

North Florida/South Georgia Veterans Health Service  
HRPP Office's Request for Continued Approval / Request to Close  
Gainesville, Florida

Principal Investigator: \_\_\_\_\_

IRB No: \_\_\_\_\_

Project Title: \_\_\_\_\_

Funding Administration: \_\_\_\_\_

**1. The Project is:**

- 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.
- Active** and human subjects are being enrolled or being followed.
- Active** but is closed to enrollment or no subjects are enrolled.

2. Total number of subjects entered into study since last report: \_\_\_\_\_

- How many subjects signed a Consent Form: \_\_\_\_\_ **or**  Consent Waiver was obtained (*skip #3*)

3. If you did not enroll any subjects since the last report period, please explain: \_\_\_\_\_

Please answer all questions: Yes/No/NA

4. A signed consent form is in my files for each subject entered into this study and is also in the medical record of each VA subject entered into this study unless consent process is waived by the IRB.  Yes  No  N/A
5. One or more subjects have claimed injury from participating in this study.  Yes  No  N/A
6. Unexpected adverse events have occurred.  Yes  No  N/A
7. Serious, but expected, adverse events have occurred.  Yes  No  N/A
- o *If item 4, 5, or 6 are "Yes", attach a detailed explanation citing dates, subjects, and circumstances, and state if a report was filed with the UF Human Studies Subcommittee (IRB) or an agency such as the NIH or FDA.*
8. Have there been any changes to your study since the last Annual Renewal?  Yes  No  N/A
- *If "yes", have you submitted a copy of all the IRB approved revisions to the VA Research Office?*  Yes  No
  - *If "no", please provide all related documents.*
9. Did the project **originally** involve safety hazards?  Yes  No  N/A
- If you answered "yes", submit the **Research Safety Annual Continuing Review Form** to the Safety Committee Coordinator. The Safety Forms can be locate at: <http://www.northflorida.va.gov/Research/SafetyCom.asp>*

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

- \_\_\_\_\_ all research projects using human subjects must receive prior approval by the IRB for Continuing Reviews and Closures
- \_\_\_\_\_ any changes to the study requires prior approval by the IRB and the IRB approved copy will be sent to the HRPP Office
- \_\_\_\_\_ a signed Informed Consent Form must be obtained from each subject before entry into the study, unless waived by the IRB
- \_\_\_\_\_ that human use in projects not receiving favorable review must be discontinued
- \_\_\_\_\_ a copy of all consent forms and such other related matters, such as correspondence, must be retained according to the NF/SG VHS Record Retention Policy.

\_\_\_\_\_  
PI Signature

\_\_\_\_\_  
Date

MICHAEL BUBB, MD.  Approved  Disapproved  
Acting ACOS for Research

\_\_\_\_\_  
Date