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

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