IRB Wise Continuing Review Example and Guidance

This presentation includes an example of a continuing review 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 continuing review, please click “My Protocols” (circled in red) at the top of the screen and then select the study that you wish to renew.
Requesting Continuing Review

Once in the selected study, please click the Tasks drop-down menu and select "Request Continuing Review."
Continuing Review Instructions

Please complete this application in order to obtain continuing approval of the study. If enrollment of new subjects will continue, be sure to upload all current consent forms, advertisements or recruitment language, and other approved documents in the ATTACH DOCUMENTS section of this application for continuing approval.

NOTE: If you wish to change any of these documents, you will need to do that in a separate action. Go ahead and complete the REQUEST CONTINUING REVIEW and submit it. Then return to the main protocol page, select REQUEST AMENDMENT from the dropdown task list, and submit the revised documents in an amendment.

Please do not upload revised documents here as part of the request for continuing approval. The IRB will not approve protocol changes as part of continuing review.

An application may be renewed no more than four times unless the study is only in the data analysis phase. After the fourth renewal, a new protocol application must be submitted instead of a continuing review if subject identifiers are maintained.

Please contact the Office of Research Integrity Assurance if assistance is needed.

These instructions are found at the top of the continuing review page. Please be sure to read these instructions as they provide guidance for continuing reviews and your submission. Please let the ORIA staff know if you have any questions.
When submitting a continuing review, you will be prompted with several sections. The "Data and Publications" section is the first section. Please answer all of the questions.
The second section in the continuing review submission is the "Subjects, Study Details" section. Please be sure to answer all of the questions in this section. Additionally, please be sure that the enrollment numbers provided in questions C and D are accurate.
The purple and gray boxes shown above appear after the second section in the submission. Both sections shown above must be completed in every continuing review submission.
Continuing Review - Review of Protocol Information

When completing the "Review of Protocol Information" section, please review the information provided and mark if the information is correct or incorrect and in need or not in need of an amendment to fix the inconsistencies.
Continuing Review - Associated Documents

If your study has either not begun or you are actively enrolling subjects, all IRB approved study documents must be uploaded so that they can be renewed for the next approval period. This includes, consent forms, recruitment documents, surveys/interview instruments, collaborating IRB approvals and documents, and grant documents.

If you are no longer enrolling subjects and the study is closed to any future enrollment, then only the grant documents (if the study is funded) need to be uploaded. However, please note that depending on the specifics of your study, other documents may be requested.
After reviewing the study information and uploading the documents, you will be asked to report on any issues that may have come up over the past year. Please answer all of the questions in this section. If you answered "yes" to any of the questions, please describe the issue in the last question of the section.
Continuing Review - Conflict of Interest

After clicking "Save and Submit Application" on the last page, you will be prompted with the submission so you can review the information that you provided. At the bottom of the screen, you will then be asked to answer the "Conflict of Interest" questions (shown above). Please answer all of the questions in this section.
Continuing Review - Endorsements

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<th>Endorsement</th>
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<tr>
<td>I will obtain informed consent from all subjects.</td>
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<td>I will report to the IRB any harmful effects to the subjects.</td>
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<td>I will renew my application if the research extends beyond one year.</td>
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<td>I will gain IRB approval before altering the research protocol or consent forms.</td>
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<tr>
<td>I will protect the rights and welfare of human research subjects and comply with the provisions of Georgia Tech's Federalwide Assurance.</td>
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Yes ▼

Enter Your Name: [Principal Investigator]

Comments:

File Uploaded:  

[Submit Continuing Review to IRB]

When your submission is ready for review, please complete the endorsement section and click "Submit Continuing Review to IRB."*

*Please Note: This action should only be done by the PI or Co-PI, as the GT IRB Policies and Procedures only allows the PI and Co-PI to submit to the IRB.

If you found issues with the information provided that need to be fixed, then please click "Edit Continuing Review."
Congratulations! You have officially submitted your continuing review application to the IRB.

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

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