LPN) competent to administer them. On approval of the principal investigator, RNs / LPNs may administer investigational drugs after they have been given and have demonstrated an understanding of basic pharmacologic information about the drugs. LPNs administering investigational drugs must be under the general supervision of an RN while doing so.

(1) The administration of any investigational drug by any route may be delayed until such time as adequate information concerning the actions, usage, dosage, toxicity, and precautions of usage is obtainable from Pharmacy Service.

(2) Prior to the administration of any investigational drug, it will be the responsibility of the principal investigator to ensure that the proper written consent from the patient was obtained. Obtaining the patient's consent will be in accordance with the provisions of the appropriate IRB, and in accordance with the provisions of M-2, Part I, Chapter 3 and VHA Handbook 1200.5.

5. **REFERENCES.** M-2, Part VII, Chapter 6, dated 3/28/91; M-2, Part I, Chapter 3, dated 12/13/93; VHA Handbook 1200.5 and RCS 10-1, dated 5/18/92; IRB SOP Manual; 21 CFR Parts 50, 56 and 312.

6. **RESCISSION.** Medical Center Policy 119-019, Investigational Drugs for Patient Use, dated October 1, 2001.

7. **REVIEW DATE.** November 5, 2007.

8. **FOLLOW-UP RESPONSIBILITY.** Chief, Pharmacy Service



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Medical Center Director