



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

www.alphaairb.com

SPONSOR/CRO STUDY APPLICATION

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

1. CONTACT INFORMATION

Sponsor: _____ Protocol No.: _____

Study Title: _____

A. SPONSOR INFORMATION

Contact Name: _____
 Address: _____
 City: _____ State: _____ Zip: _____
 Phone: _____ Fax: _____
 Email: _____

B. CONTRACT RESEARCH ORGANIZATION (CRO) INFORMATION – IF APPLICABLE

Contact Name: _____
 Company: _____
 Address: _____
 City: _____ State: _____ Zip: _____
 Phone: _____ Fax: _____
 Email: _____

C. MAIL DELIVERY INFORMATION – ALL APPROVAL DOCUMENTS ARE EMAILED TO SPONSOR AND SITES UNLESS OTHERWISE STATED BELOW.

Standard Overnight 2-Day Other:

Service Provider: FedEx UPS DHL Other:

Account No.: _____ Reference No.: _____

D. BILLING INFORMATION – PLEASE PROVIDE INVOICING CONTACT.

Same as Sponsor Same as CRO Other: *Supply information below*

Contact Name: _____
 Company: _____
 Address: _____
 City: _____ State: _____ Zip: _____
 Phone: _____ Fax: _____
 Email: _____



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2.	GENERAL STUDY INFORMATION
A.	How many total sites will be involved in this study?
B.	How many sites will be utilizing Alpha IRB as their review board?
C.	What is the anticipated date of first site submission? / /
D.	Is this study Federally funded? <input type="checkbox"/> No <input type="checkbox"/> Yes If Yes , what is your Federal-wide Assurance (FWA) number? : Please explain if the FWA number is unavailable:
E.	Has this study ever been submitted to another IRB for review? <input type="checkbox"/> Yes – list the name of the IRB(s) and the outcome of the review(s) on a separate page. <input type="checkbox"/> No
F.	Type of Research: <input type="checkbox"/> Drug/ Biologic <input type="checkbox"/> Food/Drink <input type="checkbox"/> Social/Behavioral <input type="checkbox"/> Tissue/Blood Bank <input type="checkbox"/> Device(see below) <input type="checkbox"/> Other (describe):
G.	Study Phase: <input type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/> Other:
H.	Is this a Drug or Biologic study? <input type="checkbox"/> Yes <input type="checkbox"/> No (If No, skip to L)
I.	What is the IND number for this study? No: Please support your IND # by submitting one of the following: <ol style="list-style-type: none"> 1. The sponsor protocol with the IND # listed on it 2. A letter from the sponsor 3. A letter from the FDA If there is not an IND number yet available please explain: Are you claiming exemption from IND regulation? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes , enter the qualification for IND exemption per 21 CFR 312.2 (b):
J.	Does this study involve a radioactive drug? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes , please provide a copy of the approval by a Radioactive Drug Research Committee.
K.	Is the drug or biologic being used in this research study approved by FDA? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes , is the drug or biologic being used in this study within one or more of its approved indications(s)?: <input type="checkbox"/> Yes <input type="checkbox"/> No
L.	Is this an Investigational Device study? <input type="checkbox"/> Yes <input type="checkbox"/> No (If No, skip to 3 - Subject Enrollment Information)
M.	Is the device FDA approved for the indication in this study? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes , attach a copy of the FDA generated letter; 510k clearance or PMA determination.



