

Tuscaloosa VA Medical Center

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Primary Reviewer's Study Closure Review Checklist

Principal Investigator: _____

Name of Study: _____

Name of Primary Reviewer: _____ **Date of Continuing Review:** _____

Date Study Expires: _____

In considering the information provided by the investigator for study closure, 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

| | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|-----------------------------|
| <p>a. 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.</p> | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <p>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.</p> | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

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

| | | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|-----------------------------|------------------------------------------------|
| <p>a. Approved Amendments</p> | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Not part of the study |
| <p>b. Investigator Brochure Updates</p> | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Not part of the study |
| <p>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.</p> | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Not part of the study |
| <p>d. Subject Recruitment/Advertisement materials</p> | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Not part of the study |
| <p>e. Safety Reports</p> | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Not part of the study |
| <p>f. Site Monitoring Visit Reports</p> | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Not part of the study |
| <p>g. DSMB Reports</p> | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Not part of the study |
| <p>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.</p> | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Not part of the study |
| <p>i. New risk or benefit information</p> | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Not part of the study |

3. 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 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 adverse events (serious, expected, and unexpected) 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 | |

- 4. 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
- 5. The Investigator submitted all required documentation in order to grant approval for study closure.
 Yes No

IRB ACTION FOR STUDY CLOSURE (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 additional information and/or modifications and must be re-submitted to the IRB through the normal submission scheduling procedures

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

Signature of Primary Reviewer: _____

Date: _____

Signature of Chairperson or designee: _____

Date: _____