



930 Calle Negocio, Suite B. San Clemente, CA 92673
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SITE SUBMISSION FORM (SHORT – PHASE IV)

	Sponsor: Study Title:	Protocol No.:	Important: Please Not	
1.	INVESTIGATOR & CONTACT INFORMATION			
	Principal Investigator (PI):			
	Site Name:	Phone:	Attach CV, License – PI Only	
	Mailing Address:	Fax:		
		24 Hour Phone:		
		E-mail:		
A.	Do any of the below apply to the PI involved with this study? 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 documenta- tion for all yes answers. (example forr 483 & site response)	
2.	LOCATION OF RESEARCH			
A.	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	
B.	Who will be the main contact for this study? Name: Phone: Position/Title: Email:		Correspond- ance and document handling.	
3.	SUBJECT INFORMATION			
A.	Will subjects who do not understand English be enrolled? If yes: Describe your resources to communicate with these subjects:	<input type="checkbox"/> No <input type="checkbox"/> Yes	Attach an additional sheet if needed.	
	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"/>



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B. Potentially Vulnerable Populations (select all that apply)			Describe additional protections for these populations on separate page.
<input type="checkbox"/> Children	<input type="checkbox"/> Nursing home residents	<input type="checkbox"/> Mentally impaired	
<input type="checkbox"/> Fetuses / fetal material	<input type="checkbox"/> Economically disadvantaged	<input type="checkbox"/> Students	
<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:	
C.	Describe additional protections for potentially vulnerable subjects:		
D.	If you are recruiting children in this study, indicate the age range:		Attach copy of Assent.
4. INFORMED CONSENT			
A.	Describe your process to obtain informed consent or attach your Standard Operating Procedures.		
B.	Attach your informed consent document(s) for IRB review only if you will not be using the approved AlphaIRB informed consent template.		

I certify that the information contained above is accurate. I agree to provide the 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, the IRB may suspend the study.

Printed Name Principal Investigator: _____

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