

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 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.

	STUDY TYPE:	<input type="checkbox"/> DRUG <input type="checkbox"/> DEVICE <input type="checkbox"/> BIOLOGIC <input type="checkbox"/> OTHER:		
	SPONSOR NAME:		PROTOCOL NUMBER:	
	INVESTIGATOR:		PHONE NUMBER:	
	SITE NAME:			
	SUBJECT ID:		SUBJECT INITIALS:	
	SUBJECT GENDER:	<input type="checkbox"/> FEMALE <input type="checkbox"/> MALE	DATE OF BIRTH:	
	DATE OF EVENT:		DATE OF REPORT:	
	DATE SITE BECAME AWARE OF EVENT:			
	REPORT TYPE:	<input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOW-UP # _____ <input type="checkbox"/> FINAL <input type="checkbox"/> OTHER:		

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

<input type="checkbox"/>	The event is unexpected
<input type="checkbox"/>	The event is related or possibly related to participation in the research
<input type="checkbox"/>	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.

<input type="checkbox"/>	Serious adverse event that is both unexpected and related to the research
<input type="checkbox"/>	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
<input type="checkbox"/>	Information that indicates a change to the risks or potential benefits of the research

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<input type="checkbox"/>	Breach of confidentiality
<input type="checkbox"/>	Incarceration of a participant
<input type="checkbox"/>	Complaint from a participant
<input type="checkbox"/>	Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant
<input type="checkbox"/>	Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol
<input type="checkbox"/>	Sponsor-imposed suspension for risk
<input type="checkbox"/>	Event that requires prompt reporting to the sponsor
<input type="checkbox"/>	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? <input type="checkbox"/> No <input type="checkbox"/> Yes - If yes, please describe:	
Please provide a determination as to the relatedness of the event / problem to the research study (check only one):	
<input type="checkbox"/>	Definitely related
<input type="checkbox"/>	Probably related
<input type="checkbox"/>	Possibly related
Was the subject removed from the study due to this event? <input type="checkbox"/> No <input type="checkbox"/> Yes - indicate date:	
Has the Sponsor been notified of the event? <input type="checkbox"/> No <input type="checkbox"/> Yes - indicate date:	
Does this event affect the integrity of the study data? <input type="checkbox"/> No <input type="checkbox"/> Yes	
Do you or the Sponsor recommend changes to the IRB approved informed consent form(s) or study protocol due to this event? <input type="checkbox"/> No <input type="checkbox"/> Yes (if yes, attach changes)	
Principal Investigator Signature:	
Date:	
Principal Investigator Printed Name:	