



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
	9A. IS THIS DRUG A CONTROLLED SUBSTANCE? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>(If "Yes," complete Item 9B)</i>
5. MANUFACTURER OR OTHER SPONSOR	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 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 *(Include drug interactions (synergisms, antagonisms), contraindications, etc.)*

17. ANTIDOTE

18. STATUS *(Check one)*
 INVESTIGATIONAL PHASE II COMMERCIALLY AVAILABLE
 PHASE I PHASE III OTHER *(Specify)* _____

19. NAMES OF AUTHORIZED PRESCRIBERS

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