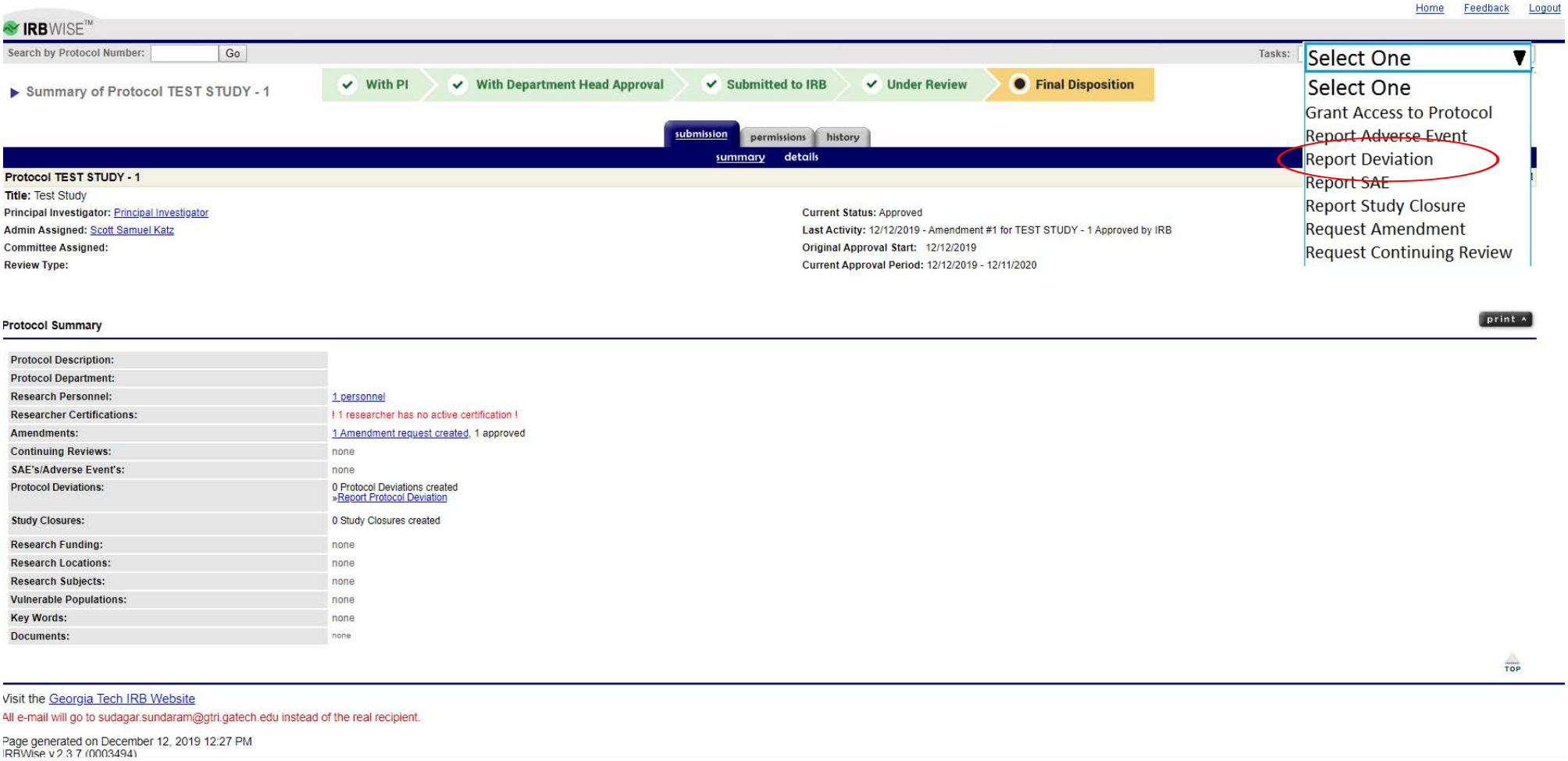
IRB Wise Protocol Deviation Example and Guidance

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.

