IRB Wise Adverse Event Example and Guidance

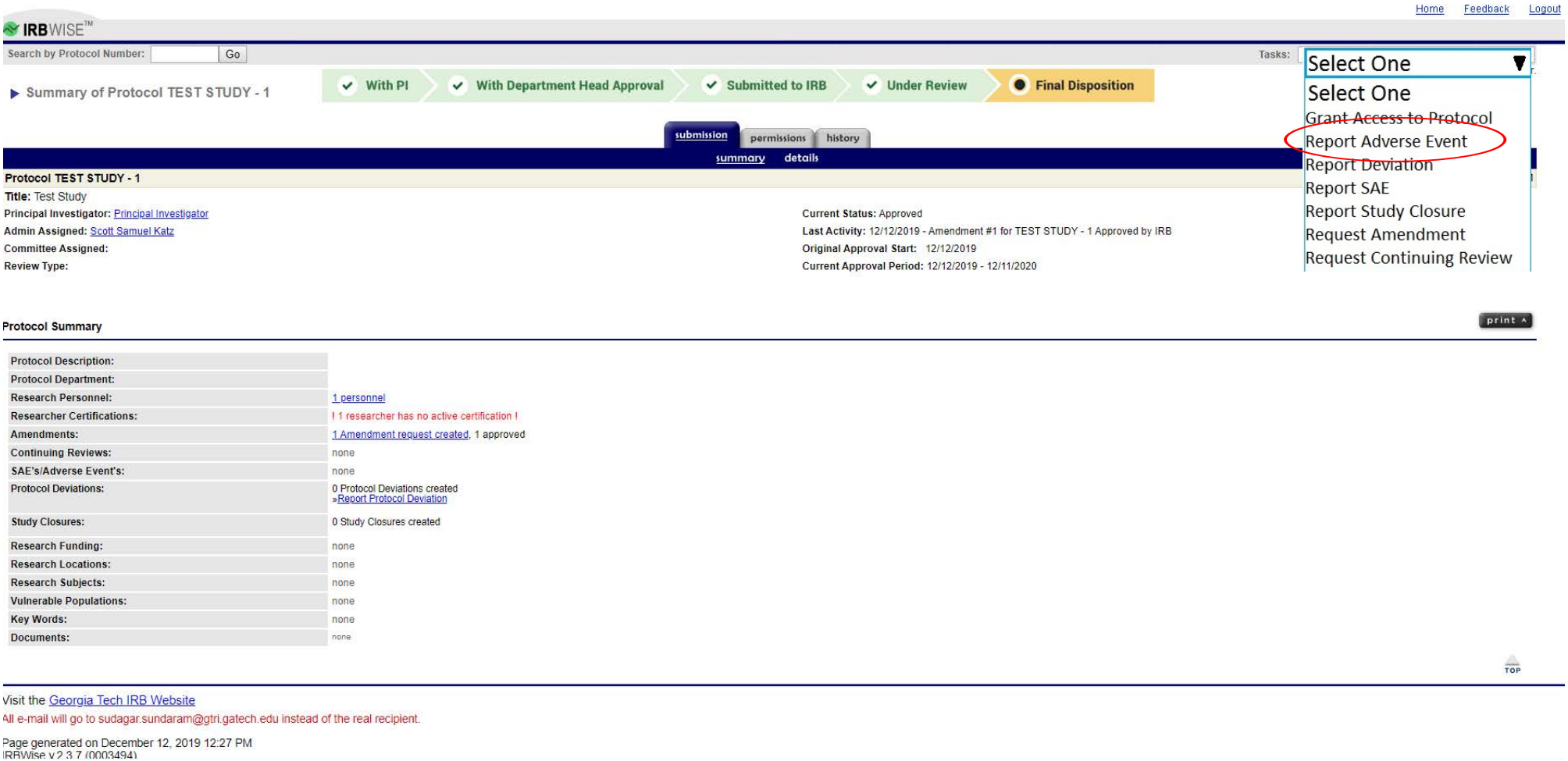
This presentation includes an example of an adverse event submission in IRB Wise and also includes guidance for each section of the submission. The screen shots are of an example and the responses are not to be taken as the correct response. Each study is different, and therefore each response and each 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

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.

