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

www.alphairb.com

IND SAFETY REPORT FORM

Use this form when submitting IND Safety Reports, or other external adverse events (MedWatch, SUSAR, CIOMS)

- **Please complete this form and attach the associated safety report and any other relevant documentation.**
- **Please use a separate form for each event being submitted (initial and follow-up report information from the same event can be combined onto one form).**

Alpha IRB requires the reporting of external adverse events that have been determined by the Investigator and/or Sponsor to be an *unanticipated problem involving risk to participants or others*. Alpha defines this as any problem, event, or new information 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
   b)and 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 must be reported to Alpha IRB promptly, but no later than ten (10) business days from the date the site became aware of the event.

*Alpha IRB recognizes that for multi-center trials the Sponsor is in a better position to analyze the significance of adverse event information for the entire study to make a determination about whether the event is an unanticipated problem and whether changes to the study are necessary. Therefore, you may rely on the Sponsor to make this assessment by providing Alpha IRB a copy of this form completed and prepared by the Sponsor.

Please be advised, the majority of IND Safety Reports are unlikely to meet Alpha IRB reporting requirements. Use the following criteria to determine if the event meets the definition of an unanticipated problem involving risk to participants or others, and therefore must be reported to Alpha IRB:

☐ YES ☐ NO	The event is **unexpected**
☐ YES ☐ NO	The event is **related or possibly related** to participation in the research
☐ YES ☐ NO	Participants or others are at a **greater risk of harm** than was previously known or recognized

IF NO IS INDICATED FOR ANY OF THE ABOVE, THE EVENT DOES NOT REQUIRE REPORTING TO ALPHA IRB.

Sponsor:		**Protocol No.:**	
Principal Investigator:		**Contact Person:**	
Phone:		**Email:**	
Mfr# / Report Identifier:		**Subject ID:**	
Date of Report:		**Date of Event:**	
Report Type:	☐ Initial ☐ Follow-up # _____ ☐ Final ☐ Other:		

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Brief description of the Adverse Event(s):

How does this event suggest that subjects or others in this study are at a "greater risk of harm than was previously known or recognized?"

What changes specific to this study are being proposed as a result of this event?

☐ Revised Consent Form(s) ☐ Protocol Amendment ☐ Updated Investigator Brochure ☐ Other:

Please attach any revisions to the study related documents indicated above.

Should the changes be forthcoming, please provide Alpha IRB with a timeline for the submission:

If no changes are being implemented, please provide rationale:

Is this report being submitted to Alpha IRB 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:**

Principal Investigator Printed Name:	
Principal Investigator Signature:	Date:

***If this form was completed by the Sponsor / CRO, please also complete the following:**

Name of Sponsor / CRO contact completing this form:	
Company / Title:	
Signature:	Date:

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