Office of Sponsored Programs
and Research Integrity
UNIVERSITY OF COLORADO
COLORADO SPRINGS

IRB New Online Application Guidance

May 2019

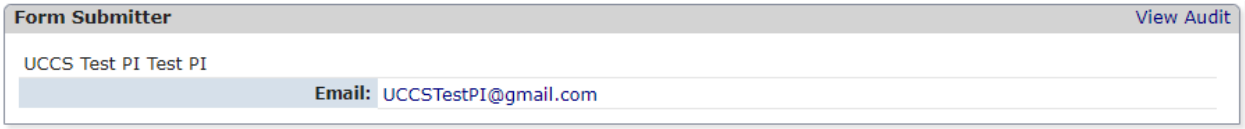
This guide is designed to assist you with a New IRB Application and gives more in depth help for specific application questions. If you still have questions or need assistance, please contact IRB staff at IRB@uccs.edu or 719-255-3903.

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.



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

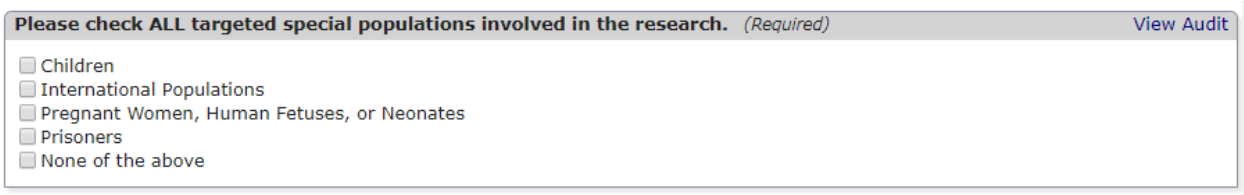
2.

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.

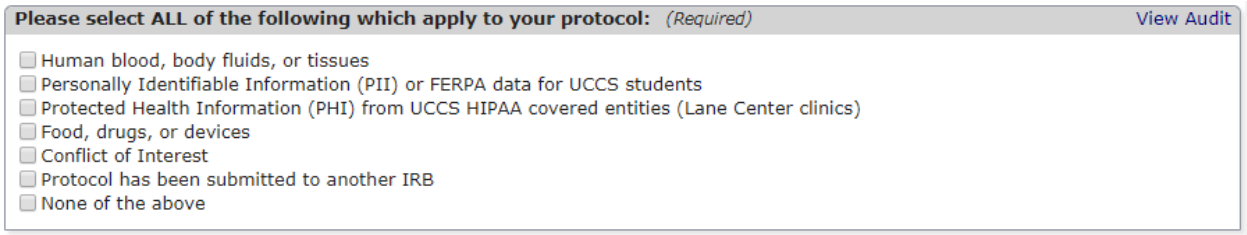
Please give your study a title. If your project is funded, please use the same title as the funded submission.

4.



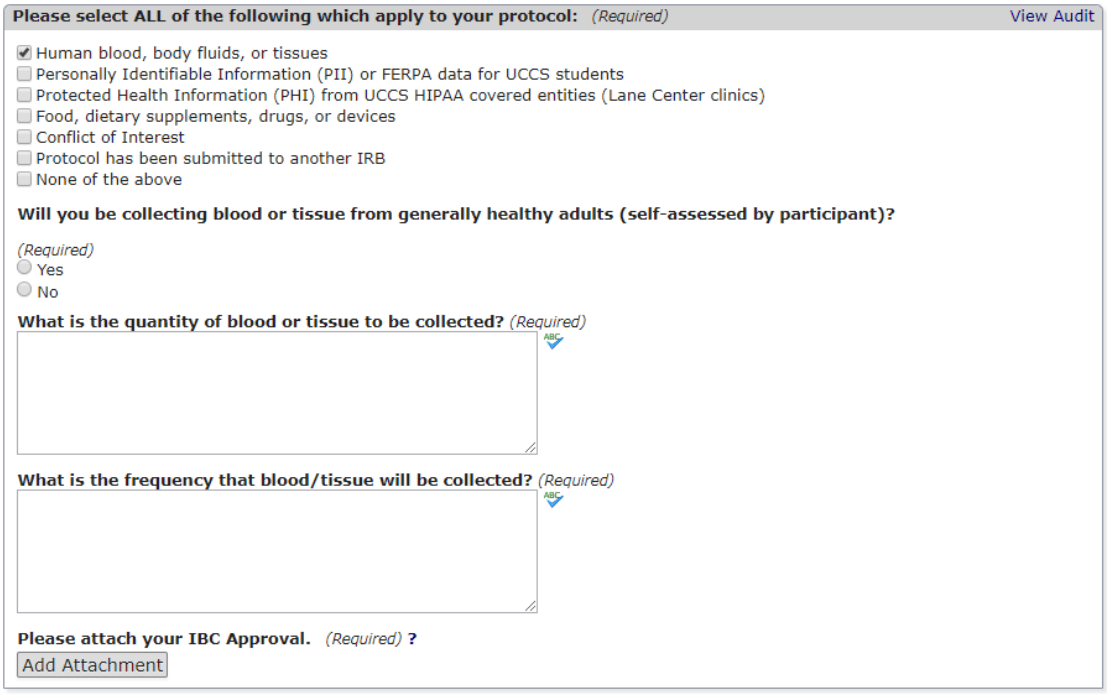
Please check the box next to ALL of the populations that apply to your study. If none, check "None of the above". Please make sure to check the appropriate box on this question if you are working with one of these populations as this question unlocks the applicable addendum questions for that population.

5.

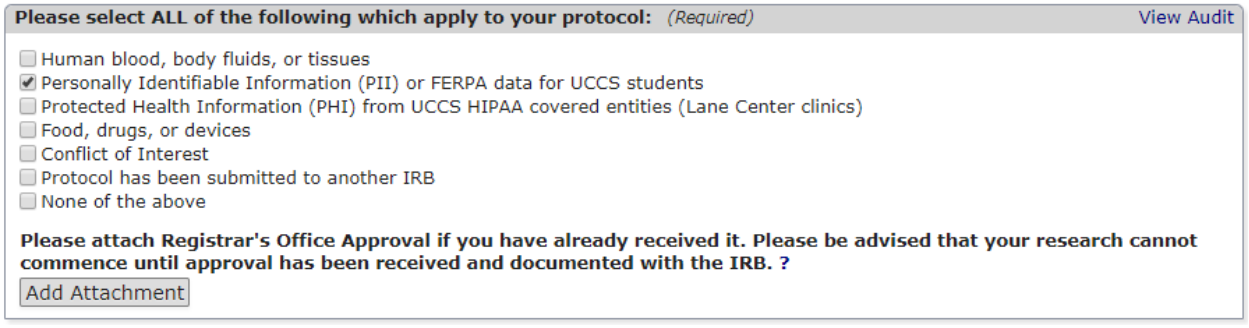


Please check the box next to any of the conditions that apply to your protocol (you can choose multiple answers). If none of these are applicable, check the box next to "None of the above". Please carefully review these, as these answers are linked to additional questions.

