



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

[www.alphairb.com](http://www.alphairb.com)

**SITE SUBMISSION FORM (MULTI-CENTER)**

<b>1.</b>	<b>Sponsor:</b> <b>Study Title:</b>	<b>Protocol No.:</b>	<b>Important: Please Note</b>
<b>2. INVESTIGATOR &amp; CONTACT INFORMATION</b>			
<b>Principal Investigator (PI):</b>			
<b>Site Name:</b>		<b>Phone:</b>	Attach PI's CV, License and 1572 (if applicable)
<b>Mailing Address:</b>		<b>Fax:</b>	
		<b>24 Hour Phone:</b>	
		<b>E-mail:</b>	
<b>A.</b>	<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?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes (IRB will contact either the sponsor or PI for additional information.) <b>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?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes (IRB will contact either the sponsor or PI for additional information.)		
<b>B.</b>	<b>Has this study ever been submitted to another IRB for review?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes		
<b>C.</b>	<b>Describe any formal GCP (Good Clinical Practice) training you and/or your staff have completed?</b>		(Examples: Investigators Meetings, Conferences, etc.)
<b>D.</b>	<b>Do any of the below apply to the PI involved with this study?</b> Been audited by the FDA? <input type="checkbox"/> No <input type="checkbox"/> Yes Been sanctioned by any State/IRB? <input type="checkbox"/> No <input type="checkbox"/> Yes 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:		Attached documentation for all yes answers. (example: Form 483 & site response)
<b>E.</b>	<b>How long has PI been conducting research?      Years</b>		
<b>F.</b>	<b>How many studies is the PI currently involved in as a PI?</b>		
<b>G.</b>	<b>Number of clinical research staff available to work on this project:</b>		
<b>3. LOCATION OF RESEARCH</b>			



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

[www.alphaairb.com](http://www.alphaairb.com)

**SITE SUBMISSION FORM (MULTI-CENTER)**

A.	<b>Will the PI be conducting study related activity at other locations</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <b>If yes</b> , complete an <b>Additional Study Location Form</b> for each location.	Include all locations for study related activities
B.	<b>Who will be the main contact for this study?</b> <b>Name:</b> _____ <b>Phone:</b> _____ <b>Position/Title:</b> _____ <b>Email:</b> _____	Correspondance and document handling.
<b>4. SUBJECT INFORMATION</b>		
A.	<b>Will subjects who do not understand English be enrolled?</b> <b>If yes:</b> Describe your resources to communicate with these subjects:	<input type="checkbox"/> No <input type="checkbox"/> Yes Attach an additional sheet if needed.
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.	<b>Potentially Vulnerable Populations (select all that apply)</b> <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.	<b>Describe additional protections for potentially vulnerable subjects:</b>	
E.	<b>If you are recruiting children in this study, indicate the age range:</b>	Attach copy of Assent.
F.	<b>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?</b>	
G.	<b>Will children or minors without parent be enrolled?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <b>If yes</b> , 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.	<b>Will subjects with legally authorized representatives (LARs) be enrolled?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <b>If yes</b> , provide justification in terms of state law or a decision by legal counsel of who constitutes a LAR in your state.	



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

[www.alphaairb.com](http://www.alphaairb.com)

**SITE SUBMISSION FORM (MULTI-CENTER)**

<b>I. What is the diversity of your research population?</b>			
<b>Ethnicity:</b>	<b>Gender:</b>	<b>Age:</b>	
African American %	Male %	0 – 18% %	
Asian %	Female %	18 – 64 %	
Caucasian %		64 - > %	
Hispanic %			
Other %			
<b>J. Are there any state or local laws that you are aware of that might impact or influence the conduct of the study?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>K. Are there community attitudes that may affect subjects in this study? If yes, describe attitudes and how they may affect subjects.</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No		Describe on separate page
<b>L. Are the PI's facilities equipped to handle emergencies?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No			
<b>Name the nearest emergency facility:</b>		<b>Distance to facility:</b>	<b>Miles</b>
<b>5. DIRECT SUBJECT ADVERTISING</b>			
<b>A. Media for subject recruitment includes: (select all that apply)</b>			
<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>B. Will a centrally coordinated advertisement program be used?</b>		<input type="checkbox"/> No <input type="checkbox"/> Yes	
<b>C. Will a central 800# facility be used for recruitment? If yes, submit the script and identify calling company.</b>		<input type="checkbox"/> No <input type="checkbox"/> Yes	
<b>6. PAYMENT TO SUBJECTS</b>			
<b>A. Are subjects being paid for participation?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes		<b>If yes, indicate total amount, (dollars or equivalent): \$</b>	Payment includes all types of reimbursement, such as fares, parking fees, etc.
<b>B. Form of Payment:</b>			
<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:		
<b>Will subject be required to submit proof of expenses?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes		<b>Will a 1099 be issued?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes	
		<b>If yes, describe procedures to protect confidentiality:</b>	



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)

**SITE SUBMISSION FORM (MULTI-CENTER)**

C.	<b>Will payment be prorated?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No If no, explain:			
D.	<b>When will subject be paid?</b>	<input type="checkbox"/> Each visit	<input type="checkbox"/> Study completion	<input type="checkbox"/> Other:	Attach an additional sheet if needed.

**7. INFORMED CONSENT**

*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.*

A.	<b>Are you requesting Waiver or Alteration of Informed Consent? If no, skip to F?</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes	
B.	<b>Why will a waiver of informed consent not adversely affect the rights and welfare of subjects?</b>		
C.	<b>Why is it impracticable to carry out the research without a waiver or alteration of informed consent?</b>		
D.	<b>How will pertinent information be provided to the subjects?</b>		
E.	<b>Why does the proposed research present no more than minimal risk to the subjects?</b>		
F.	<b>Who will explain the study to the potential subject?</b>		
G.	<b>Is this person an Investigator or Sub-investigator? If No, include the Delegation of Authority Form</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes	
H.	<b>Describe your process to obtain informed consent or attach your Standard Operating Procedures.</b> (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.	<b>Attach your informed consent document(s) for IRB review only if you will not be using the approved AlphaIRB informed consent template.</b>		

**8. PRIVACY INFORMATION**

**“Privacy Interests” – refers to the interest of individuals in being left alone, limiting access to themselves and limiting access to their information.**



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

[www.alphaairb.com](http://www.alphaairb.com)

**SITE SUBMISSION FORM (MULTI-CENTER)**

A.	<b>Will personal information collected from subjects be limited to only that which is necessary for the study purpose?</b> If No, please provide an explanation:	<input type="checkbox"/> No <input type="checkbox"/> Yes	
B.	<b>Will subjects' personal information be collected in a private setting/location?</b> Yes, please describe the setting or location: No, please provide and explanation:	<input type="checkbox"/> No <input type="checkbox"/> Yes	
C.	<b>Will the study-related assessments and procedures be conducted in a private setting/location?</b> Yes, please describe the setting or location: No, please provide and explanation:	<input type="checkbox"/> No <input type="checkbox"/> Yes	
D.	<b>Is there any additional provision at your site to protect the privacy of subjects?</b> Yes, please describe:	<input type="checkbox"/> No <input type="checkbox"/> Yes	
<b>9. CONFIDENTIALITY OF SUBJECT INFORMATION</b>			
<b>Medical records and research records are different. They are handled differently and are subject to different protection.</b> (this question relates to research data)			
A.	<b>Please indicate the provisions to maintain subject confidentiality:</b> (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	



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

[www.alphairb.com](http://www.alphairb.com)

**SITE SUBMISSION FORM (MULTI-CENTER)**

*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:** \_\_\_\_\_