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# **IRB New Online Application Guidance**

**May 2019**

This guide is designed to assist you with a New IRB Application and gives more in depth help for specific application questions. If you still have questions or need assistance, please contact IRB staff at [IRB@uccs.edu](mailto:IRB@uccs.edu) or 719-255-3903.

If you have questions about how to navigate the form or using IRBManager functions, please see the IRBManager User Manual on our [website](#).

### **Study Details:**

Please make sure to review the CITI training requirements and navigation instructions at the top of this page.

1.

<b>Form Submitter</b>	<a href="#">View Audit</a>
UCCS Test PI Test PI	
<b>Email:</b>	UCCSTestPI@gmail.com

The “Form Submitter” will be the individual who initiated the application. This will be populated automatically and cannot be changed.

2.

<b>Have you reviewed the researcher manual?</b> <i>(Required)</i>	<a href="#">View Audit</a>
<input type="radio"/> Yes	
<input type="radio"/> No	

Please make sure to review the researcher manual. It can be accessed on the [OSPRI website](#). You will be held accountable for the information it contains. Additionally, reviewing the researcher manual will cut down on revisions requested by reviewers, as you will understand the process and what is required for approval.

3.

<b>Study Title</b> <i>(Required)</i>	<a href="#">View Audit</a>
<input type="text"/>	

Please give your study a title. If your project is funded, please use the same title as the funded submission.



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4.

**Please check ALL targeted special populations involved in the research.** *(Required)* [View Audit](#)

- Children
- International Populations
- Pregnant Women, Human Fetuses, or Neonates
- Prisoners
- None of the above

Please check the box next to ALL of the populations that apply to your study. If none, check “None of the above”. Please make sure to check the appropriate box on this question if you are working with one of these populations as this question unlocks the applicable addendum questions for that population.

5.

**Please select ALL of the following which apply to your protocol:** *(Required)* [View Audit](#)

- Human blood, body fluids, or tissues
- Personally Identifiable Information (PII) or FERPA data for UCCS students
- Protected Health Information (PHI) from UCCS HIPAA covered entities (Lane Center clinics)
- Food, drugs, or devices
- Conflict of Interest
- Protocol has been submitted to another IRB
- None of the above

Please check the box next to any of the conditions that apply to your protocol (you can choose multiple answers). If none of these are applicable, check the box next to “None of the above”. Please carefully review these, as these answers are linked to additional questions.



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**IF you are collecting blood, tissue, or body fluids, you must have IBC approval. Please upload your approval document here. If you do not have permission, please stop your application here and follow the appropriate procedures to acquire IBC approval. Please answer the additional questions about frequency and size of sample collected.**

Please select ALL of the following which apply to your protocol: (Required) [View Audit](#)

- Human blood, body fluids, or tissues
- Personally Identifiable Information (PII) or FERPA data for UCCS students
- Protected Health Information (PHI) from UCCS HIPAA covered entities (Lane Center clinics)
- Food, dietary supplements, drugs, or devices
- Conflict of Interest
- Protocol has been submitted to another IRB
- None of the above

**Will you be collecting blood or tissue from generally healthy adults (self-assessed by participant)?**

(Required)

Yes

No

**What is the quantity of blood or tissue to be collected?** (Required) [ABC](#)

**What is the frequency that blood/tissue will be collected?** (Required) [ABC](#)

**Please attach your IBC Approval.** (Required) ?

**IF you are collecting PII or FERPA data for UCCS students you must have approval from the Registrar's office. Please attach your approval document(s) here (email correspondence is acceptable). If you do not have approval from the Registrar's Office, please contact them to get approval. While we will begin the review of your protocol, please be aware that your research cannot begin until you have documented approval with the IRB.**

Please select ALL of the following which apply to your protocol: (Required) [View Audit](#)

- Human blood, body fluids, or tissues
- Personally Identifiable Information (PII) or FERPA data for UCCS students
- Protected Health Information (PHI) from UCCS HIPAA covered entities (Lane Center clinics)
- Food, drugs, or devices
- Conflict of Interest
- Protocol has been submitted to another IRB
- None of the above

**Please attach Registrar's Office Approval if you have already received it. Please be advised that your research cannot commence until approval has been received and documented with the IRB. ?**



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**IF you are collecting PII or HIPAA covered data from the Lane Center or other covered entity at UCCS, you must have your protocol reviewed by the Privacy Board. The IRB will forward your protocol to the Privacy Board for review. Please be aware that this can extend the length of time it takes to complete the review of your protocol.**

Please select ALL of the following which apply to your protocol: *(Required)* [View Audit](#)

- Human blood, body fluids, or tissues
- Personally Identifiable Information (PII) or FERPA data for UCCS students
- Protected Health Information (PHI) from UCCS HIPAA covered entities (Lane Center clinics)
- Food, drugs, or devices
- Conflict of Interest
- Protocol has been submitted to another IRB
- None of the above

**Please be aware that the Privacy Board must also review your protocol. The IRB will forward your protocol and documents to the Privacy Board, you do not have to do anything. This may extend the time it takes to complete your review.**

**IF your study involves any food, drug, or device, please check this box, regardless of if it is designed as a clinical trial or not. Please note that supplements are included in this, so if you are using any sort of herb or supplement, check this box.**

Checking this box will open a subset of follow-up questions. Please carefully consider the design of your study when answering these questions.

Please select ALL of the following which apply to your protocol: *(Required)* [View Audit](#)

- Human blood, body fluids, or tissues
- Personally Identifiable Information (PII) or FERPA data for UCCS students
- Protected Health Information (PHI) from UCCS HIPAA covered entities (Lane Center clinics)
- Food, drugs, or devices
- Conflict of Interest
- Protocol has been submitted to another IRB
- None of the above

*Note: Depending on the involvement of food, drugs, or devices, it is possible that the IRB application will be directed to a third party IRB, such as COMIRB. Please note that there will be a fee associated with the external review, if required. If this is funded research, please note that the review fees will need to be included in the budget. Please contact the IRB office for additional information.*

**Does the study collect safety and/or efficacy data about a device (i.e., a contraption, contrivance, lab test, in vitro reagent, mechanical test, computer software, computer algorithm, etc.)? *(Required)***

Yes  
 No

**Are subjects given any drug or over-the counter medication, food, dietary supplement, or biologic agent as part of the study? *(Required)***

Yes  
 No



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Depending on your answers, you will potentially be asked 5 follow-up questions. Please consider these answers carefully as they help the reviewer determine if the study is subject to FDA regulations. At this time, the UCCS IRB cannot review FDA studies and they will have to be referred to an outside IRB such as COMIRB.

**Does the study collect safety and/or efficacy data about a device (i.e., a contraption, contrivance, lab test, in vitro reagent, mechanical test, computer software, computer algorithm, etc.)?** *(Required)*

Yes  
 No

**If yes, will data from the study be submitted to the FDA?** *(Required)*

Yes  
 No

**Are subjects given any drug or over-the counter medication, food, dietary supplement, or biologic agent as part of the study?** *(Required)*

Yes  
 No

**If yes, are the subjects given a food or dietary supplement?** *(Required)*

Yes  
 No

**If yes, is the purpose of the study to examine the impact of the food or dietary supplement on a disease or condition?** *(Required)*

Yes  
 No

Please document any conflicts of interest here. When you click this box, you will be shown the definition of a conflict of interest and be asked to verify that there is indeed a true conflict. If there is click "Yes".

**Please select ALL of the following which apply to your protocol:** *(Required)* [View Audit](#)

Human blood, body fluids, or tissues  
 Personally Identifiable Information (PII) or FERPA data for UCCS students  
 Protected Health Information (PHI) from UCCS HIPAA covered entities (Lane Center clinics)  
 Food, drugs, or devices  
 Conflict of Interest  
 Protocol has been submitted to another IRB  
 None of the above

**CONFLICTS OF INTEREST SHALL BE CONSIDERED TO INCLUDE:**

- Stock (holdings or options) in a sponsoring organization
- Director, advisor, or consultant to the sponsoring organization
- Other vested interests such as the inventor and/or patent holder of the drug, procedure, technique, device, or software being tested
- Overseeing a family member or students in class which you teach

**Does the PI, Co-PI or Faculty Advisor have an actual, potential or perceived conflict of interest as included above and/or defined in the University of Colorado Conflict of Interest Policies?**

*(Required)*

Yes  
 No

If you have created a management plan and filed it with the COI committee, please attach it here.



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Does the PI, Co-PI or Faculty Advisor have an actual, potential or perceived conflict of interest as included above and/or defined in the University of Colorado Conflict of Interest Policies?

(Required)

- Yes  
 No

Is there a COI Management Plan filed with the COI Committee? (Required)

- Yes  
 No

If yes, please attach a copy of the COI Management Plan.

Add Attachment

If you have not filed a plan with the committee, please explain how you intend to manage the conflict. Please be advised that you may be referred to the COI Committee.

Is there a COI Management Plan filed with the COI Committee? (Required)

- Yes  
 No

If no, please describe the conflict and how it will be managed. (Required)

If you have submitted your protocol to another IRB, please check the box. (This most commonly occurs if you are working at a military instillation or hospital/clinic setting, where the institution has its own IRB.) If that IRB has approved your project, please upload their approval letter. Ideally, we want our determination to be inline with the other IRB's approval, so their determination will aid your reviewer.

Please select ALL of the following which apply to your protocol: (Required)

[View Audit](#)

- Human blood, body fluids, or tissues  
 Personally Identifiable Information (PII) or FERPA data for UCCS students  
 Protected Health Information (PHI) from UCCS HIPAA covered entities (Lane Center clinics)  
 Food, drugs, or devices  
 Conflict of Interest  
 Protocol has been submitted to another IRB  
 None of the above

Describe the IRB (name and location) and action taken. (Required)

If approval has been received from another IRB, please attach the Approval Letter.

Add Attachment

If none of the above items apply, please check "None of the above".

6.

**Enter your proposed start date. (Required)** [Show Help](#) [View Audit](#)

Please enter your proposed start date. Please pick a realistic start date considering IRB processing time which is between 10 – 60 business days depending on the review category of the study. Exempt studies usually have the shortest turnaround time, with Full Board reviews taking the longest.

**Study Personnel:**

You will enter study personnel details on the “Study Personnel” page.

**Please note that if the email address of the researcher/additional personnel you wish to add does not show up, that individual has not logged into the system. Please have them login to IRBManager using their UCCS credentials, then they can be added to your protocol.**

1.

**Principal Investigator Information** [View Audit](#)

**Has the PI completed the required CITI training within the past three years? (Required) ?**  
 Yes  
 No

**Most Recent CITI Training Date**

**Enter the UCCS email address of the Principal Investigator. (Required)**

**PI Affiliation (Required)**  
 UCCS Faculty  
 UCCS Staff  
 Current UCCS Student

**Department/Center/Institute (Required)**

Please enter the requested information for the PI, including CITI training date. If the PI, or other personnel, are not up to date on this training, please take time to complete the requirement. The application will not be sent for review until this requirement has been satisfied by all personnel.

Please make sure and choose the correct affiliation and department. This information is used for IRB tracking and statistical reporting.

If you are faculty or a student, please make sure to fill in the name of your department and choose your college from the dropdown.





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If you are a student, you **must** have a Faculty Advisor on the project. When you choose the current student affiliation, a box will generate asking for your faculty advisor information. Your faculty advisor will have to review and approve your submission before it is sent to a reviewer.

Faculty Advisor Information		<a href="#">View Audit</a>
Faculty Advisor Name (Required)		
<input type="text"/>		
Has this person completed the required CITI training within the last three years? (Required)		
<input type="radio"/> Yes <input type="radio"/> No		
Faculty Advisor Most Recent CITI Training Date (Required)		
<input type="text"/>		
Faculty Advisor Affiliation (Required)		
<input type="radio"/> UCCS Faculty <input type="radio"/> UCCS Staff		
Faculty Advisor Department, Center or Institute		
<input type="text"/>		
Faculty Advisor College (Required)		
<input type="text"/>		

3.

Co-Investigator(s) Detailed Information				<a href="#">Show Help</a> <a href="#">View Audit</a>
Co-Investigator Information				
Email Address*	Has this person completed the required CITI training?*	Most Recent CITI Training Date	Affiliation*	Action
<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	<input type="text"/>	<a href="#">Save</a>

If you have a Co-Investigator or Co-PI, you will list them here. You must click “Save” after you enter an individual’s information. You can add multiple Co-Investigators; a new line will appear after you have saved an entry.

*Please note that Non-UCCS personnel must be approved. Research partners who are at institutions with a Federalwide Assurance may have to submit their work on the project to their own institution’s IRB. UCCS will typically not serve as the IRB of record for another institution with an FWA. Please contact IRB staff to discuss if you are working with an outside researcher or if you have questions about non-UCCS persons on the research project.*

4.

Additional Personnel Detailed Information (Non-Student) <span style="float: right; font-size: small;">Show Help View Audit</span>				
<b>Additional Personnel Information</b>				
Email Address*	Has this person completed the required CITI training?*	Most Recent CITI Training Date	Affiliation*	Action
<input style="width: 95%;" type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input style="width: 80%;" type="text"/>	<input style="width: 95%;" type="text"/>	Save

You will also add any additional study personnel, who are not students, on this page. This will include individuals such as study coordinators, clinicians involved in data collection, etc. You must click “Save” after entering an individual’s information. A new line will appear after you have saved an entry, allowing you to add additional individuals.

5.

Will student personnel be working on the project? <i>(Required)</i> <span style="float: right; font-size: small;">View Audit</span>
<input type="radio"/> Yes <input type="radio"/> No

If you have students working on the project, please select “Yes” and then answer the follow up/attach documentation.

Will additional student personnel be working on the project? <i>(Required)</i> <span style="float: right; font-size: small;">View Audit</span>
<input checked="" type="radio"/> Yes <input type="radio"/> No
<b>Have all students on the project completed the required CITI training? <i>(Required)</i></b> <input checked="" type="radio"/> Yes <input type="radio"/> No
<p>Faculty are expected to have new student researchers complete CITI training before working with any human subjects or human subjects’ data on any project. PIs are responsible for verifying and tracking CITI training for all students on a project, all students must be trained. PIs should request copies of completion certificates from their student personnel and either attach them here or email them to the IRB (excel lists are also acceptable). Once the IRB has the certificate on file, the student can work on ANY projects under that faculty member’s supervision. The IRB reserves the right to perform post-approval monitoring of student personnel and student training records on any protocol.</p> <p>Attach student CITI certificates or an excel list here. You may also email these to the IRB. You may submit one master list for all of your students. Student personnel should be updated at least once per academic year.</p>
<input type="button" value="Add Attachment"/>

Due to the high turn over of student staff on projects, the IRB is no longer tracking students on individual projects. This is to lessen the burden on faculty PI’s and the number of Requests for Change that need to be submitted. We ask Faculty to submit a list of students working on protocols (or their CITI completion certificates) to the IRB at least once per academic year. You can upload those documents here or email them to the IRB. **CITI training is still required for all students and the IRB may verify training of students working on protocols at any time.**

**External Funding and Sites:**

On this page you will answer questions about the funding and location(s) for the study. Please be as accurate as possible.

1.

<b>Have you applied for/or received external (outside UCCS) funding for this study?</b> <i>(Required)</i> <span style="float: right;"><a href="#">View Audit</a></span>
<input type="radio"/> Yes <input type="radio"/> No

Please check “Yes” if you have applied for funding, even if you have not received a determination.

If you have applied for funding, several other questions will generate. Please make sure and answer these follow-up questions.

<b>Status of External Funding</b> <i>(Required)</i> <span style="float: right;"><a href="#">View Audit</a></span>
<input type="radio"/> Pending/Under Review <input checked="" type="radio"/> Received <input type="radio"/> Not Awarded

Select the appropriate status for the funding for your project.

<b>Proposal Title</b> <i>(Required)</i> <span style="float: right;"><a href="#">Show Help</a> <a href="#">View Audit</a></span>
<input style="width: 95%;" type="text"/>

Enter the title of the funded proposal. (Ideally you should give your IRB protocol the same (or similar) title. If your titles are different, it is recommended you go back to the study details page and amend.)



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Name of Sponsor <i>(Required)</i>	<a href="#">View Audit</a>
<input type="checkbox"/> Department of Air Force	
<input type="checkbox"/> Department of Army	
<input type="checkbox"/> Department of Commerce	
<input type="checkbox"/> Department of Corrections	
<input type="checkbox"/> Department of Defense	
<input type="checkbox"/> Department of Education	
<input type="checkbox"/> Department of Energy	
<input type="checkbox"/> Department of Health and Human Services - HRSA	
<input type="checkbox"/> Department of Justice	
<input type="checkbox"/> Department of Navy	
<input type="checkbox"/> Environmental Protection Agency	
<input type="checkbox"/> Foreign Sponsor	
<input type="checkbox"/> Foundation/Association/Non-Profit	
<input type="checkbox"/> Industry	
<input type="checkbox"/> Local Government	
<input type="checkbox"/> Misc. - Federal	
<input type="checkbox"/> Misc. - Non-Federal	
<input type="checkbox"/> NASA	
<input type="checkbox"/> National Institute of Justice	
<input type="checkbox"/> National Institutes of Health	
<input type="checkbox"/> National Science Foundation	
<input type="checkbox"/> National Security Agency	
<input type="checkbox"/> State of Colorado	
<input type="checkbox"/> University/College	

Choose the funder of your project. If your funder is not listed, choose the appropriate miscellaneous option (federal, non-federal) and then enter the funder's name.

<input checked="" type="checkbox"/> Misc. - Federal
<input type="checkbox"/> Misc. - Non-Federal
<input type="checkbox"/> NASA
<input type="checkbox"/> National Institute of Justice
<input type="checkbox"/> National Institutes of Health
<input type="checkbox"/> National Science Foundation
<input type="checkbox"/> National Security Agency
<input type="checkbox"/> State of Colorado
<input type="checkbox"/> University/College
<b>Please enter the name of the Sponsor. <i>(Required)</i></b>
<input type="text"/>

For proposals that have received funding, please enter the Speed Type and OSP number if known.

<b>Speed Type</b>	<a href="#">Show Help</a> <a href="#">View Audit</a>
<input type="text"/>	
<b>OSP Number</b>	<a href="#">Show Help</a> <a href="#">View Audit</a>
<input type="text"/>	



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2.

**Will the research be conducted at UCCS?** *(Required)* [View Audit](#)

Yes  
 No

Please answer “Yes” if you are conducting research on-campus or are completing an online survey of any UCCS population, including students, staff, or faculty.

For on-campus projects, please describe the location of the project, such as Main Hall, University Center, etc. If it is an online survey, please type “online” in the textbox.

**Will the research be conducted at UCCS?** *(Required)* [View Audit](#)

Yes  
 No

**Please explain where on campus the research will take place.** *(Required)*

Please note that you will likely not need a letter of access/permission to conduct your research on campus. However, you may need permission to access particular campus spaces or special populations, such as athletes.

3.

**Are there any additional sites besides UCCS?** *(Required)* [View Audit](#)

Yes  
 No

If your site has multiple locations, please select “Yes”. A new page will be added to the application for you to add details for these sites.

**Research Site:**

If you have multiple sites, this page will be added to your application. You can add more than one site as necessary.

1.

**Research Setting Information** [Show Help](#) [View Audit](#)

**Organization/Site Name** *(Required)*

**Organization/Site Description** *(Required)*

**Location** *(Required) ?*

**Contact Person** *(Required)*

**Contact Person Email** *(Required)*

Complete all details for each site. Please note that you may be required to obtain a letter of access/permission to access the site before IRB approval is granted. If data collection will be performed through a website (e.g. survey monkey or Facebook), please include the website as the research site. In this case, please indicate that the terms of service of the website allow research to be performed.

2.

**Site will be used for (select all that apply):** *(Required)* [View Audit](#)

Recruitment  
 Data Collection  
 Consenting Participants  
 Existing Data  
 Other

Select the appropriate descriptions of how the site will be used. You may select multiple items. Repeat for any additional sites.

**Research Summary and Participant Information:**

1.

<b>Purpose/Significance</b> <span style="float: right;"><a href="#">View Audit</a></span> Provide a brief background and describe the major research question/s of the proposed study in language that can be understood by an individual outside your discipline. <i>(Required)</i>
<div style="text-align: right; padding-right: 5px;">ABC</div>

In this section, make sure to limit technical language, your protocol will likely be reviewed by someone who is not an expert in your discipline. Make sure to include enough information for your reviewer to understand the purpose of your research and your research questions. Understanding the aim of your project can help the reviewer more accurately assess the risk of the project to participants.

2.

<b>Methodology</b> <span style="float: right;"><a href="#">View Audit</a></span> Describe, in narrative format, the research design (descriptions of methods) and list procedures to be used. <i>(Required)</i>
<div style="text-align: right; padding-right: 5px;">ABC</div>
<b>Check ALL of the different procedures planned for this study. Once selected, please attach the required documents as indicated.</b> <i>(Required)</i> <input type="checkbox"/> Audiotaping/videotaping <input type="checkbox"/> Behavioral Observation <input type="checkbox"/> Device <input type="checkbox"/> Drug <input type="checkbox"/> Focus Group <input type="checkbox"/> In-person survey/questionnaire <input type="checkbox"/> Interview <input type="checkbox"/> Online survey <input type="checkbox"/> Other Procedure not Listed <input type="checkbox"/> Records Review/Biospecimens <input type="checkbox"/> Social or behavioral intervention

In the methodology section, describe the design of your research. This includes all procedures to be used. Please try to make it clear what the participant will encounter during the study: when, where, what, and how long. You should describe items such as the population to be studied, how they will be approached, what participants will experience once recruited. This should also include all measures, tools, equipment, etc. to be used in the course of the research.



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Once you have described your methodology, please choose the appropriate procedures from the list. Many of the items will require the attachment of related documents. For example, if you are using surveys or semi-structured interviews, you will be asked to attach your questions. **You must attach these documents.** If you are conducting an online survey through a tool such as Qualtrics, you can upload a word document or the PDF output of your questions.

**Check ALL of the different procedures planned for this study. Once selected, please attach the required documents as indicated. (Required)**

- Audiotaping/videotaping
- Behavioral Observation
- Device
- Drug
- Focus Group
- In-person survey/questionnaire
- Interview
- Online survey
- Other Procedure not Listed
- Records Review/Biospecimens
- Social or behavioral intervention

**To satisfy regulatory requirements, the IRB needs an outline of the scope of questions, the general topics/themes that will be covered, and/or sample questions that are planned. The IRB understands that the flow of the interview will vary but will need to see general information at the very least. Please attach. (Required)**

Depending on the type of interaction or intervention involved in your study, you may be asked to answer supplemental questions. For most procedures, you will be asked if identifiable information will be collected, and if yes, if disclosure of that information creates a risk to participants.

Additional questions for audiotaping/videotaping:

**Additional Interaction Information**

[View Audit](#)

**Is the information recorded in such a manner that subjects can be identified, directly or indirectly or through identifiers linked to the subject? (Required)**

- Yes
- No

**Would the disclosure of subjects' responses outside the research place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation? (Required)**

- Yes
- No

Please answer these questions as accurately as possible. If there is a risk associated with disclosure of subjects' responses, you will be asked to describe this risk.





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Would the disclosure of subjects' responses outside the research place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation? (Required)

- Yes
- No

Please describe the risk associated with disclosure. (Required)

Please note that a risk associated with disclosure does not mean that your protocol cannot be approved. However, you may be asked to include additional safeguards in your research.

Additional questions for behavioral observation:

Additional Interaction Information

[View Audit](#)

Is the information recorded in such a manner that subjects can be identified, directly or indirectly or through identifiers linked to the subject? (Required)

- Yes
- No

Would the disclosure of subjects' responses outside the research place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation? (Required)

- Yes
- No

Is the research an observation of public behavior? (Required) ?

- Yes
- No

Will you or any researcher participate in the activities being observed? (Required)

- Yes
- No

Depending on your answers, you may be asked to provide additional information. Again, if disclosure of responses will create risk for participants, please describe that risk.

Would the disclosure of subjects' responses outside the research place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation? (Required)

- Yes
- No

Please describe the risk associated with disclosure. (Required)



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If your research is observation of public behavior, please describe where the observation will take place. Public Behavior is defined as generally open to view by any member of a community and/or which would not involve any special permission to observe (i.e., no reasonable expectation of privacy by those being observed). Examples include, but are not limited to a park, in a mall, and at a movie theater. What occurs in a classroom would not generally be considered observation of public behavior. Similarly, observing interactions in many online forums, groups, etc. may not be considered observation of public behavior.

**Is the research an observation of public behavior? (Required) ?**

- Yes
- No

**Please describe the setting of the public observation. (Required)**



If any member of the research team is actively participating in the activity or intervention rather than just strictly observing, please describe how they will participate.

**Will you or any researcher participate in the activities being observed? (Required)**

- Yes
- No

**Please describe how researchers will be participating in the behavioral observation. (Required)**



Additional questions for devices and drugs:

**Additional Interaction Information**

[View Audit](#)

**Is the information recorded in such a manner that subjects can be identified, directly or indirectly or through identifiers linked to the subject? (Required)**

- Yes
- No

**Would the disclosure of subjects' responses outside the research place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation? (Required)**

- Yes
- No

**Please describe the risk associated with disclosure. (Required)**



You will be asked about collection of identifiable information and risk of disclosure.



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Device/Drug Information	View Audit
<b>Describe what device or drug you are using in your study. Include the name and manufacture of the device/drug and how it is being used. (Required) ?</b>	
<div style="border: 1px solid #ccc; height: 60px;"></div>	

Please provide the requested information about your drug or device. While you may have included this information elsewhere, please include it here again. This helps the researcher determine if this is subject to FDA regulations or necessitates filing an Investigative New Drug/Device Application.

Additional questions for focus groups:

Additional Interaction Information	View Audit
<b>Is the information recorded in such a manner that subjects can be identified, directly or indirectly or through identifiers linked to the subject? (Required)</b>	
<input type="radio"/> Yes	
<input checked="" type="radio"/> No	
<b>Would the disclosure of subjects' responses outside the research place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation? (Required)</b>	
<input checked="" type="radio"/> Yes	
<input type="radio"/> No	
<b>Please describe the risk associated with disclosure. (Required)</b>	
<div style="border: 1px solid #ccc; height: 20px;"></div>	

Please answer the questions about identifiable information and disclosure risks.

Additional questions for in-person survey/questionnaire:

Additional Interaction Information	View Audit
<b>Is the information recorded in such a manner that subjects can be identified, directly or indirectly or through identifiers linked to the subject? (Required)</b>	
<input type="radio"/> Yes	
<input checked="" type="radio"/> No	
<b>Would the disclosure of subjects' responses outside the research place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation? (Required)</b>	
<input checked="" type="radio"/> Yes	
<input type="radio"/> No	
<b>Please describe the risk associated with disclosure. (Required)</b>	
<div style="border: 1px solid #ccc; height: 20px;"></div>	
<b>Please describe the setting in which the in-person interview or survey/questionnaire will take place. (Required)</b>	
<div style="border: 1px solid #ccc; height: 20px;"></div>	

Please answer the questions regarding identifiable information and disclosure risk.



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Additionally, please describe the setting for your in-person survey or questionnaire. Please note that depending on the content of your survey/questionnaire you may be asked to alter the location by your reviewer, so please try and consider the most appropriate location based on your content and aims.

Additional questions for interviews:

Additional Interaction Information	View Audit
<b>Is the information recorded in such a manner that subjects can be identified, directly or indirectly or through identifiers linked to the subject? (Required)</b>	
<input type="radio"/> Yes	
<input checked="" type="radio"/> No	
<b>Would the disclosure of subjects' responses outside the research place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation? (Required)</b>	
<input checked="" type="radio"/> Yes	
<input type="radio"/> No	
<b>Please describe the risk associated with disclosure. (Required)</b>	
<input type="text"/>	
<b>Please describe the setting in which the in-person interview or survey/questionnaire will take place. (Required)</b>	
<input type="text"/>	

Please answer the questions regarding identifiable information and disclosure risk.

Additionally, please describe the setting for your in-person interview. Please note that depending on the content of your interview you may be asked to alter the location by your reviewer, so please try and consider the most appropriate location based on your content and aims.

Additional questions for online surveys:

Additional Interaction Information	View Audit
<b>Is the information recorded in such a manner that subjects can be identified, directly or indirectly or through identifiers linked to the subject? (Required)</b>	
<input type="radio"/> Yes	
<input checked="" type="radio"/> No	
<b>Would the disclosure of subjects' responses outside the research place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation? (Required)</b>	
<input checked="" type="radio"/> Yes	
<input type="radio"/> No	
<b>Please describe the risk associated with disclosure. (Required)</b>	
<input type="text"/>	

Please answer the additional questions about identifiable information and disclosure risks.

Additional questions for records review and biospecimens:

<b>Records Review/Biospecimens Source Information</b> <span style="float: right;"><a href="#">View Audit</a></span>
<p><b>Is the source publicly available?</b> <i>(Required)</i></p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p><b>Describe the sources.</b> <i>(Required)</i></p> <div style="border: 1px solid #ccc; height: 60px; margin-top: 5px;"></div> <p><b>Is the information recorded in such a manner that subjects can be identified, directly or through identifying links?</b> <i>(Required)</i></p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p><b>Please explain how information was/will be collected without identifiers.</b> <i>(Required)</i></p> <div style="border: 1px solid #ccc; height: 60px; margin-top: 5px;"></div>

Choose the appropriate response and include descriptions where necessary about the sources of the records or biospecimens. Please also describe how identifiers will be collected or not.

Additional questions for social or behavioral interventions:

<b>Additional Interaction Information</b> <span style="float: right;"><a href="#">View Audit</a></span>
<p><b>Is the information recorded in such a manner that subjects can be identified, directly or indirectly or through identifiers linked to the subject?</b> <i>(Required)</i></p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p><b>Would the disclosure of subjects' responses outside the research place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation?</b> <i>(Required)</i></p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p><b>Please describe the risk associated with disclosure.</b> <i>(Required)</i></p> <div style="border: 1px solid #ccc; height: 30px; margin-top: 5px;"></div>

Please answer the questions about identifiable information and risks of disclosure.

3.

<b>Does this protocol involve the use of medical equipment (i.e. X-rays, PET scans, MRI, etc.)? This would include any methods that add energy into the body or that could possibly increase risk or harm.</b> <i>(Required)</i> <span style="float: right;"><a href="#">View Audit</a></span>
<p><input type="radio"/> Yes <input type="radio"/> No</p>

If your protocol uses ANY type of medical equipment, even if it is not the main focus of the research, please choose “Yes” here. Even if you think that it is incidental, please still include it.



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When you click “Yes”, a table will display where you can enter the equipment. You may list multiple pieces of equipment. You must click “Save” after each entry. Once you have saved an entry a new line will generate allowing for additional entries.

#	Name of medical equipment to be used*	Describe how the equipment will be used*	Describe any known risks/safety concerns (if unknown, mark N/A)*	Action
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	Save

4.

**Participant Recruitment** [View Audit](#)

**Describe how participants will be selected and rationale for the selection criteria. (Required)**

**Describe from where the participant population will be drawn. Include when, where, and how the potential participants will be recruited. (Required)**

In the participant recruitment section please describe how participants will be selected for the study. If there are inclusion or exclusion criteria, please include them here. Additionally, please explain why the particular population is appropriate for your research, or why your study should include that population. Include a description of all of your recruitment methods. If you are using advertising materials, you will be asked to attach them on a later question.

5.

**Participant Enrollment Detailed Information** [Show Help](#) [View Audit](#)

**Participant Enrollment Information (Required)**

Participant Age Range*	Estimated Total Number of Participants*	Estimated Number of Male Participants	Estimated Number of Female Participants	Estimated Number of Non-Binary or Non-Categorizing Participants	Action
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Save

In this section, please choose the appropriate age demographics for your population and the estimated number of participants. If your study is a clinical trial or other type of study where it is appropriate, please include the estimated gender breakdown for your study. For most studies, this will not be necessary.

You can include multiple age groups. You must click “Save” after each entry. Once you have added an entry, a new line will generate where you can add the next group. Repeat as needed.



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6.

Select all of the following items to be used to identify and/or recruit potential participants. **Once selected, please attach the required documents as indicated.** (Required) [View Audit](#)

<input type="checkbox"/> Paper files (e.g., school or medical records)	<input type="checkbox"/> Electronic files (e.g., school or medical records)
<input type="checkbox"/> Other records	<input type="checkbox"/> Flyers/brochures
<input type="checkbox"/> Web postings/tweets	<input type="checkbox"/> Advertising company
<input type="checkbox"/> Letters/emails/phone scripts	<input type="checkbox"/> Recruit students in your current courses
<input type="checkbox"/> Recruit employees supervised	<input type="checkbox"/> Other

In this section, choose all recruitment methods or items you will employ to recruit participants into your study. You can choose multiple items. For the majority of these items, you will be asked to upload the documents or advertisements you will be using. If you are unsure as to what you can include on advertisements, review this section in the [researcher manual](#).

