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

<table>
<thead>
<tr>
<th>Name:</th>
<th></th>
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<tbody>
<tr>
<td>Position:</td>
<td>&lt;select one&gt;</td>
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<td>E-mail:</td>
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<td>2nd Contact:</td>
<td>name + e-mail or phone number</td>
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<tr>
<td>Group:</td>
<td><em>select if applicable</em></td>
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</table>

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.
- IRB-01 does not process revisions if your study is expired.
- All changes, no matter how minor, must be submitted for review and approval by the IRB before they are implemented. See the last page of this form for additional instructions.
- Submissions that do not meet our Submission Acceptability Standards will be returned to the PI. Visit http://irb.ufl.edu/irb01/formssubmit.htm for more information.
- All submissions must be typed.
- This form is available on the IRB-01 website at: http://irb.ufl.edu/irb01/forms.htm
- Do NOT use this form to respond to requests by the IRB in a Tabled letter or Explicit Changes letter. Instead please use the IRB’s Tabled Response form (http://irb.ufl.edu/docs/frm-tabledresp.doc) or Explicit Change Response form (http://irb.ufl.edu/docs/frm-explicit.doc).
- If you are submitting this form in conjunction with a Continuing Review, please put the Continuing Review paperwork on the top of your actual submission to the office in order to help us properly process your submission and facilitate review before your study expires.

1. Date:  

2. Principal Investigator:  
   UF ID#:  

3. IRB Project #:  

Revision to IRB Project#:  
IRB Version 11/20/2010 10/13/11
4. Project Title: 

5. What is the revision? 

6. What is the justification for and/or the purpose of the revision? 

7. This is a (select one):

   - [ ] MAJOR revision involving greater than minimal risk to research subjects. Submit THREE COPIES (the signed original copy plus two photocopies) of your submission to the IRB-01 office. This must include copies of all paperwork including grants, surveys, data collection tools, articles, etc. Collate into three distinct items (as if you were sending the submission to three different places).

   **NOTE:** changing the PI on a study that involves greater than minimal risk to subjects is considered a major revision, must be reviewed by the full Board, and three copies are needed.

   - [ ] MINOR revision involving minimal risk to research subjects. Minimal risk is defined by the Federal Code of Regulations as a probability and magnitude of harm or discomfort no greater, in and of themselves, than those in daily life or in a routine physical or psychological examination or test. Submit TWO COPIES (the signed original copy plus a photocopy) of your submission to the IRB-01 office. This must include copies of all paperwork including grants, surveys, data collection tools, articles, etc. Collate into two distinct items (as if you were sending the submission to two different places).

   - This will be sent to a chair for review. If the chair considers the risk to be greater than minimal it will be forwarded to the full Board for consideration. Which meeting it is sent to depends on when the Chair returns the submission to the office (not the date the PI submitted the paperwork). This could result in a longer review time. Only select this option if the risk to subjects is minimal.

8. Indicate what materials are being submitted along with this form:

   - [ ] Advertisement.
   - [ ] Drug package insert.
   - [ ] Informed Consent Form.
   - [ ] Investigator's Brochure.
   - [ ] Introductory Questionnaire
   - [ ] Protocol amendment.
   - [ ] Sub-investigator Study Personnel change.
   - [ ] Title change.
☐ Principal Investigator change – complete and attach the PI Change addendum form located at: http://irb.ufl.edu/docs/frm-revpi.doc

NOTE: As of December 1st, 2011, if you change any study personnel (PI, sub-I, coordinators, etc) you must download and submit the newest version of Addendum A with all study staff listed. See the IRB’s announcement at: xx

☐ Sponsor change.

NOTE: if any of the investigators or the sponsor changed please be sure to review the conflict of interest questions in the Introductory Questionnaire, Addendum A, Addendum L, Protocol, Informed Consent Form, and any other applicable forms and revise your answers if needed.

☐ Other: (Please list) ____

9. Has this revision already been implemented?
   ☐ No
   ☐ Yes. Explain when and why it was implemented: ____

10. List any specific information that needs to be included in the IRB response letter. ____

Signature of Principal Investigator ____________________________ Date ___________________________

The IRB requires the PI to sign all paperwork. The only exceptions are: (a) if a Temporary Transfer of Study Responsibility (http://irb.ufl.edu/docs/frm-transfer.doc) has been signed by the PI and a sub-Investigator on the study, or (b) if the PI has left the institution, in which case their supervisor is required to sign as the individual responsible for the study.
PROJECT REVISION--GENERAL INFORMATION

All changes, no matter how minor, must be submitted for review and approval by the IRB before they are implemented. The IRB Project Revision form is to be completed any time a change is made to any approved project documents. The form must be typed.

Types of revisions include but are not limited to:

- Change in protocol title
- Change in principal/sub investigator
- Advertisement(s)
- Amendment to protocol
- Rewording of an informed consent
- Investigator brochure revision
- Package insert
- Emergency implementation to protect subject safety; include description of event

Revisions are reviewed according to the type of revision as follows:

- **MINOR** revision involves minimal risk to subjects. Minimal risk is defined by the Federal Code of Regulations as a probability and magnitude of harm or discomfort no greater, in and of themselves, than those in daily life or in a routine physical or psychological examination or test. Minor revisions are reviewed by an IRB-01 Chair/Vice-Chair. The revision may be approved or referred to full Board.

- **MAJOR** revision usually involves greater than minimal risk to subjects. Changing the Principal Investigator on Full Board Studies is always considered a major revision. Major revisions are reviewed by the full Board and will be scheduled for an IRB meeting according to the IRB meeting deadlines.

If more than one revision is being submitted, the method of review is determined by the revision of highest risk.

VERY IMPORTANT: To Adjust or Revise IRB Documents, Follow the Procedures Below Exactly So Reviewers Can Quickly Locate and Review What Has Been Changed:

- **ALL IRB FORMS** (Protocol, Informed Consent Form, Continuing Review Report, Adverse Event Report Form, and/or Introductory Questionnaire including the Project Cover Sheet) and any related material: If the information in any of these forms is affected, send:
  1. the affected pages and **show deletions in strikeout and additions in underline**. Microsoft Word can automatically do this by using the “Track Changes” function in the Tools menu (instructions for Track Changes at: http://irb.ufl.edu/docs/track-changes.doc).
  2. a clean copy of just the affected pages. We do not currently require a clean copy of the entire document.

- **INFORMED CONSENT FORM**: If the consent is revised you must submit not only the affected pages with insertions **underlined** and deletions struck out, but also a clean (with the changes performed), complete copy of the new consent form. This clean copy will be stamped with the IRB approval period. Investigators are required to use a currently approved, stamped Consent Form.
YOU DO NOT NEED TO SUBMIT A COVER LETTER WITH THE REVISION MEMO!

If you have any questions concerning protocol revisions, please contact the IRB office at 846-1494 (352) 273-9600.