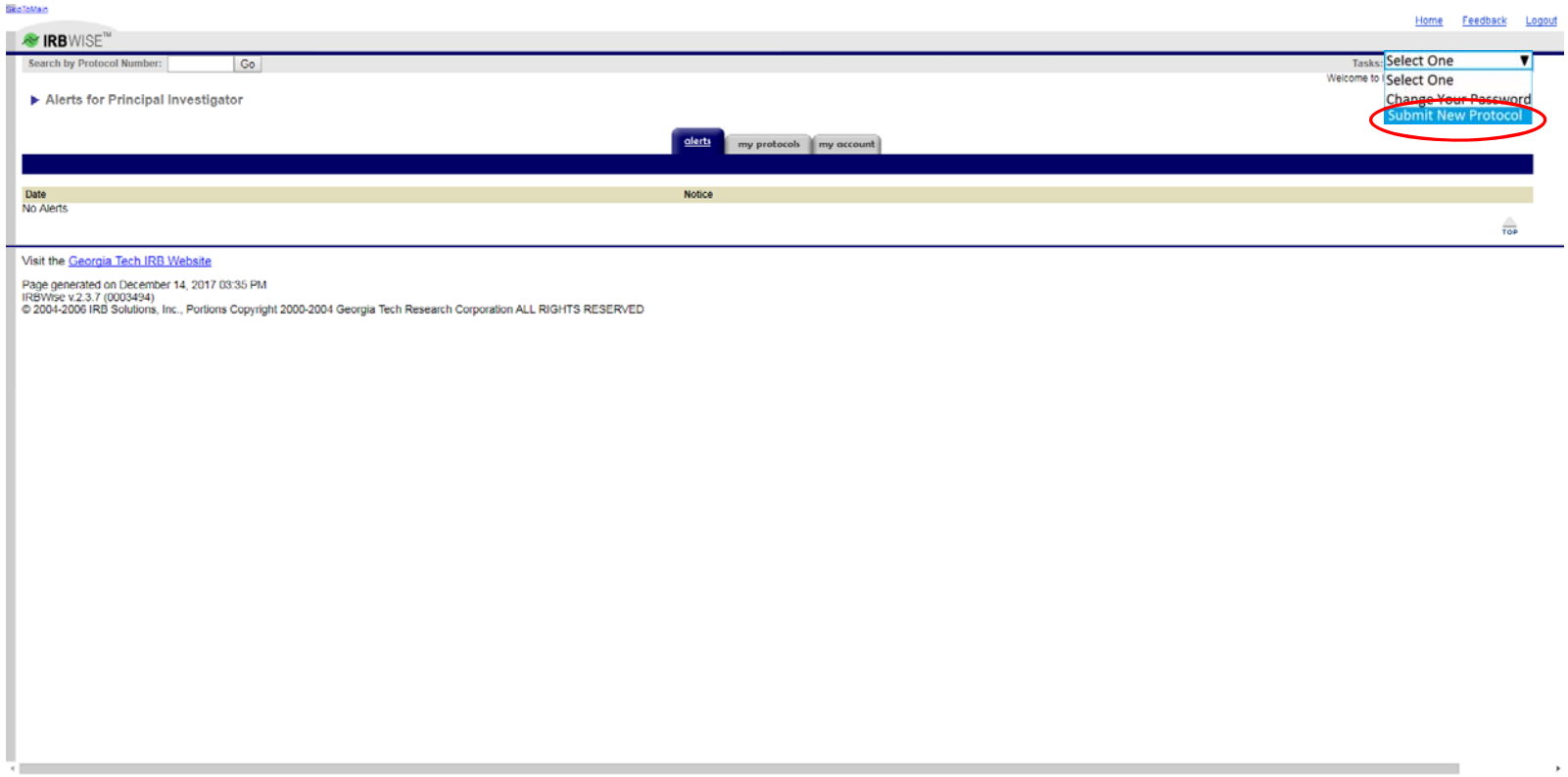
IRB Wise Shell Submission Example and Guidance

This presentation includes an example of a new Shell Submission in IRB Wise and also includes guidance for each section in IRB Wise. Shell Submissions are used by the Office of Research Integrity Assurance (ORIA) to track GT IRB deferral decisions to external IRB approval decisions. Shell Submissions are also used to track studies that fall under the Single IRB (sIRB) requirement. 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

