



1001 Avenida Pico, Suite C #497
 San Clemente, CA 92673
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www.alphaairb.com

SPONSOR - CONTINUING REVIEW REPORT

Instructions: Complete and attach any necessary supporting documentation. Submit within 60 days of the expiration date. Missing information or incomplete form may cause a delay in review.

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

Please answer *all* the questions that follow and provide the appropriate information.

1.	Study Activity and Study Documents	
a.	Is the research identified above still ongoing? Indicate which phase your study is currently in: <input type="checkbox"/> Open to Enrollment <input type="checkbox"/> Closed to Enrollment – Active <input type="checkbox"/> Closed to Enrollment – Follow-up, <i>(Subjects are still in follow-up or data collection is continuing.)</i> <input type="checkbox"/> Study Completed – Study related activity completed. <i>(All subjects at all sites have completed all protocol mandated study visits and follow-up.)</i>	<input type="checkbox"/> No <input type="checkbox"/> Yes
b.	Have there been amendments/modifications to the protocol since the previous continuing review? If yes, please provide a current version number and/or date. Version No.: Approval Date:	<input type="checkbox"/> No <input type="checkbox"/> Yes
c.	Has the consent document(s) (template) changed since the previous continuing review? If yes, please provide a current version number and/or date. Version No.: Approval Date:	<input type="checkbox"/> No <input type="checkbox"/> Yes
d.	Has the investigator's brochure or report of prior investigation - IND or IED number changed since the previous continuing review? If yes, please provide a current version number and/or date. Version No.: Approval Date:	<input type="checkbox"/> No <input type="checkbox"/> Yes
e.	Has the recruitment materials changed since the previous continuing review? If yes, please provide a current version number and/or date. Version No.: Approval Date:	<input type="checkbox"/> No <input type="checkbox"/> Yes
f.	Have the case report forms /survey instruments changed since the previous continuing review. If yes, please provide a current version number and/or date. Version No.: Approval Date:	<input type="checkbox"/> No <input type="checkbox"/> Yes



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2.	Site Information <i>(Please enter responses for each item below by providing information for all sites participation in the above referenced study/protocol. Provide information relative to the study sites approved by Alpha IRB)</i>	
a.	Number of sites Actively participating in the study? Number of sites that have completed the study? Number of sites that have withdrawn / discontinued their participation in the study? Total number of sites that have participated in this study?	_____ _____ _____ _____
b.	Have any sites reported any significant protocol deviations/violations to the Sponsor? If yes, please attach a summary.	<input type="checkbox"/> No <input type="checkbox"/> Yes
c.	Is the integrity of the study in jeopardy because of significant protocol deviations/violations? If Yes, please explain why the study should continue.	<input type="checkbox"/> No <input type="checkbox"/> Yes
3.	Site Monitoring	
a.	How have sites been monitored for this study? Description:	
b.	Have any deficiencies been found that might represent an increased risk to study subjects? If Yes, please explain:	<input type="checkbox"/> No <input type="checkbox"/> Yes
c.	Has Alpha IRB been notified of these additional identified risks? If No, Please explain:	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A
d.	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).	<input type="checkbox"/> No <input type="checkbox"/> Yes
4.	Subject Information	
a.	What is the subject enrollment goal for the study/protocol? What is the anticipated date of last subject enrolled? What is the anticipated date of last subject complete? How many subjects have enrolled in this study? <i>(enrolled = number of subject consented – the numbers of Screen Failed Subjects)</i> How many subjects are still actively participating or being followed in the study? How many subjects have completed the study? How many subject lost to Follow-up? How many subjects have withdrawn or been discontinued from the study? <i>(Please attach a summary of the reasons for subject withdrawals / discontinuations.)</i> Have there been any complaints about the research? If Yes, Please attach a summary.	_____ _____ _____ _____ _____ _____ _____ _____ <input type="checkbox"/> No <input type="checkbox"/> Yes



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b.	Please provide a breakdown of <u>all subjects entered to date</u> by race and gender in the table below:				
	Caucasian:	Latino:	African Decent:	Middle Eastern:	Male: Female:
	Native American:	Asian:	Pacific Islander:	Other:	Total:
5.	Safety Monitoring Information				
a.	Please attach a summary (since the last IRB review) of the following: (if applicable) <ul style="list-style-type: none"> • Adverse events and adverse outcomes experience by subjects. • Unanticipated problems involving risks to subjects or others. • Complaints about the research. 				
b.	Has the sponsor acquired any information that materially changes the potential benefits of the study as described in the original protocol and consent? If Yes , please explain:				<input type="checkbox"/> No <input type="checkbox"/> Yes
c.	Is there a DSMB for this study? If Yes , When was the last report and what are the current findings? If No , describe how data is being monitored to assure subject safety?				<input type="checkbox"/> No <input type="checkbox"/> Yes
d.	What is the current risk-potential benefit assessment based on the study results? <input type="checkbox"/> Unchanged <input type="checkbox"/> 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 to the best of my knowledge, as of _____ (Date)

 Sponsor/CRO Authorized Representatives Signature

 Date

 Printed Name of Sponsor/CRO

Title / Company_____

Phone_____

**Please fax Renewal Request and all required documents to: 949-940-0134 or
 Mail to: AlphaIRB
 930 Calle Negocio, Suite B
 San Clemente, CA 92673
 Attn: Continuing Review**