



COHESIVE HEALTHCARE MANAGEMENT & CONSULTING

Mangum Regional Medical Center

TITLE		POLICY	
Investigational Drugs		DRM-046	
MANUAL	EFFECTIVE DATE	REVIEW DATE	
Drug Room	10-1-2020	10-1-2020	
DEPARTMENT	REFERENCE		
Drug Room	Oklahoma Pharmacy Law Book		

SCOPE

This policy applies to patients that are using investigational drug therapy at MANGUM REGIONAL MEDICAL CENTER.

PURPOSE

The purpose of this policy is to establish standards in coordination with the Pharmacy and Therapeutics committee for the use and control of investigational drugs at MANGUM REGIONAL MEDICAL CENTER.

DEFINITIONS

Investigational drug: A chemical or biological substance that has been tested in the laboratory and approved by the US Food and Drug Administration (FDA) for testing in people during clinical trials.

POLICY

The Hospital shall ensure that if investigational drug(s) are used in the facility, it is done in a safe manner that adheres to regulations defined in the Oklahoma Pharmacy Law Book, Subchapter 6 Hospital Drug Room.

PROCEDURE

1. This facility does not initiate investigational drug use.
2. In the event a patient is admitted to the hospital and is currently taking investigational drug(s), the medical staff in coordination with the Pharmacy and Therapeutics Committee will determine if it is medically appropriate to continue the investigation drug(s).
 - a. The following is to be obtained from the principal investigator: a copy of the investigational protocol, forms required for tracking dispensing, administration and/or

- destruction of each dose, a copy of the signed consent, the IRB approval letter, any product information sheets, staff educational materials, and the study medication(s).
- b. If the investigational medication(s) is to be continued during a hospital admission, a medication order is required prior to administration.
 3. All investigational drugs shall be labeled in accordance with the labeling requirements of non-investigation drugs.
 4. Information needed to safely administer the medication is to be obtained and provided for nursing staff and the patient.
 5. Investigational drugs shall be stored in an area separated from approved pharmaceuticals and shall be secured in the hospital drug room.

REFERENCES

Oklahoma Pharmacy Law Book

REVISIONS/UPDATES

Date	Brief Description of Revision/Change