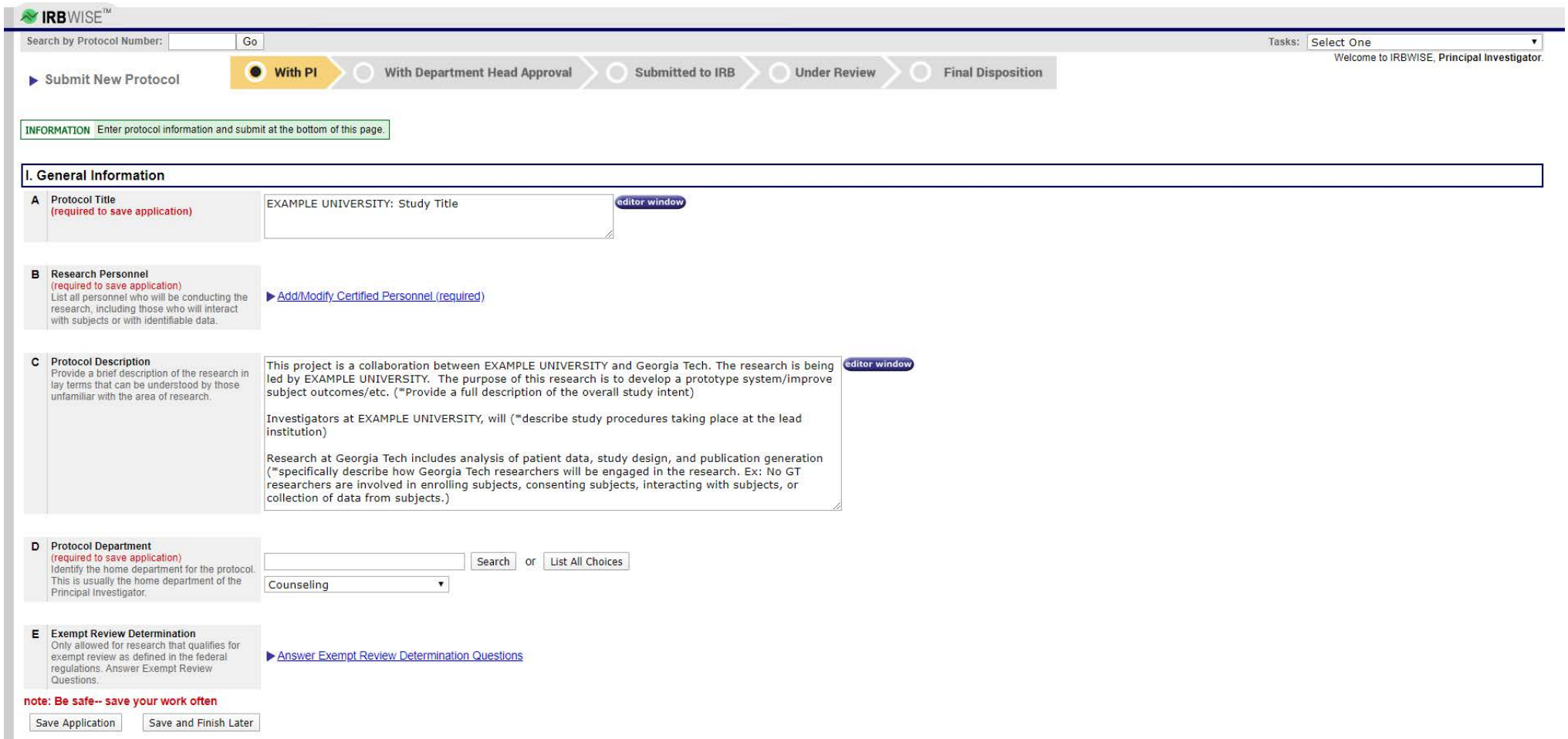
Start Page on IRB Wise



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

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

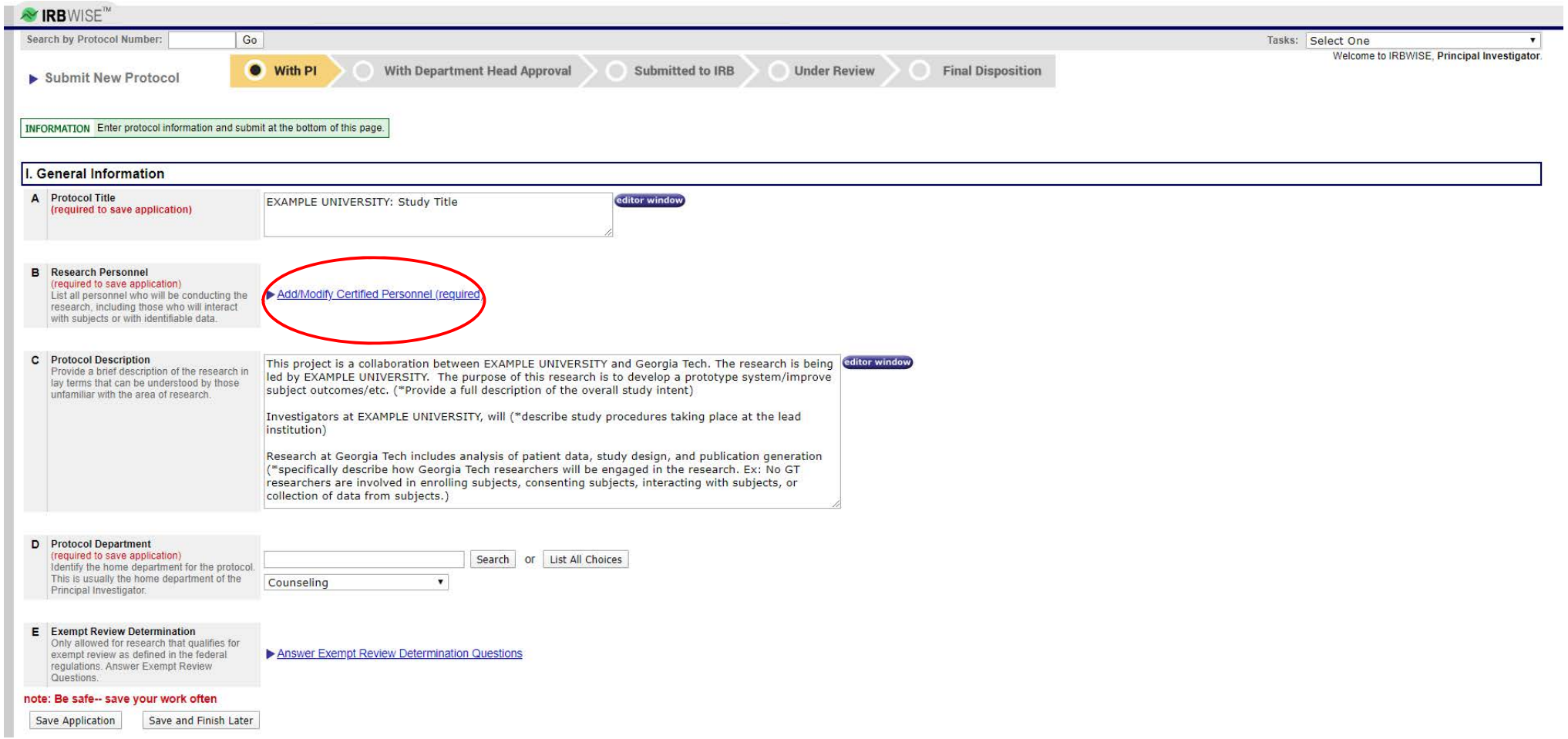
Section I. General Information



This is the first section of IRB Wise. For Shell Submissions, this is the main section that you will use to describe your study. Please see the notes below:

