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| 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 [ ] No2. 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 [ ] No3. 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 [ ] No4. 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 [ ] No5. 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 [ ] NoIf 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.)

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| Department of Veterans Affairs | INVESTIGATIONAL DRUG INFORMATION RECORD [10-9012] |
| 1. TITLE OF STUDY
 | 1. SOURCE OF DRUG (If other than manufacturer or sponsor)

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| 1. RESPONSIBLE INVESTIGATOR (Individual who signed Form FD-1573)

      | 1. THERAPEUTIC CLASSIFICATION AND EXPECTED THERAPEUTIC EFFECT(S)

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| 1. PRINCIPAL INVESTIGATOR (If different than responsible investigator)

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| 1. ALL DESIGNATIONS FOR DRUG (Generic and chemical, code, trade names, other designations)

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| 1. DOSAGE FORMS AND STRENGTHS

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| 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

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| 12A. DRUG ADMINISTERED BY (Also complete Item 12B)[ ]  PHYSICIAN ONLY [ ] PROFESSIONAL NURSE | 12B. ROUTE      | 1. USUAL DOSAGE RANGE

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| 1. KNOWN SIDE EFFECTS AND TOXICITIES

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| 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.)

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| 1. ANTIDOTE

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| 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