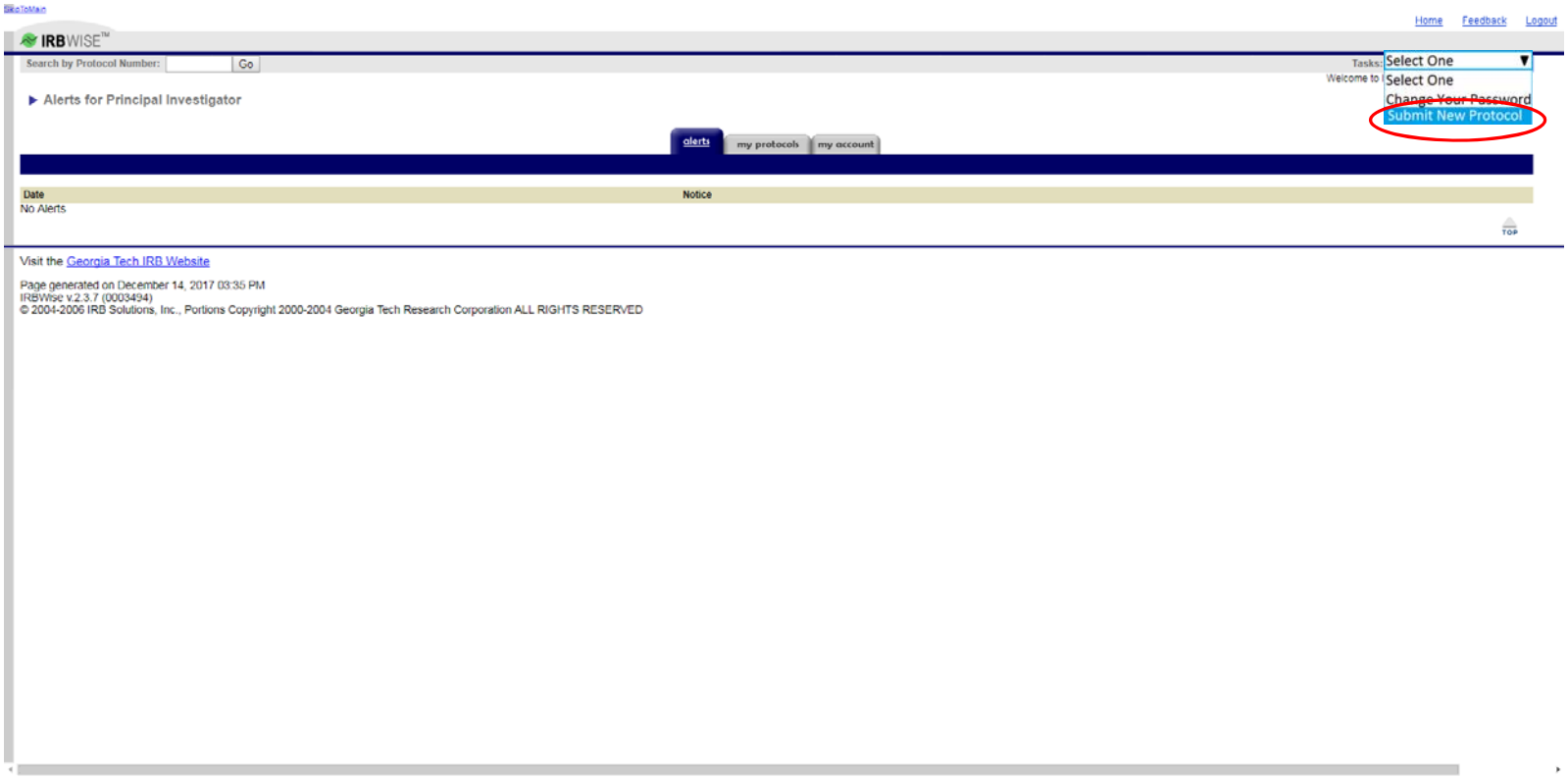
IRB Wise Exempt Submission Example and Guidance

This presentation includes an example of a new Exempt study submission in IRB Wise and also includes guidance for each section in IRB Wise. 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.

Office of Research Integrity Assurance
Georgia Institue of Technology
irb@gatech.edu

Start Page on IRB Wise



To submit a new protocol, please click “Submit New Protocol” (circled in red) in the Tasks dropdown menu on the top right of your alerts screen.

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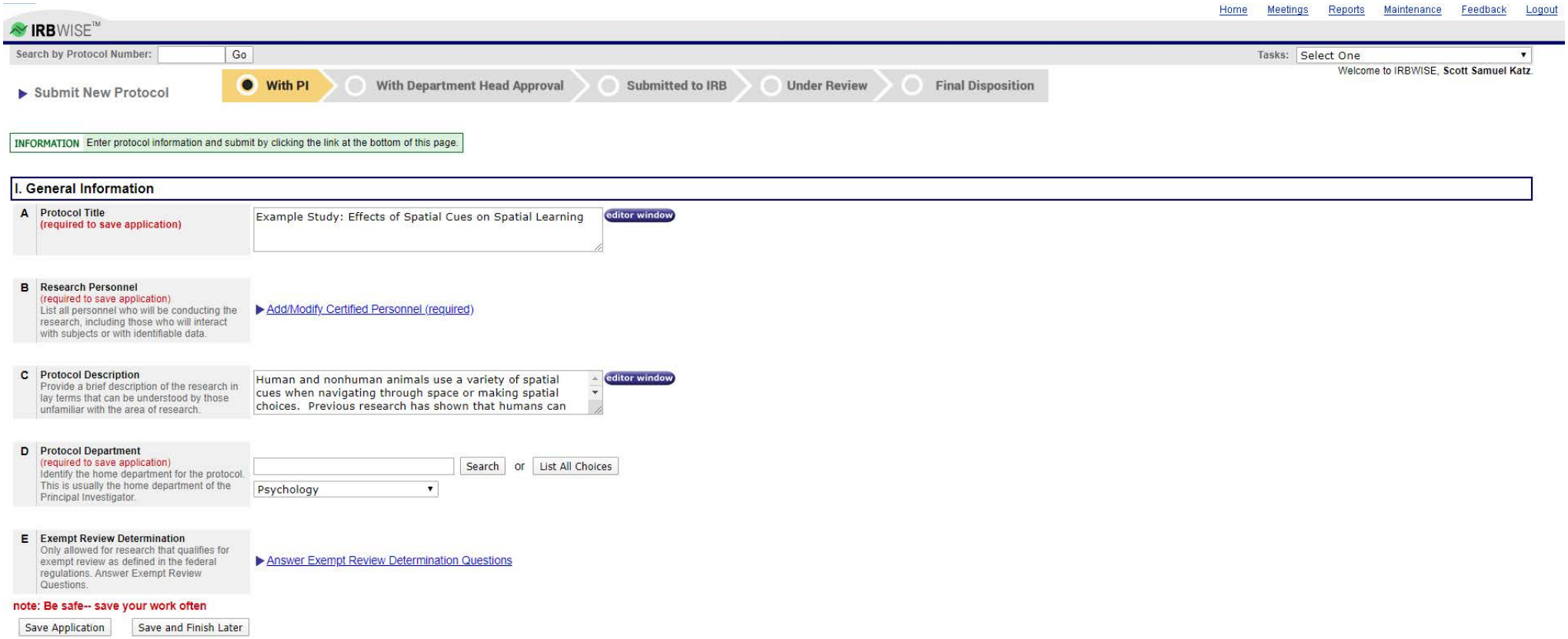
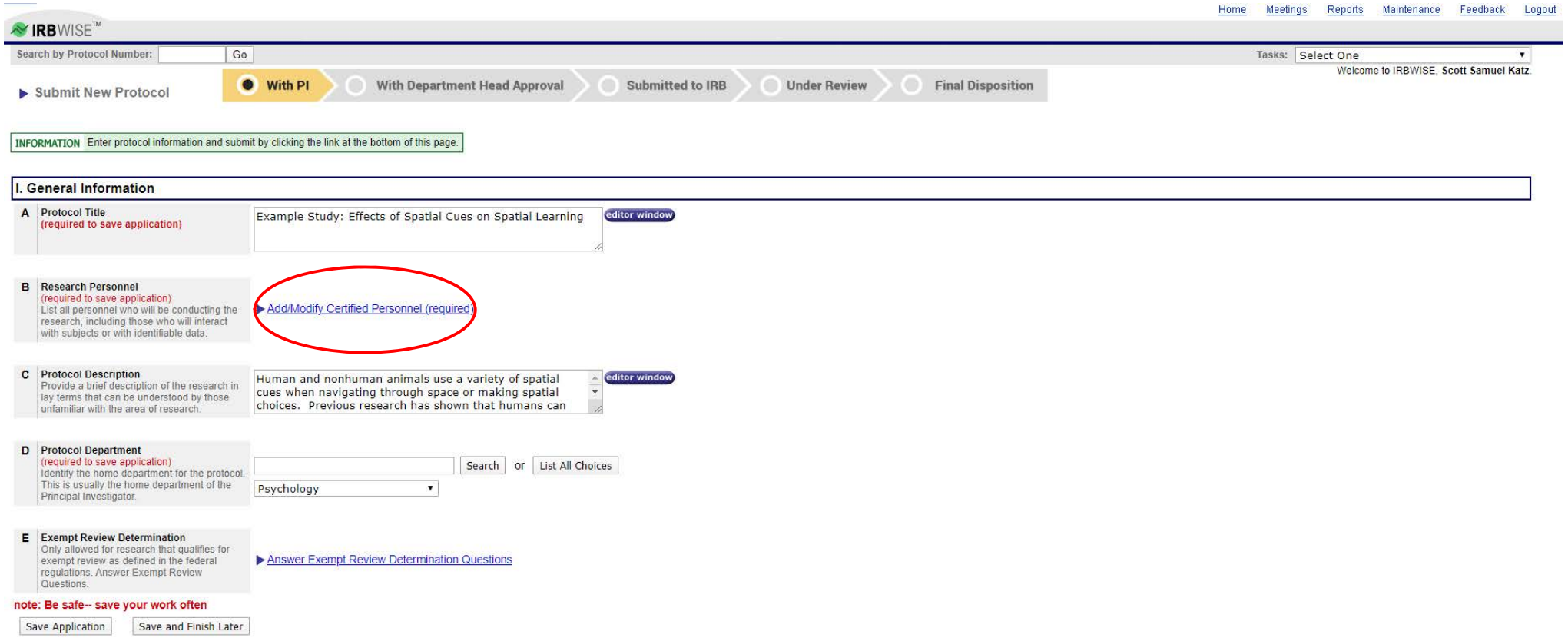
Georgia Institue of Technology
irb@gatech.edu

Section I. General Information



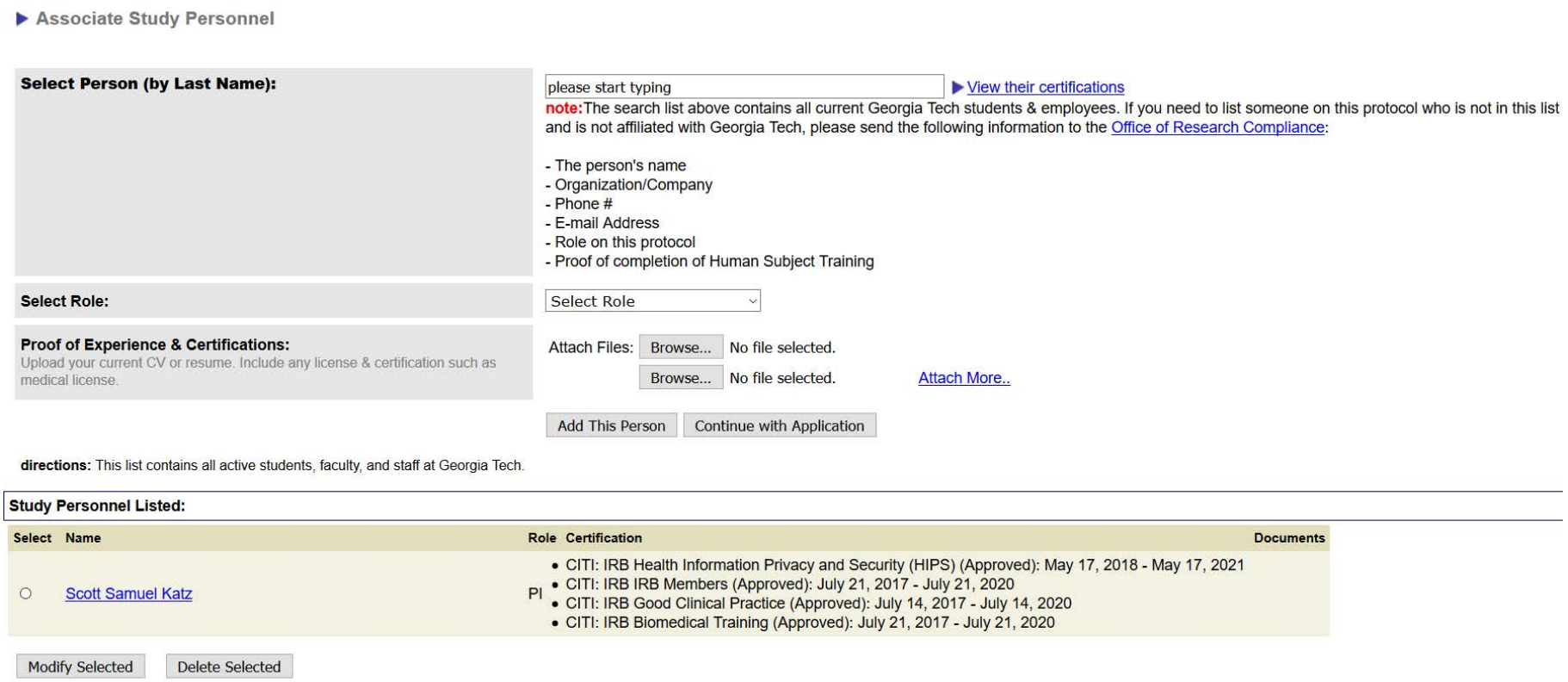
This is the first section of IRB Wise. In this section, you are asked for a title, brief description, your department, and a list of all of the research personnel.