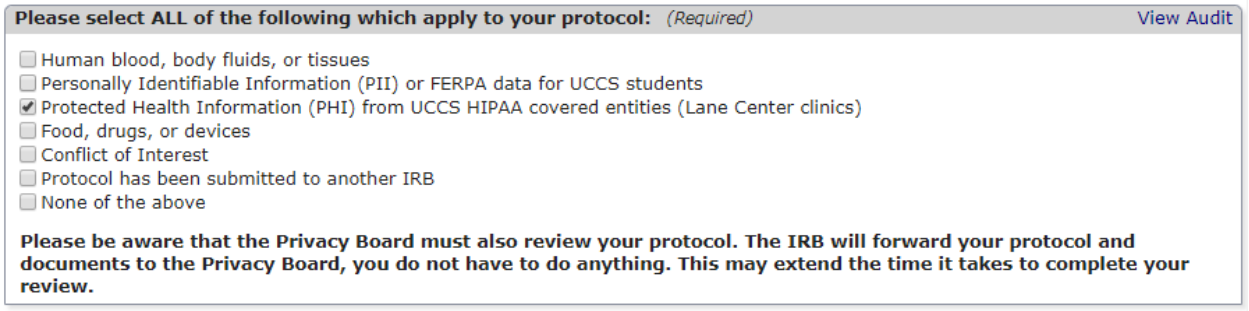
IF you are collecting blood, tissue, or body fluids, you must have IBC approval. Please upload your approval document here. If you do not have permission, please stop your application here and follow the appropriate procedures to acquire IBC approval. Please answer the additional questions about frequency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



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 award that your research cannot begin until you have documented approval with the IRB.

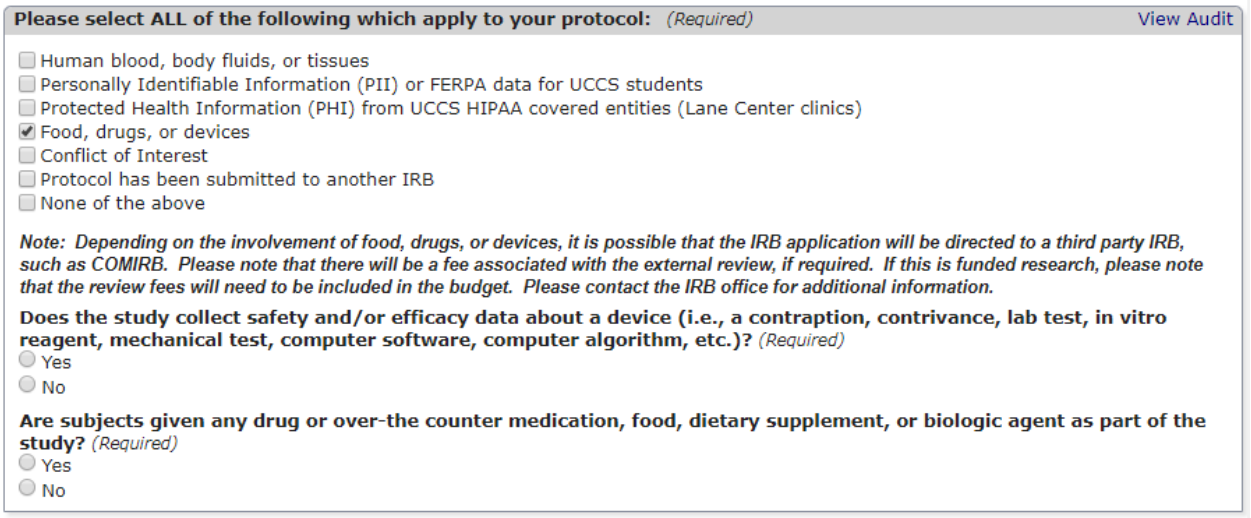


IF you are collecting PII or HIPAA covered data from the Lane Center or other covered entity at UCCS, you must have your protocol reviewed by the Privacy Board. The IRB will forward your protocol to the Privacy Board for review. Please be aware that this can extend the length of time it takes to complete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

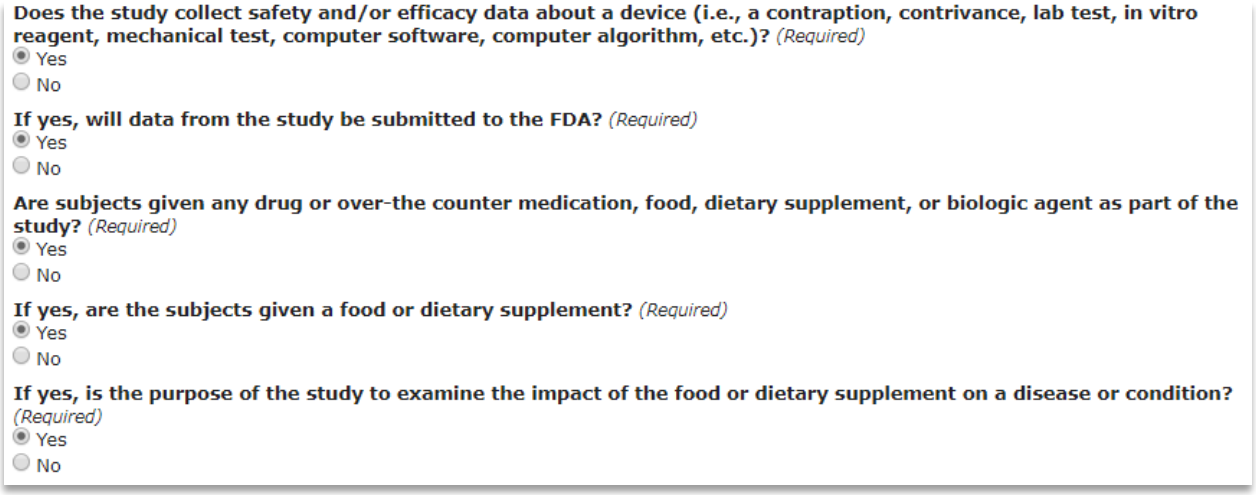


IF your study involves any food, drug, or device, please check this box, regardless of if it is designed as a clinical trial or not. Please note that supplements are included in this, so if you are using any sort of herb or supplement, check this box.

