Section 1.0

Instructions

- Studies confirmed as meeting the criteria for exemption or approved by some protocols are not subject to continuing review. However, BYU remains responsible for exercising proper oversight for research conducted under its auspices. To exercise this oversight, the IRB office will annually send a status check to all PIs.
- BYU IRB retains the authority to require, with justification, continuing review of studies approved through expedited review.
- Please type your responses in the boxes provided. Use as much space as necessary (the boxes will expand). Please answer each question – if a question is not applicable, please put N/A in the box.
- Studies that are in the data analysis phase with a possibility to enroll additional human subjects must also complete this form.

Study Information

Study Title:

IRB Number:

Initial Approval:

Principal Investigator:

Key Study Personnel (if applicable):

Department(s):

Lay Summary:

Status

Active: active enrollment and study intervention; closing a study to accrual, but continuing active study intervention in enrolled subjects; or only following subjects who have completed the active study intervention. The analysis of private, identifiable information or plans to add and remove research personnel are reasons to keep the study active.

Inactive: study is closed to enrollment and there are no plans to collect additional information. Research activities are limited to the analysis of de-identified data only.

Please indicate the study status:

- ◯ Active
- ◯ Inactive

Please indicate remaining duration of the study:

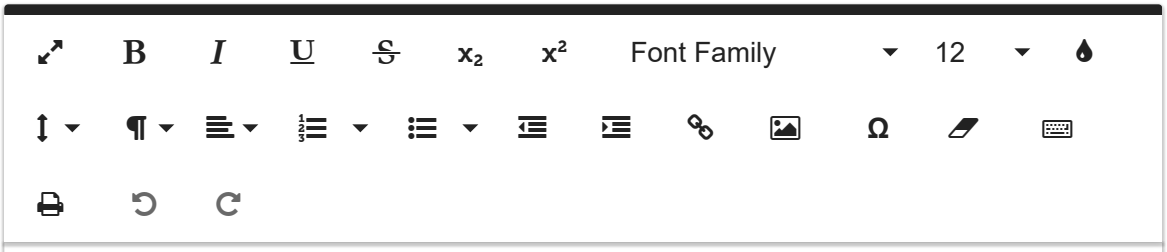
Section 2.0

Progress Report

Do any of the research activities occur at locations outside BYU?

◯ Yes ◯ No

Describe in detail the locations of the external sites and what activities will occur at locations outside BYU:



Does the study require IRB approval from any additional institutions?

○ Yes ○ No

Institution	Approval Date
No records have been added	

***Please note that copies of current IRB approvals from additional institutions are required at the end of this form.**

Check all categories that apply to your protocol:

- ☐ Human subjects intervention with use of informed consent form
- ☐ Discarded, identified pathological materials, no intervention
- ☐ Genetic analysis
- ☐ Interviews or questionnaires
- ☐ Medical records or other records from human subjects
- ☐ Other

Please specify:

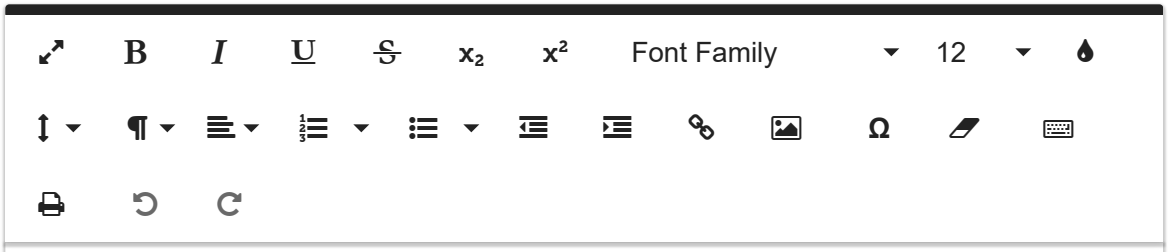
Is this study closed to enrollment of new subjects?

○ Yes ○ No

Please submit a detailed progress report. The progress report must be substantive and complete, and include:

- **Goals of the study**
- **Findings to-date**
- **Plans for the next year/review period**

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



Subject Numbers

A. Total number of subjects approved by the IRB for the study (see 8.3 of the approved application):	
B. How many subjects did you enroll in the study this last year?	

