

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

IRB WISE™

Home Feedback Logout

Search by Protocol Number: Go

Tasks: Select One
Welcome to IRBWISE, Principal Investigator.

► Protocols for Principal Investigator

alerts **my protocols** my account

Show: All of My Submissions

Page: [1] 2 | Show All

Submission	Protocol Title	Current Status	Current Approval Period	Last Update
Amendment #1 for TEST STUDY - 1	Test Study	Approved		12/12/2019
Protocol TEST STUDY - 1	Test Study	Approved	12/12/2019 - 12/11/2020	12/12/2019
Protocol		New		02/19/2018
Protocol		New		02/06/2018
Protocol TEST2016	Examining the clinical motivations for personalized health technology	Withdrawn		08/26/2016
Protocol		New		07/22/2016
Protocol	Demo BME 1300	Withdrawn		06/02/2016
Protocol	BME1300	Withdrawn		06/02/2016
Protocol	Test 123	New		01/19/2016
Protocol	Demo for HCI	Withdrawn		08/28/2015
Protocol Test123	Renu Test with OIT 508	Closed	11/22/2013 - 11/21/2014	09/22/2014
Protocol	testing #2 mpowell	New		11/22/2013
Protocol	Test Protocol	Withdrawn		04/09/2009
Protocol	222	Withdrawn		10/29/2008
Protocol	Test Protocol	Withdrawn		10/29/2008
Protocol	BME 1300 Demo 2008	Withdrawn		10/29/2008
Protocol	BME PM Lab 2008	Withdrawn		10/29/2008
Investigator Brochure #1 for null	222	Withdrawn		09/03/2008
Protocol	bmed1300 demo protocol	Withdrawn		10/11/2006
Protocol	BME 1300-	Withdrawn		10/11/2006

Total count: 20

Page: [1] 2 | Show All

TOP

Visit the [Georgia Tech IRB Website](#)
All e-mail will go to sudagar.sundaram@gttri.gatech.edu instead of the real recipient.

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

The screenshot displays the IRB WISE web application interface. At the top right, there are links for Home, Feedback, and Logout. Below the header, a search bar is present with the text "Search by Protocol Number:" and a "Go" button. A progress bar shows the protocol's status: "With PI", "With Department Head Approval", "Submitted to IRB", "Under Review", and "Final Disposition". The "Under Review" status is currently active. Below the progress bar, there are tabs for "submission", "permissions", and "history". The main content area shows the "Protocol TEST STUDY - 1" summary, including fields for Title, Principal Investigator, Admin Assigned, Committee Assigned, and Review Type. A "Tasks" dropdown menu is open on the right side, listing various actions: "Select One", "Grant Access to Protocol", "Report Adverse Event", "Report Deviation", "Report SAE", "Report Study Closure", "Request Amendment", and "Request Continuing Review". The "Request Amendment" option is circled in red. At the bottom of the page, there is a footer with contact information for the Georgia Tech IRB Website and a note about email routing.

IRB WISE™

Home Feedback Logout

Search by Protocol Number: Go

Tasks: Select One

Summary of Protocol TEST STUDY - 1

With PI With Department Head Approval Submitted to IRB Under Review Final Disposition

submission permissions history

summary details

Protocol TEST STUDY - 1

Title: Test Study

Principal Investigator: [Principal Investigator](#)

Admin Assigned: [Scott Samuel Katz](#)

Committee Assigned:

Review Type:

Current Status: Approved

Last Activity: 12/12/2019 - Amendment #1 for TEST STUDY - 1 Approved by IRB

Original Approval Start: 12/12/2019

Current Approval Period: 12/12/2019 - 12/11/2020

Report Study Closure

Request Amendment

Request Continuing Review

print

Protocol Summary

Protocol Description:

Protocol Department:

Research Personnel: [1 personnel](#)

Researcher Certifications: **! 1 researcher has no active certification !**

Amendments: [1 Amendment request created](#), 1 approved

Continuing Reviews: none

SAE's/Adverse Event's: none

Protocol Deviations: 0 Protocol Deviations created
[Report Protocol Deviation](#)

Study Closures: 0 Study Closures created

Research Funding: none

Research Locations: none

Research Subjects: none

Vulnerable Populations: none

Key Words: none

Documents: none

TOP

Visit the [Georgia Tech IRB Website](#)

All e-mail will go to sudagar.sundaram@gtri.gatech.edu instead of the real recipient.

Page generated on December 12, 2019 12:27 PM
IRB Wise v 2.3.7 (0003494)

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

Type of Amendment

► Request Amendment

INFORMATION Enter Amendment information and submit at the bottom of this page.

Amendment for TEST STUDY - 1

Admin Assigned:

Committees Assigned:

Review Type:

Current Status: New

Last Activity: 12/12/2019 - Created

Date Approved:

Protocol TEST STUDY - 1

Title: Test Study

Principal Investigator: [Principal Investigator](#)

Admin Assigned: [Scott Samuel Katz](#)

Committee Assigned:

Review Type:

[view approved Protocol details >>](#)

Current Status: Approved

Last Activity: 12/12/2019 - Amendment #2 for TEST STUDY - 1 Approved by IRB

Original Approval Start: 12/12/2019

Current Approval Period: 12/12/2019 - 12/11/2020

Please Select the Type of Change You Wish to Make:

Personnel Only Personnel And/Or Other Changes

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

[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

Type of Amendment:	
Changes in Procedures/ Protocol	<p>Describe the requested changes and how they affect the risk/benefits of Protocol:</p> <p>We will be changing the survey to include more questions that target the specific aim of this study. No change to risks. editor window</p> <p>Associate a document having the Description of the Procedures at the Associate Documents section.</p>
Change in Study Personnel	Add/Modify Certified Personnel
Change of Site	Add/Modify Site Location
Change in Enrollment	Current approved#: <input type="text"/> resulting total to be enrolled: <input type="text"/>
Change in Consent Procedures	Add/Modify Consent Procedures
Change in Consent Form	<p>Add/Modify Consent Form</p> <p>Explain the reason for changing the Consent form:</p> <p>The consent form has been modified to revise the expected length of time to complete the study. editor window</p>
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:	
<p>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</p>	
<input type="button" value="Save and Stay Here"/> <input type="button" value="Save and Finish Later"/> <input type="button" value="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:	<input type="text" value="Member, Study Team ()"/>
Select Role:	<input type="text" value="Student"/>
Proof of Experience & Certifications: Upload your current CV or resume. Include any license & certification such as medical license.	Attach Files: <input type="button" value="Choose File"/> No file chosen
	<input type="button" value="Choose File"/> No file chosen
	Attach More..
	<input type="button" value="Add This Person"/> <input type="button" value="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
<input checked="" type="radio"/> Investigator, Principal	PI	No Change to Approved Value	

▶ [Click Here to view the description for each Status Type\(s\)](#)

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

► Associate Study Personnel

SUCCESS Person Added successfully, scroll down to confirm.

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

► [View their certifications](#)

Select Person:	<input type="text" value="please start typing"/>
Select Role:	<input type="text" value="Select One"/>
Proof of Experience & Certifications: Upload your current CV or resume. Include any license & certification such as medical license.	Attach Files: <input type="button" value="Choose File"/> No file chosen
	<input type="button" value="Choose File"/> No file chosen Attach More..
	<input type="button" value="Add This Person"/> <input type="button" value="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	Document
<input type="radio"/> Investigator, Principal	PI	No Change to Approved Value	
<input type="radio"/> Member, Study Team	Student	Add New Value	

► [Click Here to view the description for each Status Type\(s\)](#)

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

[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

► Associate Locations

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

Associate Location(s):

Select Location:

Search or

(If there is a location associated with the Protocol which is not in the list above, [click here.](#))

List of Study Locations Associated:

All Active Locations from this list will replace the existing list of approved locations only when the Amendment is approved by the IRB.
hint: Please note that you can reactivate locations with status "Approved,deleted" only.

Select	Status
None	

► [Click Here to view the description for each Status.Type\(s\)](#)

Associate Other Location(s):

Short Name:	<input type="text"/>
Long Name:	<input type="text"/>
Address Line1:	<input type="text"/>
Address Line2:	<input type="text"/>
City:	<input type="text"/>
State:	<input type="text"/>
Zip:	<input type="text"/>
Country:	<input type="text"/>

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

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

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

[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
<input type="checkbox"/> Written Consent Required	Signed consent will be sought from the subject or from the subject's legally authorized representative.
<input type="checkbox"/> 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.
<input type="checkbox"/> 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)

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.

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](#)

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

► Attach Documents to Amendment for TEST STUDY - 1

SUCCESS Document added successfully.

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

Attach New Consent Forms:

Document Title:	<input type="text"/>
Delivery Method:	<input checked="" type="radio"/> Electronic Upload Select File: <input type="button" value="Choose File"/> No file chosen
Document Type:	Consent Form

Currently Attached Consent Forms

Select	Document Title	Document Type	Method Sent	File Name	Status	File Submission Date
<input checked="" type="radio"/>	Consent Form	Consent Form	Uploaded	Consent Form.docx (download)	Add New Value	December 12, 2019

- 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

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

[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

▶ Associate Funding

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

If externally funded, please type the last name of the PI in the text box and then select the corresponding grant from the drop down list.

PI and Grant Title:

(If there is a funding source associated with the Protocol which is not in the list above, [click here](#).)

List of Funding Sponsors Associated:

All Active Funding Sponsors from this list will replace the existing list of approved funding sponsors only when the Amendment is approved by the IRB.
hint: Please note that you can reactivate funding Sponsors with status "Approved,deleted" only.

Select	Grant Title
None	

▶ [Click Here to view the description for each Status Type\(s\)](#)

If internally funded (such as Foundation or start up funds), enter funding source(s) here

Grant title:

Sponsor Name

- 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

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

[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

► Associate Study Population

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

Select Vulnerable Population:

Select One

Add This Study Population

Continue with Application

List of Study Populations Associated:

All active populations from this list will replace the existing list of approved populations only when the Amendment is approved by the IRB.
hint: Please note that you can reactivate study populations with status "Approved,deleted" only.

Delete/Reactivate

None

Delete

Un-Delete

► [Click Here to view the description for each Status Type\(s\)](#)

- 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

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

[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

► Attach Documents to Amendment for TEST STUDY - 1

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

Attach New Documents:

Document Title:	<input type="text"/>
Delivery Method:	<input checked="" type="radio"/> Electronic Upload Select File: <input type="button" value="Choose File"/> No file chosen
Document Type:	Select One <input type="button" value="List of Suggested Documents"/>

Currently Attached Documents

Select	Document Title	Document Type	Method Sent	File Name
<input type="radio"/>	Consent Form	Consent Form	Uploaded	Consent Form.docx (download)
<input type="button" value="Modify/Replace"/>	<input type="button" value="Revert to Approved Version"/>	<input type="button" value="Delete"/>	<input type="button" value="Un-Delete"/>	

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

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

► REVIEW & SUBMIT AMENDMENT #3 FOR TEST STUDY - 1

INFORMATION Please review your Amendment below for accuracy. To submit your request to the IRB, use the 'Submit' button at the bottom of the page.

[submission](#) [permissions](#) [history](#)

Amendment #3 for TEST STUDY - 1

Admin Assigned: _____ **Current Status:** Submitted to IRB
Committees Assigned: _____ **Last Activity:** 12/13/2019 - Returned to PI by Administrator
Review Type: _____ **Date Approved:** _____

Protocol TEST STUDY - 1

Title: Test Study **Current Status:** Approved
Principal Investigator: [Principal Investigator](#) **Last Activity:** 12/13/2019 - Amendment #3 for TEST STUDY - 1 Returned to PI by Administrator
Admin Assigned: [Scott Samuel Katz](#) **Original Approval Start:** 12/12/2019
Committee Assigned: _____ **Current Approval Period:** 12/12/2019 - 12/11/2020
Review Type: _____
[view approved Protocol details >>](#)

Amendment Request Details

Change in Procedures:

We will be changing the survey to include more questions that target the specific aim of this study. No change to risks.

Change in Research Team:

Approved Protocol (at time of Amendment request)	Requested Change
Name Role Certification	Change Name Role Certification
Investigator_Principal PI ! No certifications !	No Change to Approved Value Investigator_Principal PI ! No certifications !
	Add New Value Member_Study_Team Student ! No certifications !

Change of Study Locations:

Approved Protocol (at time of Amendment request)	Requested Change
Location	Change Location
None	Add New Value: Studet Ctr

Documents:

The consent form has been modified to revise the expected length of time to complete the study.

Approved Protocol
(at time of Amendment request)

Document Title	Document Type	File Submission Date	Document Approval Date
None			

Requested Change

Change	Document Title	Document Type	File Submission Date	Document Approval Date
Add New Value	Consent Form (download)	Consent Form (view checklist)	December 12, 2019	

Supplemental Documents: none

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.

[<< Edit](#) [Continue >>](#) [Cancel](#)

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

► **Route Submission**

Amendment #3 for TEST STUDY - 1

Admin Assigned:	Current Status: Submitted to IRB
Committees Assigned:	Last Activity: 12/13/2019 - Returned to PI by Administrator
Review Type:	Date Approved:

Protocol TEST STUDY - 1

Title: Test Study	Current Status: Approved
Principal Investigator: Principal Investigator	Last Activity: 12/13/2019 - Amendment #3 for TEST STUDY - 1 Returned to PI by Administrator
Admin Assigned: Scott Samuel Katz	Original Approval Start: 12/12/2019
Committee Assigned:	Current Approval Period: 12/12/2019 - 12/11/2020
Review Type:	

[view approved Protocol details >>](#)

Routing Options
Please choose one of the routing options below

Send for Signature(s)
Request Signatures from the following:
No recipients. Use the search below to add recipients.

Search... or List All Choices

<search results> ▼

add recipient save changes

Submit to the IRB
Send the amendment directly to the IRB

editor window

<< Edit Finish Cancel

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.

Office of Research Integrity Assurance
Georgia Institute of Technology
Dalney Street Building
926 Dalney Street NW, Atlanta, GA 30332-0415
Email: IRB@gatech.edu
Website: <https://oria.gatech.edu/irb>