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.
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.
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 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

**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.)

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 x 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 memory 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 x 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.

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).

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).

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 unavoidable risks.

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

This is a continuation of Section II.
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

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.

<table>
<thead>
<tr>
<th>A Human Subject Interaction</th>
<th>Yes</th>
<th><img src="#" alt="Click Here" /></th>
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<tbody>
<tr>
<td></td>
<td>If no.</td>
<td><img src="#" alt="Click Here" /></td>
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</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 | ![Answer 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 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.
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.
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.

**B. Is a Georgia Tech Student Subject Pool being used?**

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<table>
<thead>
<tr>
<th>Option</th>
<th>Details</th>
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<tbody>
<tr>
<td>No</td>
<td>-</td>
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<tr>
<td>Yes</td>
<td>Psychology Department - SONA</td>
</tr>
</tbody>
</table>

**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.

**C. Describe the compensation plan for subject participation. If compensation will be cash 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 [researchintegrity.gatech.edu](http://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.

**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

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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

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

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

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.
### 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.

**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] |

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

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.

<table>
<thead>
<tr>
<th><strong>G</strong></th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>We will continue to ask throughout the study if the subjects would like to continue or stop the study.</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th><strong>H</strong></th>
<th>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.</th>
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<td>N/A</td>
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</table>

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.

<table>
<thead>
<tr>
<th><strong>I</strong></th>
<th>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.</th>
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<tr>
<td></td>
<td>N/A</td>
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</table>

**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 46.111(c), 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.

<table>
<thead>
<tr>
<th><strong>J</strong></th>
<th>Is deception or concealment proposed?</th>
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<tbody>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>N/A</td>
</tr>
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</table>

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

File Uploaded:

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.
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.
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.
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**

<table>
<thead>
<tr>
<th>A</th>
<th>Describe the plan to ensure that the data collected will directly address the research questions.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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.</td>
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<table>
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<tr>
<th>B</th>
<th>Please state how often you plan to monitor the data to determine that it is accurate and complete.</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>All of the data will be monitored weekly, to ensure that the gaming platform is operating properly and the data is complete.</td>
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</table>

<table>
<thead>
<tr>
<th>C</th>
<th>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).</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>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.</td>
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<thead>
<tr>
<th>D</th>
<th>If a keycode linking to subject identities exists, state how it will be safeguarded and who will have access to that linking information.</th>
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<tbody>
<tr>
<td></td>
<td>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.</td>
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</tbody>
</table>

<table>
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<tr>
<th>E</th>
<th>Check all of the following that will be utilized to safeguard data that are in an electronic format:</th>
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<tbody>
<tr>
<td></td>
<td>- Encryption</td>
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<td></td>
<td>- Password access</td>
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<td></td>
<td>- Portable storage (e.g., laptop, flash drive)</td>
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<td></td>
<td>- Secure network</td>
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</tbody>
</table>

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

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).
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.
If your study is taking place at an international location, then the section under Question H must be completed.
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.
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.
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.
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 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.
Please fully answer each question in this section if your study involves prisoners.
Section 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 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;
- 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]

**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] [File uploaded: ]

**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]

**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](mailto:irb@gatech.edu) 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.
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](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 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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