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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 FORM  NOV 1989 | | **10-9012** | | | | | | | | | | | COMPUTERIZED VERSION  Revised 9/98 | | | | | | | | |