

PROTOCOL DEVIATION REPORT FORM

Alpha IRB requires the reporting of all Significant Protocol Deviations / Violations 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 / Violations 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.

SPONSOR NAME:		PROTOCOL NUMBER:	
INVESTIGATOR:		PHONE NUMBER:	
SITE NAME:			

SUBJECT ID / INITIALS:		DATE OF DEVIATION:	
DATE SITE BECAME AWARE OF DEVIATION:		DATE OF REPORT:	

Please indicate the nature of the protocol deviation / violation that occurred by checking the appropriate box(es) below and provide an explanation in the area provided. Attach additional pages if necessary.

CONSENT PROCESS VIOLATION:

<input type="checkbox"/>	Subject was consented after screening procedures
<input type="checkbox"/>	Wrong consent form version used
<input type="checkbox"/>	Unapproved consent form used
<input type="checkbox"/>	English consent form used for Non-English speaking subject
<input type="checkbox"/>	Other:

PROTOCOL / PROCEDURE DEVIATION / VIOLATION:

<input type="checkbox"/>	Inclusion / exclusion criteria
<input type="checkbox"/>	Randomization error
<input type="checkbox"/>	Medication dispensing error
<input type="checkbox"/>	Laboratory test error
	Has the laboratory test been rescheduled or will it be scheduled to be redone? <input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/>	Omission / delay of study procedure
	Has the procedure been rescheduled or will it be scheduled to be redone? <input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/>	Research conducted during a lapse in IRB approval
<input type="checkbox"/>	Other:

Provide a description of the deviation / violation:

Describe the corrective actions taken, including measures taken to ensure that similar deviations / violations do not occur in the future:



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

www.alphaairb.com

Has the Sponsor been notified of the deviation / violation?		<input type="checkbox"/> No <input type="checkbox"/> Yes - indicate date:
Has the Sponsor provided an exemption for this deviation / violation?		<input type="checkbox"/> No <input type="checkbox"/> Yes - attach documentation (if applicable)
Does this deviation / violation adversely affect the safety, rights or welfare of subjects or others?		<input type="checkbox"/> No <input type="checkbox"/> Yes
Does this deviation / violation adversely affect the integrity of the study data?		<input type="checkbox"/> No <input type="checkbox"/> Yes
Principal Investigator Signature:		Date:
Principal Investigator Printed Name:		