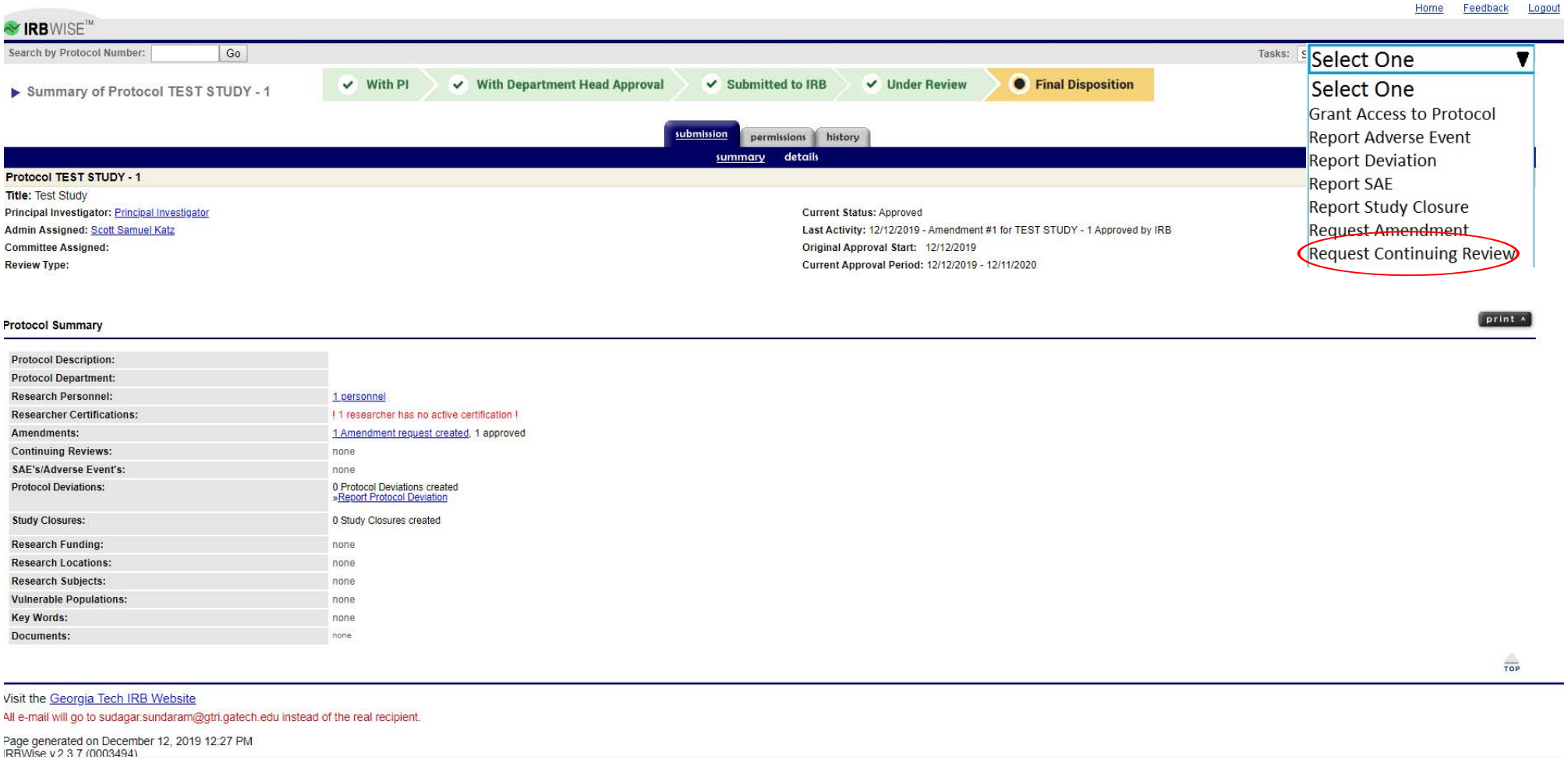
IRB Wise Continuing Review Example and Guidance

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.

Start Page on IRB Wise

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.

