Alpha IRB
1001 Avenida Pico, Suite C #497
San Clemente, CA 92673
T: 949-542-3882 F: 949-940-0134

Full Accreditation
www.alphairb.com

## SITE - CONTINUING REVIEW REPORT

**Instructions:** Complete all the questions that follow and attach any necessary supporting documentation. To ensure continuing review is conducted prior to study expiration, submit within 60 days of the expiration date. Missing information or an incomplete form may cause a delay in review.

***Please submit a copy of Principal Investigator's current medical license with this form****

| | | | |
|---|---|---|---|
| **Sponsor:** | | **Protocol No.:** | |
| **Principal Investigator**: | | | |
| **Site Name:** | | | |
| **Contact person:** | | **Phone:** | |
| **Fax:** | | **E-mail:** | |

| | |
|---|---|
| 1. | Is the research identified above still ongoing?<br>☐ **Yes** - Indicate which phase your site is currently in:<br>☐ Study is not yet initiated<br>☐ Open to Enrollment<br>☐ Closed to Enrollment – subjects still active and/or in follow-up<br>☐ On Hold – site and/or study is on hold for the following reason(s):<br>☐ **No** - Study related activity completed; however site is to remain open for the following reason(s): |
| 2. | List the current version and/or date of the protocol you are using for this study: |
| 3. | List the current version of **all consent forms** you are using for this study *(Main, Assent, Sub-study, PGx, translations, etc.)* |

| | | |
|---|---|---|
| ICF Type: *Main* | Alpha IRB Version No.: | Alpha IRB Approval Date: |
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| 4. | Complete each category below with the number of subjects in each stage: | |
| | a. Total number of active subjects (including follow-up): | + |
| | b. Total number of subjects who have completed the study: | + |
| | c. Total number of subjects that were withdrawn or discontinued the study who signed the ICF: *(Includes: withdrew consent, screen failures, lost to follow-up, etc.)* | + |
| | d. Total number of subjects who have signed the informed consent form: | = |

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| 5. | Complete each category with the number of subjects who withdrew or discontinued the study *(breakdown of 4.c. above)*: | | | |
| | Withdrew Consent: | | Screen Fail: | |
| | Lost to Follow-up: | | Adverse Event: | |
| | Other *(please explain):* | | | |

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| 6. | Provide a breakdown of all subjects who signed an ICF for the study by gender, race and ethnicity (if recorded) in the table below *(each total should equal # stated in 4.d. above)*: | | | | |
| | a. Gender: | Male: | Female: | | Total # who signed ICF: |
| | b. Ethnicity: | Hispanic or Latino: | Not Hispanic or Latino: | | Total # who signed ICF: |
| | c. Race: | White: | Black or African American: | Native Hawaiian or Other Pacific Islander: | Total # who signed ICF: |
| | | Asian: | American Indian or Alaska Native: | Other: | |

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| 7. | **Events**<br>*Please indicate whether any of the following have occurred since your site's last IRB Review that **you have not already reported/submitted to Alpha IRB?*** | ***Yes** | **No** |
| a. | Project changes (protocol amendments/revisions, ICF revisions, updated IB) | *☐ | ☐ |
| b. | Any *unanticipated problems involving risk to participants or others*[1.] or *significant protocol deviations*[2.]<br>[1.] Unanticipated problems involving risk to participants or others are defined as any problem, event, or new information that is 1) unexpected; 2) related or possibly related to participation in the research; AND 3) suggests that the research places participants or others at a greater risk of harm.<br>[2.] Significant protocol deviations are defined as any departure or change from the protocol that is unanticipated, happens without any prior agreement, and adversely affects the safety, rights or welfare of subjects or others, or the integrity of the study data. | *☐ | ☐ |
| c. | Change in site location | *☐ | ☐ |
| d. | Any changes to the PIs CV which are relevant to this study | *☐ | ☐ |
| e. | Change of the Principal Investigator | *☐ | ☐ |
| f. | Change in conflict of interest disclosure information, or new conflict of interest issues now relevant to the review of this protocol | *☐ | ☐ |
| g. | Changes in community attitudes or state laws | *☐ | ☐ |
| h. | Inspection by the FDA or other regulatory agency | *☐ | ☐ |
| i. | Any restriction, sanction, disciplinary action or other change to the PI's license | *☐ | ☐ |
| j. | Any subject complaints about the research | *☐ | ☐ |
| k. | Any recent publications in literature that are relevant to the study | *☐ | ☐ |
| l. | Data Safety Monitoring Board reports, relevant multi-center trial reports or other interim findings | *☐ | ☐ |
| m. | Any other additional or new information about the study which may affect a subject's willingness to continue their participation, or that may need to be given to prior participants | *☐ | ☐ |
| | i If yes, please explain/describe: | | |

