Department of Veterans Affairs

INVESTIGATIONAL DRUG INFORMATION RECORD

1. TITLE OF STUDY

2. RESPONSIBLE INVESTIGATOR *(Individual who signed Form FD-1573)*

3. PRINCIPAL INVESTIGATOR *(If different than responsible investigator)*

4. ALL DESIGNATIONS FOR DRUG *(Generic and chemical, code, trade-names, other designations)*

5. MANUFACTURER OR OTHER SPONSOR

6. SOURCE OF DRUG *(If other than manufacturer or sponsor)*

7. THERAPEUTIC CLASSIFICATION AND EXPECTED THERAPEUTIC EFFECT(S)

8. DOSAGE FORMS AND STRENGTHS

9A. IS THIS DRUG A CONTROLLED SUBSTANCE?

☐ YES ☐ NO *(If "Yes," complete Item 9B)*

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 *(Check appropriate box(es))*

☐ ORAL ☐ I.V. INFUSION ☐ I.V.PUSH

B. ADMINISTRATION DIRECTIONS

C. RECONSTITUTION DIRECTIONS

12A. DRUG ADMINISTERED BY *(Also complete Item 12B)*

☐ A. PHYSICIAN ONLY ☐ B. PROFESSIONAL NURSE

12B. ROUTE

13. USUAL DOSAGE RANGE

14. KNOWN SIDE EFFECTS AND TOXICITIES

I5A. DOUBLE BLIND?

☐ YES ☐ NO *(If "YES" complete Items 15B and 15C)*

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 ☐ 0THER *(Specify)*

19. NAMES OF AUTHORIZED PRESCRIBERS

A.

B.

C.

D.

20. SIGNATURE OF RESPONSIBLE OR PRINCIPAL INVESTIGATOR

DATE

22. PATIENT IDENTIFICATION *(I.D. plate or give name - last, first, middle*

21. APPROVED BY

A. SUBCOMMITTEE ON HUMAN STUDIES

21A. SIGNATURE OF CHAIRPERSON

DATE

B. RESEARCH AND DEVELOPMENT COMMITTEE

21B. SIGNATURE OF CHAIRPERSON

DATE