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

www.alphairb.com

SERIOUS ADVERSE EVENT / UNANTICIPATED PROBLEMS REPORT FORM

Alpha IRB requires the reporting of any events determined by the Investigator and/or Sponsor to be unanticipated problems involving risk to participants or others. Alpha defines this as any problem, event, or new information that that meets all of the following criteria:

1) The event is **unexpected** (in terms of nature, severity, or frequency) given:
   a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent documents; and
   b) the characteristics of the subject population being studied
2) The event is **related or possibly related** to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research)
3) The event suggests that the research places participants or others at a **greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

Events that meet the above 3 criteria 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. Events that do not meet all 3 criteria do not need to be reported.

	STUDY TYPE:	☒ DRUG ☐ DEVICE ☐ BIOLOGIC ☐ OTHER:		
	SPONSOR NAME:		PROTOCOL NUMBER:	
	INVESTIGATOR:		PHONE NUMBER:	
	SITE NAME:			
	SUBJECT ID:		SUBJECT INITIALS:	
	SUBJECT GENDER:	☐ FEMALE ☐ MALE	DATE OF BIRTH:	
	DATE OF EVENT:		DATE OF REPORT:	
	DATE SITE BECAME AWARE OF EVENT:			
	REPORT TYPE:	☐ INITIAL ☐ FOLLOW-UP # _____ ☐ FINAL ☐ OTHER:		

Does the event meet the definition of an **UNANTICIPATED PROBLEM INVOLVING RISK TO PARTICIPANTS OR OTHERS?** Confirm that all the following apply:

☐	The event is **unexpected**
☐	The event is **related or possibly related** to participation in the research
☐	Participants or others are at a **greater risk of harm** than was previously known or recognized

Please indicate the type of event / problem by checking the appropriate box below. Attach additional pages if necessary.

☐	Serious adverse event that is both unexpected and related to the research
☐	Serious problem that resulted in substantive harm or damage (or risk of substantive harm or damage) to the safety, rights, or welfare of research subjects, research staff, or others
☐	Information that indicates a change to the risks or potential benefits of the research
☐	Breach of confidentiality
☐	Incarceration of a participant

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☐	Complaint from a participant
☐	Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant
☐	Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol
☐	Sponsor-imposed suspension for risk
☐	Event that requires prompt reporting to the sponsor
☐	Other:

Provide a detailed description of the event / problem:

Describe the corrective actions taken to resolve the event / problem:

Are additional actions necessary to avoid similar instances in the future? ☐ No ☐ Yes - If yes, please describe:

Is this report being submitted within ten (10) business days from the date the site became aware of the event?
☐ Yes ☐ No - If no, please provide an explanation for the delay in reporting:

Please provide a determination as to the relatedness of the event / problem to the research study (check only one):

☐	Definitely related
☐	Probably related
☐	Possibly related
☐	Not related (does not require reporting to Alpha IRB)

Was the subject removed from the study due to this event?	☐ No ☐ Yes - indicate date:
Has the Sponsor been notified of the event?	☐ No ☐ Yes - indicate date:
Does this event adversely affect the integrity of the study data?	☐ No ☐ Yes
Do you or the Sponsor recommend changes to the IRB approved informed consent form(s) or study protocol due to this event?	☐ No ☐ Yes (if yes, attach changes)

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