1001 Avenida Pico, Suite C #497
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SPONSOR - 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.

Sponsor:		**Protocol No.:**	
Contact person:		**Phone:**	
Fax:		**E-mail:**	

In the questions below, "the study's last IRB review" refers to the study's initial IRB Approval OR last Continuing Review (whichever is more recent).

1.	**Study Activity**
a.	Is the research identified above still ongoing? ☐ **Yes** - Indicate which phase your study is currently in: ☐ Study is not yet initiated ☐ Open to Enrollment ☐ Closed to Enrollment – subjects still active and/or in follow-up ☐ **No** - All subjects at all sites have competed all protocol mandated study visits and follow-up; however study is to remain open for the following reason(s):

2.	**Study Documents**		
a.	List the current version and/or date of the protocol you are using for this study:		
b.	Have there been any amendments / modifications to the protocol since the study's last IRB review? **If Yes,** please attach a brief summary of all protocol amendments / modifications		☐ No ☐ Yes - attach summary
c.	List the current version of all consent forms (templates) you are using for this study *(Main, Assent, Sub-study, PGx, etc.)*		
	ICF Type: *Main*	Version No.:	IRB Approval Date:
	ICF Type:	Version No.:	IRB Approval Date:
	ICF Type:	Version No.:	IRB Approval Date:
	ICF Type:	Version No.:	IRB Approval Date:
d.	List the current versions and dates of all Product Information you are using for this study (Investigator's Brochures, Package Inserts, Device Manuals, etc.) **If any of the product information listed below has not be submitted to Alpha IRB, please attach a copy**		
	Product Name:	Version:	Date:
	Product Name:	Version:	Date:
	Product Name:	Version:	Date:
	Product Name:	Version:	Date:
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e.	Are there any new or revised recruitment / subject study materials that were not previously submitted to Alpha for approval? **If Yes,** please attach	☐ No ☐ Yes - attach

3.	**Site Information**	
a.	Number of Alpha IRB sites actively participating in the study: Number of Alpha IRB sites that have completed the study: Number of Alpha IRB sites that have withdrawn / discontinued their participation in the study: **Total number of Alpha IRB sites that have participated in this study:**	_____ _____ _____ _____
b.	Have any Alpha IRB sites reported any significant protocol deviations/violations to the Sponsor? **If Yes,** please attach a summary.	☐ No ☐ Yes - attach summary
c.	Is the integrity of the study in jeopardy because of significant protocol deviations/violations? **If Yes,** please explain why the study should continue:	☐ No ☐ Yes - explain ☐ N/A

4.	**Site Monitoring**	
a.	Have any deficiencies been found during site monitoring that might represent an increased risk to study subjects? **If Yes,** please explain:	☐ No ☐ Yes - explain
b.	Has Alpha IRB been notified of these additional identified risks? **If No,** please explain:	☐ No - explain ☐ Yes ☐ N/A
c.	Have any general informational or alert letters been sent to the sites about frequently occurring GCP deficiencies identified through the monitoring process? **If Yes,** Please attach copies of this/these item(s).	☐ No ☐ Yes - attach

5.	**Subject Information** - *provide subject numbers for questions d, e, f, g relative to the study sites approved by Alpha IRB*	
a.	What is the subject enrollment goal for the study/protocol?	_____
b.	What is the anticipated date of last subject enrolled?	_____
c.	What is the anticipated date of last subject complete?	_____
d.	Total number of active subjects (including follow-up):	_____
e.	Total number of subjects who have completed the study:	_____
f.	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.)* ***(Please attach a summary of the reasons for subject withdrawals / discontinuations.)***	_____ - attach summary

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g.	Total number of subjects who have signed the informed consent form:	_____
h.	Is subject enrollment for this study on target? **If No,** please attach an explanation	☐ Yes ☐ No - attach

6.	**Safety Monitoring Information**	
a.	Have there been any adverse events or adverse outcomes experienced by subjects since the study's last IRB review? **If Yes,** please attach a summary	☐ No ☐ Yes - attach summary
b.	Have there been any unanticipated problems involving risks to human subjects or others since the study's last IRB review? **If Yes,** please attach a summary	☐ No ☐ Yes - attach summary
c.	Have there been any subject complaints about the research since the study's last IRB review? **If Yes,** please attach a summary	☐ No ☐ Yes - attach summary
d.	Is there a DSMB for this study? **If No,** describe how data is being monitored to ensure subject safety? **If Yes,** when did the DSMB meet last and what are the current findings?	☐ No - explain ☐ Yes - explain
e.	Have there been any publications in literature that are relevant to the study since the study's last IRB review? **If Yes,** please attach a summary	☐ No ☐ Yes - attach summary
f.	Has the Sponsor acquired any other information that could affect the risk/benefit analysis or a participant's willingness to continue participation? **If Yes,** please explain:	☐ No ☐ Yes - explain
g.	What is the current risk-potential benefit assessment based on the study results? ☐ Unchanged ☐ Updated current risk-potential benefit assessment, please describe:	

As a representative of the Sponsor/CRO of this study, I certify that the information contained above is correct and complete to the best of my knowledge, as of _____*(Date).*

_____ _____
Sponsor/CRO Authorized Representatives Signature Date

_____
Printed Name of Sponsor/CRO Authorized Representative

_____
Title / Company

Please email, fax or mail 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