

REQUEST FOR INACTIVATION OF A RESEARCH PROTOCOL

Project Title:

IRB No:

VA Project No:

Principal Investigator:

Date:

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) be stored and for how long?

De-identified data:

Paper data (Location of paper data storage: _____ ; Duration of storage: 6 years)

Electronic data stored (location of electronic data storage: _____ ; Duration of storage: 6 years)

Specimens stored (location of specimen storage: _____ ; Duration of storage: 6 years)

Identifiable data:

Paper data (Location of paper data storage: _____ ; Duration of storage: 6 years)

Electronic data stored (location of electronic data storage: _____ ; Duration of storage: 6 years)

Specimens stored (location of specimen storage*: _____ ; Duration of storage: 6 years
**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: 6 years)

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.

Summarize the project and overall accomplishments in an abstract format detailing the study objectives, research plan, methods, findings, and clinical relevance:

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

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.

Principal Investigator Signature: _____ **Date:** _____

For Office Use Only

Reviewed and Verified by R&D Office Staff:

Date:

R&D Committee Chairman: _____ **Date:** _____