In question A, please be sure to list the institution that you are requesting we rely on before your title (e.g., "Example University: Title of study").

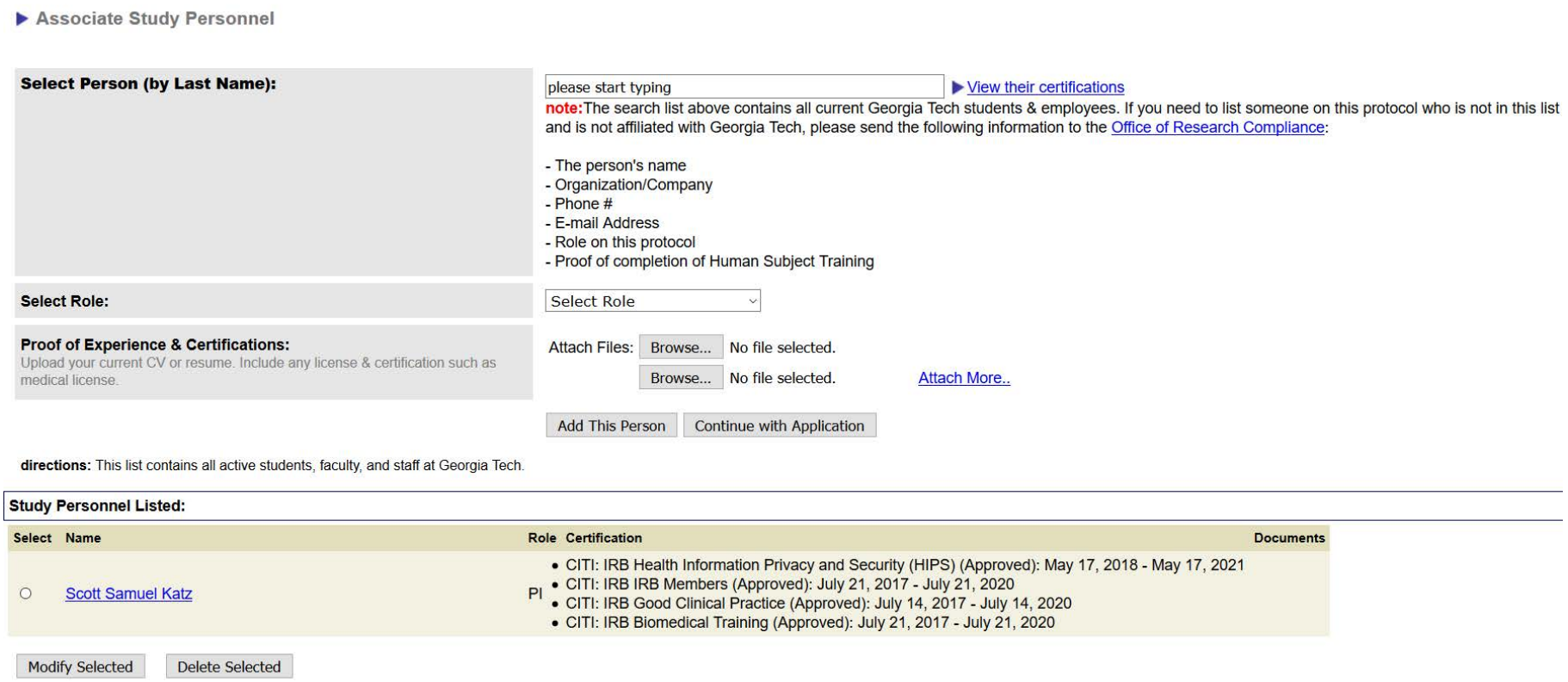
Section I. General Information – Add/Modify Personnel Window



This is the first section of IRB Wise. For Shell Submissions, this is the main section that you will use to describe your study. Please see the notes below:

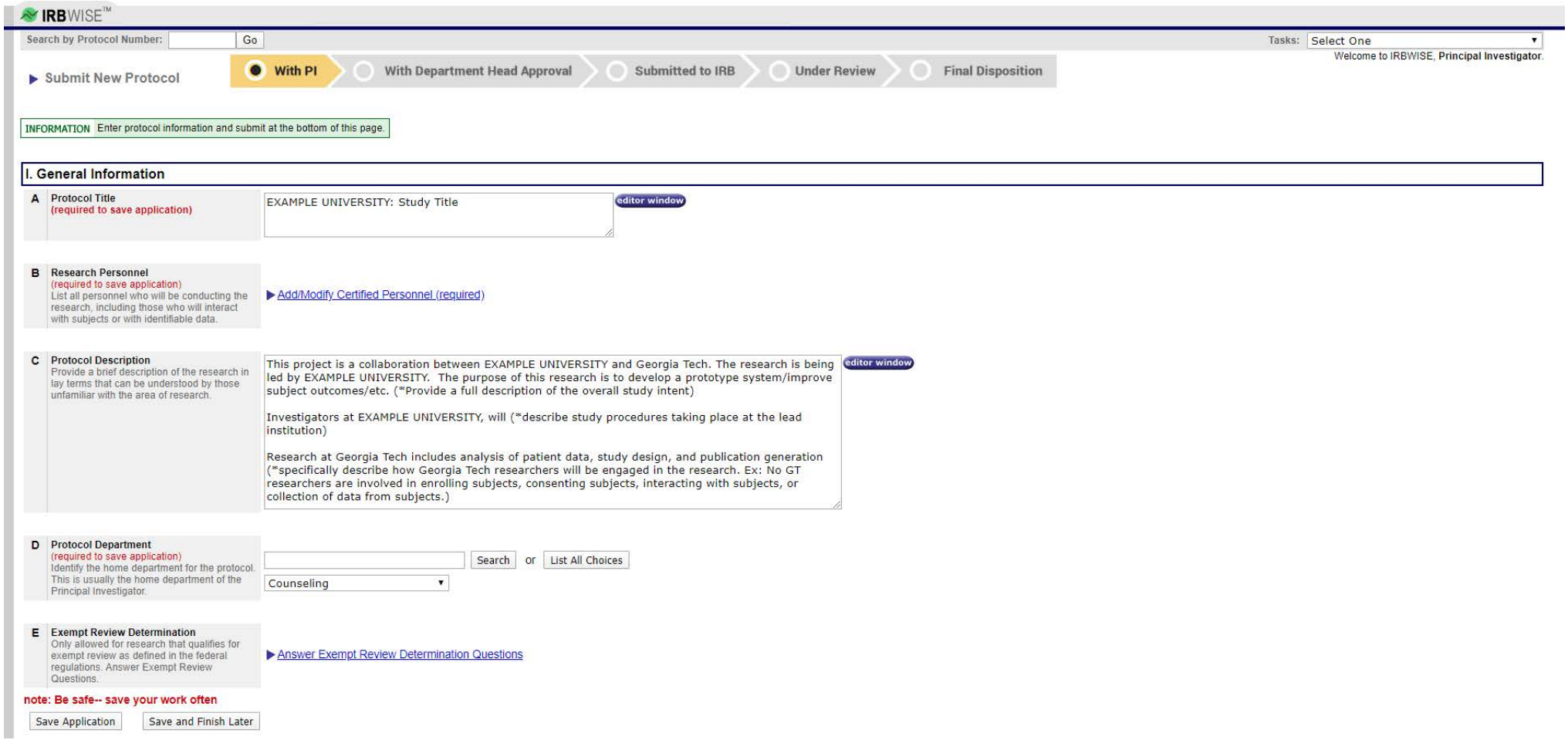
In question B, please be sure to add all Georgia Tech research personnel that are engaged in human subjects research.

Section I. General Information – Add/Modify Personnel Window



In this pop-up window, you are asked to list all of the Georgia Tech 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.

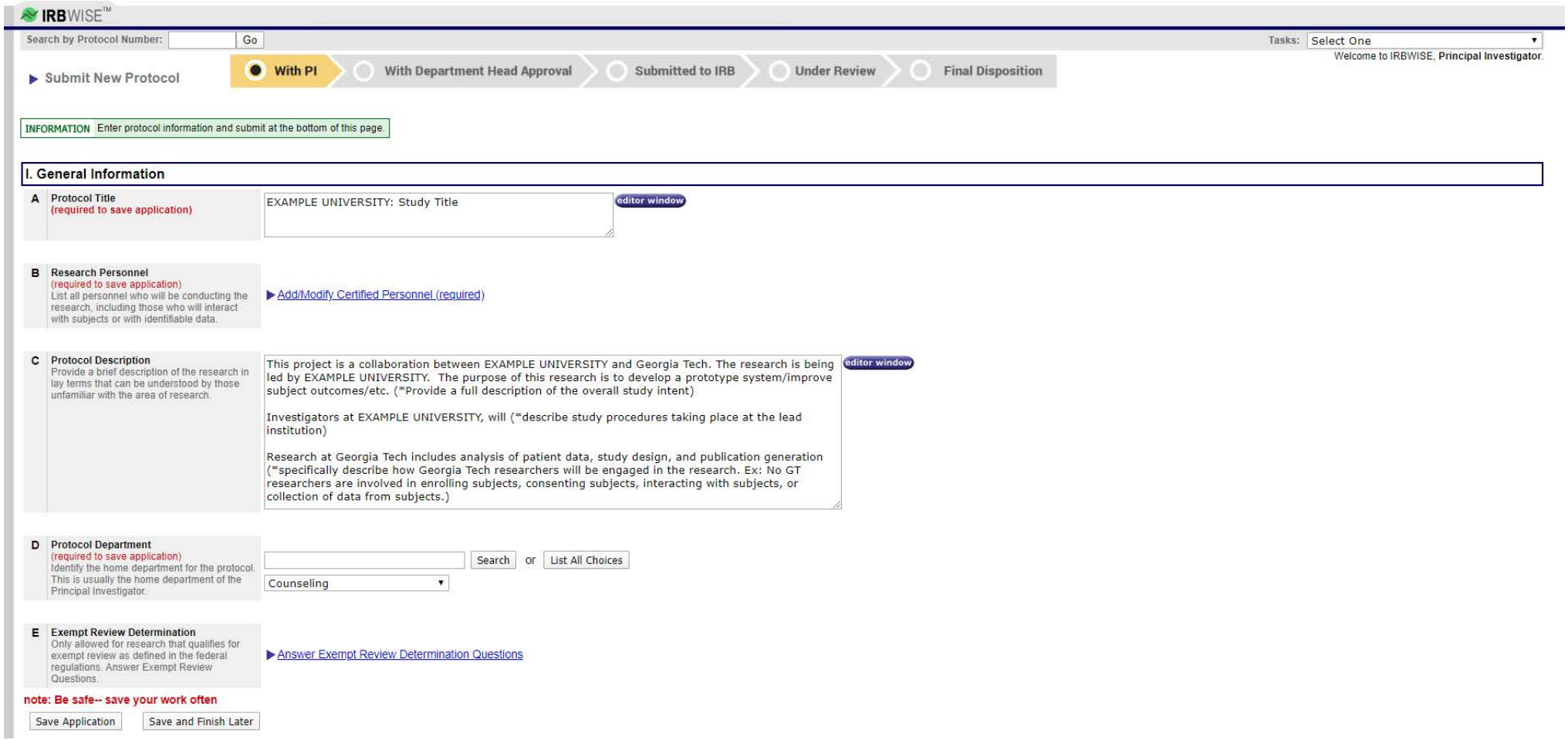
Section I. General Information – Protocol Description



