



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

www.alphaairb.com

SITE SUBMISSION FORM (SINGLE SITE)

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

1. GENERAL STUDY INFORMATION

A. Sponsor: _____ **Protocol No.:** _____

Study Title: _____

B. Study Phase: Phase I Phase II Phase III Phase IV Other:

C. 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.

D. Is this study Federally funded? No Yes
If yes, what is your Federal-wide Assurance (FWA) number? :
 Please explain if the FWA number is unavailable:

2. INVESTIGATOR & CONTACT INFORMATION

A. Principal Investigator (PI): _____

Site Name: _____	Phone: _____	Attach PI's CV, License and 1572 (if applicable)
Mailing Address: _____	Fax: _____	
	24 Hour Phone: _____	
	E-mail: _____	

B. Does the PI, the PI's immediate family, study staff or the study staff's immediate family have a financial interest (other than payment) in this study?
 No Yes (Alpha IRB will contact either the sponsor or PI for additional information.)
Does the PI, the PI's immediate family, study staff or the study staff's immediate family have an interest, other than financial, in the outcome of this study?
 No Yes (Alpha IRB will contact either the sponsor or PI for additional information.)

c. Has this study ever been submitted to another IRB for review? No Yes
If yes, list the name of the IRB(s) and the outcome of the review:



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D.	<p>Please indicate the human research participant protection training the Principal Investigator has completed within the past 3 years (Check all that apply):</p> <p><input type="checkbox"/> Review of the FDA Information Sheets, GCP Guidelines, and the Belmont Report.</p> <p><input type="checkbox"/> Completion of the CITI Program: Course in Protection of Human Research Subjects. <i>(Available through Alpha IRB).</i></p> <p><input type="checkbox"/> Completion of National Institutes of Health (NIH) Training: NIH Clinical center Clinical Research training or NIH Office of Extramural Research Protecting Human Research Participants Training.</p> <p><input type="checkbox"/> Completion of self-study or other training specific to human research participant protection</p>	
E.	<p>If you checked self-study or other training specific to human research participant protection, please check all that apply:</p> <p><input type="checkbox"/> Investigators Meetings <input type="checkbox"/> Web Based HRPP Training (please describe):</p> <p><input type="checkbox"/> Clinic/CRO/SMO Training <input type="checkbox"/> Other (please describe):</p>	
F.	<p>If the Principal Investigator has not completed any training on human research participant protection, what method of training will be completed? (Check all that apply): <i>(Note: acceptable form of training, such as those listed below, must be complete before Approval is granted)</i></p> <p><input type="checkbox"/> Investigators Meetings <input type="checkbox"/> Web Based HRPP Training (please describe):</p> <p><input type="checkbox"/> Clinic/CRO/SMO Training <input type="checkbox"/> Other (please describe):</p>	
G.	<p>Has the Principal Investigator confirmed that the research staff and key personnel at this facility have been trained and are aware of their obligations with regard to human research participant protection regulations? <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>If no please describe how this will be addressed:</p>	
H.	<p>Do any of the below apply to the PI involved with this study?</p> <p>Been audited by the FDA? <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Been sanctioned by any State/IRB? <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Had membership on any hospital staff or clinical privileges denied, revoked or suspended? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Other:</p>	<p>Attached documentation for all yes answers. (example form 483 & site response)</p>
I.	<p>How long has PI been conducting research? Years</p>	
J.	<p>How many studies is the PI currently involved in as a PI?</p>	
K.	<p>Number of clinical research staff available to work on this project:</p>	
<p>3. MAIL DELIVERY INFORMATION – HOW WOULD YOU LIKE TO RECEIVE YOUR DOCUMENTS?</p>		
A.	<p><input type="checkbox"/> Email <input type="checkbox"/> Standard Overnight <input type="checkbox"/> 2-Day <input type="checkbox"/> Other:</p>	



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B.	Service Provider: <input type="checkbox"/> FedEx <input type="checkbox"/> UPS <input type="checkbox"/> DHL <input type="checkbox"/> Other:			
C.	Account No.:	Reference No.:		
D.	Who will be the main contact for this study?		Correspondance and document handling.	
	Name:	Phone:		
	Position/Title:	Email:		
4.	LOCATION OF RESEARCH			
	Will the PI be conducting study related activity at other locations <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, complete an Additional Study Location Form for each location.		Include all locations for study related activities	
5.	SUBJECT INFORMATION			
A.	Will subjects who do not understand English be enrolled? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, describe your resources to communicate with these subjects:		Attach an additional sheet if needed.	
B.	Into what language(s) will the consent form need to be translated:			
C.	Potentially Vulnerable Populations: (select all that apply)		Attach additional protections for these populations if needed.	
	<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"/> Nursing home residents	<input type="checkbox"/> Mentally impaired		<input type="checkbox"/> Terminally ill patients
	<input type="checkbox"/> Fetuses / fetal material	<input type="checkbox"/> Economically disadvantaged		<input type="checkbox"/> Very elderly
	<input type="checkbox"/> Pregnant women	<input type="checkbox"/> Investigator's staff members		<input type="checkbox"/> Homeless
	<input type="checkbox"/> Prisoners	<input type="checkbox"/> Investigator's patients		<input type="checkbox"/> Other:
D.	Describe additional protections for potentially vulnerable subjects:		Or submit on separate page	
E.	If you are recruiting children in this study, indicate the age range:		Attach copy of Assent.	
F.	If children or minors will be enrolled, what is the legal age of consent to intervention or procedures associated with the research under state or local law?			
G.	Will children or minors without parent be enrolled? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, provide justification in terms of state law or a decision by legal counsel indication that can consent on behalf of the child to general medical care under state or local law:		Or submit on separate page	



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H.	Will subjects with legally authorized representatives (LARs) be enrolled? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes , provide justification in terms of state law or a decision by legal counsel of who constitutes an LAR in your state:	Or submit on separate page																																																						
I.	What is the diversity of your research population? <table border="0"> <tr> <td>Ethnicity:</td> <td></td> <td>Gender:</td> <td></td> <td>Age:</td> <td></td> </tr> <tr> <td>Caucasian:</td> <td>%</td> <td>Male:</td> <td>%</td> <td>0 – 18</td> <td>%</td> </tr> <tr> <td>Latino:</td> <td>%</td> <td>Female:</td> <td>%</td> <td>18 – 64</td> <td>%</td> </tr> <tr> <td>African Decent.</td> <td>%</td> <td></td> <td></td> <td>64 - ></td> <td>%</td> </tr> <tr> <td>Native American:</td> <td>%</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Middle Eastern:</td> <td>%</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Asian:</td> <td>%</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Pacific Islander:</td> <td>%</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Other:</td> <td>%</td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	Ethnicity:		Gender:		Age:		Caucasian:	%	Male:	%	0 – 18	%	Latino:	%	Female:	%	18 – 64	%	African Decent.	%			64 - >	%	Native American:	%					Middle Eastern:	%					Asian:	%					Pacific Islander:	%					Other:	%					
Ethnicity:		Gender:		Age:																																																				
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Latino:	%	Female:	%	18 – 64	%																																																			
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Native American:	%																																																							
Middle Eastern:	%																																																							
Asian:	%																																																							
Pacific Islander:	%																																																							
Other:	%																																																							
J.	Are there any state or local laws that you are aware of that might impact or influence the conduct of the study? <input type="checkbox"/> No <input type="checkbox"/> Yes																																																							
K.	Are there community attitudes that may affect subjects in this study? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes , describe attitudes and how they may affect subjects:	Describe on separate page																																																						
L.	Are the PI's facilities equipped to handle emergencies? <input type="checkbox"/> No <input type="checkbox"/> Yes If No , name the nearest emergency facility: Distance to facility: miles																																																							
6. DIRECT SUBJECT ADVERTISING																																																								
A.	Media for subject recruitment includes: (select all that apply)																																																							
	<input type="checkbox"/> Radio	<input type="checkbox"/> Television																																																						
	<input type="checkbox"/> Newspaper	<input type="checkbox"/> Bulletin board/flyer																																																						
	<input type="checkbox"/> Internet	<input type="checkbox"/> Other																																																						
B.	Will a centrally coordinated advertisement program be used? <input type="checkbox"/> No <input type="checkbox"/> Yes																																																							
C.	Will a central 800# facility be used for recruitment? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes , submit the script and identify calling company.																																																							



