

IRB Wise Adverse Event Example and Guidance

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Protocol TEST2016	Examining the clinical motivations for personalized health technology	Withdrawn		08/26/2016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Protocol	Demo BME 1300	Withdrawn		06/02/2016
Protocol	BME1300	Withdrawn		06/02/2016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Protocol	Demo for HCI	Withdrawn		08/28/2015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Protocol	Test Protocol	Withdrawn		04/09/2009
Protocol	222	Withdrawn		10/29/2008
Protocol	Test Protocol	Withdrawn		10/29/2008
Protocol	BME 1300 Demo 2008	Withdrawn		10/29/2008
Protocol	BME PM Lab 2008	Withdrawn		10/29/2008
Investigator Brochure #1 for null	222	Withdrawn		09/03/2008
Protocol	bmed1300 demo protocol	Withdrawn		10/11/2006
Protocol	BME 1300-	Withdrawn		10/11/2006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

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

Reporting an Adverse Event

The screenshot displays the IRBWISE web application interface. At the top right, there are links for Home, Feedback, and Logout. Below the search bar, 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 summary for 'TEST STUDY - 1', 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 Adverse Event' highlighted by a red circle. At the bottom, there is a 'Protocol Summary' section with a table of protocol details and a 'print' button.

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

Grant Access to Protocol

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@gti.gatech.edu instead of the real recipient.

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 "Report Adverse Event."

Adverse Event - Submission

Search by Protocol Number: Go Tasks: **Select One** Welcome to IRBWISE, Principal Investigator.

▶ Report Adverse Event **With PI** With Department Head Approval Submitted to IRB Under Review Final Disposition

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

AE #1 for TEST STUDY - 1 As Of: March 2, 2020 11:06 AM

Admin Assigned:	Current Status: Submitted to IRB
Committees Assigned:	Last Activity: 03/02/2020 - Returned to PI by Administrator
Review Type:	Date Acknowledged:

Protocol TEST STUDY - 1 As Of: March 2, 2020 11:06 AM

Title: Test Study	Current Status: Approved
Principal Investigator: Principal Investigator	Last Activity: 03/02/2020 - SAE #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 >>](#)

Adverse Event Form:

Where was the subject enrolled?	<input type="text" value="Off Site"/>
Date of Adverse Event:	December 20 2019
Provide a description of the Adverse Event: <small>(max 4000 chars.)</small>	<div style="border: 1px solid gray; padding: 5px;"><p>One subject fainted while giving blood. The procedures followed the approved procedures and the event was not unexpected (listed as a risk in the consent form and in the submission). The subject was promptly treated by the STAMPS staff, who followed standard of care for this situation. The subject was then monitored for the next hour until the STAMPS staff cleared the subject to leave on his/her own.</p></div> editor window
Associated Documentation	▶ Upload Documents

When reporting an Adverse Event, you will need to fully describe the issue that occurred, when the issue occurred, and where the issue occurred. Furthermore, you will need to discuss if this event was anticipated or unanticipated. If you have any accompanying documents, then please click "Upload Documents" so that they can also be reviewed.

Adverse Event - Submission

▶ Attach Documents to AE #1 for TEST STUDY - 1

Attach New Documents:

Document Title:	<input type="text" value="AE 1 Description"/>
Delivery Method:	<input checked="" type="radio"/> Electronic Upload Select File: <input type="button" value="Choose File"/> AE_1_Description.docx
Document Type:	<input type="text" value="Other Documents"/>

Currently Attached Documents

None

After clicking "Upload Documents," you will be asked to provide a title for the document, the document type, and then to upload the document. When ready, click "Attach the Document." After all documents have been uploaded, please click "Continue Application."

Adverse Event - Submission

Search by Protocol Number: Go Tasks: **Select One**
Welcome to IRBWISE, Principal Investigator.

▶ Report Adverse Event **With PI** ◯ With Department Head Approval ◯ Submitted to IRB ◯ Under Review ◯ Final Disposition

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

AE #1 for TEST STUDY - 1 As Of: March 2, 2020 11:06 AM
Admin Assigned: Current Status: Submitted to IRB
Committees Assigned: Last Activity: 03/02/2020 - Returned to PI by Administrator
Review Type: Date Acknowledged:

Protocol TEST STUDY - 1 As Of: March 2, 2020 11:06 AM
Title: Test Study Current Status: Approved
Principal Investigator: [Principal Investigator](#) Last Activity: 03/02/2020 - SAE #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 >>

Adverse Event Form:

Where was the subject enrolled?

Date of Adverse Event:

Provide a description of the Adverse Event: editor window

Associated Documentation [▶ Upload Documents](#)

When ready to submit the Adverse Event, please click "Save and Continue Form."

Adverse Event - Submission

Search by Protocol Number: Go Tasks:
 Welcome to IRBWISE, Principal Investigator.

► Review AE #1 for TEST STUDY - 1

AE #1 for TEST STUDY - 1 As Of: March 2, 2020 11:17 AM

Admin Assigned: Current Status: Submitted to IRB
Committees Assigned: Last Activity: 03/02/2020 - Returned to PI by Administrator
Review Type: Date Acknowledged:

Protocol TEST STUDY - 1 As Of: March 2, 2020 11:17 AM

Title: Test Study Current Status: Approved
Principal Investigator: [Principal Investigator](#) Last Activity: 03/02/2020 - SAE #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: < edit print ^ submit >
[view approved Protocol details >>](#)

Adverse Event Report Details

Date of Adverse Event:	December 20, 2019								
Where was the subject enrolled?	Off Site								
Description of the Adverse Event:	One subject fainted while giving blood. The procedures followed the approved procedures and the event was not unexpected (listed as a risk in the consent form and in the submission). The subject was promptly treated by the STAMPS staff, who followed standard of care for this situation. The subject was then monitored for the next hour until the STAMPS staff cleared the subject to leave on his/her own.								
List of attached documents:	<table border="1"><thead><tr><th>Document Title</th><th>Document Type</th><th>File Submission Date</th><th>Document Approval Date</th></tr></thead><tbody><tr><td>AE 1 Description (download)</td><td>Other Documents</td><td>March 2, 2020</td><td></td></tr></tbody></table>	Document Title	Document Type	File Submission Date	Document Approval Date	AE 1 Description (download)	Other Documents	March 2, 2020	
Document Title	Document Type	File Submission Date	Document Approval Date						
AE 1 Description (download)	Other Documents	March 2, 2020							
Supplemental Documents:	<table border="1"><thead><tr><th>File Name</th><th>Submitted Date</th><th>Submitted By</th></tr></thead><tbody><tr><td>None</td><td></td><td></td></tr></tbody></table>	File Name	Submitted Date	Submitted By	None				
File Name	Submitted Date	Submitted By							
None									

Comments:

[editor window](#)

File Uploaded: [upload file](#)

[Edit Adverse Event Information](#) [Submit Adverse Event to the IRB >>](#)

After clicking "Save and Continue Form," you will be asked to review the form one more time. Please ensure that the form is accurate and correct. When you are ready to submit the form, please click "Submit Adverse Event to the IRB." This will send the event directly to the IRB.

Congratulations! You have officially submitted your adverse event 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>