

IRB Wise Personnel Only 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Protocol TEST2016	Examining the clinical motivations for personalized health technology	Withdrawn		08/26/2016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Protocol	Demo BME 1300	Withdrawn		06/02/2016
Protocol	BME1300	Withdrawn		06/02/2016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Protocol	Demo for HCI	Withdrawn		08/28/2015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Protocol	Test Protocol	Withdrawn		04/09/2009
Protocol	222	Withdrawn		10/29/2008
Protocol	Test Protocol	Withdrawn		10/29/2008
Protocol	BME 1300 Demo 2008	Withdrawn		10/29/2008
Protocol	BME PM Lab 2008	Withdrawn		10/29/2008
Investigator Brochure #1 for null	222	Withdrawn		09/03/2008
Protocol	bmed1300 demo protocol	Withdrawn		10/11/2006
Protocol	BME 1300-	Withdrawn		10/11/2006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 a personnel only 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 IRBWISE 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 workflow stages: With PI, With Department Head Approval, Submitted to IRB, Under Review, and Final Disposition. The "Under Review" stage 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 (circled in red), and Request Continuing Review. Below the summary, there is a "Protocol Summary" section with a table of protocol details. At the bottom, there is a footer with contact information and a "TOP" button.

IRBWISE™

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

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

Visit the [Georgia Tech IRB Website](#)

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

TOP

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:

Current Status: New

Committees Assigned:

Last Activity: 12/12/2019 - Created

Review Type:

Date Approved:

Protocol TEST STUDY - 1

Title: Test Study

Current Status: Approved

Principal Investigator: [Principal Investigator](#)

Last Activity: 12/12/2019 - Continuing Review #1 for TEST STUDY - 1 Submitted to IRB

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 >>](#)

Please Select the Type of Change You Wish to Make:

Personnel Only Personnel And/Or Other Changes

Type of Amendment:

Change in Study Personnel ► [Add/Modify Certified Personnel](#)

Saves and Continue 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 personnel only amendments. Therefore, this presentation will show the path of selecting "Personnel Only" (circled in red).

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](#):

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List of Study Personnel currently associated:

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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).

Personnel Only Amendment

▶ Request Amendment

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

Amendment for TEST STUDY - 1
Admin Assigned: Current Status: New
Committees Assigned: Last Activity: 12/12/2019 - Created
Review Type: Date Approved:

Protocol TEST STUDY - 1
Title: Test Study Current Status: Approved
Principal Investigator: [Principal Investigator](#) Last Activity: 12/12/2019 - Continuing Review #1 for TEST STUDY - 1 Submitted to IRB
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 >>](#)

Please Select the Type of Change You Wish to Make:

Personnel Only Personnel And/Or Other Changes

Type of Amendment:

Change in Study Personnel ▶ [Add/Modify Certified Personnel](#)

Saves and Continue Amendment

When finished making the personnel changes, please click "Save and Continue Amendment" (circled in red).

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:

Committees Assigned:

Review Type:

Current Status: Submitted to IRB

Last Activity: 12/13/2019 - Returned to PI by Administrator

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: 12/13/2019 - Amendment #3 for TEST STUDY - 1 Returned to PI by Administrator

Original Approval Start: 12/12/2019

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

Amendment Request Details

Change in Procedures:

Personnel Only Change

Change in Research Team:

Approved Protocol
(at time of Amendment request)

Name	Role	Certification
Investigator_Principal	PI	! No certifications !

Requested Change

Change	Name	Role	Certification
No Change to Approved Value	Investigator_Principal	PI	! No certifications !
Add New Value	Member_Study_Team	Student	! No certifications !

<< 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 personnel only 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
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926 Dalney Street NW, Atlanta, GA 30332-0415
Email: IRB@gatech.edu
Website: <https://oria.gatech.edu/irb>