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.
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

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

In question B, please be sure to add all Georgia Tech research personnel that are engaged in human subjects research.
Section I. General Information – Add/Modify Personnel Window

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

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

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

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

Once questions A-D have been completed, please save your progress and scroll down to the next section (skip question E).
If your study is supported by research funding:
Section II. The Protocol: Research Design and Methodology

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

This is the pop-up window after clicking “Add/Modify Funding.” In this window, please either type the PI name or grant title in the first text box and select the correct funding. If the funding is internal, then please complete the text boxes at the bottom of the page.
Section IV – Studies Involving Department of Defense, Radiation, or Nanotechnology

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

<table>
<thead>
<tr>
<th>Possible Key Words</th>
<th>Selected Key Words</th>
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</thead>
<tbody>
<tr>
<td>Air Force</td>
<td></td>
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<tr>
<td>Army</td>
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<tr>
<td>Clinical Trial</td>
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</tbody>
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Other Keywords not Listed Above: Spatial Memory, Navigation

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

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

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

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

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

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

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

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