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<p>N.</p>	<p>If the device is <i>not</i> FDA approved or the study involves the investigational use of an FDA approved device, Please complete the following questions:</p> <p>Is there a valid IDE # issued by the FDA for this device? <input type="checkbox"/> Yes <input type="checkbox"/> No (If No, skip to O)</p> <p>If Yes, what is the IDE Number? :</p> <p>Please support your IDE # by <i>one</i> of the following:</p> <ol style="list-style-type: none"> 1. The sponsor protocol with the IDE # listed on it 2. A letter from the sponsor 3. A letter from the FDA 														
<p>O.</p>	<p>Does the device fulfill the requirements for an abbreviated IDE? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If Yes, please provide <i>one</i> of the following:</p> <ul style="list-style-type: none"> • Letter from sponsor stating that the study is a non-significant risk device study under 21 CFR 812 (m) • 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. 														
<p>P.</p>	<p>Does the device involve the use of ionizing radiation or isotopes? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Will the Sponsor be charging the Principal Investigator and or Subject for the device?</p> <p>If Yes, please describe or attach a rationale and a description of the amount to be charge. (<i>Inform the PIs and/or subjects</i>):</p>														
<p>3. SUBJECT ENROLLMENT INFORMATION</p>															
<p>A.</p>	<p>What is the subject enrollment goal for the study/protocol?</p> <p>What are the anticipated dates for the following events?</p> <p>First subject enrolled: Last subject enrolled: Last subject completed:</p>														
<p>B.</p>	<p>Potentially Vulnerable Populations:</p> <p><i>Please indicate whether the protocol design requires/includes the enrollment of any of the vulnerable populations listed below. Please select all that apply and describe any additional safeguards included in the protocol to protect the rights and welfare of these subjects:</i></p> <table border="0"> <tr> <td><input type="checkbox"/> Children/minors (note: 19 in the age of majority in Alabama and Nebraska; 21 in the age of majority in Puerto Rico.)</td> <td><input type="checkbox"/> Mentally impaired</td> </tr> <tr> <td><input type="checkbox"/> Nursing home residents/institutionalized individuals</td> <td><input type="checkbox"/> Fetuses/fetal material</td> </tr> <tr> <td><input type="checkbox"/> Terminally ill patients</td> <td><input type="checkbox"/> Very elderly</td> </tr> <tr> <td><input type="checkbox"/> Economically disadvantaged</td> <td><input type="checkbox"/> Investigator's staff members</td> </tr> <tr> <td><input type="checkbox"/> Pregnant women</td> <td><input type="checkbox"/> Prisoners</td> </tr> <tr> <td><input type="checkbox"/> Homeless</td> <td><input type="checkbox"/> Other:</td> </tr> <tr> <td><input type="checkbox"/> Investigator's patients</td> <td></td> </tr> </table>	<input type="checkbox"/> Children/minors (note: 19 in the age of majority in Alabama and Nebraska; 21 in the age of majority in Puerto Rico.)	<input type="checkbox"/> Mentally impaired	<input type="checkbox"/> Nursing home residents/institutionalized individuals	<input type="checkbox"/> Fetuses/fetal material	<input type="checkbox"/> Terminally ill patients	<input type="checkbox"/> Very elderly	<input type="checkbox"/> Economically disadvantaged	<input type="checkbox"/> Investigator's staff members	<input type="checkbox"/> Pregnant women	<input type="checkbox"/> Prisoners	<input type="checkbox"/> Homeless	<input type="checkbox"/> Other:	<input type="checkbox"/> Investigator's patients	
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C.	<p>Legally Authorized Representatives (LAR): For this study, do you intend to allow enrollment of adult subjects unable to consent for themselves (if approved by the IRB)?: <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
D.	<p>Subject Recruitment Methods: Please indicate all anticipated subject recruitment methods: <input type="checkbox"/> None <input type="checkbox"/> Print <input type="checkbox"/> Radio <input type="checkbox"/> TV <input type="checkbox"/> Newsletters <input type="checkbox"/> Flyers <input type="checkbox"/> Internet <input type="checkbox"/> Other:_____</p> <p><i>(all subject recruitment materials (including telephone screens) must be approved by the IRB prior to implementation)</i></p>
4. SAFETY MONITORING INFORMATION	
A.	<p>Is there a Data Safety Monitoring Board (DSMB) for this study? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, do you agree to submit summary reports to Alpha IRB when available <input type="checkbox"/> Yes <input type="checkbox"/> No If No, describe the provisions to monitor data to ensure the safety to subjects:</p>
B.	<p>Site Monitoring Information: How frequently will sponsor/CRO representatives visit the research site(s) for routine monitoring? Telephone: Routine On-Site Visits: For Cause On site Visits <i>(explain criteria for Selection)</i>: If Other, please explain:</p>
C.	<p>IND Safety Reports: IND Safety Reports submitted by the Sponsor/CRO will receive an acknowledgement letter. The Sponsor/CRO is responsible for providing copies of the acknowledged IND Safety Reports to individual sites. <i>For an additional fee, Alpha IRB can provide site-specific acknowledgment letters for IND Safety Reports to each individual site.</i></p>
D.	<p>Adverse Device Effect Reports: Adverse Device Effect Reports submitted by the Sponsor/CRO will receive an acknowledgment letter. The Sponsor/CRO is responsible for providing copies of the acknowledged Adverse Device Effect Reports to individual sites. <i>For an additional fee, Alpha IRB can provide site-specific acknowledgment letters for Adverse Device Effect Reports to each individual site.</i></p>
5. COMPENSATION AND MEDICAL CARE FOR RESEARCH RELATED INJURY	
	<p>Is the language in the submitted ICF that addresses compensation for research-related injury language consistent with the language in the investigators site's contracts? <input type="checkbox"/> Yes <input type="checkbox"/> No If No, please explain:</p>
6.	CONFIDENTIALITY AND HIPAA INFORMATION



