

PROTOCOL DEVIATION REPORT FORM

Alpha IRB requires the reporting of all **Significant Protocol Deviations**. Significant protocol deviations are deviations that, in the opinion of the Investigator, adversely affect the safety, rights or welfare of subjects or others, or the integrity of the study data.

Significant Protocol Deviations need to be reported to Alpha IRB promptly, but no later than ten (10) business days from the date the site became aware of the event. *Non-Significant Protocol Deviations do not need to be reported.*

Also use this form for submission of any **Planned Protocol Deviations**. A planned deviation is a deviation from the protocol that is prospective and intentional. A planned deviation typically involves an individual subject, or may involve a small group of subjects, and is not a permanent revision to the protocol. In general, all planned protocol deviations must be submitted to the IRB for review and approval prior to implementation; except where necessary to eliminate apparent immediate hazards to the human subjects.

Planned protocol deviation submissions should be submitted as far in advance as possible and must be accompanied by written documentation of Sponsor approval.

1.	SPONSOR NAME:		PROTOCOL NUMBER:	
2.	INVESTIGATOR:		PHONE NUMBER:	
3.	SITE NAME:			
4.	SUBJECT ID:		DATE OF DEVIATION:	
5.	DATE SITE BECAME AWARE OF DEVIATION:		DATE OF REPORT:	
6.	THE DEVIATION WAS/IS:	<input type="checkbox"/> Unplanned (already occurred) <input type="checkbox"/> Planned (requires prior IRB approval)		
7.	DEVIATION WAS DISCOVERED BY:	<input type="checkbox"/> Investigator <input type="checkbox"/> Coordinator <input type="checkbox"/> Monitor <input type="checkbox"/> Other:		
Please indicate the nature of the protocol deviation by checking the appropriate box(es) below and provide an explanation in the area provided. Attach additional pages and supporting documentation as necessary.				
8.	CONSENT PROCESS DEVIATION:			
A.	<input type="checkbox"/>	Informed consent was not obtained prior to initiation of study procedures		
B.	<input type="checkbox"/>	Subject was consented after screening procedures		
C.	<input type="checkbox"/>	Wrong consent form version used		
D.	<input type="checkbox"/>	Unapproved consent form used		
E.	<input type="checkbox"/>	English consent form used for Non-English speaking subject		
F.	<input type="checkbox"/>	Other:		
9.	PROTOCOL / PROCEDURE DEVIATION:			
A.	<input type="checkbox"/>	Inclusion / exclusion criteria deviation		
B.	<input type="checkbox"/>	Randomization error		
C.	<input type="checkbox"/>	Medication dispensing / dosing error		
D.	<input type="checkbox"/>	Laboratory test error		
I.		Has the laboratory test been rescheduled or will it be scheduled to be redone? <input type="checkbox"/> Yes <input type="checkbox"/> No		
E.	<input type="checkbox"/>	Omission / delay of study procedure		
I.		Has the procedure been rescheduled or will it be scheduled to be redone? <input type="checkbox"/> Yes <input type="checkbox"/> No		
F.	<input type="checkbox"/>	Research conducted during a lapse in IRB approval		
G.	<input type="checkbox"/>	Other:		

10.	Provide a <u>detailed</u> description of the deviation and the reason(s) it occurred (or will occur) (for deviations relating to informed consent, please include the ICF version number and date(s) of consent / re-consent, as appropriate):	
11.	Describe the corrective actions taken, including measures taken to ensure that similar deviations do not occur in the future (for unplanned PDs only):	
12.	Is the deviation being submitted within <u>ten (10) business days</u> from the date the site became aware of the event? <input type="checkbox"/> Yes <input type="checkbox"/> No - If no, please provide an explanation for the delay in reporting: If no, please describe a plan to prevent future delays in reporting:	
13.	Has the Sponsor been notified of the deviation?	<input type="checkbox"/> No <input type="checkbox"/> Yes - indicate date:
14.	If the deviation is planned, has the Sponsor provided prior approval / exemption?	<input type="checkbox"/> No <input type="checkbox"/> Yes - <u>attach documentation</u> <input type="checkbox"/> N/A
15.	Does this deviation adversely affect the safety, rights or welfare of subjects?	<input type="checkbox"/> No <input type="checkbox"/> Yes
A.	Please provide your rationale for why the deviation did or did not adversely affect the safety, rights or welfare of subjects:	
16.	Does this deviation adversely affect the integrity of the study data?	<input type="checkbox"/> No <input type="checkbox"/> Yes
A.	Please provide your rationale for why the deviation did or did not adversely affect the integrity of the study data:	
Principal Investigator Signature:		Date:
Principal Investigator Printed Name:		

Please email, fax or mail all required documents to:

Email: safety@alphairb.com

Fax: 949-940-0134 or

Mail: Alpha IRB, 1001 Avenida Pico, Suite C #497, San Clemente, CA 92673 - Attn: Safety