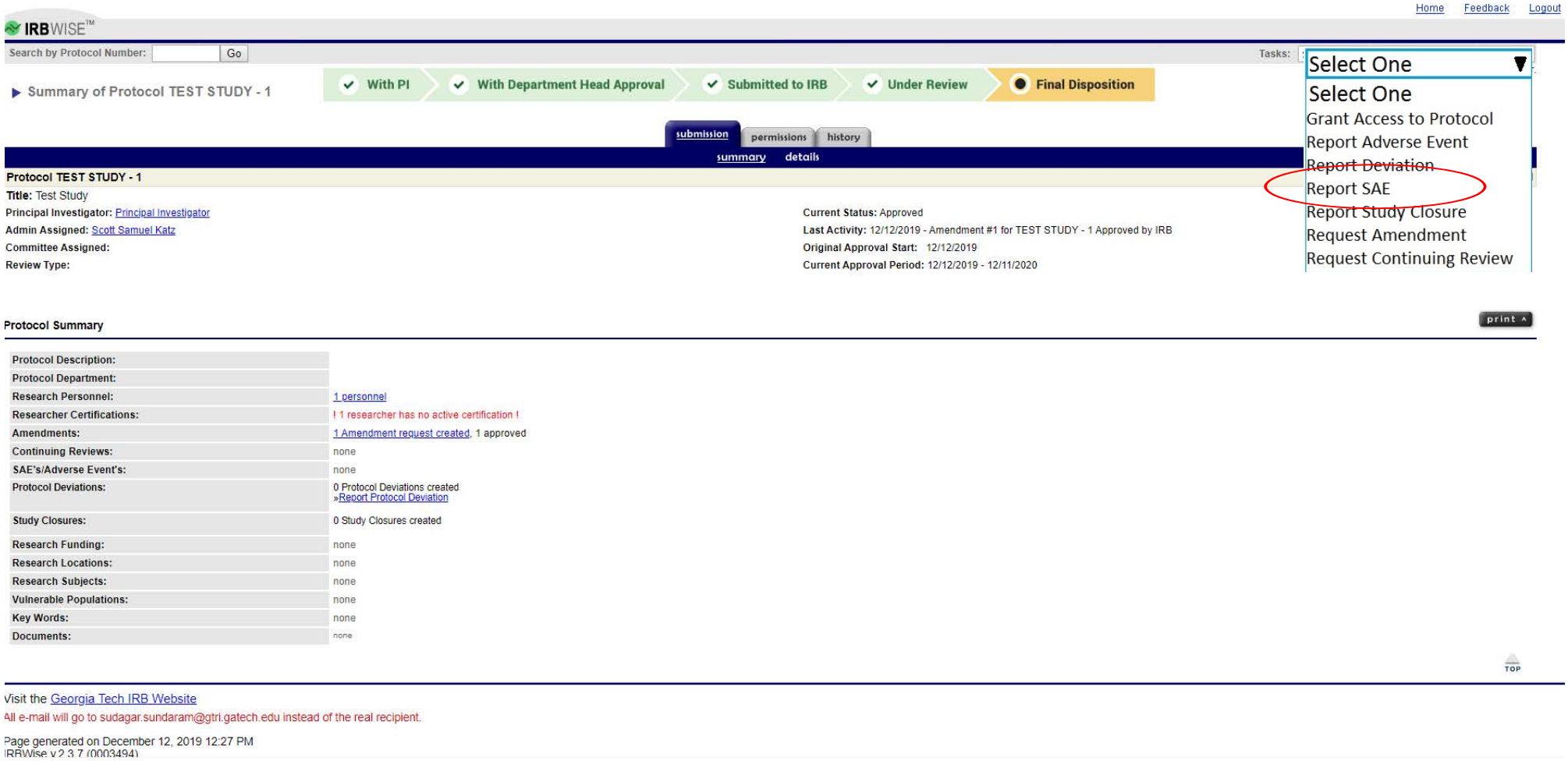
IRB Wise Serious Adverse Event (SAE) Example and Guidance

