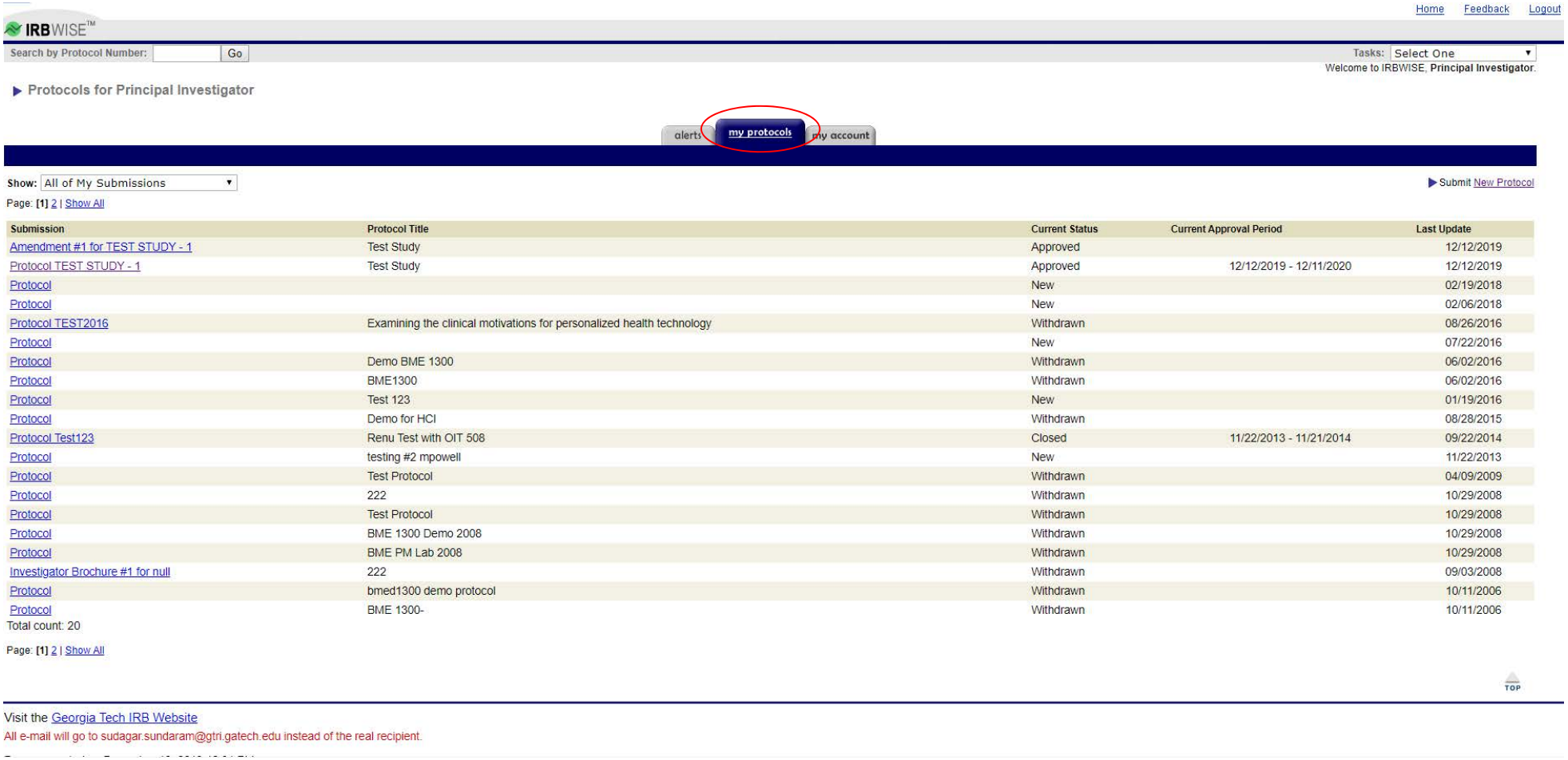
IRB Wise Amendment Submission Example and Guidance

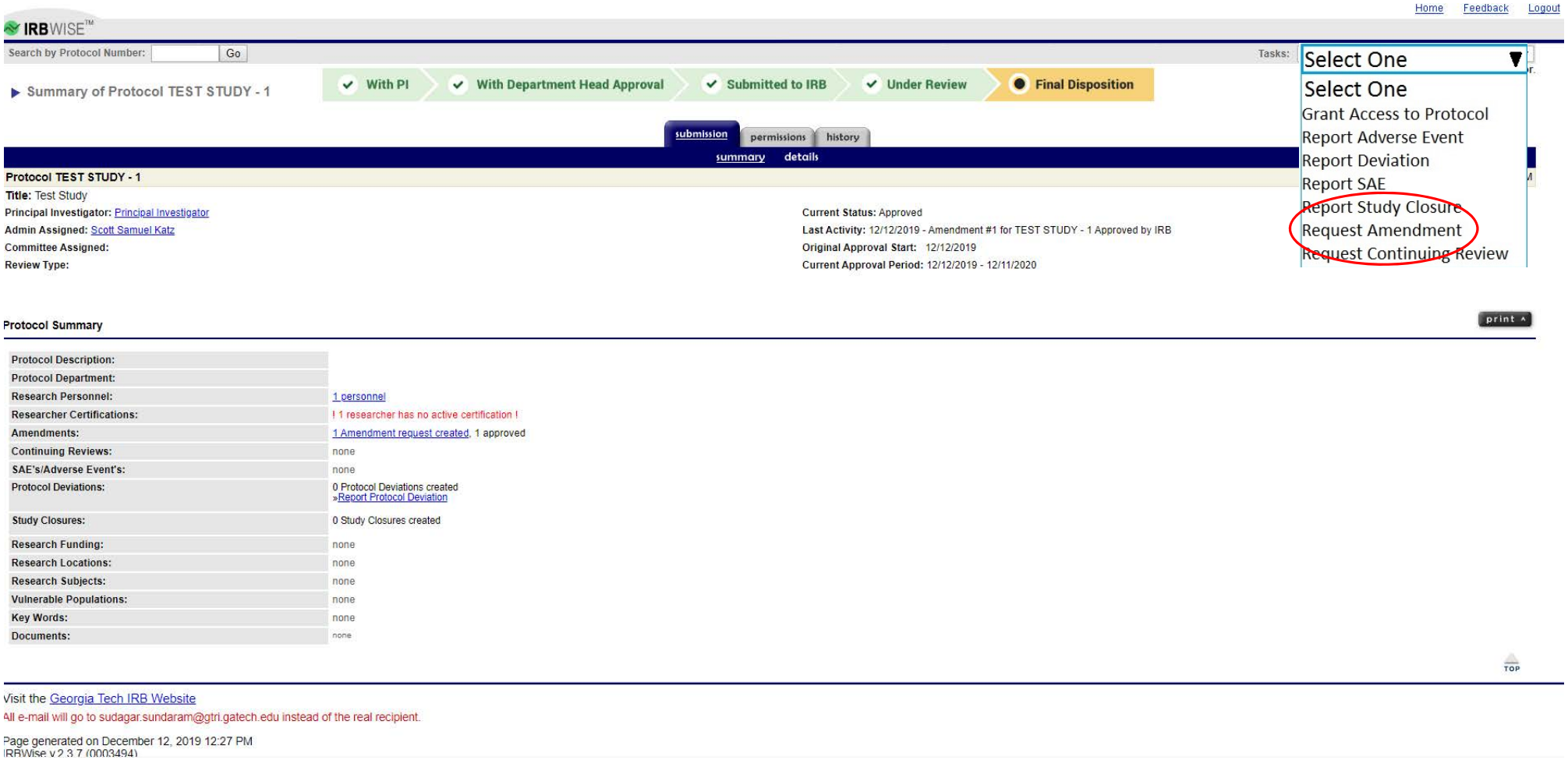
This presentation includes an example of an amendment submission in IRB Wise and also includes guidance for each section of the submission. The screen shots are of an example and the responses are not to be taken as the correct response. Each study is different, and therefore each response and each section will need to be filled out to tailor to your study. Please contact the Office of Research Integrity Assurance if you have any questions.

Start Page on IRB Wise



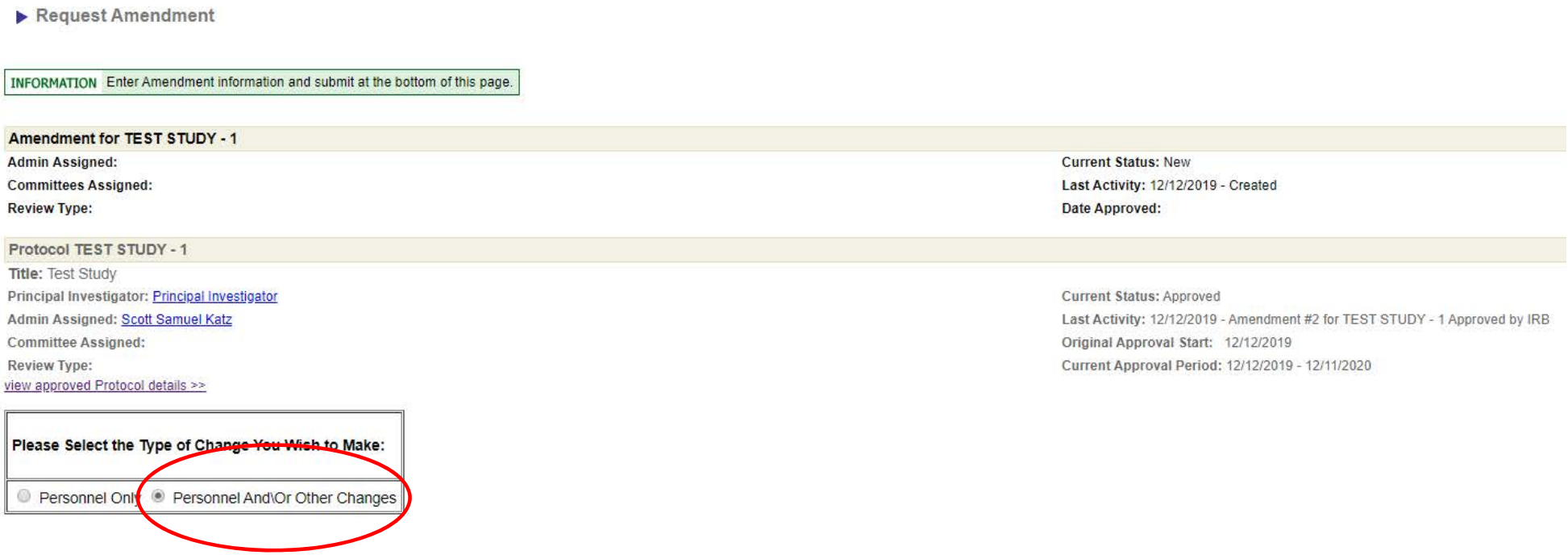
To submit an amendment, please click “My Protocols” (circled in red) at the top of the screen and then select the study that you wish to amend.

Requesting Amendment



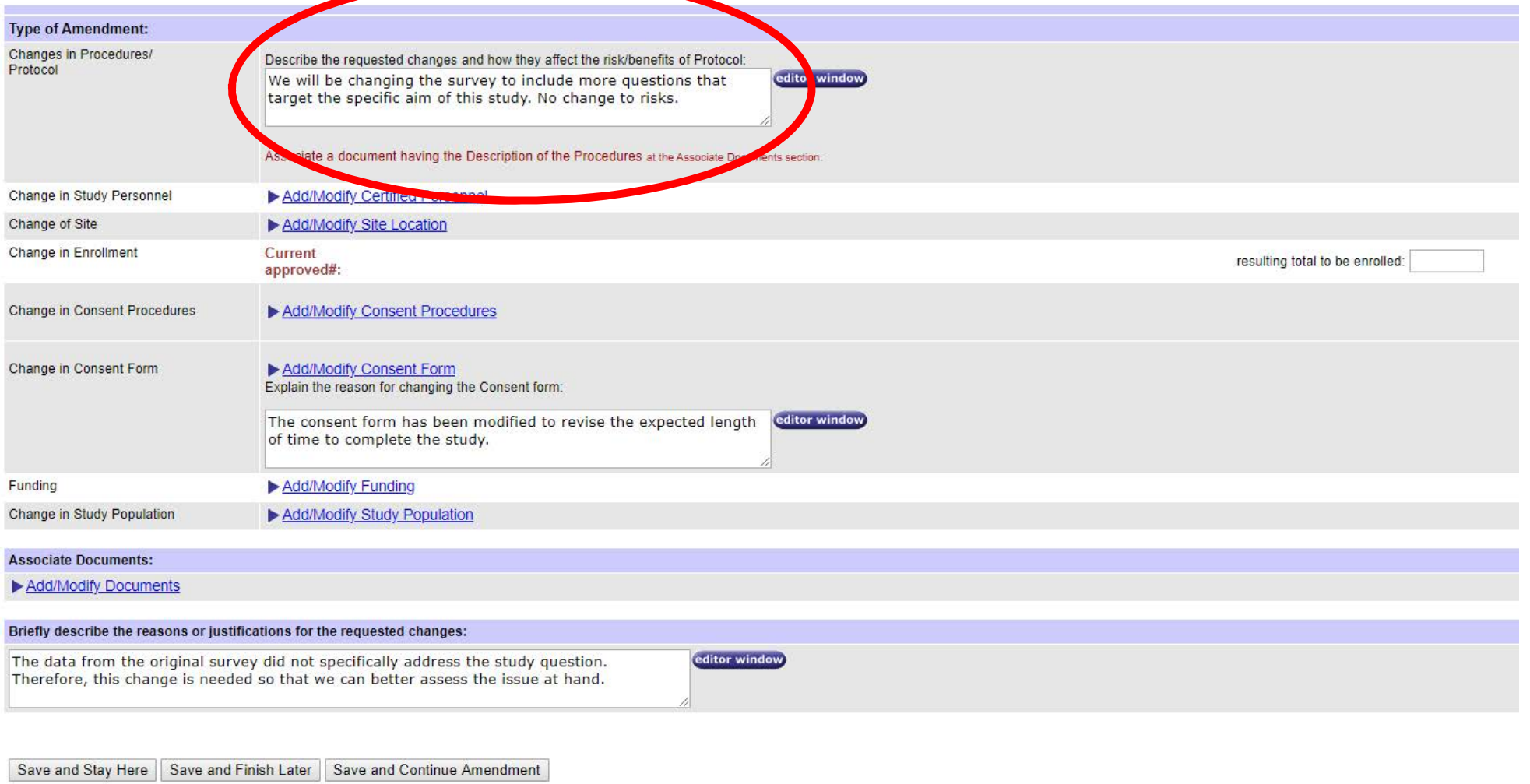
Once in the selected study, please click the Tasks drop-down menu and select "Request Amendment."

Type of Amendment



Once in the amendment, you will be prompted with this screen. From here, you need to select the type of amendment. This presentation is for general amendments. Therefore, this presentation will show the path of selecting "Personnel And/Or Other Changes" (circled in red).

Amendment - Change in Procedures/Protocol



Type of Amendment:

Changes in Procedures/ Protocol	Describe the requested changes and how they affect the risk/benefits of Protocol: We will be changing the survey to include more questions that target the specific aim of this study. No change to risks. editor window Associate a document having the Description of the Procedures at the Associate Documents section.
Change in Study Personnel	▶ Add/Modify Certified Personnel
Change of Site	▶ Add/Modify Site Location
Change in Enrollment	Current approved#: resulting total to be enrolled:
Change in Consent Procedures	▶ Add/Modify Consent Procedures
Change in Consent Form	▶ Add/Modify Consent Form Explain the reason for changing the Consent form: The consent form has been modified to revise the expected length of time to complete the study. editor window
Funding	▶ Add/Modify Funding
Change in Study Population	▶ Add/Modify Study Population

Associate Documents:

▶ Add/Modify Documents

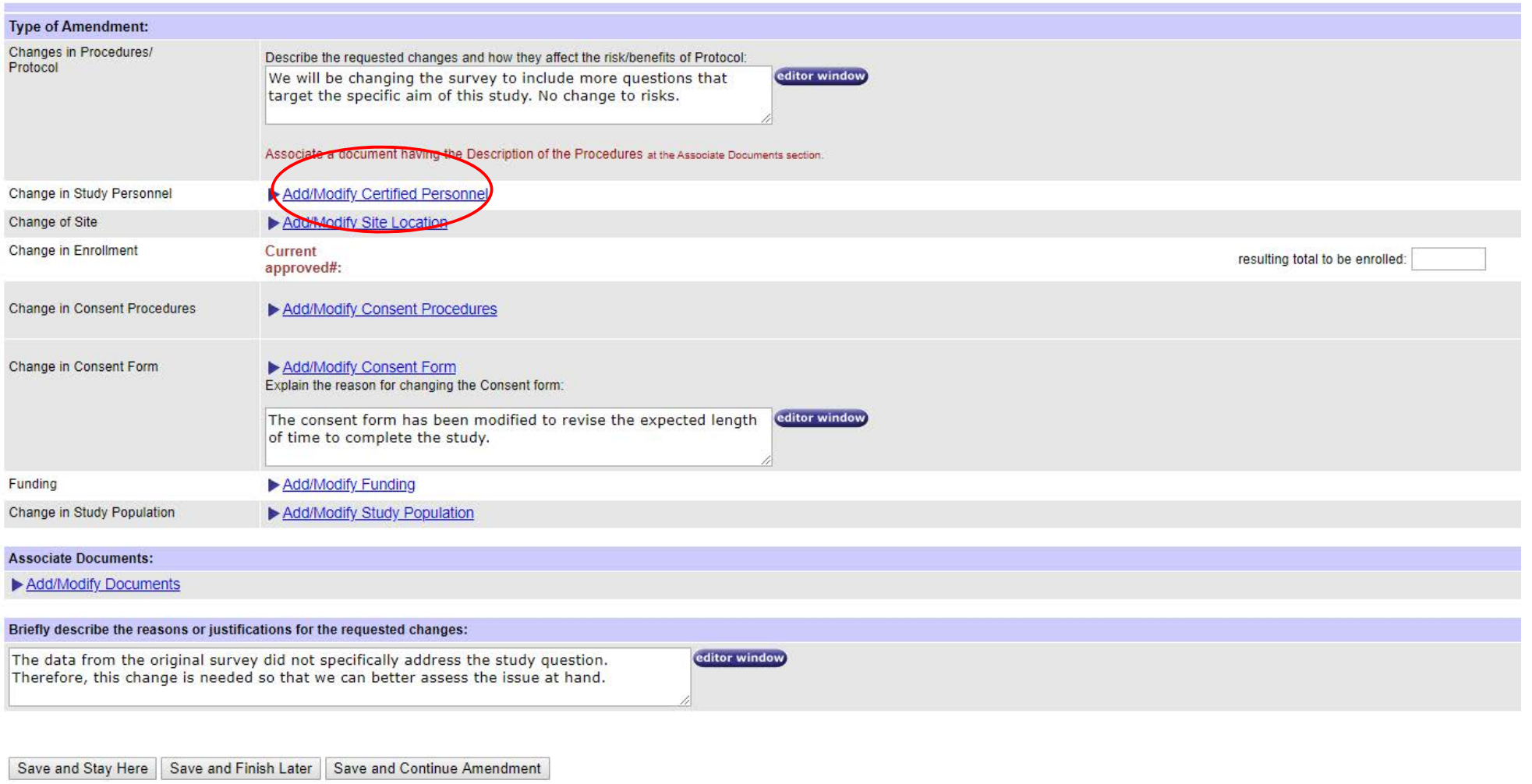
Briefly describe the reasons or justifications for the requested changes:

The data from the original survey did not specifically address the study question. Therefore, this change is needed so that we can better assess the issue at hand. editor window

Save and Stay Here | Save and Finish Later | Save and Continue Amendment

After selecting the type of amendment, you will be prompted with the following screen. The first action that should be taken is to fully describe the changes that are being requested in the amendment in the first text box (circled in red above).

Amendment - Change in Study Personnel



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Change in Study Population	▶ Add/Modify Study Population

Associate Documents:

▶ Add/Modify Documents

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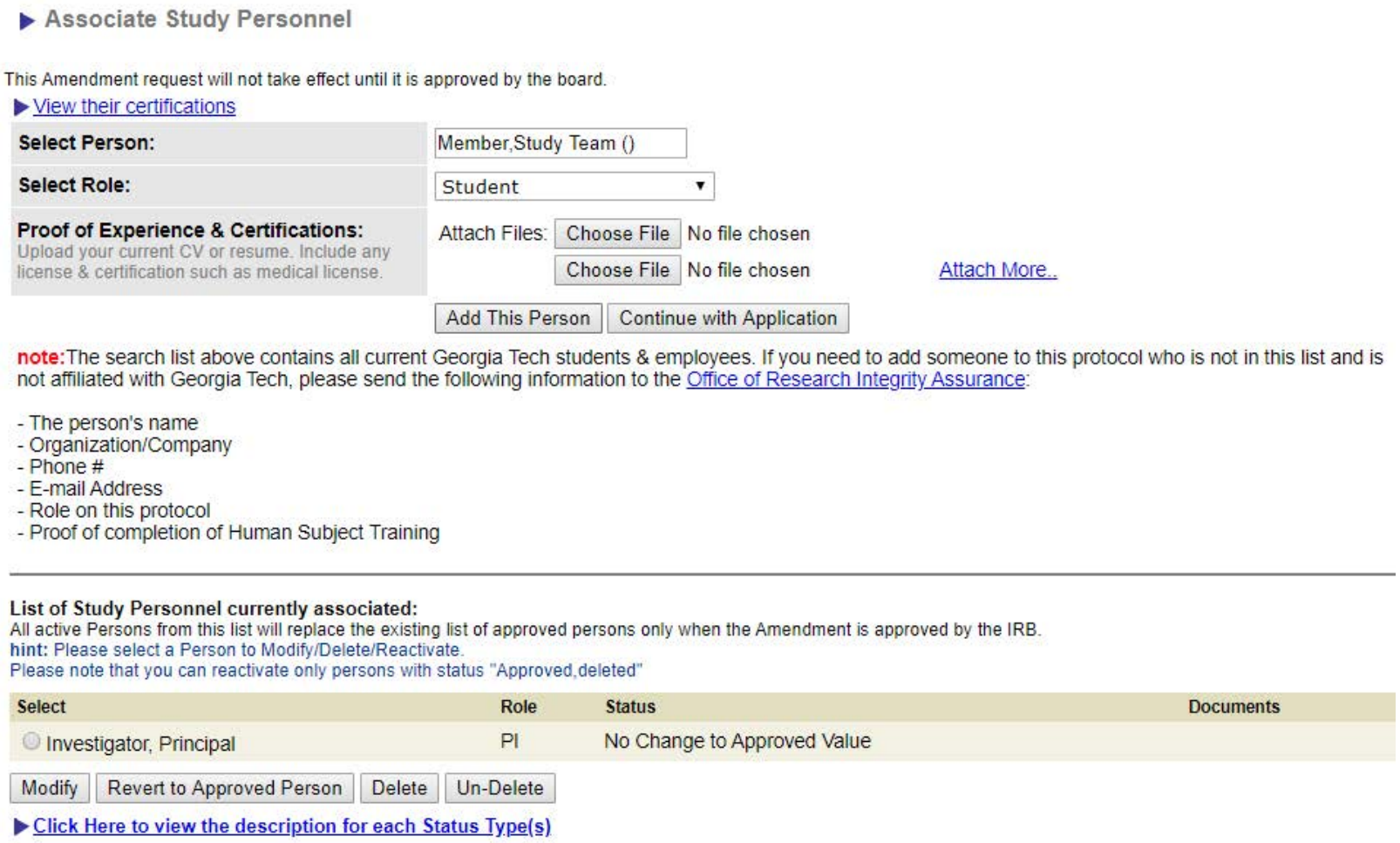
The data from the original survey did not specifically address the study question. Therefore, this change is needed so that we can better assess the issue at hand. editor window

Save and Stay Here | Save and Finish Later | Save and Continue Amendment

If you are requesting to change study personnel in addition to other changes, then please click "Add/Modify Certified Personnel" (circled in red above).

Amendment - Change in Study Personnel



▶ Associate Study Personnel

This Amendment request will not take effect until it is approved by the board.

▶ View their certifications

Select Person:	Member,Study Team ()
Select Role:	Student
Proof of Experience & Certifications: Upload your current CV or resume. Include any license & certification such as medical license.	Attach Files: Choose File No file chosen Choose File No file chosen Attach More..

Add This Person | Continue with Application

note: The search list above contains all current Georgia Tech students & employees. If you need to add someone to this protocol who is not in this list and is not affiliated with Georgia Tech, please send the following information to the Office of Research Integrity Assurance:

- The person's name
- Organization/Company
- Phone #
- E-mail Address
- Role on this protocol
- Proof of completion of Human Subject Training

List of Study Personnel currently associated:

All active Persons from this list will replace the existing list of approved persons only when the Amendment is approved by the IRB.

hint: Please select a Person to Modify/Delete/Reactivate.

Please note that you can reactivate only persons with status "Approved,deleted"

Select	Role	Status	Documents
Investigator, Principal	PI	No Change to Approved Value	

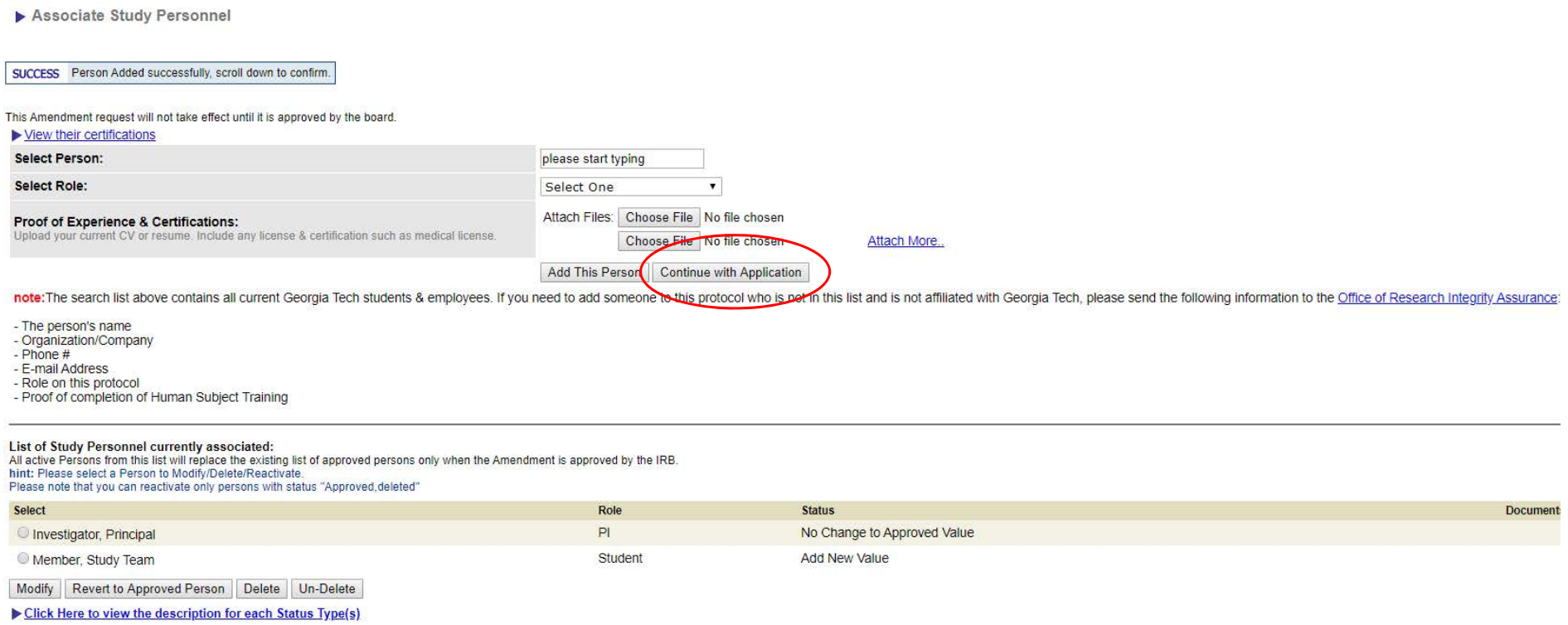
Modify | Revert to Approved Person | Delete | Un-Delete

▶ Click Here to view the description for each Status Type(s)

TOP

When requesting the change study personnel, please type the individuals name in the "Select Person" tab and select the individual that you want to add. Please be sure to type the name as Last,FIrst with no space between the comma and the first name. When selected, please select the role of the individual and click "Add This Person." You do not need to add training certificates on this screen, as the ORIA staff will check for training on the CITI website.

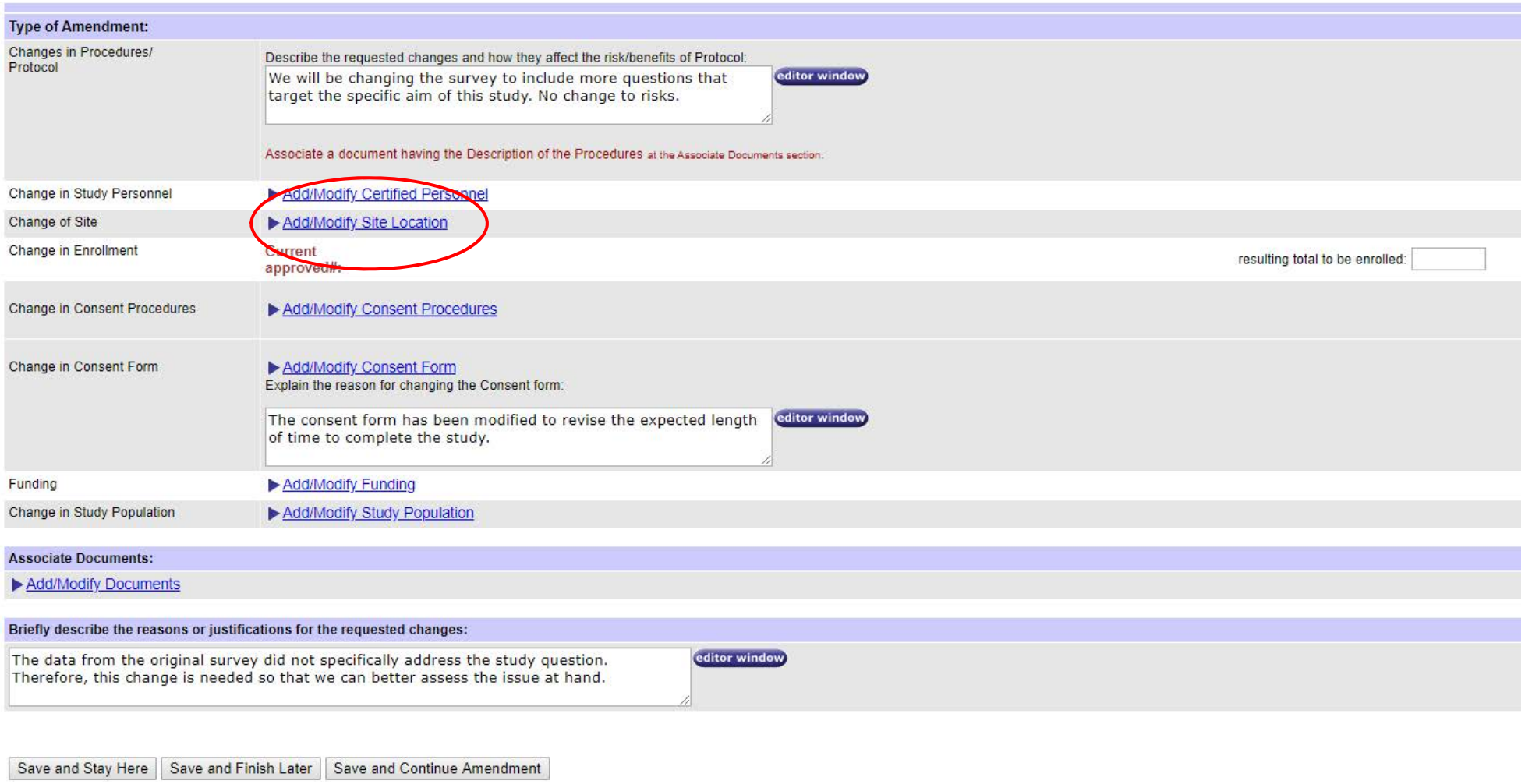
Amendment - Change in Study Personnel



The study team member will be listed in the Study Personnel list at the bottom of the screen after successfully being added (shown above). On this screen, you can also modify (change the study role) or delete existing study team members as well.

When finished, please click "Continue with Application" in the middle of the page (circled in red).

Amendment - Change in Site



Type of Amendment:

Changes in Procedures/ Protocol	Describe the requested changes and how they affect the risk/benefits of Protocol: We will be changing the survey to include more questions that target the specific aim of this study. No change to risks. editor window Associate a document having the Description of the Procedures at the Associate Documents section.
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Funding	▶ Add/Modify Funding
Change in Study Population	▶ Add/Modify Study Population

Associate Documents:

▶ Add/Modify Documents

Briefly describe the reasons or justifications for the requested changes:

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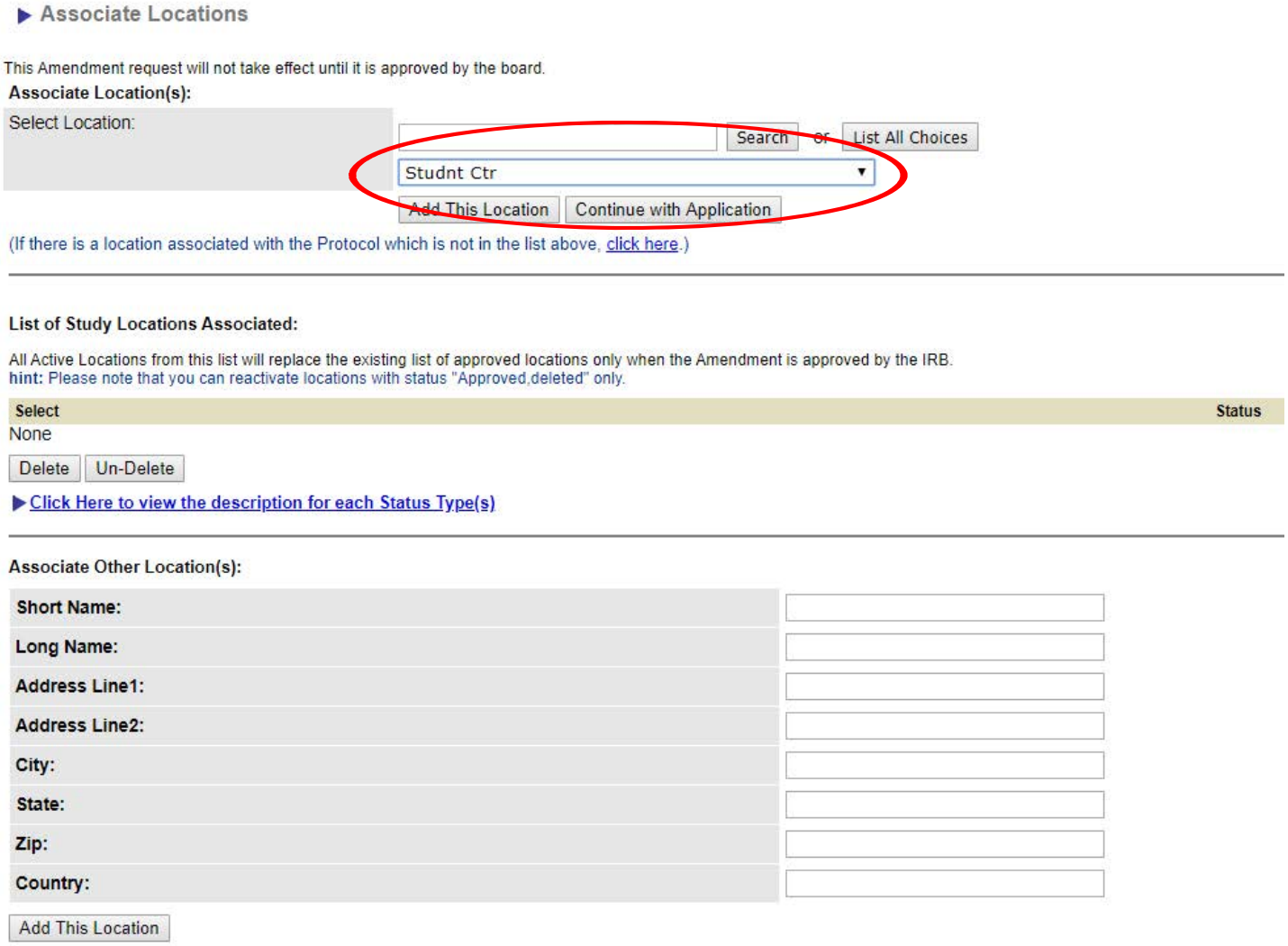
Save and Stay Here | Save and Finish Later | Save and Continue Amendment

If you are requesting a change in study site location, then please click "Add/Modify Site Location" (circled in red).

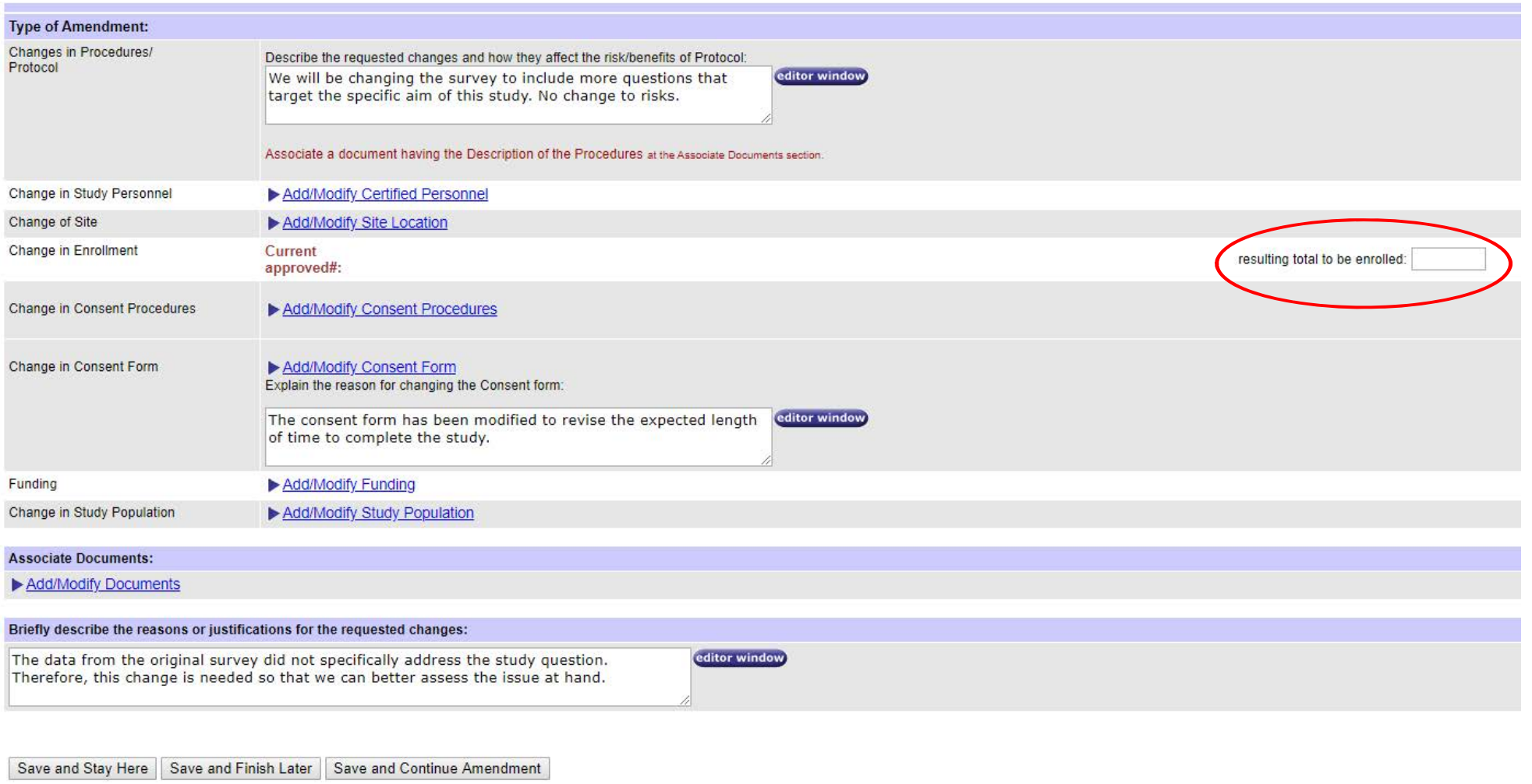
Amendment - Change in Site



If you are requesting a change in study site location, then you will need to find the site in the drop-down menu (circled in red) and click "Add This Location." If the site is not listed or is off-campus, then please add the site in the section below.

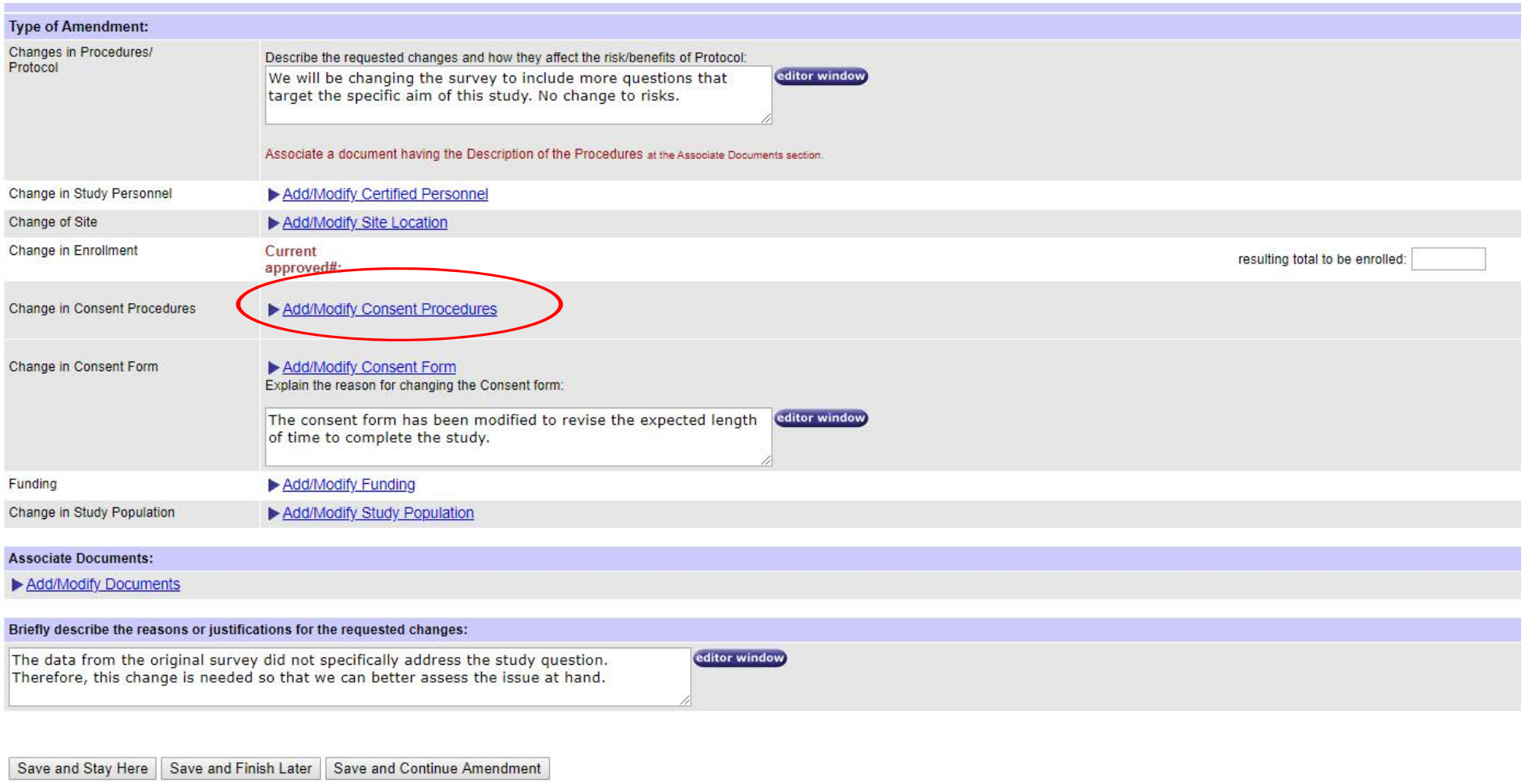
When finished, please click "Continue with Application" in the middle of the page.

Amendment - Change in Enrollment



If you are changing the enrollment numbers for the study, then please type in the new maximum number of subjects you wish to enroll in the text box to the far right of the screen (circled in red).

Amendment - Change in Consent Procedures



Type of Amendment:

Changes in Procedures/ Protocol	Describe the requested changes and how they affect the risk/benefits of Protocol: We will be changing the survey to include more questions that target the specific aim of this study. No change to risks. editor window Associate a document having the Description of the Procedures at the Associate Documents section.
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Funding	▶ Add/Modify Funding
Change in Study Population	▶ Add/Modify Study Population

Associate Documents:

▶ Add/Modify Documents

Briefly describe the reasons or justifications for the requested changes:

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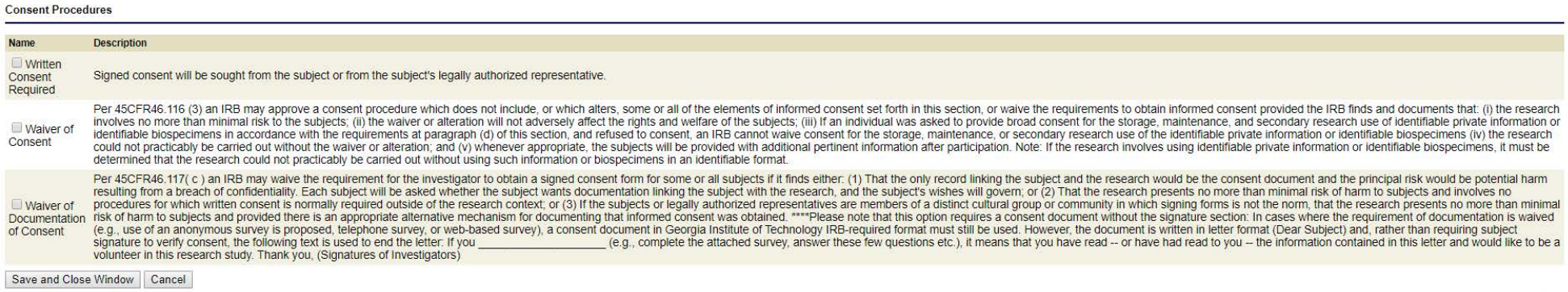
Save and Stay Here | Save and Finish Later | Save and Continue Amendment

If you are requesting that the consent procedures be changed (written, waiver of documentation, waiver of consent), then please click "Add/Modify Consent Procedures" (circled in red).

Amendment - Change in Consent Procedures



Consent Procedures

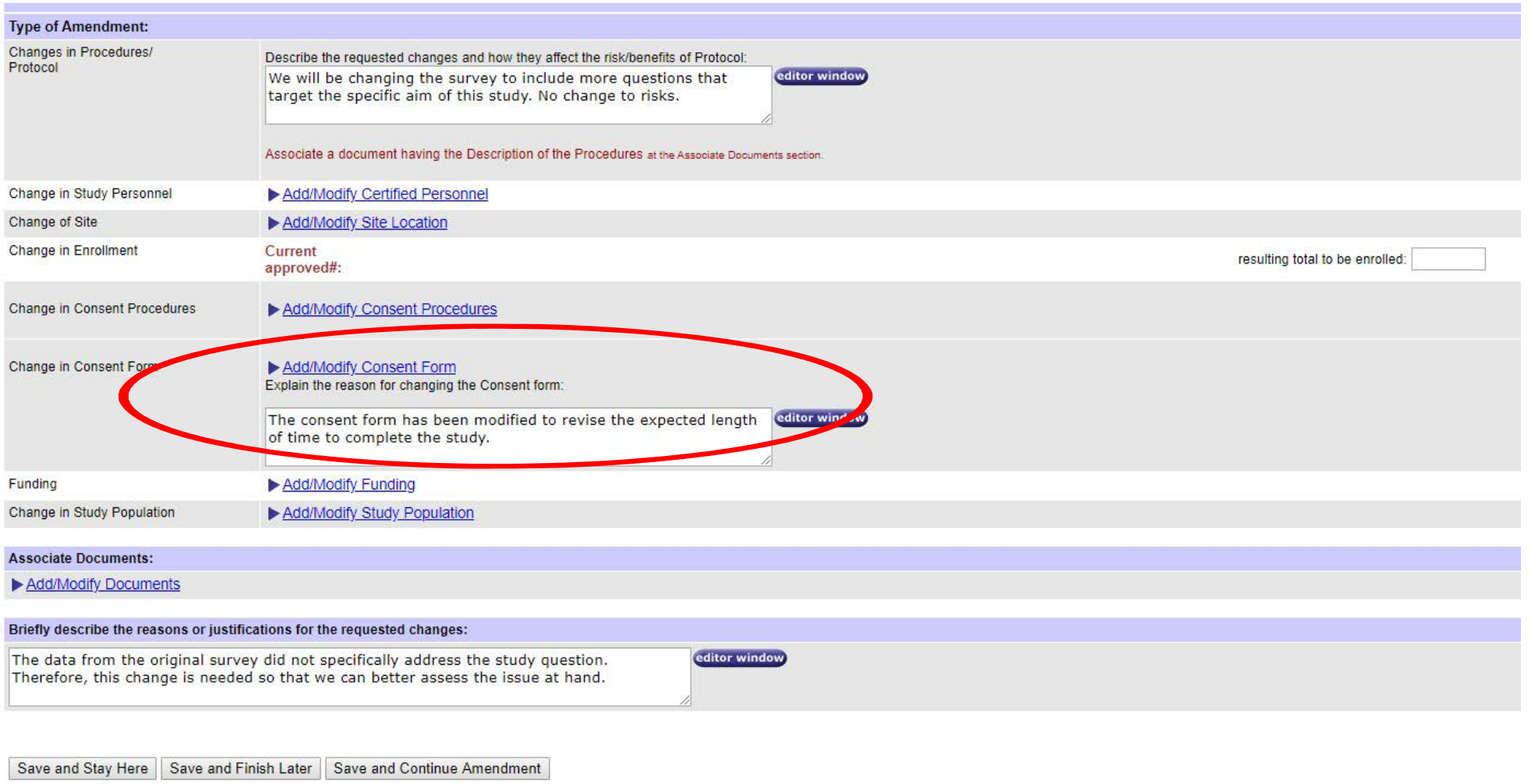
Name	Description
☐ Written Consent Required	Signed consent will be sought from the subject or from the subject's legally authorized representative.
☐ Waiver of Consent	Per 45CFR46.116 (3) an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that: (i) the research involves no more than minimal risk to the subjects; (ii) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (iii) If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens (iv) the research could not practicably be carried out without the waiver or alteration; and (v) whenever appropriate, the subjects will be provided with additional pertinent information after participation. Note: If the research involves using identifiable private information or identifiable biospecimens, it must be determined that the research could not practicably be carried out without using such information or biospecimens in an identifiable format.
☐ Waiver of Documentation of Consent	Per 45CFR46.117(c) an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or (3) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. ****Please note that this option requires a consent document without the signature section: In cases where the requirement of documentation is waived (e.g., use of an anonymous survey is proposed, telephone survey, or web-based survey), a consent document in Georgia Institute of Technology IRB-required format must still be used. However, the document is written in letter format (Dear Subject) and, rather than requiring subject signature to verify consent, the following text is used to end the letter: If you _____ (e.g., complete the attached survey, answer these few questions etc.), it means that you have read -- or have had read to you -- the information contained in this letter and would like to be a volunteer in this research study. Thank you, (Signatures of Investigators)

Save and Close Window | Cancel

After selecting "Add/Modify Consent Procedures," you will be prompted with this screen. On this screen, select the new consent procedure(s) and either leave (if you intend to continue to use this procedure) or uncheck the old procedure (if you no longer intend to use this procedure).

When finished, please click "Save and Close Window."

Amendment - Change in Consent Form



Type of Amendment:

Changes in Procedures/ Protocol	Describe the requested changes and how they affect the risk/benefits of Protocol: We will be changing the survey to include more questions that target the specific aim of this study. No change to risks. editor window Associate a document having the Description of the Procedures at the Associate Documents section.
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Funding	▶ Add/Modify Funding
Change in Study Population	▶ Add/Modify Study Population

Associate Documents:

▶ Add/Modify Documents

Briefly describe the reasons or justifications for the requested changes:

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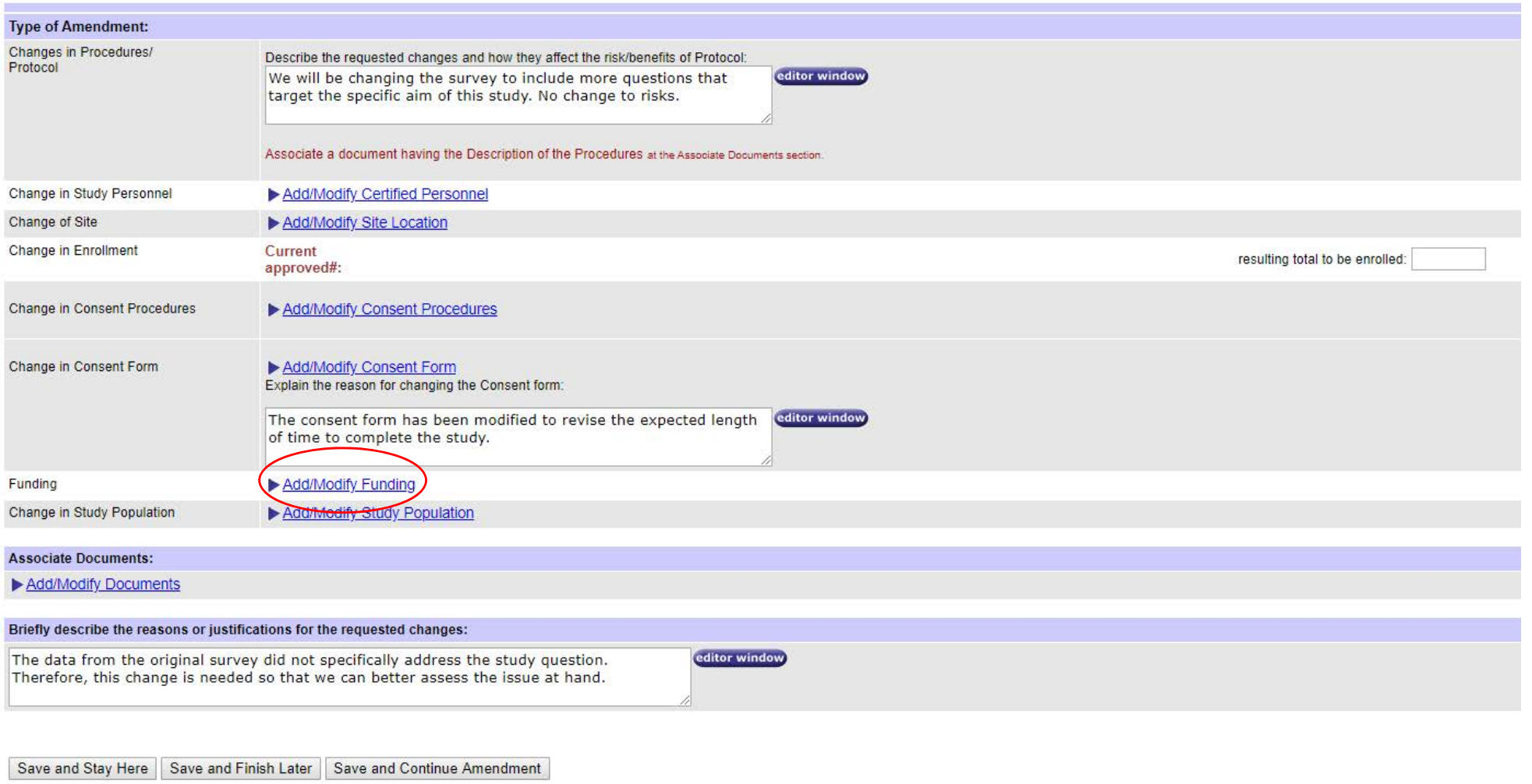
Save and Stay Here | Save and Finish Later | Save and Continue Amendment

When updating , adding, or deleting a consent form, please select "Add/Modify Consent Form." Please also be sure to briefly describe the revisions that are being made to the consent form in the text box under the link to the section.

Amendment - Change in Consent Form

- When adding a new consent form, please add the title, choose the file, and click "Attach This Document."
- When updating or replacing an existing consent form, please select the consent form in the list and click Modify/Replace. The file will then appear at the top of the screen where you can either change the title or choose a new file to upload.
- When deleting the consent form, please select the consent form in the list and click "Delete." The file will then appear at the top where you are then asked to confirm the delete again.
- Once finished, please click "Continue Application."

Amendment - Funding



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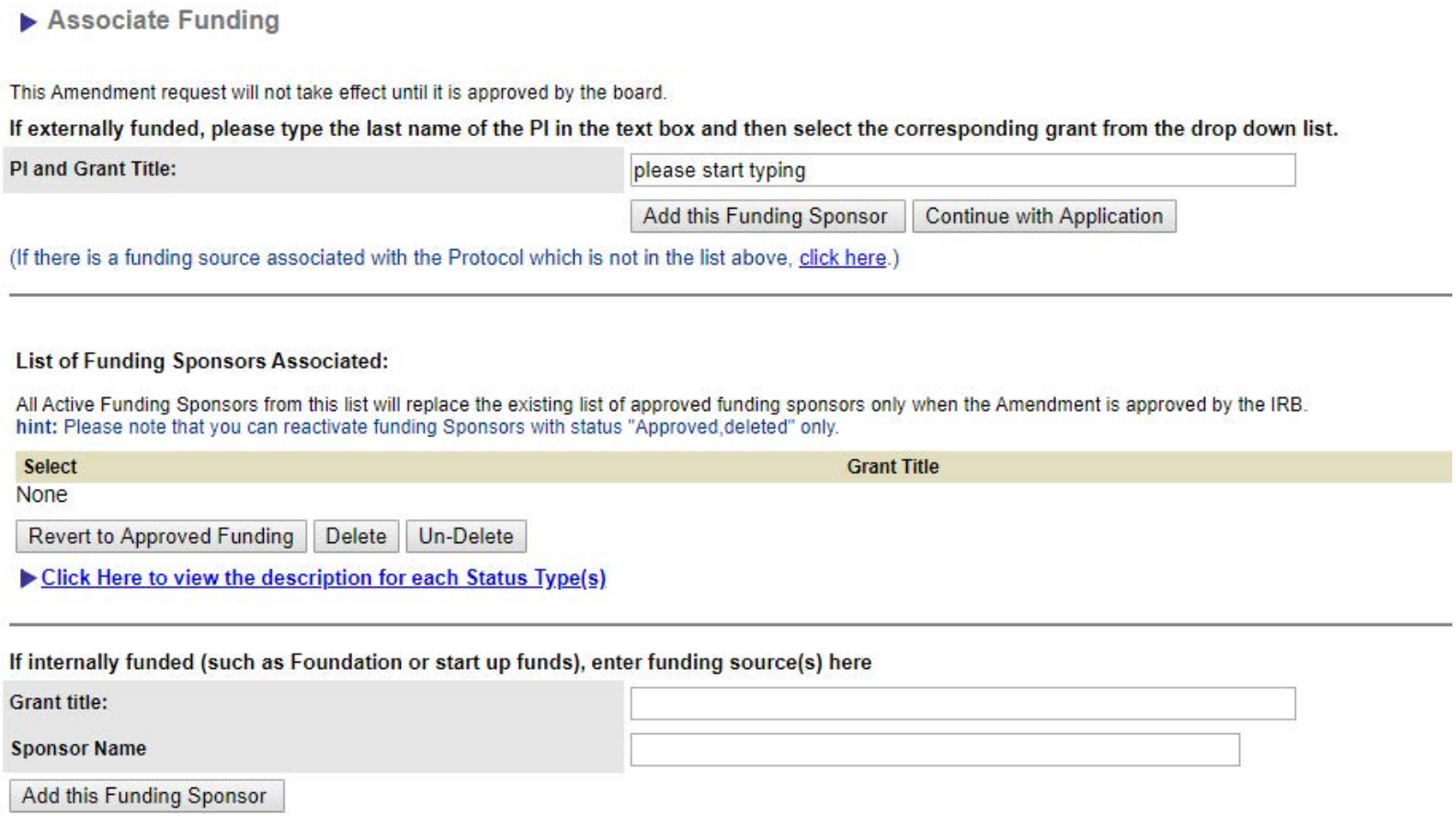
Save and Stay Here | Save and Finish Later | Save and Continue Amendment

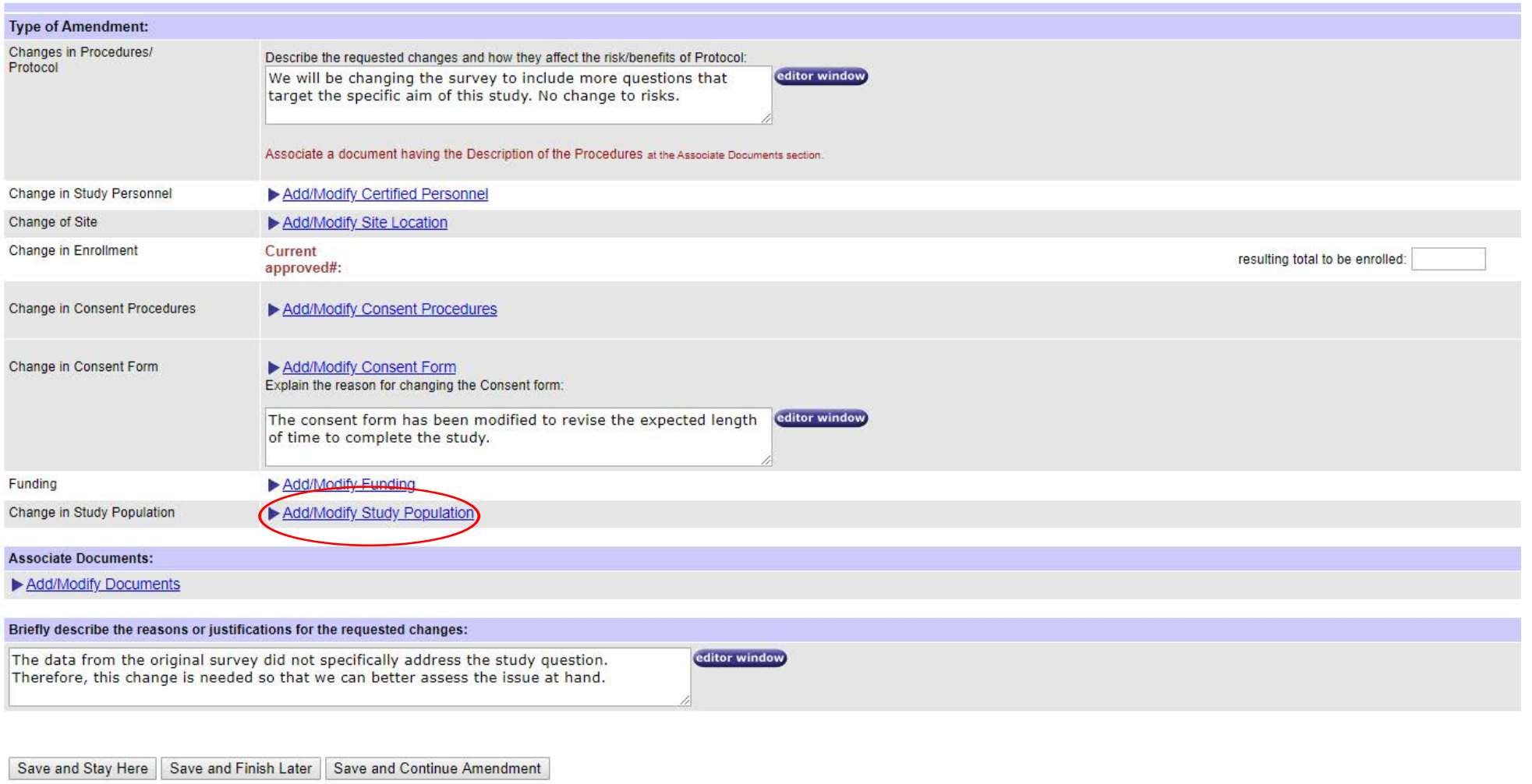
When adding, removing, or updating the funding source, please click "Add/Modify Funding" (circled in red).

Amendment - Funding



- When adding a new funding source, please type in the last name of the PI of the funding source and select the correct funding source. Please click "Add this Funding Sponsor" after selecting the proper source.
- When deleting a funding source, please select the funding source in the list and click "Delete." The file will then appear at the top where you are then asked to confirm the delete again.
- Once finished, please click "Continue with Application."

Amendment - Change in Study Population



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Associate Documents:

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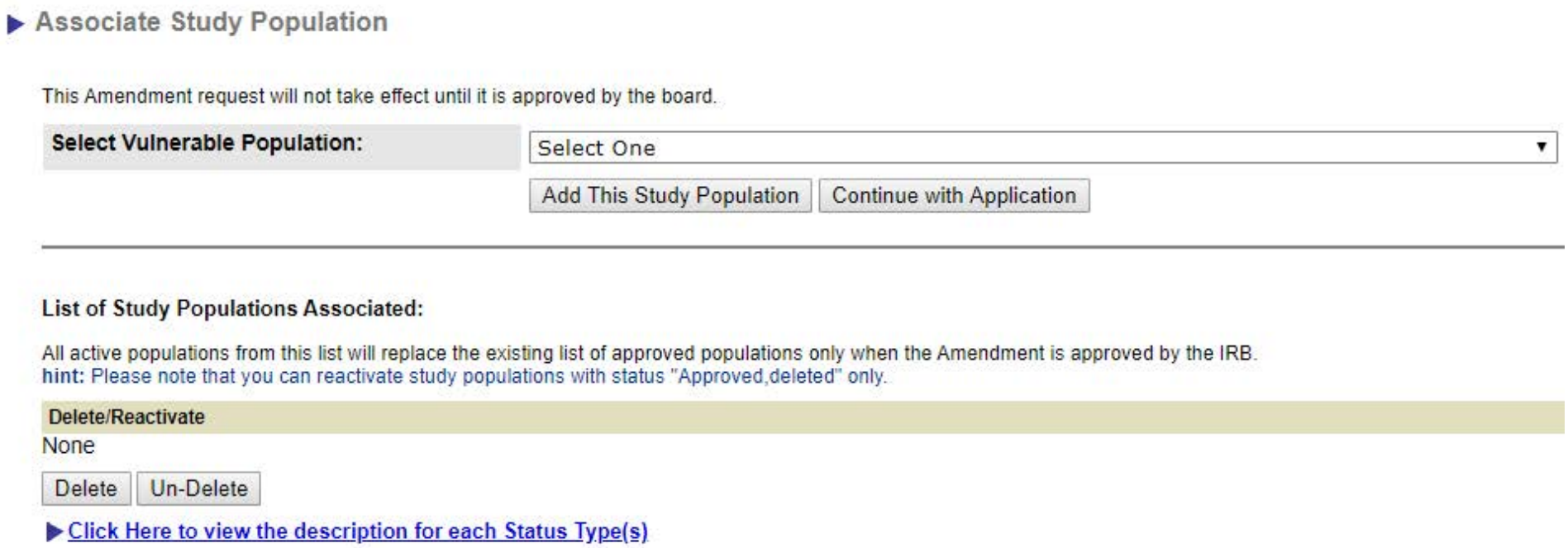
Save and Stay Here | Save and Finish Later | Save and Continue Amendment

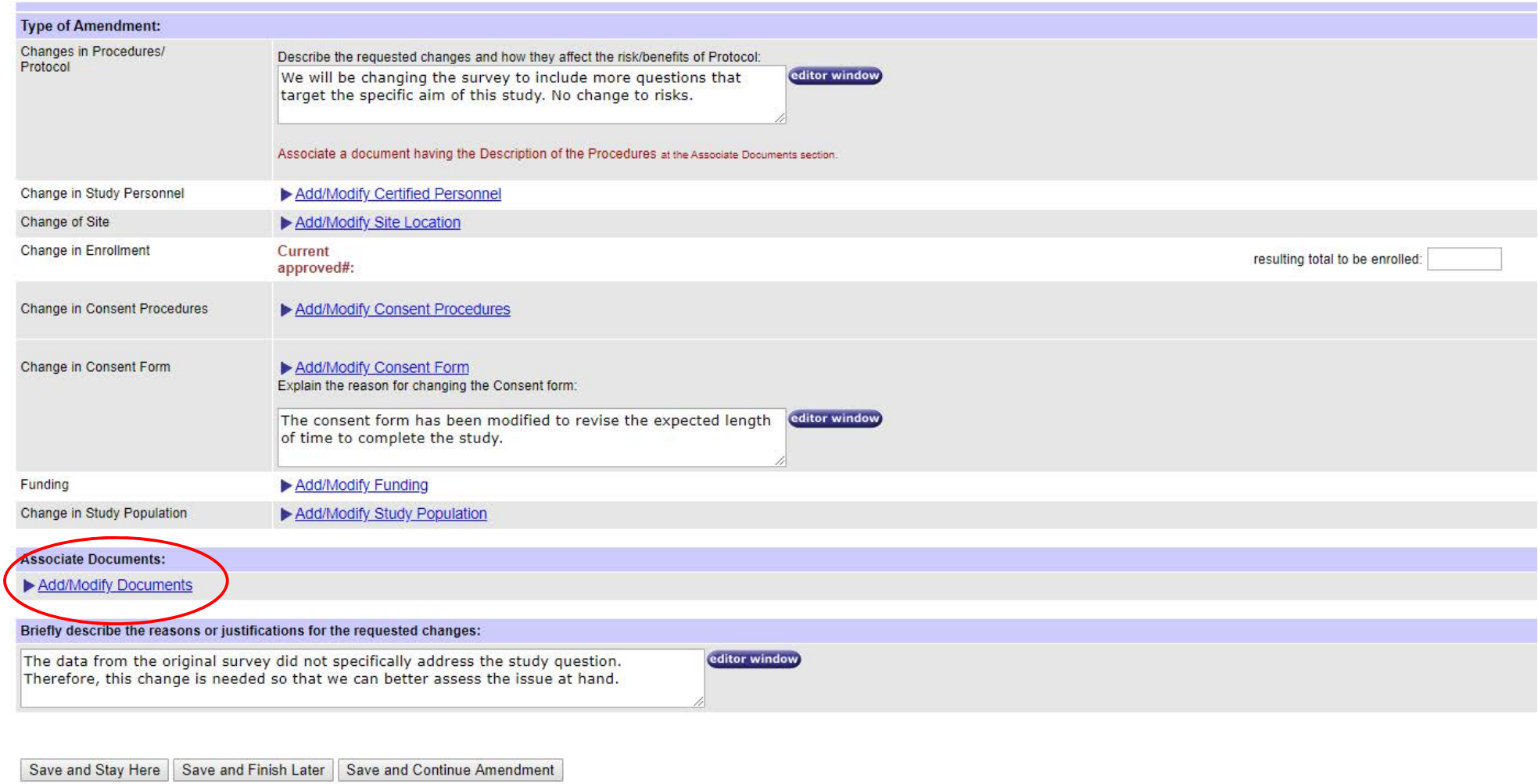
When adding, removing, or updating the study population, please click "Add/Modify Study Population" (circled in red).

Amendment - Change in Study Population



- When adding a new study population, please select the population from the drop-down menu and click "Add This Study Population."
- When removing a study population, please select the population from the list at the bottom of the screen and click "Delete."
- When finished, please click "Continue with Application."

Amendment - Add/Modify Documents



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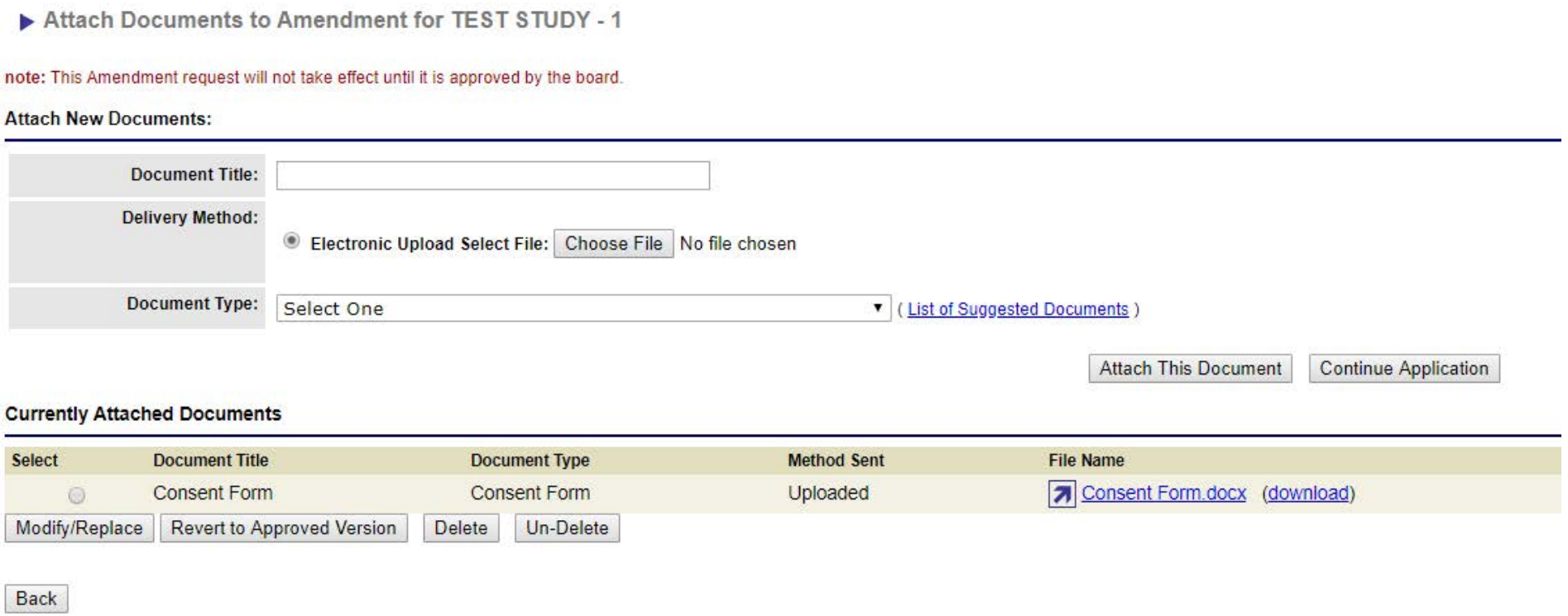
Save and Stay Here | Save and Finish Later | Save and Continue Amendment

When adding, removing, or updating study documents (recruitment, surveys, interviews, grant proposals, etc.), please click "Add/Modify Documents" (circled in red).

Amendment - Add/Modify Documents



- When adding a new document, please add the title, choose the file, and click "Attach This Document."
- When updating or replacing an existing document, please select the document in the list and click Modify/Replace. The file will then appear at the top of the screen where you can either change the title or choose a new file to upload.
- When deleting a document, please select the document form in the list and click "Delete." The file will then appear at the top where you are then asked to confirm the delete again.
- Once finished, please click "Continue Application."

Amendment - Provide Justification for Changes

Type of Amendment:

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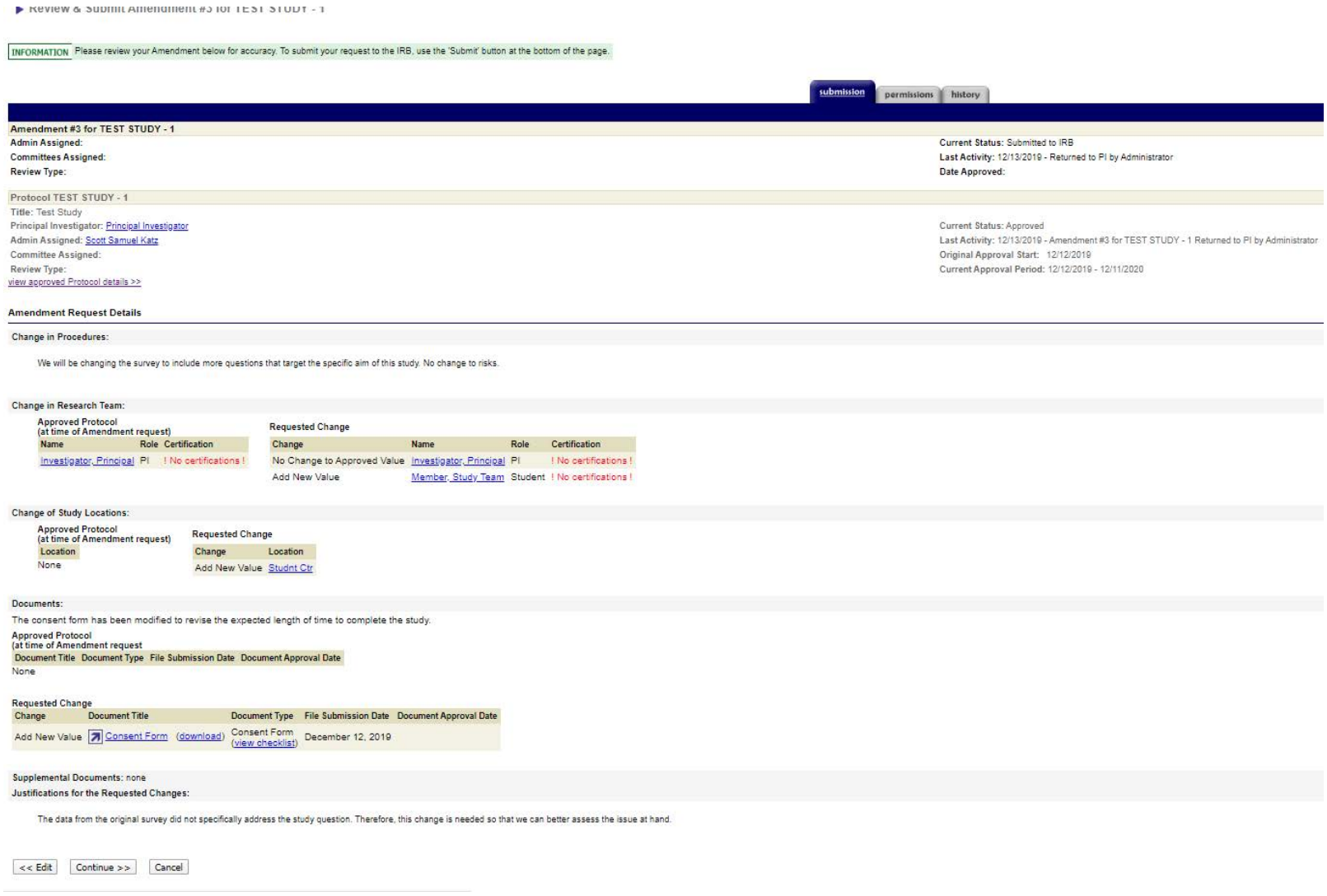
Save and Stay Here | Save and Finish Later | Save and Continue Amendment

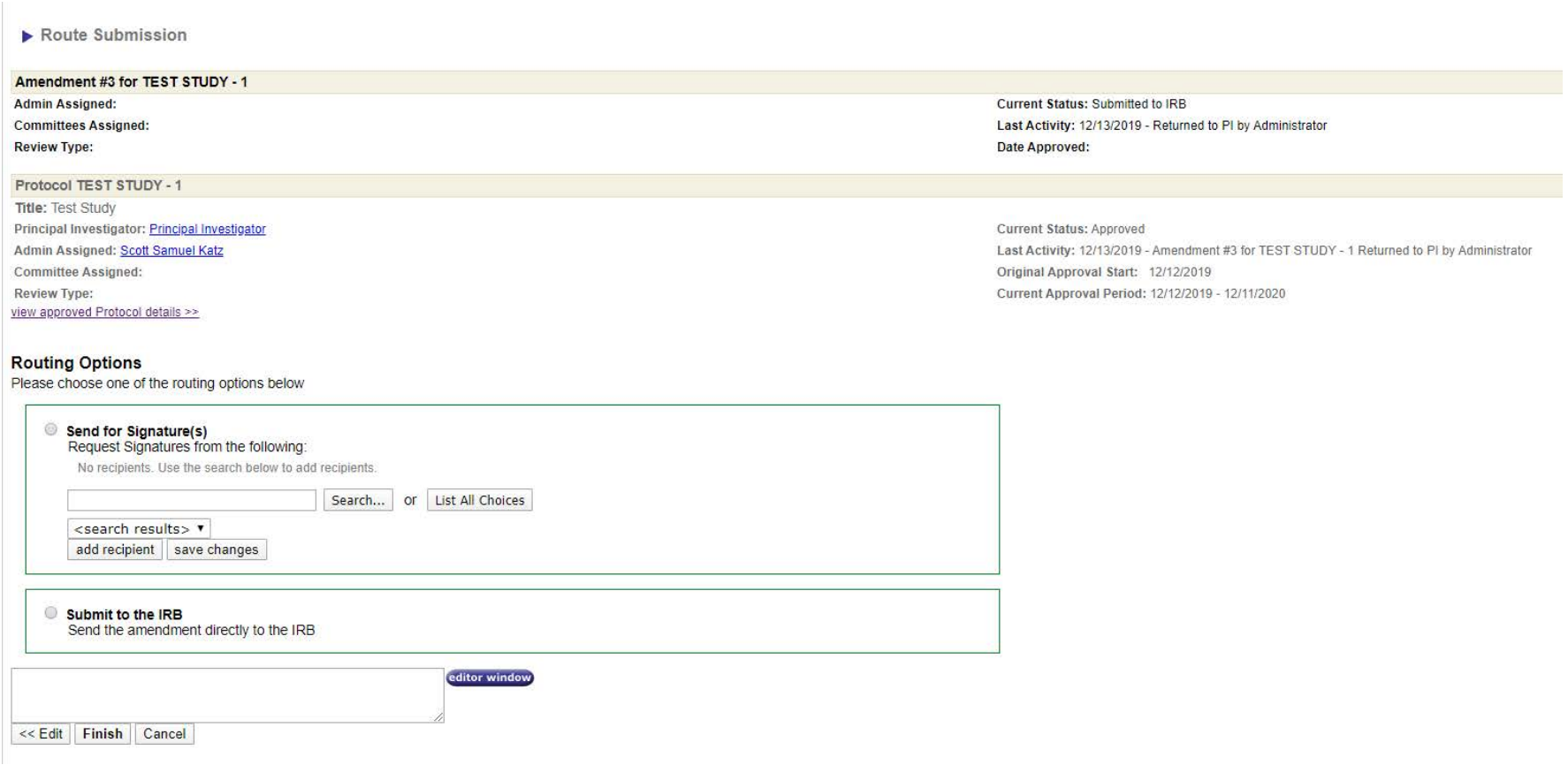
When finished making all of the changes in the amendment submission, please answer the last question and state why these changes are needed to continue your project. You will need to justify all of the changes that are being requested in the amendment.

Amendment - Review Submission



After clicking “Save and Continue Amendment,” you will be brought back to your full submission to review. If everything looks accurate, then please click "Continue." If changes need to be made, then please click "Edit."

Submitting the Amendment for IRB Review



After clicking “Continue,” you will be brought to this screen. If you are the PI of the study, then please select "Submit to the IRB." If you are not the PI or a Co-PI of the study, then please select "Send for Signature" and send to the PI or Co-PI of the study so they can sign-off on the amendment before submitting to the IRB.

Congratulations! You have officially submitted your amendment to the IRB.

Please contact the Office of Research Integrity Assurance if you have any questions regarding the submission process.

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