NORTHERN NEVADA ADULT MENTAL HEALTH SERVICES (NNAMHS)
POLICY AND PROCEDURE

SUBJECT: INVESTIGATIONAL DRUGS

NUMBER: NN-MM-05

ORIGINAL DATE: 06/16/90

REVIEW/REVISE DATE: 06/19/95, 01/04/01, 09/02/04, 8/2/07, 5/20/10, 12/5/13

APPROVAL_____Cody L. Phinney_____Agency Director

I. PURPOSE

To ensure that the use of investigational drugs is conducted ethically and in full conformity with all applicable laws and regulations.

II. POLICY

All investigational drugs will be reviewed and approved for use by the Pharmacy and Therapeutics (P&T) Committee, the Medical Director, and the Agency Director, and will be reported to the Core Leadership Committee.

III. REFERENCE

1. NAC 639 Pharmacists and Pharmacy
2. NNAMHS Policy NN-RI-16 Research
3. The Joint Commission Comprehensive Accreditation Manual for Hospitals, Medication Management Chapter.

IV. DEFINITIONS

Investigational Drug: A drug which has not received the Food Drug Administration (FDA) approval for marketing. Investigational drugs are generally in phase 3 or phase 4 clinical trials at the time of their use at this facility. This includes foreign drugs and other drugs which may be approved for use by the State of Nevada but not by the FDA.

V. PROCEDURE

1. The individual requesting permission to use an investigational drug will request approval of the P & T Committee. If the request is received longer than 2 (two) weeks from the scheduled meeting and is considered urgent, an emergency meeting can be called.
2. Upon review, all approvals will be reported to the Core Leadership Committee.
3. The individual requesting permission will be informed of the decision by the P & T Committee.
4. The P & T Committee shall monitor and supervise the use of any approved investigational drugs.
5. The NNAMHS pharmacy controls the storage, dispensing, labeling, and distribution of investigational drugs.
6. When a consumer involved in an investigational protocol is admitted to the Dini-Townsend Hospital, efforts will be made to evaluate, and if no contraindication exists, accommodate the consumers continued participation in the protocol.
7. Any recommendation for use of an investigational drug as part of a clinical trial will be referred to the NNAMHS Agency Director and the Department of Health and Human Services Institutional Review Board for approval.