



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

www.alphairb.com

SITE- 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.

Please submit the following with your form:

- **Copy of Principal Investigators Current Medical License**

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

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

1.	Is the research identified above still ongoing? Indicate which phase your site is currently in: <input type="checkbox"/> Open to Enrollment <input type="checkbox"/> Closed to Enrollment – Active <input type="checkbox"/> Closed to Enrollment – Follow-up <input type="checkbox"/> Study Completed – Study related activity completed	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
2.	Have you conducted this protocol since the last approval date?	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
3.	List the current version of the consent(s) form you are using for this study. Alpha IRB Approval Date: Version No.:					
4.	Complete each category below with the number of subjects that completed the stage:					
	a.) Total number of subjects that were withdrawn or discontinued the study: <i>(Include: withdrew consent, screen failures, lost to follow-up, etc.)</i>	+				
	b.) Total number of active subjects:	+				
	c.) Total number of subjects who completed the study:	+				
	d.) Total number of subjects who signed informed consent:	=				
5.	Complete each category of subjects who withdrew or discontinued the study:					
	Withdrew Consent:	Screen Fail:				
	Withdrew Consent due to AE:	Lost to Follow-up:				
	Other <i>(please explain)</i> :					
6.	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:



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	Native American:	Asian:	Pacific Islander:	Other:	Total:		
7.	Events				Yes	No	N/A
	<i>(Please indicate which events have occurred since your sites initial or last approval)</i>						
a.	Has the project changed in any way since the last approval? (<i>protocol amendment, informed consents</i>)				<input type="checkbox"/>	<input type="checkbox"/>	
b.	Has there been additional or new information about this study which may affect a subject's willingness to continue their participation, or that may need to be given to prior participants?				<input type="checkbox"/>	<input type="checkbox"/>	
c.	Have you reported all Adverse Events, Serious Adverse Events, Unanticipated Problems and Protocol Deviation as required by Alpha IRB?				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d.	Did any of these events require a change to the consent form(s)?				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e.	Has the site location changed?				<input type="checkbox"/>	<input type="checkbox"/>	
f.	Has there been a change to the Principal Investigator?				<input type="checkbox"/>	<input type="checkbox"/>	
g.	Have there been any changes in conflict of interest disclosure information, or are conflict of interest issues now relevant to the review of this protocol?				<input type="checkbox"/>	<input type="checkbox"/>	
h.	Has your site been audited by the FDA or other government offices since your last approval/re-approval of this study?				<input type="checkbox"/>	<input type="checkbox"/>	
i.	Have there been any complaints about the research?				<input type="checkbox"/>	<input type="checkbox"/>	
j.	Have you received any relevant recent literature?				<input type="checkbox"/>	<input type="checkbox"/>	
k.	Have there been any interim findings, including data safety monitoring reports?				<input type="checkbox"/>	<input type="checkbox"/>	
l.	Have you received any relevant multi-center trial reports?				<input type="checkbox"/>	<input type="checkbox"/>	
m.	To the best of your knowledge, have all changes to the approved research been submitted and approved by Alpha IRB?				<input type="checkbox"/>	<input type="checkbox"/>	
<i>If you answered YES to any of the above and have not already submitted this information to Alpha IRB, please submit the information with this report.</i> <i>(Forms are located on Alpha IRB's website at www.alphairb.com)</i>							
8.	Procedures				Yes	No	N/A
a.	Have you personally conducted/supervised this study?				<input type="checkbox"/>	<input type="checkbox"/>	
b.	Has all the research actively been conducted according to the approved study plan?				<input type="checkbox"/>	<input type="checkbox"/>	
c.	Has the Informed Consent been presented to all subjects as stated in your sites consenting process?				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d.	Have you implemented appropriate additional measures for the protection of any subjects that may be considered to be a member of a vulnerable population?				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g.	Current risk-potential benefit assessment based on the study results? <input type="checkbox"/> Unchanged <input type="checkbox"/> Changed						



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	If the assessment has changed , please describe the current risk – potential benefit assessment:
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By signing this form, the Principal Investigator certifies that he/she has disclosed to Alpha Independent Review Board all relevant information concerning adverse events or other issues that might affect the risk-to-benefit analysis of this study.

Principal Investigator Signature

Date

Principal Investigator Printed Name

Please fax, mail, or email, Renewal Request and all required documents to:

Fax: 949-940-0134

Email: cr@alphairb.com

Mail to: AlphaIRB

930 Calle Negocio, Suite B

San Clemente, CA 92673

Attn: Continuing Review