|  |
| --- |
| FORM IND: INVESTIGATIONAL DRUGS IN RESEARCHVA Ann Arbor Healthcare System (FWA-00000348)Subcommittee on Human Studies (IRB-00000264)2215 Fuller Rd. Phone: 734-761-7950Ann Arbor, MI 48105 FAX: 734-761-7693 |
| PRINCIPAL INVESTIGATOR: |
| TITLE OF STUDY: |
| If you answer YES to \*any\* of these 5 questions, an IND from the FDA is required.  1. Will this study use an investigational drug that is not FDA approved?  [ ] Yes [ ] No  2. Will the study be conducted with a commercially available drug to support a new indication or to support a change in advertising or labeling of the product?  [ ] Yes [ ] No  3. Will the study use a commercially available drug that is being administered via a new route (that significantly increases the risks) or for use in a different part of the body?  [ ] Yes [ ] No  4. Will the study use a commercially available drug that is being given at a dosage level that might significantly increase the risk to the subject population?  [ ] Yes [ ] No  5. Will the study use a commercially available drug that is going to be used in a new patient population that may result in a significant increase in risk(s) to the patient population?  [ ] Yes [ ] No  If you answer Yes to at least one question in 1-5, then please submit  documentation of the IND number from the sponsor or FDA. IND # => \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *(Acceptable documentation includes indication of the IND number on the protocol or Investigator’s Brochure or a letter/ email from either the sponsor or the FDA acknowledging that an IND has been obtained.*   * The VA IRB will determine if an IND approval from the FDA is required for this study. * The VA Research Pharmacist will contact FDA to validate an existing IND approval number.   VA IRB POLICIES FOR ALL DRUG STUDIES   * VA investigators conducting investigational drug studies must follow applicable requirements including Handbook 1108.04 – “Investigational Drugs and Supplies.” * The Investigator must provide the Research Service Investigational Pharmacy information on each subject receiving the investigational drug. * The investigator must submit VA Form 10-9012 for each drug to be used in the study (Form 10-9012 informs prescribers and other clinical personnel of any side effects and any known antidote of the investigational agent, as well as who is the designated contact person for questions.)     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Principal Investigator Date |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Department of Veterans Affairs | | | INVESTIGATIONAL DRUG INFORMATION RECORD [10-9012] | | | | | | |
| 1. TITLE OF STUDY | | | | | | 1. SOURCE OF DRUG (If other than manufacturer or sponsor) | | | | |
| 1. RESPONSIBLE INVESTIGATOR (Individual who signed Form FD-1573) | | | | | | 1. THERAPEUTIC CLASSIFICATION AND EXPECTED THERAPEUTIC EFFECT(S) | | | | |
| 1. PRINCIPAL INVESTIGATOR (If different than responsible investigator) | | | | | |
| 1. ALL DESIGNATIONS FOR DRUG (Generic and chemical, code, trade names, other designations) | | | | | |
| 1. DOSAGE FORMS AND STRENGTHS | | | | |
| 9a. IS THIS DRUG A CONTROLLED SUBSTANCE?  YES NO If “Yes” complete Item 9B) | | | | |
| 1. MANUFACTURER OR OTHER SPONSOR | | | | | | 9b. CLASSIFICATION | | | | |
| 10. STABILITY AND STORAGE REQUIREMENTS | | | | | | | | | | |
| 1. PRIOR TO MIXING, STORAGE SHOULD BE (Check applicable box(es)   AT ROOM TEMPERATURE IN REFRIGERATOR IN FREEZER PROTECTED FROM LIGHT OTHER (Specify) | | | | | | | | | | |
| 1. AFTER MIXING, DRUG REMAINS STABLE IN REFRIGERATOR FOR (Check appropriate box and enter quantity)        MINUTES       HOURS       DAYS | | | | | | | | | | |
| 11. DRUG ADMINISTRATION PROCEDURES | | | | | | | | | | |
| 1. ROUTES OF ADMINISTRATION (Check appropriate boxes)   ORAL  I.V. INFUSION  I.V. PUSH | 1. ADMINISTRATION DIRECTIONS | | | | | | | 1. RECONSTITUTION DIRECTIONS | | |
| 12A. DRUG ADMINISTERED BY (Also complete Item 12B)  PHYSICIAN ONLY PROFESSIONAL NURSE | | | | | 12B. ROUTE | | 1. USUAL DOSAGE RANGE | | | |
| 1. KNOWN SIDE EFFECTS AND TOXICITIES | | | | | | | | | | |
| 15A. DOUBLE BLIND?  (IF “YES” COMPLETE  YES NO ITEMS 15B AND 15C) | | 15B. NAME OF INDIVIDUAL WHO HAS CODE DESIGNATION | | | | | | 15C. TELEPHONE NUMBERS | | |
| DAYTIME | EVENING | |
| 1. SPECIAL PRECAUTIONS (Include drug interactions [synergisms, antagonisms], contraindications, etc.) | | | | | | | | | | |
| 1. ANTIDOTE | | | | | | | | | | |
| 1. STATUS (Check one)   INVESTIGATIONAL  PHASE II  COMMERCIALLY AVAILABLE  PHASE I  PHASE III  OTHER (Specify) | | | | | | | | | | |
| 19. NAMES OF AUTHORIZED PRESCRIBERS | | | | | | | | | | |
| A. | | | | | | B. | | | | |
| C. | | | | | | D. | | | | |
| 1. SIGNATURE OF RESPONSIBLE OR PRINCIPAL INVESTIGATOR | | | | DATE | | 22. PATIENT IDENTIFICATION (I.D. plate or given name – last, first, middle) | | | | |
| 21. APPROVED BY | | | | | |
| SUBCOMMITTEE ON HUMAN STUDIES | | | | | |
| 21A. SIGNATURE OF CHAIRPERSON | | | | DATE | |
| RESEARCH AND DEVELOPMENT COMMITTEE | | | | | |
| 21B. SIGNATURE OF CHAIRPERSON | | | | DATE | |

VA Form 10-9012 \* U.S. GPO:1997-519-315/91055