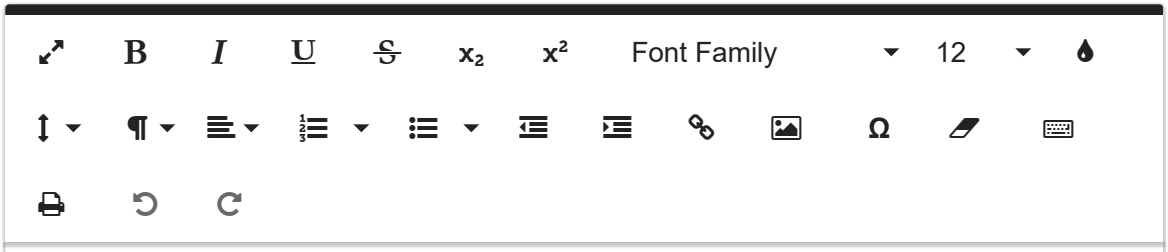
C. Total number of subjects enrolled during the lifecycle of the study (if this is the first year of the study, the number for B and C are the same):	
D. Of the total subjects screened in the past approval period, how many have been ineligible to participate in the study (if applicable)? If not applicable, type N/A.	
E. Number of subjects still to be enrolled (this number should be equal to A - C): **If this brings the sample to greater than the total number approved listed in A, submit a modification.**	

Have any subjects withdrawn from the study?

○ Yes ○ No

Total number of subjects who withdrew from the study:

Why did the subject withdraw from the study?



Modifications

The following is a list of modifications that have been submitted for this study:

Deviation: Any unapproved changes, deviations, or departures from the study design or procedures of a research project that are under the investigator's control and that have not been reviewed and approved by the IRB.

Have there been any deviations from the approved protocol?

○ Yes ○ No

Please describe the deviations:

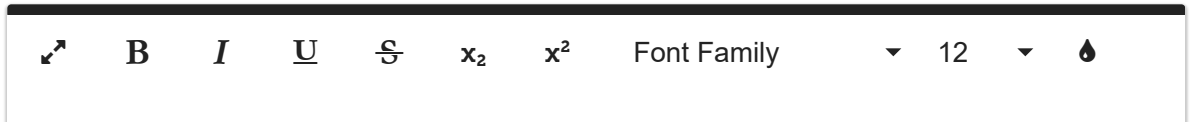
If there are any changes at this time (adding a new co-investigator, modifying the study procedures, etc.), you must complete and submit the modification form. This can be accessed by returning to the study management page and selecting the modification form. The modification form is separate from the continuing review form, so it must be completed, submitted, and processed separately from this form.

Adverse Events or Unanticipated Problems

Have there been any complaints from subjects in the past approval period?

○ Yes ○ No

Please describe:



Adverse events: any untoward or unfavorable medical occurrence 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.

Have there been any adverse events or unanticipated problems in the past approval period?

○ Yes ○ No

Please explain in detail:

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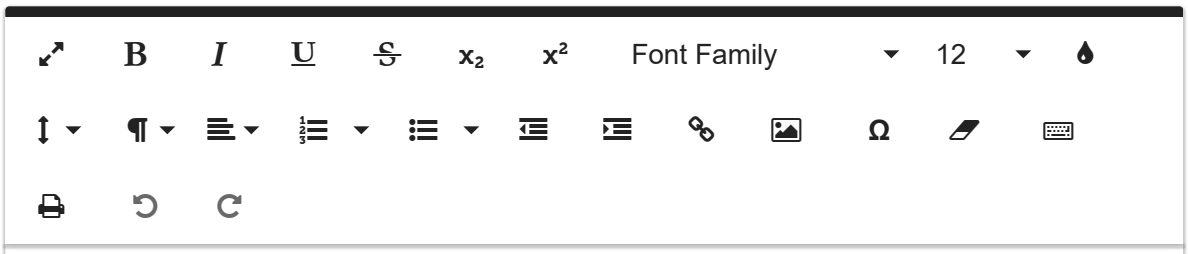
Was the IRB notified of the event or problem?

○ Yes ○ No

Please explain why this was not done:



Publications, Presentations, and Recent Findings

Have there been any presentations or publications resulting from this study during the past approval period?

