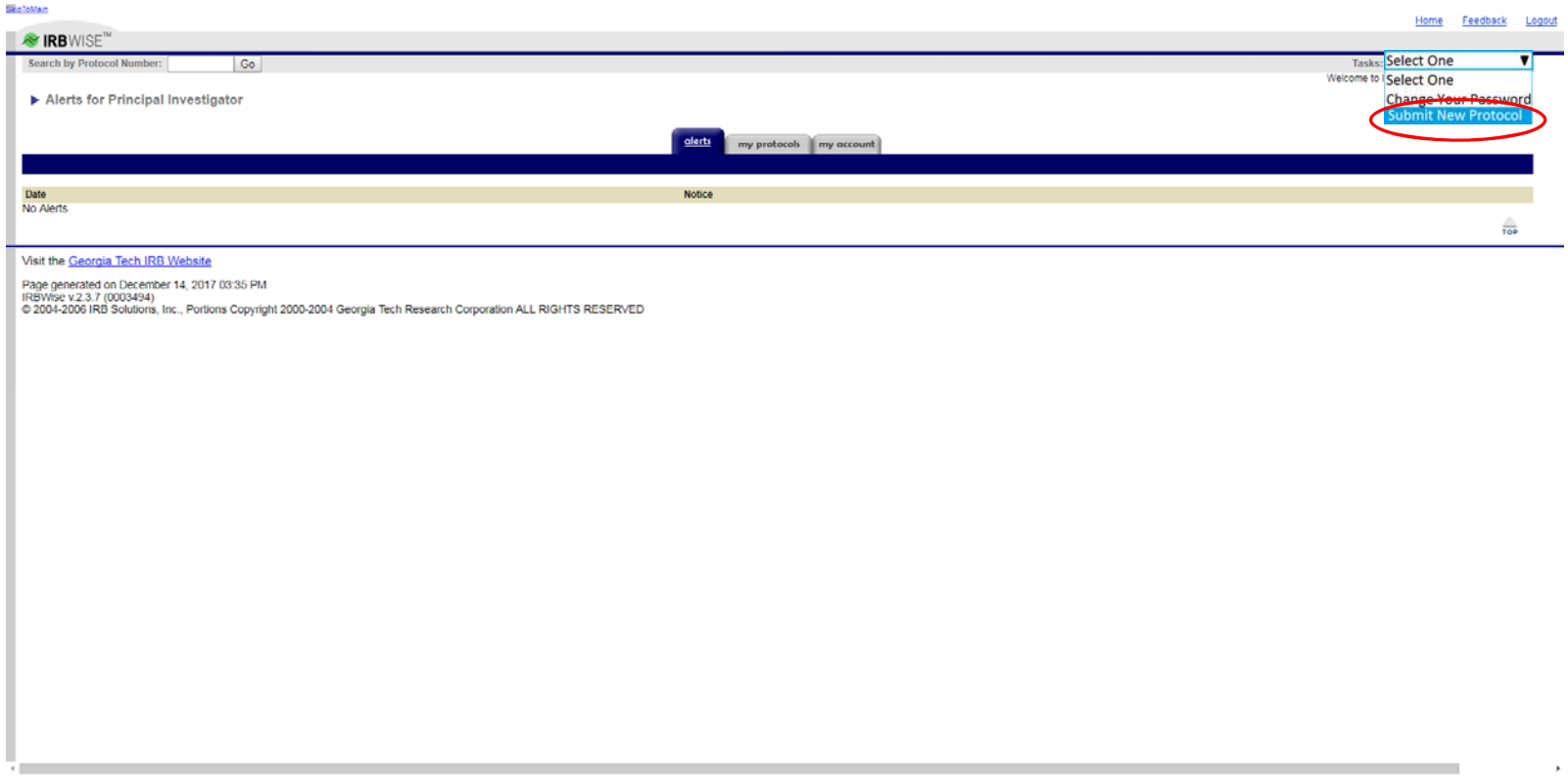
IRB Wise Submission Example and Guidance

This presentation includes an example of a new 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

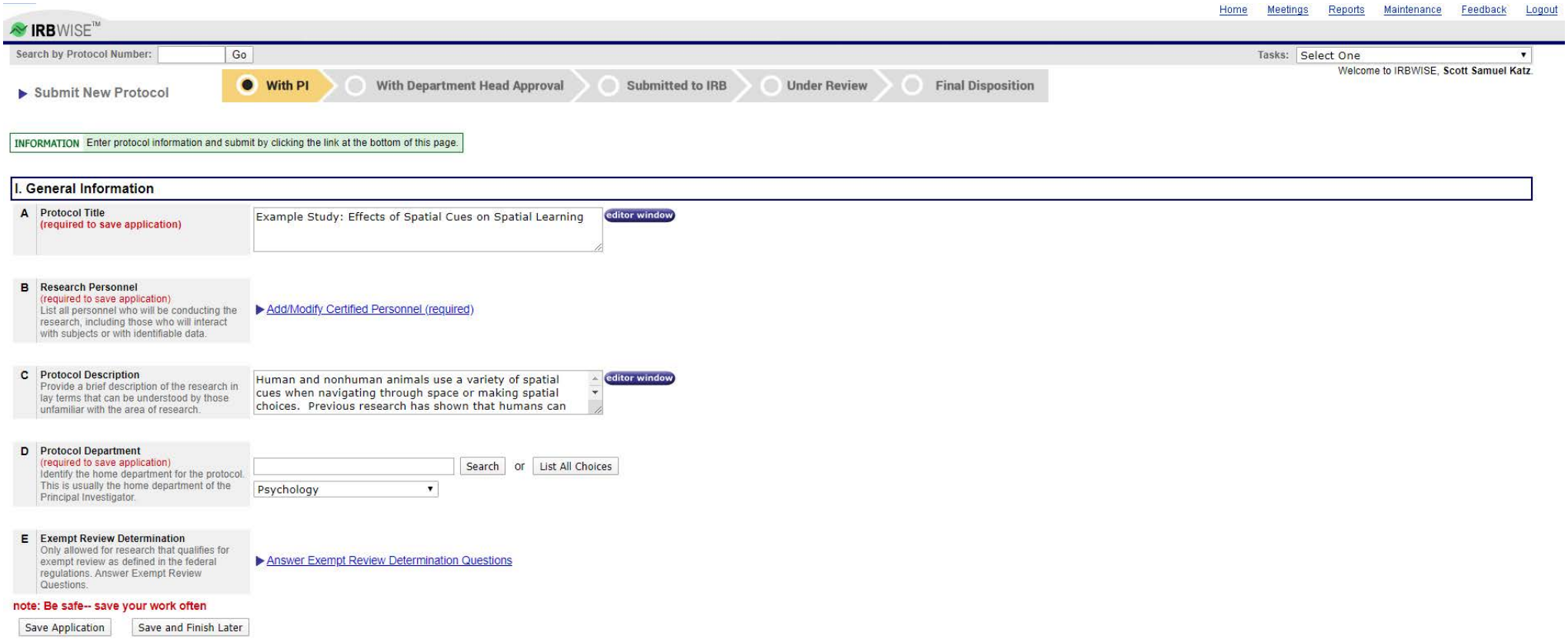
Start Page on IRB Wise



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.

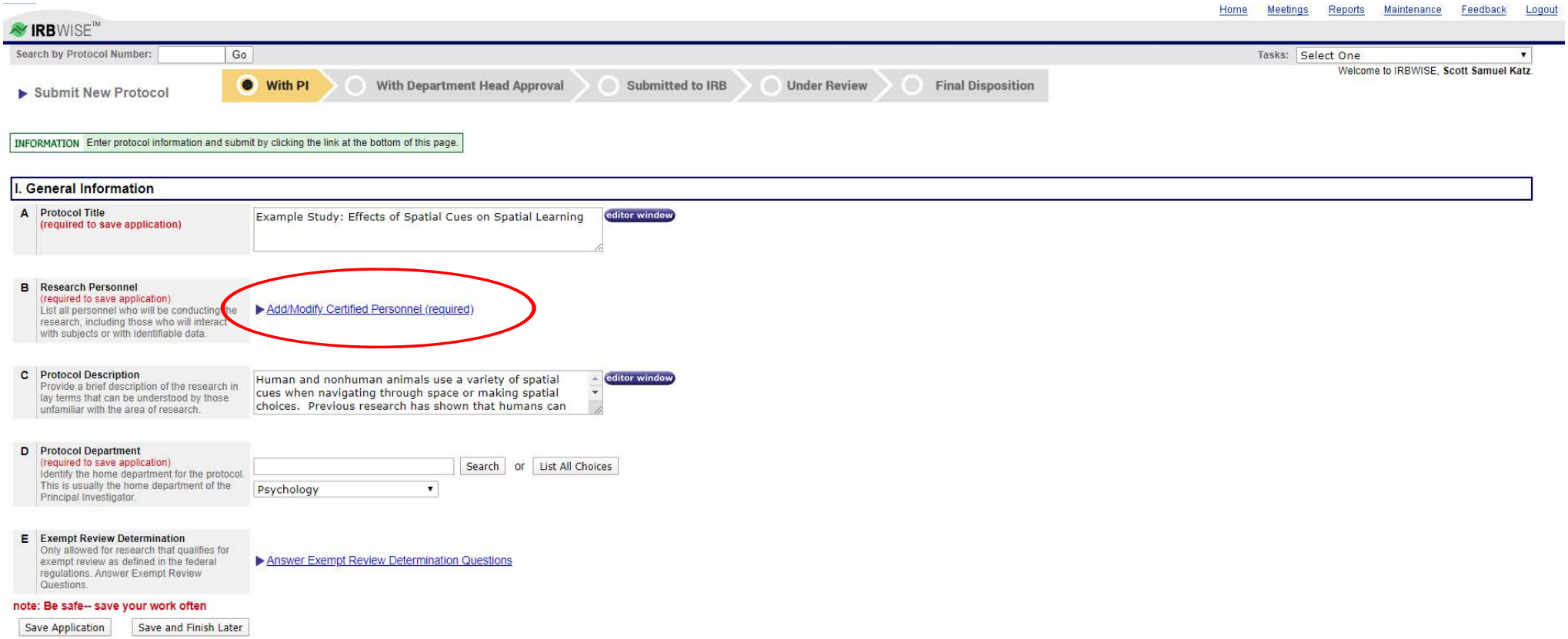
Office of Research Integrity Assurance
Georgia Institue of Technology
irb@gatech.edu

Section I. General Information



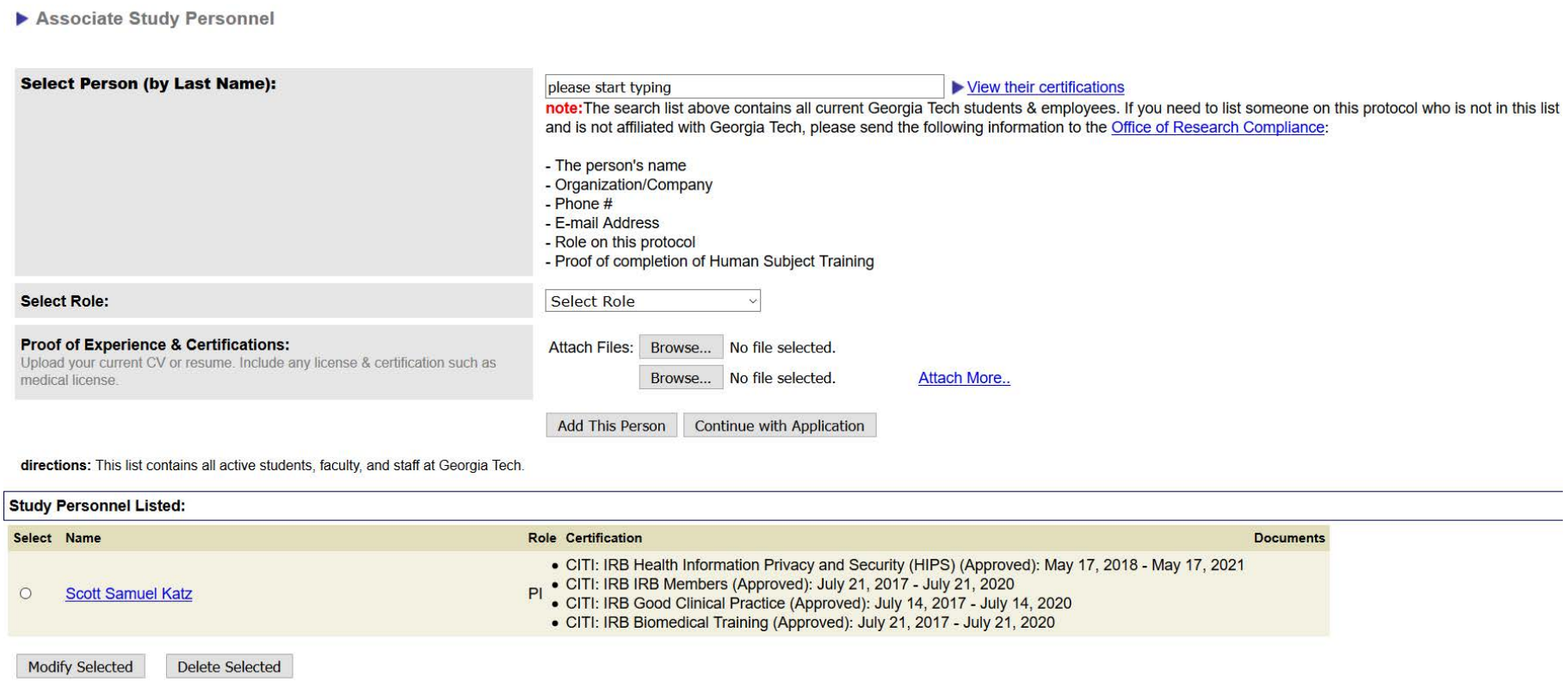
This is the first section of IRB Wise. In this section, you are asked for a title, brief description, your department, and a list of all of the research personnel.

Section I. General Information – Add/Modify Personnel Window



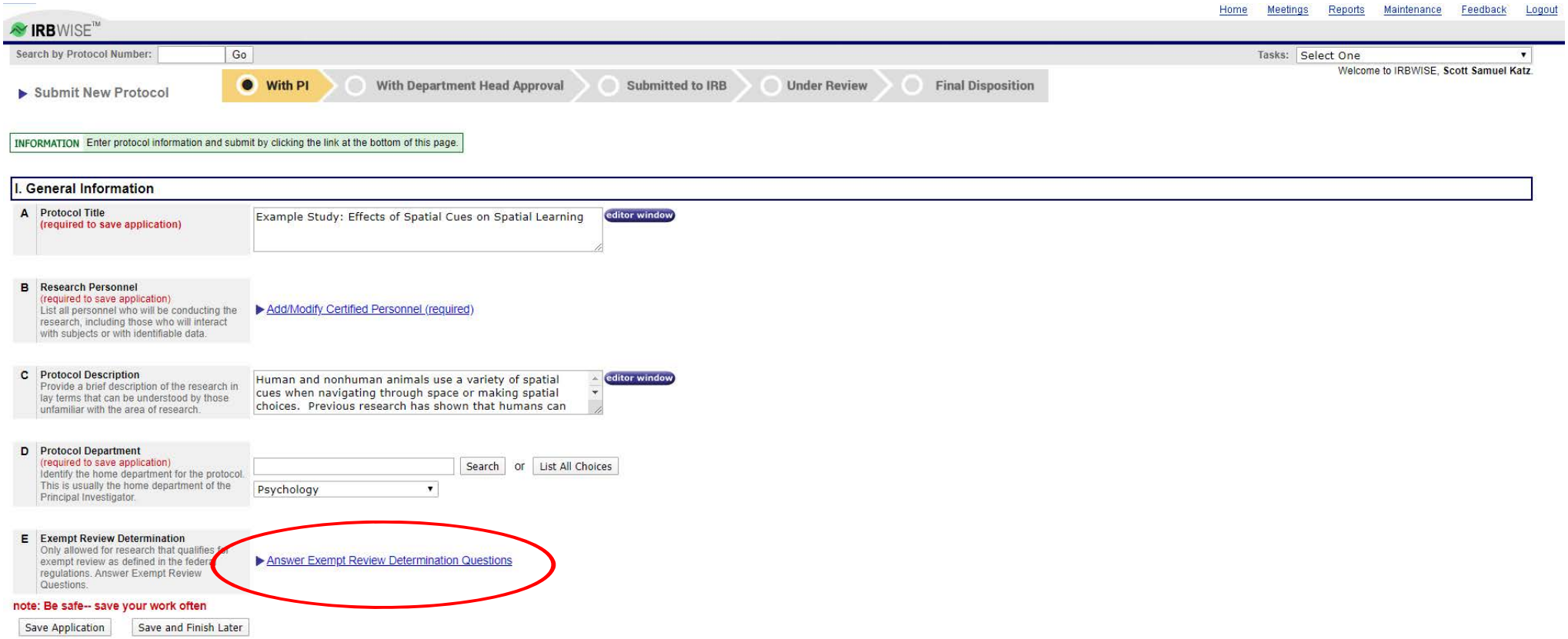
When adding study personnel, please click on the Add/Modify Certified Personnel link (circled above).

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. A separate presentation has been prepared for Exempt Research as well.

Section II. The Protocol: Research Design and Methodology

II. The Protocol: Research Design and Methodology

A **Describe the research design, including the proposed research methodology. For research directly involving human subjects, describe in chronological order the procedures that will occur. If subjects will be assigned to various conditions, describe how and why assignments will be made. (Examples of studies not directly involving human subjects, but still needing IRB approval, include prospective record reviews, observation of behavior without manipulation, and use of anonymized data).**

editor window

Prior to conducting the virtual room experiment, the subjects will give their consent to the study and fill out a demographic survey.

An interactive 3-D virtual environment will be used for this study. The virtual environment will contain 36 containers organized in a 6 - 6 matrix. Eight of the raised bins will be marked in blue, and the remaining bins were unmarked (white colored). To provide an orienting cue, the wall opposite the start location will be lighter than the other three.

Participants will be randomly assigned to one of two groups: visual pattern or visual random. The participants will complete 20 trials in which they will search for eight hidden target locations located among the 36 bins. These goal locations will be arranged in a circle pattern. The circle pattern will move about the search space to a random location from trial to trial, but the goal locations will always maintain the same spatial relations to each other (i.e., in the shape of a circle). Participants will be required to search for these eight goal locations. Participants will begin each trial at the same starting position.

For participants in the visual pattern group, the eight red bins will be arranged in a circle pattern that will be consistent but not coincident with the hidden spatial pattern. These eight red bins will always maintain the same spatial relationship to each other (i.e., in the shape of a circle) and will move to a random location from trial to trial, but their movement will be independent of the hidden spatial pattern. For participants in the visual random group, the red bins were randomly arranged within the 6 - 6 matrix from trial to trial, and their movement will also be independent of the hidden spatial pattern.

Participants will be asked to locate the hidden bins in each virtual room. Upon finding a hidden target, the speakers will make a "ding" sound. Once all eight hidden targets are discovered, the screen will reset to the next virtual room.

B **State the duration of subject participation. How many hours, days, weeks or months? Specify number of sessions and, to the extent possible, state total amount of time for subject participation.**

editor window

Each session (20 trials) will last approximately 1 hour. Each subject will only complete one session.

C **Describe study assessments and other data collection methods. Upload all instruments, including rating scales, questionnaires, surveys, focus group and interview guides, and so on at the end of this online application in the ATTACH DOCUMENTS section.**

(NOTE: The IRB recognizes that such specificity may not be possible in ethnographic or anthropological studies. In such cases, provide sufficient detail for the board to understand the study methodology).

editor window

The video game Valve Hammer Editor and Half-Life Team Fortress Classic platform will be used to simulate the virtual rooms. These programs will track all of the subject's movement, which will then be exported in a text file.

A demographic survey will be administered to ask for age, gender, and gaming experience.

D **Fully describe any potential benefits of this study. All ethical studies pose some benefit-- whether to individual research subjects, to the greater community, as a building block for further development of treatment, and so on. (If subjects will not benefit from participating, this should be disclosed in the benefits section of the consent document).**

editor window

The subjects are not expected to benefit from this study. This study intends to add to the existing knowledge of spatial memory and provide further insights for future research in this area. The ultimate goal is to increase the knowledge on how we navigate through our world to make comparisons of potential routes of travel and navigation between known locations more efficient.

E **Fully describe any known risks to subjects participating in this study and, to the best of your knowledge, indicate the likelihood of such risks occurring. Also state any measures to be taken to minimize or eliminate risks or to manage unpreventable risks.**

editor window

Some subjects may experience nausea due to the experience of navigating in a virtual room on the computer. To reduce this risk, we are screening for those who are prone to nausea before the experiment in the demographic survey and will ask the subjects if they are willing to continue every 15 minutes.

No other risks are expected outside of those in daily life when using a computer and filling out forms.

In this section, you are asked to answer multiple questions about your research. Please be sure to fully answer each question in this section.

Section II. The Protocol: Research Design and Methodology - Continued

F **Describe the statistical analysis plan, its design, and the rationale for the plan.**

Both errors and choice type will be analyzed from this data. A two-way mixed analysis of variance (ANOVA) will be used to determine if there are difference between the two conditions for these two types of data points.

Additionally, the data will also compared to the demographic data collected via the survey to see if there are any group differences.

editor window

G **What are the anticipated start and end dates for the proposed research? Include the expected number of years that data analysis will continue.**

Federal regulations currently require that IRB approval remain active during data analysis (if subject data are not de-identified) even though subject enrollment and interaction may be complete. Be sure to include the period of data analysis when calculating the end date if you will maintain subject identifiers.

Anticipated start date: January, 2018
Anticipated end date: May, 2018
Anticipated data analysis end date: December, 2018

editor window

H **Upload a fully annotated bibliography or reference section, including the results of the literature search done in support of this proposed study.**

This material may be added in the ATTACH DOCUMENTS SECTION at the end of the online application and is required for CLINICAL STUDIES only.

Katz, S.S., Brown, M.F. & Sturz, B.R. Psychon Bull Rev (2014) 21: 114. https://doi.org/10.3758/s13423-013-0477-1

editor window

I **If this is a student class project, provide the course title and number and the name of the instructor.**

editor window

J **GEORGIA INSTITUTE OF TECHNOLOGY INVESTIGATORS ONLY: If funding is pending, specify the potential funding source in the field here. (IRBWISE is linked only to active awards on record in the Georgia Tech Office of Sponsored Programs and not to pending proposals). If the study is already externally funded, please select the specific project in the funding section M below.**

editor window

K **Georgia Tech applicants: If available, enter the DOC ID number here.**

L **GEORGIA STATE UNIVERSITY INVESTIGATORS ONLY: Please specify the funding source in the field below. IRBWISE is not linked to GSU's Office of Sponsored Programs, so the search feature in the next question is not applicable to GSU investigators.**

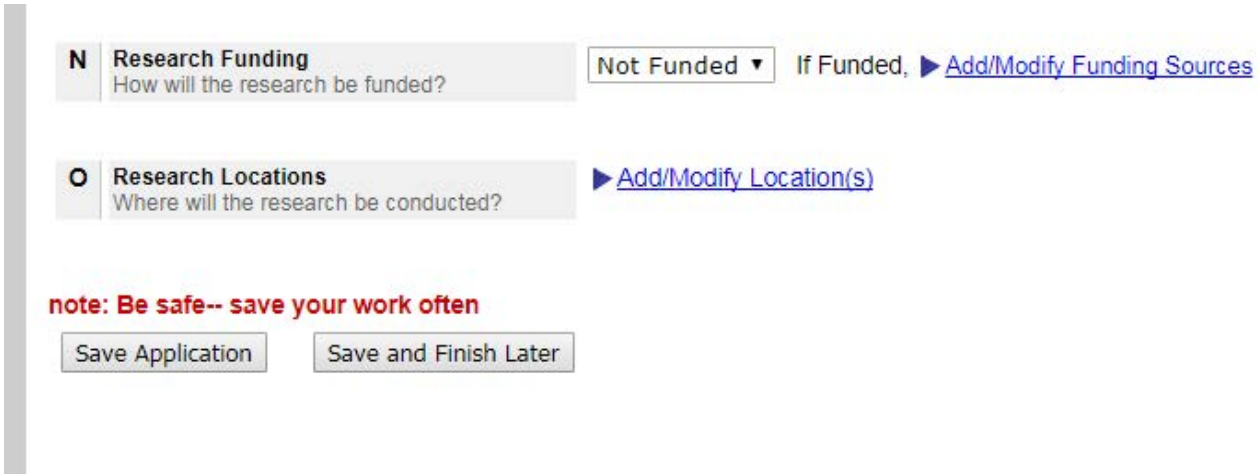
editor window

M **GEORGIA INSTITUTE OF TECHNOLOGY INVESTIGATORS ONLY: If this study is a sub award please list the PRIME information below.**

editor window

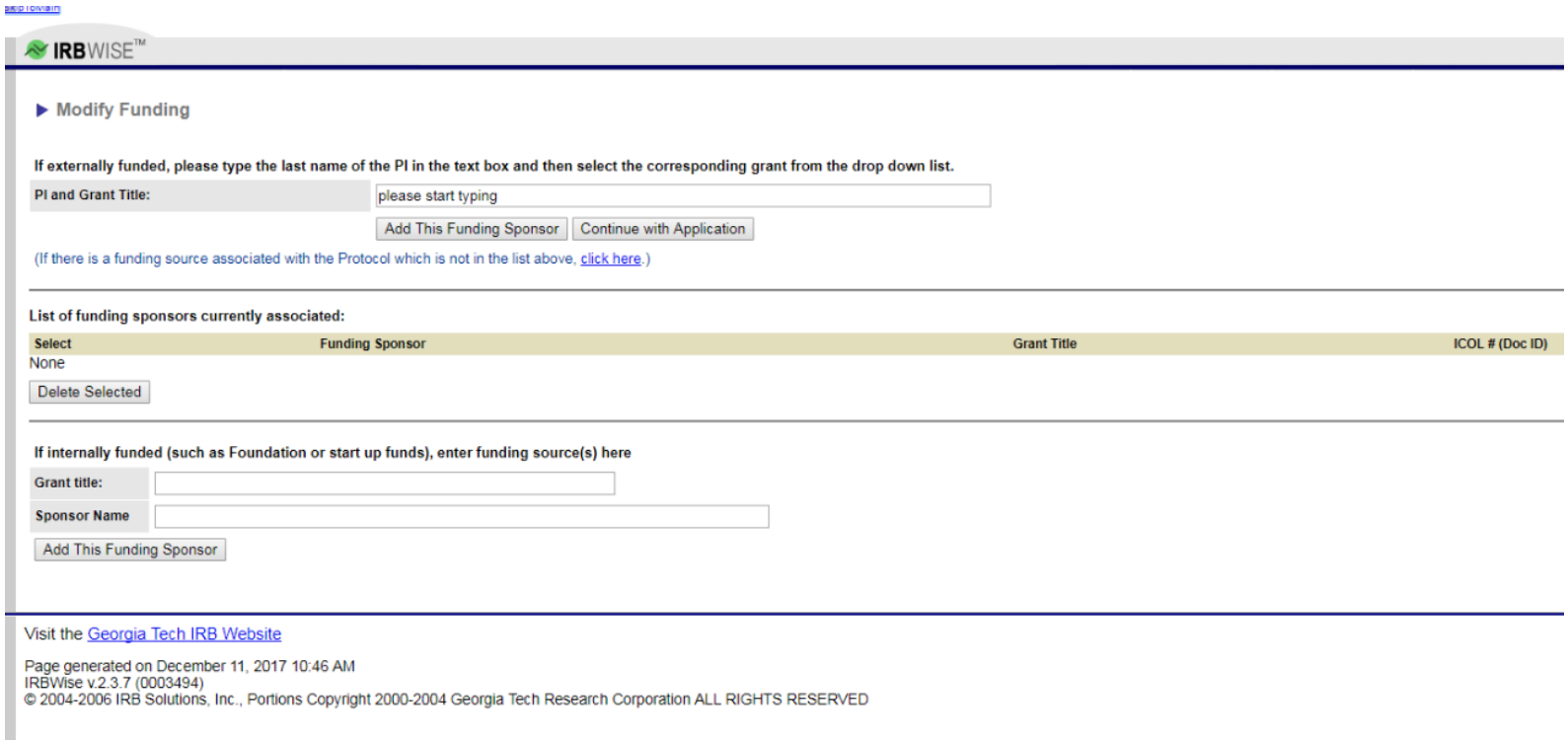
This is a continuation of Section II.

Section II. The Protocol: Research Design and Methodology - Continued



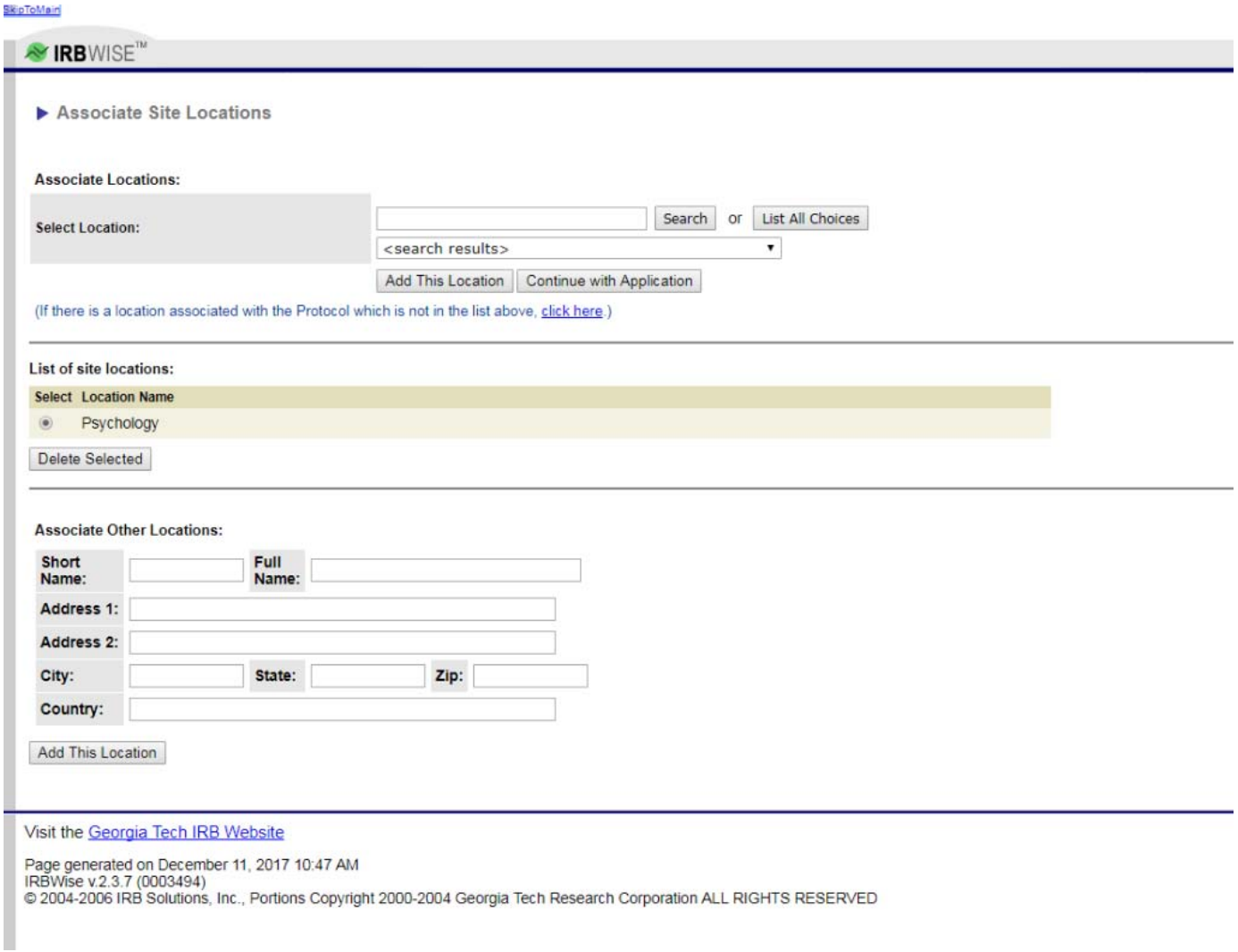
This is a continuation of Section II. For these last two questions, you will need to click on the links (blue text) to fill out the information. All research should answer question O, regarding where the study will take place.

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



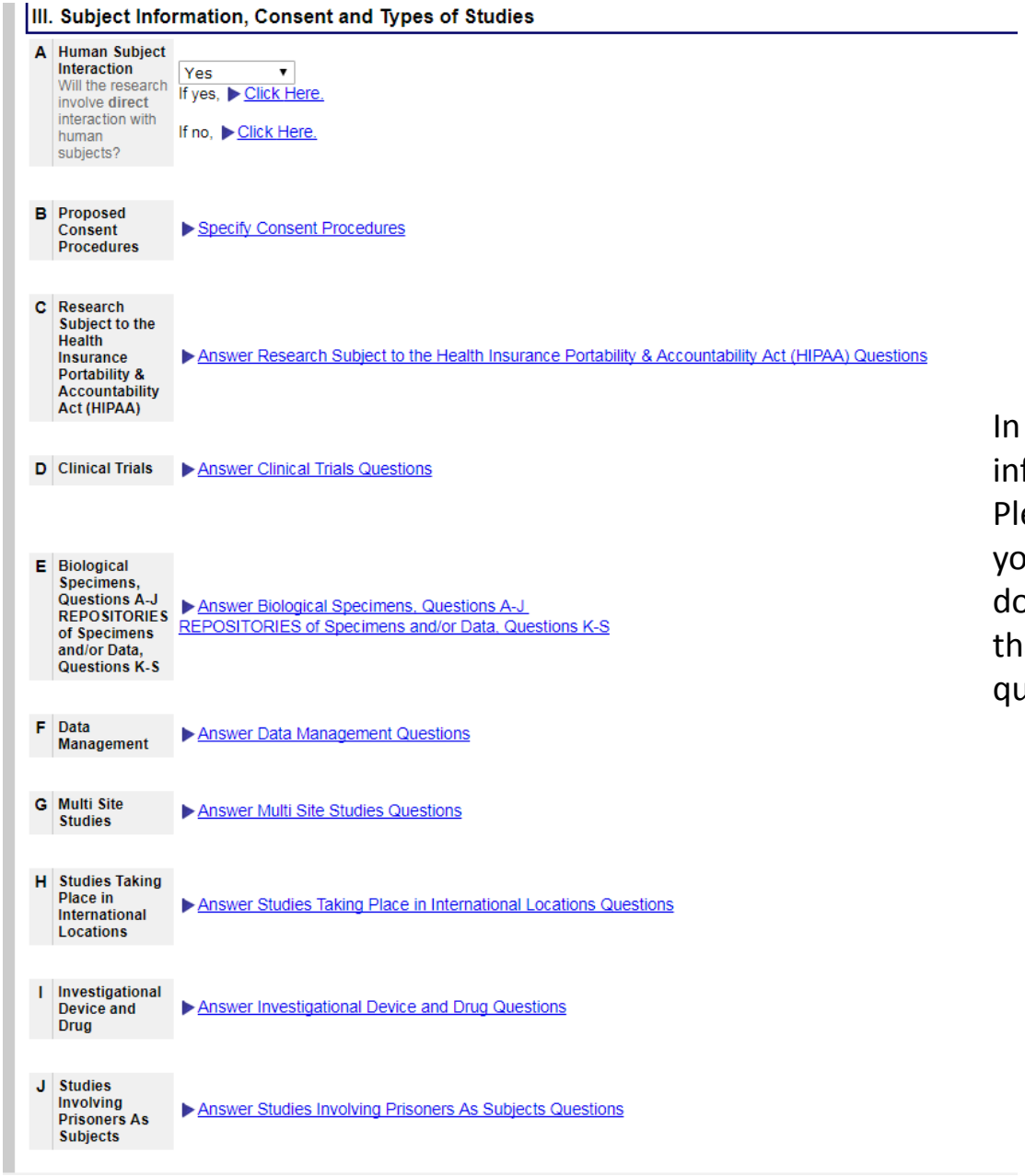
This is the pop-up window after clicking “Add/Modify Funding.” In this window, please either type the PI name or grant title in the first text box and select the correct funding. If the funding is internal, then please fill the text boxes at the bottom of the page.

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



This is the pop-up window for adding study locations. In this window, please either select the location from the drop-down menu for where your research will take place. If you research will take place at a location that is not listed, then please list the location in the text boxes at the bottom of the page.

Section III. Subject Information, Consent and Types of Studies

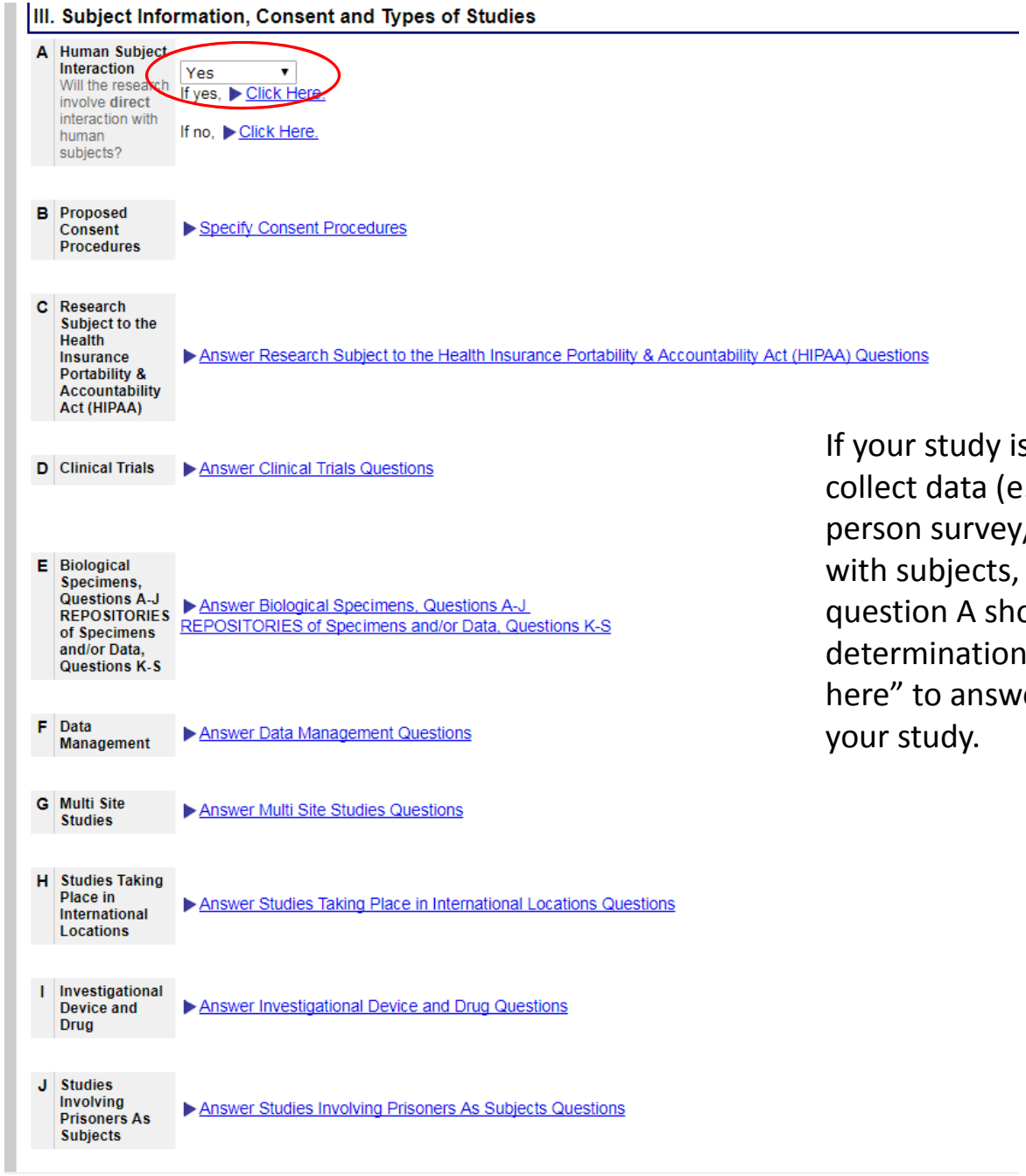


III. Subject Information, Consent and Types of Studies

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

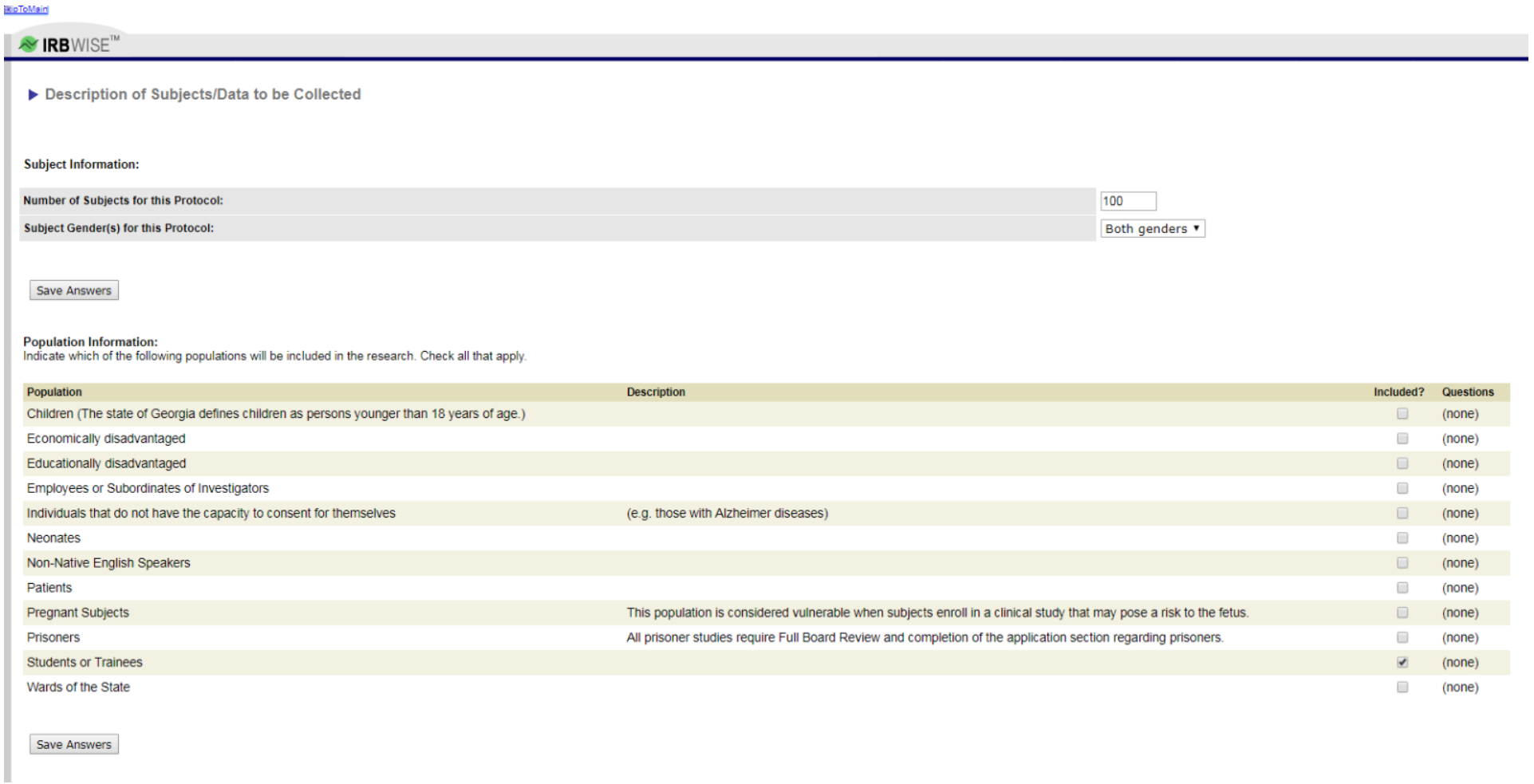
In section III, you are asked to fill out information in multiple pop-up windows. Please answer all of the sections that apply to your research. The sections that do not apply do not need to be filled out. Please be aware that most research requires that at least questions A, B, and F be filled out.

Section III - Question A



If your study is interacting with subjects to collect data (e.g., online survey/interview, in-person survey/interview, in-person interaction with subjects, etc.), then your answer to question A should be “yes.” After making this determination, please click the link “if yes, click here” to answer more specific questions about your study.

Section III - Question A



If you clicked “yes” to question A, this pop-up window above will appear. There are several sections in this window that need to be fully answered. Please also be sure to answer the first few questions shown here at the top of the window.

Section III - Question A

Subjects, Inclusion, and Exclusion Criteria

A **In relation to your research, if your communication with subjects is via email and online, there may be a chance that subjects may be located within the EU at the time of correspondence or completing the survey. Of course, you are free to include subjects who are located in the EU at the time of participation in the email or survey, but you will need to provide the EU GDPR Researcher's Privacy Notice, obtain an additional GDPR consent from each subject (more information here: http://researchintegrity.gatech.edu/irb/policies/policies-procedures) along with a more stringent data management plan for data collected. Please confirm if or how your study will address EU GDPR.**

EU GDPR Consent Form
EU GDPR Privacy Notice
GT EU GDPR Policy

No. all interactions with subjects will be in person

B **Provide the scientific justification for the number of subjects to be enrolled in the study.**

For clinical protocols, it is important to STATISTICALLY justify the number of participants needed and to state a precise number to be enrolled.

For non-clinical and minimal risk studies, participant numbers may be stated as a range, (i.e.: 100-500. We will mail surveys to 500 addresses and hope to have responses from 100 participants). If responses are received from more than 100 participants, over-enrollment will not have occurred. Web-enabled recruitment may result in far more responses than anticipated or needed. Researchers should be prepared to shut down a web recruitment site immediately if responses exceed the number of approved participants. Over-enrollment must be reported to the IRB as a protocol violation or deviation, and it may be unethical to accept responses from participants whose data are not needed and will not be utilized.

We are seeking to enroll 50 subjects per condition. This number is supported by previous psychology research (Katz, Brown, and Sturz, 2014) to show a desired effect in multiple conditions.

editor window

C **State the study population INCLUSION criteria. Inclusion criteria should be designed so that the study population has the attributes necessary for the purpose of the research to be accomplished.**

Inclusion (and exclusion) criteria may include age, race, sex, ethnicity, type and stage of disease, medical history, certain behaviors, occupation, and so on. By explicitly defining these criteria, researchers increase the likelihood of obtaining reliable and useful data.

Inclusion criteria are listed below:
- 18 years or older
- normal or corrected vision
- normal or corrected hearing
- fluent in English

editor window

D **State the study population EXCLUSION criteria. Exclusion criteria are those that disqualify potential subjects from participating.**

Exclusion (and inclusion) criteria may include age, race, sex, ethnicity, type and stage of disease, medical history, certain behaviors, occupation, and so on. By explicitly defining these criteria, researchers increase the likelihood of obtaining reliable and useful data.

Exclusion criteria are listed below:
- Under 18 years old
- vision impairment
- hearing impairment
- not fluent in English

editor window

This is a continuation of the pop-up window that appears if you answered “yes” to question A of section III.

Section III - Question A

E **Federal regulations require that women and minorities be included in CLINICAL research unless the researcher provides a clear and compelling rationale and justification that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. If you will be specifically excluding women or any minority group or subpopulation of a minority group, provide the rationale and justification here:**

N/A editor window

F **Federal regulations require that children be included in CLINICAL research unless their exclusion can be scientifically or ethically justified. If you are excluding children from a study about the cause, treatment and cure of diseases that affect children, provide the justification here.**

No minors. See justification below

No minors are to be included. This is not a clinical trial. editor window

G **Provide steps to be taken to ensure additional protection of the rights and welfare of vulnerable populations. A vulnerable population is vulnerable to coercion and undue influence, in recognition that coercion or undue influence refers to the ability to make an informed decision about participating in research. An example is an individual with impaired decision-making capacity.**

All subjects will be asked to consent prior to participating. Throughout the study and during the consent process, we will ask the subjects if they have any questions and if they are willing to continue to participate. editor window

H **Indicate subject age range(s) below. Check all that apply.**

- ☐ 0 (Birth) - 5 years
- ☐ 06 years - 11 years
- ☐ 12 years - 17 years
- ☑ 18 years - 89 years
- ☐ 90 years and older

This is a continuation of the pop-up window that appears if you answered “yes” to question A of section III.

Section III - Question A

Recruitment & Compensation

A **Describe in detail the recruitment plan. Specify where and how potential subjects will be identified. By recruitment ads, word of mouth, email? If using flyers, email, advertisements, screen shots from websites, or other documents, upload copies in the ATTACHED DOCUMENT SECTION.**

If recruitment will be by word of mouth, provide a brief script. The IRB does not expect the script to be followed verbatim; however, the recruitment language must be reviewed.

We will recruit through flyers and on the Psychology Department SONA website. The flyers will be posted around campus. Both the flyers and the SONA recruitment language are attached.

editor window

B **Is a Georgia Tech Student Subject Pool being used? NOTE: Only the School of Psychology and the College of Management have formal Student Subject Pools. In order to recruit from among either group, advance arrangements must be made with the manager of that pool.**

- ○ No
- ◉ Yes

Psychology Department - SONA

editor window

C **Describe the compensation plan for subject participation. If compensation will be class credit, state how much credit will be granted for student participation. Include plans for prorating compensation if subject does not complete study.**

NOTE:

If a lottery or raffle is proposed as compensation: the State of Georgia requires a license for a true lottery. A license is not generally required if non-participants may enter the lottery without being in the study.

U.S. Tax Law requires a mandatory withholding of 30% for nonresident alien payments of any type.

Consult the IRB Policies and Procedures at www.researchintegrity.gatech.edu for additional guidance on both points.

All subjects will receive 0.5 SONA credits for every 30 minutes of participation. The study should last up to an hour, therefore we expect 1 SONA credit will be awarded for participation.

editor window

D **Finder Fees. While it may be appropriate for a small fee to be paid to individuals who refer willing research subjects, such fees may only be used for recruitment in minimal risk studies of a non-clinical nature. If finder fees are proposed, indicate the relationship of the finder with potential subjects, whether he/she has a financial interest in the study or its outcome, and describe the fee structure in full.**

N/A

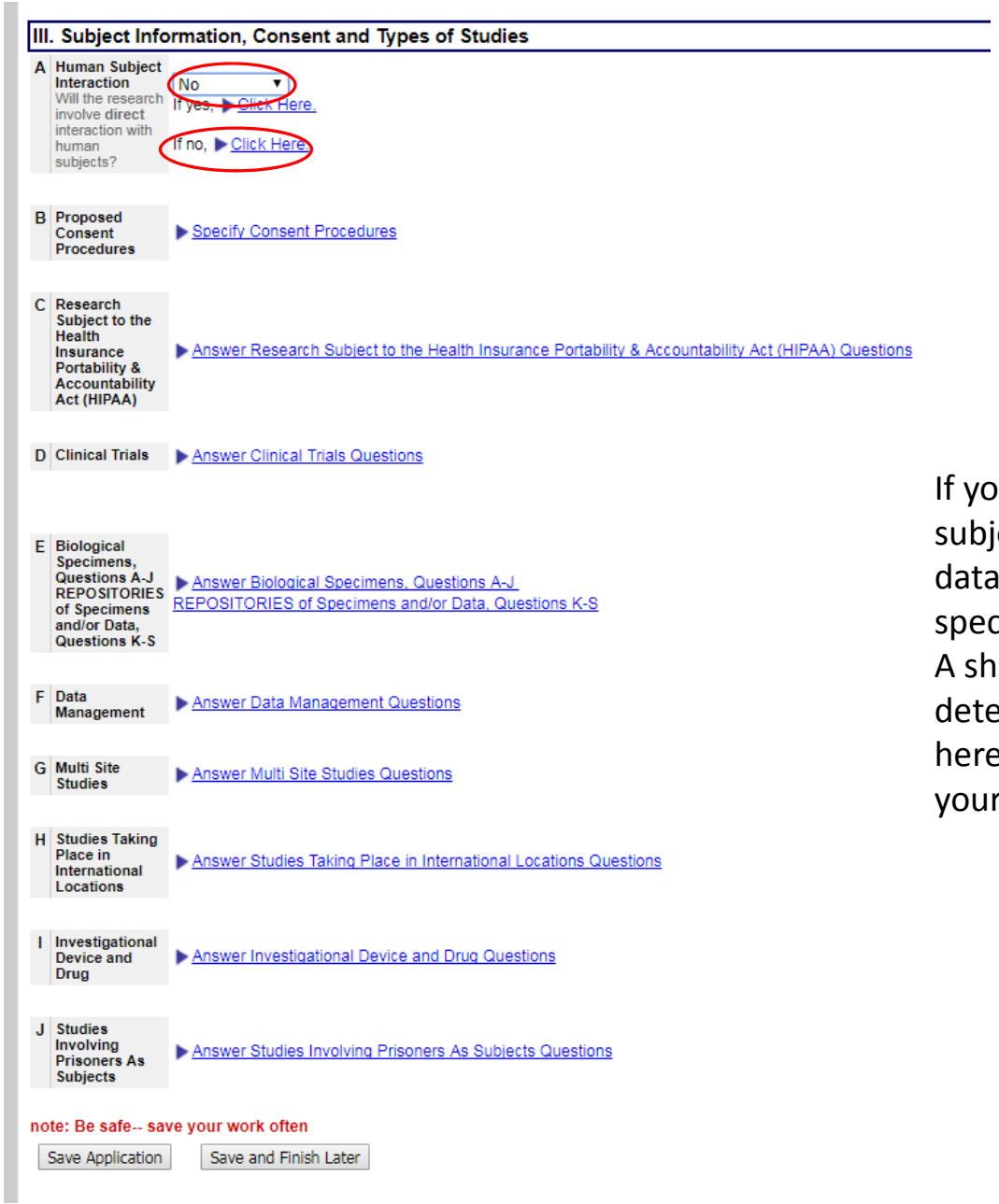
editor window

Save Answers

Save & Continue with Application | Cancel

This is a continuation of the pop-up window that appears if you answered “yes” to question A of section III.

Section III - Question A



III. Subject Information, Consent and Types of Studies

A	**Human Subject Interaction** Will the research involve direct interaction with human subjects?	No ▼ 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
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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
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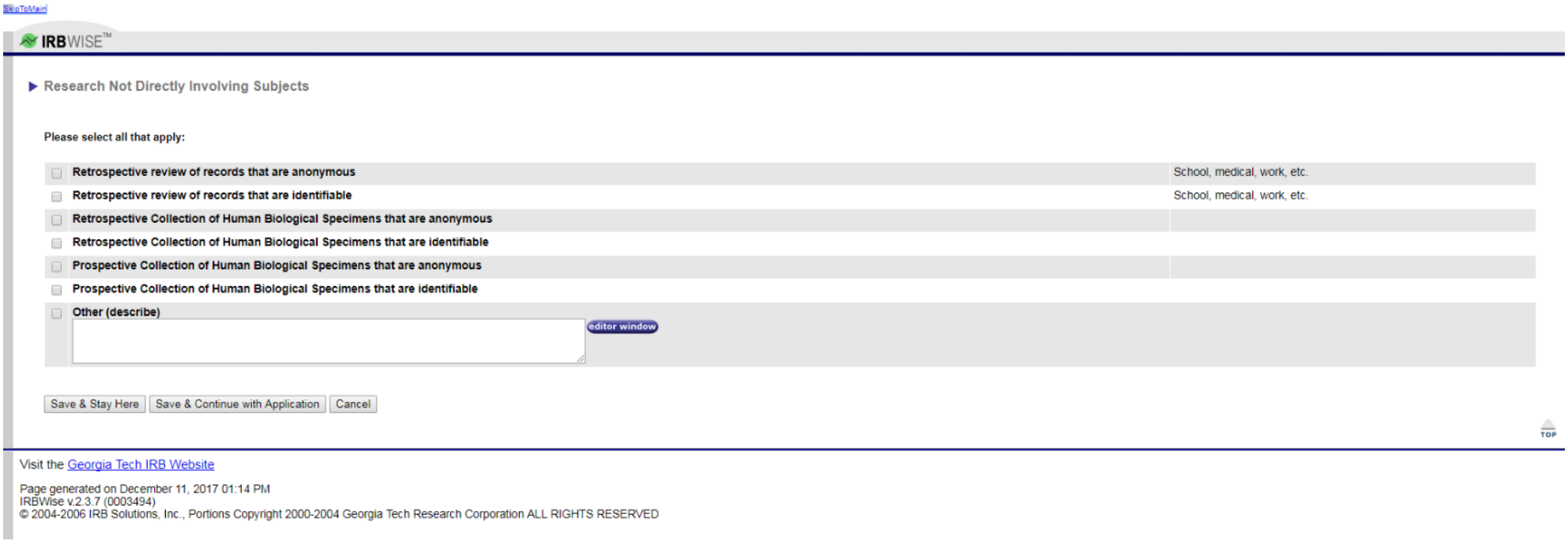
note: Be safe-- save your work often

Save Application | Save and Finish Later

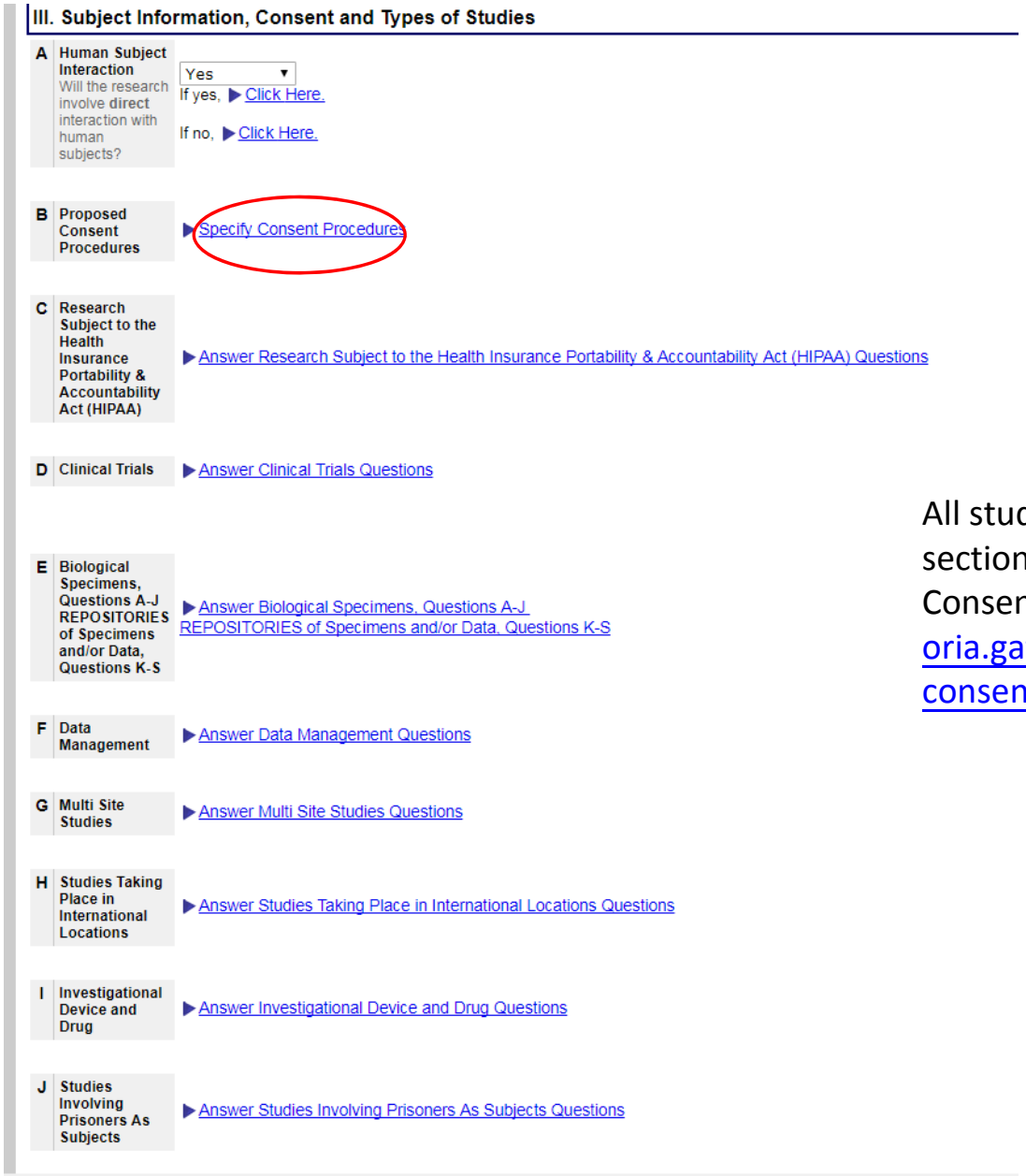
If your study does not involve interacting with subjects to collect data (e.g., analyzing existing data sets, analyzing existing biological specimen, etc.), then your answer to question A should be “no.” After making this determination, please click the link “if no, click here” to answer more specific questions about your study.

Section III - Question A



If you clicked “no” to question A, this pop-up window will appear. Please be sure to select what best applies to your study.

Section III - Question B



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
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All studies must fill out the Informed Consent section. More information regarding Informed Consent can be found on our website (https://oria.gatech.edu/irb/hsr/irb-informed-consent).

Section III - Question B

▶ **Subject Consent Information**

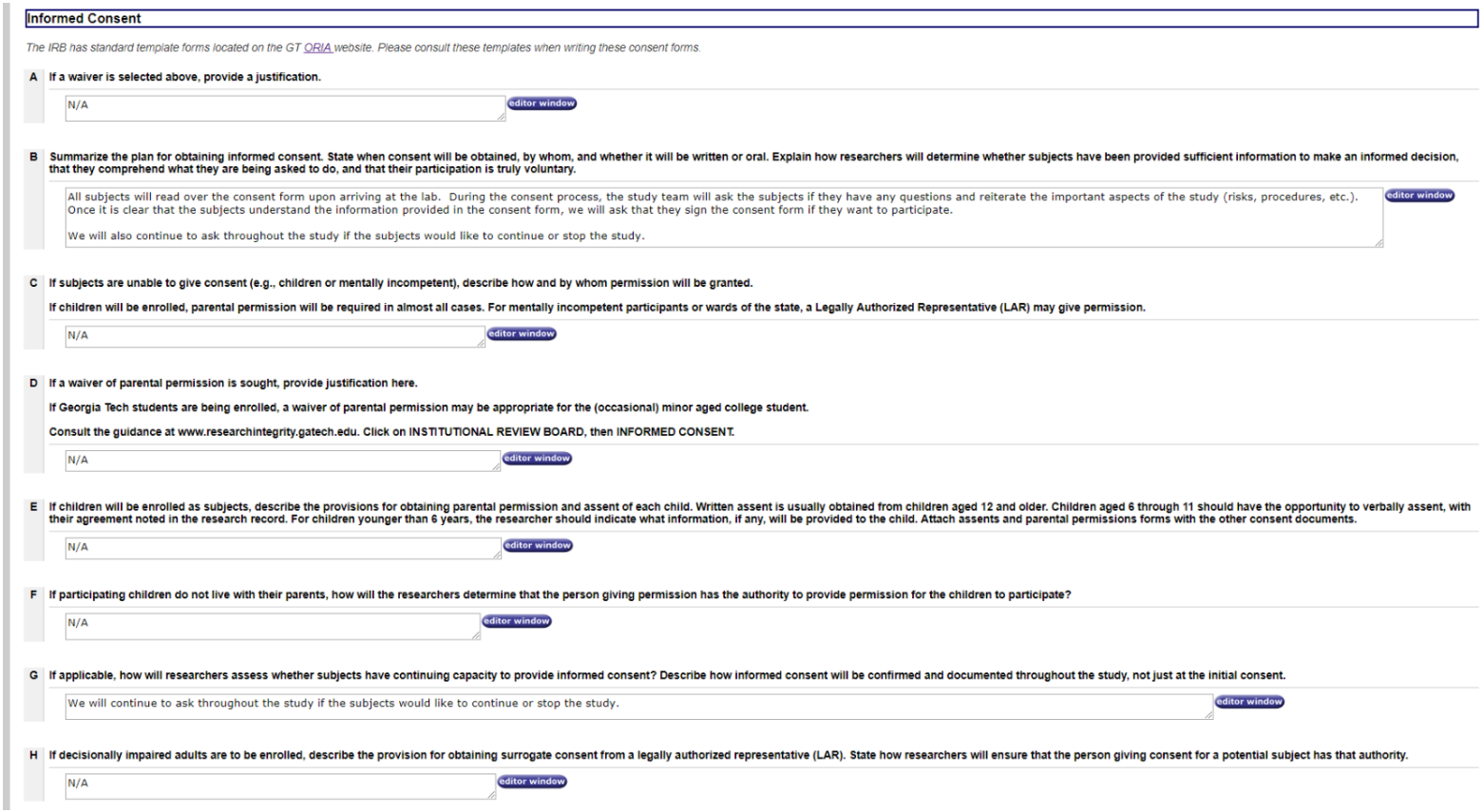
Consent Procedures:

directions: Check all proposed consent procedures.

Name	Description
☑ Written Consent Required	Signed consent will be sought from the subject or from the subject's legally authorized representative.
☐ Waiver of Consent	Per 45CFR46.116 (3) an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that: (i) the research involves no more than minimal risk to the subjects; (ii) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (iii) If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens (iv) the research could not practicably be carried out without the waiver or alteration; and (v) whenever appropriate, the subjects will be provided with additional pertinent information after participation. Note: If the research involves using identifiable private information or identifiable biospecimens, it must be determined that the research could not practicably be carried out without using such information or biospecimens in an identifiable format.
☐ Waiver of Documentation of Consent	Per 45CFR46.117(c) an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or (3) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. ****Please note that this option requires a consent document without the signature section: In cases where the requirement of documentation is waived (e.g., use of an anonymous survey is proposed, telephone survey, or web-based survey), a consent document in Georgia Institute of Technology IRB-required format must still be used. However, the document is written in letter format (Dear Subject) and, rather than requiring subject signature to verify consent, the following text is used to end the letter: If you _____ (e.g., complete the attached survey, answer these few questions etc.), it means that you have read -- or have had read to you -- the information contained in this letter and would like to be a volunteer in this research study. Thank you, (Signatures of Investigators)

In the Informed Consent Procedures section, please select what type of consenting procedures you plan to use for your study. Please pay attention to the description of each selection, for that they describe what each procedure is and when they can be used.

Section III - Question B



Informed Consent

The IRB has standard template forms located on the GT ORIA website. Please consult these templates when writing these consent forms.

A **If a waiver is selected above, provide a justification.**

N/A editor window

B **Summarize the plan for obtaining informed consent. State when consent will be obtained, by whom, and whether it will be written or oral. Explain how researchers will determine whether subjects have been provided sufficient information to make an informed decision, that they comprehend what they are being asked to do, and that their participation is truly voluntary.**

All subjects will read over the consent form upon arriving at the lab. During the consent process, the study team will ask the subjects if they have any questions and reiterate the important aspects of the study (risks, procedures, etc.). Once it is clear that the subjects understand the information provided in the consent form, we will ask that they sign the consent form if they want to participate.

We will also continue to ask throughout the study if the subjects would like to continue or stop the study. editor window

C **If subjects are unable to give consent (e.g., children or mentally incompetent), describe how and by whom permission will be granted.**

If children will be enrolled, parental permission will be required in almost all cases. For mentally incompetent participants or wards of the state, a Legally Authorized Representative (LAR) may give permission.

N/A editor window

D **If a waiver of parental permission is sought, provide justification here.**

If Georgia Tech students are being enrolled, a waiver of parental permission may be appropriate for the (occasional) minor aged college student.

Consult the guidance at www.researchintegrity.gatech.edu. Click on INSTITUTIONAL REVIEW BOARD, then INFORMED CONSENT.

N/A editor window

E **If children will be enrolled as subjects, describe the provisions for obtaining parental permission and assent of each child. Written assent is usually obtained from children aged 12 and older. Children aged 6 through 11 should have the opportunity to verbally assent, with their agreement noted in the research record. For children younger than 6 years, the researcher should indicate what information, if any, will be provided to the child. Attach assents and parental permissions forms with the other consent documents.**

N/A editor window

F **If participating children do not live with their parents, how will the researchers determine that the person giving permission has the authority to provide permission for the children to participate?**

N/A editor window

G **If applicable, how will researchers assess whether subjects have continuing capacity to provide informed consent? Describe how informed consent will be confirmed and documented throughout the study, not just at the initial consent.**

We will continue to ask throughout the study if the subjects would like to continue or stop the study. editor window

H **If decisionally impaired adults are to be enrolled, describe the provision for obtaining surrogate consent from a legally authorized representative (LAR). State how researchers will ensure that the person giving consent for a potential subject has that authority.**

N/A editor window

Please answer all of the questions in this section. If a waiver is being requested, please describe how your study meets the criteria for a waiver in question A.

Section III - Question B

Informed Consent

The IRB has standard template forms located on the GT ORIA website. Please consult these templates when writing these consent forms.

A **If a waiver is selected above, provide a justification. Please refer to the requirements listed next to your waiver selection for reference.**

N/A editor window

B **Summarize the plan for obtaining informed consent by answering all of the following:**
a. State when consent will be obtained, by whom, and whether it will be written or oral
b. Explain how researchers will determine whether subjects have been provided sufficient information to make an informed decision
c. Explain how researchers will determine whether subjects comprehend what they are being asked to do
d. Explain how researchers will determine whether subjects participation is truly voluntary.

All subjects will read over the consent form upon arriving at the lab. During the consent process, the study team will ask the subjects if they have any questions and reiterate the important aspects of the study (risks, procedures, etc.). Once it is clear that the subjects understand the information provided in the consent form, we will ask that they sign the consent form if they want to participate.

We will also continue to ask throughout the study if the subjects would like to continue or stop the study. editor window

C **If subjects are unable to give consent (e.g., "children" or "individuals with impaired decision making capacity"), describe how and by whom permission will be granted.**

If children will be enrolled, parental permission will be required in almost all cases. For individuals with impaired decision making capacity or wards of the state, a Legally Authorized Representative (LAR) may give permission.

N/A editor window

D **If a waiver of parental permission is sought, provide justification here.**

If Georgia Tech students are being enrolled, a waiver of parental permission may be appropriate for the (occasional) minor aged college student.

Consult the guidance at submitting a protocol on the IRB website. Click on forms for consent templates.

N/A editor window

E **If children will be enrolled as subjects, describe the provisions for obtaining parental permission and assent of each child. Written assent is usually obtained from children aged 12 and older. Children aged 6 through 11 should have the opportunity to verbally assent, with their agreement noted in the research record. For children younger than 6 years, the researcher should indicate what information, if any, will be provided to the child. Attach assents and parental permissions forms with the other consent documents.**

N/A editor window

F **If participating children do not live with their parents, how will the researchers determine that the person giving permission has the authority to provide permission for the children to participate?**

N/A editor window

Informed consent section continued. Please be sure to answer all of the questions.

Section III - Question B

G **If applicable, how will researchers assess whether subjects have continuing capacity to provide informed consent? Describe how informed consent will be confirmed and documented throughout the study, not just at the initial consent.**

We will continue to ask throughout the study if the subjects would like to continue or stop the study. editor window

H **If individuals with impaired decision making capacity are to be enrolled, describe the provision for obtaining surrogate consent from a legally authorized representative (LAR). State how researchers will ensure that the person giving consent for a potential subject has that authority.**

N/A editor window

I **If non-English speaking subjects will be enrolled, explain how their consent will be obtained. Address both written translation of the consent form and the availability of oral interpretation. Attach a certified translation of the consent form in the language of non-English speaking subjects.**

N/A editor window

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J **Is deception or concealment proposed?**

A study proposing the use of adequately justified deception or concealment may qualify for a waiver of consent. Deception in a study occurs when subjects are intentionally told something untrue about the study, such as its real purpose. Concealment occurs when the researcher intentionally withholds some of the research details from subjects. Deception is not authorized in FDA-regulated studies. On the other hand, the HHS regulations at 45 CFR 46.116(d), allow deception or concealment only when a waiver of informed consent is justified.

If the study involves DECEPTION, the following language must appear in the procedures section of the consent documents: During the study, you may be led to believe some things that are not true. When the study is over, we will tell you everything. At that time you can decide whether to let us use your information. You have the right to then require that your information be destroyed and not be used in the study.

For studies proposing CONCEALMENT, the following language should appear in the procedures section of the consent documents: We will not tell you everything about the study in advance. When the study is over, we will tell you everything. At that time you can decide whether to let us use your information. You have the right to then require that your information be destroyed.

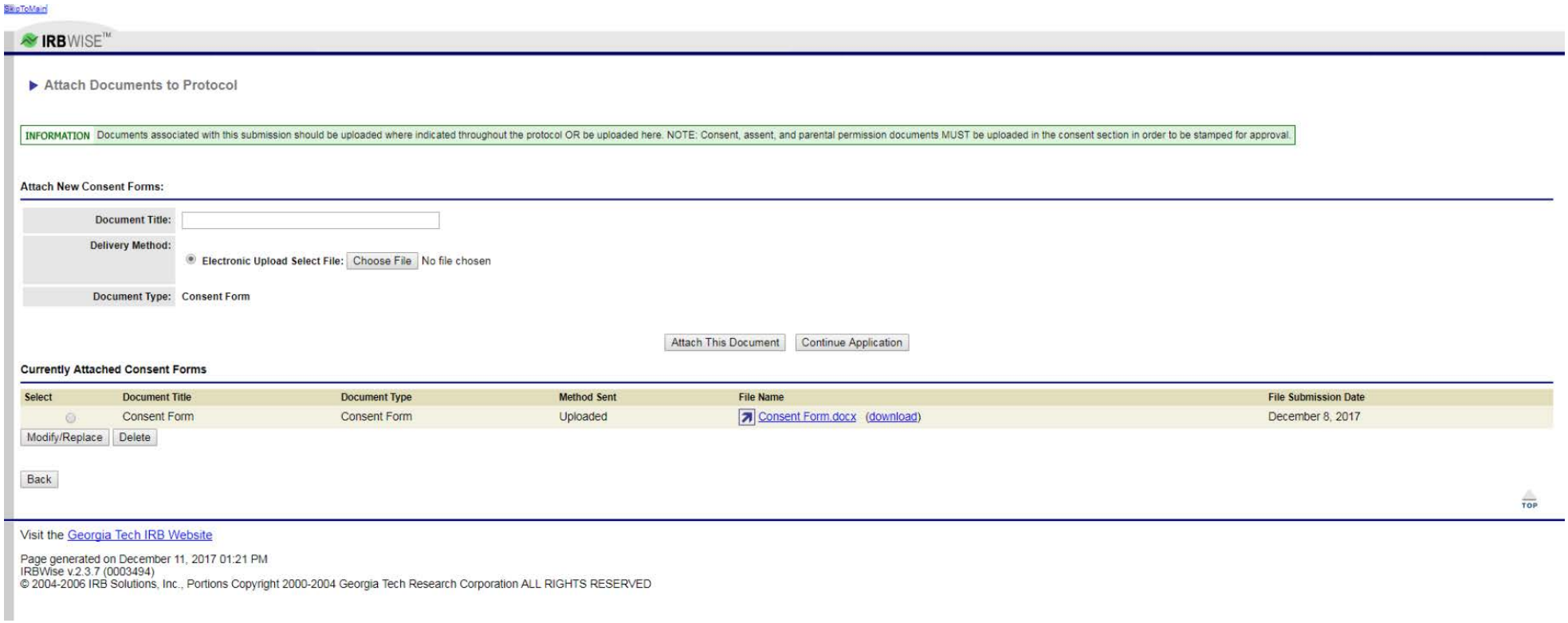
No

N/A editor window

▶ Upload documents

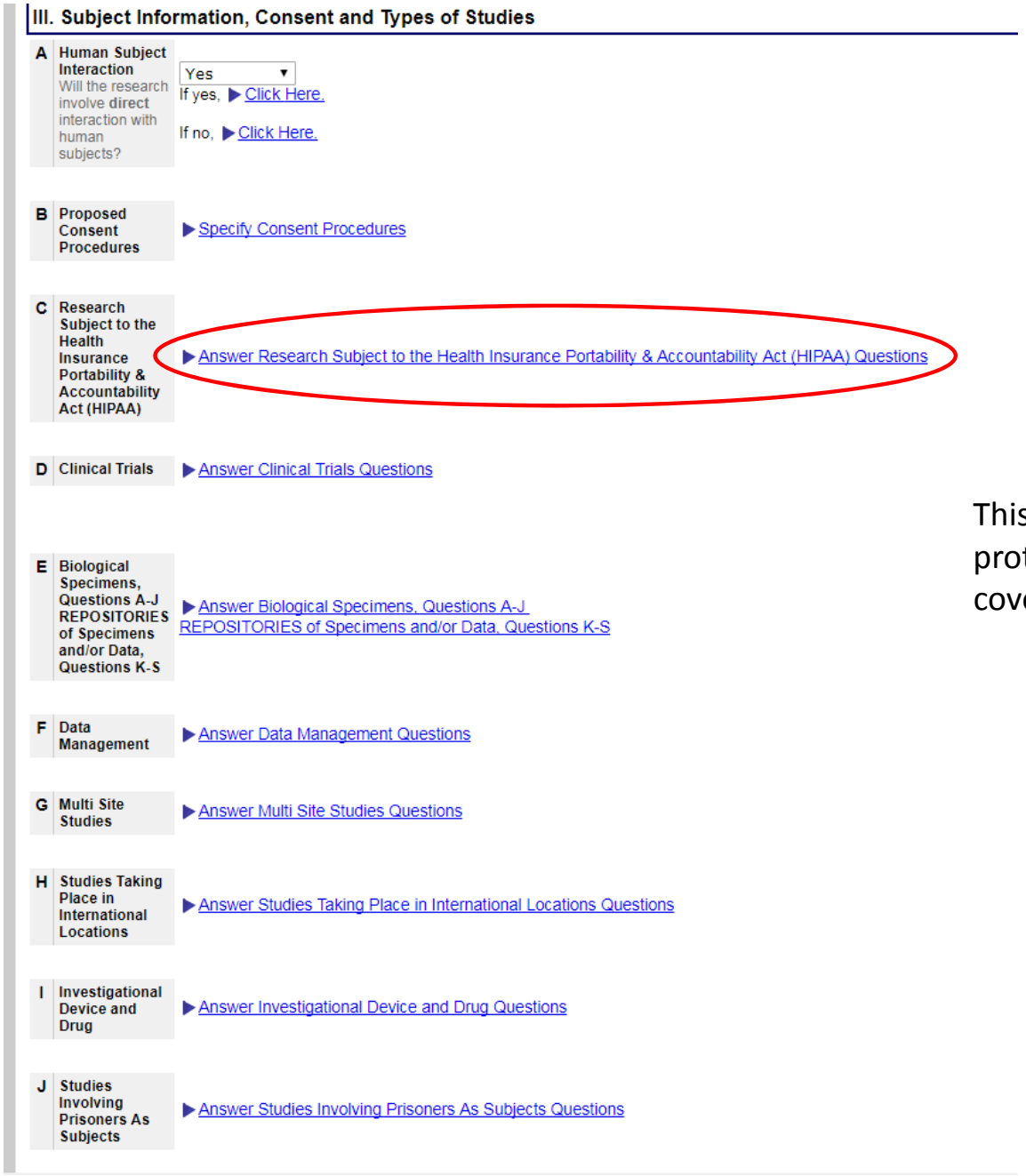
To upload your consent document, please click on the “Upload documents” link at the bottom of the page.

Section III - Question B



This is the pop-up window after clicking “Upload documents.” When on this page, please upload all of the consent documents that you will use for your study. Please be sure to use our most current template when creating your consent form. This template can be found on our website: https://oria.gatech.edu/irb/submitting-protocol/forms

Section III - Question C

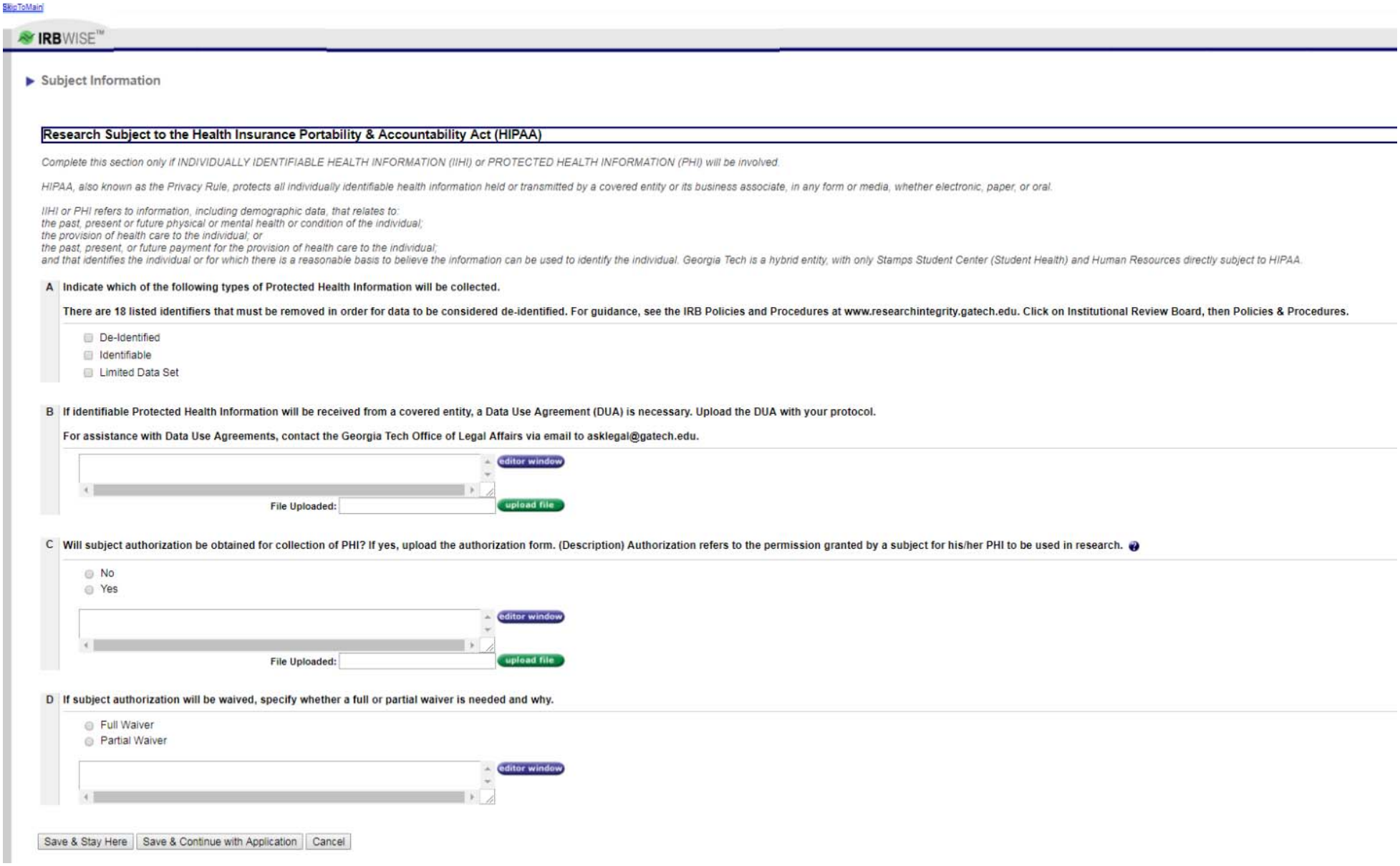


III. Subject Information, Consent and Types of Studies

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

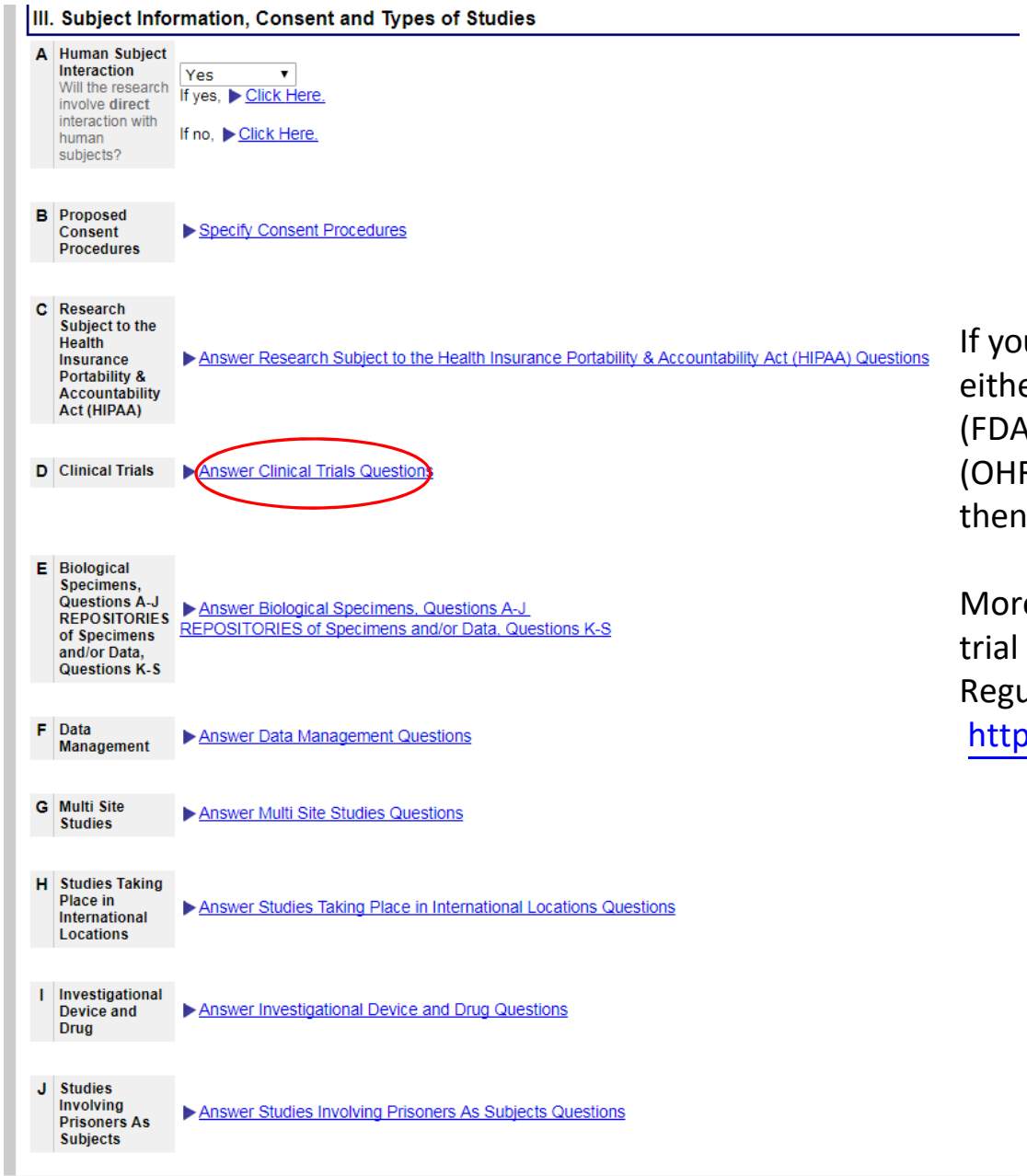
This section is required when obtaining protected health information (PHI) from a covered entity (e.g., hospital, doctor, etc.).

