

## Chapter 16

# INVESTIGATIONAL DRUGS

## A. Definitions

1. **Investigational Drug** means a drug that is being tested for, but has not yet received marketing approval by the FDA for human use; or a drug that has FDA approval for at least one use but is being studied for new indications, new routes of administration or new dosage forms.
2. **IND Number** is a number assigned to an Investigational Drug that is approved by the FDA for use in a Clinical Trial involving human subjects.
3. **Investigational Use of Marketed Products** means the investigational use of an approved marketed drug with the principal intent of developing information about the safety and efficacy of the drug for uses other than those for which it was approved by the FDA. The investigational use of marketed products requires an IND and approval of the clinical trial by the IRB.

## B. Types of Investigational Drug Studies

1. **Single Patient Use** is used to describe an investigational drug used by a practitioner for a single or limited number of patient(s). It is usually a patient in a desperate situation who is unresponsive to or an unlikely candidate for other therapies, or in a situation where no approved or generally recognized treatment is available. A "Single Patient Use" is NOT Emergency Use, it is an anticipated use of an investigational drug for a patient who is in a desperate situation who has been unresponsive to or is an unlikely candidate for traditional therapies.

**NOTE:** The term **compassionate use** is not recognized by the Food and Drug Administration (the "FDA") but is occasionally used by pharmaceutical companies in reference to the actual written protocol. These "compassionate use" protocols require full-board IRB review.

### 2. Treatment IND or Treatment Protocol Under Existing IND

Under the FDA regulations, an Investigational New Drug (IND) sponsor, i.e., a pharmaceutical company, or licensed medical practitioner may apply for a Treatment IND or a treatment protocol administered under an existing IND. If the FDA grants the Treatment IND, the investigational drug may be used to treat patients with seriously life-threatening diseases for whom no comparable or satisfactory alternative drug or therapy is available.

3. **Open Label Protocols** are considered to be in investigational stages, usually Phase III or Phase IV of a clinical trial, unless noted otherwise by the sponsor. Open Label protocols **must be reviewed by the IRB according to the standard full-board review format, prior to use.** IND numbers will be required prior to IRB approval for those protocols that are being conducted under an active IND number prior to research approval.
4. **Parallel Track Drugs** require review by the IRB Chairperson in an emergency situation, or full-board review when the drug is under active clinical investigation.

**5. Investigational drugs designated as "Group C"** - These drugs used in cancer therapies may be designated by the FDA and the National Cancer Institute as "Group C" drugs. Under certain conditions, they may be administered for treatment purposes. Group C drugs which are under an active clinical investigation requires review by the full-board IRB.

## **C. Role of Physician and Nurse in the Administration of Investigational Drugs**

### **1. Physician**

a. The physician practitioner has principle responsibility for the administration of an investigational drug, or any other investigational product, to a patient that is enrolled in an IRB approved drug study.

b. The physician practitioner is responsible for administering the investigational drug in an approved "emergency use" situation.

### **2. Nurse**

a. The physician practitioner may incorporate the assistance of non-investigator nurses to administer an investigational drug to a patient(s) who is enrolled in an IRB approved research drug study.

b. The physician researcher is responsible for notifying the nurse manager if an impending research protocol is to be conducted on a particular unit.

The PI along with the Pharmacy's Investigational Drug Service, is responsible for orienting the nurses that will be involved, on that unit, of the research protocol including: information about the study and the drug itself, possible side effects, verify that all research approvals have been received (i.e., IRB, pharmacy, etc.) and other necessary and related information. The Department of Pharmacy's Investigational Drug Service will be able to provide the required nursing education and inservices (i.e., drug information sheet regarding drug dosing) to meet the intent of this regulation.

c. The non-investigator (i.e., unit) nurse may not administer informed consent or enroll patients for the physician practitioner unless the nurse is included on the approved IRB forms.

## **D. Essential Steps and Key Points for the Nurse who will Administer Investigational Drugs to Research Patients**

Nurses may participate in the administration of an investigational drug to a "research patient" utilizing the following essential steps and key points:

Essential Steps:

1. Verify the physician researcher's order.
2. Verify that the patient's informed consent has been signed, the Principal Investigator's signature is present, and is included on the patient's chart.

### **Investigational Drugs**

1. If the nurse has not been oriented by the Department of Pharmacy or Physician Researcher (PI or designee) regarding the research protocol, or does not have a Drug Information Sheet available to explain the pharmacological and therapeutic effects of the drug, then the PI or physician must administer the investigational drug. The Drug Information Sheet is available from the Department of Pharmacy and will be dispensed to the nurse in preparation of the first dose.
2. Administer the drug according to the physician's orders. The principal investigator must be notified prior to not administering or discontinuing a drug.
  1. Document on the MAR that investigational therapy was given. The patient's response to the investigational drug therapy, such as side effects or any adverse reaction, must be recorded on the patient's chart and reported to the PI if an adverse reaction is suspected.