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

15A. 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 ☐ OTHER *(Specify)* _____

19. NAMES OF AUTHORIZED PRESCRIBERS

A.

B.

C.

D.

20. SIGNATURE OF RESPOMSIBLE OR PRINCIPAL INVESTIGATOR

DATE

22. PATIENT IDENTIFICATION *(I.D. plate or given 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

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