



930 Calle Negocio, Suite B. 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: <input type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/> Other:	
C. Is this an Investigational Device study? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please provide the following: <ul style="list-style-type: none"> • 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. 	
2. INVESTIGATOR & CONTACT INFORMATION	
A. Principal Investigator (PI):	
Site Name:	Phone:
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? <input type="checkbox"/> No <input type="checkbox"/> Yes (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? <input type="checkbox"/> No <input type="checkbox"/> Yes (IRB will contact either the sponsor or PI for additional information.)	
C. Has this study ever been submitted to another IRB for review? <input type="checkbox"/> No <input type="checkbox"/> Yes	
D. Describe any formal GCP (Good Clinical Practice) training you and/or your staff have completed?	(Examples: Investigators Meetings, Conferences, etc.)



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B. Into what language(s) will the consent form need to be translated:				
<input type="checkbox"/> Spanish	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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:				
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 who can consent on behalf of the child to general medical care under state or local law.				
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.				
I. What is the diversity of your research population?				
Ethnicity:	Gender:	Age:		
African American %	Male %	0 – 18% %		
Asian %	Female %	8 – 64 %		
Caucasian %		64 - > %		
Hispanic %				
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? If yes, describe attitudes and how they may affect subjects.		<input type="checkbox"/> No <input type="checkbox"/> Yes		
L. Are the PI's facilities equipped to handle emergencies? <input type="checkbox"/> No <input type="checkbox"/> Yes Name the nearest emergency facility: Distance to facility: Miles				



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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"/> Letters to patients		
<input type="checkbox"/> Newspaper	<input type="checkbox"/> Bulletin board/flyer	<input type="checkbox"/> Letters to providers		
<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? If yes , submit the script and identify calling company.			<input type="checkbox"/> No <input type="checkbox"/> Yes	
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): \$		Payment includes all types of reimbursement, such as fares, parking fees, etc.
B. Form of Payment:				
<input type="checkbox"/> Reimbursement only	<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:			
Will subject be required to submit proof of expenses? <input type="checkbox"/> No <input type="checkbox"/> Yes	Will a 1099 be issued? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes , describe procedures to protect confidentiality:			
C. Will payment be prorated?		<input type="checkbox"/> Yes <input type="checkbox"/> No If no , explain:		
D. 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? If no , skip to F?			<input type="checkbox"/> No <input type="checkbox"/> Yes	
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? If No, include the Delegation of Authority Form	<input type="checkbox"/> No <input type="checkbox"/> Yes
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):	
I.	Attach your informed consent document(s) for IRB review only if you will not be using the approved AlphaIRB informed consent template.	
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
D.	Is there any additional provision at your site to protect the privacy of subjects? Yes, please describe:	<input type="checkbox"/> No <input type="checkbox"/> Yes



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10.	CONFIDENTIALITY OF SUBJECT INFORMATION		
	Medical records and research records are different. They are handled differently and are subject to different protection. (this question relates to research data)		
A.	Please indicate the provisions to maintain subject confidentiality: (check all that apply)		
	<input type="checkbox"/>	Paper based records will be kept in a secure location and only accessible to personnel involved with the study.	
	<input type="checkbox"/>	Computer based files will be password protected and only be made available to personnel involved with the study.	
	<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.	
	<input type="checkbox"/>	When feasible, identifiers will be removed from study related information.	
	<input type="checkbox"/>	Other, please provide and explanation:	
B.	Will personnel not directly related to the research have access to study records or data (billing office, medical records, hospital personnel, etc?)	<input type="checkbox"/> No <input type="checkbox"/> Yes	

I certify that the information contained above is accurate. I agree to provide Alpha IRB with the information it requires to conduct initial and continuing review of this study including serious or unexpected adverse events on a timely basis and to follow all Federal and State laws and regulations that govern medical research. If the information is not provided, Alpha IRB may suspend the study.

Printed Name Principal Investigator: _____

Signature Principal Investigator: _____ **Date:** _____

STUDY CHECKLIST
Please include the following in your submission package:



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- Protocol
- Investigator's Drug Brochure (IND Studies)
- Study Material(s): Ad(s) Diary Questionnaire(s) Other: _____
- Sample Informed Consent(s) (in Word Format) : Master ICF Genetic HIPAA Assent
- Other: