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

www.alphairb.com

CLOSE-OUT REPORT

Close-Out Reports need to be submitted within 30 days after completion of the study.

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.	The study/site identified above is closed due to: ☐ Study completion ☐ Site not used ☐ Other - please explain:	Date the study closed:
2.	Have all subjects at your site finished their final visits and all follow-up activities (such as phone calls, post-card contacts, or long-term follow up required by the protocol)?	☐ No ☐ Yes ☐ N/A – no subjects screened/enrolled
3.	Has the sponsor or the sponsor representative indicated the study is closed at your site?	☐ No ☐ Yes
4.	If the study was conducted under a Federalwide Assurance, has all data analysis at the site been completed?	☐ No ☐ Yes ☐ N/A
5.	a. Total number of subjects who completed the study:	+
	b. Total number of subjects that were withdrawn or discontinued the study who signed the ICF: *(Includes: withdrew consent, screen failures, lost to follow-up, etc.)*	+
	c. Total number of subjects who signed the informed consent form:	=

6.	Provide a breakdown of <u>all subjects who signed an ICF for the study</u> by gender, race and ethnicity (if recorded) in the table below *(each total should equal # stated in 5.c. 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:	

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

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8.	**Events** *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.] [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. [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 or change in Principal Investigator	*☐	☐
d.	Change in conflict of interest disclosure information, or new conflict of interest	*☐	☐
e.	Changes in community attitudes or state laws	*☐	☐
f.	Inspection by the FDA or other regulatory agency	*☐	☐
g.	Any restriction, sanction, disciplinary action or other change to the PI's license	*☐	☐
h.	Any subject complaints about the research	*☐	☐
i.	Any recent publications in literature that are relevant to the study	*☐	☐
j.	Data Safety Monitoring Board reports, relevant multi-center trial reports or other interim findings	*☐	☐
k.	Any other additional or new information about the study which would change the risk/benefit analysis, 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)*			
9.	To the best of your knowledge, have all changes to the approved research been submitted and approved by Alpha IRB? ☐ Yes ☐ No - If no, please provide an explanation: ☐ N/A - there were no changes to research during this last approval period		

By signing this form, the Principal Investigator certifies that the above information is correct and complete and that he/she 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 Signature _____ Date _____

Please email, fax or mail Close-out Request and all required documents to:

Email: cr@alphairb.com, Fax: 949-940-0134 or Mail to: Alpha IRB, 1001 Avenida Pico, Suite C #497, San Clemente, CA 92673 - Attn: Close-out