

Department of Veterans Affairs
Harry S. Truman Memorial Veterans' Hospital
800 Hospital Drive
Columbia, Missouri

HPM 589A4-338
October 6, 2006
Issued by: Research

INVESTIGATIONAL DEVICES

1. **PURPOSE:** To describe the procedures to be followed for receiving, storing, securing, and dispensing investigational devices and to establish a policy and procedure governing the use of Investigational Device Exemption (IDE) at the Harry S. Truman Memorial Veterans' Hospital (HSTMVH).

2. **POLICY:** Federal law prohibits the distribution of new medical devices until the Food and Drug Administration (FDA) has reviewed clinical data and determined the safety and effectiveness of a particular product for a specific use in human patients. Investigational devices for human use will be stored and dispensed through the Pharmacy Service at the HSTMVH. The University of Missouri Health Sciences Institutional Review Board (HS-IRB) and the Department of Veterans Affairs (VA) Research and Development (R&D) Committee will approve all protocols involving investigational devices. The Principal Investigator conducting an investigational device study at the HSTMVH will be responsible for ensuring that all investigational devices are delivered to the Research Pharmacist and stored in a secure area within the pharmacy and dispensed in accordance with this policy.

3. **DEFINITIONS:**

a. Investigational Device. A new medical device not yet approved by the FDA that is in clinical stages of evaluation for general use and is not available for distribution through regular channels of interstate commerce.

b. Medical Device. The term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

c. Unapproved Medical Device. A device that is used for a purpose or condition for which the device requires, but does not have an approved application for pre-market approval under Section 515 of the Food, Drug, and Cosmetic (FD&C) Act. Medical devices that have not received marketing clearance under Section 510(k) of the FD&C Act are also considered unapproved devices.

4. PROCEDURE:

a. The Principal Investigator, or a designated research staff member, will be responsible for delivering investigational devices to the Research Pharmacist for proper storage. The storage area for the investigational device must be separate from storage areas for approved devices. An investigational device, or its immediate package, must bear a label with the following information: the name and place of business of the manufacturer, packer or distributor, the quantity of contents, if appropriate, and a statement as follows: "CAUTION: Investigational Device. Limited by Federal law to investigational use." The label, or other labeling, must describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warning, and precautions.

b. The Research Pharmacist will be responsible for receiving and dispensing investigational devices and will maintain a log containing the following information for each device:

(1) Receipt: (a) Number of devices received, (b) Date, (c) Name of the device, (d) Serial number, and (e) Model number.

(2) Dispensing: (a) Name of issuer, (b) Name of subject receiving the device, (c) Name of the device, (d) Serial number of the device, and (e) Number of devices left in inventory.

c. The investigator will be responsible for coordinating with the Research Pharmacist to ensure that investigational devices are secured in a locked room or in a locked cabinet within a designated research area that is not accessible to anyone other than the Principal Investigator or their research staff.

d. A detailed account of the above listed requirements will be submitted to the Research Office with the research proposal for R&D Committee review and approval prior to implementation of the project.

e. Upon completion or termination of a clinical investigation, the investigator will return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.

f. When a sponsor or investigator claims that an investigational device is not a significant risk, the HS-IRB will make an independent determination as to whether or not the device poses a significant risk. Specifically, the HS-IRB will consider if the device presents a potential for serious risk to the health, safety, or welfare of a participant under circumstances as follows: (a) if the device is intended as an implant, (b) if the device is purported or represented to be for use in supporting or sustaining human life, and (c) if the device is for use, or of substantial importance, in diagnosing, curing, mitigating, treating disease, or otherwise preventing impairment of human health. All HS-IRB determinations regarding investigational devices will be communicated to the investigator, and the Human Research Compliance Officer (HRCO), and where appropriate, the sponsor.

g. In situations where FDA-regulated test articles are used, the FDA regulations will apply regardless of the funding source. The investigator will be responsible for ensuring the investigation is conducted according to the signed investigators application, the investigational plan, and all applicable regulations. The investigator also will be responsible for protecting the rights, safety, and welfare of participants.

h. When a sponsor of a research investigation involving an investigational test article exists, the HS-IRB will evaluate whether the sponsor function complies with FDA and other applicable regulations.

5. **REFERENCES:** 21 CFR 812.140, VHA Handbook 1200.5

6. **FOLLOW-UP RESPONSIBILITY:** ACOS/R&D

7. **RESCISSION:** HPM589A4-338 dated April 20, 2006

APPROVED:

MARIE L. WELDON, FACHE
Acting Director

Key Words: Investigational
Device
Research
FDA