

SECTION IX

INVESTIGATIONAL DRUGS

CONNECTICUT VALLEY HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION IX: INVESTIGATIONAL DRUGS CHAPTER 9.1: USE OF INVESTIGATIONAL DRUGS

POLICY: Initiation of new investigational drug protocols come under the direct supervision of the principal investigator and must be approved by the research review committee. Patients admitted on investigational drugs may continue to use them without the approval of the Research Review Committee if the drug use is sanctioned by the principle investigator and the attending physician, and sufficient information is provided concerning the drugs pharmacology to allow appropriate clinical monitoring.

PROCEDURE:

1. Investigational drug protocols initiated must be approved by the Research Committee before an investigational medication may be administered.
2. The following procedure will be followed if a patient is admitted with an investigational drug:
 - A. Immediately notify the principal investigator of the patient's hospital admission.
 - B. Determine if the medication is to be continued.
 - C. Obtain a copy of the signed informed consent.
 - D. Obtain information from the investigator concerning drug dosage form, dosage range, storage requirements, adverse reactions, usage, and contraindications.
 - E. Investigational drugs may be administered only after the attending physician and administration nurse receives basic pharmacologic information about the drug.
3. Investigational drugs will be destroyed according to manufacturer's policy or hospital policy.