



# High Desert Health System POLICY AND PROCEDURE

POLICY NUMBER: 645  
VERSION: 1

## **SUBJECT: INVESTIGATIONAL DRUGS**

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### **PURPOSE:**

To define the policy and procedures to follow for the use of investigational drugs in patients/residents treated at High Desert Health System (HDHS).

### **POLICY:**

Investigational drug usage will not be initiated at HDHS. HDHS may accept patients/residents for transfer or treatments who are currently taking investigational drugs under protocol at other facilities. In such cases the following procedures must be followed.

### **PROCEDURES:**

Whenever a patient/resident taking an investigational drug is scheduled for to be treated in a HDHS clinic, the following steps will be taken to insure proper treatment, therapeutic monitoring, and record keeping:

1. The principal investigator must send the complete protocol and signed informed consent form to the HDHS Medical Director, or designee for approval for use of the investigational drug at HDHS.
2. The distribution and utilization of the investigational drug must have direct supervision of the principal investigator.
3. The HDHS physician accepting the patient may use the investigational drug only if there is informed written consent from the patient/resident or surrogate. The protocol must be approved for use at HDHS by Hospital Administration, Medical Director, or designee, and the Chair of the Pharmacy and Therapeutics (P&T) or designee. The P&T Committee will review and approve the protocol at the next regular meeting.
4. The principal investigator initiating the investigational drug must provide written approval to continue therapy for the specific patient/resident. This will be forwarded to the Medical Director, or designee, for review and the original will be maintained in the patient's/resident's medical record.
5. A copy of the approved protocol, including all written approvals above, shall be maintained in the HDHS Pharmacy. This document is received from the Medical Director.

6. Essential information concerning the investigational drug must be readily available in the Pharmacy.
7. An HDHS attending physician will be designated as the temporary investigator of the investigational drug to be administered and will keep in contact with the principal investigator during the course of the therapy at HDHS.
8. The attending physician must write an order on the patient's/resident's medical record authorizing the use of the experimental drug.
9. The Pharmacy will acquire, transport, store, dispense, and dispose of the investigational drug as per protocol. The Pharmacy will accurately collect required information and data and monitor administration of the drug per protocol. All information and data must be forwarded to the principal investigator as required. A copy of all information and data collected will be maintained in the HDHS Pharmacy.
10. The patient/resident may have written orders from the attending physician allowing the patient/resident to be transported to the originating hospital or clinic for necessary evaluation, testing, observation, or treatment.
11. All essential data must be sent to HDHS from the original hospital or clinic, including laboratory test results and other essential monitoring data from the principal investigator.
12. Emergency use of an investigational drug must also follow these procedures.
13. Pharmacy will educate and train appropriate clinical staff in the use of the investigational drug as necessary.
14. Investigational drugs will not be dispensed on discharge from HDHS. The principal investigator will be responsible for supplying the patient with the investigational drug after discharge.

**REFERENCES:**

1999 JCAHO Standard RI .3.

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