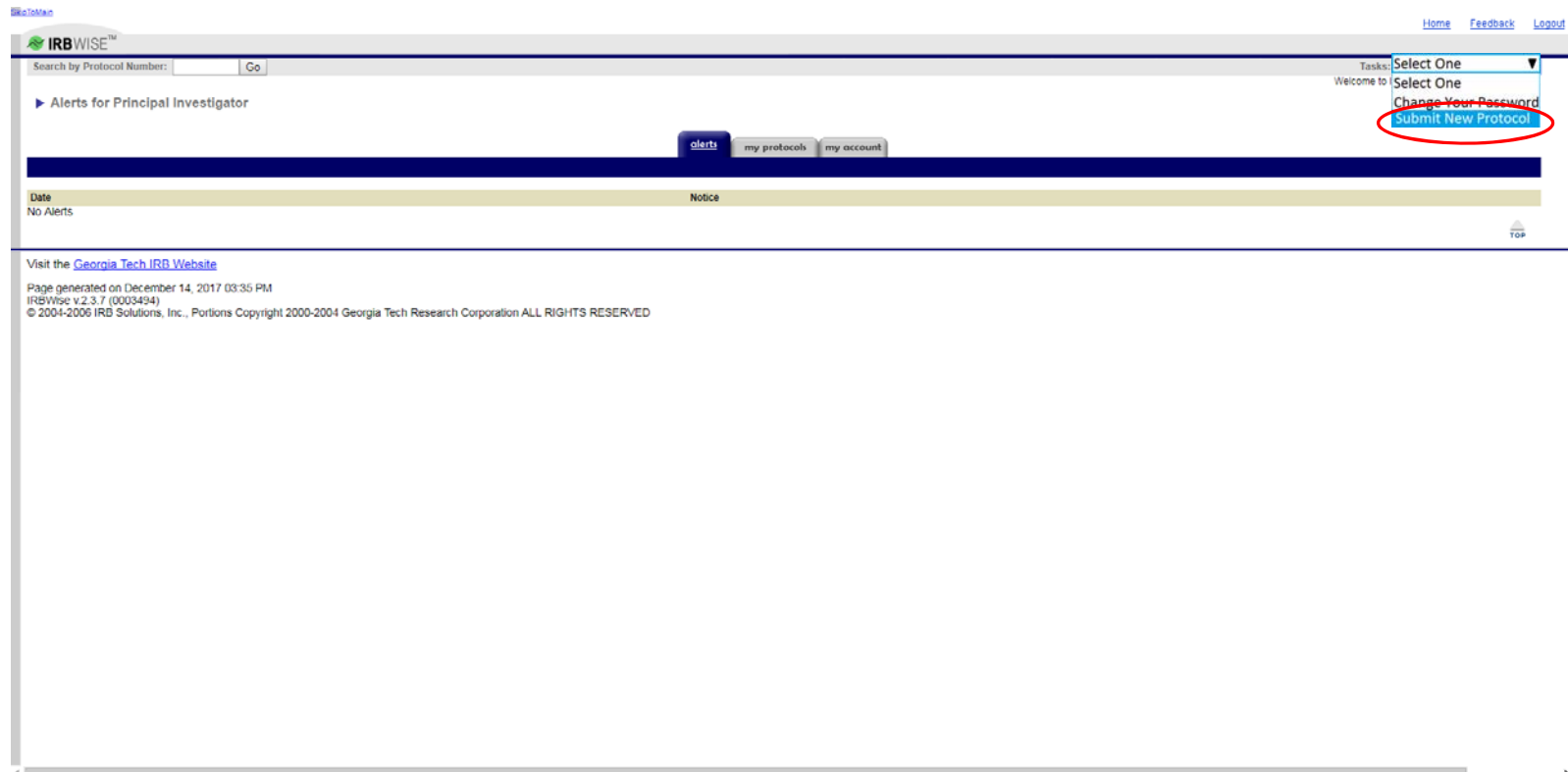


# IRB Wise Shell Submission Example and Guidance

This presentation includes an example of a new Shell Submission in IRB Wise and also includes guidance for each section in IRB Wise. Shell Submissions are used by the Office of Research Integrity Assurance (ORIA) to track GT IRB deferral decisions to external IRB approval decisions. Shell Submissions are also used to track studies that fall under the Single IRB (sIRB) requirement. The screen shots are of an example and the responses are not to be taken as the correct response. Each study is different, and therefore each response and each section will need to be filled out to tailor to your study. Please contact the Office of Research Integrity Assurance if you have any questions.