***If you answered YES to any of the above, please submit the information with this report.** (Forms are located on Alpha IRB's website at www.alphairb.com)*

| 8. | **Procedures** |
|---|---|
| a. | Have you personally conducted/supervised this study?<br>☐ Yes<br>☐ No - If no, please provide an explanation: |
| b. | Do you continue to have sufficient resources (personnel, time, space, equipment, etc.) to conduct this study?<br>☐ Yes<br>☐ No - If no, please provide an explanation: |
| c. | Has the Informed Consent process been presented to all subjects as stated in the consenting process that was reviewed and approved by the IRB?<br>☐ Yes<br>☐ No - If no, indicate the reason below:<br>☐ No subjects have been consented/screened yet<br>☐ Other – please provide an explanation: |
| d. | Have you consented any subjects considered to be members of a vulnerable population?<br>☐ No<br>☐ Yes - If yes, have you implemented the additional measures for the protection of these subjects, as was indicated in your site submission form? ☐ Yes ☐ No<br>If no, please provide an explanation: |
| e. | Has your site used advertising / recruitment materials during this last approval period?<br>☐ No<br>☐ Yes - If yes, were these materials approved by Alpha IRB? ☐ Yes ☐ No<br>If no, please submit a copy of the material(s) and provide an explanation: |
| f. | To the best of your knowledge, have all changes to the approved research been submitted and approved by Alpha IRB?<br>☐ Yes<br>☐ No - If no, please provide an explanation:<br>☐ N/A - there were no changes to research during this last approval period |

| 9. | Current risk-potential benefit assessment based on the study results:<br>☐ Unchanged<br>☐ Changed<br>If the assessment has **changed**, please describe the current risk – potential benefit assessment: |
|---|---|
| 10 | Please indicate the human research participant protection training the Principal Investigator and study staff have completed since during this last approval period (Check all that apply):<br>☐ Attendance at seminars and conferences specific to human research participant protection, such as PRIMR, OHRP, etc.<br>☐ Completion of the CITI Program refresher modules (*Available through Alpha IRB).*<br>☐ Completion of National Institutes of Health (NIH) Training: NIH Clinical center Clinical Research Training or NIH Office of Extramural Research Protecting Human Research Participants Training.<br>☐ Other online training specific to human research participant protection. (please describe):<br>☐ Completion of self-study or other training specific to human subjects protections. (describe):<br>☐ None*<br>*Note - Investigators and members of their research teams should complete continuing education at least every two (2) years after Initial IRB approval for as long as they are involved in human subjects research. Please see the Alpha IRB Sponsor/Investigator IRB Requirements and Guidebook for a list of acceptable forms of training or contact Alpha IRB. |

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By signing this form, I am confirming that I am the Principal Investigator (PI) or the PI's designee authorized to submit on behalf of the PI and that the PI is aware of the information contained in this submission. I certify that the above information is correct and complete and that the Principal Investigator has disclosed to Alpha Independent Review Board all relevant information concerning events or other issues that might affect the risk-to-benefit analysis of this study.

Principal Investigator (or Designee) Printed Name

Title (for Designee):

Principal Investigator (or Designee) Signature

Date

**Please email, fax, or mail Renewal Request and all required documents to:**
**Email: cr@alphairb.com**
**Fax: 949-940-0134**
**Mail to: Alpha IRB**
**1001 Avenida Pico, Suite C #497**
**San Clemente, CA 92673**
**Attn: Continuing Review**