CONTINUING REVIEW OF RESEARCH PROTOCOLS

Project Title:

VA Project No:

Principal Investigator:

Annual Review Expiration Date:

Is this a final report – (all data have been collected and analyzed)? ☐ **YES (for human studies complete page 5 & Appendix C; for animal studies complete pages 4 & 5)** ☐ **NO (Complete form as applicable)**

Project Personnel (i.e., Co-investigators, Collaborators, Study Coordinators, Research Nurses, Support Staff): Please verify or update project personnel list.

Name (Last, First)	Active Personnel	New Personnel
	☐ YES ☐ NO	☐ YES * ☐ NO
	☐ YES ☐ NO	☐ YES * ☐ NO
	☐ YES ☐ NO	☐ YES * ☐ NO
	☐ YES ☐ NO	☐ YES * ☐ NO
	☐ YES ☐ NO	☐ YES * ☐ NO
	☐ YES ☐ NO	☐ YES * ☐ NO
Cont'd on Page 7	☐ YES ☐ NO	☐ YES * ☐ NO

*For all new personnel complete Appendix A (human studies) or Appendix B (non-human studies) **AND** refer to the Research Service website (http://www.south-texas.med.va.gov/research/html/personnel.htm) 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.**

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?

☐ **NO –** (update of Conflict of Interest Disclosures are not required)

☐ **YES –** (updated Conflict of Interest Disclosures are attached)

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?

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

☐ **YES –** (updated VA Research Data Security Checklist is attached)

For Office Use Only

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

CONTINUING REVIEW OF RESEARCH PROTOCOLS

Project Title:

VA Project No:

Principal Investigator:

Annual Review Expiration Date:

Human Subjects Research Section (Required for all projects involving human subjects or their identifiable private information)

☐ ***Check here if this section is not applicable to this project***

IRB #:

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) ☐ **NO** ☐ **N/A**

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**

Is this an IRB approved EXEMPT protocol?

☐ **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 –** (Complete Project Update/Summary Section –page 5)

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

CONTINUING REVIEW OF RESEARCH PROTOCOLS

Project Title:

VA Project No:

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Annual Review Expiration Date:

Research Safety Section (Required for all projects involving biological, chemical, physical, and radiation hazards)

☐ ***Check here if this section is not applicable to this project***

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

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

☐ **NO** ☐ **YES** (attach a revised "Research Protocol Safety Survey" indicating changes)
NOTE: The Research Safety Committee and the R&D Committee must approve changes prior to implementation.

Have all research personnel reviewed the current "Research Protocol Safety Survey"?
☐ **NO** ☐ **YES**

For Office Use Only

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

APPROVAL **DISAPPROVAL**

Safety Subcommittee Chairman Signature _____
Date:

CONTINUING REVIEW OF RESEARCH PROTOCOLS

Project Title:

VA Project No:

Principal Investigator:

Annual Review Expiration Date:

Animal Subjects Section (Required for all projects using animal subjects)

☐ ***Check here if this section is not applicable to this project***

Status: ☐ Project has terminated ☐ Project is active and animal subjects are being used ☐ Project is active but animal subjects are not being used and will not be used in the future for this project. Delete animal use approval.	**Protocol No**: **Approval Period:** **Funding Source:**
1. Has the animal use been in accordance with the approved protocol?	☐ **YES** ☐ **NO**
2. Are there changes in animal use anticipated during this approval period? If yes, attach the amended ACORP.	☐ **YES** ☐ **NO**

Verify the animal usage FOR THIS PROJECT to date:				
Species / strain:	USDA Class (A, B, C, D, or E)	Total number approved:	Total number used to date:	Total number remaining:

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

APPROVAL **DISAPPROVAL**

IACUC Subcommittee Chairman Signature _____
Date:

CONTINUING REVIEW OF RESEARCH PROTOCOLS

Project Title:

VA Project No:

Principal Investigator:

Annual Review Expiration Date:

Project Update/Summary Section: (Required for all human EXEMPT projects, animal projects, laboratory non-human/non-animal projects)
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 abstract should be edited to make any changes to study objectives, research plan, methods, findings, and clinical relevance. This update/summary will be presented to the R&D Committee as part of the Annual Review of the project.