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7. PAYMENT TO SUBJECTS		
A.	Are subjects being paid for participation? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, indicate total amount, (dollars or equivalent): \$	
B.	Form of Payment: <input type="checkbox"/> Reimbursement only (Payment includes all types of reimbursements such as fares, parking fees, etc.) <input type="checkbox"/> Check <input type="checkbox"/> Cash <input type="checkbox"/> Gift Certificate <input type="checkbox"/> Payment Card <input type="checkbox"/> Voucher <input type="checkbox"/> Other:	
C.	Will subject be required to submit proof of expenses? <input type="checkbox"/> No <input type="checkbox"/> Yes	
D.	Will a 1099 be issued? <input type="checkbox"/> No <input type="checkbox"/> Yes If Yes, select all that apply to protect confidentiality <input type="checkbox"/> Mail to subjects address provided to our site <input type="checkbox"/> Subject may receive from site with proper ID	
E.	Will payment be prorated? <input type="checkbox"/> Yes <input type="checkbox"/> No If No, explain:	
F.	When will subject be paid? <input type="checkbox"/> Each visit <input type="checkbox"/> Study completion <input type="checkbox"/> Other:	Attach an additional sheet if needed.
8. INFORMED CONSENT		
<i>An IRB may approve a consent document that does not include, or alters, some or all of the elements of informed consent. Provide justifications for the following questions for requesting a waiver of written informed consent.</i>		
A.	Are you requesting Waiver or Alteration of Informed Consent? <input type="checkbox"/> No <input type="checkbox"/> Yes If no, skip to F?	
B.	Why will a waiver of informed consent not adversely affect the rights and welfare of subjects?	



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C.	Why is it impracticable to carry out the research without a waiver or alteration of informed consent?	
D.	How will pertinent information be provided to the subjects?	
E.	Why does the proposed research present no more than minimal risk to the subjects?	
F.	Who will explain the study to the potential subject?	
G.	Is this person an Investigator or Sub-investigator? <input type="checkbox"/> No <input type="checkbox"/> Yes If no, include the Delegation of Authority Form	
H.	Describe your process to obtain informed consent or attach your Standard Operating Procedures. (Please include the person who will provide consent or permission, and any waiting period between information and the prospective subjects and obtaining consent, steps taken to minimize the possibility of coercion or undue influence, the information to be communicated to the prospective subject or the legally authorized representative):	Or submit on separate page
I.	Is the language in the submitted ICF that addresses compensation for research-related injury language consistent with the language in the Sponsor contract? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If no, please explain:	
9. PRIVACY INFORMATION		
“Privacy Interests” – refers to the interest of individuals in being left alone, limiting access to themselves and limiting access to their information.		
A.	Will personal information collected from subjects be limited to only that which is necessary for the study purpose? If No, please provide an explanation:	<input type="checkbox"/> No <input type="checkbox"/> Yes
B.	Will subjects’ personal information be collected in a private setting/location? Yes, please describe the setting or location: No, please provide and explanation:	<input type="checkbox"/> No <input type="checkbox"/> Yes
C.	Will the study-related assessments and procedures be conducted in a private setting/location? Yes, please describe the setting or location: No, please provide and explanation:	<input type="checkbox"/> No <input type="checkbox"/> Yes



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<p>D. Is there any additional provision at your site to protect the privacy of subjects? <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Yes, please describe:</p>	<input type="checkbox"/> No <input type="checkbox"/> Yes	
<p>10. CONFIDENTIALITY OF SUBJECT INFORMATION</p>		
<p>Medical records and research records are different. They are handled differently and are subject to different protection. (this question relates to research data)</p>		
<p>A. Please indicate the provisions to maintain subject confidentiality: (check all that apply)</p>		
<input type="checkbox"/>	<p>Paper based records will be kept in a secure location and only accessible to personnel involved with the study.</p>	
<input type="checkbox"/>	<p>Computer based files will be password protected and only be made available to personnel involved with the study.</p>	
<input type="checkbox"/>	<p>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>	
<input type="checkbox"/>	<p>When feasible, identifiers will be removed from study related information.</p>	
<input type="checkbox"/>	<p>Other, please provide and explanation:</p>	
<p>B. Will personnel not directly related to the research have access to study records or data? <input type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, check all that apply)</p> <p><input type="checkbox"/> Billing Office <input type="checkbox"/> Medical Records <input type="checkbox"/> Hospital Personal <input type="checkbox"/> Other:</p>		
<p>11. SAFETY MONITORING INFORMATION</p>		
<p>Is there a Data Safety Monitoring Board (DSMB) for this study? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, You agree to submit summary reports to Alpha IRB when available <input type="checkbox"/> Yes If No, describe the provisions to monitor data to ensure the safety to subjects:</p>		<p>Or submit on separate page</p>



