

Request for Annual VA Renewal of Research Exempt from IRB Review
North Florida/South Georgia Veterans Health Service
Gainesville, Florida

Principal Investigator: _____

IRB No: _____

Project Title: _____

Funding Administration: _____

1. Date of IRB Exempt determination: _____

2. Project Status: *(Check one)*

Terminated: *Please complete the 2 boxes below after you have read and acknowledged.*

All research data has been collected, inventoried, filed, and archived in an approved facility records storage area as required.

Please explain where the data (*electronic/hard copies*) will be stored: _____

All duplicated data on portable media that is no longer needed has been destroyed according to media sanitization policies.

Project remains active, no human subjects are currently enrolled or being followed and none will be enrolled in the future.

3. Please explain the purpose of keeping this study open requiring R&D re-approval: _____

4. Total number of subjects enrolled or specimens/data/records collected/studied since last report: _____

5. Have there been any changes to this study since IRB approval? YES NO

o *If "yes", did the IRB determine the study was still exempt?* YES NO

o *Were all revisions submitted to the VA Research Office?* YES NO

If "no", please provide all related documents to Research Service Office

6. Have there been any problems, complaints, concerns, comments or adverse events during this review period? YES NO

o *If yes, please describe.*

As the Principal Investigator of this protocol, I am aware that: *(Please initial each line to show your acknowledgement)*

____ *Any changes in this protocol require prior approval by the IRB (in accordance with local IRB policy) and a copy of the IRB approved changes will be forwarded to the HRPP Office;*

____ *This project requires annual re-approval by the R&D Committee and notification from the ACOS/R that this research may continue;*

____ *All records related to this research must be maintained according to the Record Retention Policy.*

PI Signature

Date

MICHAEL BUBB, MD. Approved Disapproved

Acting ACOS for Research

Date