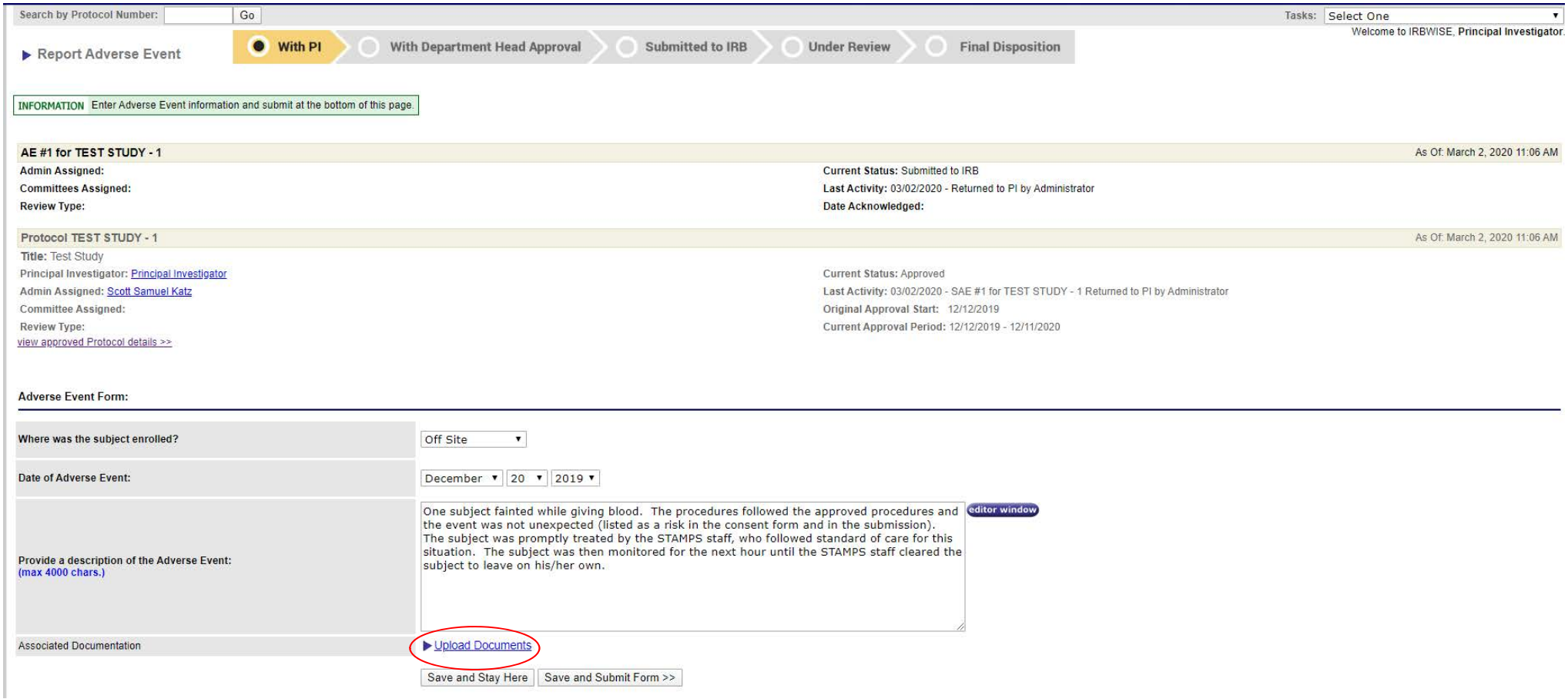
Office of Research Integrity Assurance
Georgia Institue of Technology
irb@gatech.edu

