



**ROBERT WOOD JOHNSON
MEDICAL SCHOOL**

University of Medicine & Dentistry of New Jersey

Title: Pharmacy and Phase I Trial Dose Modifications		
Effective Date: 04/24/08	Last Review Date: 04/28/08	
Services: Pharmacy, Division of Medical, Surgical, Pediatric, Gynecologic and Urologic Oncology, Department of Radiation Oncology		

I. BACKGROUND

The scientific goal of a Phase I trial is to determine a dose suitable for later efficacy testing as monotherapy or in combination regimens. Phase I trials typically begin at a low dose that is likely to be safe based on information derived from prior experience in animals. Small cohorts of one to three patients are then treated at progressively higher doses until reproducible biological effects are noted. Escalation generally continues until drug related toxicity reaches a predetermined level, at which time the trial would stop, or until unexpected and unacceptable toxicity has been documented.

II. POLICY

It is the policy of CINJ to ensure that the Pharmacy is systematically informed of the current dosing cohort for all patients enrolled in Phase I Trials. This information will be communicated via a dose assignment memo that will be prepared by the principal investigator and through review of patient registration in Oncore™

III. ACCOUNTABILITY

The Director of the Division of Pharmaceutical Sciences, the Chief Medical Officer and the Chief Operating Officer are accountable to ensure adherence to this policy.

IV. PROCEDURE

- A. All phase I doses are cross-referenced by the pharmacist to the current version of the clinical trial, patient registration in Oncore™, and the dose assignment memorandum.
- B. The dose assignment memorandum is available in Oncore™. This documentation is required at the time of initial dosing in a cohort at CINJ, including studies in which dose escalation has already occurred at another center; the expansion of an existing dosing cohort; escalation, de-escalation, or other dose modification of an existing dosing cohort.

- C. A copy of the dose assignment memorandum is printed by the pharmacist for each dosing cohort and stored in the pharmacy's protocol binder. Enrollment in the dosing cohort will be documented on the memorandum and include patient initials, study number, date of initial dosing in the cohort, and the initials of the dispensing pharmacist.
- D. A printed copy of the patient registration and dose assignment memo will be stored in the patient's pharmacy record for future reference.

SIGNATURES:

Revised by Michael P. Kane Date 5/7/2009
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Reviewed by Regina S. Cunningham Date: 5/7/2008
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Approved by Robert S. DiPaola Date 5/14/08
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