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

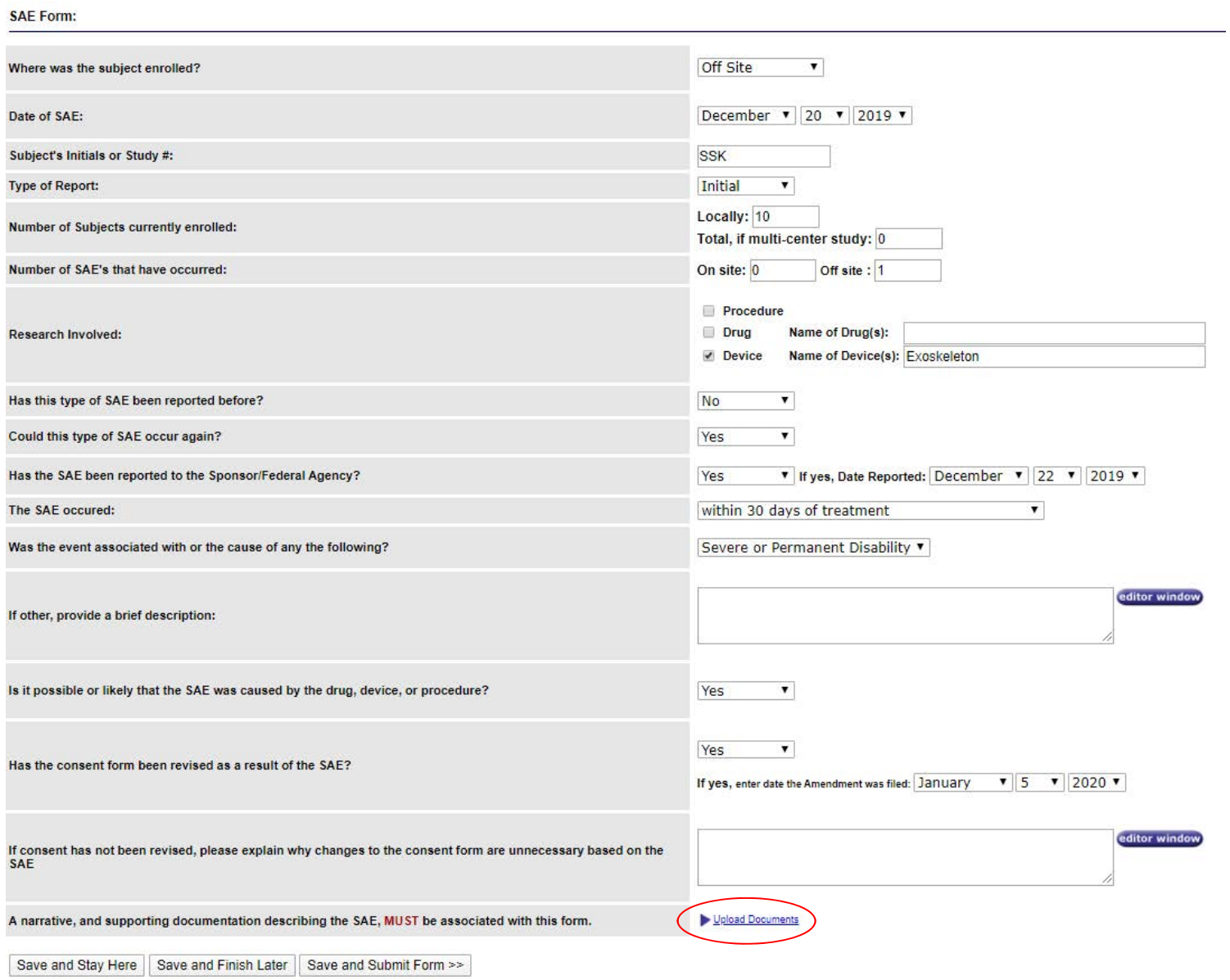
To submit an SAE, please click “My Protocols” (circled in red) at the top of the screen and then select the study that the event is associated with.

Reporting an SAE



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:	Procedure Drug Name of Drug(s): 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 occured:	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:	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	editor window
A narrative, and supporting documentation describing the SAE, MUST be associated with this form.	Upload Documents

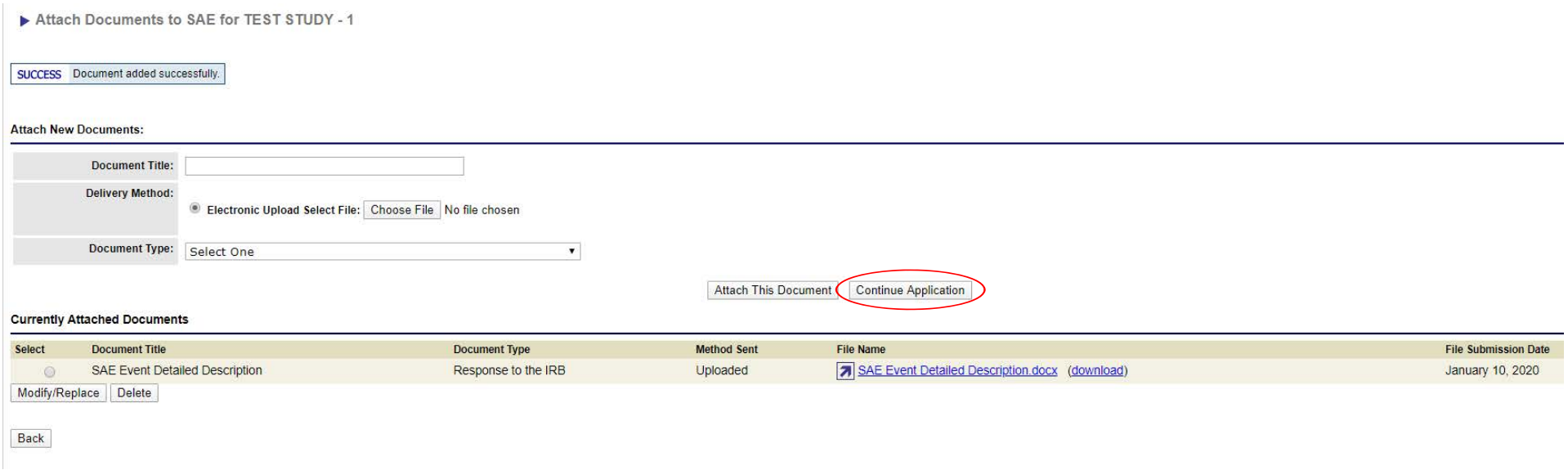
Save and Stay Here | Save and Finish Later | Save and Submit Form >>

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

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



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:	☐ Procedure ☐ Drug Name of Drug(s): ☑ 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 occured:	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:	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	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 occured:	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 Date Reported: December 22, 2019 11:46 AM
The SAE occured:	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:	Document Title: SAE Event Detailed Description (download) — Document Type: Response to the IRB — File Submission Date: January 10, 2020 — Document Approval Date:
Supplemental Documents:	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 infomration 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.

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