USE OF INVESTIGATIONAL DRUGS

Policy:

Investigational Drugs (INDs) will refer to those drugs, which have not yet been released by the Federal Food and Drug Administration for general use or are commercially available drugs used as part of an investigational protocol. Therefore, they will include drugs bearing the following cautionary labeling: “CAUTION – NEW DRUG – Limited by Federal Law to Investigational Use.” INDs are also used under provisions of an investigational drug, as authorized by the Food and Drug Administration to a physician investigator. Principal Investigator will refer to the physician signing the FDA release for obtaining the drug(s). Co-investigator(s) may be designated by the principal investigator.

Procedure:

1. All protocols involving investigational drugs must be approved by the Institutional Review Board (IRB) before they may be initiated.

2. All investigational drugs for inpatient use shall be stored and dispensed from the Pharmacy, according to guidelines established by the P&T Committee. Upon the discretion of the pharmacy director and principal investigator, an exception may be made based on clinical necessity.

3. It shall be the responsibility of the pharmacy director to establish suitable procedures for the proper labeling and dispensing of these drugs in accordance with the principal investigator’s orders.

4. The signed informed consent form as required by the institution’s IRB must be obtained prior to commencing therapy. It is the principal investigator’s responsibility to ensure the consent form is complete before initiation of the protocol.

5. It is the responsibility of the principal investigator to provide the Pharmacy Director with the signature and legible written names of
all co-investigators authorized to release investigational drugs from the Pharmacy. No drugs can be released from the Pharmacy until such time as the physician’s order is received in the Pharmacy with the authorized signature and LSU protocol number of pre-approved nomenclature. The pharmacy director or designee implements a procedure to be followed for dispensing each IND. Pharmacy will maintain an inventory log of drugs dispensed. Contact Pharmacy for fees associated with handling investigational drugs.

6. Study drugs may be dispensed by the physician investigator when research is performed on outpatients. It is expected that the principal investigator will take appropriate and adequate steps to ensure proper security of all investigational drugs. In this case, the investigator will maintain all records.

7. A pharmacist may initiate or adjust drug therapy and/or order laboratory tests associated with a drug study protocol when requested to do so by the principal investigator. Any pharmacist participating in such a protocol must be trained and deemed competent to participate by the principal investigator or his/her designee.

8. The form "Investigation Drug Information Record" is a portion of the Request for Approval of Investigational Drugs Involving Use of Human Subjects, which is submitted to the IRB for review. It is the responsibility of the principal investigator to place a copy of each form in the patient’s medical record so that it is available for all staff. A completed form containing this information shall be on file in the Pharmacy Department. It is expected that the principal investigator or a designated person familiar with the research will be available to answer questions that may arise and are not covered in this data. It shall be the responsibility of the principal investigator to collaborate with pharmacy and nursing to make any necessary arrangements for the administration and control of these drugs on the individual nursing units.

9. All health care professionals, prior to administering an investigational drug, must complete competency assessment form to be filed within their respective departments. Competency assessment forms (S/N 1146 may be obtained on each nursing unit or from the department director.)
10. All adverse reactions must be reported to the investigator, hospital pharmacy, the IRB and the sponsor. The investigator is ultimately responsible for completing the necessary paperwork in reporting adverse reactions to appropriate local, state and federal agencies.

Approved by Clinical Board: 1/16/01, 2/17/04
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