MIAMI VAHCS

Request for Study Closure of a Project Involving Human Subjects

Principal Investigator:

Project Title:

Protocol #

Funding/Administration:

You are required to submit the following attachment(s):

1. **Project Data Sheet (PDS)**
2. **Provide the Tracking Log for Reportable and Non-Reportable Events**

PROJECT STATUS

☐ **Study has ended and all data analysis is complete**

☐ **Study has ended, but data analysis of de-identified data will continue**

☐ **Termination of Research Project by Sponsor**

☐ **Termination of Research Project by the IRB**

☐ **Other (explain):**

TYPE OF STUDY *(Indicate the type of research)***:**

☐ *Clinical drug trial* ☐ *Survey/Questionnaire* ☐ *Clinical device trial* ☐ *Chart Review* ☐ *Prospective study*

☐ *Other (please describe)*:

PATIENT ACCRUAL / WITHDRAWAL AT MIAMI VAMC

1.Total number of subjects (or chart reviews) approved for enrollment by the VAMC IRB:

2.Total number of subjects who were consented but did not meet inclusion criteria or voluntarily withdrew prior to research procedures enrolled into study procedures:

3.Total number of subjects (or chart reviewed) that met inclusion criteria (enrolled into research procedures) since the initial approval:

4.Are you the lead investigator of a multi-center research trial? ☐ Yes ☐ No (If no, skip to question #6)
If "Yes", provide the name of location to other institution(s)?

4a.Have all participating sites closed their study? ☐ Yes ☐ No
If "No" - This study can't be closed

If "Yes" – You must provide all study closure documentation from other participating sites.

5. Indicate whether SAE/AE and/or DSMB/DMC have been reported? ☐ Yes ☐ No
If "no", provide explanation:

THE FOLLOWING QUESTIONS MUST BE ANSWERED

NOTE: If this is a Retrospective Chart Review Study, skip to next section

1. **Since the last IRB review have problems emerged in recruiting or retaining participants or obtaining informed consent?** ☐ Yes (*If "Yes", describe below)* ☐ No

2. **Since the last IRB review, how many participants have been removed from the study by the P.I. for any reason, including safety concerns, inability to follow study procedures, etc.** ☐

   Indicate below reason(s) given by the PI for removing participants from the study.

3. **How many participants have voluntarily withdrawn their consent after entering into the study?** ☐

   Indicate below reason(s) given by the participant for withdrawing from the study.

4. **Have there been any changes to the inclusion/exclusion criteria?**

   ☐ Yes If, "yes", *describe below.* ☐ No

5. **Since the last IRB review, have there been any problems or changes in the following:**

Subject Recruitment:	☐ Yes ☐ No	**Advertising:**	☐ Yes ☐ No
Subject Compensation:	☐ Yes ☐ No	**Inclusion or Exclusion criteria:**	☐ Yes ☐ No
Costs to Subjects:	☐ Yes ☐ No	**Investigator Inducements:**	☐ Yes ☐ No
Informed consent:	☐ Yes ☐ No	**Privacy or confidentiality protections:**	☐ Yes ☐ No
Safety Monitoring:	☐ Yes ☐ No	**Vulnerable subject protections:**	☐ Yes ☐ No

   ****If yes, were all the problems or changes prospectively reviewed and approved by the IRB prior to implementation.**

   ☐ **Yes** ☐ **No** *(please explain)*:

PROTECTING SUBJECT PRIVACY AND CONFIDENTIALITY OF DATA

1. **Is the plan to protect subject privacy and confidentiality of data still adequate? This would include protections addressing: source of data (e.g. databases, paper records), data storage (within the Miami VA Hospital during the required 5 year period) of identifiable and non-identifiable data.**
   ☐ Yes ☐ No - If "no", describe below

SUMMARY OF RESULTS (FINDINGS)

1. **Summarize your findings to date; including preliminary results and interim findings where available** *(Provide information regarding the overall status of your research study. i.e. # of subjects completed, enrolled, being followed, # of completed experiments, any deviation from initial plan)***.**

   ☐ *Check Box if this information has been included in the Project Data Sheet (PDS) form. If not, insert in text box:*

2. **Since the inception of the study, have there been any publications generated from this research?**
   ☐ **Yes** (*attach a copy of all publications)*
   ☐ **No**

STUDY CLOSURE

1. **Date study closed:** ☐

2. **Reason for protocol closure (check all that apply and provide the reason for Study Closure in space provided below):**

   ☐ research plan completed
   ☐ procedure or drug/device now approved
   ☐ never received or have lost funding
   ☐ PI/major participant left institution
   ☐ not enough subjects
   ☐ adverse event(s)
   ☐ other (please specify):

3. **If the study design included any element of deception of the subjects, have all subjects been debriefed?**
☐ Yes ☐ No - If, “No”, describe below

4. **Have participants been offered summaries of the study results?**
☐ Yes ☐ No - If, “No”, describe below

5. **Has provision been made for subsequent care of the subjects?**
☐ Yes ☐ No - If, “No”, describe below

ACKOWLEDMENT STATEMENT: I _____, am aware that all research related records must be kept locally for 5 years. At the end of the 5 years, I am required to archive all research related records through Medical Administrative Service, as per the VA Record Retention Schedule.

Investigator Acknowledgement

Acknowledgement of Review