☐ ***Check here if this section is not applicable to this project***

CONTINUING REVIEW OF RESEARCH PROTOCOLS

Project Title:

VA Project No:

Principal Investigator:

Annual Review Expiration Date:

Provide publication citation(s) related to this project (do not attach copies):

Principal Investigator Signature: _____ Date: _____

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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:

Principal Investigator:

Annual Review Expiration Date:

Project Personnel (i.e., Co-investigators, Collaborators, Study Coordinators, Research Nurses, Support Staff): Please verify or update project personnel list.

Name (Last, First)	Active Personnel	New Personnel
	☐ YES ☐ NO	☐ YES * ☐ NO
	☐ YES ☐ NO	☐ YES * ☐ NO
	☐ YES ☐ NO	☐ YES * ☐ NO
	☐ YES ☐ NO	☐ YES * ☐ NO
	☐ YES ☐ NO	☐ YES * ☐ NO
	☐ YES ☐ NO	☐ YES * ☐ NO
	☐ YES ☐ NO	☐ YES * ☐ NO
	☐ YES ☐ NO	☐ YES * ☐ NO
	☐ YES ☐ NO	☐ YES * ☐ NO

APPENDIX A Human Studies

PROJECT TITLE:

NAME	ROLE (i.e. PI, Co-Inv, Research Assoc.)	DEGREE	Phone	Email	TYPE OF VA APPOINTMENT (i.e. VA, WOC, Contract)	VA SERVICE	HUMAN STUDIES			
							CITI	Data Security Training		
								VA Information Security 201	VA Info. Security Awareness	VHA Privacy Policy

APPENDIX B Non-Human Studies

PROJECT TITLE:

NAME	ROLE (i.e. PI, Co-Inv, Research Associate)	DEGREE	PHONE	EMAIL	TYPE OF VA APPOINTMENT (i.e. VA, WOC, Contract)	VA SERVICE	Non-Human STUDIES					
							For Animal Studies (f applicable)			Data Security Training		
							Working with IACUC	Working with (specify animal species here)	Post Proc Care (If applicable)	VA Information Security 201	VA Information Security Awareness	VHA Privacy Policy

APPENDIX C: Request for Inactivation of a Research Protocol

Number of subjects accrued (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)

1. How many VETERAN subjects were enrolled at the STVHCS since the study started?

2. How many VETERAN subjects enrolled at the STVHCS completed the study?

3. How many nonveteran subjects were enrolled and seen at the STVHCS since the study started?

4. How many nonveteran subjects enrolled and seen at the STVHCS completed the study?

Did the study involve the use of an Investigational Drug(s) or Device(s) that require a VA Form 10-9012 (Investigational Drug Record Form)?

☐ **YES** (notify Research Pharmacy of study termination) ☐ **NO**

The PI must work with the Research Pharmacy to initiate the appropriate action for disposition of any investigational drugs or devices remaining at the time of study inactivation.

Where will research data (i.e., paper or electronic) and/or specimens be stored and for how long?

☐ De-identified data:

- ☐ Paper data (Location of paper data storage:_____ ; Duration of storage:_____)
- ☐ Electronic data stored (location of electronic data storage:_____ ; Duration of storage: _____)
- ☐ Specimens stored (location of specimen storage: _____ ;Duration of storage:_____)

☐ Identifiable data:

- ☐ Paper data (Location of paper data storage:_____ ; Duration of storage:_____)
- ☐ Electronic data stored (location of electronic data storage:_____ ; Duration of storage: _____)
- ☐ Specimens stored (location of specimen storage*: _____ ;Duration of storage:_____)
  must be a VA approved storage site
- ☐ Key to a coding system utilized to link identifiable information to de-identified information (location of storage: _____ ; Duration of storage: _____)

Name and contact information of study personnel designated as point of contact for stored records:
Name: Phone: E-mail:

For industry sponsored projects, provide sponsor contact information for the stored records:
Name: Phone: E-mail:

Note: if there are changes to the information provided, you must notify the VA R&D office.

APPENDIX C: Request for Inactivation of a Research Protocol

Date the protocol or the STVHCS site was inactivated at the UTHSCSA IRB:

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.