Start Page on IRB Wise

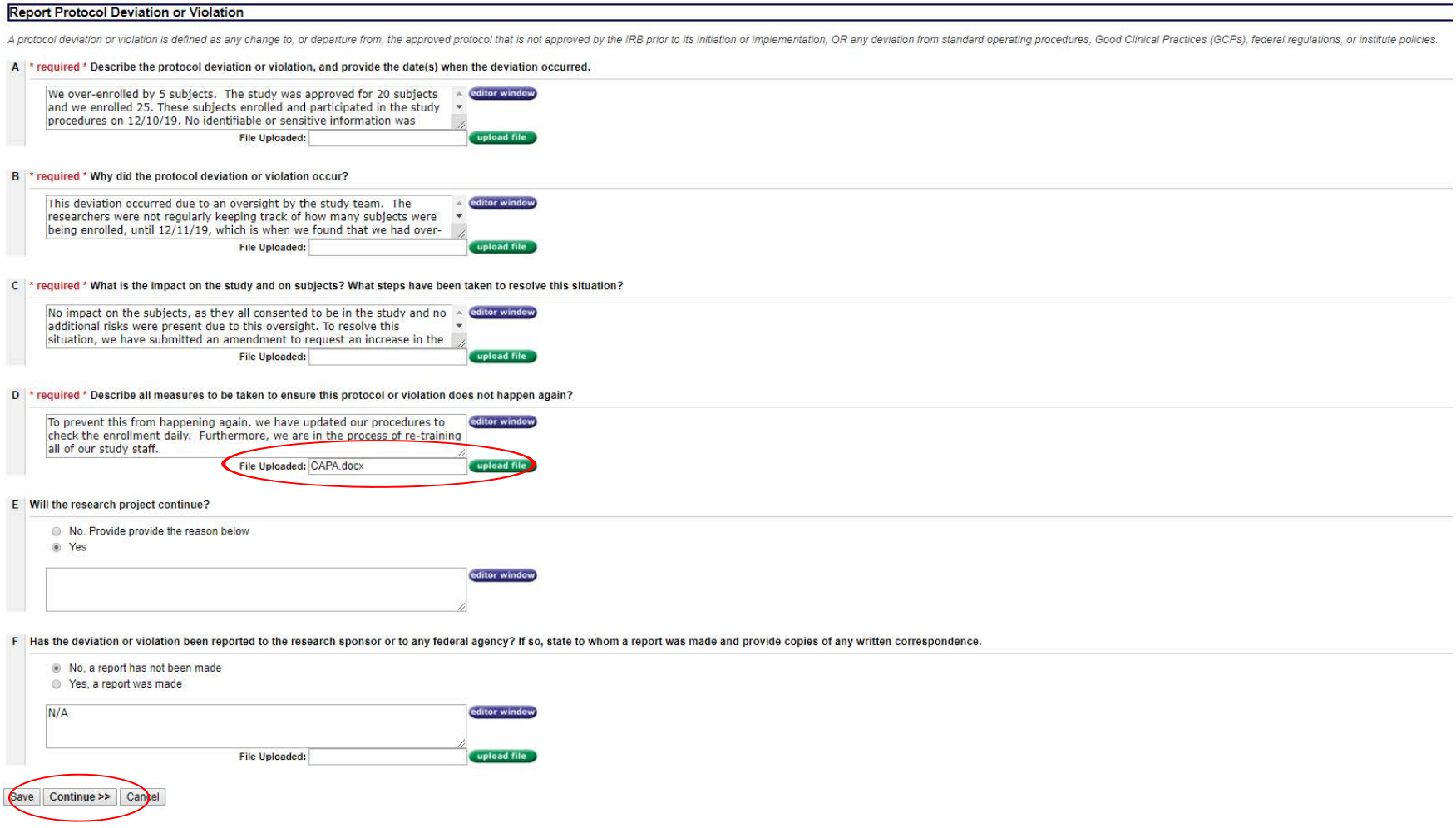
To submit a protocol deviation, please click “My Protocols” (circled in red) at the top of the screen and then select the study that the deviation is associated with.

