

WBAMC Protocol #: Date submitted: Date reviewed: Date IRB appr:
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WHEN SUBMITTING PROTOCOL, MAKE SURE TO INCLUDE THE FOLLOWING:

- 1) *COPY OF PROTOCOL VIA EMAIL*
- 2) *CVs FOR ALL INVESTIGATORS*
- 3) *ORIGINAL SIGNATURES FOR ALL EXCEPT Chief, Dept. of Clinical Investigation*
- 4) *INCLUDE ALL DATA COLLECTION SHEETS AND APPENDICES*

***NOTE: PLEASE DELETE ALL ITALICIZED INSTRUCTIONS PRIOR TO SUBMISSION!!***

**HUMAN USE CLINICAL INVESTIGATION PROTOCOL  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
El Paso, Texas 79920-5001**

**1. PROJECT TITLE:**

**2. INVESTIGATOR(S): *(Please attach CVs)***

**a. PRINCIPAL INVESTIGATOR AND DEPARTMENT:** *(Please list only one.)*

**b. ASSOCIATE INVESTIGATOR(S) AND DEPARTMENT(S):**

**3. LOCATION OF STUDY: *(List department/clinic/section affected and provide impact statements.)***

**list Other Participating Medical Facilities, if applicable:**

**4. TIME REQUIRED TO COMPLETE: *(Including data analysis, manuscript preparation.)***

**5. Study Summary: *(State consisely your overall research plan—"Reader's Digest version".)***

**6. Military Relevancy:**

**7. STUDY HYPOTHESIS (OR RESEARCH QUESTION):**

**8. BACKGROUND AND REVIEW OF THE LITERATURE: *(State what has been accomplished or published in the proposed area of study. Describe the way in which the project will relate to, or differ from, that which has been accomplished.)***

**1) Literature source(s) searched:**

**2) Date of search:**

**3) Keywords of search:**

**4) Results of search:** *Please attach any relevant abstracts not listed in the bibliography.*

5) **Bibliography:** *(Cross reference all citations in this list within the body of the protocol.)*

9. **METHODS:**

a. **Outline of research design:** *(State details of research plan including when relevant investigational groups, control groups, differences between procedures in plan and “standard of care”, specific definitions for variables, and how the design will address the hypothesis/research question listed above.)*

b. **Number of subjects:**

c. **Age Range:**

d. **Sex:** *(If limited to only male or only female, please justify with reasons.)*

e. **Inclusion criteria:**

f. **Exclusion criteria:**

g. **Source of subjects:** Department of Defense beneficiaries only

h. **Subject recruitment, identification procedures, or advertising:** *(For example, “daily review of positive blood cultures in microbiology laboratory” or “ombudsman will inform all soldiers going through SRP of possible study participation”, “flyers will be posted in Fitness Center”etc. Please provide a copy of any advertisements, flyers, etc)*

i. **Project Medications:** *(Please respond NA or delete section if no medications are involved.)*

1. Complete name of all medications
2. Source/supplier of all medication to include controls and lot numbers
3. Storage location
4. Dose range, schedule, administration, and duration
5. Radioactivity specifications
6. Administration
7. Pre-drug period
8. Accompanying medications (those allowed)
9. If needed, what antidotes must be available
10. Labeling of study medication
11. Disposition of unused medication at termination/completion

j. **Equipment/Devices/Instruments(Surveys etc):** *(Please provide information pertaining to accuracy, precision, validity, and reliability as relevant. Please attach any surveys or other written instruments.)*

**k. Pre-study/consent screening/testing for eligibility:**

**l. Specimens to be collected:**

- 1) schedule
- 2) evaluation
- 3) storage
- 4) labeling and disposition
- 5) laboratory performing evaluation
- 6) special precautions

**m. Clinical assessments:** *(Include clinic visits, procedures, follow-ups, frequency of lab testing or specimen acquisition, etc.)*

**n. Disposition of data:** The principal investigator will maintain data until the study is completed, terminated, or closed. All data will then be disposed of IAW applicable policies and/or regulations.

**o. Methods used for data collection:** *(Please attach data collection forms, case forms, databases formats, etc.)*

**10. Statistical measures in analyzing data:** *(Include power analysis and measures planned to describe, make comparison, etc. )*

**11. HUMAN SUBJECT PROTECTION**

**a. Analysis of risks and benefits to subjects and risks to those conducting research:**

**b. Precautions to be taken to minimize or eliminate risks to subjects and those conducting the research:**

**c. Plan for protecting private health information.**

**d. Alternatives to participation:** *(If not covered in discussion of “standard of care” above.)*

**12. DEPARTURE FROM PROTOCOL FOR INDIVIDUAL PATIENTS:**

**a. When allowed:** There will be no departure from the proposal as written unless necessary for the safety of a subject or investigator.

**b. Who will be notified:** A departure from the protocol is not anticipated; however, if methods outside of the proposal are implemented, we will notify the IRB Chair/Chief DCI and the investigators associated with the study.

**13. ADVERSE REACTIONS:**

**a. Definition:** An *adverse event (AE)* is an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy). A *serious adverse event (SAE)* is one that leads to hospitalization or death, regardless of whether it is deemed study related or not.

**b. Immediate reporting (SAE):** The Chair, Institutional Review Board (or the DCCS) will be immediately notified of a serious adverse event by telephone, with follow-up notification in writing (within 24 hours) of the circumstances surrounding the incident.

**c. Routine reporting (AE):** The Chair, Institutional Review Board will be notified in writing within 10 working days of the circumstances surrounding the incident if the event is non-serious (an unexpected event not listed in the consent).

**14. MODIFICATION OF PROTOCOL:** Request for modification of the protocol, to include termination or extension, will be made in writing to the Chair, Institutional Review Board.

**15. USE OF INFORMATION AND PUBLICATIONS ARISING FROM THE STUDY:** Information from this study may be used for presentations at medical conferences and/or publications in medical journals. All manuscripts, abstracts or other forms of data presentation must be submitted to Department of Clinical Investigation for approval prior to sending out from WBAMC. Disclosure of the data will be subject to Federal laws and Department of Defense regulations.

**16. FUNDING IMPLICATIONS:** *If you require research funding from DCI, this must be discussed with the Assistant Chief, DCI.*

**17. HUMAN USE COMMITTEE:** The WBAMC Human Use Committee will provide initial and continuing review of this project.

**18. DATE PREPARED:**

Please provide on a separate page

**19. SIGNATURES (Provide Protocol # and title):**

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Principal Investigator (name, rank, title, Dept.)	Date
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Associate Investigator(s) name, rank, title, Dept. & Institution (if not WBAMC)	Date
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Chief, Department of (name, rank, title)	Date
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(Chief of any department(s) impacted by your study) (name, rank, title)	Date
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BRUCE D ADAMS, COL, MC Chief, Department of Clinical Investigation IRB Chair	Date
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**CHECKLIST**

**- ATTACH A COPY OF ALL FORMS (DATA SHEETS, QUESTIONNAIRES, ETC.) TO BE USED IN THE PROTOCOL**

**- INCLUDE SIGNATURES FOR ALL THOSE LISTED ON SIGNATURE PAGE(S)**

**- VERIFY THAT DCI HAS CVs AND CITI TRAINING VERIFICATION FOR ALL INVESTIGATORS**