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|  | Department of Veterans Affairs | **INVESTIGATIONAL DRUG INFORMATION RECORD** |
| 1. TITLE OF STUDY      | 6. SOURCE OF DRUG *(If other than manufacturer or sponsor)*      |
| 2. RESPONSIBLE INVESTIGATOR *(Individual who signed Form FD-1572)*      | 7. THERAPEUTIC CLASSIFICATION AND EXPECTED THERAPEUTIC EFFECT(S)      |
| 3. PRINCIPAL INVESTIGATOR *(If different than responsible investigator)*      |
| 4. ALL DESIGNATIONS FOR DRUG *(Generic and chemical, code, trade-names, other designations)*      |
| 8. DOSAGE FORMS AND STRENGTHS      |
| 9A. IS THIS DRUG A CONTROLLED SUBSTANCE?[ ]  YES [ ]  NO *(If “Yes”, complete item 9B)* |
| 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 *(Check appropriate box(es))* | B. ADMINISTRATION DIRECTIONS      | C. RECONSTITUTION DIRECTIONS      |
| [ ]  ORAL | [ ]  I.V. INFUSION |
| [ ]  I.V. PUSH | [ ]  OTHER       |
| 12A. DRUG ADMINISTERED BY *(Also complete Item 12B)* | 12B. ROUTE      | 13. USUAL DOSAGE RANGE      |
| [ ]  A. PHYSICIAN ONLY | [ ]  B. PROFESSIONAL NURSE |
| 14. KNOWN SIDE EFFECTS AND TOXICITIES      |
| 15A. DOUBLE BLIND? | 15B. NAME OF INDIVIDUAL WHO HAS CODE DESIGNATION      | 15C. TELEPHONE NUMBERS |
| [ ]  YES | [ ]  NO | (*If “Yes”, complete Items 15B and 15C)* | 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.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 |
| VA FORMNOV 1989 | **10-9012** | COMPUTERIZED VERSIONRevised 9/98 |