RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

POLICY AND PROCEDURE MANUAL
PHARMACY SERVICES

SECTION: **INPATIENT PHARMACY SERVICES**

SUBJECT: **INVESTIGATIONAL DRUGS**

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POLICY

Investigational drugs, namely those medications which are FDA-approved Investigational New Drugs, can only be used after Institutional Review Board (IRB) approval. The Director of Pharmacy or a designee, is a member of the IRB Committee. Exceptions will be made for "Emergency" requests and "Compassionate Use."
The Investigational Drug Service Pharmacist (IDSP) shall provide a system for the procurement, storage, dispensing, record keeping, and disposition associated with the use of investigational drugs within the hospital in accordance with federal and State laws as well as hospital rules and regulations.

PROCEDURE

A. A copy of the final investigational drug study protocol approved by the IRB, as well as a copy of the informed consent shall be retained by the Pharmacy for appropriate reference.

B. Properly labeled investigational drugs shall be used only under the direct supervision of the principal investigator or his designates. Nurses may administer those drugs only after they have been given comprehensive pharmacological information about the drug by the investigator or designee. The pharmacy will act as a central control unit to stock and dispense investigational drugs.

C. Investigational drugs are to be stocked in the pharmacy and dispensed therein.

D. An investigational drug ordered for "compassionate use" and/or from a transferring facility is permitted, providing a consent form and a copy of the protocol has been obtained in advance of administration. [See Policy and Procedure 1.14.1]

E. On an annual basis the Pharmacy and Therapeutics Committee is kept abreast of all ongoing investigational drug studies.

F. Disposition at termination of study or expiration of investigational drugs involves contacting the manufacturer to facilitate the process. The IDSP segregates the investigational drug inventory from other "salvage" inventory for such time as required for the manufacturer to pick up the inventory for return to its place of origin.

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Approved By: