

INVESTIGATIONAL DRUG INFORMATION RECORD

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>	
6. MANUFACTURER OR OTHER SPONSOR	5. DOSAGE FORMS AND STRENGTHS
	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 *(Check applicable box(es))*

AT ROOM TEMPERATURE
 IN REFRIGERATOR
 IN FREEZER
 PROTECTED FROM LIGHT
 OTHER *(Specify)*

B. AFTER MIXING, DRUG REMAINS STABLE IN REFRIGERATOR FOR *(Check appropriate box and enter quantity)*

_____ MINUTES
 _____ HOURS
 _____ DAYS

11. DRUG ADMINISTRATION PROCEDURES

A. ROUTES OF ADMINISTRATION <i>(Check appropriate boxes)</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"/> PHYSICIAN ONLY <input type="checkbox"/> PROFESSIONAL NURSE	12B. ROUTE	13. USUAL DOSAGE RANGE
14. KNOWN SIDE EFFECTS AND TOXICITIES		
15A. DOUBLE BLIND? <i>(IF "YES" COMPLETE ITEMS 15B AND 15C)</i> <input type="checkbox"/> YES <input type="checkbox"/> NO	15B. NAME OF INDIVIDUAL WHO HAS CODE DESIGNATION	15C. TELEPHONE NUMBERS DAYTIME: _____ EVENING: _____

16. SPECIAL PRECAUTIONS *(Include drug interactions [synergisms, antagonisms], contraindications, etc.)*

17. ANTIDOTE

18. STATUS *(Check one)*

INVESTIGATIONAL
 PHASE II
 COMMERCIALY AVAILABLE
 PHASE I
 PHASE III
 OTHER *(Specify)*

19. NAMES OF AUTHORIZED PRESCRIBERS

A.	B.
C.	D.

19. SIGNATURE OF RESPONSIBLE OR PRINCIPAL INVESTIGATOR	DATE
22. PATIENT IDENTIFICATION <i>(I.D. plate or given name - last, first, middle)</i>	

21. APPROVED BY

SUBCOMMITTEE ON HUMAN STUDIES	
21A. SIGNATURE OF CHAIRPERSON	DATE
RESEARCH AND DEVELOPMENT COMMITTEE	
21B. SIGNATURE OF CHAIRPERSON	DATE