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.
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.
Only studies that meet the specific criteria can be reviewed under Limited IRB 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.
Section II. The Protocol: Research Design and Methodology

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.

C Describe study assessments and other data collection methods. Upload all instruments, including rating scales, questionnaires, surveys, focus groups 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).

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).

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.

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 differences between the two conditions for these two types of data points. Additionally, the data will also be compared to the demographic data collected via the survey to see if there are any group differences.

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

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.


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

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 it below.

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.

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

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.
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

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://research.integrity.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.

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.: 100-400). 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.

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

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

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

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 | [Edit 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 | [Edit 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 | [Edit 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 | [Edit 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 | [Edit 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.

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

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

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.

N/A

To upload your consent document, please click on the “Upload documents” link at the bottom of the page.
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://researchintegrity.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.).
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" 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://researchintegrity.gatech.edu/clinical-trials](https://researchintegrity.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.
Section III - Question E

<table>
<thead>
<tr>
<th>Question</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>F</td>
<td>Has Environmental Health &amp; 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.</td>
</tr>
<tr>
<td></td>
<td>Yes, the IBMSC letter of approval is uploaded.</td>
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<td></td>
<td>File Uploaded: [upload file]</td>
</tr>
<tr>
<td>G</td>
<td>If specimens are coming from an off-campus entity, is a MATERIALS TRANSFER AGREEMENT (MTA) in place? Please upload the MTA here.</td>
</tr>
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<td></td>
<td>Select One</td>
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<td></td>
<td>File Uploaded: [upload file]</td>
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<tr>
<td>H</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Yes, specimens will come from the international source identified below</td>
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<td></td>
<td>File Uploaded: [upload file]</td>
</tr>
<tr>
<td>I</td>
<td>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.</td>
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<tr>
<td></td>
<td>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:</td>
</tr>
<tr>
<td></td>
<td>1. The findings are validated by a CLIA-certified laboratory;</td>
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<td></td>
<td>2. The findings may have significant implications for the subjects’ health concerns;</td>
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<tr>
<td></td>
<td>3. A course of action to ameliorate or treat these concerns is readily available; and</td>
</tr>
<tr>
<td></td>
<td>4. The subject agreed during the consent process to be informed about validated findings.</td>
</tr>
<tr>
<td>J</td>
<td>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 <a href="http://www.researchintegrity.gatech.edu">www.researchintegrity.gatech.edu</a>)</td>
</tr>
<tr>
<td></td>
<td>Yes, rDNA or siRNA will be used, and I will provide the IBC letter of approval</td>
</tr>
<tr>
<td></td>
<td>File Uploaded: [upload file]</td>
</tr>
</tbody>
</table>

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

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.

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.

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.

D. If a keycode 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.

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.
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

**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.

<table>
<thead>
<tr>
<th>A</th>
<th>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.</th>
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</thead>
<tbody>
<tr>
<td>B</td>
<td>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/oriently. 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.</td>
</tr>
<tr>
<td></td>
<td>Yes. Researcher was invited into the community.</td>
</tr>
<tr>
<td></td>
<td>No. Researcher was not invited into community.</td>
</tr>
<tr>
<td>C</td>
<td>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.</td>
</tr>
<tr>
<td>D</td>
<td>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.</td>
</tr>
</tbody>
</table>

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

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

**A.** 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](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 | Enter 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 | Enter window |

**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 section 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 | Enter window |

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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://researchintegrity.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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