Requesting a Protocol Deviation



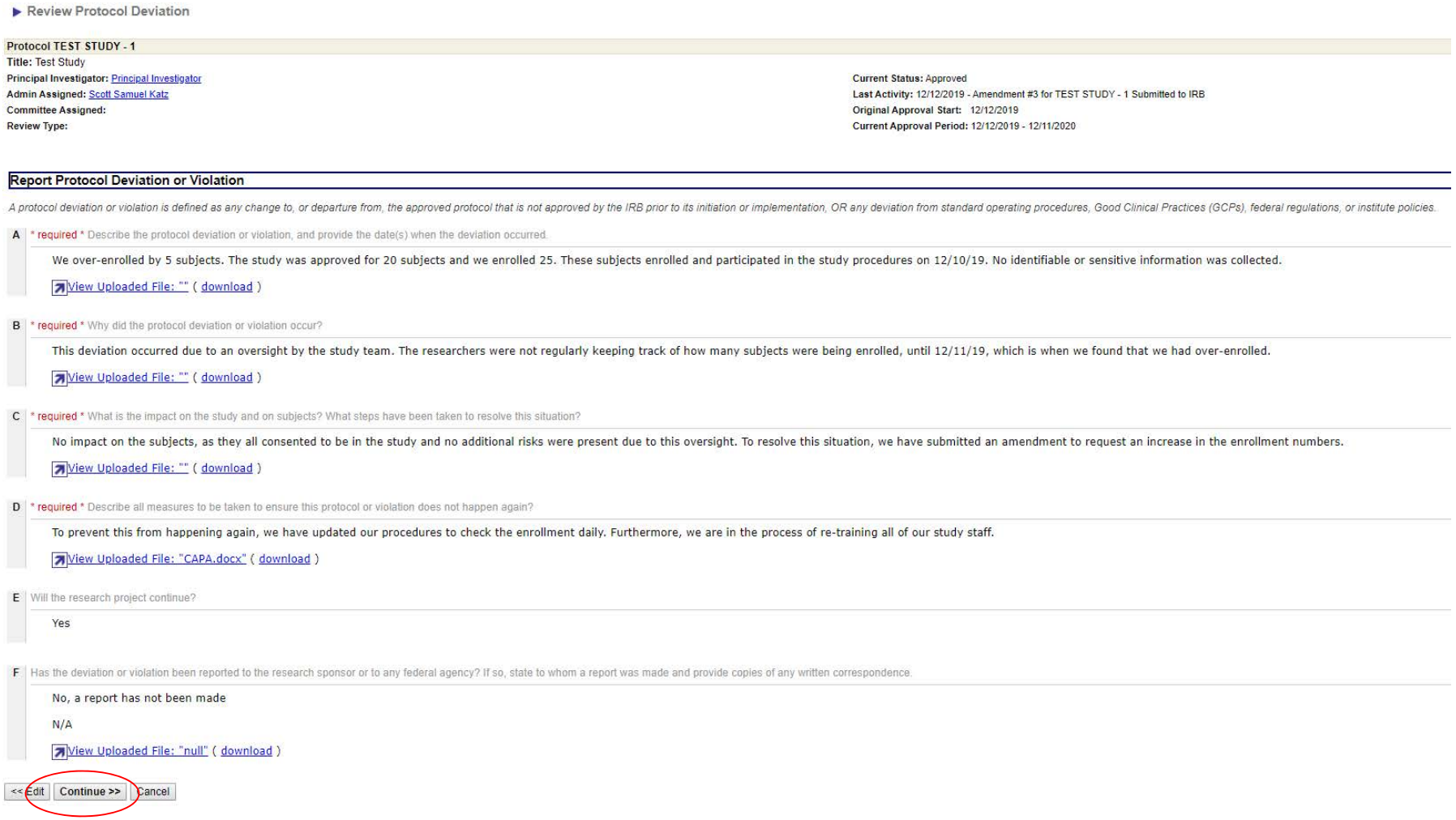
Once in the selected study, please click the Tasks drop-down menu and select "Report Deviation."

Protocol Deviation - Submission



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 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



▶ Review Protocol Deviation

Protocol TEST STUDY - 1

Title: Test Study
Principal Investigator: Principal Investigator
Admin Assigned: Scott Samuel Katz
Committee Assigned:
Review Type:

Current Status: Approved
Last Activity: 12/12/2019 - Amendment #3 for TEST STUDY - 1 Submitted to IRB
Original Approval Start: 12/12/2019
Current Approval Period: 12/12/2019 - 12/11/2020

Report Protocol Deviation or Violation

A protocol deviation or violation is defined as any change to, or departure from, the approved protocol that is not approved by the IRB prior to its initiation or implementation, OR any deviation from standard operating procedures, Good Clinical Practices (GCPs), federal regulations, or institute policies.

A * required * Describe the protocol deviation or violation, and provide the date(s) when the deviation occurred.

We over-enrolled by 5 subjects. The study was approved for 20 subjects and we enrolled 25. These subjects enrolled and participated in the study procedures on 12/10/19. No identifiable or sensitive information was collected.

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B * required * Why did the protocol deviation or violation occur?

This deviation occurred due to an oversight by the study team. The researchers were not regularly keeping track of how many subjects were being enrolled, until 12/11/19, which is when we found that we had over-enrolled.

