Policy:

• Investigational drugs will refer to those drugs which have not yet been released by the Federal Food and Drug Administration for general use. Therefore, they will include drugs bearing the following cautionary labeling “CAUTION New Drug - Limited by Federal Law to Investigational Use.”

Roles of Sponsors and Investigators:

• Drugs in these studies may only be used under the direction of a “qualified investigator” (staff physician) who is approved by the FDA (has signed the FDA release for obtaining the drugs) to administer investigational drugs and who is authorized by the sponsor (usually a manufacturer). Sponsors must have filed for FDA 1571 with the Food and Drug Administration (FDA) and investigators must have a Form FDA 1572 on file with the sponsor. When the physician receives the investigation drug, he/she may not give these drugs to any other patients except those on his/her service. He/she may not give these drugs to any other physician, or to any other physician’s patients, with the exception of authorized sub-investigators approved for participation as sub-investigators in the study.

Procedure:

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

• The physician must provide a copy of the protocol being followed and information about the drug. Information must be provided to the staff regarding the handling and administration of the drug.

• A copy of the investigational drug Informed Consent form as required by the IRB which has been signed by the patient will be obtained and placed in the research record prior to initiation of therapy. It is the investigating physician’s responsibility to ensure the Informed consent form is complete before initiation of the protocol.

• It shall be the Clinical Research Coordinator’s responsibility to resupply the drug when the initial supply has been used.

• It is the responsibility of the principal physician investigator to provide the signature and legible written names of all sub-investigators authorized to release investigational drugs.
Study drugs may be dispensed by the physician investigator when research is performed on outpatients. It is expected that the physician investigator will assure and account for the security and safety of all investigational drugs. In this instance, the investigator will maintain records.

**Labeling and Storage:**

Investigational drugs shall be properly labeled, stored and dispensed in accordance with the current FDA requirements and the physician investigator’s orders. All such drugs shall be stored in a separate area. No investigational drug stock shall be maintained in any other area within the practice.

Labeling of investigational drugs shall contain at least the following:

- Patients initials and study number
- Name of prescribing physician
- Name and strength of drug (or code)
- Complete directions for use (affixed to the container or available to the person administering the drug).
- Number of dosage units in container when dispensed
- Lot number
- Expiration date
- FOR INVESTIGATIONAL USE ONLY

**Drug Information:**

- Essential information on such drugs shall be maintained in the organization.
- Information shall include the dosage form, dosage range, storage requirements, route of administration, strength, actions, uses, side effects, adverse effects, contraindications, interactions and symptoms of toxicity.

**Dispensing of Investigational drugs:**

On approval of the principal investigator, practitioners authorized to use the drug or clinical research coordinators may administer these drugs. Clinical research coordinators shall not administer these drugs until they have been provided with basic pharmacologic information about these drugs and have attested to an understanding of this information.

**Informed Consent:**

Those patients that are potential subjects in research, investigation, and clinical trials will be provided with adequate information that will allow them to make an informed choice to participate in the activity or refuse to participate in the activity. Patients are informed that refusal to participate or the choice to discontinue participation at any time will not compromise their access to care, treatment, and services. Before requesting consent for participation in a research protocol, the patient must be informed regarding:

- Description of the purpose of the research
- Duration expected for the patient to participate
- Description of benefits to be expected
- Description of potential discomforts and risks
- Description of alternative services
• Full explanation of procedure to be followed, including any that are experimental in nature
• Assurances of right to refuse to participate without compromising the patient’s ability to receive care, treatment and/or services.

All consent forms related to research will indicate:

• Name of person who supplied prospective participant with information
• Date of form was signed
• Address the participant’s right to privacy
• Confidentiality
• Safety

A copy of the informed consent will be placed in the patient’s research record.

Administration of an Investigation Drug:

Only a member of the research staff approved by the Principal Investigator can administer an investigational drug.

Prior to administration of an investigational drug, the individual administering the medication will:

• Verify informed consent has been granted by the patient. A copy of the informed consent must be available in the research record. Investigational medication(s) will not be administered without proper consent. The individual administering the medication will contact the physician investigator if the consent is not located on the record.
• Review drug information regarding the pharmacology, proper administration and disposal, toxicities, and monitoring guidelines for the investigational drug.
• It is the responsibility of the physician investigator to provide the staff with adequate information regarding the investigational drug.
• Verify the appropriate dose and directions for use.

After administration of an investigational drug, the individual who has administered the medication will:

• Document on the source of documentation the drug, dose, route and date the drug was given.
• If the individual administering the medication is not the investigator, the individual administering the medication will inform the principal physician investigator of any side effects, adverse reactions or unexpected patient responses to the drug. The physician investigator must report these events to the practice organization and the IRB. The physician investigator is ultimately responsible for completing the necessary documentation in reporting adverse reactions to appropriate state, local and federal agencies.
• The physician investigator will address and manage to the best of his/her ability, any harmful consequence(s) the patient may have experienced due to research related physical, psychological, social, and financial or other injury.
• Document in the appropriate progress notes any side effects and patient responses to the drug.
• Return any remaining or unused drug.

Disposition Upon Dismissal of Patient or Discontinuing Therapy:

• When the patient is dismissed or therapy is discontinued, all portions of the unused investigational drug shall be returned. These drugs shall not remain at patient care areas.
Double-Blinded Studies:

- If a double-blind study is undertaken, the organization shall maintain a code system so that the true identity can be readily known in an emergency situation. Staff involved in patient care shall be informed as to the pertinent side effects and contraindications, and other information necessary to the administration of a particular drug.

Date Policy to be reviewed: 07/15