Please provide contact information for a representative who can answer any questions that the IRB might have concerning this submission:

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<th>Name:</th>
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| 2nd Contact:  | name + e-mail or phone number  
| Group: *select if applicable* |  

This box is for IRB-01 use ONLY.

Project Number:  

We request that this submission be reviewed by:  

<<Select One>>

Form Instructions:

- Make sure your Microsoft Word program is set to display “Hidden Text”. This document contains helpful information, examples, and instructions that are only visible (and will never print) when the “Hidden Text” feature is enabled. “Hidden Text” will be displayed highlighted yellow, italics, and underlined. Go to the “Tools” menu, “Options”, on the “View” tab make sure “Hidden Text” has a check mark, and click “OK”. (Word 2007 users can download how to display Hidden Text at: http://irb.ufl.edu/docs/hidden07.doc).

- Effective June 2008: Submit THREE COPIES (the signed original copy plus two photocopies) of your submission to the IRB-01 office.

- Please help us process and review your submission by submitting it the order listed in Question 36 (Guide also available at http://irb.ufl.edu/docs/order.docx).

Date:

Principal Investigator:

PI UF ID#:

IRB Project #:

Project Title:

1. We wish to (select one):

[ ] continue this study. You must ATTACH A CLEAN, CURRENT COPY OF YOUR PROTOCOL. Go to Question 2.
☐ **close this study.** All enrollment, interventions, data collection, and data analysis of identified data are completed. See NOTE 1 (hidden text) below.

- **Will subjects need "post-study" treatments?**
  
  ☐ **Yes.** Describe treatments, how they receive it, etc: [______].
  
  ☐ **No.** Justify: [______]
  
  ☐ **Not applicable.** Explain: [______].

2. **During this review period, have there been any changes, no matter how minor, to any part of this research project, including the IRB approved forms (Introductory Questionnaire, Protocol, Informed Consent Form, Investigator Brochure, or any other materials reviewed by the IRB)?**

  ☐ **No.** Go to Question 3.
  
  ☐ **Yes.** If yes, select one:

  ☐ All changes implemented to this project have been previously reported to and approved by the IRB.

  ☐ Changes have been implemented but were not submitted to the IRB. Explain: [______]

3. **Are you submitting any new revisions along with this Continuing Review/Study Closure Report?**

  ☐ **No.**

  ☐ **Yes.** You **must** include: (1) a Project Revision Form, (2) all altered pages of the Introductory Questionnaire, Protocol, ICF, or other project documents with insertions underlined and deletions struck-out, as well as a clean copy of the pertinent pages.

4. **Study sponsor:** Is your study sponsored?

  ☐ **No.** Skip to Question 7.

  ☐ **Yes.** Provide the name(s) of your study’s sponsor(s): [______]. Answer Questions 5 and 6.

5. **Have there been any changes to the study’s sponsor(s) during the past review period?**

  ☐ **No.**

  ☐ **Yes.** Provide the name(s) of any new sponsors: [______].
6. Are the study sponsors correctly listed on the Introductory Questionnaire and all of the Informed Consent Forms for this study?
   □ Yes.
   □ No. You must revise all of your paperwork to correctly identify the study sponsor(s). Follow the directions outlined in Question 3.

7. Have there been any changes in the potential conflict of interest information described in your Introductory Questionnaire for any of the investigators (including the Principal Investigator, Co-PI, and/or Sub-Investigators) associated with this project?
   □ No. Skip to Question 9.
   □ Yes. Describe: ______. Continue to Question 8.

8. Have any changes in potential conflict of interest been reported to the Division of Sponsored Research?
   □ No.
   □ Yes. Explain: ______.

9. External audit: Has the Food and Drug Administration, study sponsor, or any other agency audited this project during this review period?
   □ No. Go to Question 10.
   □ Yes. Have you enclosed reports for all external audits that occurred in the past review period?
     □ Yes.
     □ No. Indicate who audited your study, when all audits occurred, and when the audit reports will be provided to the IRB: ______.

10. Study results: Have you or any of the local sub-investigators reported any data from your study?
    □ No.
    □ Yes. Provide a copy of the publication or meeting proceedings.