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C * required * What is the impact on the study and on subjects? What steps have been taken to resolve this situation?

No impact on the subjects, as they all consented to be in the study and no additional risks were present due to this oversight. To resolve this situation, we have submitted an amendment to request an increase in the enrollment numbers.

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D * required * Describe all measures to be taken to ensure this protocol or violation does not happen again?

To prevent this from happening again, we have updated our procedures to check the enrollment daily. Furthermore, we are in the process of re-training all of our study staff.

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E Will the research project continue?

Yes

F Has the deviation or violation been reported to the research sponsor or to any federal agency? If so, state to whom a report was made and provide copies of any written correspondence.

No, a report has not been made

N/A

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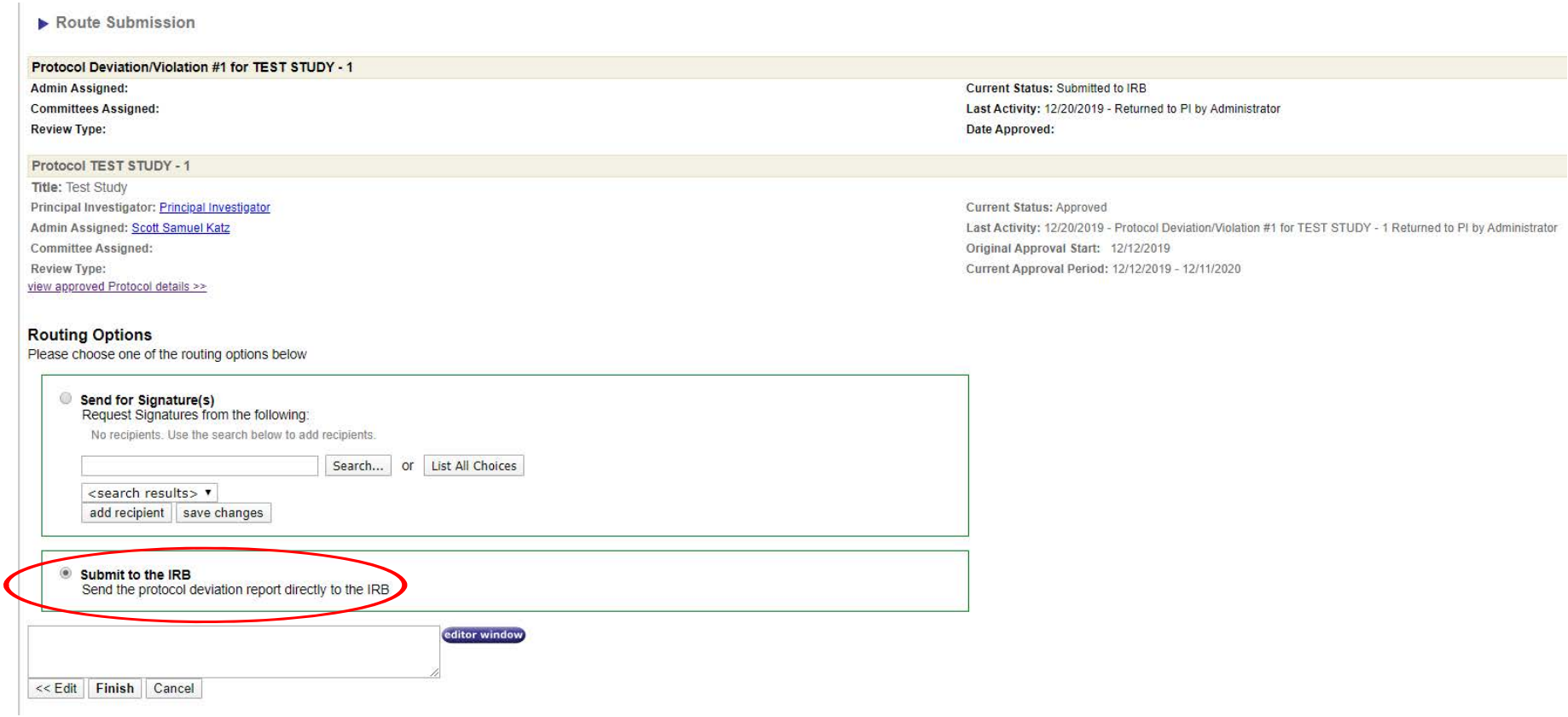
<< Edit | Continue >> | Cancel

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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