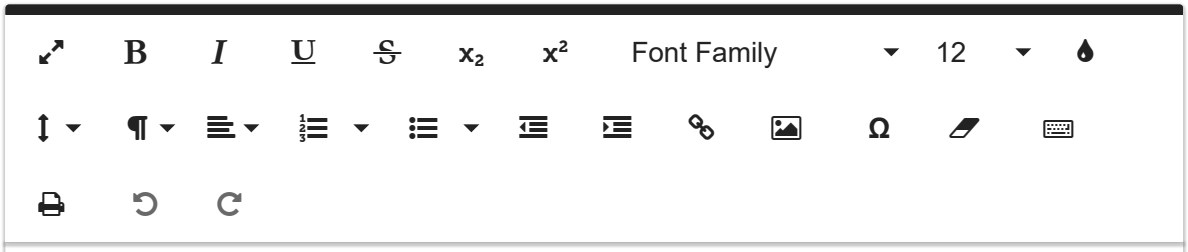
○ Yes ○ No

*** Please note that a copy of the abstract or the complete publication is required at the end of this form.**

Have there been any recent findings either from this study, or a related study (through a literature review for example), that would have an effect on this study's risk/benefit analysis?

○ Yes ○ No

Please describe and cite references:

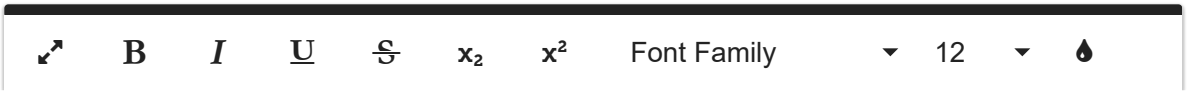


Conflicts of Interest and Commercialization

Does any member of the research team have a potential conflict of interest with this study that could affect study subjects and/or study outcome? Click here to read the BYU IRB SOPs regarding investigator conflicts of interest.

○ Yes ○ No

Please describe and disclose the potential conflict of interest:



Please describe the ways in which you have and will minimize harm to research subjects and/or the objectivity of research:

Does the PI or Co-I have a current conflict disclosure form on file?

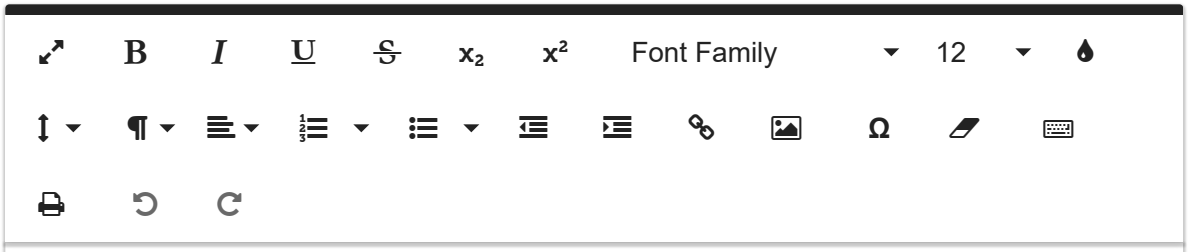
◯ Yes ◯ No

Attachments

Are you using the date-stamped consent form that was previously approved?

◯ Yes
◯ No
◯ N/A - This study does not have a previously approved consent form

Please explain why you are not using the previously approved consent form.



