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.
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.
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.
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 II. The Protocol: Research Design and Methodology

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

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.
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.

<table>
<thead>
<tr>
<th>Section III - Question A</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Human Subjects</strong></td>
</tr>
<tr>
<td>Interaction with the subjects involve direct interaction with human subjects?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

- **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**
  - 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 Prisons As Subjects**
  - Answer Studies Involving Prisons As Subjects Questions
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

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

This is a continuation of the pop-up window that appears if you answered “yes” to question A of section III.
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.
All studies must fill out the Informed Consent section. More information regarding Informed Consent can be found on our website (http://researchintegrity.gatech.edu/about-irb/irb-informed-consent).
Section III - Question B

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

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 section continued. Please be sure to answer all of the questions.
Section III - Question B

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.
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.
If your study is considered to be a “clinical trial,” then this section needs to be filled out. Clinical Trials include:

1. **TRIALS OF DRUGS AND BIOLOGICS:** Controlled clinical investigations (other than Phase One investigations) of a product subject to regulation by the Food and Drug Administration (FDA);

2. **TRIALS OF DEVICES:** Controlled trials with health outcomes, OTHER THAN small feasibility studies and pediatric post-market surveillance.
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

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.
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.).
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.
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.
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.
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### Section III - Question F

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.

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<tr>
<th>III. Subject Information, Consent and Types of Studies</th>
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<td>A. Human Subject Interaction with the research involving direct interaction with human subjects?</td>
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<td>B. Proposed Consent Procedures</td>
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Section III - Question F

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

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

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

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.
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

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

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.
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

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.
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

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.

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Email: IRB@gatech.edu
Website: http://researchintegrity.gatech.edu/irb