Reporting an Adverse Event



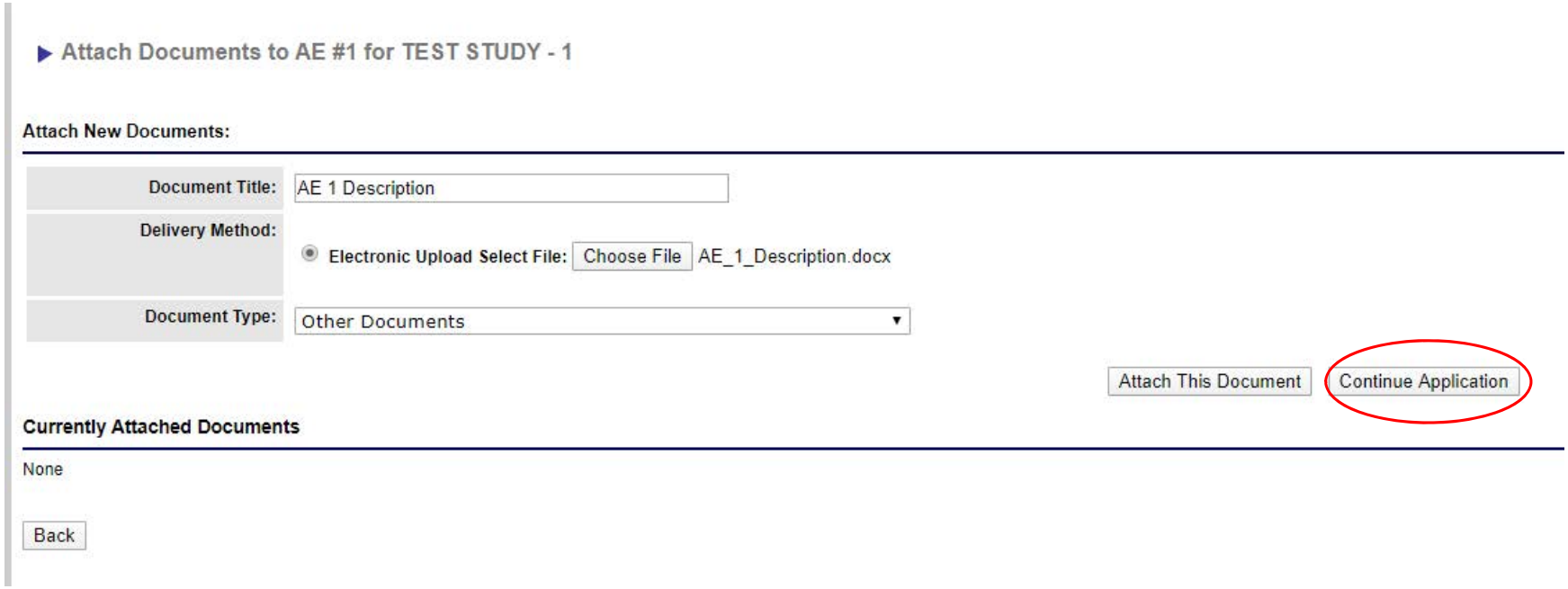
Once in the selected study, please click the Tasks drop-down menu and select "Report Adverse Event."

Adverse Event - Submission



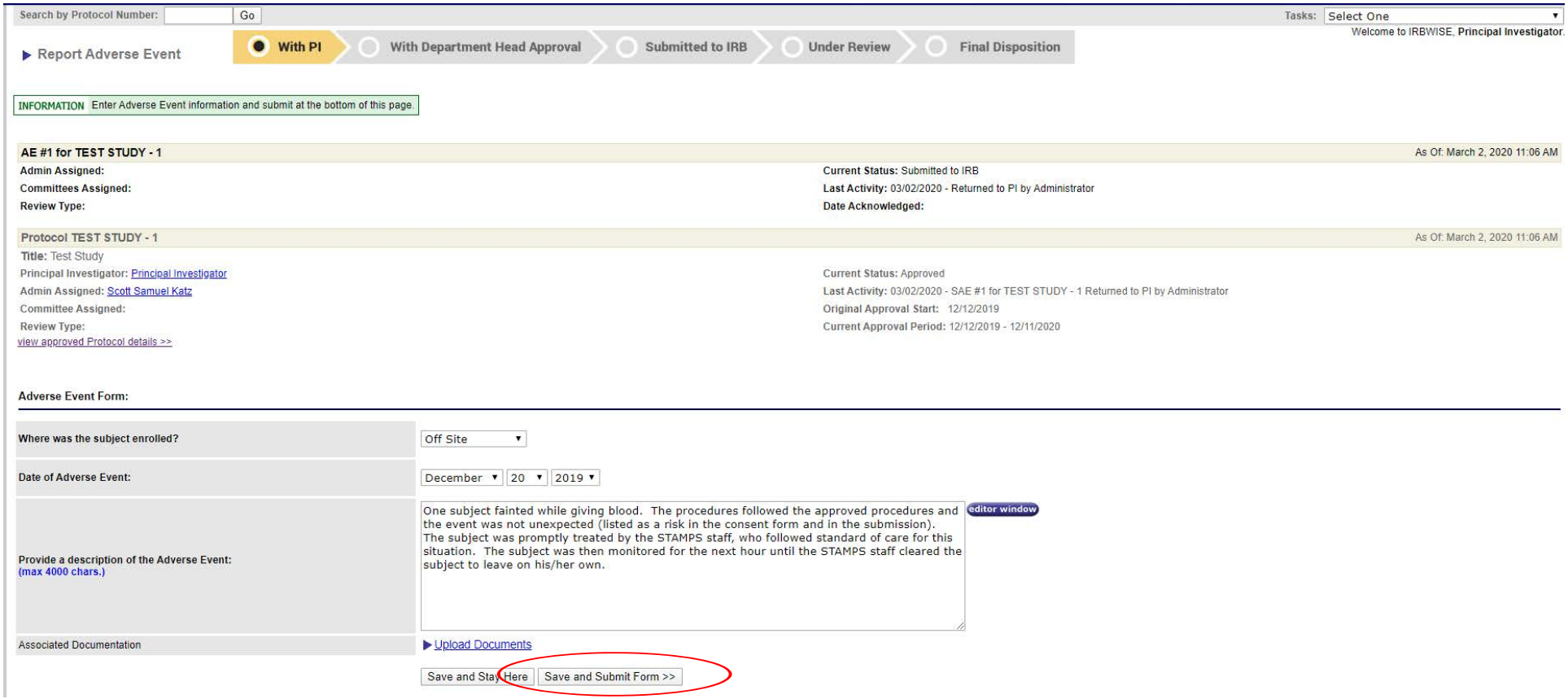
When reporting an Adverse Event, you will need to fully describe the issue that occurred, when the issue occurred, and where the issue occurred. Furthermore, you will need to discuss if this event was anticipated or unanticipated. If you have any accompanying documents, then please click "Upload Documents"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

