

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>)

When a protocol has been completed or the STVHCS is no longer an active site the following must be true: VA funding is no longer being obtained; enrollment of new subjects is permanently closed; data, private information, and/or clinical specimens are no longer being collected for research purposes (including long term follow up); subjects are no longer being treated under the research protocol; research assessments or procedures are no longer being performed; data/specimen analysis has been completed locally or if analysis continues locally the data has been permanently de-identified.

1. Project Personnel (i.e., Principal investigator, Co-investigators, Collaborators, Study Coordinators, Research Nurses, Support Staff):

Name (Last, First)	ROLE (i.e. PI, Co-Inv, Research Associate)	email	Phone	Exempt Personnel*	New Personnel**	Active Personnel
				<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO

*Study personnel who are not physically conducting research on VA property, only have access to de-identified data and/or not directly working with research subjects

Refer to the Research Service website (<http://www.southtexas.va.gov/Research/Personnel.asp>) for all required forms to establish research privileges. **NOTE: New personnel may not work on protocols until research privileges have been approved by the R&D Office.

CONTINUING REVIEW OF RESEARCH PROTOCOLS

Project Title:

VA Project No:
IRB Protocol No:

Principal Investigator:

Date:

2. Conflict of Interest:

Have there been changes in the financial arrangements or other non-financial arrangements for investigators or study personnel on this project that would require update of the Conflict of Interest Disclosures?

- YES** – (updated Conflict of Interest Disclosures are attached <http://www.southtexas.va.gov/Research/Documents/LFf.pdf>)
 NO – (update of Conflict of Interest Disclosures are not required)

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: (NOTE: obtaining an individual's information or specimens is considered accruing {i.e., chart reviews, one time blood draws} and these numbers should be included)

- a. How many VETERAN subjects have been enrolled since this project was initiated?
b. How many VETERAN subjects continue to be followed for this project?
c. How many NONVETERAN subjects have been enrolled at the STVHCS since this project was initiated?
d. How many NONVETERAN subjects continue to be followed at the STVHCS for this project?

5. Pharmacy:

a. 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
 N/A

b. 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)
 N/A

CONTINUING REVIEW OF RESEARCH PROTOCOLS

Project Title:

VA Project No:

IRB Protocol No:

Principal Investigator:

Date:

6. Is this an IRB approved EXEMPT protocol or has it been determined to be nonhuman research?

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.)

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.

CONTINUING REVIEW OF RESEARCH PROTOCOLS

Project Title:

VA Project No:

IRB Protocol No:

Principal Investigator:

Date:

7. Publications:

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

Principal Investigator Signature (REQUIRED): _____ **Date:** _____

For R&D Office Use Only

Reviewed and Verified by R&D Office Staff:

Date:

APPROVAL

DISAPPROVAL

R&D Committee Chairman Signature _____

Date:

CONTINUING REVIEW OF RESEARCH PROTOCOLS

Project Title:

VA Project No:
IRB Protocol No:

Principal Investigator:

Date:

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. Does this research project have Radiation Safety approval?

- NO**
 YES (provide current Radiation Safety expiration date _____)

For questions related to Radiation Safety approval contact Evelyn Cooke (210)617-5300 x 14035

For Office Use Only

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

APPROVAL DISAPPROVAL

Safety Subcommittee Chairman Signature _____
Date: