

IRB Wise Serious Adverse Event (SAE) Example and Guidance

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Protocol TEST2016	Examining the clinical motivations for personalized health technology	Withdrawn		08/26/2016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Protocol	Demo BME 1300	Withdrawn		06/02/2016
Protocol	BME1300	Withdrawn		06/02/2016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Protocol	Demo for HCI	Withdrawn		08/28/2015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Protocol	Test Protocol	Withdrawn		04/09/2009
Protocol	222	Withdrawn		10/29/2008
Protocol	Test Protocol	Withdrawn		10/29/2008
Protocol	BME 1300 Demo 2008	Withdrawn		10/29/2008
Protocol	BME PM Lab 2008	Withdrawn		10/29/2008
Investigator Brochure #1 for null	222	Withdrawn		09/03/2008
Protocol	bmed1300 demo protocol	Withdrawn		10/11/2006
Protocol	BME 1300-	Withdrawn		10/11/2006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

The screenshot displays the IRBWISE web application interface. At the top, there is a search bar for Protocol Number and navigation 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 main content area is titled "Protocol TEST STUDY - 1" and includes tabs for submission, permissions, and history. A dropdown menu is open, showing options such as "Grant Access to Protocol", "Report Adverse Event", "Report Deviation", "Report SAE", "Report Study Closure", "Request Amendment", and "Request Continuing Review". The "Report SAE" option is circled in red. Below the dropdown, the protocol summary is displayed, including details like Title, Principal Investigator, Admin Assigned, Committee Assigned, Review Type, Current Status, Last Activity, Original Approval Start, and Current Approval Period. A "Protocol Summary" section follows, listing various protocol details such as Protocol Description, Department, Research Personnel, Certifications, Amendments, Reviews, SAEs, Deviations, Closures, Funding, Locations, Subjects, Populations, Keywords, and Documents. At the bottom, there is a footer with contact information for the Georgia Tech IRB Website and a note about email routing.

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

SAE - Submission

SAE Form:

Where was the subject enrolled?	Off Site
Date of SAE:	December 20 2019
Subject's Initials or Study #:	SSK
Type of Report:	Initial
Number of Subjects currently enrolled:	Locally: 10 Total, if multi-center study: 0
Number of SAE's that have occurred:	On site: 0 Off site: 1
Research Involved:	<input type="checkbox"/> Procedure <input type="checkbox"/> Drug Name of Drug(s): <input checked="" type="checkbox"/> Device Name of Device(s): Exoskeleton
Has this type of SAE been reported before?	No
Could this type of SAE occur again?	Yes
Has the SAE been reported to the Sponsor/Federal Agency?	Yes If yes, Date Reported: December 22 2019
The SAE occurred:	within 30 days of treatment
Was the event associated with or the cause of any the following?	Severe or Permanent Disability
If other, provide a brief description:	<input type="text"/> editor window
Is it possible or likely that the SAE was caused by the drug, device, or procedure?	Yes
Has the consent form been revised as a result of the SAE?	Yes If yes, enter date the Amendment was filed: January 5 2020
If consent has not been revised, please explain why changes to the consent form are unnecessary based on the SAE	<input type="text"/> editor window
A narrative, and supporting documentation describing the SAE, MUST be associated with this form.	Upload Documents
<input type="button" value="Save and Stay Here"/> <input type="button" value="Save and Finish Later"/> <input type="button" value="Save and Submit Form >>"/>	

When reporting an SAE, you will need to fully describe the issue that occurred by completing the whole section. Additionally, you will need to provide a narrative that fully describes the event. This narrative must be uploaded in the "Upload Documents" section circled in red.

SAE - Submission

▶ Attach Documents to SAE for TEST STUDY - 1

Attach New Documents:

Document Title:	<input type="text" value="SAE Event Detailed Description"/>
Delivery Method:	<input checked="" type="radio"/> Electronic Upload Select File: <input type="button" value="Choose File"/> SAE Event D...iption.docx
Document Type:	<input type="text" value="Response to the IRB"/>

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."

SAE - Submission

▶ Attach Documents to SAE for TEST STUDY - 1

SUCCESS Document added successfully.

Attach New Documents:

Document Title:

Delivery Method: Electronic Upload Select File: No file chosen

Document Type:

Currently Attached Documents

Select	Document Title	Document Type	Method Sent	File Name	File Submission Date
<input type="radio"/>	SAE Event Detailed Description	Response to the IRB	Uploaded	SAE Event Detailed Description.docx (download)	January 10, 2020

When ready to continue, please click "Continue Application."

SAE - Submission

SAE Form:

Where was the subject enrolled?	Off Site
Date of SAE:	December 20 2019
Subject's Initials or Study #:	SSK
Type of Report:	Initial
Number of Subjects currently enrolled:	Locally: 10 Total, if multi-center study: 0
Number of SAE's that have occurred:	On site: 0 Off site: 1
Research Involved:	<input type="checkbox"/> Procedure <input type="checkbox"/> Drug Name of Drug(s): <input checked="" type="checkbox"/> Device Name of Device(s): Exoskeleton
Has this type of SAE been reported before?	No
Could this type of SAE occur again?	Yes
Has the SAE been reported to the Sponsor/Federal Agency?	Yes If yes, Date Reported: December 22 2019
The SAE occurred:	within 30 days of treatment
Was the event associated with or the cause of any the following?	Severe or Permanent Disability
If other, provide a brief description:	<div style="border: 1px solid gray; height: 40px; width: 100%;"></div> editor window
Is it possible or likely that the SAE was caused by the drug, device, or procedure?	Yes
Has the consent form been revised as a result of the SAE?	Yes If yes, enter date the Amendment was filed: January 5 2020
If consent has not been revised, please explain why changes to the consent form are unnecessary based on the SAE	<div style="border: 1px solid gray; height: 40px; width: 100%;"></div> editor window
A narrative, and supporting documentation describing the SAE, MUST be associated with this form.	Upload Documents
Save and Stay Here Save and Finish Later Save and Submit Form >>	

After uploading your documents, click "Save and Submit Form" when you are ready to submit the SAE.

SAE - Submission

SAE Report Details

Date of SAE:	December 20, 2019								
Where was the subject enrolled?	Off Site								
Subject's Initials or Study #	SSK								
Type of Report:	Initial								
Number of Subjects Currently Enrolled Locally:	10								
Total Number of Subjects Currently Enrolled (if multi-center study):	0								
Number of SAE's that have occurred:	0 On-site, 1 Off-site								
Research Involved:	Device: Exoskeleton								
Has this type of SAE been reported before?	No								
Could this type of SAE occur again?	Yes								
Has the SAE been reported to the sponsor?	Yes								
The SAE occurred:	Date Reported: December 22, 2019 11:46 AM within 30 days of treatment								
Was the event associated with or the cause of an of the following?	Severe or Permanent Disability								
Is it possible or likely that the SAE was caused by the drug, device, radiation, or procedure?	Yes								
Has the consent form been revised as a result of the SAE?	Yes								
Please explain why the changes to the consent form are unnecessary based on the SAE.	null								
List of attached documents:	<table><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>SAE Event Detailed Description (download)</td><td>Response to the IRB</td><td>January 10, 2020</td><td></td></tr></tbody></table>	Document Title	Document Type	File Submission Date	Document Approval Date	SAE Event Detailed Description (download)	Response to the IRB	January 10, 2020	
Document Title	Document Type	File Submission Date	Document Approval Date						
SAE Event Detailed Description (download)	Response to the IRB	January 10, 2020							
Supplemental Documents:	<table><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									

Comment:

editor window

File Uploaded:

upload file

Edit SAE Information

Submit Adverse Event to the IRB >>

After clicking "Save and Submit Form," you will be asked to review all of the information that you have provided. If this information is accurate, then please click "Submit Adverse Event to the IRB." If any information needs to be changed, then please click "Edit SAE Information."

Congratulations! You have officially submitted your SAE 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>