IRB Wise Protocol Deviation Example and Guidance

This presentation includes an example of a protocol deviation 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 a protocol deviation, please click “My Protocols” (circled in red) at the top of the screen and then select the study that the deviation is associated with.
Once in the selected study, please click the Tasks drop-down menu and select "Report Deviation."
The Protocol Deviation submission requests information about the incident, how you intend to address the issue, and how you intend to prevent similar issues from reoccurring. When filling out this submission, please be sure to upload your CAPA document to question D. A template can be found on our Forms page (https://oria.gatech.edu/irb/submitting-protocol/forms). When finished, please click "Continue" at the bottom of the screen.
Protocol Deviation - Submission

After clicking "Continue," you will be asked to review the information provided. If the information is complete and correct, then please click "Continue" again. If not, then please click "Edit" to return to the previous screen.
Protocol Deviation - Submission

After clicking "Continue," you will be prompted to officially submit the Protocol Deviation. Please select "Submit to the IRB" and click "Finish" when ready to submit. Please click "Edit" if the submission is not ready to be submitted.
Congratulations! You have officially submitted your protocol deviation to the IRB.

Please contact the Office of Research Integrity Assurance if you have any questions regarding the submission process.

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