11. How do you identify and recruit potential subjects?
    □ Under a previously approved HIPAA Waiver of Authorization for Recruitment. Describe: ______
    □ Other. Describe: ______

12. Have any subjects signed an informed consent form and/or have you initiated any study procedures including collecting data from patient medical records using a waiver of informed consent?
    □ No. Explain why you have not started this project: ______. Skip to Question 28.
    □ Yes. Continue below.
13. Subjects have been enrolled in this project. **Did the IRB waive the requirement to obtain or document Informed Consent (ICF) to enroll all subjects in this study?**
   - [ ] Yes. How many subjects have you enrolled in this project under your waiver: __________. **Skip to Question 20.**
   - [ ] No. Continue to Question 14.

14. **Provide the date on which the first subject signed the Informed Consent Form (ICF) at this site:** __________

15. **Was an Informed Consent Form (ICF) signed by each subject or their legally authorized representative?**
   - [ ] Yes.
   - [ ] No. Explain: __________

16. **Copy of ICF for Subjects:** Did all subjects or their legal representative receive a copy of the ICF?
   - [ ] Yes.
   - [ ] No. Explain: __________

17. **Provide the date on which the last (most recent) subject signed the Informed Consent Form (ICF) at this site:** __________

18. **Have you enclosed a copy of the last signed ICF?**
   - [ ] Yes.
   - [ ] No. Explain: __________

19. **How many subjects have been enrolled since the study started?**

   \[
   \begin{array}{cccccc}
   \text{Active Subjects} & + & \text{Subjects in Follow Up} & + & \text{Withdrawn (include deaths)} & + \text{Screen Failures} & + \text{Completed Subjects} & = \text{Total subjects enrolled} \\
   \end{array}
   \]

   Total males enrolled: 0
   
   Total females enrolled: 0

20. **As listed in your last approved Introductory Questionnaire (IQ), how many subjects have the IRB approved for enrollment into this project?** __________
21. Have you enrolled more subjects than currently listed in this project’s last approved Introductory Questionnaire (IQ)?

☐ No.
☐ Yes. Explain why: [ ]

22. Is the VA involved in this project?

☐ No. Skip to Question 23.
☐ Yes. Answer (a) through (d) below:

(a) How many Veterans have been enrolled in the project? [ ]

(b) If non-Veterans were enrolled, what was done to ensure Veterans had priority access to the project? [ ]

(c) How many of your subjects fall into the following categories:

American Indian or Alaska Native: [ ]
Asian: [ ]
Black/African American: [ ]
Hispanic or Latino: [ ]
Native Hawaiian or Pacific Islander: [ ]
White: [ ]
Unknown or not reported: [ ]

(d) How many of your subjects fall into the following categories:

Children: [ ]
Pregnant Women: [ ]
Decisionally impaired: [ ]
Prisoners: [ ]

23. Have any subjects belonged to one of the vulnerable populations listed below either (1) at the time they were enrolled in the project or (2) at any point during their participation in the research project?

☐ No vulnerable subjects have been enrolled.
☐ Yes. The following vulnerable subjects have been enrolled:

☐ Children
☐ Prisoners/parolees
☐ Fetuses
☐ Shands/VA staff
☐ Institutional residents
☐ Terminally ill subjects
☐ Pregnant women
☐ UF staff/students
☐ Impaired subjects

24. Describe any subject complaints, concerns, or comments about the study:

[ ]
25. Were all project procedures on all subjects completed as described in the protocol?
   - Yes.
   - No. Explain: [ ]
   - Not applicable. Explain: [ ].

26. As indicated in Question 19 above, have any subjects withdrawn from this study during the past review period?
   - Yes. Explain why all subjects withdrew: [ ]
   - No.

27. Have all of the IRB-approved provisions for monitoring subject safety been implemented?
   - Yes.
   - No. Explain: [ ].

28. Have any adverse events or unanticipated problems involving risks to subjects or others occurred during this review period?
   - No. See NOTE 5 below (hidden text).
   - Yes. New adverse events or unanticipated problems involving risks to subjects or others occurred and have been added to the Cumulative Adverse Event Table.

