

## **Investigational Drug Accountability**

### **1. PURPOSE**

- a. To create uniform study drug dispensing and accountability standards.
- b. To establish a procedure for the proper control, storage, dispensing, and handling of investigational drugs in accordance with US Food and Drug Administration, State, and Federal standards.

### **2. RESPONSIBILITY**

The Associate Dean for Research will ensure compliance with this policy.

### **3. POLICY**

The use and control of investigational drugs in the New Jersey Dental School clinics shall comply with rules and regulations of the Federal Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), the State of New Jersey, and UMDNJ policies and procedures as they pertain to human subject research. Before the initiation of any clinical drug study in the Dental School clinics, the UMDNJ Institutional Review Board (IRB) must approve both the study protocol and the informed consent document. The Principal Investigator must properly store and dispense all investigational drugs and maintain accurate dispensing and inventory records. The safety and welfare of the subjects participating in the clinical drug trial must be recognized as the prime consideration in the management of the clinical trial.

### **4. DEFINITIONS**

#### **4.1. Investigational Drugs**

- 4.1.1 Drugs that have not been approved by the FDA but are under study through an Investigational New Drug (IND) application.
- 4.1.2 Drugs that have FDA approval for at least one indication and are being studied for new indications, new routes of administration, or new dosage forms, or are being studied to confirm effectiveness in new patient populations.

#### **4.2. Principal Investigator (PI)**

The individual responsible for ensuring that the study is being conducted according to the investigational plan and applicable regulations.

#### **4.3. Authorized Investigators**

Individuals (e.g., research fellows, residents) who will be assisting the PI in the conduct of the investigation.

#### **4.4. Institutional Review Board (IRB)**

A multidisciplinary committee whose responsibility is to approve and oversee all investigations carried out on human subjects at UMDNJ. This committee evaluates each proposed clinical research study with respect to its compliance

with ethical, legal, and scientific standards. Its approval must be obtained before investigational drugs are dispensed.

#### **4.5. Source Documents**

Original records (e.g., drug dispensing records, subject files and records) created in the course of the clinical investigation.

#### **4.6. Sponsor**

An individual, company, institution or organization that takes responsibility for the initiation, management and/or financing of a clinical trial, but does not conduct the actual investigation.

### **5. POLICIES AND ASSOCIATED PROCEDURES**

#### **5.1 Study Drug Prescription**

- 5.1.1 Study drugs will be dispensed only by those who are authorized by the IRB approved protocol, principal investigator, state and federal regulations, and NJDS policies.
- 5.1.2 Study drugs will be dispensed according to the dose, route, and frequency written in the specific protocol
- 5.1.3 Used containers and unused study drug will be collected back from the subject(s), unless the study protocol states other means of disposition that are in compliance with federal and state regulations.
- 5.1.4 Subjects will be instructed in the proper storage, use and precautions, and potential known risks of the study drug.
- 5.1.5 Study drug will be properly accounted for and tracked with adequate documentation.
- 5.1.6 Deviations from the IRB approved protocol described treatment regimen are only allowed if they are to protect subjects from newly discovered risks.

#### **5.2 Receipt and Inventory of Study Drug**

5.2.1. The PI or designated individual will:

- 5.2.1.1. Upon receipt of the investigational drug, inventory the shipment ensuring that the information on the packing slip matches exactly with what has been sent to the site, including the amount, lot numbers and quantity, and document the results of this inventory.

5.2.1.2. Promptly bring any discrepancies, breakage or evidence of tampering to the attention of the Sponsor.

5.2.1.3. Retain a copy of the shipping inventory, packing slips, and documentation of inventory in the study's records

### **5.3 Study Drug Labeling**

5.3.1 Study drugs for sponsoring companies are pre-labeled and the labels should not be defaced or changed in any way without written permission of the sponsor; it is recommended that an additional label be placed to include the study staff contact name/number, but only if the sponsor agrees.

5.3.2 If the PI is responsible for labeling, minimal labeling requirements include:

Name of institution

Name of study

Full name of subject and/or subject number/initials (For prescription drugs, the subject's full name is required)

Directions for use and warnings

Name of authorized prescriber and telephone or pager number.

Required precautionary information (e.g., controlled substance information, if applicable; food, water, alcohol, etc. restrictions or requirements; if drug is a controlled substance, the phrase "Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed")

Expiration date

Statement "For investigational use only"

### **5.4. Storage of the Study Drug**

Study drugs should be stored in a secure environment, with access limited to essential and appropriate research personnel, according to the storage requirements detailed in the protocol or supplied by the Sponsor. The drugs

should be kept locked in a cabinet in a locked/secure area. The study drugs should be stored at the appropriate temperature and a storage area temperature log should be maintained, if appropriate.

#### **5.5. Dispensing of Study Drug**

5.5.1. The PI shall dispense or administer the study drug only to subjects under his/her personal supervision or under the supervision of a co-investigator.

5.5.2. The investigator shall not dispense or supply the study drug to any person not authorized to receive it.

5.5.3. A study binder will be created for all investigational drug studies. The binder will include specific dispensing instructions, randomization log, drug accountability form, record of drug dispensing, drug invoice, drug return form and labels (if applicable), study protocol, investigator's brochure or copy of package insert, copy of blank consent form, and copy of current IRB approval notice. If individual subject codes are used for blinding, the binder will also include an envelope containing an individual envelope for each subject number that will contain information concerning the respective subject product assignment; these individual subject envelopes will be opened only the case of an adverse event requiring identification of the specific agent a subject has been using.

5.5.4. Each time a study drug is dispensed, there should be documentation as to the amount dispensed, to whom it is dispensed, and the date and signature or initials of the person dispensing the drug.

5.5.5. Subjects should be advised to return all used and unused containers/units to the site of original dispensing. Study personnel should record the amount (number of bottles and pills, etc) and date of return. Attempts to retrieve the containers/units from subjects who have not returned them should be documented.

5.5.6. Any discrepancies between the amounts used by subjects (actual or suspected) and the amount returned should be documented, as well as the reasons for the discrepancies.

#### **5.6. Return/Destruction of Study Drug**

5.6.1. At the conclusion of the study ensure that all documentation regarding receipt, storage, dispensing, return of used containers, and accountability is complete and accurate.

5.6.2. Unused drug obtained from a sponsor for the specific purpose of a

research study must be returned to the sponsor or be discarded on site using appropriate procedures upon written authorization from the sponsor to do so.

- 5.6.3. Unused drug obtained from University Hospital Pharmacy must be returned to the pharmacy for proper destruction, unless otherwise specified in the protocol.
- 5.6.4. Unused study drug must not be passed on to other investigators, used for animal research, or dispensed to non-study subjects.
- 5.6.5. Drug study records must be kept for at least \_\_\_years.