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As Principal Investigator I recognize my responsibility for the conduct of this study, including the conduct of my sub-investigator and staff and agree to all of the following:

- 1) I have read, understand and will follow the approved protocol in accordance with ICH Guidelines for Good Clinical Practice, the applicable Federal regulations, state laws, local regulations governing clinical research and any additional IRB requirements, including the policies set forth in the current Alpha IRB Investigator Guidebook (available online at www.alphairb.com).
- 2) I will not initiate this research study until I have received approval documentation from Alpha IRB.
- 3) I will obtain written approval to modify the study protocol or informed consent before implementing any changes to the protocol or informed consent except when an immediate change is necessary to eliminate an apparent and immediate hazard to human subjects and I agree to report to the IRB within 5 working days any change to research that is necessary for subject safety that was implemented without IRB approval.
- 4) I or my designee will obtain an IRB approved informed consent for each potential subject (or legally authorized representative, guardian, individual authorized to provide surrogate consent, as applicable) *unless waived by the IRB* allowing adequate time in a private environment to read and review and consider their participation in this study. Prospective subjects will have the informed consent explained orally and be given the opportunity to ask questions and have them answered and to be able to take the consent document home to consider with family / friends / personal physician.
- 5) I or my designee will carefully explain the treatment and compensation of research related injuries.
- 6) I attest that my contracts with the sponsor obligates the sponsor to promptly report to Alpha Independent Review Board, Inc. any findings of study monitors that could affect the safety of participants, affect the willingness of participants to continue participation, influence the conduct of the study, or alter the IRB's approval to continue the study.
- 7) I will notify the IRB within 5 working days from the date of discovery any deviation from the protocol affecting safety or validity, every serious adverse event; unexpected and related adverse event or problem, breaches of confidentiality, complaints from subjects when the complaints indicate unexpected risks or cannot be resolved by the research team, information that indicated a change to the risks or potential benefits of the research, findings or allegations of non-compliance, changes in FDA labeling or withdrawal from the marketing of a drug, device or biologic used in a research protocol, incarceration of a subject in a protocol overseen by Alpha IRB, events that requires reporting to sponsor, sponsor-imposed suspensions for risk, FDA 483's, warning letters and or other audit correspondence and my written response to the finding and corrective action (if applicable), any other audit report by a regulator agency and/or sponsor or IRB and any problem that I consider to be unanticipated and indicates that subjects or others are at increased risk of harm.
- 8) I attest that my contract with the sponsor obligates the sponsor to communication of results from a research study to participants when those results directly affected their safety or medical care
- 9) I will obtain IRB approval of all recruitment materials prior to their use.
- 10) I will submit Research Continuing Review Forms and Site Continuing Review Forms by their due date and will respond to all requests from Alpha IRB in a timely manner.
- 11) I agree to notify Alpha IRB in writing when the study has closed.
- 12) I agree to allow Alpha IRB to check the validity of my license and the information on my resume and to perform site visits. This form will not be considered confidential and it may be viewed by regulatory bodies, accrediting bodies and others with a legal right.



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13) I will protect the rights, safety and welfare of each participant to the best of my ability and will put their personal rights and welfare first.

I certify that the information provided in the application is true and correct. My signature below indicates that I will comply with my responsibilities as Principal Investigator, as outlined above for the protection of human subjects.

Printed Name Principal Investigator: _____

Signature Principal Investigator: _____ Date: _____

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

- 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 IRBs that have been or will be asked to review the study