IRB Modification Request

Study Information

Study Title:

IRB Number:

Initial Approval:

Principal Investigator:

Co-Investigators:

Department(s):

Lay Summary:

Type of Modification

Select all that apply:

- ☐ New Data Collection Procedure(s)
- ☐ Study Title Change
- ☐ Change in Study Personnel
- ☐ Change of Site
- ☐ Change in Enrollment
- ☐ Consent Change
- ☐ Recruitment Materials
- ☐ Instruments (surveys, questionnaires, interviews, etc.)
- ☐ Other Changes

Please specify:

[   ]

For each modification selected, complete the associated text box below explaining the change. At the end of the form, follow the instructions to create a revision of the actual application so the committee can review the proposed changes.

New Data Collection Procedure(s)

List each new research activity in bullet point form, and provide the location and duration of each activity (if applicable). Please fully describe how the new data collection procedure(s) will be implemented for each research activity.

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Provide a justification for the changes and how these changes align with approved study aims. At the end of the form, you will follow the instructions to create a revision of the actual application. Please be sure to update section 7.3 to align the application with this modification.

If the change in procedures will affect the consent and recruitment material(s), please upload the revised documents below in the Attachments section.

Study Title Change

Old Title:

New Title:

[   ]

At the end of the form, you will follow the instructions to create a revision of the actual application. Please be sure to update section 1.0 of the revised application.

Change in Study Personnel

Before submitting this modification to add new personnel, please note that investigators must complete their iRIS profiles by uploading current CVs. Required CITI courses must also be completed before the modification can be approved.

Use the table below to add and remove key study personnel (KSP). The first four sections are for adding KSP and Study Contacts. The last section is for removing personnel.

If applicable, please add the new Principal Investigator for the Study:

If applicable, please select the new Research Staff personnel:

A) Additional Investigators

B) Research Staff

C) Non-Study Personnel
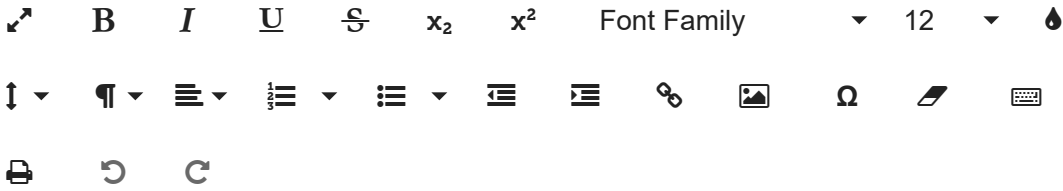
If applicable, please add any new Study Contact:

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

If applicable, please select any existing Personnel you wish to remove:

Change of Site

List each site change and provide a justification. If applicable, describe the process to access the sites and to obtain permission to conduct and/or recruit at these sites. At the end of the

form, you will follow the instructions to create a revision of the actual application. Please be sure to update the appropriate section to align the revised application with this modification.
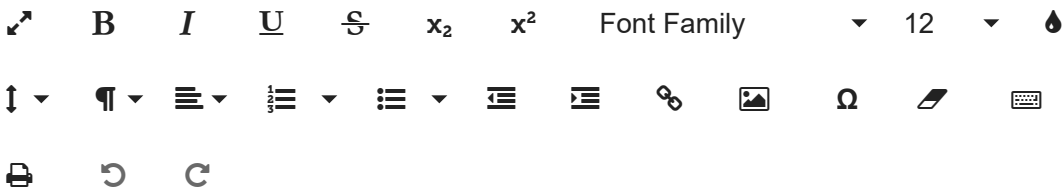
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Will the change of site(s) change the enrollment process?

○ Yes   ○ No

Please thoroughly describe below. At the end of the form, you will follow the instructions to create a revision of the actual application. Please be sure to update section 1.0 of the revised application to align the application with this modification.

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Change in Enrollment

Please thoroughly describe the change(s) in enrollment below. Enrollment changes may include an increase or decrease in sample size, change in inclusion/exclusion criteria, etc. Please justify the change and explain how the change is consistent with the approved aims of the study. At the end of the form, you will follow the instructions to create a revision of the actual application. Please be sure to update the appropriate section to align the revised application with this modification.
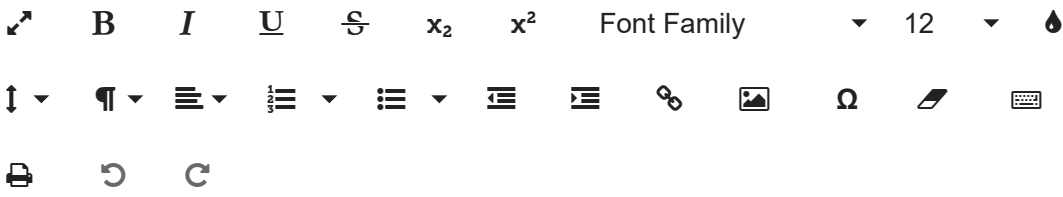
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If a change in enrollment will affect the consent and recruitment material(s), please upload the revised documents below in the Attachments section.

Consent Change

Please thoroughly describe the change(s) in consent below. Do not copy and paste the actual text of the consent in this section; you will be asked to upload the file at the end of this page. At the end of the form, you will follow the instructions to create a revision of the actual application. Please be sure to update the appropriate section to align the revised application with this modification.

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If this change will affect the consent and recruitment material(s) please upload the revised documents below in the Attachments section.

Recruitment Materials

Please thoroughly describe the changes to recruitment materials(s). Do not copy and paste the actual text of the recruitment materials in this section. You will upload the revised/additional recruiting materials later on this page. List each site change and provide a justification. If applicable, describe the process to access the sites and to obtain permission to conduct and/or recruit at these sites. At the end of the form, you will follow the instructions to create a revision of the actual application. Please be sure to update the appropriate section to align the revised application with this modification.

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Please upload the revised recruitment material(s) below in the Attachments section.

Instruments (surveys, questionnaires, interviews, etc.)

Please thoroughly describe changes to the instruments, surveys, or questionnaires and describe any changes from the approved protocol. Do not copy and paste the actual text of the instruments in this section. You will upload the revised/additional recruiting materials later on this page. At the end of the form, you will follow the instructions to create a revision of the actual application. Please be sure to update the appropriate section to align the revised application with this modification.

Please upload the new instrument(s) in the document section at the end of this form.

Other Changes

Please thoroughly describe additional changes below. Please justify the changes and how they still align to the approved study aims. At the end of the form, you will follow the instructions to create a revision of the actual application. Please be sure to update each section of the application to align with this modification.

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Documents

Please use the table below to upload any necessary document(s): consent forms, research site permissions, recruiting materials, instruments, additional research personnel certifications.

Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document

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

Revised Application

Now that you have explained the modification, you will need to revise the application so the committee can see the proposed changes. Use the following step-by-step instructions to complete this process.

1. **Click the gray button below labeled "Click here to attach the application"**
2. **A pop-up will appear with a table showing your currently approved application. On the right side, click the option to "Add Revison". On the second pop-up, click "OK" to create the revision.**
3. **This will take you to a new version of your application. You can now move through the application and make your proposed changes in the relevant sections. Just like the original application, it's very important to use the Save buttons to save the changes.**
4. **<u>DO NOT</u> make any changes to study personnel.**
5. **Once you make all the proposed changes, you should click the "Back" button to move from the revised application to this section of the modification form. You should now see the revised application listed below. You can now use the Save and Continue to Next Section button to sign off and submit the modification form for committee review.**

No Application has been associated with this submission.