

IRB Wise Protocol Deviation Example and Guidance

This presentation includes an example of a protocol deviation 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Protocol TEST2016	Examining the clinical motivations for personalized health technology	Withdrawn		08/26/2016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Protocol	Demo BME 1300	Withdrawn		06/02/2016
Protocol	BME1300	Withdrawn		06/02/2016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Protocol	Demo for HCI	Withdrawn		08/28/2015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Protocol	Test Protocol	Withdrawn		04/09/2009
Protocol	222	Withdrawn		10/29/2008
Protocol	Test Protocol	Withdrawn		10/29/2008
Protocol	BME 1300 Demo 2008	Withdrawn		10/29/2008
Protocol	BME PM Lab 2008	Withdrawn		10/29/2008
Investigator Brochure #1 for null	222	Withdrawn		09/03/2008
Protocol	bmed1300 demo protocol	Withdrawn		10/11/2006
Protocol	BME 1300-	Withdrawn		10/11/2006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

To submit a protocol deviation, please click “My Protocols” (circled in red) at the top of the screen and then select the study that the deviation is associated with.

Requesting a Protocol Deviation

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 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 'Final Disposition' step 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 details like Title, Principal Investigator, Admin Assigned, and Current Status. A dropdown menu is open on the right side, listing various tasks, with 'Report Deviation' highlighted by a red circle. 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 page generation timestamp.

IRBWISE™

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 Adverse Event

Report Deviation

Report SAE

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

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
IRBwise v.2.3.7 (0003494)

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

Protocol Deviation - Submission

Report Protocol Deviation or Violation

A protocol deviation or violation is defined as any change to, or departure from, the approved protocol that is not approved by the IRB prior to its initiation or implementation, OR any deviation from standard operating procedures, Good Clinical Practices (GCPs), federal regulations, or institute policies.

A * required * Describe the protocol deviation or violation, and provide the date(s) when the deviation occurred.

We over-enrolled by 5 subjects. The study was approved for 20 subjects and we enrolled 25. These subjects enrolled and participated in the study procedures on 12/10/19. No identifiable or sensitive information was

File Uploaded:

upload file

B * required * Why did the protocol deviation or violation occur?

This deviation occurred due to an oversight by the study team. The researchers were not regularly keeping track of how many subjects were being enrolled, until 12/11/19, which is when we found that we had over-

File Uploaded:

upload file

C * required * What is the impact on the study and on subjects? What steps have been taken to resolve this situation?

No impact on the subjects, as they all consented to be in the study and no additional risks were present due to this oversight. To resolve this situation, we have submitted an amendment to request an increase in the

File Uploaded:

upload file

D * required * Describe all measures to be taken to ensure this protocol or violation does not happen again?

To prevent this from happening again, we have updated our procedures to check the enrollment daily. Furthermore, we are in the process of re-training all of our study staff.

File Uploaded: CAPA.docx

upload file

E Will the research project continue?

- No. Provide provide the reason below
 Yes

editor window

F Has the deviation or violation been reported to the research sponsor or to any federal agency? If so, state to whom a report was made and provide copies of any written correspondence.

- No, a report has not been made
 Yes, a report was made

N/A

File Uploaded:

upload file

Save Continue >> Cancel

The Protocol Deviation submission requests information about the incident, how you intend to address the issue, and how you intend to prevent similar issues from reoccurring. When filling out this submission, please be sure to upload your CAPA document to question D. A template can found on our Forms page (<https://oria.gatech.edu/irb/submitting-protocol/forms>). When finished, please click "Continue" at the bottom of the screen.

Protocol Deviation - Submission

► Review Protocol Deviation

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 #3 for TEST STUDY - 1 Submitted to IRB

Original Approval Start: 12/12/2019

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

Report Protocol Deviation or Violation

A protocol deviation or violation is defined as any change to, or departure from, the approved protocol that is not approved by the IRB prior to its initiation or implementation, OR any deviation from standard operating procedures, Good Clinical Practices (GCPs), federal regulations, or institute policies.

A *required* Describe the protocol deviation or violation, and provide the date(s) when the deviation occurred.

We over-enrolled by 5 subjects. The study was approved for 20 subjects and we enrolled 25. These subjects enrolled and participated in the study procedures on 12/10/19. No identifiable or sensitive information was collected.

[View Uploaded File: ""](#) (download)

B *required* Why did the protocol deviation or violation occur?

This deviation occurred due to an oversight by the study team. The researchers were not regularly keeping track of how many subjects were being enrolled, until 12/11/19, which is when we found that we had over-enrolled.

[View Uploaded File: ""](#) (download)

C *required* What is the impact on the study and on subjects? What steps have been taken to resolve this situation?

No impact on the subjects, as they all consented to be in the study and no additional risks were present due to this oversight. To resolve this situation, we have submitted an amendment to request an increase in the enrollment numbers.

[View Uploaded File: ""](#) (download)

D *required* Describe all measures to be taken to ensure this protocol or violation does not happen again?

To prevent this from happening again, we have updated our procedures to check the enrollment daily. Furthermore, we are in the process of re-training all of our study staff.

[View Uploaded File: "CAPA.docx"](#) (download)

E Will the research project continue?

Yes

F Has the deviation or violation been reported to the research sponsor or to any federal agency? If so, state to whom a report was made and provide copies of any written correspondence.

No, a report has not been made

N/A

[View Uploaded File: "null"](#) (download)

<< Edit | **Continue >>** | Cancel

After clicking "Continue," you will be asked to review the information provided. If the information is complete and correct, then please click "Continue" again. If not, then please click "Edit" to return to the previous screen.

Protocol Deviation - Submission

► **Route Submission**

Protocol Deviation/Violation #1 for TEST STUDY - 1

Admin Assigned:	Current Status: Submitted to IRB
Committees Assigned:	Last Activity: 12/20/2019 - 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: 12/20/2019 - Protocol Deviation/Violation #1 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 protocol deviation report directly to the IRB

editor window

<< Edit Finish Cancel

After clicking "Continue," you will be prompted to officially submit the Protocol Deviation. Please select "Submit to the IRB" and click "Finish" when ready to submit. Please click "Edit" if the submission is not ready to be submitted.

Congratulations! You have officially submitted your protocol deviation 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>