

CONTINUING REVIEW OF RESEARCH PROTOCOLS

Project Title:

VA Project No:

IRB Protocol No:

Principal Investigator:

Date:

NOTE: If this is a final report you must complete the Request for Inactivation of a Research Protocol Form (<http://www.southtexas.va.gov/Research/Documents/Inactivation.pdf>)

1. Personnel: Please attach most current and applicable IRB Inst M, Form B-2, Step 2-Inst or CIRB VA Form 104, VA Form 115b, VA Form 134a. The personnel list will be used to verify Research VA privileges. Reviewed and Verified by R&D Office Date: _____

2. Conflict of Interest:

Submit updated Financial Conflict of Interest form for all research Investigators. (This includes all PIs, Co-PIs, and Sub-Investigators. Please submit in electronic format only and do not lock document.)

YES – (updated Conflict of Interest Disclosures are attached <http://www.southtexas.va.gov/Research/Documents/ResearchFinancialConflictofInterest.pdf>)

3. Data Security:

Have there been changes in the collection, storage, or use of VA-sensitive research data for this project that would require update of the VA Research Data Security Checklist?

YES – (updated VA Research Data Security Checklist is attached http://www.southtexas.va.gov/Research/Forms_STVHCS_Research.asp)

NO – (update of VA Research Data Security Checklist is not required)

4. Subject Accrual:

a. How many VETERAN subjects have been enrolled or subject charts reviewed since this project was initiated?

b. Is this project approved to enroll NONVETERAN subjects at the VA Site? YES NO (IF YES, how many NONVETERANS have been enrolled at the VA site since this project was initiated?)

c. Is this project closed to new enrollment? YES NO

(IF YES, are any subjects that were enrolled at the VA site currently being followed? YES NO)

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5. Pharmacy:

a. Have there been any modifications to personnel that require a change to the original VA Form 10-9012 (Investigational Drug Record Form)? **If any listed authorized prescribers are no longer active personnel on this form or if any authorized prescribers should be added based on addition of newly active personnel, an updated 10-9012 must be attached to reflect such changes.**

YES (updated 10-9012 form attached http://www.southtexas.va.gov/Research/Forms_STVHCS_Research.asp)

NO

NA

b. Have there been any modifications in the experimental procedures related to the handling of Investigational Drugs or Devices that require a change to the original VA Form 10-9012 (Investigational Drug Record Form)?

YES (updated 10-9012 form attached http://www.southtexas.va.gov/Research/Forms_STVHCS_Research.asp)

NO

NO LONGER REQUIRED (All Pharmacy Interventions Completed)

NA

c. Does the Research Pharmacy have a copy of the current protocol, consent form, and VA 10-9012 form?

YES

NO (Provide copies of current documents to the Research Pharmacy)

NO LONGER REQUIRED (All Pharmacy Interventions Completed)

NA

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**6. Is this an IRB approved EXEMPT protocol or has it been determined to be nonhuman research?
(If your study HSC number ends in an “E or N” your study is exempt. If your study HSC number ends in an H your study is not exempt)**

YES – Provide a descriptive update/ summary of progress made on this project. If the project has been completed during the last year, summarize what the project accomplished overall. The description should include any changes to study objectives, research plan, methods, findings, or clinical relevance. This update/summary will be presented to the R&D Committee as part of the Annual Review of the project.

NO – (Documents submitted to the UTHSCSA IRB for Continuing Review will be obtained from the IRB for review by the R&D Committee. No duplicate IRB documents need to be submitted.)

7. Funding:

a. Is/was this project funded by any source?

YES (If YES, provide funding source
(Funding end date
(Grant or Funding #

NO
NO cost extension

b. Has the funding source changed since the last continuing review?

YES **NO**

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8. Research Safety Review

Please review your currently approved “Research Protocol Safety Survey” and respond to the following questions:

a. Are any new or modified experimental procedures involving the use of biological, chemical, physical, or radiation hazards anticipated in the re-approval period that are **not contained in the currently approved** “Research Protocol Safety Survey”?

NO

YES (attach a revised “Research Protocol Safety Survey” http://www.southtexas.va.gov/Research/Forms_STVHCS_Research.asp)

NOTE: The Research Safety Committee and the R&D Committee must approve changes prior to implementation.

b. Have all research personnel reviewed the current “Research Protocol Safety Survey”?

NO

YES

c. Have there been any changes which may affect Radiation Safety approval?

NOT APPLICABLE (the study does not require radiation safety approval)

NO

YES Radiation Safety approval date (Same as SRS annual approval date) _____

For questions related to Radiation Safety approval contact the Radiation Safety Office at (210)617-5300 x 14037

NO LONGER REQUIRED (All Radiation Interventions Completed)

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For Office Use Only

Reviewed and Verified by R&D Office Staff:

Date:

APPROVAL

DISAPPROVAL

Safety Subcommittee Chairman Signature _____ Date:

9. Publications:

Provide publication citation(s) that have resulted from work on this project (do not attach copies):

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CHECK APPROPRIATE BOX (ONLY CHECK ONE) AND SIGN BELOW

I have reviewed the current and approved Research Scope of Practice for all applicable personnel and verify that it includes all required duties and procedures for conducting this project. NOTE: If changes to a Research Scope of Practice are needed to cover the required duties and procedures for conducting this project, a new Research Scope of Practice must be submitted and approved prior to adding these personnel to the protocol.

No personnel listed above are subject to the Research Scope of Practice policy (all personnel listed are licensed physicians or are only involved in non-human research).

I verify if exempt personnel are listed, they meet the definition of exempt provided above and will only be assigned duties consistent with this definition. I verify the information submitted on this form is accurate at the time of submission.

Name and contact information of person completing this form:

PI Signature _____ Date _____

For R&D Office Use Only

Reviewed and Verified by R&D Office Staff: _____ Date: _____

APPROVED by R&DC APPROVED by all appropriate subcommittees of the R&DC DISAPPROVED by R&DC

ACOS for Research Signature _____ Date: _____