



1. TITLE OF STUDY:	6. SOURCE OF DRUG <i>(If other than manufacturer or sponsor)</i>
2. RESPONSIBLE INVESTIGATOR <i>(Individual who signed Form FD-1573)</i>	7. THERAPEUTIC CLASSIFICATION AND EXPECTED THERAPEUTIC EFFECT (S)
3. PRINCIPAL INVESTIGATOR <i>(If different than responsible investigator)</i>	
4. ALL DESIGNATIONS FOR DRUG <i>(Generic and chemical, code, trade-names, other designations)</i>	8. DOSAGE FORMS AND STRENGTHS
5. MANUFACTURER OR OTHER SPONSOR	9A. IS THIS DRUG A CONTROLLED SUBSTANCE? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>(If "Yes," complete Item 9B)</i>
	9B. CLASSIFICATION:

10. STABILITY AND STORAGE REQUIREMENTS

A. PRIOR TO MIXING, STORAGE SHOULD BE <i>(Check applicable box(es))</i> <input type="checkbox"/> AT ROOM TEMPERATURE <input type="checkbox"/> IN REFRIGERATOR <input type="checkbox"/> IN FREEZER <input type="checkbox"/> PROTECTED FROM LIGHT <input type="checkbox"/> OTHER <i>(Specify)</i> _____
B. AFTER MIXING, DRUG REMAINS STABLE IN REFRIGERATOR FOR <i>(Check appropriate box and enter quantity)</i> <input type="checkbox"/> _____ MINUTES <input type="checkbox"/> _____ HOURS <input type="checkbox"/> _____ DAYS

11. DRUG ADMINISTRATION PROCEDURES

A. ROUTES OF ADMINISTRATION <i>(Check appropriate box(es))</i> <input type="checkbox"/> ORAL <input type="checkbox"/> I.V. INFUSION <input type="checkbox"/> I.V. PUSH	B. ADMINISTRATION DIRECTIONS	C. RECONSTITUTION DIRECTIONS
12A. DRUG ADMINISTERED BY <i>(Also complete Item 12B)</i> <input type="checkbox"/> A. PHYSICIAN ONLY <input type="checkbox"/> B. PROFESSIONAL NURSE	12B. ROUTE	13. USUAL DOSAGE RANGE
14. KNOWN SIDE EFFECTS AND TOXICITIES		
15A. DOUBLE BLIND? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>(If "Yes," complete Items 15B and 15C)</i>	15B. NAME OF INDIVIDUAL WHO HAS CODE DESIGNATION	15C. TELEPHONE NUMBERS DAYTIME EVENING

16. SPECIAL PRECAUTIONS <i>(Include drug interactions (synergisms, antagonisms), contraindications, etc.)</i>		
17. ANTIDOTE		
18. STATUS <i>(Check one)</i> <input type="checkbox"/> INVESTIGATIONAL <input type="checkbox"/> PHASE II <input type="checkbox"/> COMMERCIALLY AVAILABLE <input type="checkbox"/> PHASE I <input type="checkbox"/> PHASE III <input type="checkbox"/> OTHER <i>(Specify)</i> _____		

19. NAMES OF AUTHORIZED PRESCRIBERS

A.	B.
C.	D.
20. SIGNATURE OF RESPONSIBLE OR PRINCIPAL INVESTIGATOR	DATE
21. APPROVED BY	
A. SUBCOMMITTEE ON HUMAN STUDIES	
21A. SIGNATURE OF CHAIRPERSON	DATE
B. RESEARCH AND DEVELOPMENT COMMITTEE	
21B. SIGNATURE OF CHAIRPERSON	DATE
22. PATIENT IDENTIFICATION <i>(I.D. plate or given name – last, first, middle)</i>	

INVESTIGATIONAL DRUGS IN RESEARCH WITH HUMAN SUBJECTS

An investigational drug for clinical use is one for which a sponsor has filed an IND (Investigational New Drug) application with, and which has been approved by, the FDA.

A VA Form 10-9012, Investigational Drug Information Record, **must** be completed on all active studies **(if, applicable)**.

The original of this form will be kept on file in Pharmacy Service as a part of the study protocol. A copy for each patient, with the appropriate patient identification, will be filed in the patient's medical record by faxing the form to **2862**. A copy should be given to the nurse-in-charge on the unit where the patient is located. A copy routed to the Research Office (151) to be filed with the study files.

If you have questions, please call Dr. Davis or the Research Office (151).

Additional forms may be reproduced.