Section III - Question C



If obtaining PHI from a covered entity, then please answer all of the questions in this section.

Section III - Question D



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
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F	**Data Management**	▶ Answer Data Management Questions
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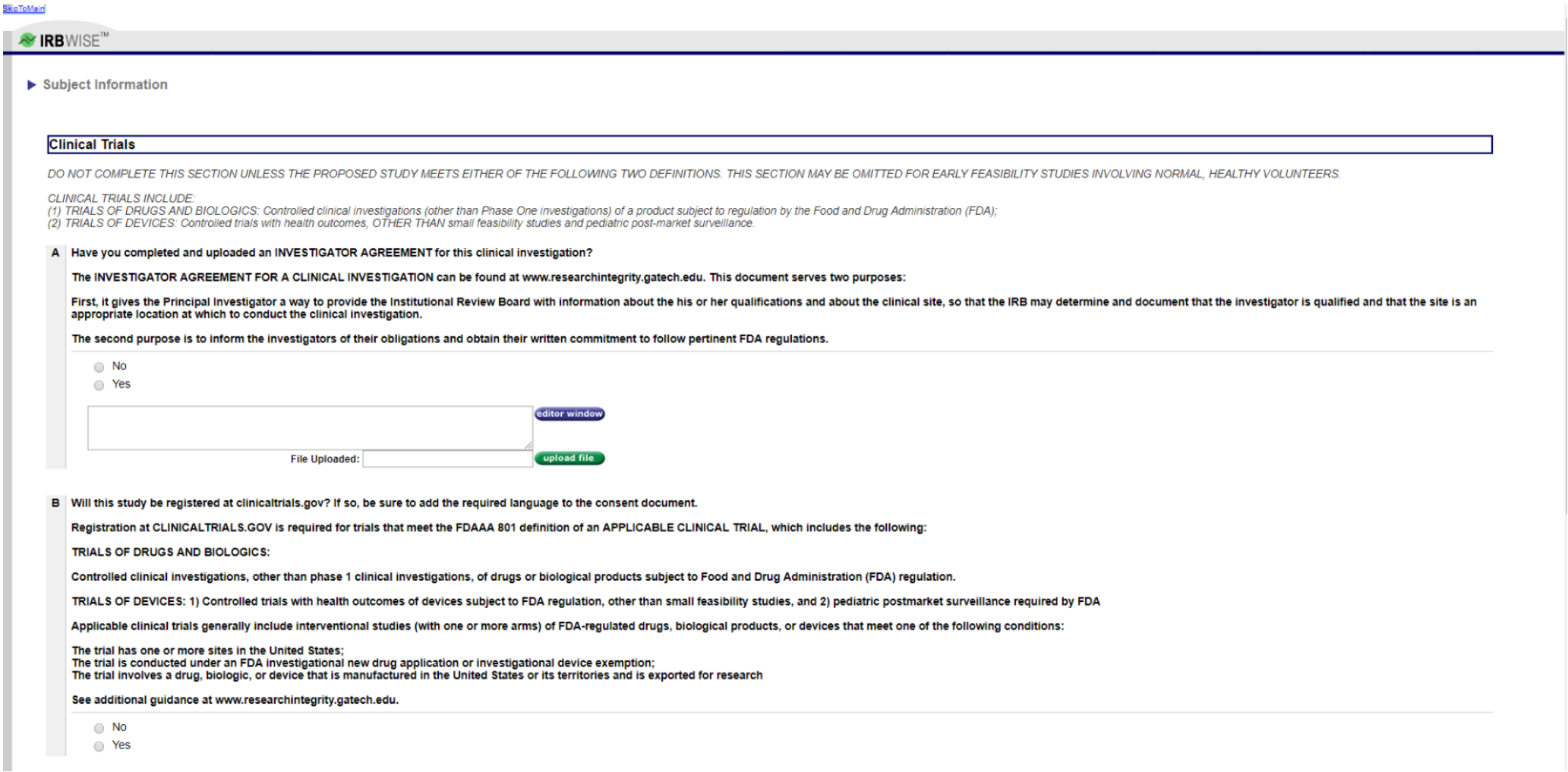
H	**Studies Taking Place in International Locations**	▶ Answer Studies Taking Place in International Locations Questions
I	**Investigational Device and Drug**	▶ Answer Investigational Device and Drug Questions
J	**Studies Involving Prisoners As Subjects**	▶ Answer Studies Involving Prisoners As Subjects Questions

If your study is considered to be a "clinical trial" by either the Food and Drug Amendments Act of 2007 (FDAAA), the Office of Human Research Protections (OHRP), or the National Institute of Health (NIH), then this section needs to be completed.

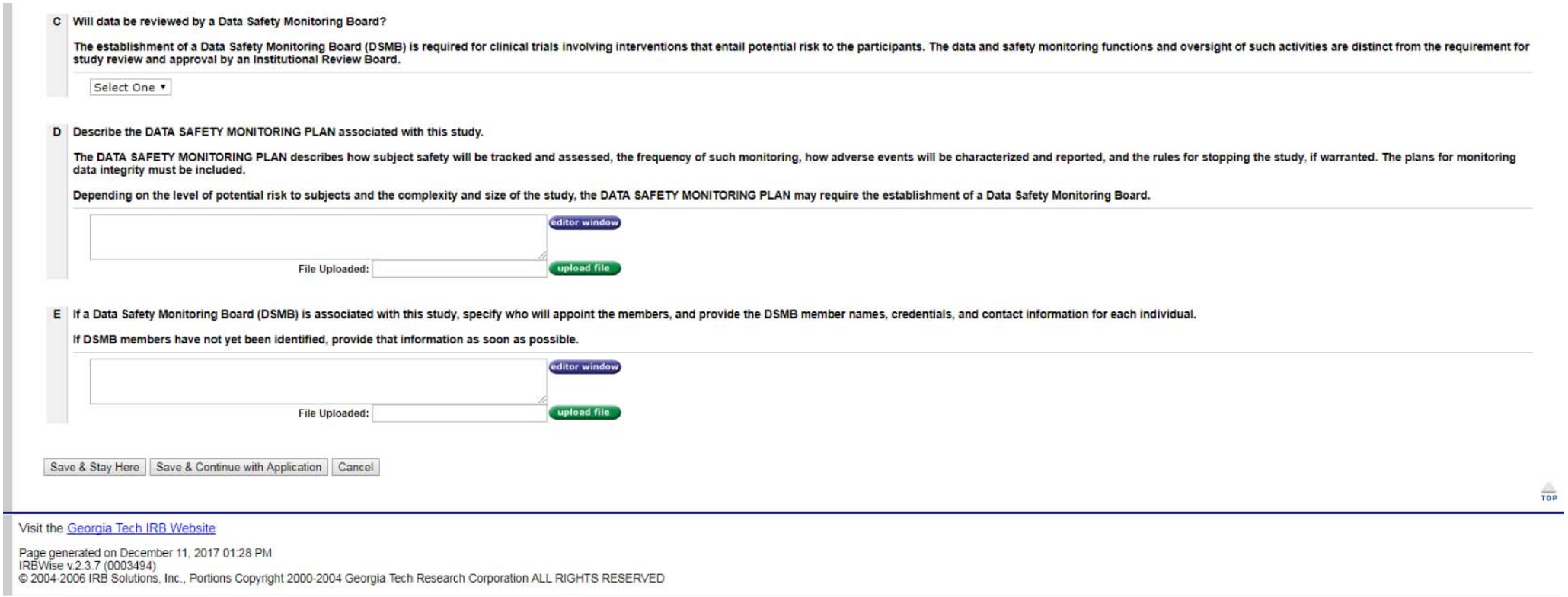
More information about what is considered a clinical trial can be found on the Georgia Tech Office of Regulatory Affairs and Clinical Trials website: https://oria.gatech.edu/clinical-trials

Section III - Question D



Please be sure to fill out this section if your study is considered to be defined as a clinical trial.

Section III - Question D



C **Will data be reviewed by a Data Safety Monitoring Board?**

The establishment of a Data Safety Monitoring Board (DSMB) is required for clinical trials involving interventions that entail potential risk to the participants. The data and safety monitoring functions and oversight of such activities are distinct from the requirement for study review and approval by an Institutional Review Board.

Select One

D **Describe the DATA SAFETY MONITORING PLAN associated with this study.**

The DATA SAFETY MONITORING PLAN describes how subject safety will be tracked and assessed, the frequency of such monitoring, how adverse events will be characterized and reported, and the rules for stopping the study, if warranted. The plans for monitoring data integrity must be included.

Depending on the level of potential risk to subjects and the complexity and size of the study, the DATA SAFETY MONITORING PLAN may require the establishment of a Data Safety Monitoring Board.

editor window

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E **If a Data Safety Monitoring Board (DSMB) is associated with this study, specify who will appoint the members, and provide the DSMB member names, credentials, and contact information for each individual.**

If DSMB members have not yet been identified, provide that information as soon as possible.

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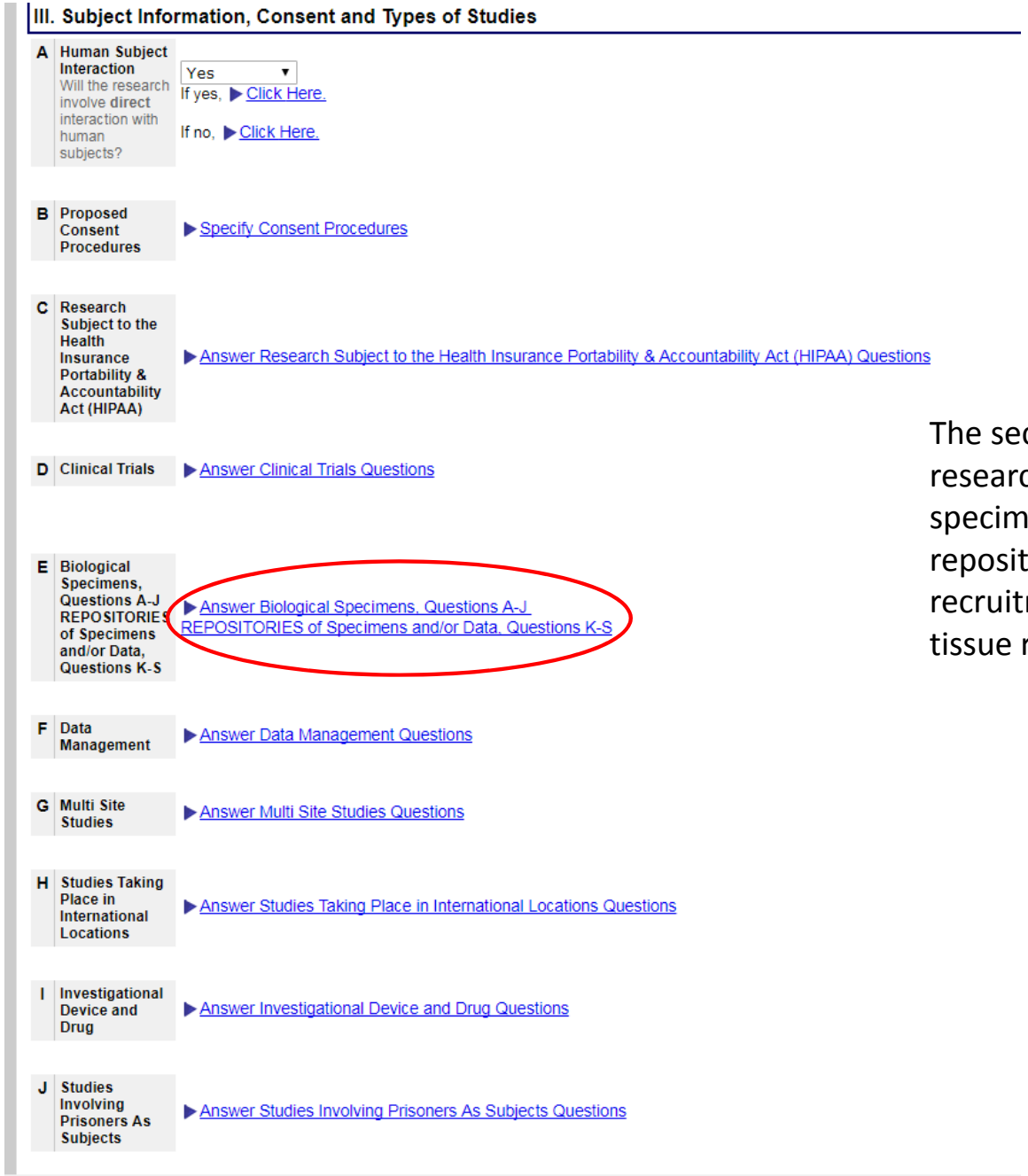
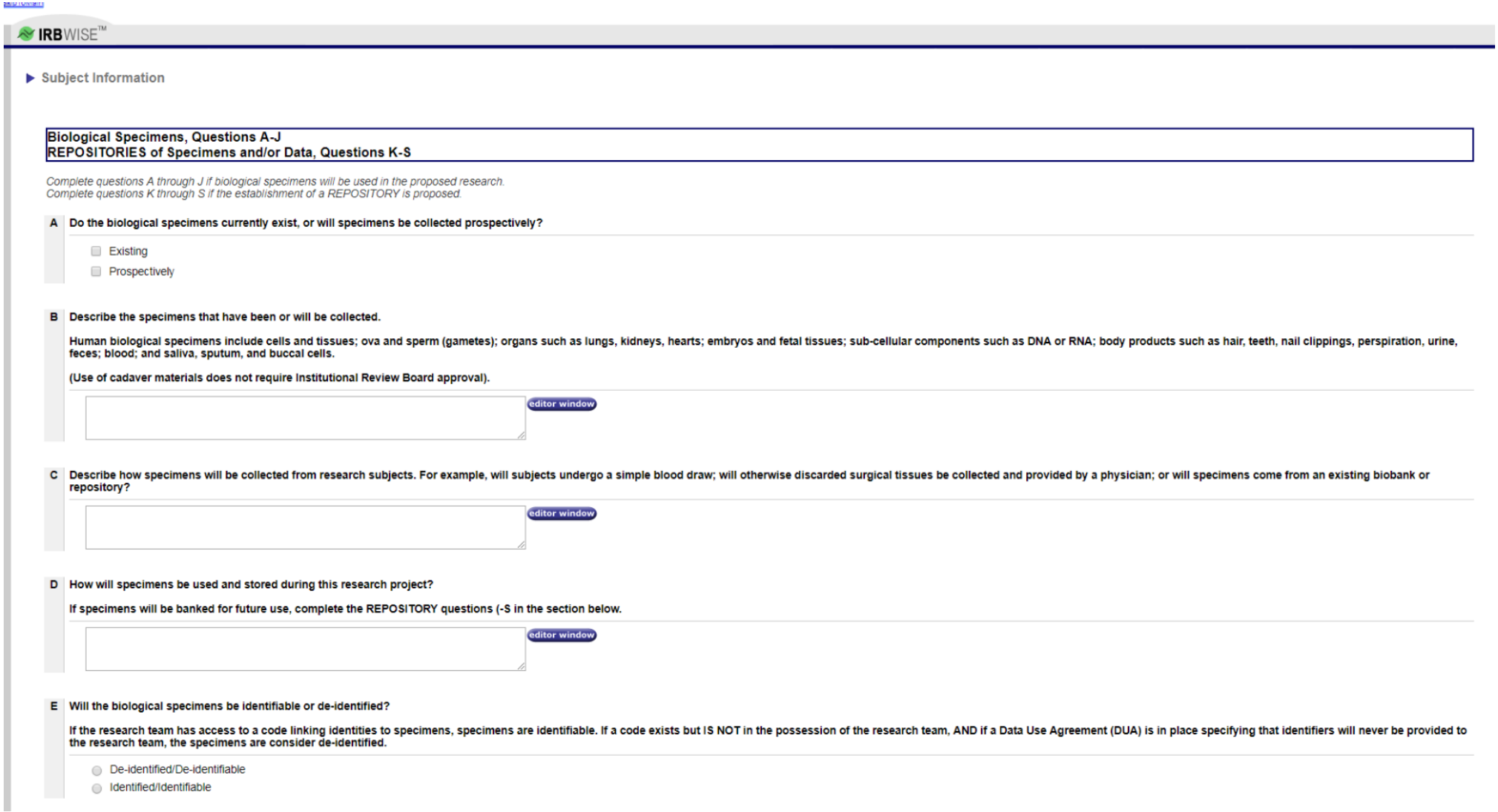
This is the Clinical Trial section continued. Please be sure to answer all of the questions in this section if they apply to your study.

Section III - Question E



The section under question E applies to both research that is collecting/obtaining biological specimen and studies that are setting up repositories and databases for future use (e.g., recruitment databases, data repositories, tissue repositories, etc.).

Section III - Question E



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▶ Subject Information

Biological Specimens, Questions A-J
REPOSITORIES of Specimens and/or Data, Questions K-S

Complete questions A through J if biological specimens will be used in the proposed research.
Complete questions K through S if the establishment of a REPOSITORY is proposed.

A Do the biological specimens currently exist, or will specimens be collected prospectively?

- ☐ Existing
- ☐ Prospectively

B Describe the specimens that have been or will be collected.

Human biological specimens include cells and tissues; ova and sperm (gametes); organs such as lungs, kidneys, hearts; embryos and fetal tissues; sub-cellular components such as DNA or RNA; body products such as hair, teeth, nail clippings, perspiration, urine, feces; blood; and saliva, sputum, and buccal cells.

(Use of cadaver materials does not require Institutional Review Board approval).

editor window

C Describe how specimens will be collected from research subjects. For example, will subjects undergo a simple blood draw; will otherwise discarded surgical tissues be collected and provided by a physician; or will specimens come from an existing biobank or repository?

editor window

D How will specimens be used and stored during this research project?

If specimens will be banked for future use, complete the REPOSITORY questions (-S in the section below.

editor window

E Will the biological specimens be identifiable or de-identified?

If the research team has access to a code linking identities to specimens, specimens are identifiable. If a code exists but IS NOT in the possession of the research team, AND if a Data Use Agreement (DUA) is in place specifying that identifiers will never be provided to the research team, the specimens are consider de-identified.

- ○ De-identified/De-identifiable
- ○ Identified/Identifiable

If your study involves the collection of biological samples, please answer questions A – J. If your study involves the creation of a repository or database, then please fill out questions K – S.

Section III - Question E

F **Has Environmental Health & Safety approval been obtained for the proposed work with biological specimens? Upload here the Institutional Biological Materials Safeguards Committee approval letter specifically for this study.**

- ○ No, IBMSC approval is pending.
- ○ YES, the IBMSC letter of approval is uploaded.

editor window

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G **If specimens are coming from an off-campus entity, is a MATERIALS TRANSFER AGREEMENT (MTA) in place? Please upload the MTA here.**

When biological specimens will be sent to or from Georgia Institute of Technology, a Materials Transfer Agreement is required. The MTA clarifies how the materials may be used and defines rights and responsibilities for both the provider and the recipient. MTAs are handled by the Office of Industry Engagement.

Select One

editor window

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H **If biological specimens will be imported from outside of the United States, approval from the Centers for Disease Control may be required and other regulations may also apply. Indicate here whether biological specimens will come from outside of the United States and, if so, specify the source, including name, entity, and international address. Upload any approvals from CDC or other agencies.**

- ○ No, specimens will not come from outside of the United States
- ○ Yes, specimens will come from the international source identified below

editor window

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I **If this study will involve genetic research, describe below the type of genetic research to be performed and how researchers will handle the discovery of genetic information that may be of concern to subjects or their relatives.**

The proposed return of research findings to research participants must be approved by the IRB and should occur only when all of the following apply:
(1). The findings are validated by a CLIA-certified laboratory;
(2). The findings may have significant implications for the subject's health concerns;
(3). A course of action to ameliorate or treat these concerns is readily available; and
(4). The subject agreed during the consent process to be informed about validated findings.

editor window

J **Is the use of rDNA or SiRNA proposed? If so, upload the Institutional Biosafety Committee (IBC) letter of approval for this specific study. (For additional guidance, consult the IBC's webpage linked from www.researchintegrity.gatech.edu).**

- ○ No, neither rDNA nor SiRNA is proposesd.
- ○ Yes, rDNA or SiRNA will be used, and I will provide the IBC letter of approval.

editor window

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Biological samples and repositories section continued. If your study involves the collection of biological samples, please answer questions A – J. If your study involves the creation of a repository or database, then please fill out questions K – S.

Section III - Question E

K ESTABLISHING A REPOSITORY: If you intend to establish a REPOSITORY, answer the remaining questions in this section and specify REPOSITORY TITLE in the field below.

Researchers may establish collections of images, data, biological specimens, and more with the intent to maintain and store these over a period of time, to receive additional materials and/or data from multiple sources, and to share them with other researchers for future research purposes while controlling access to and use of materials and data. Taken together, these activities constitute the establishment of a REPOSITORY, which may also be called a tissue bank, biobank; registry, databank, database, or simply repository. Examples of repositories include data from Massive Online Open Courses (MOOCs), medical records and MRI images, while biobanks might contain cancer cells, tumors and other human biological specimens.

This REPOSITORY protocol must satisfactorily address the three major elements of a repository:
1. Collection of materials or information by contributing investigators,
2. Materials and data storage and management (Repository Operating Procedures), and
3. Use by recipient investigators.

The title of this proposed REPOSITORY is specified here:

editor window

L REPOSITORY GUARDIAN: Name the individual who will be responsible for day-to-day operations of the repository. The guardian may be the Repository Principal Investigator or another individual. If the guardian is not also the PI on the repository protocol, attach his/her CV or resume, or provide a statement of the guardian's qualifications to carry out these responsibilities.

editor window

M COLLECTION OR ACQUISITION:
The process of materials/data acquisition must be described here, including the conditions under which materials/data will be accepted. Describe here the data or materials being submitted to the REPOSITORY for storage and use in future research.

NOTE: When materials or data are submitted to the repository, a separate Repository Submittal Agreement must be executed with each source entity. The Repository Submittal Agreement template proposed for use with this repository must be attached to this protocol for review by the IRB. (For a sample Repository Submittal Agreement, see Appendix 26 of the IRB Policies & Procedures Manual at http://researchintegrity.gatech.edu/irb).

editor window

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N Describe the process for ensuring that local IRB approval is in place for each site contributing materials/data to the repository.

The informed consent process must provide for separate consent or authorization for the banking and future use of these materials/data. The process should require that copies of the local IRB approval letter and consent form or authorization be included in the submission of materials/data to the repository.

editor window

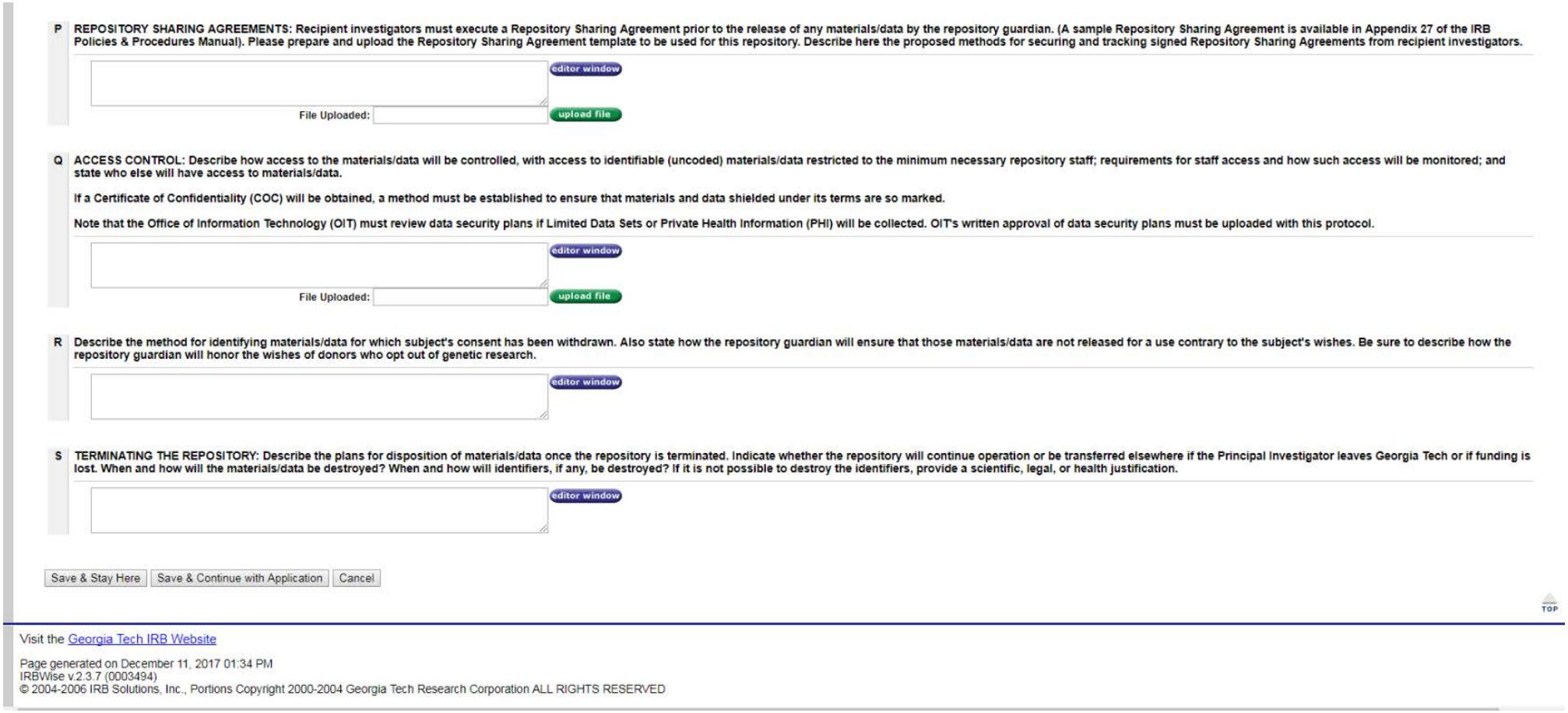
O DATA USE AGREEMENTS: The Repository Guardian is responsible for ensuring that a Data Use Agreement (DUA) is executed each time the repository receives limited data sets from medical records or any other identified/identifiable data. The DUA must be maintained in the repository's official records and be available for inspection by the Georgia Tech Institutional Review Board.

Describe here the process by which the Guardian will ensure that DUAs are executed each time the repository receives limited data sets from medical records or any identified/identifiable data.

editor window

Biological samples and repositories section continued. If your study involves the collection of biological samples, please answer questions A – J. If your study involves the creation of a repository or database, then please fill out questions K – S.

Section III - Question E



P **REPOSITORY SHARING AGREEMENTS: Recipient investigators must execute a Repository Sharing Agreement prior to the release of any materials/data by the repository guardian. (A sample Repository Sharing Agreement is available in Appendix 27 of the IRB Policies & Procedures Manual). Please prepare and upload the Repository Sharing Agreement template to be used for this repository. Describe here the proposed methods for securing and tracking signed Repository Sharing Agreements from recipient investigators.**

editor window

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Q **ACCESS CONTROL: Describe how access to the materials/data will be controlled, with access to identifiable (uncoded) materials/data restricted to the minimum necessary repository staff; requirements for staff access and how such access will be monitored; and state who else will have access to materials/data.**

If a Certificate of Confidentiality (COC) will be obtained, a method must be established to ensure that materials and data shielded under its terms are so marked.

Note that the Office of Information Technology (OIT) must review data security plans if Limited Data Sets or Private Health Information (PHI) will be collected. OIT's written approval of data security plans must be uploaded with this protocol.

editor window

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R **Describe the method for identifying materials/data for which subject's consent has been withdrawn. Also state how the repository guardian will ensure that those materials/data are not released for a use contrary to the subject's wishes. Be sure to describe how the repository guardian will honor the wishes of donors who opt out of genetic research.**

editor window

S **TERMINATING THE REPOSITORY: Describe the plans for disposition of materials/data once the repository is terminated. Indicate whether the repository will continue operation or be transferred elsewhere if the Principal Investigator leaves Georgia Tech or if funding is lost. When and how will the materials/data be destroyed? When and how will identifiers, if any, be destroyed? If it is not possible to destroy the identifiers, provide a scientific, legal, or health justification.**

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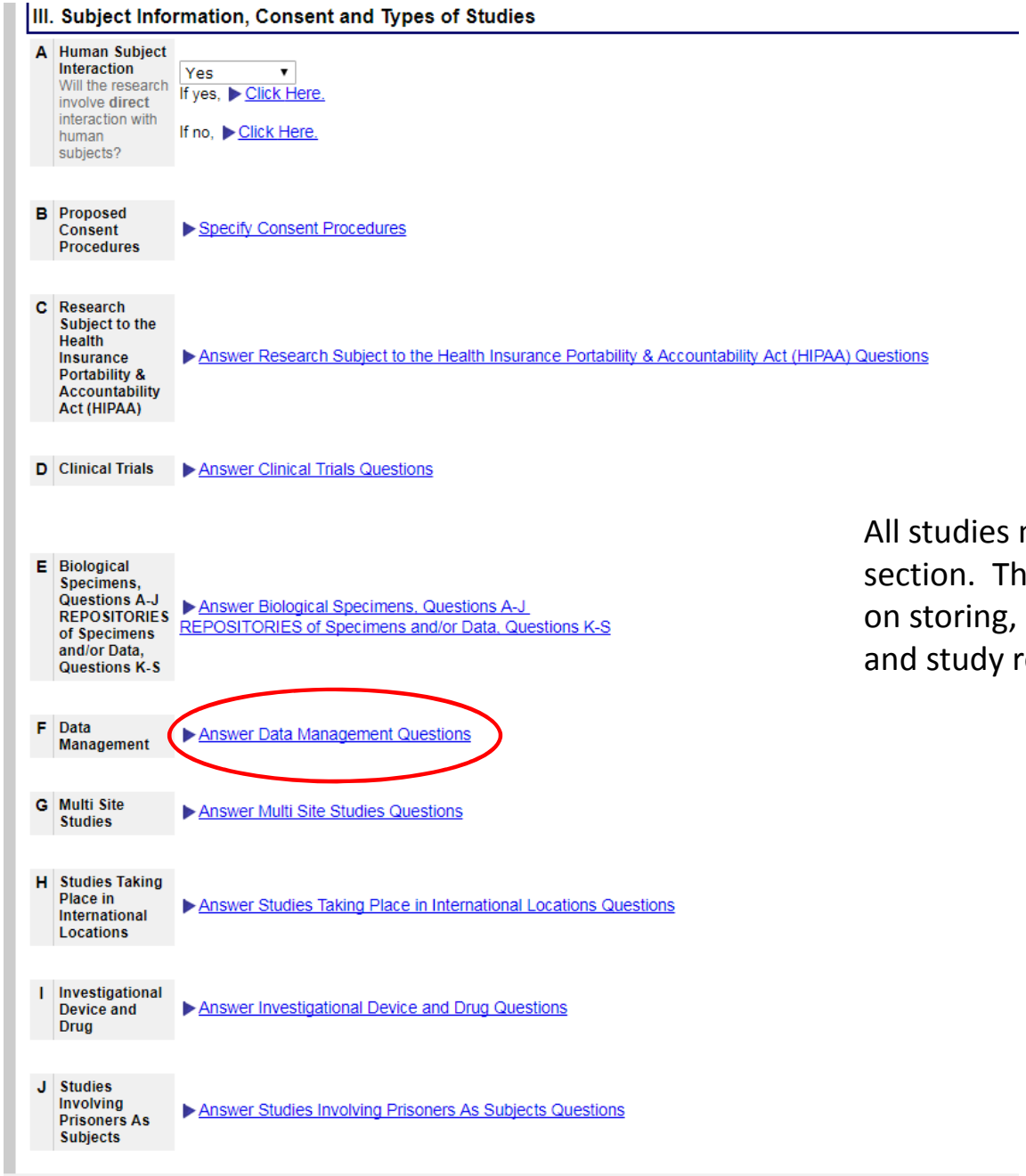
Biological samples and repositories section continued. If your study involves the collection of biological samples, please answer questions A – J. If your study involves the creation of a repository or database, then please fill out questions K – S.

Section III - Question F



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

All studies must fill out the Data Management section. This section asks about how you plan on storing, protecting, and destroying the data and study records.

Section III - Question F

Data Management

A **Describe the plan to ensure that the data collected will directly address the research questions.**

The data gathered from the gaming platform will directly relate to the study question, in that it will show how the subjects navigated in the virtual room. Furthermore, the demographic data may provide insights to group differences in relation to performance. This data will in turn inform the study question by showing how the subjects navigated.

editor window

B **Please state how often you plan to monitor the data to determine that it is accurate and complete.**

All of the data will be monitored weekly, to ensure that the gaming platform is operating properly and the data is complete.

editor window

C **Describe procedures for maintaining confidentiality of the data to be collected or received. Describe how the data will be safeguarded from access by those not authorized. How will data be transmitted among research personnel? Where relevant, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect identifiers).**

All of the electronic data will be stored on secure computer that remains in the lab behind a locked door. The physical records (surveys and signed consent forms) will be stored in a locked file cabinet in the same lab, behind a lock and key. Only authorized study personnel listed on this study will have access to the raw data and signed consent forms.

editor window

D **If a key/code linking to subject identities exists, state how it will be safeguarded and who will have access to that linking information.**

A key connecting the demographic survey to the electronic data will be stored on secure computer that remains in the lab behind a locked door. Only authorized study personnel listed on this study will have access to this key.

editor window

E **Check all of the following that will be utilized to safeguard data that are in an electronic format:**

- ☑ Encryption
- ☐ Other
- ☑ Password access
- ☐ Portable storage (e.g., laptop, flash drive)
- ☑ Secure network

Please be sure to fully answer each question in this section in regards to the data, how it will be monitored, stored, protected, and destroyed.

Section III - Question F

F **Check all of the following that apply for safeguarding tangible materials:**

- [x] Data coded by researcher team with key/code secured and kept separately
- [x] Data de-identified by research team
- [x] Locked cabinet
- [x] Locked suite or office
- [ ] Other

G **With whom, outside the immediate research team, will identifiable data be shared? Upload data use agreements, if any.**

N/A

editor window

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H **Describe the plans for disposition of research related records (i.e., all data, signed consent forms, videos, photographs, etc.) once the study has ended. Please be sure to address the following:**
A. How and when will the materials be destroyed?
B. How and when will identifiers, if any, be destroyed?
C. If it is not possible to destroy the identifiers, provide a scientific, legal, or health justification.

Please be aware that the federal regulations require that all research related records be maintained for a minimum of 3 years following the completion of the study.

All of the data, signed consent forms, and the key linking the data will be stored for 3 years after the completion of the data analysis and will be destroyed after the 3 year mark.

editor window

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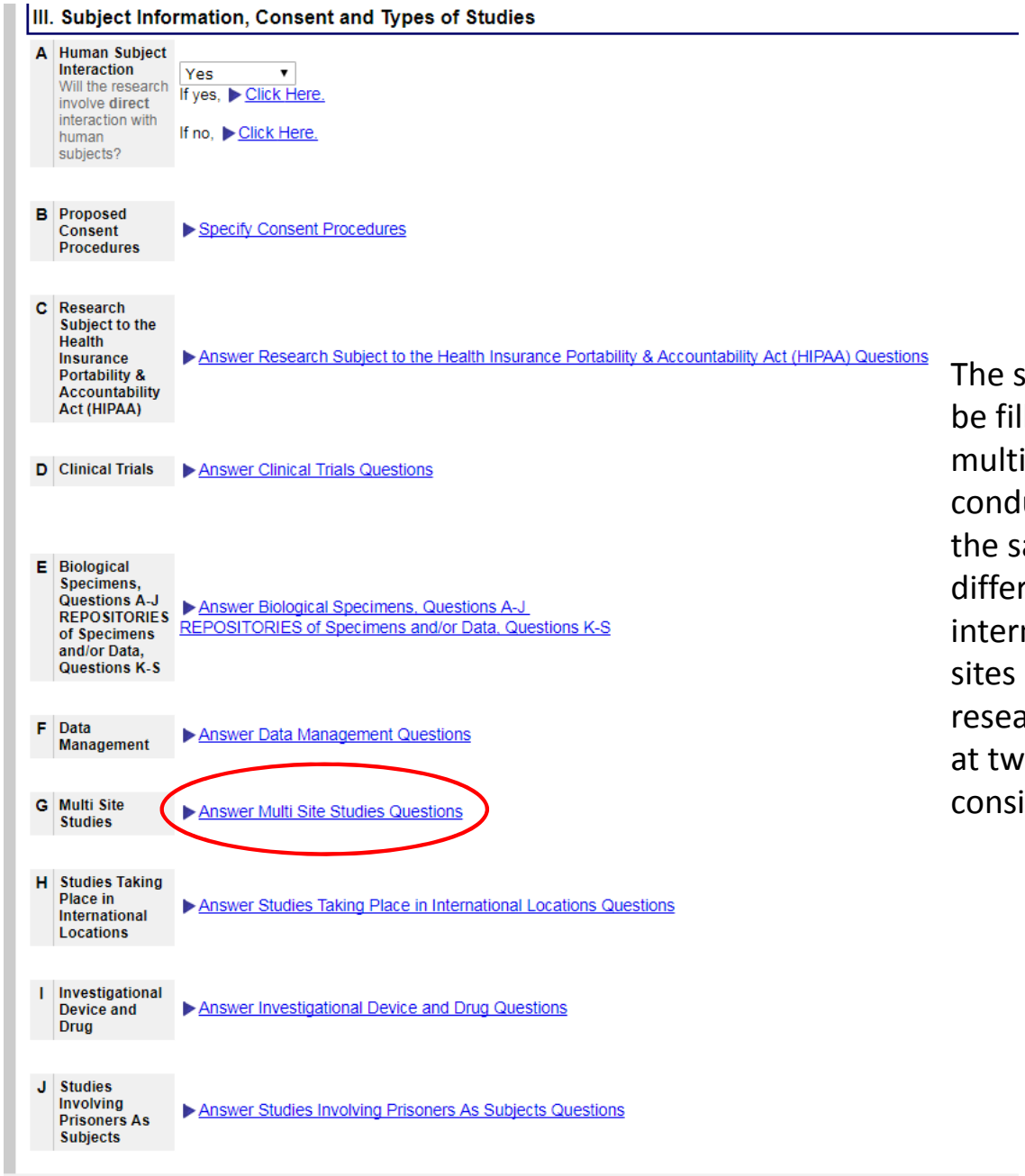
Data Management section continued: Please be sure to fully answer all of the questions in this section. Please also be aware that federal regulations require that the study records be maintained for a minimum of 3 years following the completion of the study.

Section III - Question G

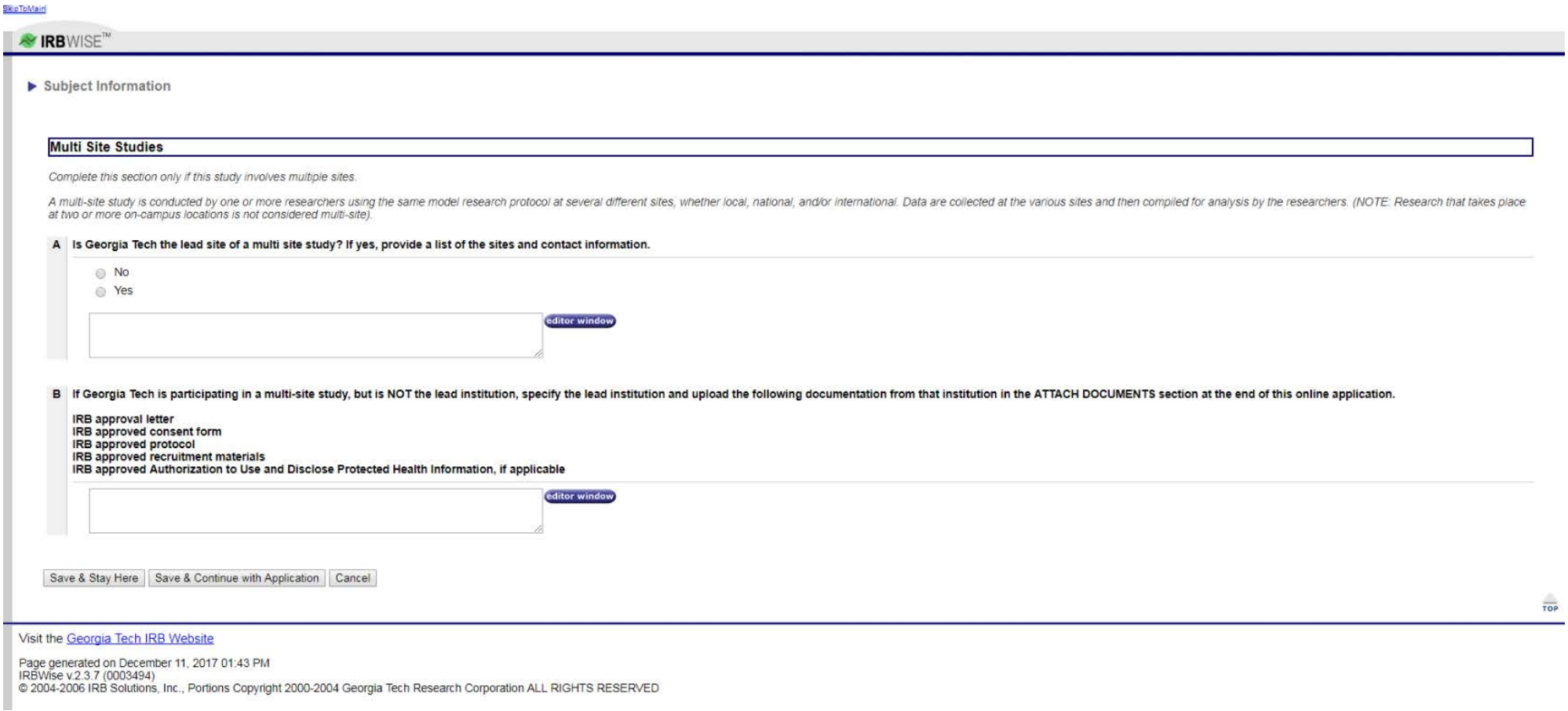


III. Subject Information, Consent and Types of Studies

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

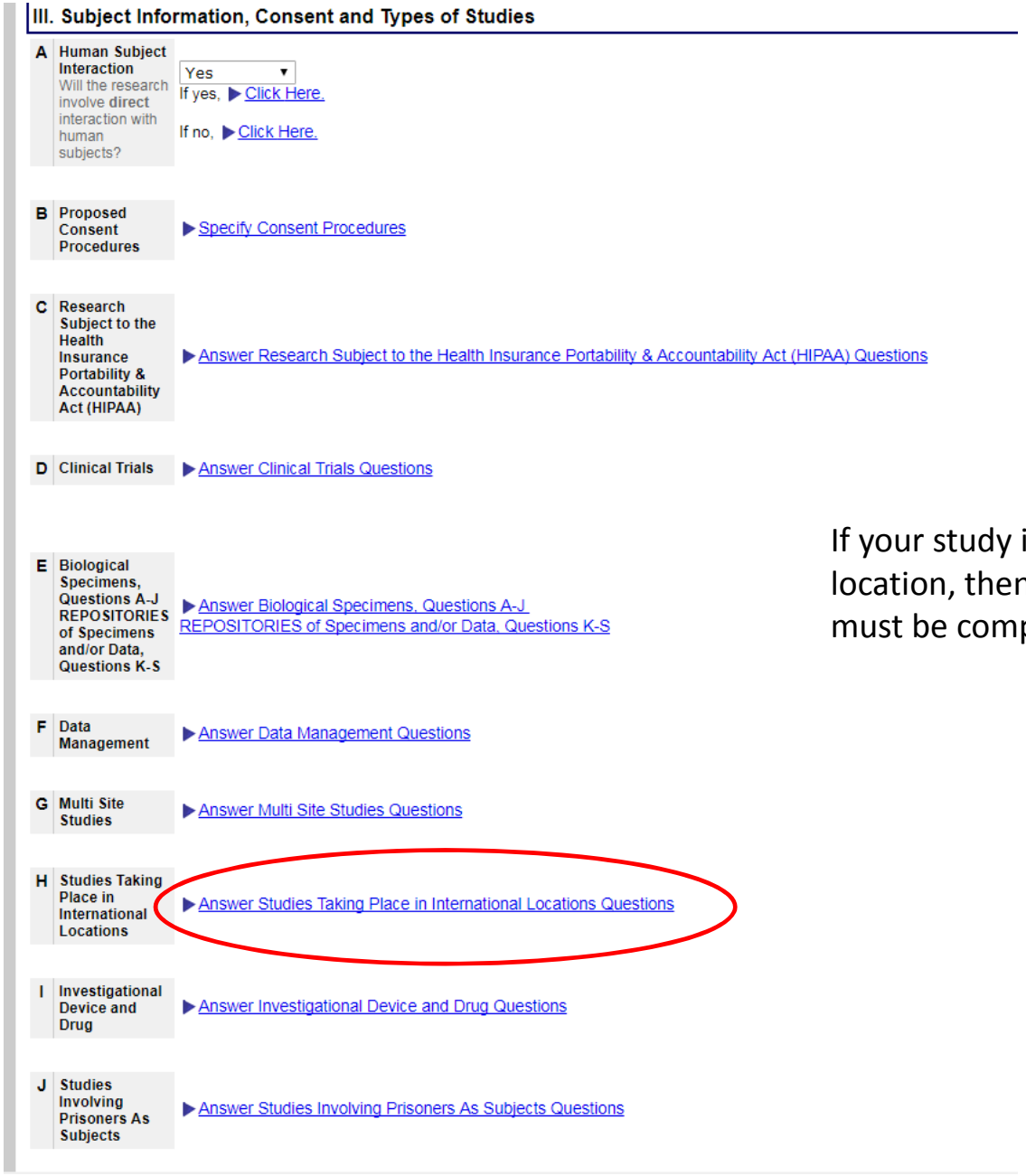
The section following question G only needs to be filled out if your study is considered to be a multi-site study. A multi-site study is conducted by one or more researchers using the same model research protocol at several different sites, whether local, national, and/or international. Data are collected at the various sites and then compiled for analysis by the researchers. (NOTE: Research that takes place at two or more on-campus locations is not considered multi-site).

Section III - Question G



If your study is considered as a multi-site study, then please fill out this section. Please note that if GT is not the lead site, then the IRB documents (IRB approval, consent forms, data collection documents, recruitment forms, etc.) from the lead site will need to be uploaded to the Attach Documents section at the end of the submission.

Section III - Question H



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 your study is taking place at an international location, then the section under Question H must be completed.

Section III - Question H

Studies Taking Place in International Locations

Complete this section only if the proposed work will take place outside of the United States.

REGARDING TRANSLATION REQUIREMENTS: When consent forms, recruitment materials, or other documents must be translated into a foreign language, they should be reviewed and approved by the Institutional Review Board PRIOR TO BEING TRANSLATED in order to avoid an additional translation expense.

Translations must be accompanied by a certified affidavit of accurate translation from a professional translator service unaffiliated with the study. The same procedure applies when documents must be translated from another language into English, although IRB review cannot be conducted until the translation is accomplished. The Office of Research Integrity Assurance can assist with obtaining translations for unfunded studies. Please allow a few days for translation certification during IRB review.

A **Specify the country or countries outside of the United States where this proposed work will take place. Include names of cities, villages, and other locations.**

editor window

B **Was the researcher invited into the community? If yes, state by whom or what entity, and provide documentation for the collaboration. Include contact information for the local sponsor/entity.**

If the researcher was not invited into the community, describe how the researcher will have culturally appropriate access to the community in order to conduct the study.

- ○ No, Researcher was not invited into community.
- ○ Yes, Researcher was invited into the community.

editor window

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C **If the host country has an ethics committee or other regulatory entity (IRB equivalent), the researcher must obtain its approval prior to starting research in-country. Provide the name and contact information for that entity, and upload here a copy of the letter of approval. If the letter is not written in English, also upload a certified English translation.**

The Georgia Tech IRB recognizes that some research sites will have no local review committee or process. In some cases, tribal/village chiefs will provide verbal permission for the study to be conducted, or the approval process will be rather casual. In such cases, describe below how that approval has been obtained.

editor window

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D **Describe how cultural norms or local laws differ from U.S. culture with respect to research autonomy of individuals or groups, consent procedures, recruitment techniques, age of majority, whether parental permission is required, etc. Include an explanation of what cultural sensitivities will be required to conduct this study.**

editor window

Please fully answer each question if your study will take place at an international location. Please also be sure to upload the requested documents using the “upload file” function under certain question in this section.

Section III - Question H

E Describe any aspects of the cultural, political, or economic climate that might increase the risks for participants. For instance, certain diseases are particularly stigmatizing in some cultures, or political circumstances might hamper the ability of citizens to speak openly. If such conditions exist in this study location, describe the steps that will be taken to minimize these risks to subjects.

editor window

F What is the native language of potential subjects? Describe the ability of researchers to speak, read or write their language. If appropriate, explain provisions for translators.

editor window

G If the researcher is a student, describe how the student will communicate with the advisor during the conduct of the research. Address how the advisor will oversee the research.

editor window

H If this study will take place in the EU/EEA, please address how you will manage the requirements of the General Data Protection Regulation. You must use the EU GDPR Consent form and Researcher Privacy Notice.
EU GDPR Consent Form
EU GDPR Privacy Notice
GT EU GDPR Policy

editor window

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I Finally, attach (as a supplemental document) a signed and dated statement of cultural appropriateness prepared by someone not involved in this protocol but who has specific knowledge about the region where the proposed work will take place. The statement can be a memo, email, or letter and should reference the protocol title and describe the expertise of the individual preparing the statement. The statement should say that he or she has reviewed the proposed research procedures and confirms that the proposed work does not conflict with local and cultural norms. In the text box below, enter the name and title of the person providing the statement of cultural appropriateness. Also attach the statement as a supplemental document.

editor window

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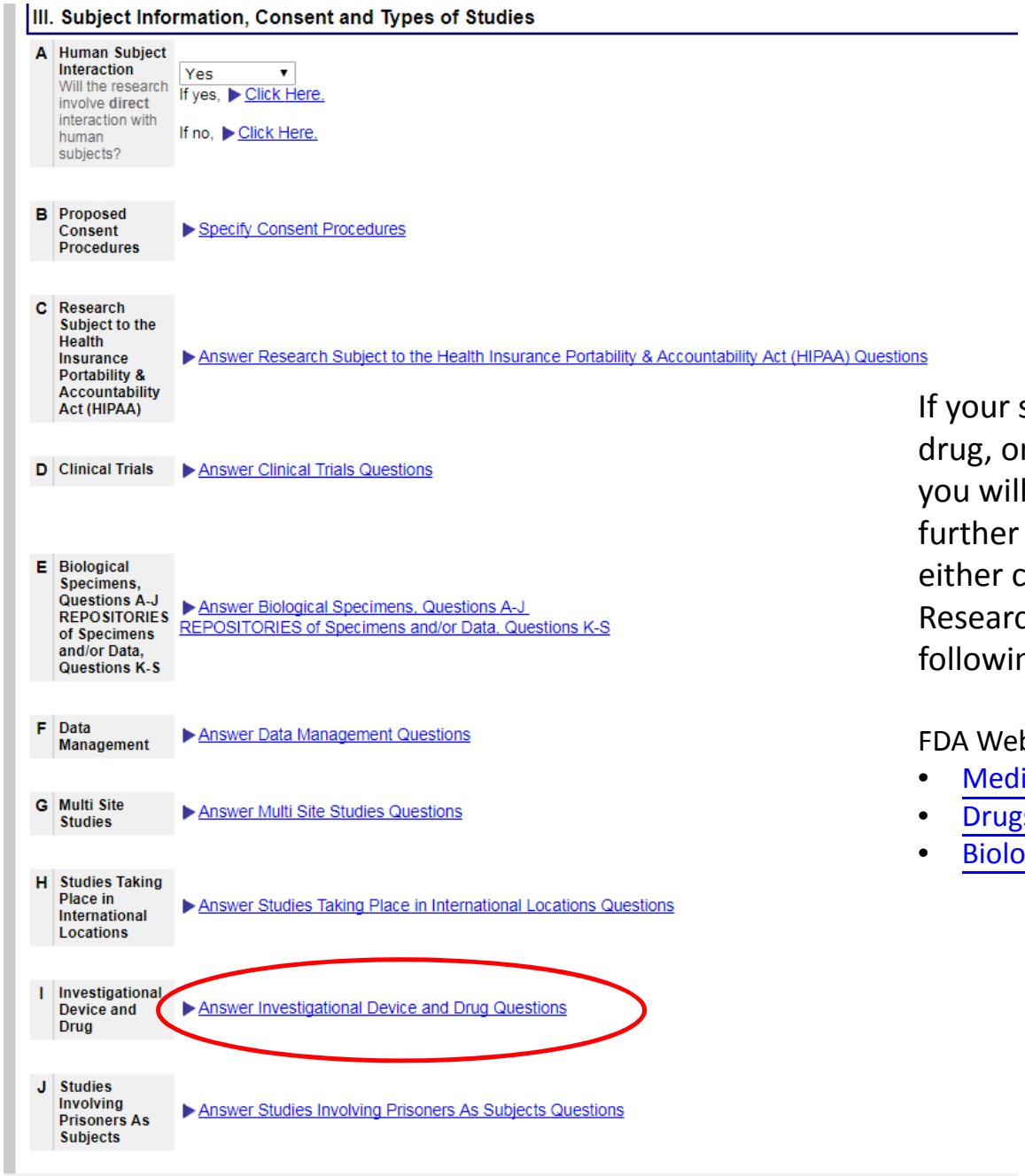
Save & Stay Here | Save & Continue with Application | Cancel

This is a continuation of the international study section. Please be sure to fully answer each question in this section.

Section III - Question I



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
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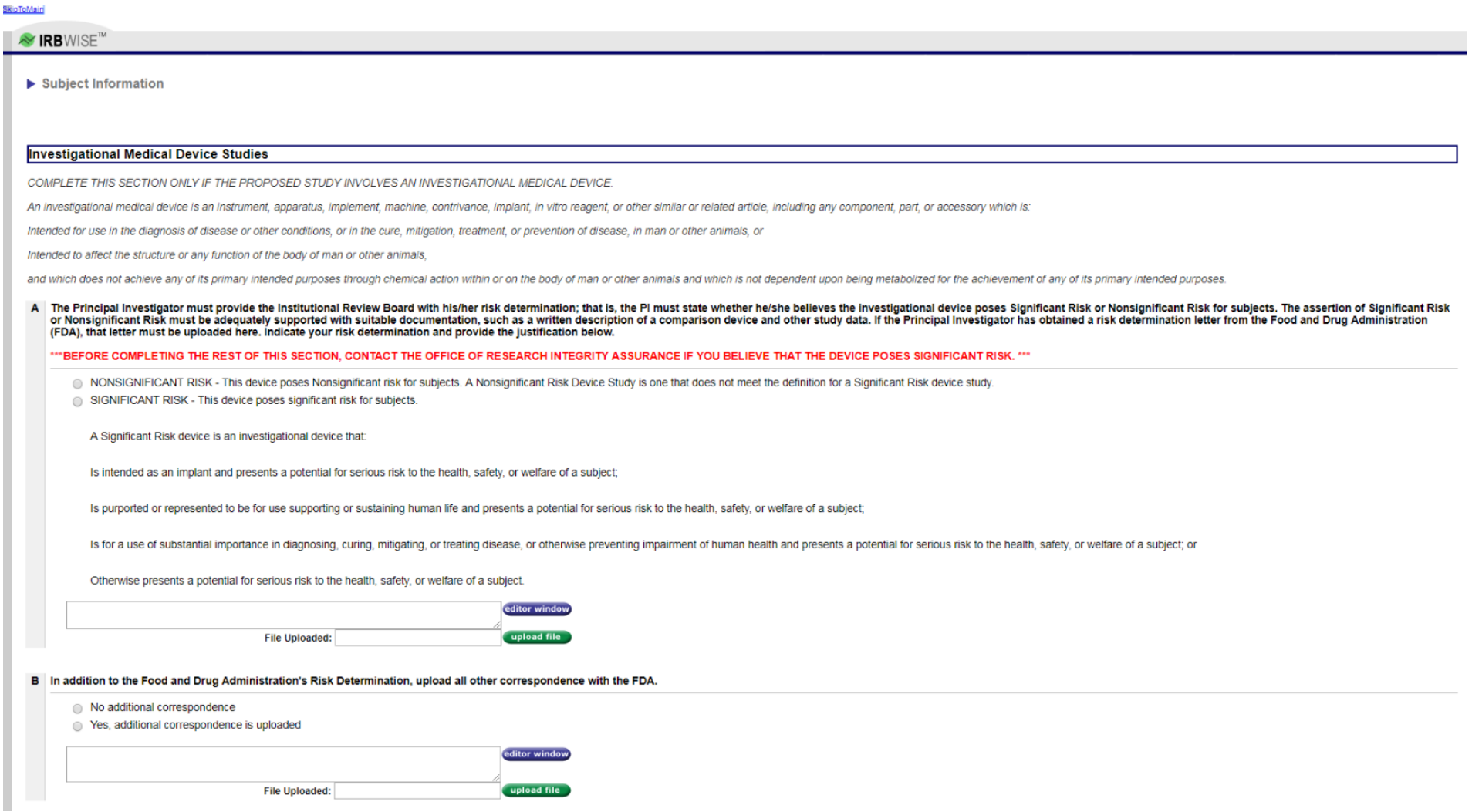
I	**Investigational Device and Drug**	▶ Answer Investigational Device and Drug Questions
J	**Studies Involving Prisoners As Subjects**	▶ Answer Studies Involving Prisoners As Subjects Questions

If your study is investigating a medical device, drug, or biologic as defined by the FDA, then you will need to complete this section. For further information regarding this, please either consult the staff in the Office of Research Integrity Assurance or review the following FDA websites

FDA Websites:

- Medical Devices
- Drugs
- Biologics

Section III - Question I



There are two sections in this pop-window. Please answer the first section if you are using a medical device and the second section if you are using a drug or biologic.

Section III - Question I

C What is the name of the device?

editor window

D Select the appropriate check boxes below that describe the investigational medical device. Click all that apply.

- Accessory to a Medical Device
- Algorithm
- Combination Device (drug and/or device and/or biologic)
- Component
- In Vitro Diagnostic
- In Vivo (implant)
- Medical App
- Off Label Use of FDA-Cleared Device
- Other
- Software
- Stand Alone Device

E What is the specific, intended use of the investigational medical device? What disease, disorder, or condition, if any, is this investigational medical device intended to diagnose, cure, mitigate, treat, or prevent? How will this proposed use differ from currently available devices?

editor window

F If applicable, describe how it is intended to affect the structure or any function of the body of man or other animals.

editor window

G Specify the manufacturer of the device, including name, address, contact person, and telephone number.

editor window

H List the device components, ingredients, and properties.

editor window

I Provide complete instructions for use of the Investigational Medical Device.

editor window

J List the principles of operation.

editor window

This is a continuation of the medical device section in question I.
Please be sure to fully answer all of the questions in this section.

Section III - Question I

K Describe the methods, facilities and controls used for the manufacture of the device, including plans for packing, storage and, if applicable, installation.

editor window

L Provide the device or technology label language.
The general labeling requirements for medical devices are contained in 21 CFR Part 801 and 812, while In Vitro Diagnostic (IVD) labeling requirements are specified at 21 CFR 809.10. Some of these may not pertain to your technology. Specify label language here.

editor window

M Discuss bench testing regarding safety of the device. Any safety and sterilization certification letters should be uploaded, and compliance with ISO standards should be discussed.

editor window

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N Report relevant prior clinical, animal and laboratory testing of the device. This report must include the following:

A bibliography of all publications, whether adverse or supportive, that are relevant to an evaluation of the safety and effectiveness of the device
Copies of all published and unpublished adverse information
A summary of all other unpublished information (whether adverse or supportive) that is relevant to an evaluation of the safety and effectiveness of the device
If nonclinical laboratory data are provided, a statement that such studies have been conducted in compliance with the Good Laboratory Practice (GLP) regulation in 21 CFR Part 58.
If the study was not conducted in compliance with the GLP regulation, include a brief statement of the reason for noncompliance.

editor window

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O If the Food and Drug Administration has issued an Investigational Device Exemption Number, provide it here.

editor window

P The Food & Drug Administration assigns devices to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device.

Specify the FDA Device Class and Regulatory Controls applicable to this device by checking one of the three classes (and corresponding requirements) below:

- Class I General Controls With Exemptions
- Class I General Controls Without Exemptions
- Class II General Controls and Special Controls With Exemptions
- Class II General Controls and Special Controls Without Exemptions
- Class III General Controls and Premarket Approval

editor window

Q If the device will be exported for any purpose during this study, identify the person and address to whom it will be exported, and explain why the export will occur.

editor window

This is a continuation of the medical device section in question I.
Please be sure to fully answer all of the questions in this section.

Section III - Question I

R If any components, parts, ingredients, or other materials comprising this device will be imported, state the source of export including name of entity and full address for each component, part, ingredient, or other material.

editor window

S Describe the procedures for monitoring the investigation at all study sites.

editor window

T What safeguards are in place to ensure that the investigational device will only be used as described in the protocol?

editor window

U DIAGNOSTIC DEVICE STUDIES:

Diagnostic device studies [e.g., in vitro diagnostic (IVD) studies, technologies, assays] are exempt from the requirements of 21 CFR Part 812 under certain circumstances. The study is exempt as long as the sponsor complies with the requirements at 21 CFR 809.10(c) for labeling, and if the testing
(1) is noninvasive;
(2) does not require an invasive sampling procedure that presents significant risk;
(3) does not by design introduce energy into a subject; and
(4) is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product and/or procedure or validated by a certified CLIA laboratory.

If the diagnostic device does not qualify under the requirements at 21 CFR 809.10(c) and numbers 1, 2, 3 and 4, then the IVD is subject to the medical device IDE requirements at 21 CFR 812 and will require FULL BOARD review.
Does this diagnostic device qualify for exemption under 21 CFR 809.0(c)?

Select One

V If the diagnostic device will be validated against another established product and/or procedure or validated by a CLIA laboratory, describe the validation procedures.

editor window

W If this investigational technology operates in conjunction with software or any other technology, these would become part of the In Vitro Diagnostic device and must be stated here. If applicable, list the device components, ingredients, and properties.

Select One

editor window

X If this study is investigator-initiated, the Principal Investigator is considered the Sponsor of the study. Describe how the Principal Investigator will satisfy the considerable additional FDA responsibilities associated with serving as Sponsor.

editor window

Save Answers

This is a continuation of the medical device section in question I.
Please be sure to fully answer all of the questions in this section.

Section III - Question I

Investigational New Drug Studies

Georgia Tech conducts pharmaceutical studies in collaboration with other appropriate clinical entities. Consult the Office of Research Integrity Assurance.

COMPLETE THIS SECTION FOR STUDIES INVOLVING AN INVESTIGATIONAL DRUG.