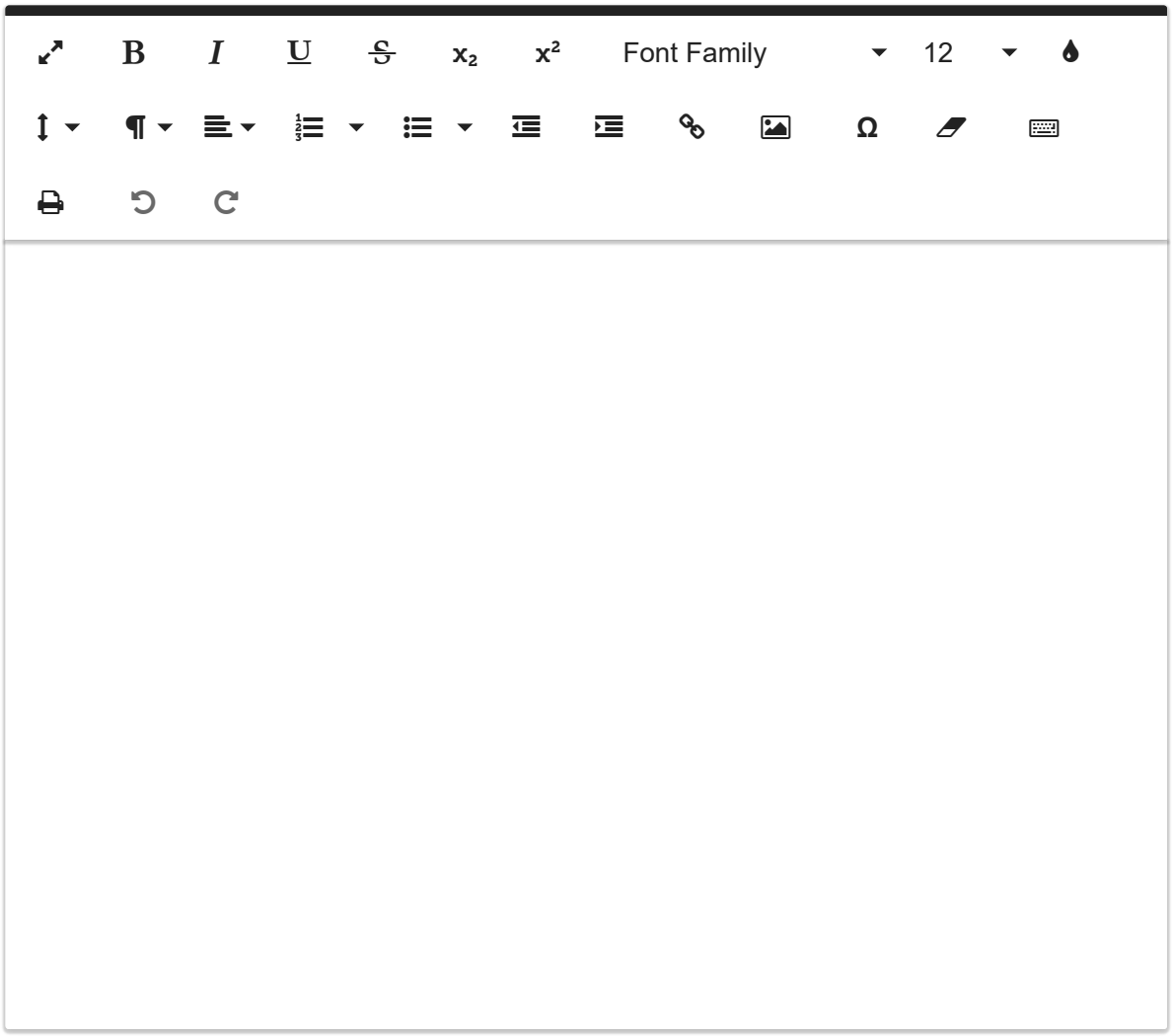
If you need to revise the consent form, you must complete and submit the modification form. This can be accessed by returning to the study management page and selecting the modification form. The modification form is separate from the continuing review, so it must be completed, submitted, and processed separately from this form.

Are you using the date-stamped recruitment material(s) that was previously approved?

◯ Yes

- ◯ No
- ◯ N/A - This study does not have a previously approved recruitment material

Please explain why you are not using the previously approved recruitment material(s).



If you need to revise the recruitment materials, or add new recruitment materials, you must complete and submit the modification form. This can be accessed by returning to the study management page and selecting the modification form. The modification form is separate from the continuing review, so it must be completed, submitted, and processed separately from this form.

You indicated in section 2.1 that this study required IRB approval from additional institutions. Please upload copies of current IRB approvals from additional institutions in the below table.

You indicated in section 2.5 that this study resulted in presentations or publications. Please upload a copy of the abstract or the complete publication in the below table.

Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document

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

Section 3.0

You indicated that your study is inactive, meaning that the study is closed to enrollment, there are no plans to collect additional information, and research activities are limited to the analysis of de-identified data only. Because your study is inactive, you do not need to complete this continuing review form to

renew your study. Instead, please return to the study management page and select the closure form. Once you have signed and submitted the closure form to the committee, the form will be processed by the IRB office and the study will be closed.