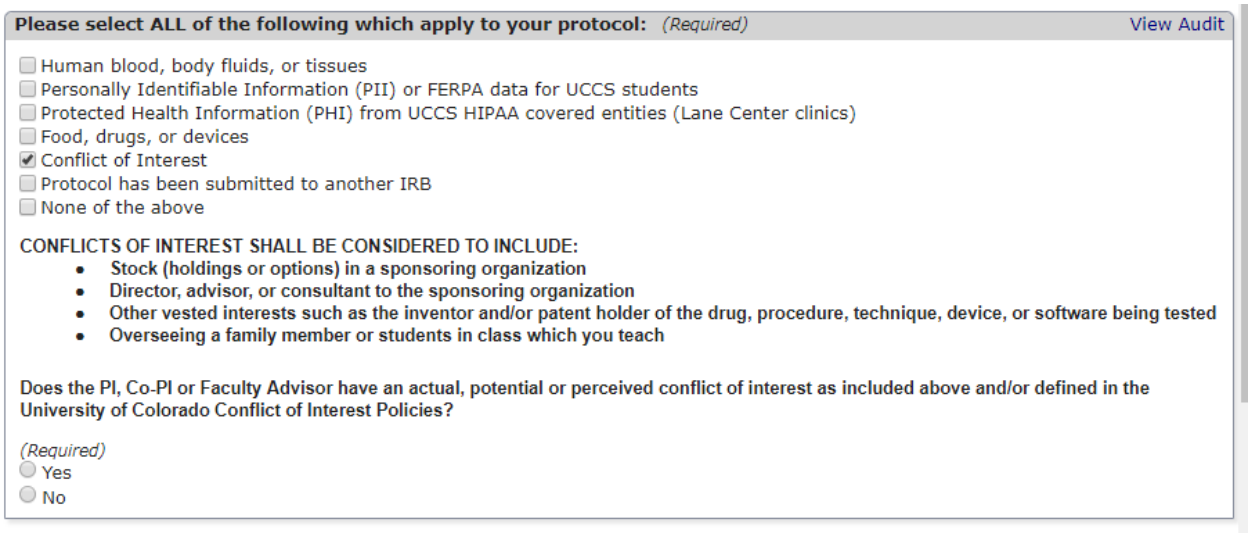
Checking this box will open a subset of follow-up questions. Please carefully consider the design of your study when answering these questions.



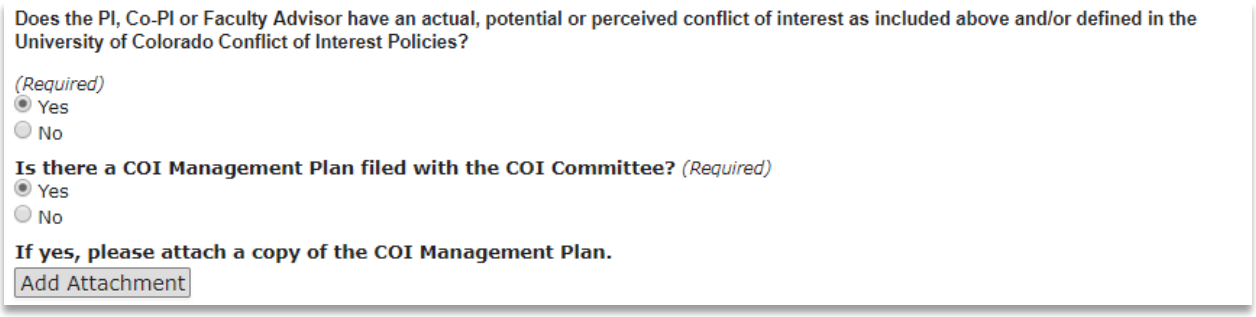
Depending on your answers, you will potentially be asked 5 follow-up questions. Please consider these answers carefully as they help the reviewer determine if the study is subject to FDA regulations. At this time, the UCCS IRB cannot review FDA studies and they will have to be referred to an outside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



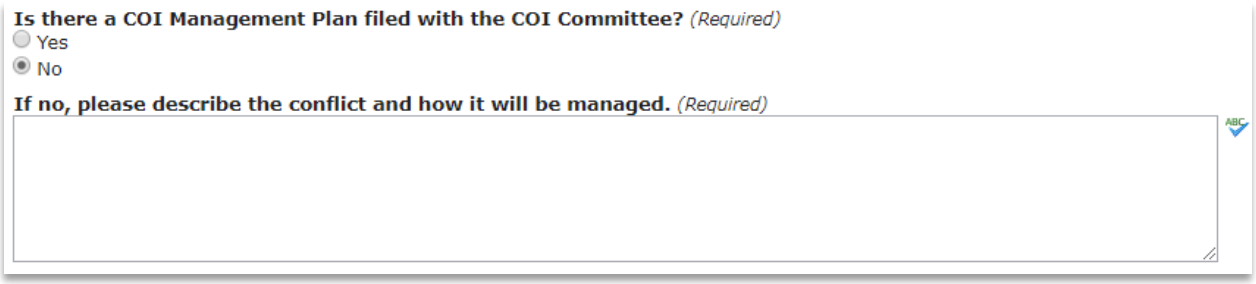
Please document any conflicts of interest here. When you click this box, you will be shown the definition of a conflict of interest and be asked to verify that there is indeed a true conflict. If there is click “Yes”.



