

**Tuscaloosa VA Medical Center**

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**Primary Reviewer's Continuing Review Checklist**

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

**Name of Study:** \_\_\_\_\_

**Name of Primary Reviewer:** \_\_\_\_\_ **Date of Continuing Review:** \_\_\_\_\_

In considering the information provided by the investigator for the continuing review, please answer the questions and provide comments as needed. If an item does not apply to the protocol under review, please make note of the reason why.

**1. Investigator Qualifications, Resources, and Conflict of Interests**

<b>a.</b> Changes in staff and resources since the last Continuing Review that have not been previously reported to the IRB were evaluated and were appropriate to human subject protections.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>b.</b> Research resources continue to be appropriate to conduct of this study according to HRPP standards and regulations	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>c.</b> Conflict of Interest Forms for the investigators and study staff that have not been previously reported to the IRB were submitted (and the ones that were originally submitted were re-submitted annually to the Medical Center's Compliance Officer) and there does not appear to be any potential conflict of interests that may influence their decisions and abilities to conduct the research study.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>d.</b> Human subject protection training of investigators and research staff is up-to-date (updated within the last 12 months) and appropriate to the protection of human subjects.	<input type="checkbox"/> Yes	<input type="checkbox"/> No

**2. Study Design**

<b>a.</b> The study design and purpose continues to be appropriate to the protection of human subjects.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>b.</b> The scientific rationale continues to be appropriate to the protection of human subjects.	<input type="checkbox"/> Yes	<input type="checkbox"/> No

**3. Subject Selection**

<b>a.</b> Request for Continued Approval of Human Use/progress report is complete, which includes the gender of subjects and minority status of those entered into the protocol, and is appropriate to human subject's protection.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>b.</b> There have been no problems in assuring that subjects continue to receive medical treatment after completion of participation in the study.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>c.</b> Subject selection criteria are equitable and are appropriate to the purposes of the research, are consistent with VA, DHHS and FDA policies.	<input type="checkbox"/> Yes	<input type="checkbox"/> No

*Equitable means that the burdens, risks, and benefits of the research are fairly distributed and do not place disproportionate burdens on any racial, ethnic, gender, vulnerable, or other disadvantaged group and do not systematically exclude persons who might benefit from the research.*

**4. Vulnerable Subjects**

- a. The reasons and justification for use of vulnerable subjects is appropriate to the protection of human subjects and additional protections are adequate to protect the rights and welfare of vulnerable subjects.
  - Yes
  - No
  - Not part of the study
  
- b. Vulnerable Populations are appropriately identified.  Yes  No  Not part of the study
  
- c. When incompetent individuals or persons with impaired decision-making capacity as participants were included in the study, the following items were adequately addressed:
  1. The subjects were not being proposed as participants simply because they were readily available.
  2. The proposed research entailed no significant risks, tangible or intangible, or if the research presents some probability of harm, there is a greater probability of direct benefit to the participant.
  3. The research does not impose risk of injury, unless that research is intended to benefit that participant and the probability of benefit is greater than the probability of harm.
  4. Procedures are devised to ensure that participants' legally authorized representatives are well informed regarding their roles and obligations to protect incompetent participants or persons with impaired decision making capacity.
  - Yes
  - No
  - Not part of the study

**5. Risks to Subjects and Provisions for Data and Safety Monitoring**

a. Risks to subjects were minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
b. Risks to participants were minimized, whenever appropriate, by using procedures already being performed on the subject for diagnostic or treatment purposes	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
c. Risks to subjects were reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result from the research	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
d. The research plans makes adequate provisions for managing adverse events and for monitoring the safety of subjects and the data collected to ensure the safety of subjects	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
e. Is there a DSMB and if so, have DSMB reports been submitted?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
f. Research risks as distinguished from risks of therapeutic activities (when applicable) were acceptable	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
g. New risks or new information discovered that might affect the subject's willingness to participate were considered and subjects were informed.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
h. Safety and risk factors for participants are adequately described in the consent form based upon findings to date.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
i. Social risks of the research were adequately considered	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
j. Economic risks of the research were adequately considered	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
k. Legal risks of the research were adequately considered	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
l. Risks are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that may be expected to result	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
m. The appropriateness of and rationale for elements warranting special attention (i.e. placebo; challenge studies; wash-out periods; deviations	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study

from standard care) is appropriate to the protection of human subjects			
n. Provisions for safety monitoring are adequate. 45CFR46.111 (a)(6)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
o. Provisions for privacy and maintaining confidentiality of data are adequate. 45CFR46.111 (a)(7)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

**6. The Investigator properly submitted all of the following to the IRB since the last continuing review:**

a. Approved Amendments	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
b. Investigator Brochure Updates	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
c. Protocol Deviations, Serious Adverse Events, Adverse Events (Expected Adverse Events and Unexpected) that do not meet criterion h. below. Reported in spreadsheet or table format.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
d. Subject Recruitment/Advertisement materials	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
e. Safety Reports	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
f. Site Monitoring Visit Reports	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
g. DSMB Reports	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
h. Unanticipated problems and protocol deviations that may result in harm to subjects or others (i.e., greater than minimal risk) that are related or possibly related to the drug, device, biological, or other research intervention). Initially reported with the Problem Reporting Form and then in spreadsheet or table format at time of continuing review.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
i. New risk or benefit information	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study

**7. Informed Consent (If there was a waiver for informed consent approved for this study, go to next section)**

The consent form submitted is the currently IRB approved version, is complete and is accurate.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
The consent form process was conducted appropriate to HRPP regulations.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
Surrogate consent was obtained appropriately and according to VA Policy.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Newly proposed changes to the consent form were submitted as a "consent form revision," and the changes are appropriate	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
The requirements for HIPAA have been adequately addressed.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

**8. Progress Report, Review of Study IRB Records, Informed Consent and Submitted Documents**

The Request for Continued Approval of Human Use form was submitted, which sufficiently summarizes the research methodology and procedures.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
The number of subjects entered and withdrawn (including the reason for withdrawal) for the review period and since the inception of the research project is appropriate to human subject protection.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> No prospective human subjects involved in study.
The summary of research findings to date, including summary of subject experiences (benefits, adverse reactions) is sufficient and appropriate to human subject protection.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
The summary of serious adverse events and adverse events was considered, and does not significantly change the risk/benefit assessment.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> No prospective human subjects involved in study.

The summary of unanticipated problems involving risks to subjects or others was considered, and does not significantly change the risk/benefit assessment.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
The number of subject withdrawals and reasons for withdrawals was considered, and does not significantly change the risk/benefit assessment.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Complaints about the research since the last IRB review were considered, and do not significantly change the risk/benefit assessment.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> No complaints filed
Summary of new information available regarding the research project that may change the risk/benefit was considered, and does not significantly change the risk/benefit assessment.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Summary of relevant recent literature was considered and does not significantly change the risk/benefit assessment.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Summary of scientific findings was considered and does not significantly change the risk/benefit assessment.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
The investigator's assessment of the risk and benefits based on study results was considered and is adequate.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Amended or updated Investigator's Brochures was considered and does not significantly change the risk/benefit assessment.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Amendments or modifications to the research was considered and does not significantly change the risk/benefit assessment.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Relevant multi-center trial reports, safety monitoring reports, and DSMB reports was considered and does not significantly change the risk/benefit assessment.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
A copy of the current approved (most recent) Informed Consent document (IRB stamped version), tracked version, and an updated version (if applicable) was submitted appropriately.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of Study
A copy of the current approved (most recent) Abstract (IRB stamped version), tracked version, and an updated version with findings-to-date was submitted appropriately.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
A copy of the current approved (most recent) Protocol (IRB stamped version), tracked version, and an updated version was submitted appropriately.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
A copy of all protocol amendments not incorporated in the most recent protocol was submitted appropriately.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

9. The Investigator has certified that results of this study will be communicated to subjects and the IRB as they become available, if needed to protect the safety of patients.

Yes                       No

10. The Investigator adhered to the IRB Conditions of Approval and Criteria for Approval in 46.111 are met in order to secure Continuing Review approval.

Yes                       No

**IRB ACTION (Choose only one!)**

- Approved** - As submitted - no revisions required
- Contingent Approval with Expedited Review** - Minor modifications or clarifications that are requested and may be verified by the IRB Chair or a designated IRB member.
- Contingent Approval with Convened IRB review** - Modifications that requires changes to the study protocol and review by the convened IRB.
- Tabled** - Requires significant modifications and must be re-submitted to the IRB through the normal submission scheduling procedures
- Disapproved** - Requires major protocol changes and must be re-submitted to the IRB through the normal submission scheduling procedures.

**LIST contingencies, modifications or clarifications needed or reasons for table or disapproval:**

**RISK LEVEL (check one):**

- Less than minimal**
- Minimal**
- Moderate**
- High**

**CONTINUING REVIEW (check one, based on the level of risk):**

- Annually**
- Every \_\_\_ months**

*Signature of Primary Reviewer:* \_\_\_\_\_ *Date:* \_\_\_\_\_