Adverse Event - Submission



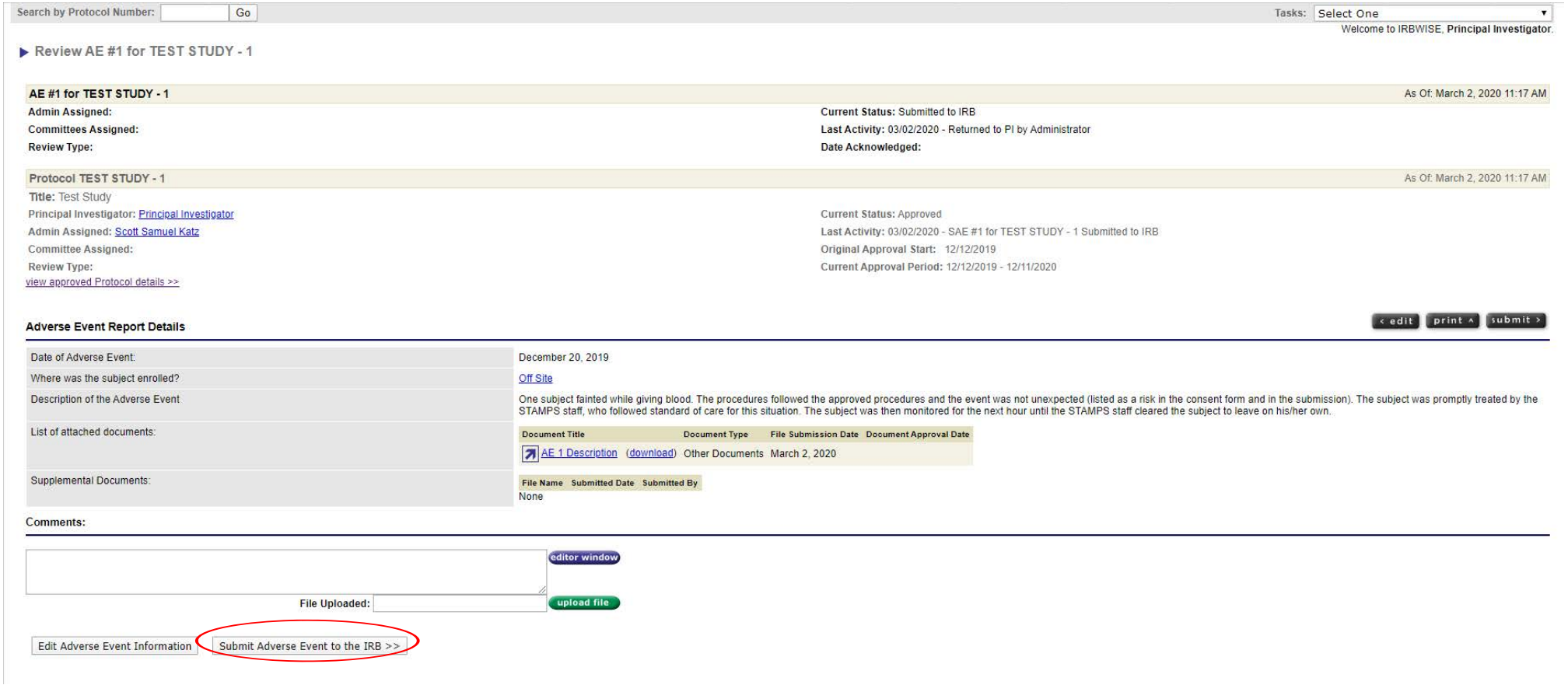
After clicking "Upload Documents," you will be asked to provide a title for the document, the document type, and then to upload the document. When ready, click "Attach the Document." After all documents have been uploaded, please click "Continue Application."

Adverse Event - Submission



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

Adverse Event - Submission



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.

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