



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

[www.alpha-irb.com](http://www.alpha-irb.com)

**SPONSOR/CRO STUDY APPLICATION**

*\*We accept study submissions by email, fax or mail.*

**1. GENERAL STUDY INFORMATION**

**A. Sponsor:** \_\_\_\_\_ **Protocol No.:** \_\_\_\_\_

**Study Title:** \_\_\_\_\_

**B. Has this study ever been submitted to another IRB for review?**  
 Yes – list the name of the IRB(s) and the outcome of the review(s) on a separate page.  
 No

**C. Study Phase:**  Phase I  Phase II  Phase III  Phase IV  Other:

**D. Is this an Investigational Device study?**  Yes  No  
 If Yes, please provide the following:

- Letter from sponsor stating that the study is a non-significant risk device study.
- FDA letter granting an Investigational Device Exemption for the proposed use.
- Letter explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2(c) or otherwise exempt.

**E. How many total sites will be involved in this study?** \_\_\_\_\_

**F. How many sites will be utilizing Alpha IRB as their review board?** \_\_\_\_\_

**G. What is the anticipated date of first site submission?**      /      /

**2. SPONSOR INFORMATION**

**A. Contact Name:** \_\_\_\_\_  
**Company:** \_\_\_\_\_  
**Address:** \_\_\_\_\_  
**City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **Zip:** \_\_\_\_\_  
**Phone:** \_\_\_\_\_ **Fax:** \_\_\_\_\_  
**Email:** \_\_\_\_\_

**B. Please indicate the name of the contact person to be copied on all IRB correspondence to sites:**  
**Name:** \_\_\_\_\_  
**Company:** \_\_\_\_\_



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<b>3. CONTRACT RESEARCH ORGANIZATION (CRO) INFORMATION – IF APPLICABLE</b>		
<b>Contact Name:</b> <b>Company:</b> <b>Address:</b> <b>City:</b> <b>State:</b> <b>Zip:</b> <b>Phone:</b> <b>Fax:</b> <b>Email:</b>		
<b>4. MAIL DELIVERY INFORMATION – WHAT TYPE OF SHIPPING DO YOU PREFER?</b>		
A. <input type="checkbox"/> Standard Overnight <input type="checkbox"/> 2-Day <input type="checkbox"/> Other:		
B. <b>Service Provider:</b> <input type="checkbox"/> FedEx <input type="checkbox"/> UPS <input type="checkbox"/> DHL <input type="checkbox"/> Other:		
C. <b>Account No.:</b>		<b>Reference No.:</b>
<b>5. BILLING INFORMATION – PLEASE PROVIDE INVOICING CONTACT.</b>		
<input type="checkbox"/> Same as Sponsor	<input type="checkbox"/> Same as CRO	<input type="checkbox"/> Other: <i>Supply information below.</i>
<b>Contact Name:</b> <b>Company:</b> <b>Address:</b> <b>City:</b> <b>State:</b> <b>Zip:</b> <b>Phone:</b> <b>Fax:</b> <b>Email:</b>		
<b>6. SAFETY MONITORING INFORMATION</b>		
Is there a Data Safety Monitoring Board (DSMB) for this study? <input type="checkbox"/> No <input type="checkbox"/> Yes If No, describe the provisions to monitor data to ensure the safety to subjects:		



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<b>7.</b>	<b>STUDY CHECKLIST</b>
	Please include the following in your submission package:
	<input type="checkbox"/> Protocol <input type="checkbox"/> Investigator's Drug Brochure (IND Studies) <input type="checkbox"/> Study Material(s): <input type="checkbox"/> Ad(s) <input type="checkbox"/> Diary <input type="checkbox"/> Questionnaire(s) <input type="checkbox"/> Other: _____ <input type="checkbox"/> Sample Informed Consent(s) (in Word Format) : <input type="checkbox"/> Master ICF <input type="checkbox"/> Genetic <input type="checkbox"/> HIPAA <input type="checkbox"/> Assent <input type="checkbox"/> Other:

**Additional Information:**

To guarantee your study will be reviewed at the next available Board meeting, documentation will need to be received by the submission deadline. *See Board Schedule.*