Section I. General Information – Add/Modify Personnel Window



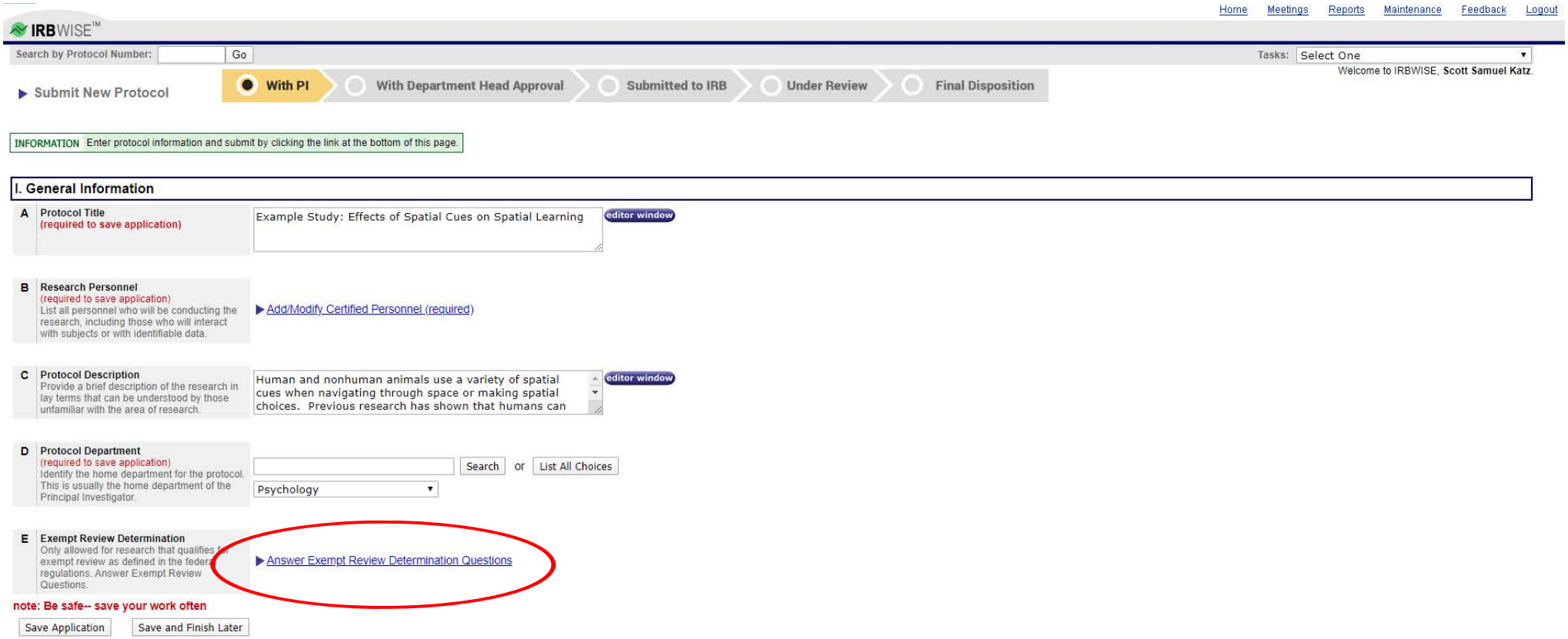
When adding study personnel, please click on the Add/Modify Certified Personnel link (circled above).

Section I. General Information – Add/Modify Personnel Window



In this pop-up window, you are asked to list all of the research personnel who will be involved in the research. Please type the name in the first text box and select the correct individual. Please be sure to also select a role for each individual. Please note that only faculty can be listed as PI and Co-PI. Additionally, we manually check for CITI once we receive your submission. Therefore, do not worry if you have completed the training and "No Certifications" is listed next to your name. We will check on our end once we receive your submission.

Section I. General Information – Exempt Study Window



Only studies that meet the specific criteria can be reviewed under Exempt Review. Please see our website for more information. If your study does meet the criteria, then please complete this section (circled above) and skip the rest of the submission unless instructed otherwise.

Section I. General Information – Exempt Study Window

INFORMATION Several types of research are exempt from the federal regulations. A few examples include teaching practice assessments, surveys, interviews, behavioral studies, analysis of previously collected samples or data, and food quality and taste studies. Research that does not qualify is anything that poses a risk to the subjects, research involving minors that is not education related, research involving sensors (e.g., EKG, EMG, MRI, pedometer, etc.) and research involving FDA regulated products. More clarification can be found on our website (https://researchintegrity.gatech.edu/institutional-review-boards-submitting-protocol/submission-decision-tree).

Exempt Review Determination

If you believe your study is Exempt (meets the criteria listed above in the green box), then please only complete this section, Section IV - Studies involving Department of Defense, Radiation, or Nanotechnology, and upload all of your study documents to Section VI - Attach Documents at the end of the main application.

A **Does your study qualify for exempt review based on the IRB decision tree ?**

- ○ No
- ◉ Yes

B **Does the research involve minors?**

- ○ N/A
- ◉ No
- ○ Yes

C **Is the research conducted in an established or a commonly accepted education setting and is studying normal educational practices, such as research on curriculum, teaching practices, pedagogical methods, classroom management, etc.?**

- ○ N/A
- ◉ No
- ○ Yes

D **Does the research involve secondary research for which consent is not required? For example: Secondary research uses of identifiable private information or identifiable bio-specimens**

- ○ N/A
- ◉ No
- ○ Yes

E **Does the research involve demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads?**

- ○ N/A
- ◉ No
- ○ Yes

After clicking "Answer Exempt Review Determination Questions," this pop-up window will appear. Please be sure to review the information in the green box and the instructions listed above question A prior to completing this section. If your study does fall under one of the federally defined exempt categories, then please answer complete this section.

Section I. General Information – Exempt Study Window

F **Is the research a taste and food quality evaluation and/or a consumer acceptance study? Specifically: (i) wholesome foods without additives are consumed or (ii) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.**

- ○ N/A
- ◉ No
- ○ Yes

G **Please select all of the procedures that you will use to collect data*:**

- ☑ Audio recording/video recording/photographs
- ☑ Behavioral Intervention/Interactive Tasks
- ☐ Bio-specimen collection
- ☐ Blood draws
- ☐ Focus Group
- ☐ Interview
- ☐ Other, please attach a description with the other study documents
- ☐ Passive Observation
- ☐ Research on educational practices
- ☐ Sensor recordings (EMG, EKG, MRI, pedometer, etc.)
- ☑ Survey, educational test, psychological tests

H **Will vulnerable populations be included in the study?***

- ◉ No
- ○ Yes, please describe in the box below

editor window

I **Describe how you intend to use the data/information collected in this study.**

We intend to analyze the data to determine if there is a dedicated psychological phenomenon that can account for human navigation. We intend to publish and present the results in academic journals/conferences.

editor window

J **What are the provisions (physical/technical safe guards) to protect the privacy of subjects and to maintain confidentiality of data? If using PHI please attach approval from GT OIT.***

All survey and electronic data will be stored on the GT encrypted hard drive and will be located in the PI's office behind lock and key. All paper documents, including signed consent forms, will be stored in a locked filing cabinet in the PI's office behind lock and key. Only approved study team members will have access to the data and signed consent forms.

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This is a continuation of the Exempt Window. Please be sure to answer all of the questions in this section.

Section I. General Information – Exempt Study Window

K **Will identifiers (e.g., name, address, audio, video, birth date, IP address, etc.) be associated with the data at any point?***

- ○ No
- ◉ Yes, please describe in the box below

GT ID, audio, and video will be collected during the study. editor window

L **Describe the extent to which identifiable private information will be coded or linked.***

All of the data will be coded by random alphanumeric code. This code will be associated with each individual in a master key file, which will be encrypted and only accessed by the study team. This file will only be stored on the PI's encrypted computer. editor window

M **What is the potential risk of harm to a subject should the data/information be re-identified, lost, stolen, compromised or used in way that was not described in the research study?***

The data being collected is innocuous and if the data were to be re-identified, lost, stolen, or compromised, there would be little to no risk to the individual. editor window

N **Will the data/information be shared or transferred to a third party (outside the approved study team) or otherwise disclosed or released? If sharing data containing PHI/PII outside of the study team please upload the Data Use Agreement (DUA).***

- ◉ No
- ○ Yes, please describe in the box below

editor window

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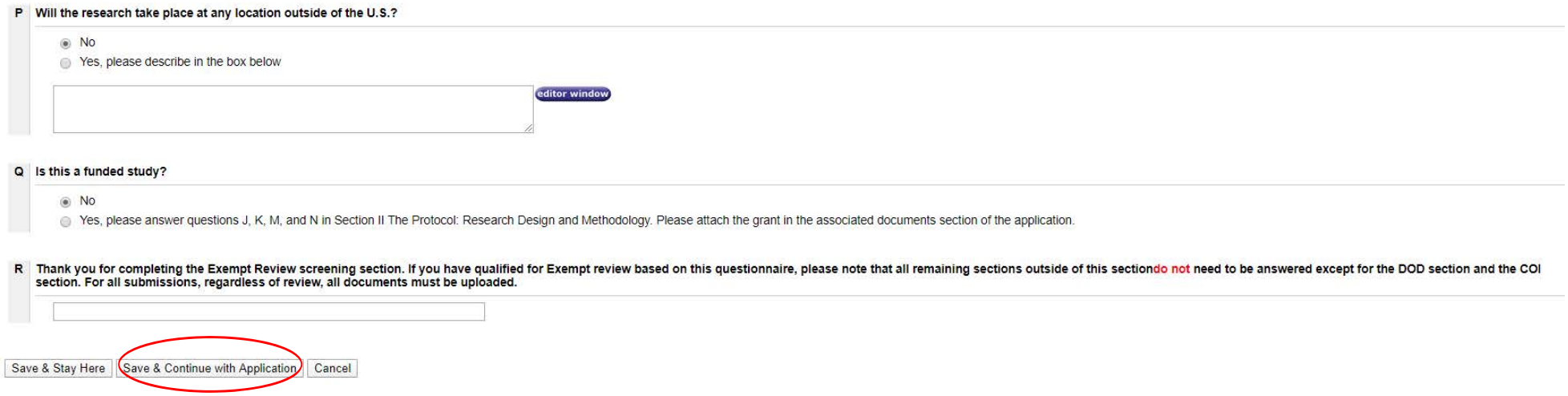
O **What is the likely retention period or life of the data/information?***

- ☑ 0-05 years
- ☐ 06-10 years
- ☐ 11 + years

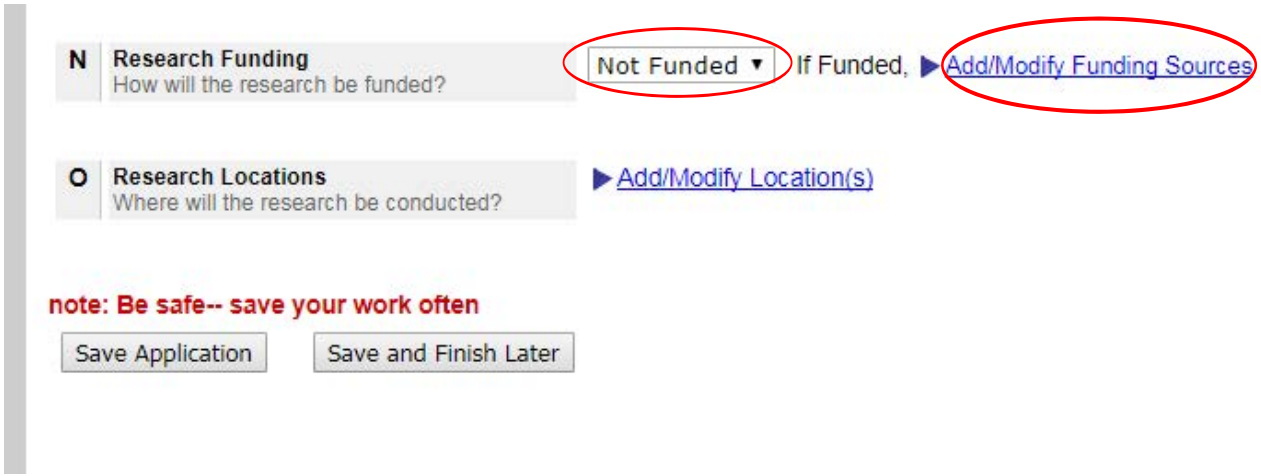
This is a continuation of the Exempt Window. Please be sure to answer all of the questions in this section.

Section I. General Information – Exempt Study Window



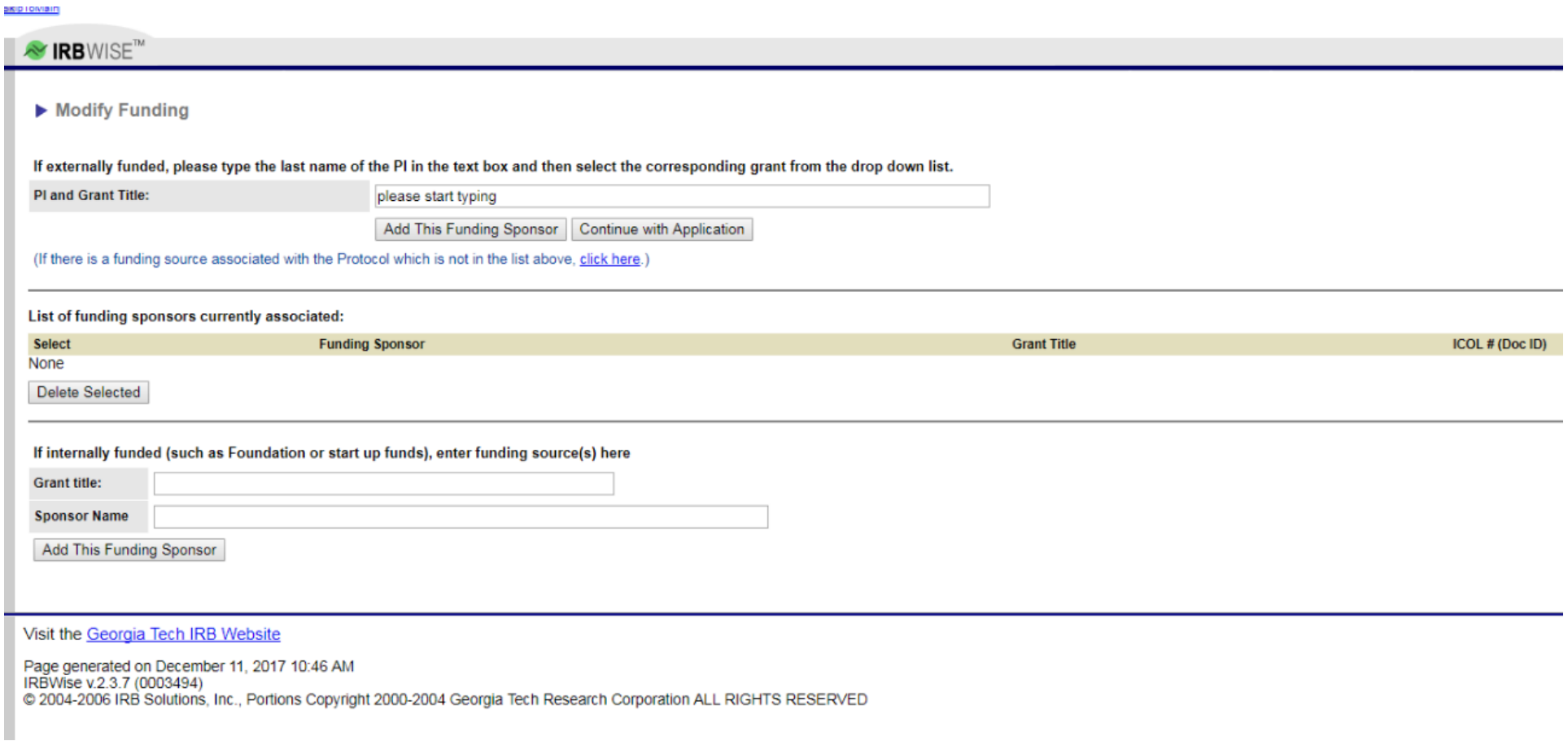
This is a continuation of the Exempt Window. Please be sure to answer all of the questions in this section. Once finished completing this section, please follow the instructions in question R and click "Save and Continue with Application."

If your study is supported by research funding:
Section II. The Protocol: Research Design and Methodology



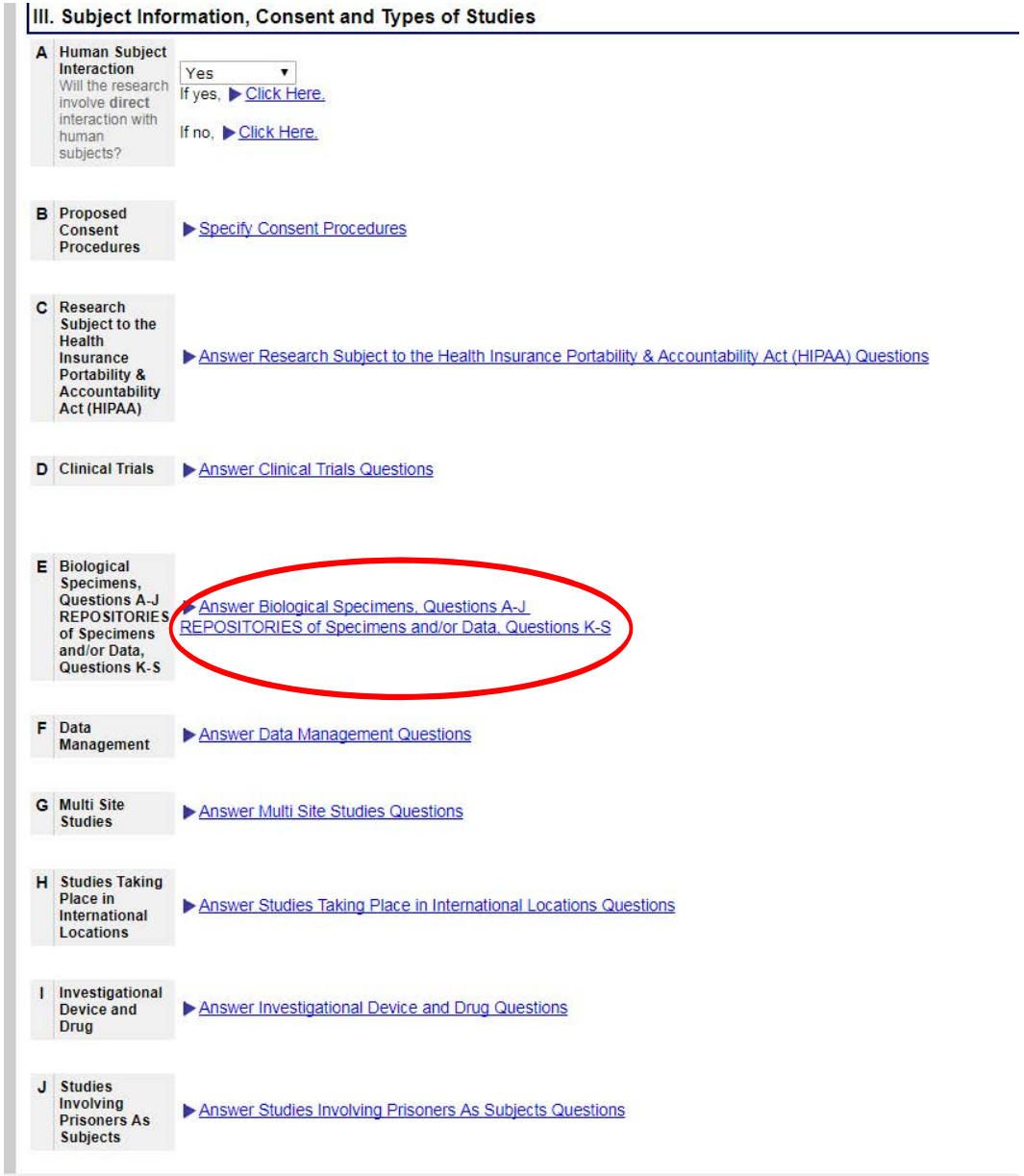
This is a screen shot of the last two questions in Section II (the rest of section II can be skipped). If your Exempt study is supported by research funding, then you will need to select the type of funding and then click on the link (blue text) in question N to fill out the information regarding the funding.

Section II. The Protocol: Research Design and Methodology – Funding Window



This is the pop-up window after clicking “Add/Modify Funding.” In this window, please either type the PI name or grant title in the first text box and select the correct funding. If the funding is internal, then please comlpete the text boxes at the bottom of the page.

Section III – Subject Information, Consent and Types of Studies

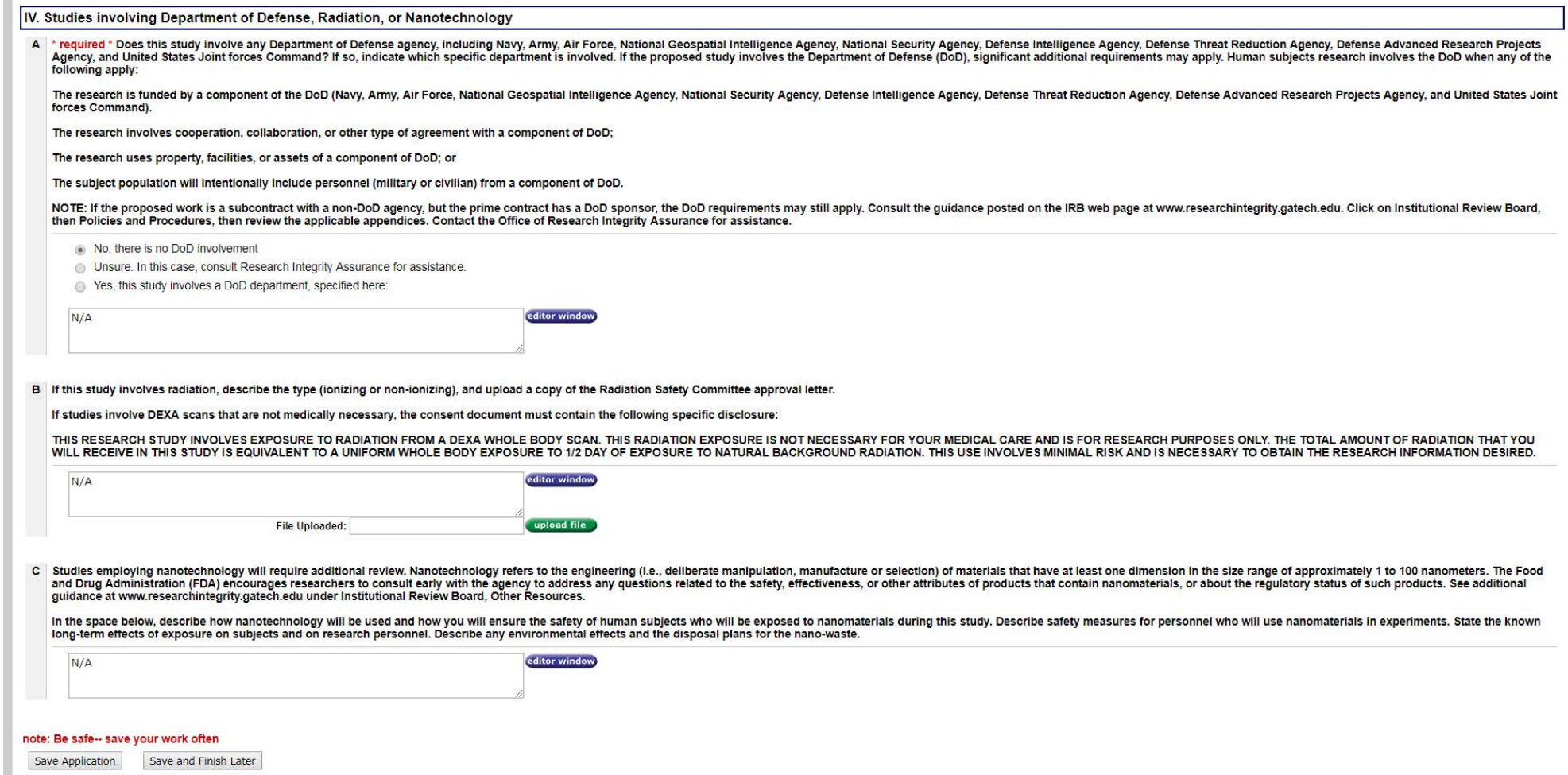


III. Subject Information, Consent and Types of Studies

A	**Human Subject Interaction** Will the research involve direct interaction with human subjects?	Yes If yes, ▶ Click Here. If no, ▶ Click Here.
B	**Proposed Consent Procedures**	▶ Specify Consent Procedures
C	**Research Subject to the Health Insurance Portability & Accountability Act (HIPAA)**	▶ Answer Research Subject to the Health Insurance Portability & Accountability Act (HIPAA) Questions
D	**Clinical Trials**	▶ Answer Clinical Trials Questions
E	**Biological Specimens, Questions A-J REPOSITORIES of Specimens and/or Data, Questions K-S**	▶ Answer Biological Specimens, Questions A-J REPOSITORIES of Specimens and/or Data, Questions K-S
F	**Data Management**	▶ Answer Data Management Questions
G	**Multi Site Studies**	▶ Answer Multi Site Studies Questions
H	**Studies Taking Place in International Locations**	▶ Answer Studies Taking Place in International Locations Questions
I	**Investigational Device and Drug**	▶ Answer Investigational Device and Drug Questions
J	**Studies Involving Prisoners As Subjects**	▶ Answer Studies Involving Prisoners As Subjects Questions

If you are obtaining an identifiable data set or identifiable human specimen for your research, you will need to answer question E of this section. In question E, you will be asked multiple questions including to fully describe where the data or specimen are being stored, how they will be maintained, and who will have access to them. The rest of this section can be skipped.

Section IV – Studies Involving Department of Defense, Radiation, or Nanotechnology



IV. Studies involving Department of Defense, Radiation, or Nanotechnology

A * required * **Does this study involve any Department of Defense agency, including Navy, Army, Air Force, National Geospatial Intelligence Agency, National Security Agency, Defense Intelligence Agency, Defense Threat Reduction Agency, Defense Advanced Research Projects Agency, and United States Joint forces Command? If so, indicate which specific department is involved. If the proposed study involves the Department of Defense (DoD), significant additional requirements may apply. Human subjects research involves the DoD when any of the following apply:**

The research is funded by a component of the DoD (Navy, Army, Air Force, National Geospatial Intelligence Agency, National Security Agency, Defense Intelligence Agency, Defense Threat Reduction Agency, Defense Advanced Research Projects Agency, and United States Joint forces Command).

The research involves cooperation, collaboration, or other type of agreement with a component of DoD;

The research uses property, facilities, or assets of a component of DoD; or

The subject population will intentionally include personnel (military or civilian) from a component of DoD.

NOTE: If the proposed work is a subcontract with a non-DoD agency, but the prime contract has a DoD sponsor, the DoD requirements may still apply. Consult the guidance posted on the IRB web page at www.researchintegrity.gatech.edu. Click on Institutional Review Board, then Policies and Procedures, then review the applicable appendices. Contact the Office of Research Integrity Assurance for assistance.

- (•) No, there is no DoD involvement
- ( ) Unsure. In this case, consult Research Integrity Assurance for assistance.
- ( ) Yes, this study involves a DoD department, specified here:

N/A editor window

B **If this study involves radiation, describe the type (ionizing or non-ionizing), and upload a copy of the Radiation Safety Committee approval letter.**

If studies involve DEXA scans that are not medically necessary, the consent document must contain the following specific disclosure:

THIS RESEARCH STUDY INVOLVES EXPOSURE TO RADIATION FROM A DEXA WHOLE BODY SCAN. THIS RADIATION EXPOSURE IS NOT NECESSARY FOR YOUR MEDICAL CARE AND IS FOR RESEARCH PURPOSES ONLY. THE TOTAL AMOUNT OF RADIATION THAT YOU WILL RECEIVE IN THIS STUDY IS EQUIVALENT TO A UNIFORM WHOLE BODY EXPOSURE TO 1/2 DAY OF EXPOSURE TO NATURAL BACKGROUND RADIATION. THIS USE INVOLVES MINIMAL RISK AND IS NECESSARY TO OBTAIN THE RESEARCH INFORMATION DESIRED.

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C **Studies employing nanotechnology will require additional review. Nanotechnology refers to the engineering (i.e., deliberate manipulation, manufacture or selection) of materials that have at least one dimension in the size range of approximately 1 to 100 nanometers. The Food and Drug Administration (FDA) encourages researchers to consult early with the agency to address any questions related to the safety, effectiveness, or other attributes of products that contain nanomaterials, or about the regulatory status of such products. See additional guidance at www.researchintegrity.gatech.edu under Institutional Review Board, Other Resources.**

In the space below, describe how nanotechnology will be used and how you will ensure the safety of human subjects who will be exposed to nanomaterials during this study. Describe safety measures for personnel who will use nanomaterials in experiments. State the known long-term effects of exposure on subjects and on research personnel. Describe any environmental effects and the disposal plans for the nano-waste.

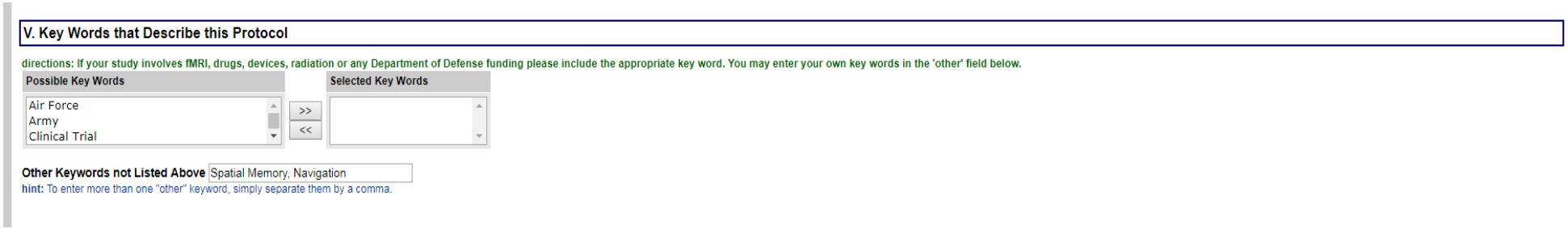
N/A editor window

note: Be safe-- save your work often

Save Application | Save and Finish Later

After completing Sections I, II, and III, you will need to complete Section IV. This is a required section. Please fully answer each question. If your study does involve the Department of Defense, including any of the military branches, then additional requirements may be needed. Please see our Policies and Procedures for more information.

Section V – Key Words that Describe this Protocol



In this section, please select all of the key words that relate to your study. If the key words do not appear on the predetermined list, then please type the key words in the text box underneath the list of key words.

Section VI – Attach Documents

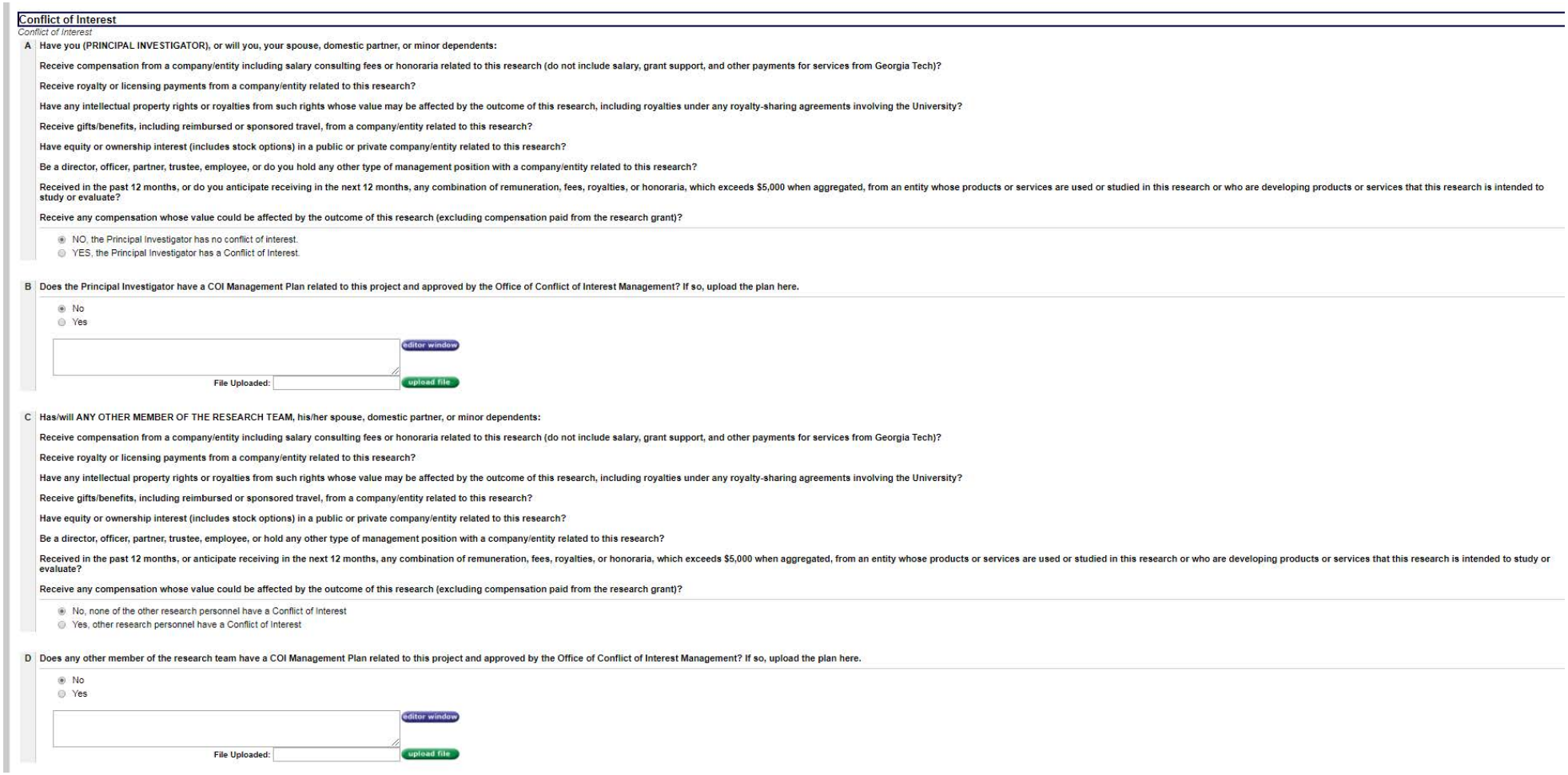
In this section, please click the “upload documents” link and upload all relevant documents to your study. This includes protocol documents, funding documents, recruitment, surveys, interview questions, pictures and descriptions of an experimental apparatus, device brochures, etc.

Templates for certain required documents can be found on our website: https://oria.gatech.edu/irb/submitting-protocol/forms

Submitting the Study for IRB Review

When you are ready to submit your study, please click the “Save and Continue Application” button. If you want to finish your submission at a later date, then please click “Save and Finish Later.”

Submitting the Study for IRB Review – Conflict of Interest



Conflict of Interest

Conflict of Interest

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

editor window

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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

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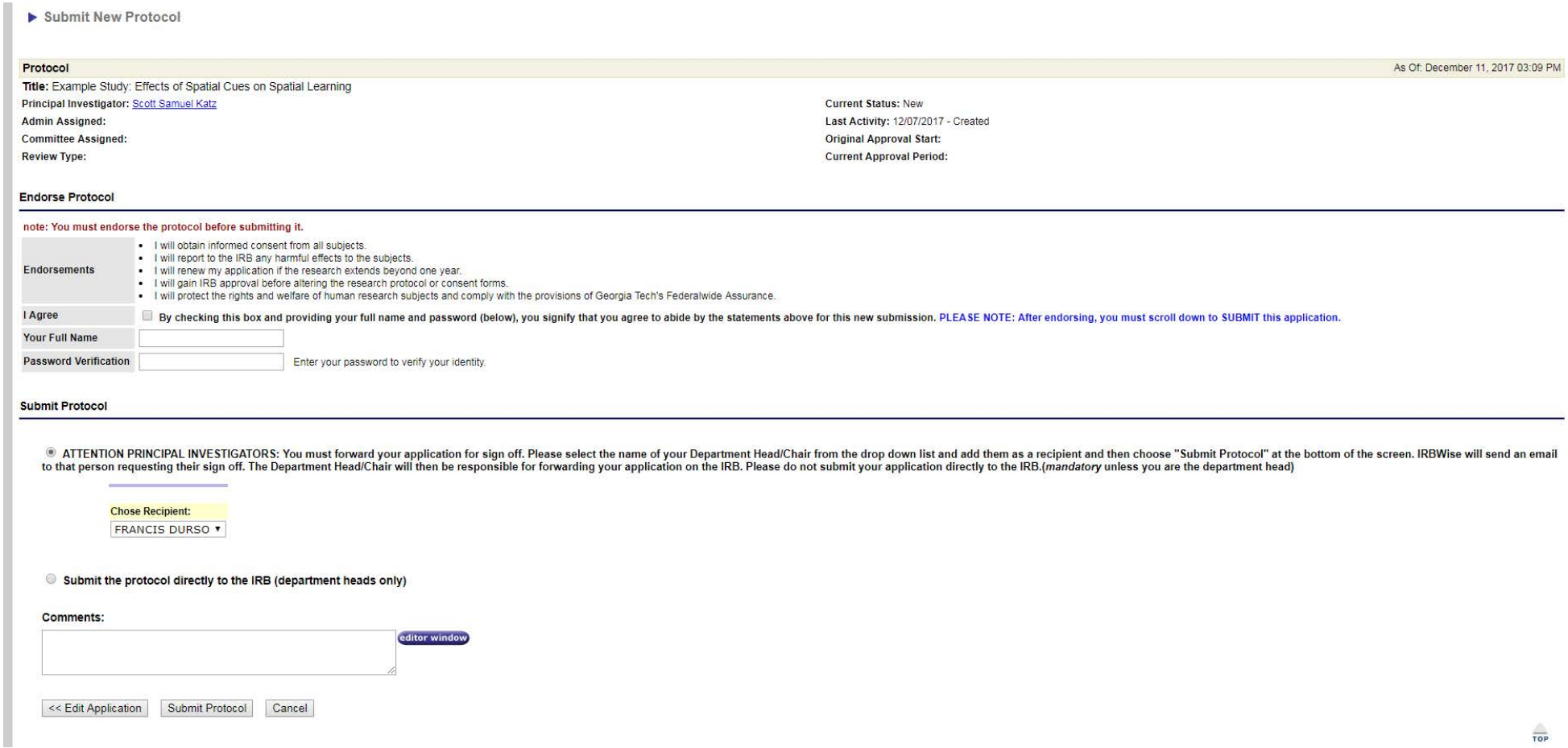
After clicking “Save and Continue Application,” you will be brought back to your full submission to review. At the bottom of this submission is an additional section that asks if you or any study team members have a financial conflict of interest. If you are unsure about this, please either contact the Office of Research Integrity of Assurance or the Conflict of Interest Management Office. When finished, please click “Save and Continue” at the bottom of the screen.

Submitting the Study for IRB Review



After clicking “Save and Continue,” you will be brought to this screen. You will first need to endorse the protocol at the top of the page. After doing so, please select who the study will be sent to for review at the bottom of the page. Please read the instructions next to each selection, for that there are specific rules on who can submit.

Congratulations! You have officially submitted your Exempt application to the IRB.

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

Office of Research Integrity Assurance
Georgia Institute of Technology
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926 Dalney Street NW, Atlanta, GA 30332-0415
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Website: https://oria.gatech.edu/irb