# Start Page on IRB Wise



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

# Section I. General Information

IRB WISE™

Search by Protocol Number:  Go

Tasks: Select One  
Welcome to IRBWISE, Principal Investigator.

Submit New Protocol

With PI (selected) With Department Head Approval Submitted to IRB Under Review Final Disposition

**INFORMATION** Enter protocol information and submit at the bottom of this page.

### I. General Information

**A Protocol Title**  
(required to save application)  
EXAMPLE UNIVERSITY: Study Title [editor window](#)

**B Research Personnel**  
(required to save application)  
List all personnel who will be conducting the research, including those who will interact with subjects or with identifiable data.  
[Add/Modify Certified Personnel \(required\)](#)

**C Protocol Description**  
Provide a brief description of the research in lay terms that can be understood by those unfamiliar with the area of research. [editor window](#)

This project is a collaboration between EXAMPLE UNIVERSITY and Georgia Tech. The research is being led by EXAMPLE UNIVERSITY. The purpose of this research is to develop a prototype system/improve subject outcomes/etc. (\*Provide a full description of the overall study intent)

Investigators at EXAMPLE UNIVERSITY, will (\*describe study procedures taking place at the lead institution)

Research at Georgia Tech includes analysis of patient data, study design, and publication generation (\*specifically describe how Georgia Tech researchers will be engaged in the research. Ex: No GT researchers are involved in enrolling subjects, consenting subjects, interacting with subjects, or collection of data from subjects.)

**D Protocol Department**  
(required to save application)  
Identify the home department for the protocol. This is usually the home department of the Principal Investigator.

Search or

Counseling

**E Exempt Review Determination**  
Only allowed for research that qualifies for exempt review as defined in the federal regulations. Answer Exempt Review Questions.  
[Answer Exempt Review Determination Questions](#)

**note: Be safe-- save your work often**

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

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

# Section I. General Information – Add/Modify Personnel Window

IRBWISE™

Search by Protocol Number:  Go

Tasks: Select One  
Welcome to IRBWISE, Principal Investigator.

Submit New Protocol **With PI** With Department Head Approval Submitted to IRB Under Review Final Disposition

**INFORMATION** Enter protocol information and submit at the bottom of this page.

### I. General Information

**A Protocol Title**  
(required to save application)  
EXAMPLE UNIVERSITY: Study Title [editor window](#)

**B Research Personnel**  
(required to save application)  
List all personnel who will be conducting the research, including those who will interact with subjects or with identifiable data.  
[Add/Modify Certified Personnel \(required\)](#)

**C Protocol Description**  
Provide a brief description of the research in lay terms that can be understood by those unfamiliar with the area of research. [editor window](#)  
This project is a collaboration between EXAMPLE UNIVERSITY and Georgia Tech. The research is being led by EXAMPLE UNIVERSITY. The purpose of this research is to develop a prototype system/improve subject outcomes/etc. (\*\*Provide a full description of the overall study intent)  
Investigators at EXAMPLE UNIVERSITY, will (\*\*describe study procedures taking place at the lead institution)  
Research at Georgia Tech includes analysis of patient data, study design, and publication generation (\*\*specifically describe how Georgia Tech researchers will be engaged in the research. Ex: No GT researchers are involved in enrolling subjects, consenting subjects, interacting with subjects, or collection of data from subjects.)

**D Protocol Department**  
(required to save application)  
Identify the home department for the protocol. This is usually the home department of the Principal Investigator.  
 Search or List All Choices  
Counseling

**E Exempt Review Determination**  
Only allowed for research that qualifies for exempt review as defined in the federal regulations. Answer Exempt Review Questions.  
[Answer Exempt Review Determination Questions](#)

**note: Be safe-- save your work often**

Save Application Save and Finish Later

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

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

# Section I. General Information – Add/Modify Personnel Window

## ► Associate Study Personnel

**Select Person (by Last Name):**

[► View their certifications](#)

**note:** The search list above contains all current Georgia Tech students & employees. If you need to list someone on this protocol who is not in this list and is not affiliated with Georgia Tech, please send the following information to the [Office of Research Compliance](#):

- The person's name
- Organization/Company
- Phone #
- E-mail Address
- Role on this protocol
- Proof of completion of Human Subject Training

**Select Role:**

**Proof of Experience & Certifications:**  
Upload your current CV or resume. Include any license & certification such as medical license.

Attach Files:  No file selected.

No file selected. [Attach More..](#)

**directions:** This list contains all active students, faculty, and staff at Georgia Tech.

### Study Personnel Listed:

Select	Name	Role Certification	Documents
<input type="radio"/>	<a href="#">Scott Samuel Katz</a>	PI <ul style="list-style-type: none"> <li>• CITI: IRB Health Information Privacy and Security (HIPS) (Approved): May 17, 2018 - May 17, 2021</li> <li>• CITI: IRB IRB Members (Approved): July 21, 2017 - July 21, 2020</li> <li>• CITI: IRB Good Clinical Practice (Approved): July 14, 2017 - July 14, 2020</li> <li>• CITI: IRB Biomedical Training (Approved): July 21, 2017 - July 21, 2020</li> </ul>	

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

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

Version 03/2020

# Section I. General Information – Protocol Description

IRBWISE™

Search by Protocol Number:  Go

Tasks: Select One  
Welcome to IRBWISE, Principal Investigator.

Submit New Protocol

With PI

With Department Head Approval

Submitted to IRB

Under Review

Final Disposition

**INFORMATION** Enter protocol information and submit at the bottom of this page.

## I. General Information

**A Protocol Title**  
(required to save application)

EXAMPLE UNIVERSITY: Study Title [editor window](#)

**B Research Personnel**  
(required to save application)  
List all personnel who will be conducting the research, including those who will interact with subjects or with identifiable data.

[Add/Modify Certified Personnel \(required\)](#)

**C Protocol Description**  
Provide a brief description of the research in lay terms that can be understood by those unfamiliar with the area of research.

This project is a collaboration between EXAMPLE UNIVERSITY and Georgia Tech. The research is being led by EXAMPLE UNIVERSITY. The purpose of this research is to develop a prototype system/improve subject outcomes/etc. (\*Provide a full description of the overall study intent)

[editor window](#)

Investigators at EXAMPLE UNIVERSITY, will (\*describe study procedures taking place at the lead institution)

Research at Georgia Tech includes analysis of patient data, study design, and publication generation (\*specifically describe how Georgia Tech researchers will be engaged in the research. Ex: No GT researchers are involved in enrolling subjects, consenting subjects, interacting with subjects, or collection of data from subjects.)

**D Protocol Department**  
(required to save application)  
Identify the home department for the protocol. This is usually the home department of the Principal Investigator.

Search or [List All Choices](#)

Counseling

**E Exempt Review Determination**  
Only allowed for research that qualifies for exempt review as defined in the federal regulations. Answer Exempt Review Questions.

[Answer Exempt Review Determination Questions](#)

**note: Be safe-- save your work often**

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

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



# Section I. General Information

IRBWISE™

Search by Protocol Number:  Go

Tasks: Select One  
Welcome to IRBWISE, Principal Investigator.

Submit New Protocol **With PI** With Department Head Approval Submitted to IRB Under Review Final Disposition

**INFORMATION** Enter protocol information and submit at the bottom of this page.

### I. General Information

**A Protocol Title**  
(required to save application)  
EXAMPLE UNIVERSITY: Study Title [editor window](#)

**B Research Personnel**  
(required to save application)  
List all personnel who will be conducting the research, including those who will interact with subjects or with identifiable data.  
[Add/Modify Certified Personnel \(required\)](#)

**C Protocol Description**  
Provide a brief description of the research in lay terms that can be understood by those unfamiliar with the area of research. [editor window](#)  
This project is a collaboration between EXAMPLE UNIVERSITY and Georgia Tech. The research is being led by EXAMPLE UNIVERSITY. The purpose of this research is to develop a prototype system/improve subject outcomes/etc. (\*\*Provide a full description of the overall study intent)  
Investigators at EXAMPLE UNIVERSITY, will (\*\*describe study procedures taking place at the lead institution)  
Research at Georgia Tech includes analysis of patient data, study design, and publication generation (\*\*specifically describe how Georgia Tech researchers will be engaged in the research. Ex: No GT researchers are involved in enrolling subjects, consenting subjects, interacting with subjects, or collection of data from subjects.)

**D Protocol Department**  
(required to save application)  
Identify the home department for the protocol. This is usually the home department of the Principal Investigator.  
 Search or   
Counseling

**E Exempt Review Determination**  
Only allowed for research that qualifies for exempt review as defined in the federal regulations. Answer Exempt Review Questions.  
[Answer Exempt Review Determination Questions](#)

**note: Be safe-- save your work often**

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

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

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

**N** **Research Funding**  
How will the research be funded?  If Funded, [Add/Modify Funding Sources](#)

**O** **Research Locations**  
Where will the research be conducted? [Add/Modify Location\(s\)](#)

**note: Be safe-- save your work often**

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



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

[HELP | LOGIN](#)

**IRBWISE™**

► **Modify Funding**

If externally funded, please type the last name of the PI in the text box and then select the corresponding grant from the drop down list.

PI and Grant Title:

(If there is a funding source associated with the Protocol which is not in the list above, [click here](#).)

---

List of funding sponsors currently associated:

Select	Funding Sponsor	Grant Title	ICOL # (Doc ID)
None			

---

If internally funded (such as Foundation or start up funds), enter funding source(s) here

Grant title:

Sponsor Name

---

Visit the [Georgia Tech IRB Website](#)

Page generated on December 11, 2017 10:46 AM  
IRBwise v.2.3.7 (0003494)  
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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 complete the text boxes at the bottom of the page.

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

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

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

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

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

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

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

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

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

N/A editor window

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

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

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

N/A editor window

File Uploaded: upload file

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

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

N/A editor window

**note: Be safe-- save your work often**

Save Application Save and Finish Later

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

## Section V – Key Words that Describe this Protocol

### V. Key Words that Describe this Protocol

directions: If your study involves fMRI, drugs, devices, radiation or any Department of Defense funding please include the appropriate key word. You may enter your own key words in the 'other' field below.

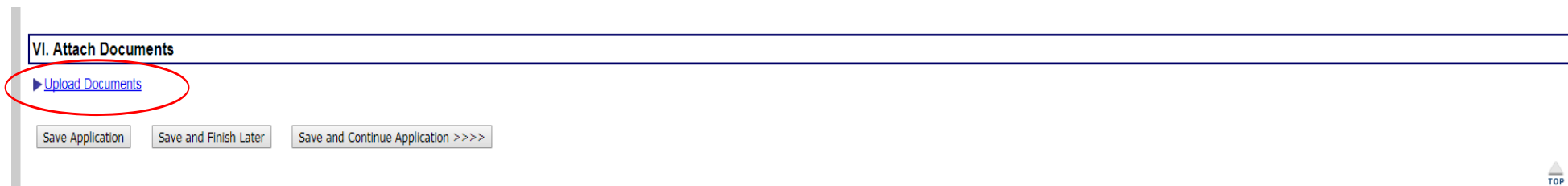
Possible Key Words		Selected Key Words
Air Force Army Clinical Trial	>> <<	

Other Keywords not Listed Above

hint: To enter more than one "other" keyword, simply separate them by a comma.

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

## Section VI – Attach Documents



In this section, please click the “upload documents” link and upload all relevant documents to your study. This includes that pertain to both the other institution and the GT specific study.

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

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

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

# Submitting the Study for IRB Review

## VI. Attach Documents

[▶ Upload Documents](#)

Save Application

Save and Finish Later

Save and Continue Application >>>>

TOP

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

# Submitting the Study for IRB Review – Conflict of Interest

**Conflict of Interest**  
*Conflict of Interest*

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

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

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

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

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

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

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

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

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

NO, the Principal Investigator has no conflict of interest.  
 YES, the Principal Investigator has a Conflict of Interest.

---

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

No  
 Yes

[editor window](#)

File Uploaded:  [upload file](#)

---

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

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

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

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

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

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

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

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

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

No, none of the other research personnel have a Conflict of Interest  
 Yes, other research personnel have a Conflict of Interest.

---

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

No  
 Yes

[editor window](#)

File Uploaded:  [upload file](#)

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



# Submitting the Study for IRB Review

▶ [Submit New Protocol](#)

<b>Protocol</b>		As Of: March 11, 2020 01:11 P
<b>Title:</b> EXAMPLE UNIVERSITY: Study Title		
<b>Principal Investigator:</b> <a href="#">Scott Samuel Katz</a>		
<b>Admin Assigned:</b>		<b>Current Status:</b> New
<b>Committee Assigned:</b>		<b>Last Activity:</b> 03/06/2020 - Created
<b>Review Type:</b>		<b>Original Approval Start:</b>
		<b>Current Approval Period:</b>

## Endorse Protocol

**note:** The PI is typically the person who should endorse the protocol. You may forward it to the PI or endorse it yourself.

<b>Endorsements</b>	<ul style="list-style-type: none"><li>• I will obtain informed consent from all subjects.</li><li>• I will report to the IRB any harmful effects to the subjects.</li><li>• I will renew my application if the research extends beyond one year.</li><li>• I will gain IRB approval before altering the research protocol or consent forms.</li><li>• I will protect the rights and welfare of human research subjects and comply with the provisions of Georgia Tech's Federalwide Assurance.</li></ul>
<b>I Agree</b>	<input type="checkbox"/> By checking this box and providing your full name and password (below), you signify that you agree to abide by the statements above for this new submission.
<b>Your Full Name</b>	<input type="text"/>
<b>Password Verification</b>	<input type="password"/> Enter your password to verify your identity.

## Submit Protocol

- ATTENTION SUPPORT STAFF AND STUDENT INVESTIGATORS:** If you are support staff or a student investigator you must forward this application to the person listed as Principal Investigator on this application for sign off. Please do not submit this application to the Dept. Head or Chair directly. Click the radio button and then choose "Submit Protocol" at the bottom of the screen. IRBwise will send an email to the PI requesting their sign off. Principal Investigator: Katz, Scott Samuel
- ATTENTION PRINCIPAL INVESTIGATORS:** This protocol application must be forwarded for departmental sign off for submission to the IRB. Select your department chair or lab director from the following list, and then click on SUBMIT PROTOCOL. The department chair or lab director will submit the protocol application to the IRB. IF YOU SKIP THIS STEP AND SUBMIT YOUR PROTOCOL APPLICATION DIRECTLY TO THE IRB, IT WILL BE RETURNED WITHOUT REVIEW. (Department heads/lab directors should submit their own protocol applications directly to the IRB).

**Chose Recipient:**

- Submit the protocol directly to the IRB (department heads only)

**Comments:**

editor window

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



Congratulations! You have officially submitted your Shell  
Submission to the IRB.

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

Office of Research Integrity Assurance  
Georgia Institute of Technology  
Dalney Street Building  
926 Dalney Street NW, Atlanta, GA 30332-0415  
Email: [IRB@gatech.edu](mailto:IRB@gatech.edu)  
Website: <https://oria.gatech.edu/irb>