Section 1.0

Instructions

Complete this form when data collection and the analysis of private identifiable data are complete.

Please answer each question completely – if a question is not applicable, please put N/A in the box.

Study Information

Study Title:

IRB Number:

Initial Approval (if applicable):

Principal Investigator:

Key Study Personnel (if applicable):

Department(s):

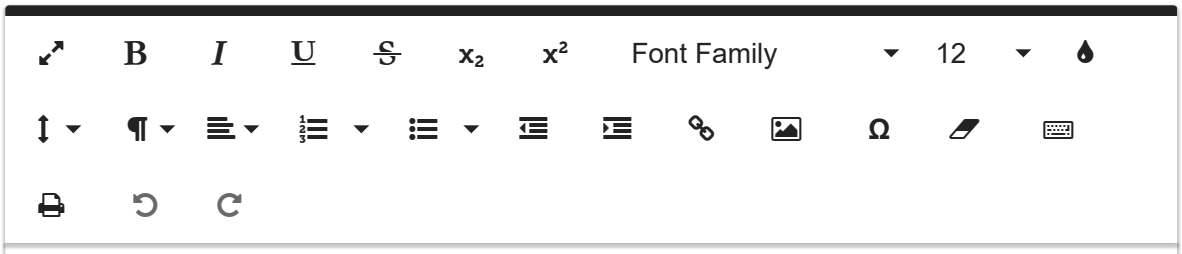
Lay Summary:

Status

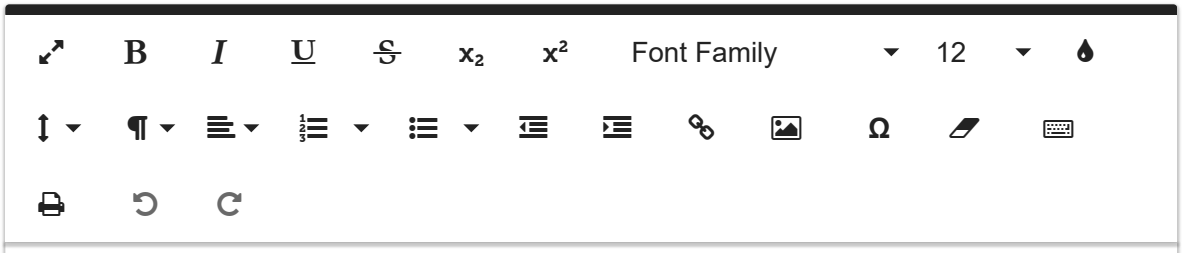
Please indicate the study status:

- ◯ Never Commenced
- ◯ Completed (must have concluded interventions/interventions with human subjects and data analysis are complete)
- ◯ Incomplete (no plans to complete the study)

Please state reasons why the study never commenced.



Explain why the study is ending prematurely.



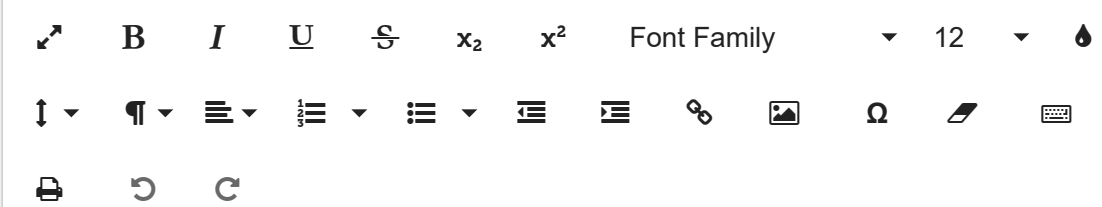
Section 2.0

Study Summary

Please submit a detailed study summary (3-4 paragraphs should suffice). The study summary must be substantive and complete, and include:

- Goals of the study
- Findings to-date
- Reason(s) why the study is closed

Please address each bullet point; incomplete responses will be sent back to you.



Subject Numbers

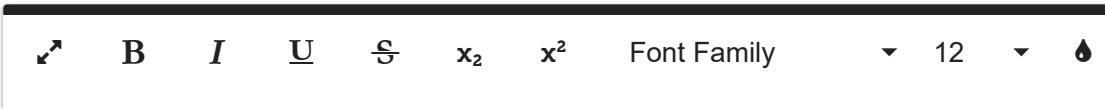
A. Total number of subjects who were recruited for the study:	
B. Number of subjects who were enrolled in the study:	
C: Of the total, how many were ineligible to participate in the study?	

Did any subjects withdraw from the study?

○ Yes ○ No

Total number of subjects who withdrew from the study:

Why did the subject withdraw from the study?



Adverse Events or Unanticipated Problems

Adverse events: any untoward or unfavorable medical occurence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory findings), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice). Adverse events encompass both physical and psychological harms.

Unanticipated problems: 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 document; and (b) the characteristics of the subject population being studied; related or possibly related to participation in the research (in this guidance document, 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); and suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Were there any adverse events or unanticipated problems encountered during the study?

○ Yes ○ No

Please explain in detail:

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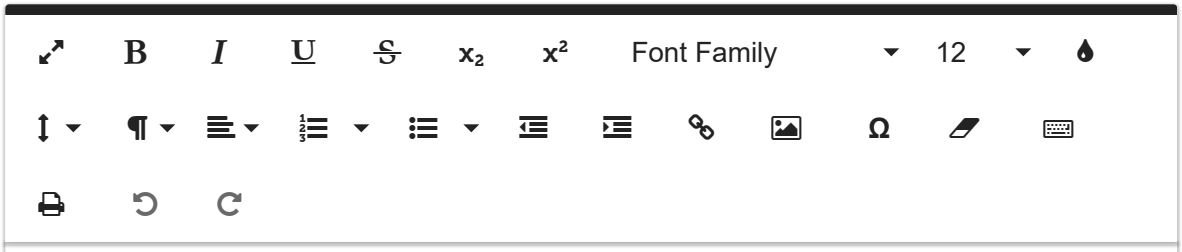
Was the IRB notified of the event or problem?

○ Yes ○ No

Please explain why this was not done:



Publications and Presentations

Have there been any presentations or publications resulting from this study?

◯ Yes ◯ No

Please submit a copy of the abstract or the complete publication.

Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document

No Document(s) have been attached to this form.