29. Is this a multi-center study?
   - No.
   - Yes. How many subjects have met eligibility requirements and enrolled in the study since the study started? [ ]

30. Does this study have an oversight committee or Data Safety Monitoring Board (DSMB)?
   - No.
   - Yes.
      - A copy of the most recent DSMB report is attached, even if previously submitted (please put it immediately after this continuing report form).
      - A report is not available. Answer (a) – (b)
         - (a) Has the DSMB met according to their plan?
            - Yes
            - No. Justify [ ]
         - (b) Indicate a date when a report will be available or justify why a written report will not be generated: [ ]
31. Is there any other new information (from the research itself or other sources) that alters the risk/benefit ratio of this study?
   ☐ No.
   ☐ Yes. Explain: __________

32. Risk/benefit ratio evaluation: did the risk/benefit ratio of this study change for any reason during this review period?
   ☐ No.
   ☐ Yes. Explain: __________

33. Have you finished enrolling subjects on this project?
   ☐ No, we hope to enroll additional new subjects. **Skip to Question 34.**
   ☐ Yes, enrollment of new subjects is completed (no additional subjects will be enrolled). Select one of the answers below:
     ☐ Study interventions continue on at least one subject. **NOTE: You must receive continuing IRB approval to continue study interventions. Skip to Question 36.**
     ☐ All therapeutic interventions are completed on all subjects and all that remains is (a) data collection and/or (b) follow-up as described in the ICF. Describe what activities remain: __________. **NOTE: You must receive continuing IRB approval to conduct these activities. NOTE TO IRB: move to longitudinal review if previously considered a full Board study. Skip to Question 36.**
     ☐ All interventions are completed on all subjects and only statistical analysis of already collected data with identifiers or links to identifiers remains. **NOTE: You must receive continuing IRB approval to conduct these activities. NOTE TO IRB: move to longitudinal review if previously considered a full Board study. Skip to Question 36.**
     ☐ All interventions are completed on all subjects and only statistical analysis of already collected data that is now de-identified or no links to identifiers remains. **NOTE: You may close the study. If so, you must attach a letter signed by the PI certifying that the data has been de-identified. Refer to Question 1 about funding issues. NOTE TO IRB: if the PI does not close the study you may move it to longitudinal review if previously considered a full Board study. Skip to Question 36.**
     ☐ All interventions, data collection, and data analysis are completed. **NOTE: You may close the study. Refer to Question 1 about funding issues. Skip to Question 36.**
34. Do you hope to enroll more subjects than currently listed in this project’s last approved Introductory Questionnaire (IQ)?

☐ No.
☐ Yes. Explain why: 

35. As indicated in NOTE 6 (hidden text above), you are required to submit new, clean, unstamped copies of all ICFs for this project. Are all appropriate ICFs for this project attached to this continuing review?

☐ Yes.
☐ Not applicable – as indicated in Question 13 the IRB has previously approved a waiver of Informed Consent.
☐ No. Explain: 

36. Which items are being submitted with this Continuing Review/Study Closure report?

☐ REQUIRED: Newest Addendum A with all study staff listed and roles listed.
☐ A clean, current copy of your protocol.
☐ Most recently signed ICF with subject's identifiers blacked out.
☐ Clean, unstamped ICF(s) in current format – check IRB website:
  http://irb.ufl.edu/irb01/forms.htm
☐ REQUIRED: Cumulative Adverse Event Table (sorted by event type, column 1) available at:
  http://irb.ufl.edu/docs/AETable.doc
☐ REQUIRED: Minor Deviation Tracking Log (sorted by description, column 1) available at:
  http://irb.ufl.edu/docs/DevTable.doc
☐ DSMB report.
☐ Audit report.
☐ New information on risk/benefit ratio.
☐ Project Revision Form with strikeout/underlined pages from pertinent IRB forms.
☐ Publication(s) or meeting proceedings.
☐ DSMB report
Print a copy of this form and:  (1) Type and sign your name below.

(2) Make a copy of the signed report for your regulatory file.

Person completing CR Form (typed): [ ]  Date: [ ]
(Sign below)

Signature: ____________________________________________________________

Signature of Principal Investigator: ________________________________________

NOTE: this report must be signed by the PI unless you have attached a properly completed copy of a Temporary Transfer of PI Responsibility (available at http://irb.ufl.edu/irb01/forms.htm).

FYI: Clinical Trials Compliance Office Issue

Have you added any technical/professional services (i.e. blood draws, tissue samples, tests, procedures, examinations, evaluations, etc)?

☐ No.
☐ Yes – your study must be evaluated for fiscal and billing risk regardless of payor (i.e. Study Sponsor, study participant, and/or their 3rd party payor (insurance), or GCRC). Follow all UF clinical research fiscal compliance policy, standards and procedures. To obtain your billing plan approval, email Research Administration and Compliance, or contact the Research Administration and Compliance Office at 273-5398. Learn more at: http://ctc.health.ufl.edu/index.shtml