Select all of the following items to be used to identify and/or recruit potential participants. **Once selected, please attach the required documents as indicated.** (Required) [View Audit](#)

<input checked="" type="checkbox"/> Paper files (e.g., school or medical records)	<input type="checkbox"/> Electronic files (e.g., school or medical records)
<input type="checkbox"/> Other records	<input checked="" type="checkbox"/> Flyers/brochures
<input type="checkbox"/> Web postings/tweets	<input type="checkbox"/> Advertising company
<input type="checkbox"/> Letters/emails/phone scripts	<input type="checkbox"/> Recruit students in your current courses
<input type="checkbox"/> Recruit employees supervised	<input type="checkbox"/> Other

**Attach any flyers and/or brochures that will be used.** (Required)

**Where appropriate, please attach any additional recruitment documents that were not included in selections above.**

For some recruitment methods, you will be asked to describe them rather than upload documents. Please be as detailed as possible in these cases to aid your reviewer.

Select all of the following items to be used to identify and/or recruit potential participants. **Once selected, please attach the required documents as indicated.** (Required) [View Audit](#)

<input type="checkbox"/> Paper files (e.g., school or medical records)	<input type="checkbox"/> Electronic files (e.g., school or medical records)
<input checked="" type="checkbox"/> Other records	<input checked="" type="checkbox"/> Flyers/brochures
<input type="checkbox"/> Web postings/tweets	<input type="checkbox"/> Advertising company
<input type="checkbox"/> Letters/emails/phone scripts	<input type="checkbox"/> Recruit students in your current courses
<input type="checkbox"/> Recruit employees supervised	<input type="checkbox"/> Other

**Describe the other records that will be used for recruitment.** (Required)

**Attach any flyers and/or brochures that will be used.** (Required)

**Where appropriate, please attach any additional recruitment documents that were not included in selections above.**



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7.

Does the research involve ANY of the following populations? (Required)		<a href="#">View Audit</a>
<input type="checkbox"/> Cognitively Impaired	<input type="checkbox"/> Educationally disadvantaged individuals	
<input type="checkbox"/> Economically disadvantaged individuals	<input type="checkbox"/> Subjects who are supervised by or are students of the investigator	
<input type="checkbox"/> Non-English speaking individuals	<input type="checkbox"/> Active duty military/veterans	
<input type="checkbox"/> Placental/fetus tissue	<input type="checkbox"/> People living outside the United States	
<input type="checkbox"/> Native Peoples/Tribal Communities	<input type="checkbox"/> Research involves NONE of the populations listed	

This section captures populations that may require additional considerations, but who are not vulnerable populations with specific regulatory requirements. Please pay attention to any disclaimers or additional information you are provided based on these choices. Please also be aware that inclusion of these populations may lead your reviewer to ask for additional safeguards or procedural adjustments in order for your protocol to be approved.

Does the research involve ANY of the following populations? (Required)		<a href="#">View Audit</a>
<input type="checkbox"/> Cognitively Impaired	<input type="checkbox"/> Educationally disadvantaged individuals	
<input type="checkbox"/> Economically disadvantaged individuals	<input type="checkbox"/> Subjects who are supervised by or are students of the investigator	
<input checked="" type="checkbox"/> Non-English speaking individuals	<input type="checkbox"/> Active duty military/veterans	
<input type="checkbox"/> Placental/fetus tissue	<input type="checkbox"/> People living outside the United States	
<input type="checkbox"/> Native Peoples/Tribal Communities	<input type="checkbox"/> Research involves NONE of the populations listed	
<b>Please note that you will need to submit consent and recruitment materials in the language of your participants.</b>		

For non-native English speakers, you will need to submit translated materials.

Does the research involve ANY of the following populations? (Required)		<a href="#">View Audit</a>
<input type="checkbox"/> Cognitively Impaired	<input type="checkbox"/> Educationally disadvantaged individuals	
<input type="checkbox"/> Economically disadvantaged individuals	<input type="checkbox"/> Subjects who are supervised by or are students of the investigator	
<input type="checkbox"/> Non-English speaking individuals	<input type="checkbox"/> Active duty military/veterans	
<input type="checkbox"/> Placental/fetus tissue	<input type="checkbox"/> People living outside the United States	
<input checked="" type="checkbox"/> Native Peoples/Tribal Communities	<input type="checkbox"/> Research involves NONE of the populations listed	
<b>If your research involves Native People or Tribal Communities, approval from the group may be required.</b>		
<b>What is the status of obtaining access/permission to this group? (Required)</b>		
<input type="radio"/> Approval/Letter of Access In Process		
<input type="radio"/> Approval/Letter of Access Obtained		
<input type="radio"/> Need UCCS IRB Approval First		
<input type="radio"/> No Approval/Letter of Access Required		

For most research with American Indian/Alaska Native populations or other tribal communities, you will need permission from the appropriate official. If you need assistance in determining if permission is necessary, please contact IRB staff.





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**Does the research involve ANY of the following populations?** (Required) [View Audit](#)

<input type="checkbox"/> Cognitively Impaired	<input type="checkbox"/> Educationally disadvantaged individuals
<input type="checkbox"/> Economically disadvantaged individuals	<input type="checkbox"/> Subjects who are supervised by or are students of the investigator
<input type="checkbox"/> Non-English speaking individuals	<input checked="" type="checkbox"/> Active duty military/veterans
<input type="checkbox"/> Placental/fetus tissue	<input type="checkbox"/> People living outside the United States
<input type="checkbox"/> Native Peoples/Tribal Communities	<input type="checkbox"/> Research involves NONE of the populations listed

**Please note that if the research is taking place on a military installation, or if the research is conducted while members are on duty, additional military approvals may be required.**

If you are working with active duty military or veterans, depending on the location and purpose of the research you may need permission from government officials or military IRB approval.

8.

**Describe how coercion or perceived coercion of research participants will be avoided for all research populations (i.e., provide detail regarding subjects who are students of, or supervised by, the investigator).** [Show Help](#) [View Audit](#)  
(Required)

Coercion occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, if an investigator tells a student that non-participation in their study could affect their grade. In this section please describe how coercion will be avoided. Avoiding coercion, or perceived coercion, is particularly important if you are working with populations who are more susceptible to coercion such as economically and educationally disadvantaged populations.

**Data Monitoring:**

1.

**Data Monitoring Information** [View Audit](#)

**Describe where the data will be stored, who will have access to the data, and measures taken to secure the data. Include procedures for maintaining participant confidentiality. For any hardcopy data, CD, tapes, specimens, etc., describe any physical safeguards that will be in place; for example, locked cabinet/office, data de-identified, encryption, approved cloud storage (Dropbox is not permitted).**

(Required) ?

In this section, you will describe how you will store and safeguard data. In some instances, you may be asked to take additional safeguards like encrypting data by your reviewer. Please be aware that you can use cloud storage such as Google drive only if the information you are

storing poses little to no risk to the participants if there is a data breach. Dropbox, however is currently not allowed to be used.

2.

**Describe how the privacy of the participants and the confidentiality of the data will be maintained (i.e., participants will be assigned an ID number to protect identity).** *(Required)* [View Audit](#)

In this section, please provide details about your plan to ensure the confidentiality of your participants' data. This includes how data will be de-identified (if applicable). Additionally, if you are not collecting any identifiers, please note this here. Please note that IP addresses are considered identifiable.

3.

**Are you accessing a database/dataset that required a privacy or confidentiality agreement?** *(Required)* [View Audit](#)

Yes  
 No

Please click "Yes" here if you must sign any type of agreement to access the data set. PI's cannot sign these types of agreements; only certain university officials can sign these agreements. Please work with OSPRI staff to ensure proper execution of these agreements.

4.

[Show Help](#) [View Audit](#)

**Describe the plans for the final disposition or de-identification of data that are identifiable in any way (directly or indirectly via codes) once the study has ended. If the data will be kept indefinitely, describe the format of the data and purpose of retention. If data will be destroyed, describe the timeline and method.** *(Required)*

In this section, please describe how data will be dealt with at the end of the study. Describe how data will be destroyed, if applicable, or how data will be stored if it is being kept. Please note that research records must be kept for 3 years after the completion of the project for audit purposes.

5.

**Name those who will identify, document, and report adverse or unanticipated events.** *(Required)* [Show Help](#) [View Audit](#)

Please name the individuals who will be responsible for reporting adverse or unanticipated events. More than one individual can have this responsibility. Be aware that all adverse or unanticipated events, no matter how minor of a deviation, must be reported to the IRB within 5 days of occurrence.

