



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

www.alphairb.com

CONTINUING REVIEW REPORT

COMPLETE AND RETURN WITHIN 60 DAYS BEFORE THE EXPIRATION OF THE APPROVAL PERIOD. MISSING OR INCOMPLETE FORM CAN DELAY REAPPROVAL.

THE FOLLOWING ITEMS NEED TO ACCOMPANY THIS FORM:

- Copy of Principal Investigators Medical License
- Copy of the first page of each current Informed Consent Form(s)

Sponsor: Protocol No.:	(IRB USE - Date Received _____)
Principal Investigator: Site Name: Address:	
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? If NO, <ul style="list-style-type: none"> • the project still in the proposal stage <input type="checkbox"/> • unfunded at this time but to remain open, <input type="checkbox"/> • being terminated or withdrawn <input type="checkbox"/> Other: Please explain the status:	<input type="checkbox"/> No <input type="checkbox"/> Yes
2.	Have you conducted this protocol since the last approval date?	<input type="checkbox"/> No <input type="checkbox"/> Yes
3.	Are you using a consent form(s) for this study? If Yes, a copy of the first page of the each current informed consent form(s) are required to accompany this report.	<input type="checkbox"/> No <input type="checkbox"/> Yes
4.	How many subjects were studied since this study was initiated?	
5.	How many subjects were enrolled in this study since the last approval date?	



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6.	Number of subjects withdrawn from study? Reason(s) for withdrawal:							
7.	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
8.	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
9.	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 Alpha IRB's website.)</i>							<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A
10.	Did any on these events require a change to the consent form(s)?							<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A
11.	Has the project changed in any way since the last approval that has not yet been reported to Alpha IRB? <i>(Changes include protocol amendments, Investigator changes, and/or revisions to the consent document.)</i> If Yes , provide the appropriate documentation of any changes not previously reported for review and approval by Alpha IRB.							<input type="checkbox"/> No <input type="checkbox"/> Yes
12.	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? If YES , please explain and provide information to be given to existing or prior participants.							<input type="checkbox"/> No <input type="checkbox"/> Yes



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13.	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? If YES, please explain:	<input type="checkbox"/> No <input type="checkbox"/> Yes
14.	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
15.	Have there been any complaints about the research?	<input type="checkbox"/> No <input type="checkbox"/> Yes
16.	Have you received any relevant recent literature?	<input type="checkbox"/> No <input type="checkbox"/> Yes
17.	Have there been any interim findings, including data safety monitoring reports?	<input type="checkbox"/> No <input type="checkbox"/> Yes
18.	Have you received any relevant multi-center trial reports?	<input type="checkbox"/> No <input type="checkbox"/> Yes
19.	What is the current risk-potential benefit assessment based on the study results? Assessment:	

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 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**