A drug is defined by the Food and Drug Administration as:
A substance recognized by an official pharmacopoeia or formulary.
A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
A substance (other than food) intended to affect the structure or any function of the body.
A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological)

A **Specify the clinical entity where the research will take place and provide the names of research collaborators at that location.**

editor window

B **State the drug name, including brand and generic names.**

editor window

C **Provide the Investigational New Drug (IND) Number, if any, assigned by FDA.**

editor window

D **Provide the drug manufacturer name, and include address and telephone number.**

editor window

E **Indicate how the investigational drug will be evaluated in this study, whether being used off label, in accordance with current FDA approval, or as an investigational new mode. Include mode of administration.**

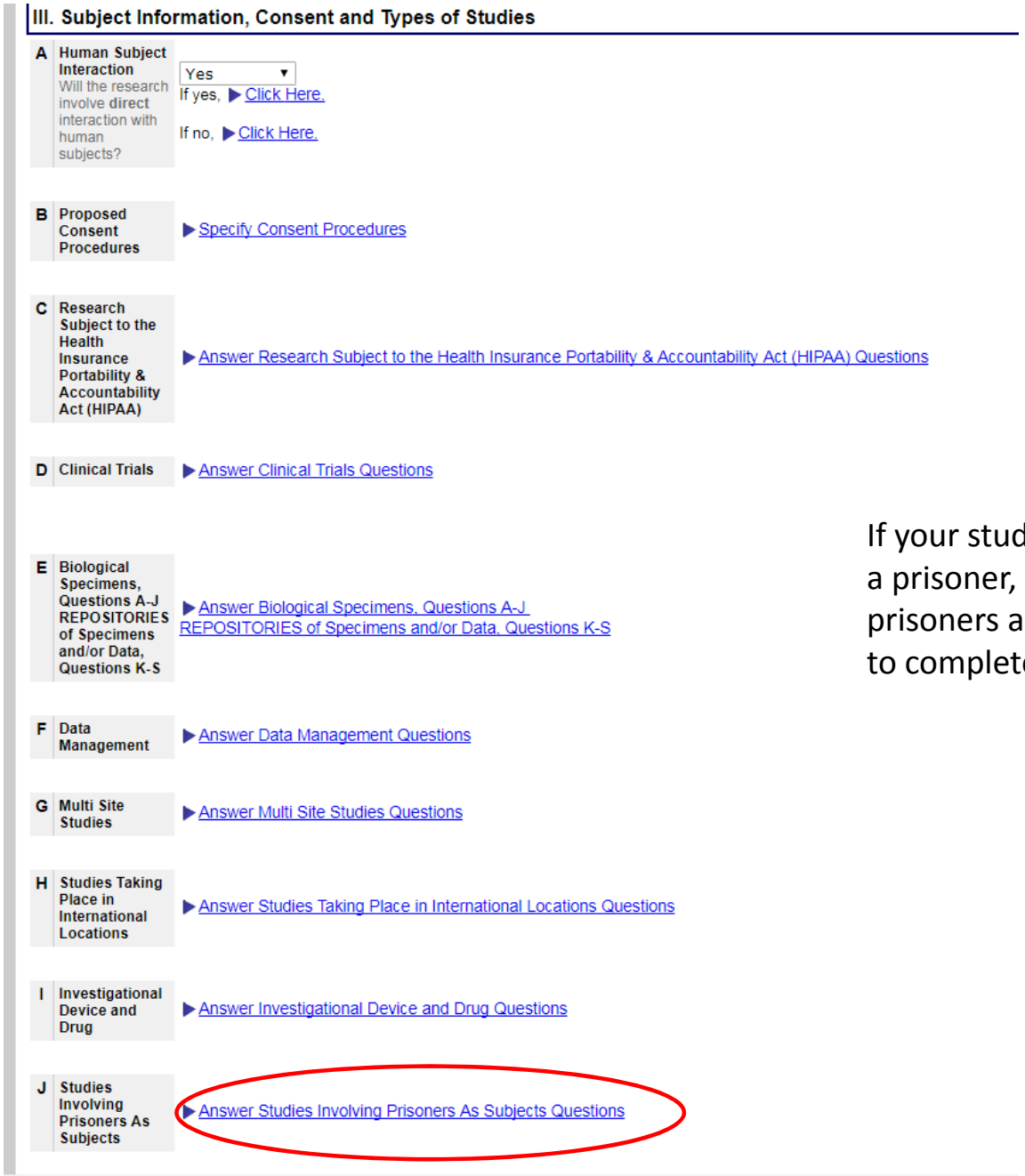
editor window

F **For each drug that is to be administered, upload a copy of the packet insert and Federal Form 1572 in the ATTACH DOCUMENTS section of the application. If these are not available, explain why.**

editor window

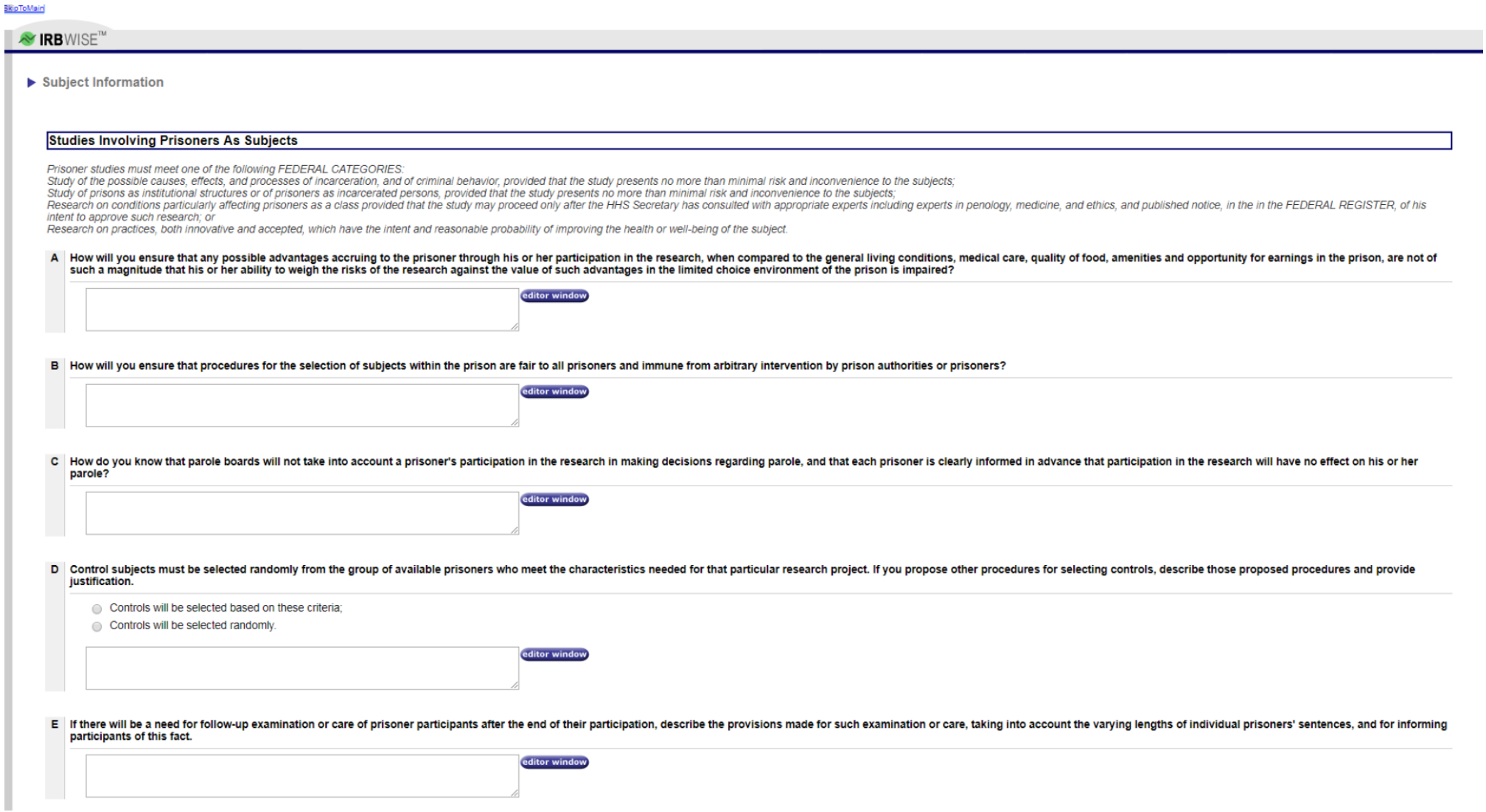
This is the second section under question I regarding drugs and biologics. Please fully answer each question in this section if your study involves a drug or biologic.

Section III - Question J



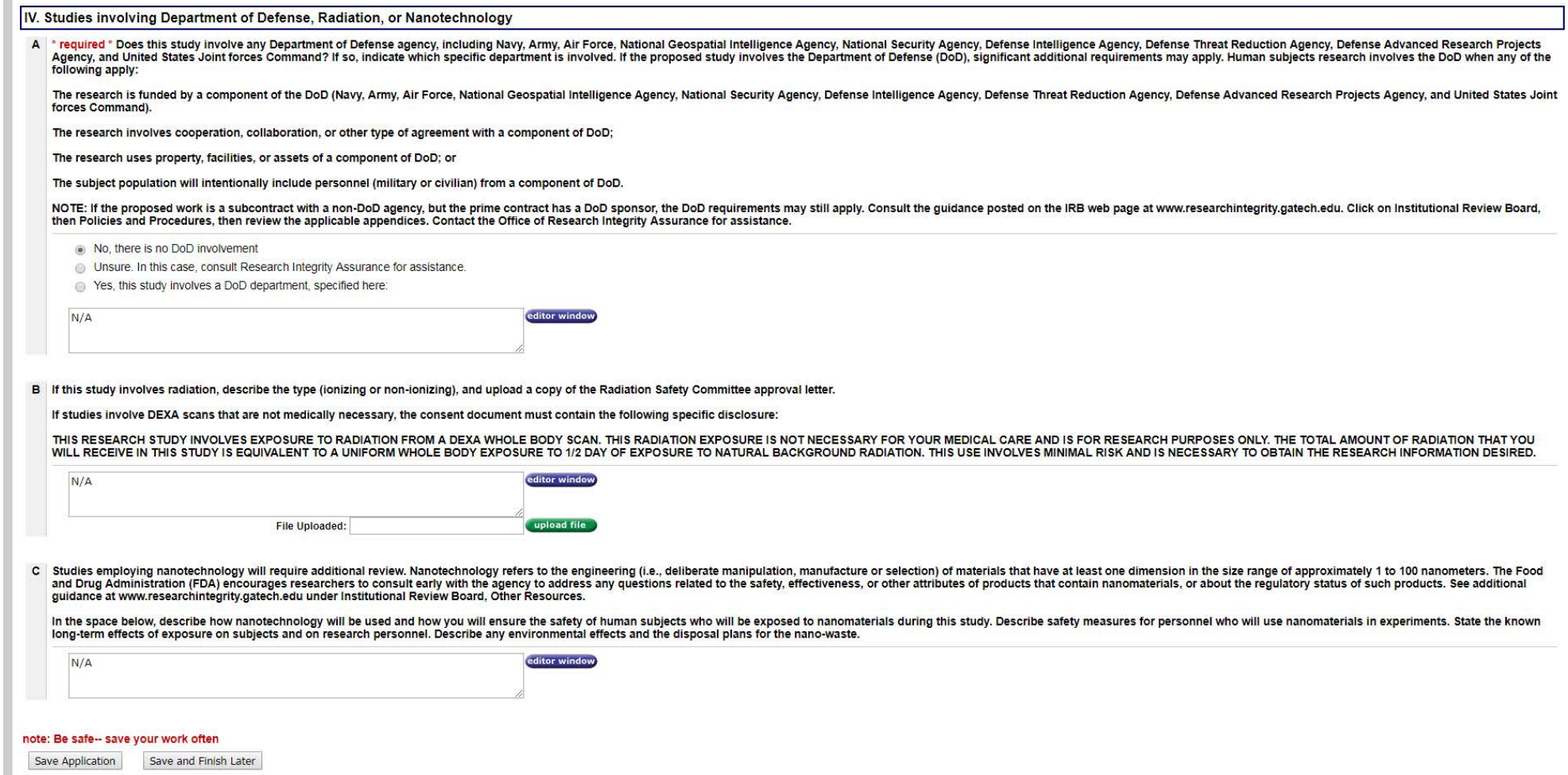
If your study includes anyone who is currently a prisoner, or if you are directly targeting prisoners as a study population, then you need to complete question J.

Section III - Question J



Please fully answer each question in this section if your study involves prisoners.

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

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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.

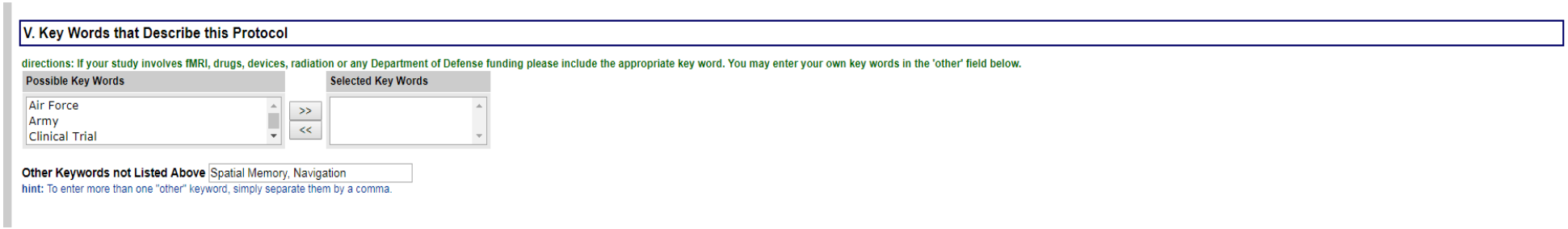
N/A editor window

note: Be safe-- save your work often

Save Application | Save and Finish Later

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

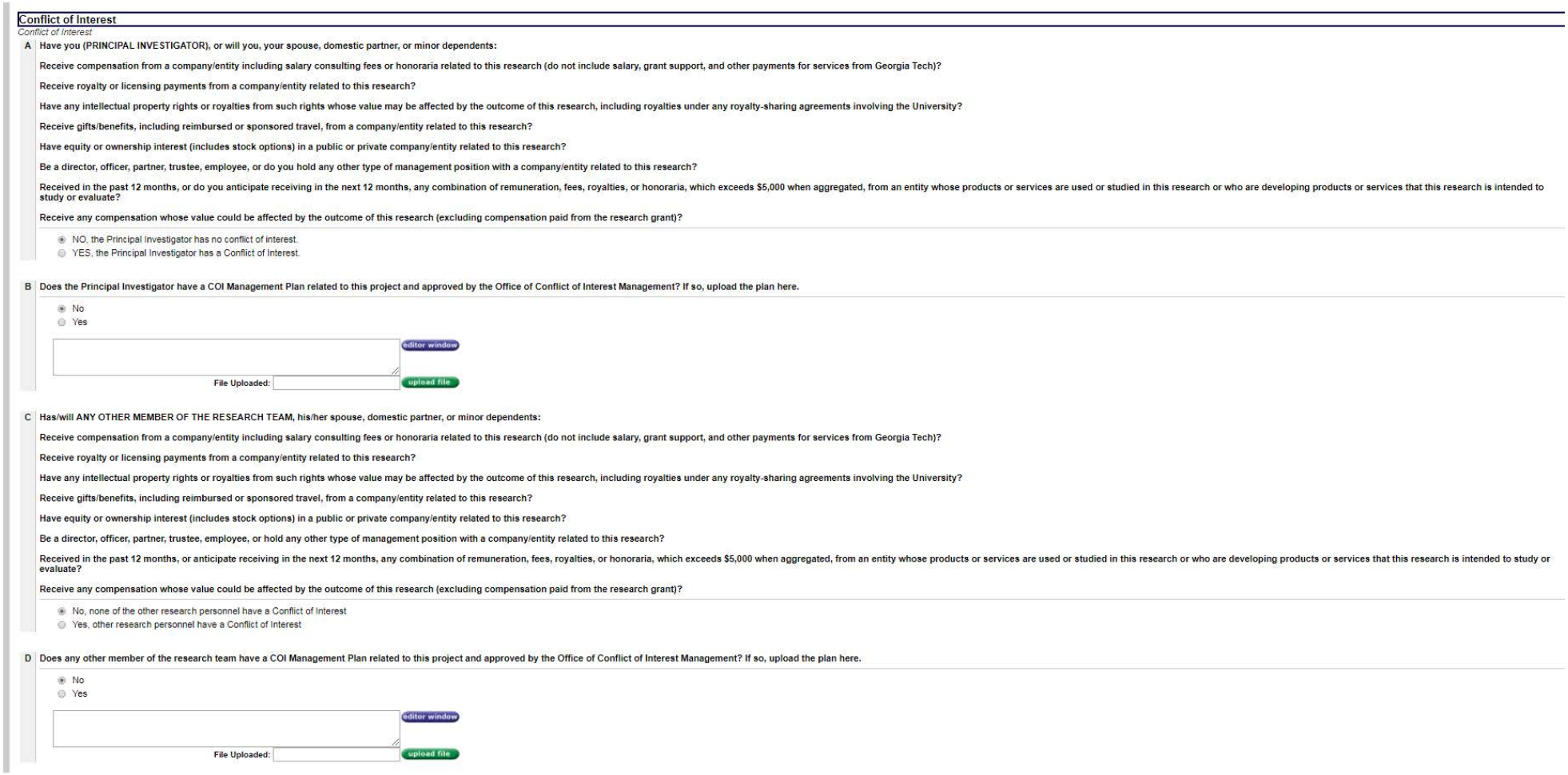
In this section, please click the “upload documents” link and upload all relevant documents to your study. This includes protocol documents, funding documents, recruitment, surveys, interview questions, pictures and descriptions of an experimental apparatus, device brochures, etc.

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

editor window

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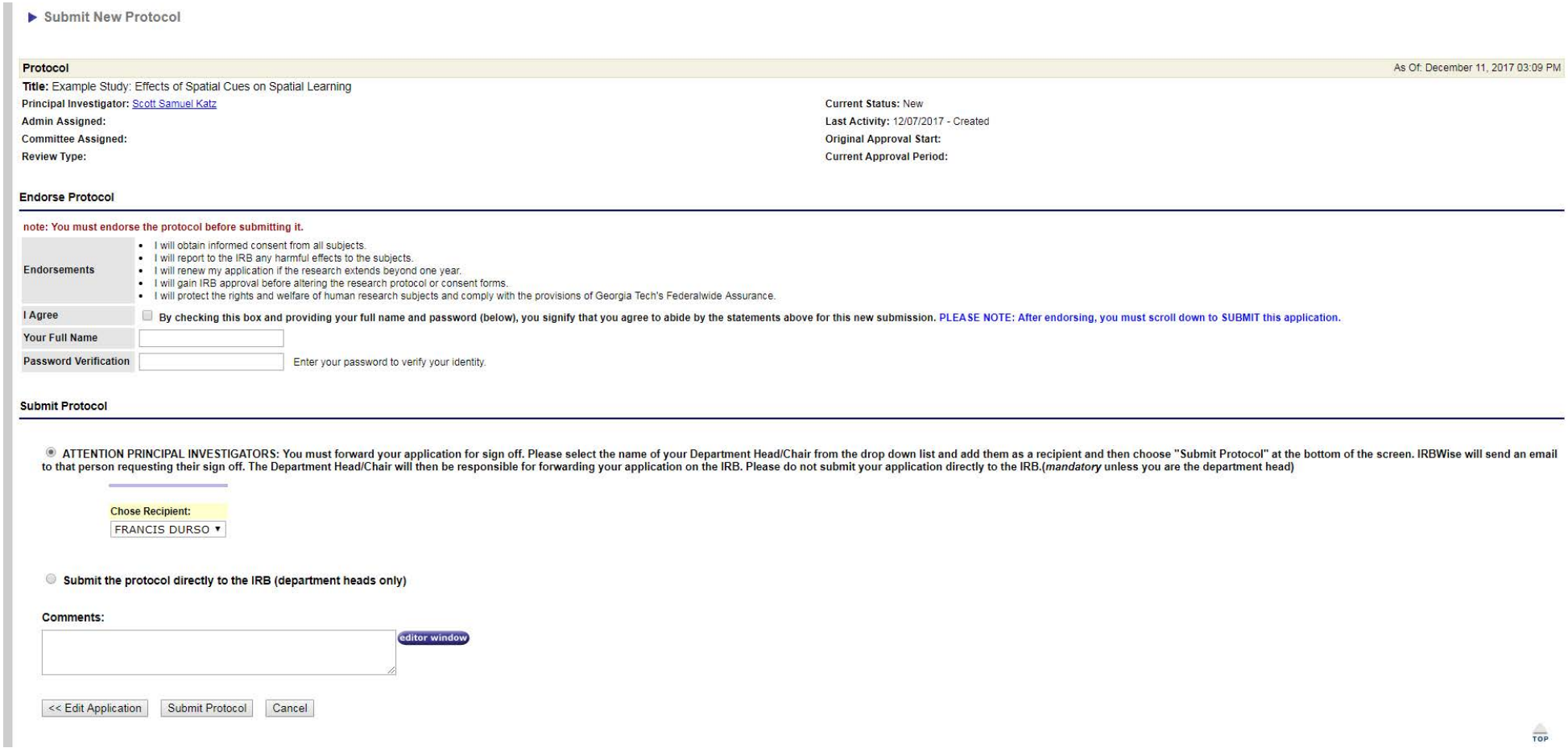
After clicking “Save and Continue Application,” you will be brought back to your full submission to review. At the bottom of this submission is an additional section that asks if you or any study team members have a financial conflict of interest. If you are unsure about this, please either contact the 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 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
Dalney Street Building
926 Dalney Street NW, Atlanta, GA 30332-0415
Email: IRB@gatech.edu
Website: https://oria.gatech.edu/irb