**Risk Assessment and Informed Consent:**

1.

**Risk and Benefit Analysis** [View Audit](#)

**Describe all benefits of the research (benefits to individual participants, society, and/or science). If none, state "none" in the space provided and in the informed consent document.** *(Required)*

**Describe all risks and potential risks (e.g. physical, mental, emotional, and/or legal) to the participants. All studies entail at least some risk (e.g. annoyance, frustration).** *(Required) ?*

**Describe how the risks are reasonable in relation to the anticipated benefits.** *(Required)*

**Describe safeguards that will be taken to protect participants' rights, welfare, and reduce risks (e.g. medical consultation, counseling, etc.).** *(Required)*

This section asks questions about the risks and benefits to study participants. Please consider these items carefully. All research, no matter how mundane, has some risk (i.e. boredom or frustration). Not all studies will have a direct benefit to the participant. If that is the case, please

instead describe the benefit to science, the discipline, etc. If there are no benefits from the study, list “None”.

In the last question of this section, you will describe safeguards that are in place to protect participants’ welfare and reduce potential risks. For studies involving ingestion of a substance, please carefully consider all potential adverse reactions and have an action plan in place for those contingencies. For these types of studies, you should also have sound exclusion criteria to exclude individuals with a high likelihood of adverse reaction. For studies with a risk of psychological harm, be sure to have appropriate resources for participants as needed.

2.

**Informed Consent Information** Show Help View Audit

**Attention: in some instances researchers may be mandatory reporters and may not be able to maintain confidentiality. Examples of this include, but are not limited to, child abuse and neglect, criminal activity, or harm to self or others. If any member of your research team is a mandatory reporter, you and your research team need to assess whether there is a reasonable possibility that mandatory reporting circumstances or events will be encountered. If so, subjects need to be provided with information about mandatory reporting circumstances and the limitations of confidentiality in the consent documents. For examples, see our [consent language guidance document](#). For a list of state mandated mandatory reporters click [here](#).**

Please attach your informed consent document(s) here.

**Are you requesting a waiver of written documentation of informed consent (i.e., online survey where a signature is not possible)? (Required) ?**

Yes  
 No

**Are you requesting an alteration of informed consent (i.e., no consent, consent is altered to omit certain required elements)? (Required) ?**

Yes  
 No

**Describe the consent process, including who will be obtaining the consent. (Required) ?**

Please make sure that you have the most up to date consent template and upload it here. If you are unsure if you have the correct template, check our [website](#). If you are working with non-English speaking populations, please also attach a translated version.

Please note the information about mandatory reporters and modify your consent documents as necessary. Please also note there may be other language that may need to be added to your consent document based on the design of your study. These situations and suggested language to be included can be found [here](#).

Here you will be asked if you are requesting a waiver of the documentation of consent. Requesting this waiver is appropriate in several situations. For instance, if you are conducting an online survey where participants cannot sign a paper form that you can keep for your records, then you will click “Yes”. Similarly, it is appropriate in situations where the only

identifying document would be the consent and the potential for being linked to the study would create a risk of harm if that information was released.

Likewise, in certain situations, it is appropriate to request an alteration of informed consent.

In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

- (i) The research involves no more than minimal risk to the subjects;
- (ii) The research could not practicably be carried out without the requested waiver or alteration;
- (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

**Describe the consent process, including who will be obtaining the consent. (Required) ?**

Make sure and describe the consent process in detail. This is the who, what, where, when, and how. This is a very important part of your application. Consenting to research is an ongoing process, with the aim of best informing participants so that they can make an informed decision about participating in research. One of the major concerns of the IRB is the protection of a participants' rights; the consent process is the cornerstone of this. Please make sure to be clear about how this process will be undertaken.

3.

**Please describe the amount of time participants will be committing to, in order to participate in the study (i.e., 2 hours a week plus 30 mins travel to study site). (Required)**



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Please be realistic in your description of the time participants will spend participating in your research, considering things like travel time. Please also make sure that the time listed here matches that listed on your consent form.

4.

Will research participants be offered compensation for participating in the research? *(Required)* [View Audit](#)

Yes  
 No

Click “Yes” if you are offering any type of compensation to your participants, monetary or otherwise. If you have questions about compensation, please see the appropriate section of the [researcher manual](#).

If you are offering compensation, please describe what is being offered. Additionally, if you are offering compensation, please make sure to be clear in your consent form exactly when compensation will be received. For example, if you are completing a pre and post survey, be clear as to if compensation will be given after the first or last survey.

Will research participants be offered compensation for participating in the research? *(Required)* [View Audit](#)

Yes  
 No

**Describe the nature of the compensation, including dollar value and schedule of payment. This information should also be stated in the informed consent document. *(Required)***

**Note: for international research, if you are offering compensation, an additional question will generate on this page.**

Will research participants be offered compensation for participating in the research? *(Required)* [View Audit](#)

Yes  
 No

**Describe the nature of the compensation, including dollar value and schedule of payment. This information should also be stated in the informed consent document. *(Required)***

**Is the compensation being offered consistent with local wages or standard of living? *(Required)***

Yes  
 No



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**If your compensation is not consistent with the local wages/standard of living (high or low) you will be asked to explain the deviation.**

Is the compensation being offered consistent with local wages or standard of living? *(Required)*

- Yes  
 No

Provide an explanation why the compensation is NOT consistent with local wages or standard of living. *(Required)*

5.

Describe any plans to share results of the research with participants. *(Required)*

[View Audit](#)

If you intend on sharing results with participants, please describe that here. Please differentiate if you are going to provide individual or aggregate results. Note that you are not required to share any results with participants. If you do not plan on sharing results, please state this. This should also be in your consent document.

**Addendums:**

**Research involving children:**

When you choose “Children” under special populations on the Study Details page, the addendum for research involving children will be added to your application. Please answer all questions on this page. Click [here](#) if you need to review the regulations regarding research involving children.

1.

What is the age range of the children? *(Required)*

[View Audit](#)

Please enter the age range for the children participating in your study. You will enter this here and in the participant details. Please do both.

2.

**Where will the children participate?** *(Required)* [View Audit](#)

Home  
 School  
 University lab/Office  
 Hospital  
 Other

**Is the research being conducted in a group setting (i.e., classroom)?** *(Required)*

Yes  
 No

Please click the appropriate location where the interactions with children will take place. Please note that if you are working in a school district that you will need to make sure you are adhering to district requirements. Many school districts have their own IRB's, and you may be required to submit an application to their IRB as well as the UCCS IRB. We have compiled a list of [contacts for local districts](#) for your use. **If your district is not on this list, you will still be responsible for contacting the appropriate official and following their requirements.**

3.

**Will the risks change according to the age of the participants?** *(Required)* [View Audit](#)

Yes  
 No

Some procedures may pose different risks to different aged children. If this is, or potentially could be, the case for your study, please click "Yes" and describe how those risks may change by age group.

**Will the risks change according to the age of the participants?** *(Required)* [View Audit](#)

Yes  
 No

**How will the risks change according to the age of the participants?** *(Required)*



4.

[Show Help](#) [View Audit](#)

**Child Assent**

**Will assent be obtained from each child?** *(Required)*

Yes  
 No

**Describe how assent will be obtained.** *(Required)*

**Describe how assent will be documented.** *(Required)*

**Please attach your child assent document(s) here.**

For studies involving children aged 6-18, it is best practice to receive assent from the child to participate in the study. If you are not obtaining child assent, a reviewer may ask for justification or require adding child assent as a condition of approval. Please answer questions in this section accordingly for your study and attach the assent document(s).

5.

[View Audit](#)

**Will subjects who attain 18 years of age while enrolled be consented?** *(Required)*

Yes  
 No

**Please attach the consent document(s) for this case here.**

For some studies, you may have individuals who turn 18 and have the autonomy to consent for themselves to participate in a study. Please consider if you will obtain consent from these individuals at this point and keep them in the study. If so, please attach the consent document here.

6.

[Add Note](#) [View Audit](#)

**Parental consent**

**Will parental permission be obtained?** *(Required)*

Yes  
 No

**Does the protocol request parental over-ride of a child's dissent?** *(Required)*

Yes  
 No

**Please attach your parental consent document(s) here (if not attached previously).**

Except in rare cases, parental consent from both parents is required for any study involving children. For exceptions, see the regulations governing research with children [here](#). If you



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attached parental consent under the informed consent section, you do not have to attach it again here.

