



930 Calle Negocio, Suite B, 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 or termination of the study.

Sponsor:		(IRB USE - Date Received _____)
Protocol No.:		
Principal Investigator:		
Site Name:		
Address:		
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: <ul style="list-style-type: none"> • Completion <input type="checkbox"/> • Termination <input type="checkbox"/> • Withdrawn <input type="checkbox"/> • Other: Please explain: 	
2.	Have all subjects at your site finished their final visits and any follow-up activities (such as phone calls, post-card contacts, or long-term follow up required by the protocol) are completed?	<input type="checkbox"/> No <input type="checkbox"/> Yes
3.	Has the sponsor or the sponsor representative indicated the study is closed at your site?	<input type="checkbox"/> No <input type="checkbox"/> Yes
4.	If the study was conducted under Federalwide Assurance, has all data analysis at the site is completed?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A
5.	Did any subjects experience an adverse event?	<input type="checkbox"/> No <input type="checkbox"/> Yes
A.	Were these events previously reported to Alpha IRB? If NO , please explain: or attach the required document(s) for review. <i>(Forms are located on Alpha IRB's website.)</i>	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A
6.	Did any subjects experience a serious adverse/unanticipated event?	<input type="checkbox"/> No <input type="checkbox"/> Yes
A.	Were these events previously reported to Alpha IRB? If NO , attach the required documents for review. <i>(Forms are located on AlphaIRB's website.)</i>	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A



930 Calle Negocio, Suite B, San Clemente, CA 92673
 T: 949-542-3882 F: 949-940-0134

www.alpha-irb.com

7.	Did any of these events require a change to the consent form(s)?							<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A	
8.	How many subjects were enrolled in this study since the last approval date?								
9.	Please provide a breakdown of <u>all subjects entered to date</u> by race and gender in the table below:								
	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic origin	Hispanic	White, not of Hispanic origin	Other/Unknown		Male	
								Female	
							=	Total	
10.	Number of subjects withdrawn from study? Reason(s) for withdrawal:								
11.	Has there been a change to the site location or a change of Principle Investigator that has not yet been reported?							<input type="checkbox"/> No <input type="checkbox"/> Yes	
12.	Has there been a change in conflict of interest (financial disclosure)?							<input type="checkbox"/> No <input type="checkbox"/> Yes	
13.	Have there been changes in community attitudes or state laws since your initial approval or your last report?							<input type="checkbox"/> No <input type="checkbox"/> Yes	
14.	Have there been any subject complaints or injuries that have not yet been reported?							<input type="checkbox"/> No <input type="checkbox"/> Yes	
15.	Has the project changed in any way since the last approval?							<input type="checkbox"/> No <input type="checkbox"/> Yes	
16.	Has your site been audited by the FDA or other government offices since your last approval/re-approval of this study? If YES, please provide a copy of the audit report.							<input type="checkbox"/> No <input type="checkbox"/> Yes	

By signing this form, the Principal Investigator certifies that he/she has disclosed to Alpha IRB all relevant information concerning adverse events or other issues that might affect the risk-to-benefit analysis of this study.

Principal Investigator Signature

Date

Please fax Close-out Request and all required documents to: 949-940-0134

or

**Mail to: AlphaIRB , 930 Calle Negocio Suite B, San Clemente, CA 92673
 Attn: Close-out**