

## IRB Adverse Event Form

### Definitions

**Unanticipated Problem:** Any incident, experience, or outcome that is:


- *unexpected* (in terms of the nature, severity, or frequency) given (a) the description of the likely harms in the protocol, the consent form or the other materials submitted to the IRB and (b) the characteristics of the subject population;
- *related* to a subject's participation in the research; and
- suggests that the research places subjects or others at *greater risk of harm* - physical, psychological, economic or social harms - than was previously known or recognized.

**Adverse Event:** Any untoward or unfavorable medical occurrence in a human subjects; including any abnormal sign, symptom, or disease that is temporally related to the research, whether or not it is related to the subject's participation in the research. Adverse events encompass both physical and psychological harms.

### Event occurred on campus or off?

--none--

**Describe the Adverse Event (include where the event occurred, severity, duration, action taken, outcome, personnel involved and corrective action plan, if applicable).**



Empty text area for describing the adverse event.

**In the opinion of the Principal Investigator, did this event cause harm to the participant or others?**

Yes  No







**Was the event unanticipated?**













Yes  No




**Was the event related to the research?**

Yes  
 No  
 Maybe

**Please explain:**

  **  ~~~~  $x_2$   $x^2$  Font Family ▼ 12 ▼ 

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**Is this event listed in the protocol?**

Yes  No

**Is the event listed in the consent form?**

Yes  No

**Is a modification required in the protocol?**

Yes  No

**In the consent form?**

Yes  No

**If applicable, what plan has been implemented to ensure that this type of event will not occur again?**

**Select below if this does not apply.**

N/A

A rich text editor toolbar is displayed above a large, empty text input area. The toolbar includes icons for: link, bold (B), italic (I), underline (U), strikethrough (ABC), subscript (x<sub>2</sub>), superscript (x<sup>2</sup>), font family dropdown, font size dropdown (12), text color, bulleted list, numbered list, indent, outdent, link, unlink, insert image, insert table, undo, redo, and print.