This is the first section of IRB Wise. For Shell Submissions, this is the main section that you will use to describe your study. Please see the notes below:

In question C, please fully discuss what is taking place at Georgia Tech and how Georgia Tech is involved in the research. The screenshot above provides a good example and detailed instructions of how to complete this section.

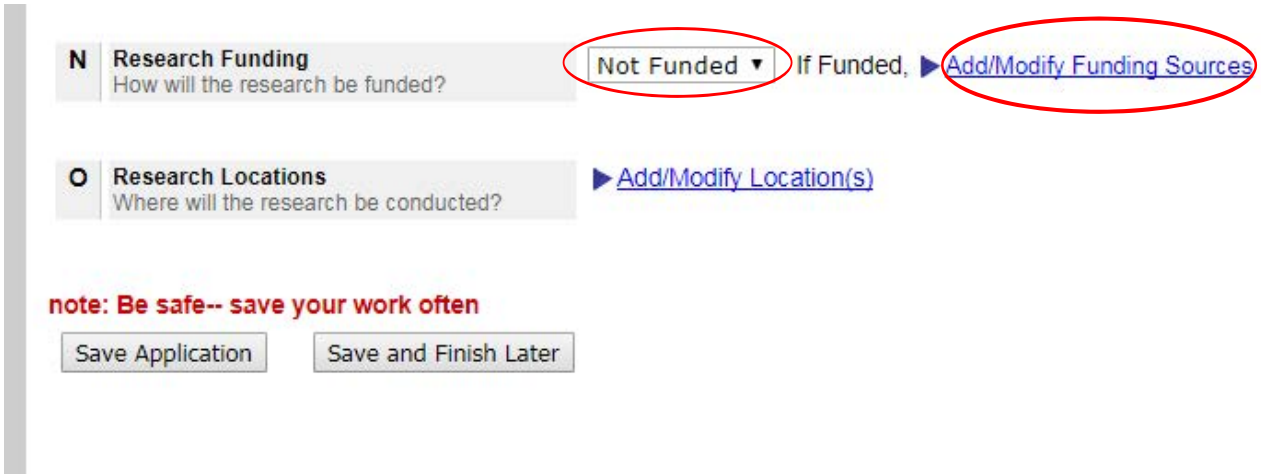
Section I. General Information



This is the first section of IRB Wise. For Shell Submissions, this is the main section that you will use to describe your study. Please see the notes below:

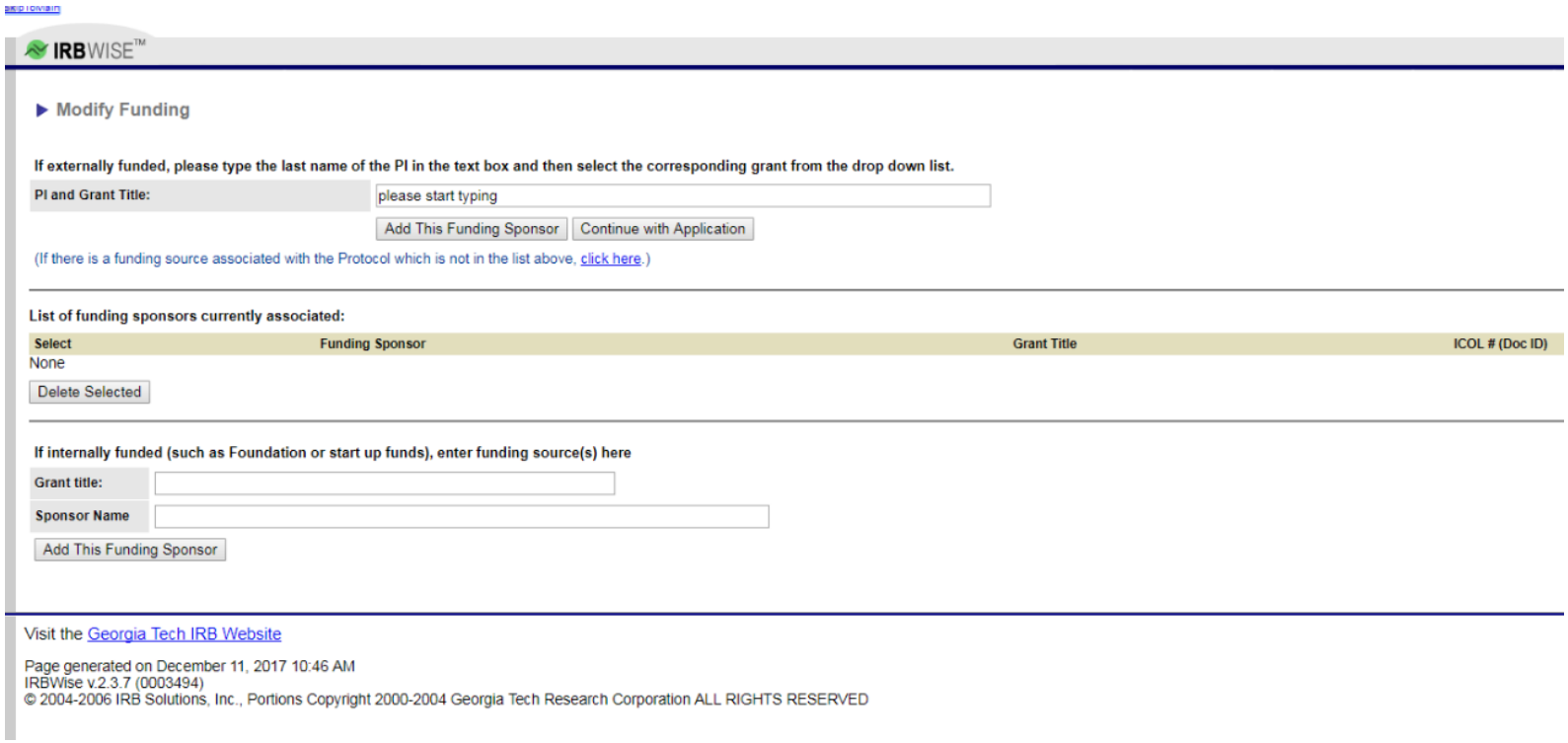
Once questions A-D have been completed, please save your progress and scroll down to the next section (skip question E).

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



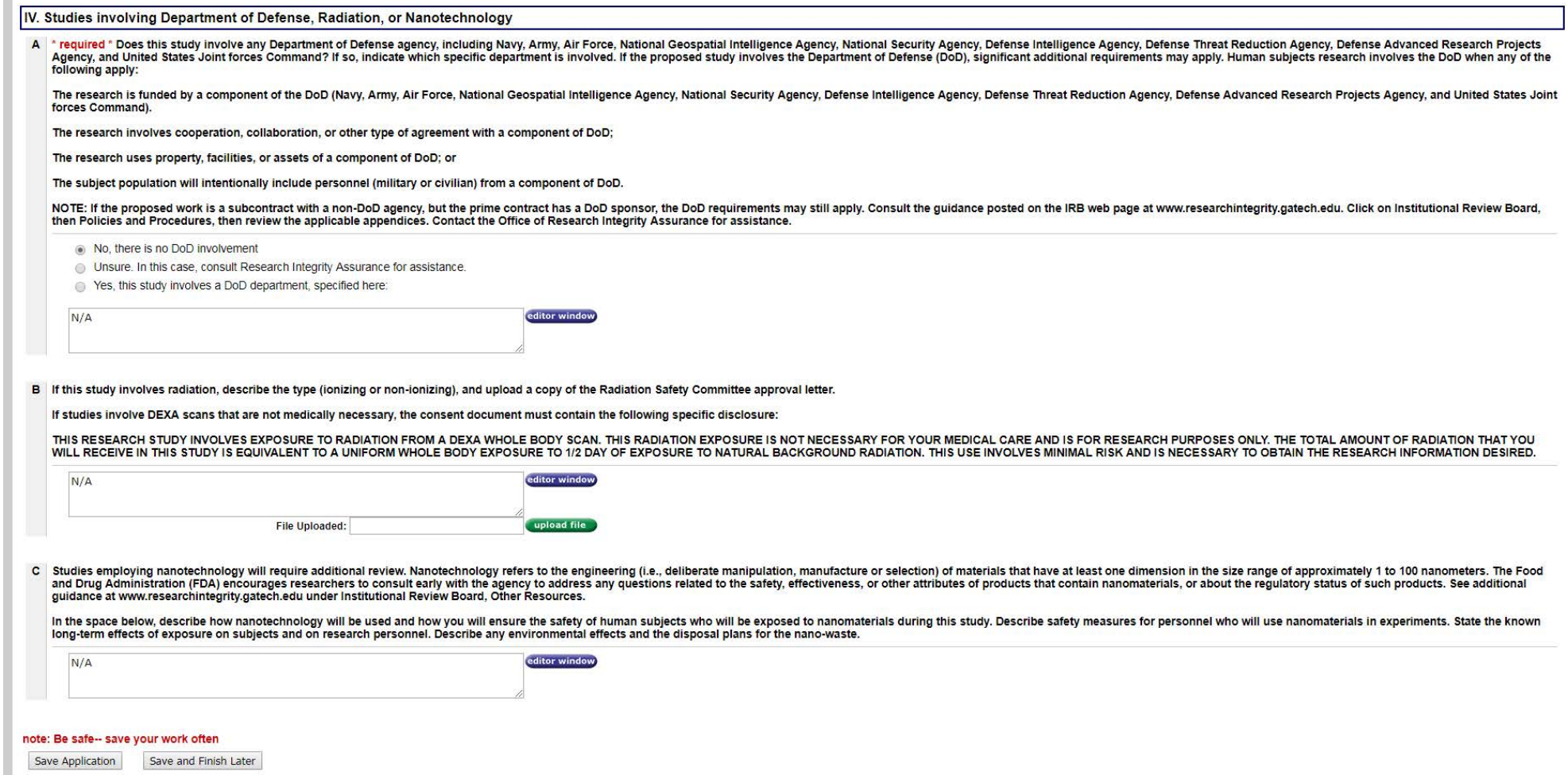
This is a screen shot of the last two questions in Section II (the rest of section II can be skipped). If your study is supported by research funding, then you will need to select the type of funding and then click on the link (blue text) in question N to fill out the information regarding the funding.

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 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.

N/A editor window

File Uploaded: upload file

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.

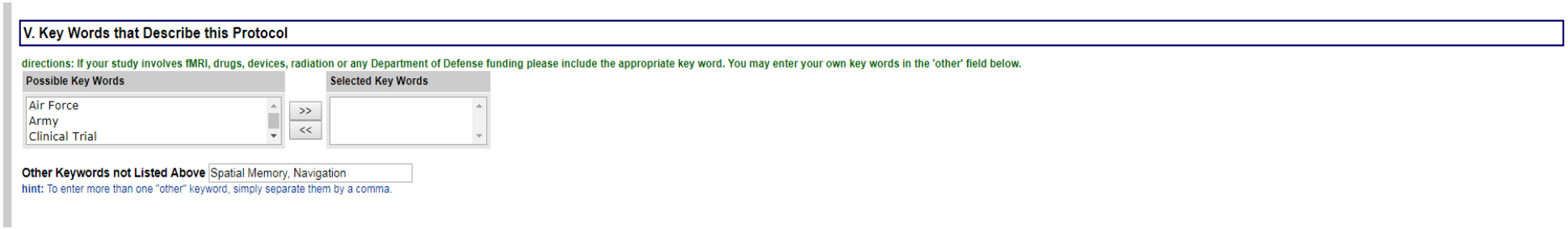
N/A editor window

note: Be safe-- save your work often

Save Application | Save and Finish Later

After completing Section I and the funding questions in Section II, you will need to complete Section IV (Section III can be skipped). 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 that pertain to both the other institution and the GT specific study.

For the other institution, you will need to upload the approved protocol documents, consent documents, recruitment, surveys, interview questions, and IRB approval letters.

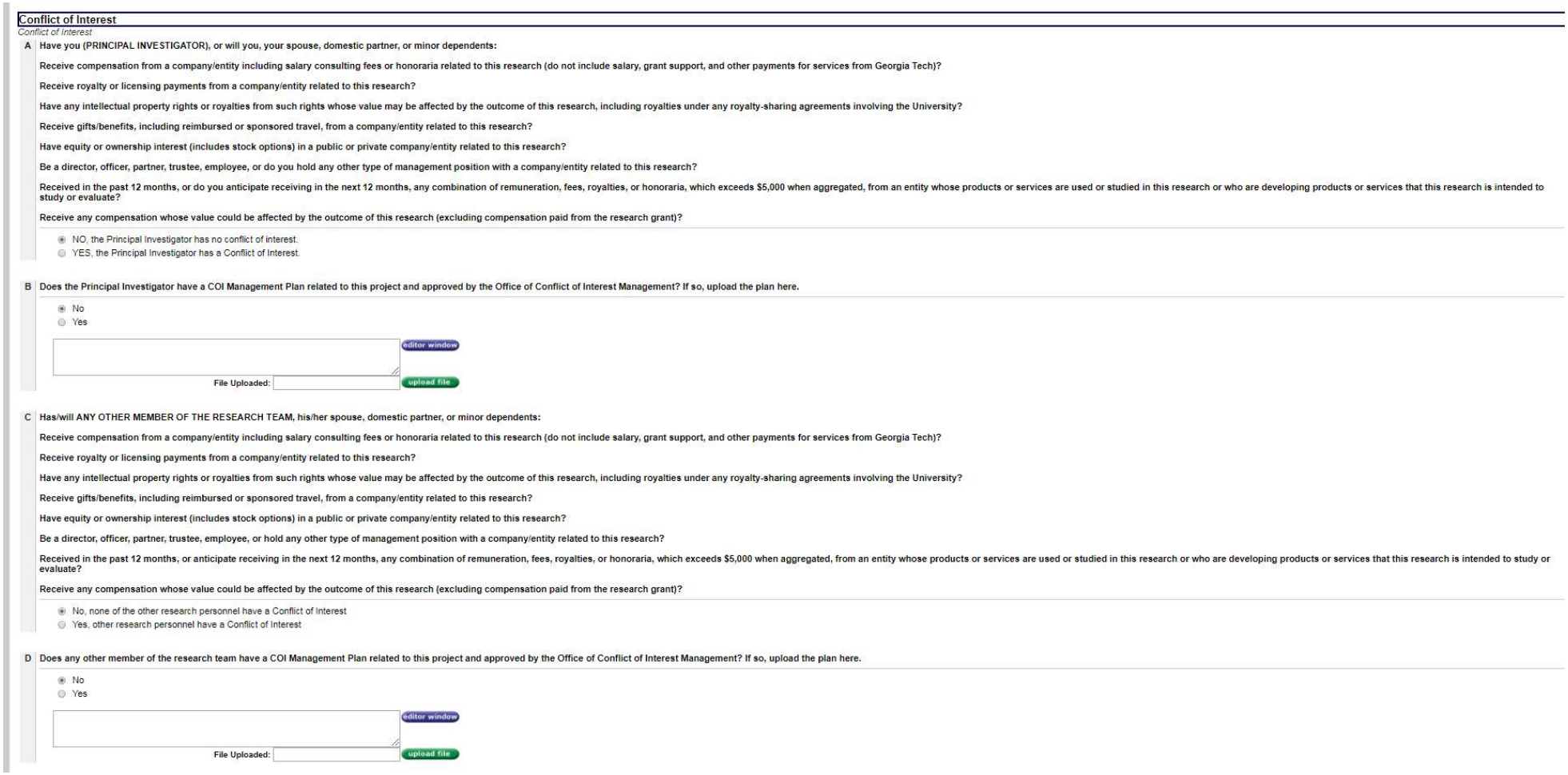
For the GT specific documents, you will need to upload documents such as the funding documents, pictures and descriptions of an experimental apparatus, device brochures, etc.

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

File Uploaded: 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.

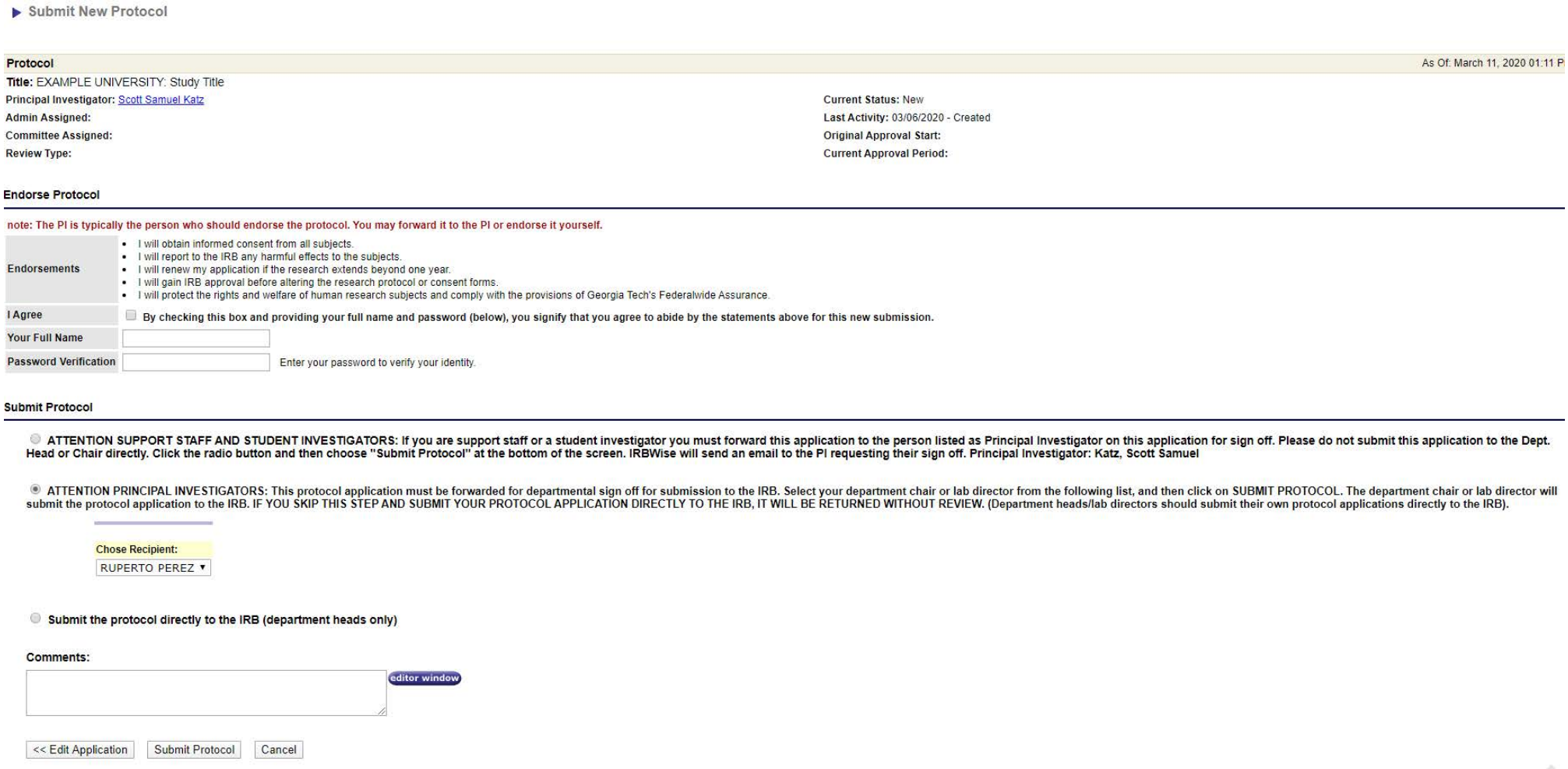
- (•) No
- ( ) Yes

editor window

File Uploaded: upload file

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 Shell Submission 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
Dalney Street Building
926 Dalney Street NW, Atlanta, GA 30332-0415
Email: IRB@gatech.edu
Website: https://oria.gatech.edu/irb