7.

**Will the research involve Wards (custody) of the State, or any other agency, institution, or entity other than the parents?** *(Required)* [View Audit](#)

Yes  
 No

Wards of the state have additional protections. These questions are intended to ensure that the proper protections and safeguards are in place for studies involving wards.

**Will the research involve Wards (custody) of the State, or any other agency, institution, or entity other than the parents?** *(Required)* [View Audit](#)

Yes  
 No

**Check which of the following apply:** *(Required)*

The research is related to their status as wards.  
 The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

**Have the appropriate provisions been made to appoint advocates to act on the behalf of wards in the study?** *(Required)*

Yes  
 No

Please answer the additional questions regarding wards in your study as they apply.

If your study involves wards, advocates must be appointed per the regulations. "One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization." [45 CFR 46.409](#).

**Research involving pregnant women, fetuses, and neonates:**

When you choose “Pregnant Women, Human Fetuses, or Neonates” under special populations on the Study Details page, the associated addendum will be added to your application. Please answer all questions on this page. Click [here](#) if you need to review the regulations which apply to research involving these populations.

1.

**Which of the following will be participants of the research?** *(Required)* [View Audit](#)

Pregnant Women  
 Fetuses  
 Neonates

Check all that apply. Please note that there are specific regulatory guidelines for all 3 groups.

For pregnant women and/or fetuses:

2.

**Questions Involving Pregnant Women or Fetuses** [View Audit](#)

**What is your reasoning for including this vulnerable population (pregnant women/fetus/placental tissue)?** *(Required)*

**Have scientifically appropriate clinical and pre-clinical studies been performed, including studies involving pregnant women and non-pregnant animals that provide data for assessing potential risks to pregnant women and fetuses?** *(Required)*

Yes  
 No

**Please explain how the procedures provide the least possible risk for achieving the objectives of the research.** *(Required)*

**The interventions or procedures indicated in the application have prospect for direct benefits for:** *(Required)*

The pregnant woman only  
 The fetus only  
 Both the pregnant woman and the fetus  
 Neither the pregnant woman nor the fetus

**Who will provide informed consent, if required?** *(Required)*

**Does the proposed research involve, after delivery, the placenta, the dead fetus, or fetal material?** *(Required)*

Yes  
 No

Please answer the additional questions with as much detail as possible. There are regulatory restrictions guiding what research can be conducted with pregnant women and fetuses. Please be aware that studies involving these populations will most likely be reviewed by the full board.



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**Have scientifically appropriate clinical and pre-clinical studies been performed, including studies involving pregnant women and non-pregnant animals that provide data for assessing potential risks to pregnant women and fetuses?** (Required)

- Yes  
 No

**Please describe.** (Required)

This question is particularly relevant for studies using drugs, devices, supplements, etc. Please provide enough information for your reviewer to make an informed assessment of risk. Studies that are more than minimal risk are unlikely to be approved for these populations.

**Please explain how the procedures provide the least possible risk for achieving the objectives of the research.** (Required)

This question expands on risk. This is especially pertinent if there are multiple methods available with varying levels of risk.

**The interventions or procedures indicated in the application have prospect for direct benefits for:** (Required)

- The pregnant woman only  
 The fetus only  
 Both the pregnant woman and the fetus  
 Neither the pregnant woman nor the fetus

Please check all that apply. Based on your answers, you may be asked follow-up questions.

**The interventions or procedures indicated in the application have prospect for direct benefits for:** (Required)

- The pregnant woman only  
 The fetus only  
 Both the pregnant woman and the fetus  
 Neither the pregnant woman nor the fetus

**Who will provide informed consent, if required?** (Required)

**Will any researchers engaged in research have any part in any decision with regards to terminating the pregnancy?** (Required)

- Yes  
 No

**Will any researchers engaged in the research any any part in determining the viability of the neonate?** (Required)

- Yes  
 No

**Will any inducements, monetary or otherwise, be offered to terminate a pregnancy for the purpose of this research?** (Required)

- Yes  
 No

**Does the proposed research involve, after delivery, the placenta, the dead fetus, or fetal material?** (Required)

- Yes  
 No

For neonates:

3.

[View Audit](#)

**Questions Involving Neonates**

**What is your reasoning for including neonates?** *(Required)*

**Have scientifically appropriate clinical and pre-clinical studies been conducted that provide data for assessing potential risks?** *(Required)*

Yes  
 No

**Please describe.** *(Required)*

**Who will obtain parental permission? Please describe their level of experience and understanding of the potential impact on the neonates.** *(Required)*

**Will neonates that have been determined to be viable be included in the study?**  
*Viable - Being able, after delivery, to survive (given benefit of the available medical theory) to the point of independently maintaining heartbeat and respiration. (Required)*

Yes  
 No

**Does the proposed research involve non-viable neonates?**  
*Non-viable - A neonate after delivery that although living, has futility of care concerns. Examples of futility of care are lethal congenital genetic defects, extreme prematurity, or other lethal abnormalities. (Required)*

Yes  
 No

**Does the proposed research involve neonates of uncertain viability?** *(Required)*

Yes  
 No

Just as with pregnant women and fetuses, please be as detailed as possible in your answers. These questions assist reviewers in determining risk. Please be aware that studies that present more than minimal risk to neonates are unlikely to be approved. Studies involving neonates will most likely to be reviewed by the full board.

**Research involving prisoners:**

When you choose “Prisoners” under special populations on the Study Details page, the associated addendum will be added to your application. Please answer all questions on this page. Please note, there are specific regulatory guidelines for research involving prisoners. If you are unfamiliar with these regulations, you can review them [here](#).

1.

[View Audit](#)

**Prisoner Involvement Information**

**Will prisoners be recruited and consented for procedures while incarcerated?** *(Required)*

Yes  
 No

**In the case of a participant's release and subsequent re-incarcerations, the participant will NOT be re-consented and research treatment will continue.** *(Required)*

Yes  
 No

**Please justify why prisoners should be included in this research.** *(Required)*

ABC

There are only certain categories of research that can be conducted with prisoners. They cannot be used simply because they are a convenient population. Please make sure and thoroughly justify why this population is being included.

2.

[View Audit](#)

**Prisoner Safeguard Evaluation**

**Are there any possible advantages to the prisoners through their participation in the research (when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison) that are of such a magnitude that their ability to weigh the risks of the research against the value of such advantages is compromised?** *(Required)*

Yes  
 No

**Explain any possible advantages.** *(Required)*

ABC

If your study poses any advantages to the participants, please describe them in detail here. Prisoners are particularly vulnerable to coercion, and small items that have little to no value in normal circumstances may have high value in a prison context. So, please consider even the slightest possible advantage and list it here.



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The following questions address the risk to prisoners and the fairness of participation.

**Are the risks involved in the research commensurate with risks that would be accepted by non-prisoner volunteers?**

(Required)

- Yes  
 No

**Are the procedures for the selection of subjects within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities or other prisoners?**

*Note: Unless the PI provides a justification in writing for following some other procedure, control subjects must be selected randomly from the group of available subjects who meet the inclusion criteria.*

(Required)

- Yes  
 No

**Is information presented in language that is understandable to the subject population?**

*Note: The consent form and process must reflect the language and an approach that will be comprehensible to this subject population that is at risk for lower reading levels.*

(Required)

- Yes  
 No

**How will you assure that the parole board will not take into account a prisoner's participation in the research while making parole decisions?** (Required)

**Is each prisoner clearly informed in advance that participation in the research will have no effect on their parole?**

(Required)

- Yes  
 No

The following questions may or may not apply to your study as they focus mostly on interventions, such as clinical interventions. If they do not apply, please answer "N/A".

**As there may be a need for follow-up examination or care after the end of the study, please provide the IRB with sufficient information below to make the required determination under 45 CFR 46.305(a)(7).**

**What are the potential complications that may result from participation in the research?** (Required)

**What is the possible duration of such complications?** (Required)

**What are the types of examinations and care that would typically be needed for such complications?** (Required)

**Describe the provisions for such examinations and care to subjects after their participation in the research has ended.**

(Required)

**Does the research require follow-up beyond the period of incarceration?** (Required)

- Yes  
 No

**What provisions have been made for locating the individual following release?** (Required)

As previously noted, research involving prisoners is only permitted for particular reasons/intended outcomes. To be approved, your research must fall in one of five approved categories. Please choose the category that applies to your research, and then describe how your research falls into that category.

