RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

POLICY AND PROCEDURE MANUAL
PHARMACY SERVICES

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SECTION:	**INPATIENT PHARMACY SERVICES**		
		APPROVED:	Thinh Tran, Pharm. D
SUBJECT:	**Investigational Drugs from other Facilities**	PAGES:	1 of 2

Policy

Patients who will be admitted to Rancho Los Amigos National Rehabilitation Center with Investigational Drugs which were approved and dispensed by another facility must comply with the following procedure.

Procedure

1. Prior to admission, the Centralized Admission Referral Operations (CARO) will assess if a patient is receiving a study medication and ensure that the following documents will be sent to them, preferably via email.
    a. The signed consent form (**faxed copy required**), which will be disseminated by the CARO Community Liaison Charge Nurse (or designee) to the respective Unit nurse manager (or designee) for chart inclusion.
    b. Study protocol. An abbreviated protocol is acceptable at the time of admission; however, the complete protocol must be sent by the investigator.
    c. All amendments
    d. Proof of the IRB committee/institution protocol approval, including date of approval.
    e. Patient's diagnosis, co-morbidities, height, weight, current medications, and pertinent labs and information needed to monitor the patient.
2. Once the Admitting Physician determines that the patient will be arriving with a study medication, s/he will contact the principal investigator or his/her designee to determine if the study medication is to be continued during the hospitalization.
3. If the study medication is to be continued during the patient's hospitalization, the Admitting Physician will notify the Case Management Coordinator who will send a copy of the above documents to the following:
    a. Rancho Research Institute
    b. The Chairperson of the IRB.
    c. The Investigational Drug Service Pharmacist (IDSP)

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d. CARO. They will hold the document until the patient arrives. The document will be sent with all other admitting documents as part of the patient's current medical record.

4. The admitting physician will:
    a. Obtain approval to administer the medication from the IRB chairperson or the P&T chairperson in his absence prior to the administration of the medication.
    b. Document the approval on the patient's current physician's order sheet.
    c. Write an order to administer the study medication. The directions for use must follow the study protocol.
5. The Attending Physician may give emergency approval for the administration of the medication(s) for a period not to exceed 96 hours.
6. The IDSP will educate the pharmacy and nursing personnel concerning the study including the potential effects and side effects of the medication(s).
7. The admitting nurse on the designated unit will contact the IDSP or the on-duty-inpatient pharmacist regarding the study medication. They will make arrangements for pick-up and processing of the medication for use on the nursing unit.

8. The IDSP pharmacist will dispense the medication once:
    a. S/he receives a physician order indicating that the IRB, P&T Chairperson or Attending Physician has approved the use for the designated patient AND
    b. S/he determines that all the required documents have been received by the pharmacy.
9. The Chairpersons of the IRB and P&T Committees will give a report to their respective committee regarding the medication and patient at the first committee meetings following the patient's admission.