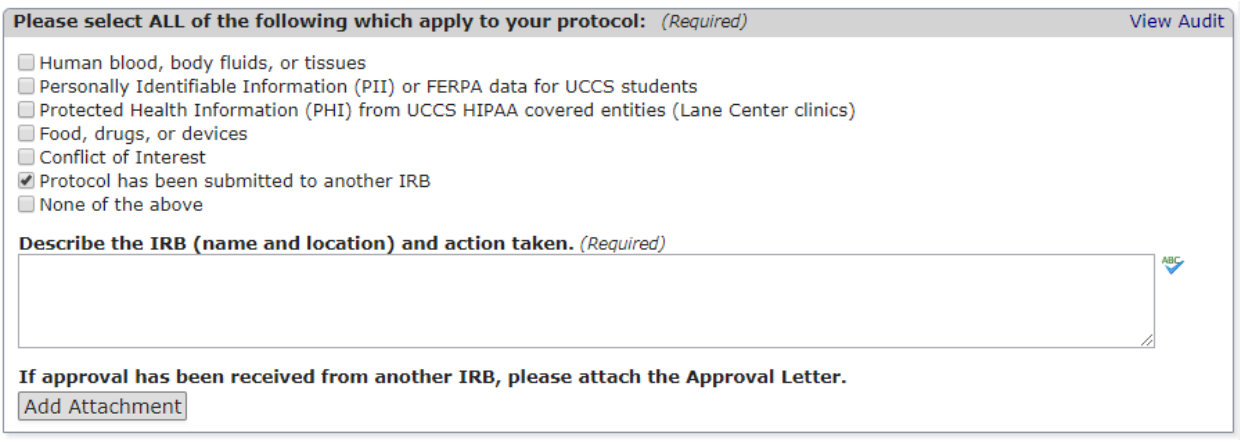
If you have created a management plan and filed it with the COI committee, please attach it here.



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.



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 reveiwer.



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

6.

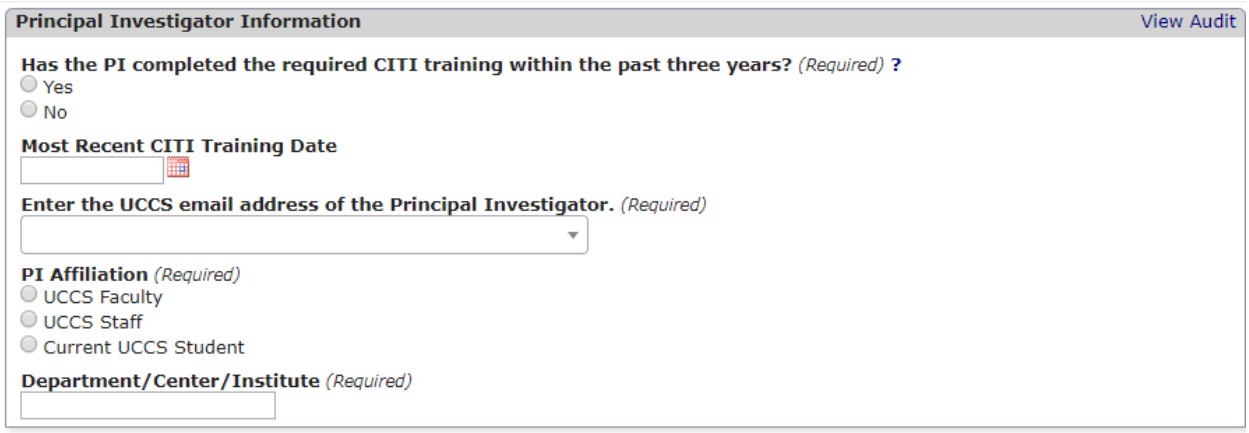
Please enter your proposed start date. Please pick a realistic start date considering IRB processing time which is between 10 – 60 business days depending on the review category of the study. Exempt studies usually have the shortest turnaround time, with Full Board reviews taking the longest.

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.

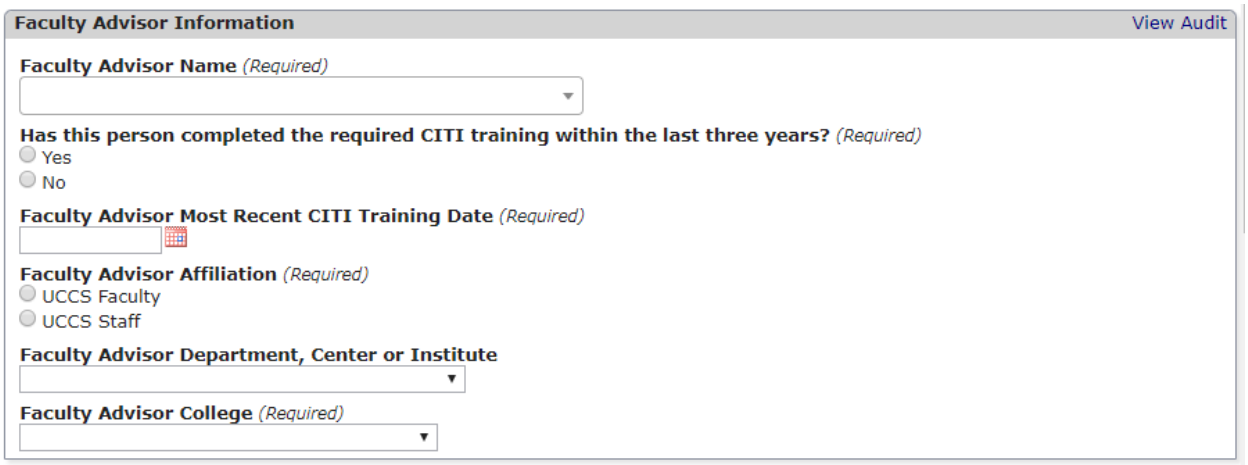


Please enter the requested information for the PI, including CITI training date. If the PI, or other personnel, are not up to date on this training, please take time to complete the requirement. The application will not be sent for review until this requirement has been satisfied by all personnel.

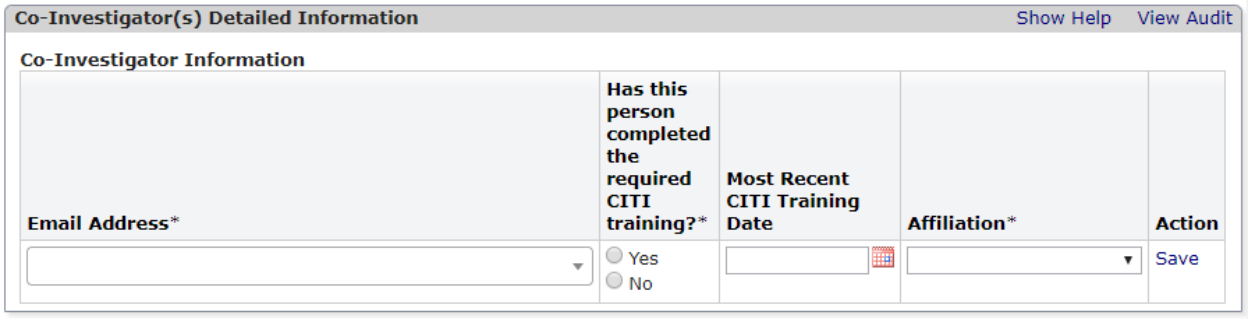
Please make sure and choose the correct affiliation and department. This information is used for IRB tracking and statistical reporting.