Continuing Review - Data and Publications

Data and Publications - Continuing Review Application

A **Is data collection complete?**

- (•) No, research involving human subjects is ongoing and will continue.
- ( ) No, the research has not begun
- ( ) Yes, data collection is complete. IF SUBJECTS WERE ENROLLED, ENTER THE DATE ENROLLMENT CLOSED.

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B **If data collection is complete, indicate whether data analysis will continue.**

- ( ) Analysis continues of de-identified data. (All codes and/or links to subject identity have been destroyed).
  STOP! A CONTINUING REVIEW IS NOT NEEDED AND THE STUDY CAN BE CLOSED. SELECT STUDY CLOSURE FROM THE MAIN PROTOCOL PAGE TASK DROP DOWN LIST.
- ( ) Continuing analysis of data that contain a link/code to a subject

editor window

C **Provide a brief summary of the goals and any results (preliminary or final) obtained in the study. If there are no results to report at this time, so state and explain why.**

This study plans on on investigating if spatial learning by landmark/beacons is related to or separate from learning from spatial patterns. The data is still in preliminary stages and no results are available to be reported at this time.

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D **Are there any recent findings, new literature, or other information relevant to the risk factors of the research that might affect the willingness of a subject to participate in the study?**

No ▾

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E **During the past year, have any abstracts or publications resulted from this study?**

if yes, list them below. Studies involving the Department of Defense require that copies of abstracts & publications be uploaded in the ATTACH DOCUMENTS section.

N/A

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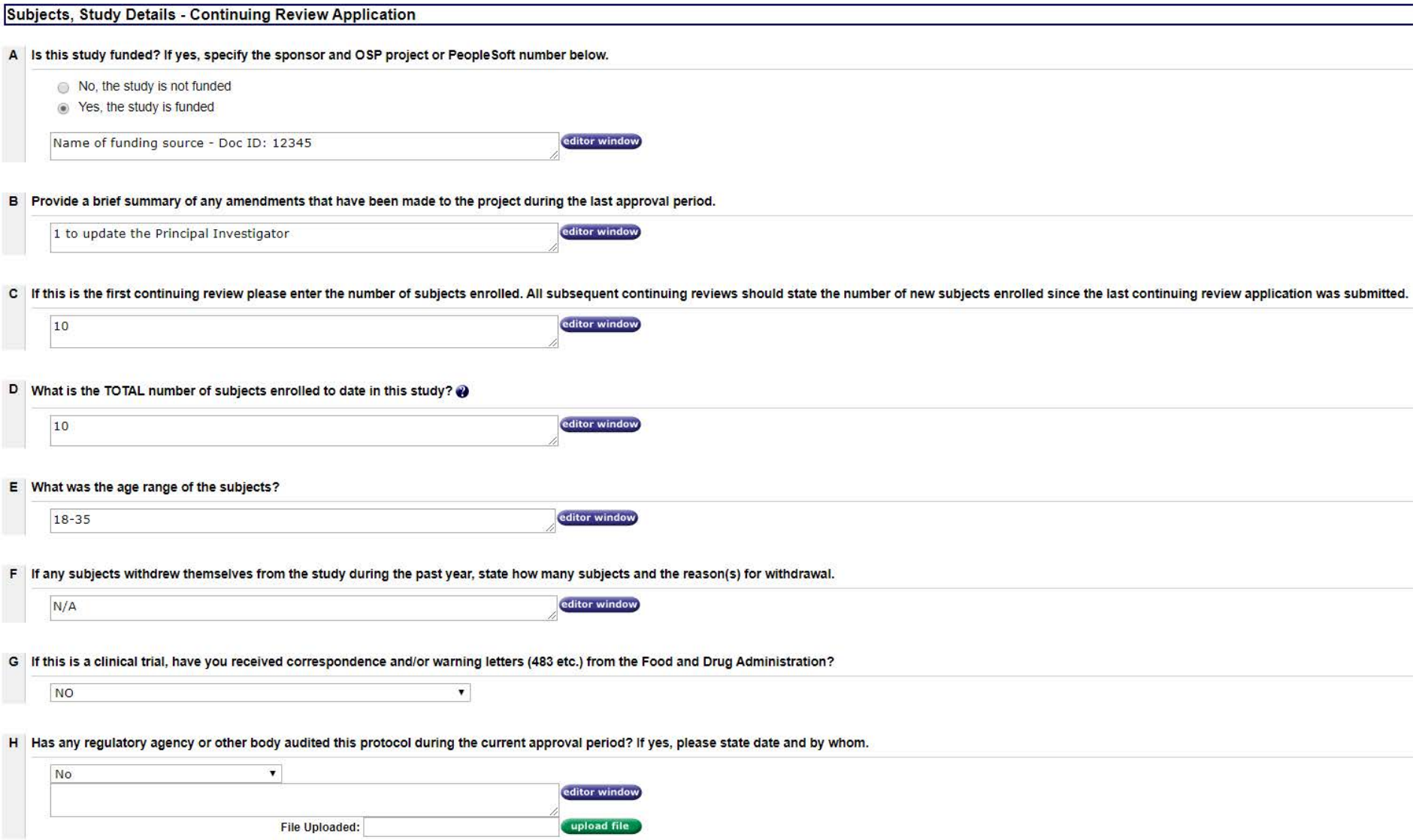
When submitting a continuing review, you will be prompted with several sections. The "Data and Publications" section is the first section. Please answer all of the questions.

Continuing Review - Subjects, Study Details



Subjects, Study Details - Continuing Review Application

A Is this study funded? If yes, specify the sponsor and OSP project or PeopleSoft number below.

- ○ No, the study is not funded
- ◉ Yes, the study is funded

Name of funding source - Doc ID: 12345 editor window

B Provide a brief summary of any amendments that have been made to the project during the last approval period.

1 to update the Principal Investigator editor window

C If this is the first continuing review please enter the number of subjects enrolled. All subsequent continuing reviews should state the number of new subjects enrolled since the last continuing review application was submitted.

10 editor window

D What is the TOTAL number of subjects enrolled to date in this study?

10 editor window

E What was the age range of the subjects?

18-35 editor window

F If any subjects withdrew themselves from the study during the past year, state how many subjects and the reason(s) for withdrawal.

N/A editor window

G If this is a clinical trial, have you received correspondence and/or warning letters (483 etc.) from the Food and Drug Administration?

NO ▾

H Has any regulatory agency or other body audited this protocol during the current approval period? If yes, please state date and by whom.

No ▾

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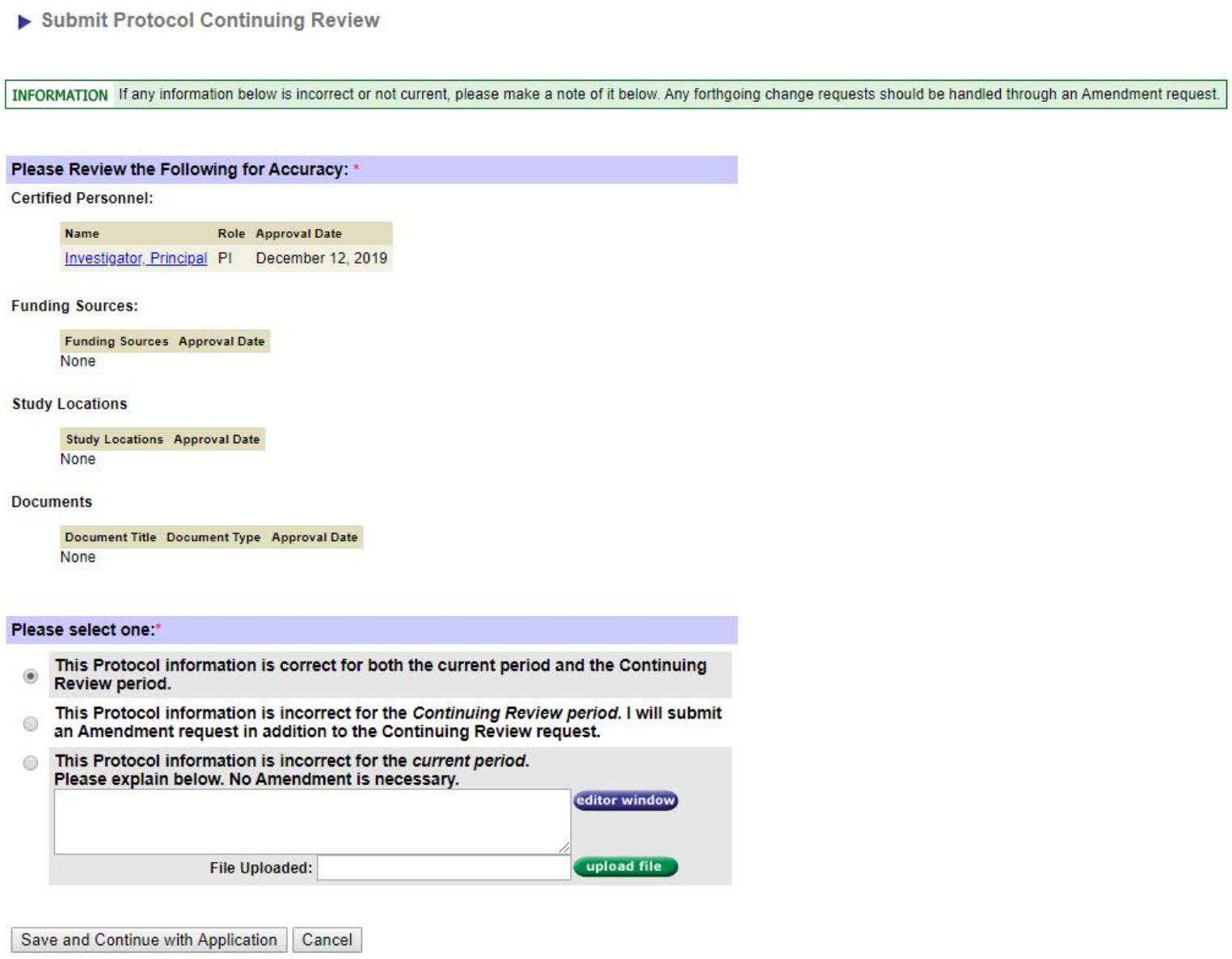
The second section in the continuing review submission is the "Subjects, Study Details" section. Please be sure to answer all of the questions in this section. Additionally, please be sure that the enrollment numbers provided in questions C and D are accurate.

Continuing Review - Review of Protocol Information and Associated Documents

Review Approved Protocol Information: *	
Please review Protocol information for accuracy	▶ Click Here
Associated Documents :	
Associate documents with the Continuing Review application that will be uploaded.	▶ Click Here to Associate Documents **note:** If contact with human subjects will continue, you MUST submit for approval the forms that will be utilized during the proposed continuation period.

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 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

▶ Attach Documents to Continuing Review for TEST STUDY - 1

SUCCESS Document added successfully.

note: It is not possible to modify the contents of an approved document. If you want to do so, please fill out the Amendment request form and follow the instructions in the Upload Documents section of the form.

Attach New Documents:

Document Title:

Delivery Method: Electronic Upload Select File: Choose File No file chosen

Document Type: Select One (List of Suggested Documents)

Attach This Document | Continue Application

Currently Attached Documents

Select	Document Title	Document Type	Method Sent	File Name	File Submission Date
○	Consent Form	Consent Form	Uploaded	Consent Form.docx (download)	December 12, 2019
○	Survey	Surveys, Questionnaires, and Other Such Instruments	Uploaded	Survey.docx (download)	December 12, 2019
○	Grant Proposal	Other Documents	Uploaded	Grant Proposal.docx (download)	December 12, 2019
○	Recruitment Document	Recruitment	Uploaded	Recruitment Document.docx (download)	December 12, 2019

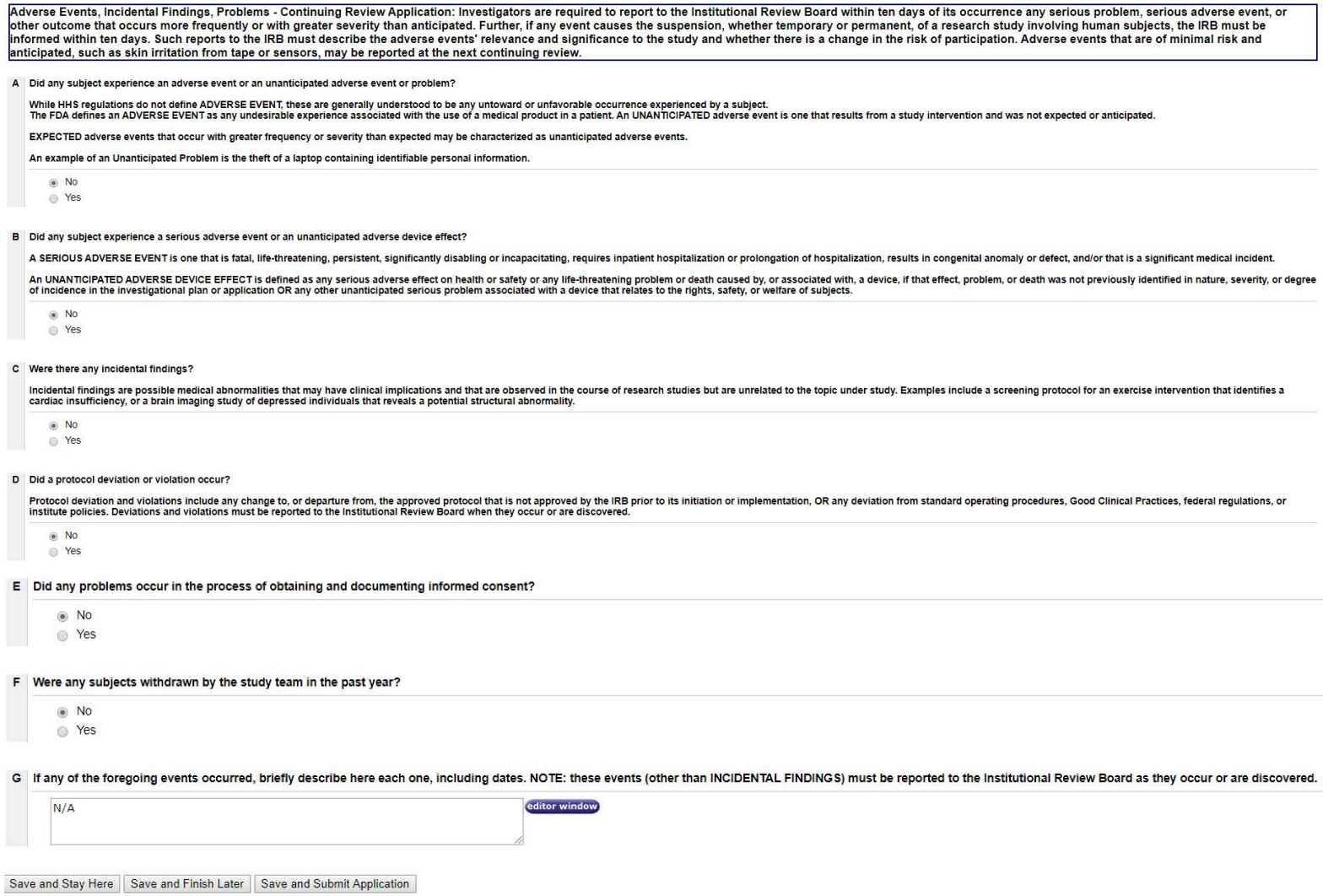
Modify/Replace | Delete

Back

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.

Continuing Review - Adverse Events, Incidental Findings, Problems



Adverse Events, Incidental Findings, Problems - Continuing Review Application: Investigators are required to report to the Institutional Review Board within ten days of its occurrence any serious problem, serious adverse event, or other outcome that occurs more frequently or with greater severity than anticipated. Further, if any event causes the suspension, whether temporary or permanent, of a research study involving human subjects, the IRB must be informed within ten days. Such reports to the IRB must describe the adverse events' relevance and significance to the study and whether there is a change in the risk of participation. Adverse events that are of minimal risk and anticipated, such as skin irritation from tape or sensors, may be reported at the next continuing review.

A Did any subject experience an adverse event or an unanticipated adverse event or problem?

While HHS regulations do not define ADVERSE EVENT, these are generally understood to be any untoward or unfavorable occurrence experienced by a subject.
The FDA defines an ADVERSE EVENT as any undesirable experience associated with the use of a medical product in a patient. An UNANTICIPATED adverse event is one that results from a study intervention and was not expected or anticipated.

EXPECTED adverse events that occur with greater frequency or severity than expected may be characterized as unanticipated adverse events.

An example of an Unanticipated Problem is the theft of a laptop containing identifiable personal information.

- (•) No
- ( ) Yes

B Did any subject experience a serious adverse event or an unanticipated adverse device effect?

A SERIOUS ADVERSE EVENT is one that is fatal, life-threatening, persistent, significantly disabling or incapacitating, requires inpatient hospitalization or prolongation of hospitalization, results in congenital anomaly or defect, and/or that is a significant medical incident.

An UNANTICIPATED ADVERSE DEVICE EFFECT is defined as any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application OR any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

- (•) No
- ( ) Yes

C Were there any incidental findings?

Incidental findings are possible medical abnormalities that may have clinical implications and that are observed in the course of research studies but are unrelated to the topic under study. Examples include a screening protocol for an exercise intervention that identifies a cardiac insufficiency, or a brain imaging study of depressed individuals that reveals a potential structural abnormality.

- (•) No
- ( ) Yes

D Did a protocol deviation or violation occur?

Protocol deviation and violations include 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, federal regulations, or institute policies. Deviations and violations must be reported to the Institutional Review Board when they occur or are discovered.

- (•) No
- ( ) Yes

E Did any problems occur in the process of obtaining and documenting informed consent?

- (•) No
- ( ) Yes

F Were any subjects withdrawn by the study team in the past year?

- (•) No
- ( ) Yes

G If any of the foregoing events occurred, briefly describe here each one, including dates. NOTE: these events (other than INCIDENTAL FINDINGS) must be reported to the Institutional Review Board as they occur or are discovered.

N/A

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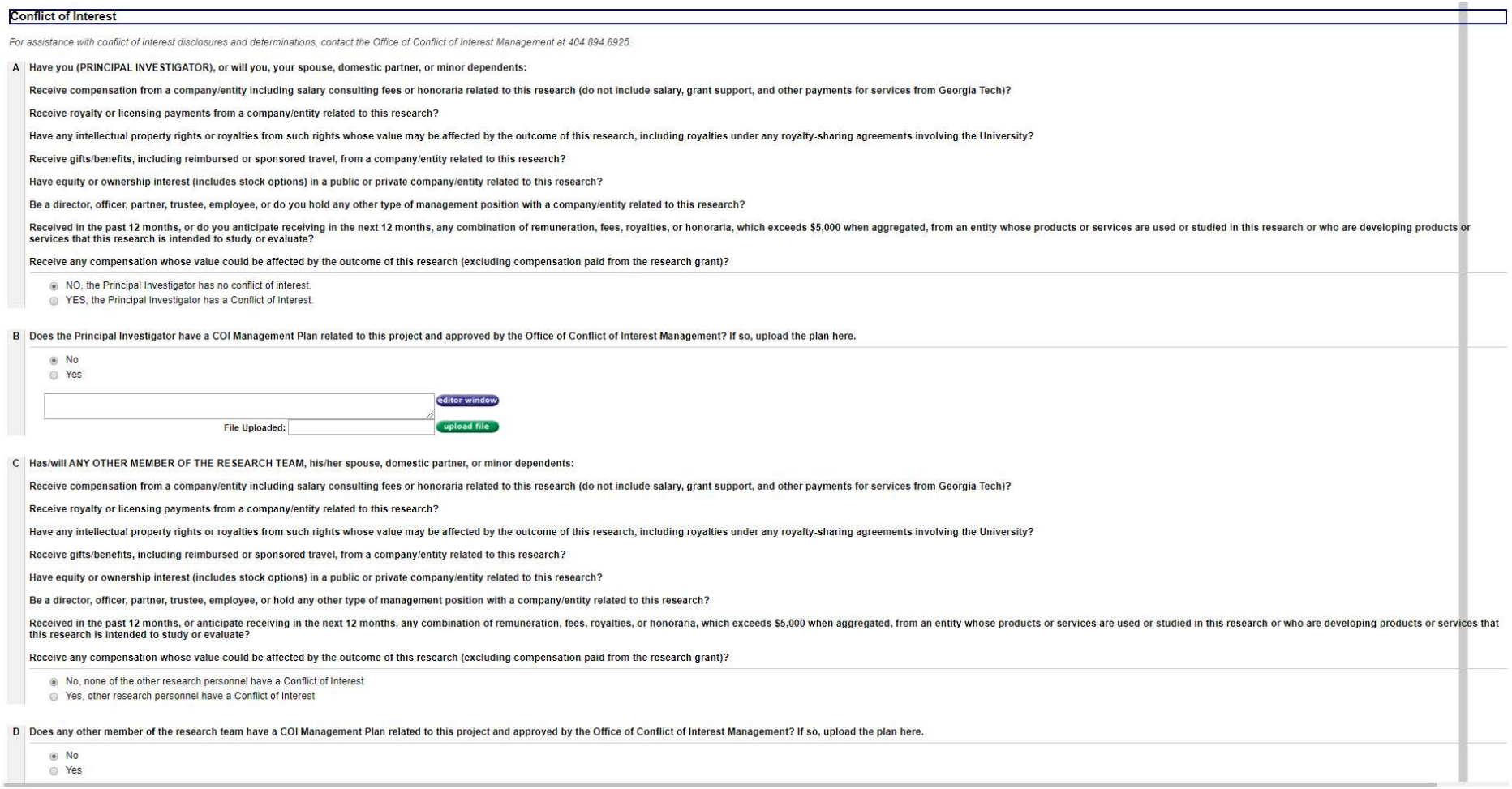
Save and Stay Here | Save and Finish Later | Save and Submit Application

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



Conflict of Interest

For assistance with conflict of interest disclosures and determinations, contact the Office of Conflict of Interest Management at 404.894.6925.

A **Have you (PRINCIPAL INVESTIGATOR), or will you, your spouse, domestic partner, or minor dependents:**

Receive compensation from a company/entity including salary consulting fees or honoraria related to this research (do not include salary, grant support, and other payments for services from Georgia Tech)?

Receive royalty or licensing payments from a company/entity related to this research?

Have any intellectual property rights or royalties from such rights whose value may be affected by the outcome of this research, including royalties under any royalty-sharing agreements involving the University?

Receive gifts/benefits, including reimbursed or sponsored travel, from a company/entity related to this research?

Have equity or ownership interest (includes stock options) in a public or private company/entity related to this research?

Be a director, officer, partner, trustee, employee, or do you hold any other type of management position with a company/entity related to this research?

Received in the past 12 months, or do you anticipate receiving in the next 12 months, any combination of remuneration, fees, royalties, or honoraria, which exceeds $5,000 when aggregated, from an entity whose products or services are used or studied in this research or who are developing products or services that this research is intended to study or evaluate?

Receive any compensation whose value could be affected by the outcome of this research (excluding compensation paid from the research grant)?

- (•) NO, the Principal Investigator has no conflict of interest.
- ( ) YES, the Principal Investigator has a Conflict of Interest.

B **Does the Principal Investigator have a COI Management Plan related to this project and approved by the Office of Conflict of Interest Management? If so, upload the plan here.**

- (•) No
- ( ) Yes

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upload file

C **Has/will ANY OTHER MEMBER OF THE RESEARCH TEAM, his/her spouse, domestic partner, or minor dependents:**

Receive compensation from a company/entity including salary consulting fees or honoraria related to this research (do not include salary, grant support, and other payments for services from Georgia Tech)?

Receive royalty or licensing payments from a company/entity related to this research?

Have any intellectual property rights or royalties from such rights whose value may be affected by the outcome of this research, including royalties under any royalty-sharing agreements involving the University?

Receive gifts/benefits, including reimbursed or sponsored travel, from a company/entity related to this research?

Have equity or ownership interest (includes stock options) in a public or private company/entity related to this research?

Be a director, officer, partner, trustee, employee, or hold any other type of management position with a company/entity related to this research?

Received in the past 12 months, or anticipate receiving in the next 12 months, any combination of remuneration, fees, royalties, or honoraria, which exceeds $5,000 when aggregated, from an entity whose products or services are used or studied in this research or who are developing products or services that this research is intended to study or evaluate?

Receive any compensation whose value could be affected by the outcome of this research (excluding compensation paid from the research grant)?

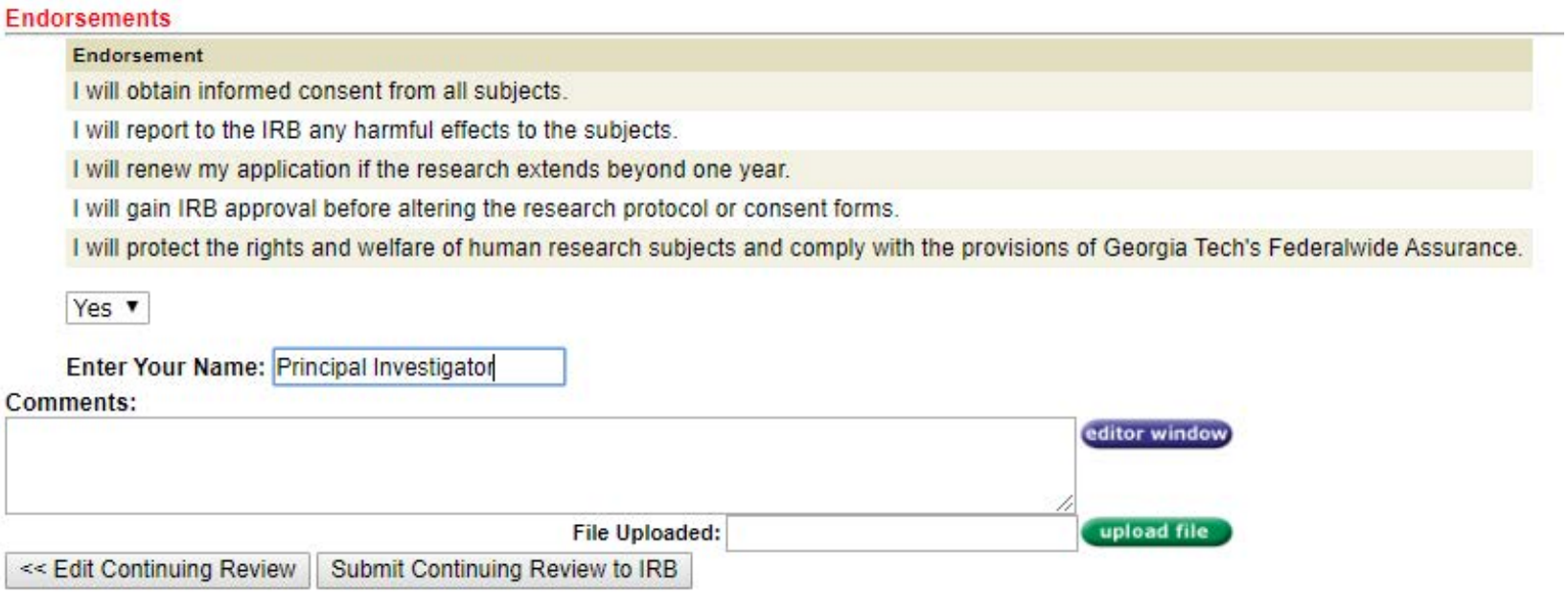
- (•) No, none of the other research personnel have a Conflict of Interest
- ( ) Yes, other research personnel have a Conflict of Interest

D **Does any other member of the research team have a COI Management Plan related to this project and approved by the Office of Conflict of Interest Management? If so, upload the plan here.**

- (•) No
- ( ) Yes

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 the questions in this section.

Continuing Review - Endorsements



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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