

Chapter 17

DRUG HANDLING PROCEDURES FOR RESEARCH STUDIES AND THE ROLE OF THE CAMC PHARMACY

A. CAMC Pharmacy

CAMC's Department of Pharmacy and Drug Information shall serve as the central site for the management, storage, handling, control, dispensing, inventory and tracking of Investigational Drugs. All drugs for Clinical Trials approved by the CAMC/WVU IRB that will be dispensed by the CAMC Pharmacy or administered to CAMC inpatients must be registered with the Pharmacy's Investigational Drug Service (IDS). The IDS Pharmacist, may be reached at 388-9913 for further information.

B. Role of Principal Investigator during Protocol Development

Clinical Drug Trials involving investigational or FDA approved drugs require that the PI and/or Study Coordinator contact the IDS Pharmacist at 388-9913 to discuss any performance expectations of the Pharmacy's Investigational Drug Service throughout the course of the study. Clinical Trials that are "PI initiated" will require close collaboration with the IDS Pharmacist during the preparation of the IRB Drug Data Form. The PI should be prepared to discuss the following with the IDS Pharmacist:

1. foreseeable risks;
2. description of alternative treatments available;
3. description of the Clinical Trial procedures and the expected length of therapy with the drug or device;
4. a statement of who will have access to any Clinical Trial records that contain patient identifiers

REGULATORY NOTE: If a physician uses a commercially available device, drug, or other health product for an indication not in the approved labeling as part of his/her practice of medicine and does not intend to collect any type of data, he or she has the responsibility to be well informed about the drug, device or other health product. Use of a device, drug or other health product in this manner as part of the practice of medicine (in a manner not designed to develop information about the safety and efficiency of the health product) for uses other than those for which it was approved, or conducted under an investigational protocol(IND/IDE) does not require review by the IRB.

C. Investigational Drug Service Administrative Costs

The PI will include during budget preparation an 'administrative handling' fee for the Investigational Drug Service. The PI or Study Coordinator shall contact the IDS Pharmacist at 388-9913 during budget preparation for sponsored research in order to calculate the amount to be included in the budget for pharmacy participation in the drug trial. The PI will be able to review the itemized pharmacy budget. This form is separate from the Drug Data Form (IRB Form #5)

D. Purchase of Investigational Drugs.

CAMC shall not purchase investigational drugs. CAMC expects the Sponsor to provide all Investigational Products for Clinical Trial purposes.

Exception to purchasing Guidelines for certain Investigational drugs: With the advance written notification of the Sponsor, insurer verification, and approval by CAMC, the Sponsor may charge CAMC for the purchase of an Investigational Drug which is the subject of a Clinical Trial at CAMC. The PI shall notify Patient Accounts in writing of the existence of these special agreed upon circumstances.

E. Shipping and Delivery

The Sponsor of the Clinical Trial will be responsible for shipping and delivering the drugs or devices to the IDS, c/o Department of Pharmacy & Drug Information at the division in which the drug will be stored. The appropriate number of Investigational Products necessary to conduct the Clinical Trial shall have each been properly tested and labeled in accordance with FDA regulations and will be verified by the IDS Pharmacist. The PI will be responsible for confirming delivery to the CAMC Department of Pharmacy & Drug Information.

F. Receipt of Drug

Upon receipt of an Investigational Drug by the Department of Pharmacy and Drug Information, the PI and the IDS Pharmacist shall meet to review any further requirements of the Clinical Trial as outlined in the approved IRB Drug Data Form.

G. Supplies

The PI and the IDS Pharmacist shall be jointly responsible for ensuring that sufficient supplies of the Investigational drugs are available throughout the course of the Clinical Trial.

Investigational Drugs that are in supply for an approved IRB protocol may not be used for an Emergency Use Procedure without approval from the PI of the approved protocol and the IRB Chairman's prior review.

H. Recordkeeping

All records will be kept and maintained by the IDS Pharmacist and the PI for a period of two (2) years after the date on which the Clinical Trial is terminated or completed. The records will be stored in the Department of Pharmacy and Drug Information.

I. Inventory

The IDS Pharmacist will maintain a perpetual inventory record for Investigational Drugs involved in a Clinical Trial at CAMC. The records will be stored in the Department of Pharmacy & Drug Information.

J. Study Close-out

The IDS Pharmacist will be responsible for the return, transfer and/or disposal of all unused Investigational Products according to the specific instructions provided by the Sponsor and the approved protocol.

K. Sponsor and Federal Audits

The PI will be responsible for notifying the Director of Research and Grants Administration and the IRB Chairperson in writing or by e-mail regarding any impending Sponsor or federal audits. The Director of Research and Grants Administration and IRB Chairperson, or their representatives, shall be present for the exit summary meeting. If the audit involves investigational drugs, the PI shall notify the Investigational Drug Service Pharmacist in advance of the inspection dates.