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.

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.



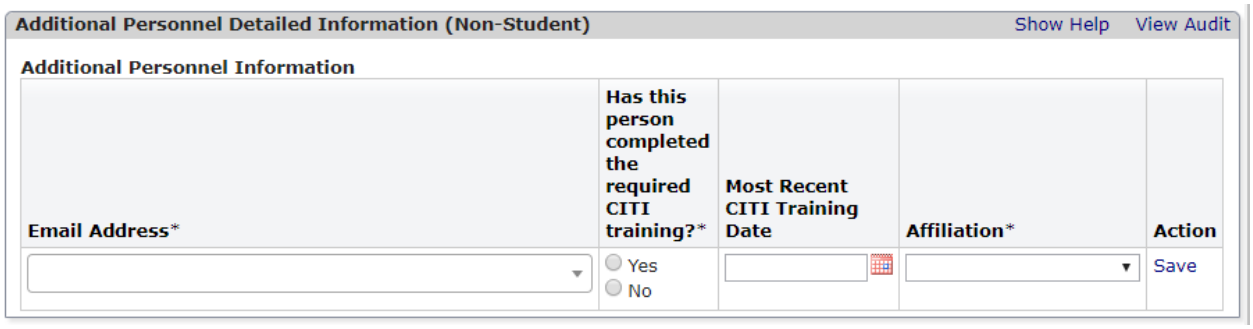
3.



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.

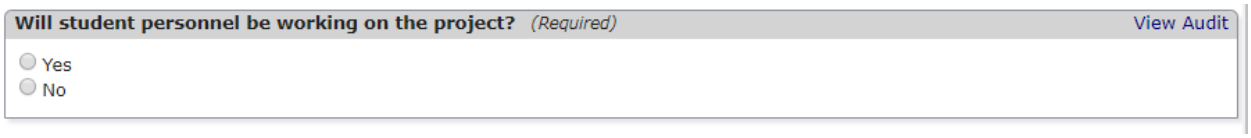
Please note that Non-UCCS personnel must be approved. Research partners who are at institutions with a Federalwide Assurance may have to submit their work on the project to their own institution's IRB. UCCS will typically not serve as the IRB of record for another institution with an FWA. Please contact 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.

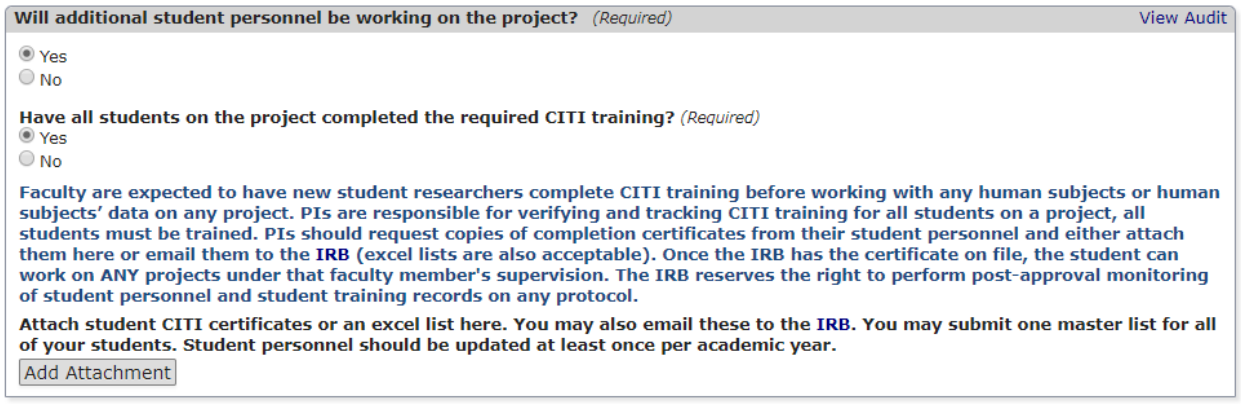


You will also add any additional study personnel, who are not students, on this page. This will include individuals such as study coordinators, clinicians involved in data collection, etc. You must click "Save" after entering an individual's information. A new line will appear after you have saved an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

5.



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

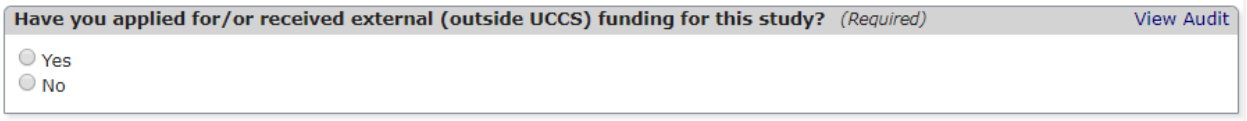


Due to the high turn over of student staff on projects, the IRB is no longer tracking students on individual projects. This is to lessen the burden on faculty PI's and the number of Requests for Change that need to be submitted. We ask Faculty to submit a list of students working on protocols (or their 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.

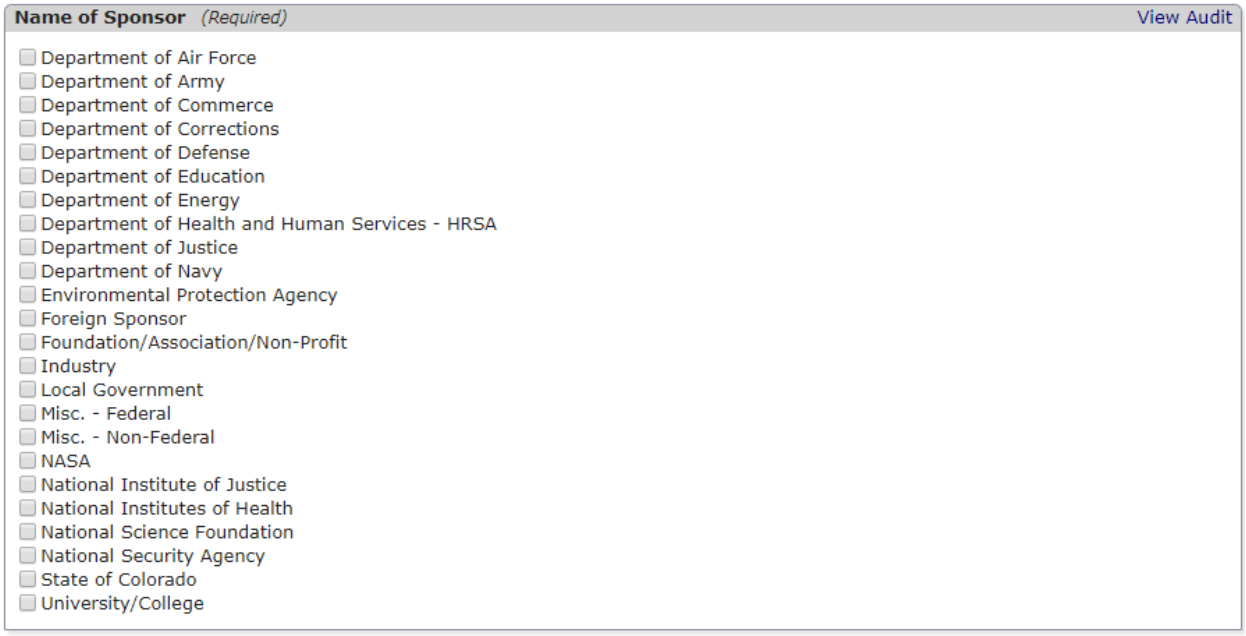


Please check "Yes" if you have applied for funding, even if you have not received a determination.

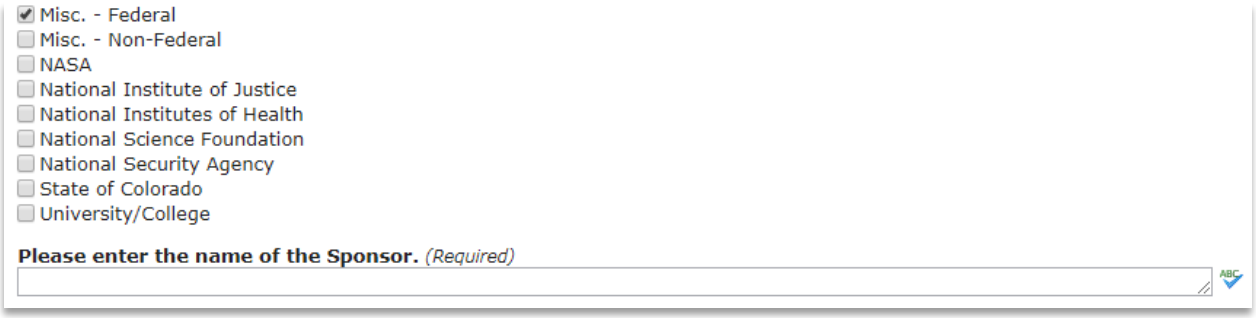
If you have applied for funding, several other questions will generate. Please make sure and answer these follow-up questions.

Select the appropriate status for the funding for your project.

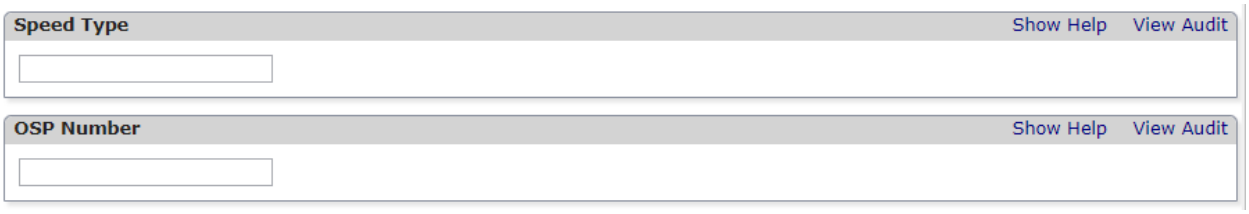
Enter the title of the funded proposal. (Ideally you should give your IRB protocol the same (or similar) title. If your titles are different, it is recommended you go back to the study details page and amend.)



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.



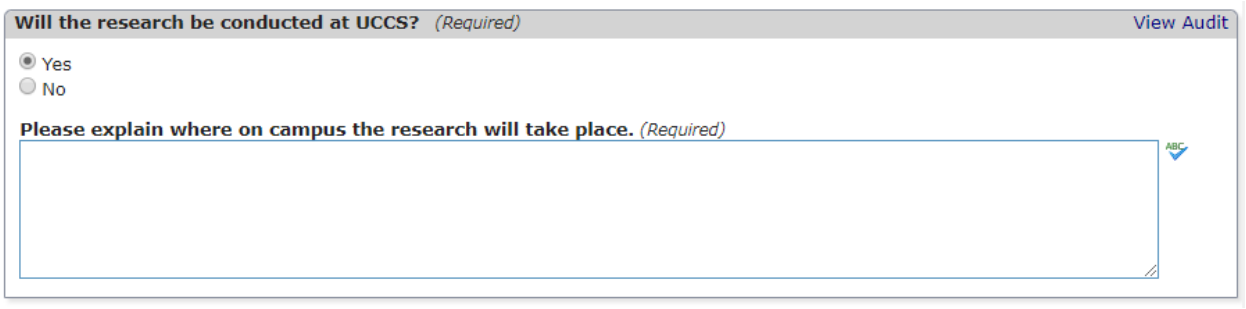
For proposals that have received funding, please enter the Speed Type and OSP number if known.



2.

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.



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.

