IREDELL HEALTH SYSTEM

Investigational Drugs	
Approved by: Randi Raynor, PharmD, MBA, BCPS	Last Revised/Reviewed Date: 05/2022
P&T Committee	Date: 06/2022

Definition:
Investigational drugs are drugs that have not been released by the Federal Food and Drug Administration (FDA) for general distribution and use. These drugs usually bear the following statement on the label:

CAUTION: New Drug – Limited by Federal (or US) Law to Investigational Use

Investigational drugs are released by manufacturers only to approved investigators who have completed the appropriate FDA Statement of Investigator forms.

Policies:
1. The Institutional Review Board (IRB) is responsible for the review and approval of investigational drug studies at Iredell Memorial Hospital. Refer to IRB policies and procedures for additional information.
2. Investigational drugs will be used only under the supervision of the principal investigator (PI), who must assume the responsibility of securing the informed consent of all patients who receive the drug.
3. The PI is responsible for supplying the investigational drugs to the pharmacy along with any inventory control logs as required by the sponsor. Initial receipt of the drugs will be documented on a pharmacy perpetual inventory log or one supplied by the sponsor. The log sheet will be kept with the drug stock.
4. The PI is responsible for providing a copy of the study protocol and essential information about the investigational drug to the pharmacy. This information includes the dosage form, dosage range, storage requirements, route of administration, strength, actions, uses, side effects, adverse effects, contraindications, interactions and symptoms of toxicity. The pharmacy department will serve as the central unit where essential information on investigational drugs is maintained and made available to appropriate personnel.
5. Investigational drugs will be dispensed and administered only upon receipt of an order by a provider authorized to use the medication.
6. Administration of investigational drugs will be in accordance with approved policies and procedures or protocol.
7. The pharmacy department will ensure that investigational drugs are properly labeled, stored, dispensed and distributed, as outlined in this policy.
8. An accurate record of doses received, dispensed and administered shall be maintained.
9. The use of placebo treatment is prohibited, unless in the context of an Institutional Review Board (IRB) approved clinical trial.

Procedures:
1. Appropriate information for all drugs approved for investigational use will be furnished to the pharmacy department by the PI. The information must include a copy of the study protocol, essential drug information as outlined above, a copy of the signed informed consent, any documentation forms and other pertinent information.
2. The pharmacy department will disseminate the pertinent information to appropriate nursing personnel. Education for persons who administer these drugs shall include the following:

    a. How to administer the drugs
    b. Pharmacological action of the drugs
    c. Expected response to the drugs
    d. Possible adverse effects of the drugs
    e. Appropriate response to adverse effects of the drugs
    f. Other clinical implications associated with the use of the drugs
3. The signed consent form must be sent to the Health Information Management department, where it will be scanned into the patient's medical record.
4. Investigational drugs will be sent to the pharmacy for identification, storage, labeling, and dispensing.
5. Investigational drugs will be stored separately from other drugs, in locked storage within the pharmacy. Appropriate storage requirements (temperature, lighting, etc.) should be specified in the product literature from the sponsor. If the storage requirements are unknown, the pharmacy will contact the PI or study sponsor to verify storage requirements.
6. Investigational drugs shall be properly labeled in accordance with current FDA requirements. Labels of investigational drugs shall contain at least the following:
    a. Patient name and location
    b. Name and strength of drug (or code)
    c. Complete directions for use (affixed to the contained or available to the person administering the drug)
    d. Number of dosage units in container when dispensed
    e. Lot number and expiration date
    f. Name or initials of dispensing pharmacist
    g. "For Investigational Use Only"
7. A perpetual inventory of investigational drugs will be maintained. A controlled drug administration record or other documentation form as supplied by the sponsor will be used by nursing personnel to record each dose administered.
8. Administration of investigational drugs shall be in accordance with the approved protocol and per establishing nursing policies and procedures.
9. Any adverse effects will be reported immediately by nursing personnel to the PI and to the provider, if different from the PI. Nursing personnel will also notify the pharmacy department of the adverse reaction and will enter the information into the online adverse event reporting system.
10. When the patient is discharged or therapy is discontinued, all portions of the unused investigational drug shall be returned to the pharmacy to ensure their return to the provider or PI.

11. Procedure for Continuation of Therapy When Provider Is Not the Principal Investigator

a. When a patient already receiving an investigational drug is admitted to the hospital and the admitting provider wishes for the patient to continue to receive the investigational drug, the admitting provider is responsible for obtaining information about the drug from the PI. This information must include a copy of the study protocol, essential drug information as outlined above, a copy of the signed informed consent, any documentation forms, and other pertinent information. Once the provider evaluates this information and determines that no contraindications for use of the drug exist, the patient may continue participation in the protocol upon order of the provider.
b. The admitting provider is responsible for forwarding the above information about the study drug to the pharmacy department for dissemination to appropriate nursing personnel.
c. The admitting provider is responsible for obtaining a copy of the signed informed consent form or obtaining the patient's informed consent. The signed consent form must be sent to the Health Information Management department, where it will be scanned into the patient's medical record.

d. Administration of a patient's personal supply of an investigational drug may be continued upon provider order. See "Home Medications" policy.
e. All of the steps described in the "Procedures" section above must be followed for patients continuing investigational drugs upon admission to the hospital.

INITIAL EFFECTIVE DATE: 03/2012
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