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).

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

◯ Yes ◯ No

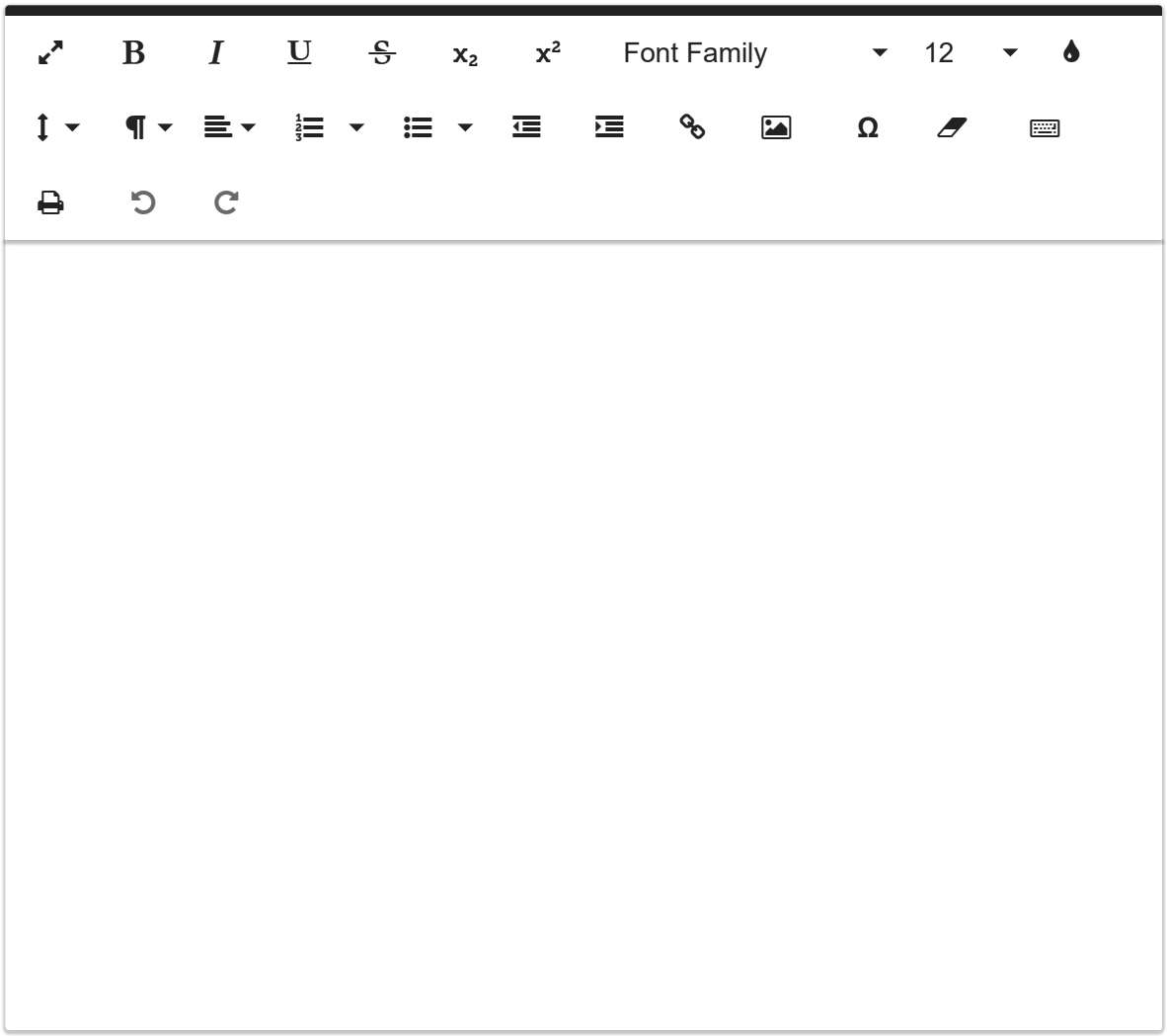
Was the event unanticipated?

◯ Yes ◯ No

Was the event related to the research?

◯ Yes
◯ No
◯ Maybe

Please explain:



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