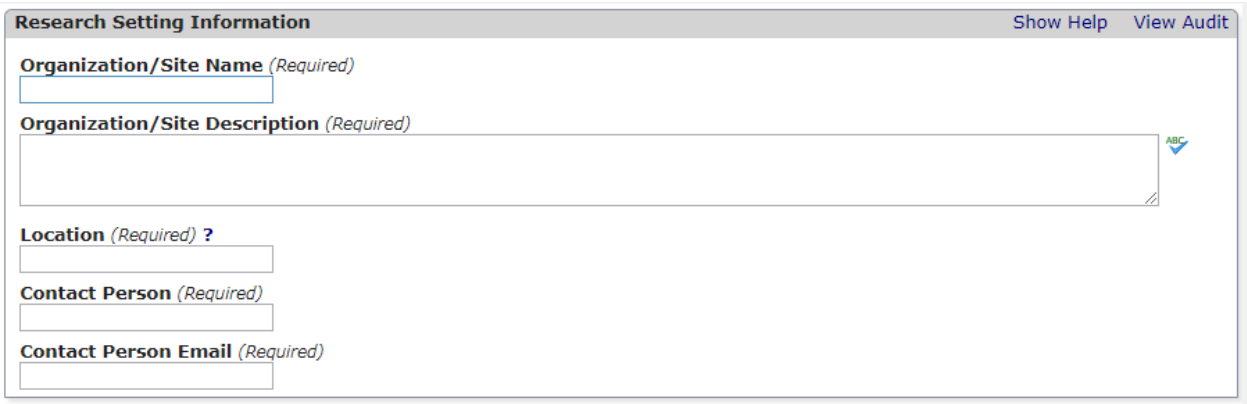
3.

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:

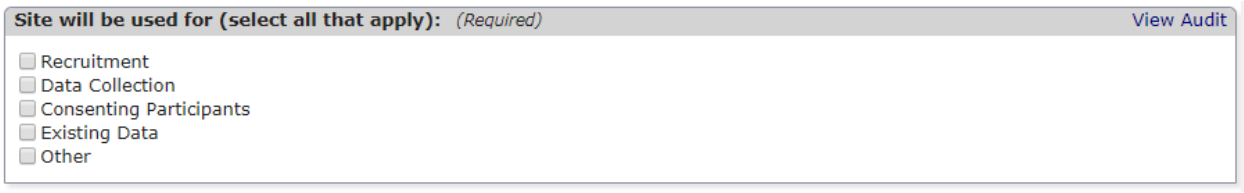
If you have multiple sites, this page will be added to your application. You can add more than one site as necessary.

1.



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.

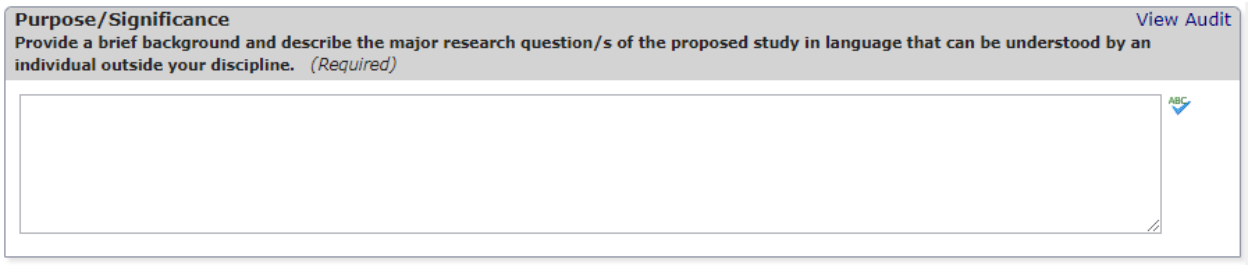


Select the appropriate descriptions of how the site will be used. You may select multiple items.

Repeat for any additional sites.

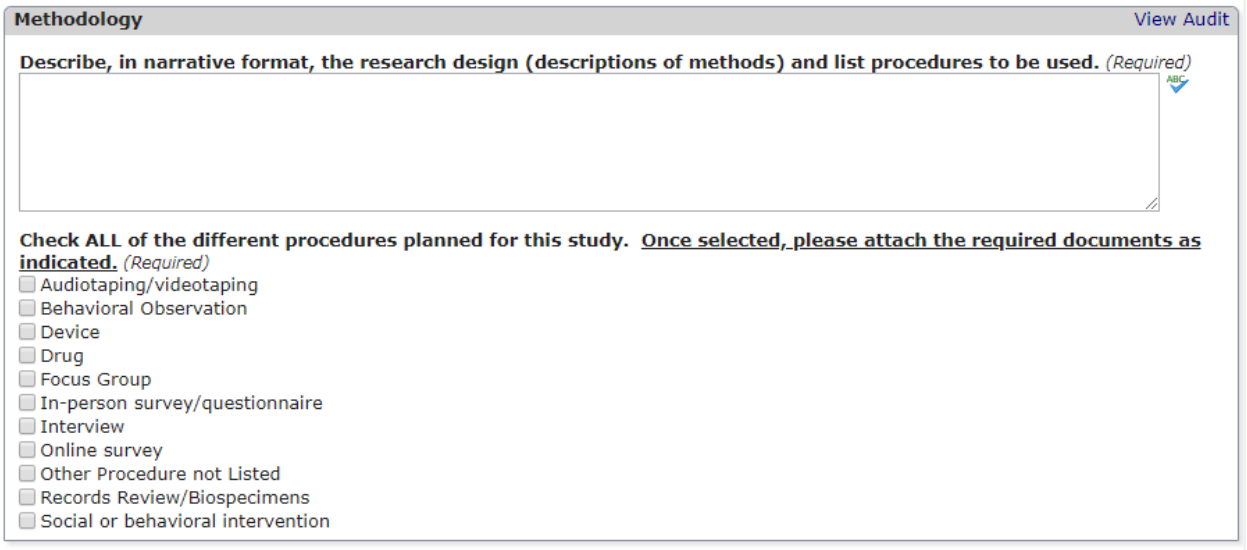
Research Summary and Participant Information:

1.



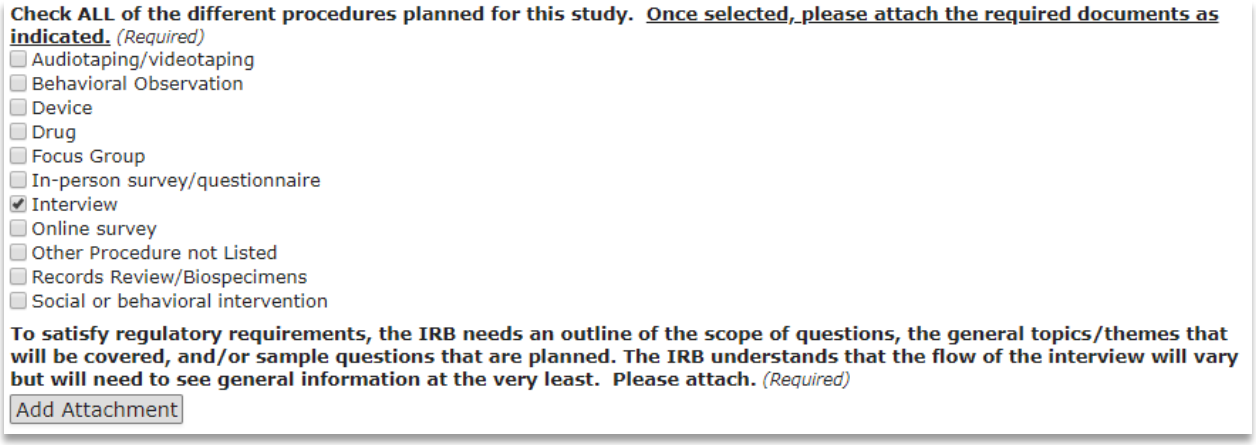
In this section, make sure to limit technical language, your protocol will likely be reviewed by someone who is not an expert in your discipline. Make sure to include enough information for your reviewer to understand the purpose of your research and your research questions. Understanding the aim of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