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	<i>("Confidentiality" refers to individual's wishes as to how his/her identifiable private information will be handled, managed, and disseminated. Confidentiality is a means of protection that information, usually by safeguarding it from unauthorized disclosure.)</i>
A.	<p>Please indicate the provisions to maintain subject confidentiality: (check all that apply)</p> <p><input type="checkbox"/> Paper based records will be kept in a secure location and only accessible to personnel involved with the study.</p> <p><input type="checkbox"/> Computer based files will be password protected and only be made available to personnel involved with the study.</p> <p><input type="checkbox"/> Study personnel will be required to sign statements agreeing to protect the security and confidentiality of study information prior to being granted access to any related information.</p> <p><input type="checkbox"/> When feasible, identifiers will be removed from study related information.</p> <p><input type="checkbox"/> Other, please provide and explanation:</p>
B.	<p>Will personnel not directly related to the research have access to study records or data?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, check all that apply)</p> <p><input type="checkbox"/> Billing Office</p> <p><input type="checkbox"/> Medical Records</p> <p><input type="checkbox"/> Hospital Personal</p> <p><input type="checkbox"/> Other:</p>
7. PRIVACY INFORMATION	
	<i>"Privacy Interests" – refers to the interest of individuals in being left alone, limiting access to themselves and limiting access to their information.</i>
A.	<p>Will personal information collected from subjects be limited to only that which is necessary for the study purpose? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If No, please provide an explanation:</p>
B.	<p>Are there any additional provisions included in the protocol to protect the privacy of subjects? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If Yes, please describe:</p>



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By signing below the sponsor agrees to and affirms compliance with the following terms:

The sponsor/CRO is responsible for selection only qualified investigator, with sufficient time to conduct the research properly and the appropriate potential to recruit the required number of suitable subjects, as appropriate experts to conduct the research study. Sponsors/CROs must comply with all requirements regarding research activities, including federal, state, local and IRB requirements. Only complete and accurate information should be submitted to the IRB for review and approval.

Sponsor must evaluated and ensure that the appropriate resource and infrastructure to support the conduct of clinical research are maintained at the site(s). The site(s) must be in compliance with the sponsor’s requirements for handling medical emergencies. The site(s) must store research records in such a way to protect the privacy and confidentiality of subject information.

Each sponsor/CRO should ensure that the manufacture and formulation of the investigational product conforms to federal regulation. If the study will utilize a comparator, ensure that manufacture and formulation of the comparator also conforms to federal requirements. Each sponsor/CRO should also ensure the appropriate control (storage, dispensation, and accountability) of the investigational product at the site(s) as require by federal, state, and local law.

Sponsor / CRO (and Principal Investigators) must submit to the IRB in writing any unanticipated problems involving risk to human subjects or others. This notification to the IRB must occur promptly and no later than 5 working days for the time of identification of the unanticipated problem. All results from the research study that affect the subject safety or medical care will be communicated to study participants in writing through the investigator.

The sponsor/CRO must ensure by adequate site selection methods and ongoing monitoring that the study staff at the research site(s) are conducting research in compliance with Regulatory and IRB Requirements including the policies set forth in the current Alpha IRB Investigators Guidebook (available online at www.alphairb.com).

Signature: _____ Date: _____
 (Sponsor/CRO Authorized Representative)

Printed Name: _____

Title _____ Company _____

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.*



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STUDY CHECKLIST

Please include the following in your submission package:

- Protocol Supported by valid IND # (if applicable)
- Investigator's Drug Brochure (IND Studies) or Package insert (FDA approved drugs)
- Study Material(s): Ad(s) Diary Questionnaire(s) Other:
- Sample Informed Consent(s) (in Word Format) : Master ICF Genetic HIPAA Assent
- Other:

Device Studies: *(Please make sure these elements are included in your protocol or submission before submitting your study for review.)*

- Protocol that includes a statement of the name, purpose and intended use of the device along with objectives and duration of the investigation.
- Protocol Supported Risk Analysis of all subjects.
- Description of the device that includes important components, ingredients, properties and principles of operation the device and copies of all applicable labeling.
- Written procedures for monitoring the device and its safe use.
- Any additional written reports on prior investigation conducted with the device.
- Names of other institution which may take part in the investigation, as well as IRB information from the IRB's that have been or will be asked to review the study.