[View Audit](#)

**Prisoner Research Category**

**Indicate which one of the following five categories best describes the involvement of prisoners in his research. (Required)**

Category i: A study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

Category ii: A study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

Category iii: Research on conditions particularly affecting prisoners as a class (e.g. vaccine trials and other research on hepatitis that is more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary (DHHS) has consulted with the appropriate experts including experts in penology, medicine, and ethics and published notice in the Federal Register, of his or her intent to approve such research.

Category iv: Research on practices, both innovative and accepted, that have the intent and reasonable probability of improving the health or well-being of the subjects.

Category v: Epidemiology Studies Only. Please note this must meet specific criteria as stated in 45 CFR 46 Subpart C.

**Please provide justification for the category you have selected above (i-iv or epidemiology waiver). (Required)**

**International research:**

When you choose “International Populations” under special populations on the Study Details page, the associated addendum will be added to your application. Please answer all questions on this page. Please be aware that you may be asked to name a consultant who is familiar with the locale of your research to serve as an expert to review the appropriateness of your procedures and materials for the population/location.

1.

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**International Setting**

**Are you traveling overseas to collect data or specimens or for any research activities? (Required)**

Yes

No

**Are you directing or receiving funding for any research activities to be performed in another country? (Required)**

Yes

No

Please note that you will fill out the addendum even if you are not traveling to that country, as long as you are interacting with individuals in another country.



2.

**Cultural Aspects**
[View Audit](#)

**Will all of the research subjects be fluent in English?** *(Required)*

Yes  
 No

**Describe the cultural norms and customs as they relate to the research including individual autonomy, age of majority, cultural appropriateness of research questions, social, economic, and political concerns regarding the research, etc.** *(Required)*

**Describe how you obtained the information described above about the local context of this international setting?** *(Required)*

**Cite and outline any local laws that pertain to this research study.** *(Required)*

Please be detailed in this section. The answers you provide will assist reviewers in determining if your study has taken into consideration all necessary aspects of working with your proposed population.

**Will all of the research subjects be fluent in English?** *(Required)*

Yes  
 No

**Describe how the informed consent document has been modified to meet the local needs of the international setting (i.e., translated).** *(Required)*

If you are working with a non-English speaking population, which is likely, please be aware you will be expected to provide consent and recruitment materials in the native language of your research population. In some case, this may mean translating documents into multiple languages.

3.

**Describe how informed consent and comprehension will be obtained from research subjects within the appropriate cultural norms for the study location.** *(Required)*
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This question might feel similar to the previous question about consent; however, it is asking about the process of consent and not just the document itself. Please describe who will be consenting participants, where consent will take place, etc. Certain cultural norms may



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influence how you consent participants. For example, in many cultures, women must have a male chaperone present when talking with strangers. Please describe any such details here.

4.

**Expertise and Consultation** View Audit

**What are your qualifications to conduct the research study in this international setting?** *(Required)*

**Will you be collaborating with local people (i.e., researchers, university, community leaders, etc.)?** *(Required)*

Yes  
 No

**How will international review take place?** *(Required)*

Local IRB/Ethics Committee  
 Local Consultant

**Provide a copy of the local IRB/Ethics Committee approval letter.**

**Attach a copy of the completed International Research Consultant Form. It is available on the [IRB website](#).** *(Required)*

When conducting international research, it is important to have some expertise in the culture/location where you are conducting research. Please describe your expertise here. Additionally, all international research must have a local review. If there is an IRB or ethics committee for the country you are intending to conduct your research, you will need to submit your research according to their processes. If you have completed this process, attach your approval here. If there is not an IRB or ethics committee, you will need to name a consultant. The form is located on the [IRB website](#). Please complete this document and attach to your application.

5.

**Logistics of Travel** Show Help View Audit

**When do you plan on traveling?** *(Required)*

**Will this be a single visit?** *(Required)*

Yes  
 No

**How will you monitor unanticipated problems/complaints?** *(Required)*

**How will you report unanticipated problems to the UCCS IRB and the local review committees involved?** *(Required)*

**How will you submit any Requests for Change to the UCCS IRB and the local review committees while outside the United States?** *(Required)*

This section deals with logistics of travel. Please answer all questions. If you are not actually traveling, i.e. conducting research online, please enter “N/A” where appropriate.

6.

**Dissemination of Results**
[View Audit](#)

**Describe what results from this research study might be of importance to the community that is the subject of study?**  
*(Required)*

**Describe how the study results will be disseminated back to the community on which the study was performed.**  
*(Required)*

Often communities involved in this type of research may have limited access to the internet or other resources such as academic journals, yet it is important to share significant information that comes from your research with the community that facilitated it, especially if it will benefit them. Please describe your plan for disseminating the results to your participants or the larger community.

**Note: for international research, if you are offering compensation, an additional question will generate on the “Risk Assessment and Informed Consent” page.**

**Will research participants be offered compensation for participating in the research?** *(Required)*
[View Audit](#)

Yes  
 No

**Describe the nature of the compensation, including dollar value and schedule of payment. This information should also be stated in the informed consent document.** *(Required)*

**Is the compensation being offered consistent with local wages or standard of living?** *(Required)*

Yes  
 No

**If your compensation is not consistent with the local wages/standard of living (high or low) you will be asked to explain the deviation.**

**Is the compensation being offered consistent with local wages or standard of living?** *(Required)*

Yes  
 No

**Provide an explanation why the compensation is NOT consistent with local wages or standard of living.** *(Required)*



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**Investigator’s Responsibility and Acknowledgement:**

The final page of the application states the investigator’s responsibilities and acknowledgment. Please make sure to read and understand these points as you will be held to them. If you have questions, please contact us at [IRB@uccs.edu](mailto:IRB@uccs.edu).

**INVESTIGATOR’S CONTINUING RESPONSIBILITY TO IRB**

*Once the study has been approved, it is the Principal Investigator’s (PI) responsibility to:*

- Ensure additional personnel take the CITI training and understand their responsibility when working with human participants.
- Report all changes in research activity related to the study by submitting a Report of Change to the IRB.
- Provide the IRB all study and consent form amendments and revisions.
  - IRB must approve these changes prior to their implementation.
  - All changes to advertisements recruiting study participants must also receive prior approval by the IRB.
- Promptly report any injury, adverse event, or detrimental incident experienced by a research participant that is or may be related to the research procedures.
- Renew study with the IRB at least ten business days prior to study expiration.
  - All studies requiring continuing review must be reviewed at least annually.
  - Some studies will have the continuing review more frequently as determined in the initial review and approval.
  - Retro-active approval for lapsed studies is not allowed.
  - If the study approval lapses, you may be required to destroy any data collected or work completed during the lapsed time period.
- Inform the IRB if there is a newly identified Conflict of Interest or perceived Conflict of Interest.
- Notify the IRB when the study is complete.

Failure to comply with these federally mandated responsibilities may result in suspension or termination of the study.

**INVESTIGATOR ACKNOWLEDGMENT**

I have listed all potential Conflicts of Interest.

- I have read the definitions of Misconduct in Research.
- I have read the Training requirements for IRB review.
- I have read the Investigator’s Continuing Responsibilities to the IRB.
- I understand the definitions of Scientific Misconduct and Conflicts of Interest and my continuing responsibilities to the IRB.
- I understand submitting this application to the IRB does not constitute IRB approval, and that I will not proceed with my research (including recruitment initiation and obtaining participant informed consent) until I receive an approval letter from the IRB.
- By submitting this application, I attest to my agreement to conduct this research study in such a manner that acts of misconduct in research and conflicts of interest will not be committed and I will comply with the continuing responsibilities to the UCCS IRB.
- I will conduct my study in compliance with the UCCS IRB Standard Operation Procedures.

**By submitting this form**, as Principal Investigator, I hereby certify that to the best of my knowledge, the information furnished above is true and complete, and that I have read and understand the Investigator Acknowledgement section. I understand that if found to be otherwise, it is sufficient cause for refusal or dismissal. I authorize representatives of the University of Colorado Colorado Springs to make any and all appropriate inquiries regarding the information listed in this supplement. I hereby release you or others from any liability or damage that may result from furnishing the information requested. [Show Help](#) [View Audit](#)

To sign, enter password for [UCCSTestPI@gmail.com](mailto:UCCSTestPI@gmail.com)

Once you are finished with the application, sign and submit your application. You may also save and return later to submit. Please be aware that your application will not be processed until you have clicked “Submit” on the final page.



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