2.



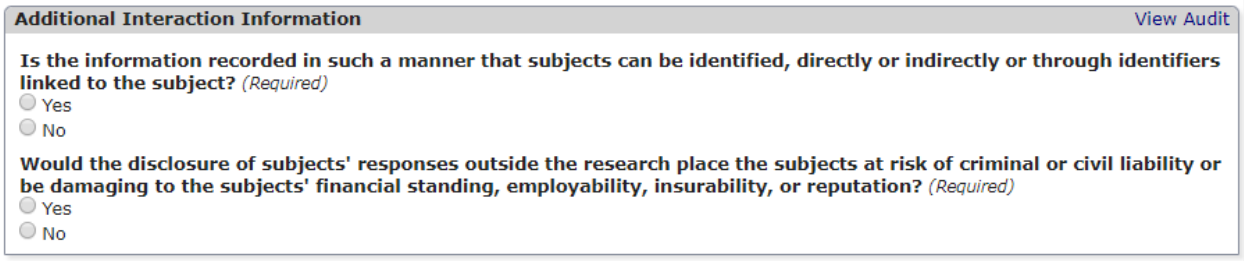
In the methodology section, describe the design of your research. This includes all procedures to be used. Please try to make it clear what the participant will encounter during the study: when, where, what, and how long. You should describe items such as the population to be studied, how they will be 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.

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.

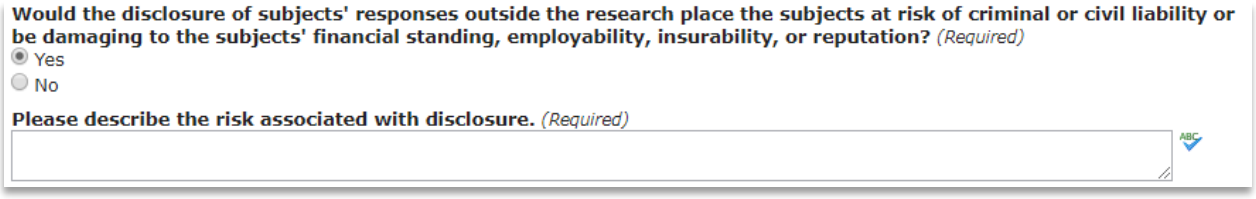


Depending on the type of interaction or intervention involved in your study, you may be asked to answer supplemental questions. For most procedures, you will be asked if identifiable information will be collected, and if yes, if disclosure of that information creates a risk to participants.

Additional questions for audiotaping/videotaping:

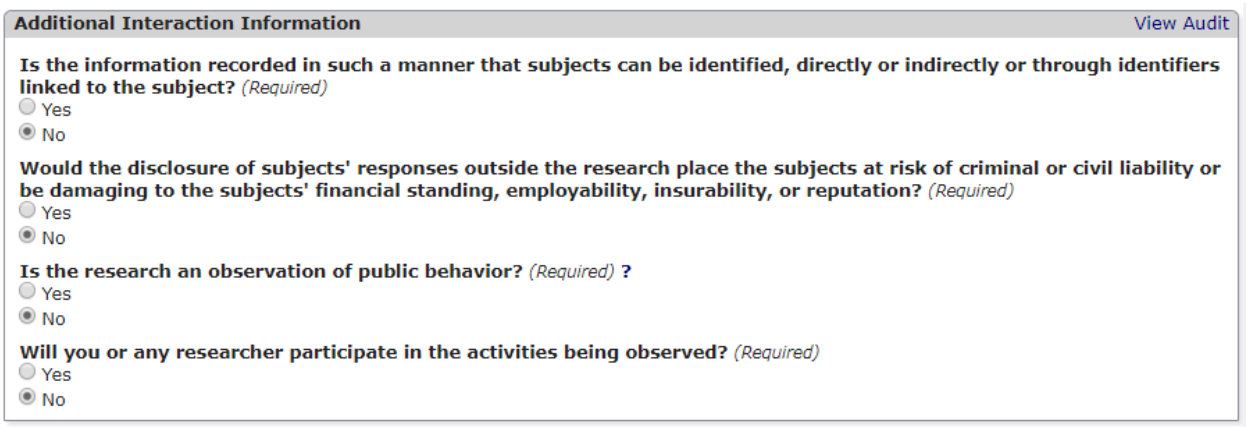


Please answer these questions as accurately as possible. If there is a risk associated with disclosure of subjects' responses, you will be asked to describe this risk.

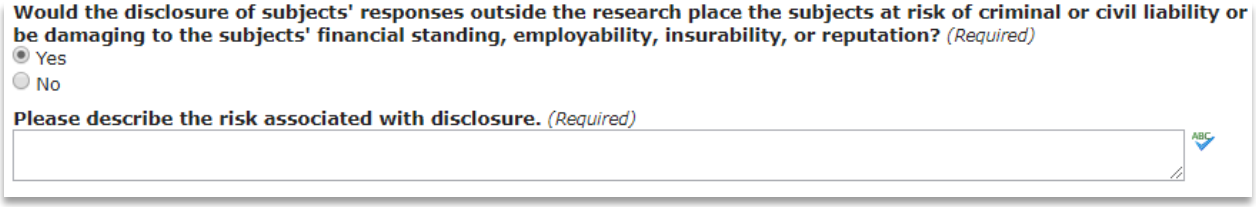


Please note that a risk associated with disclosure does not mean that your protocol cannot be approved. However, you may be asked to include additional safeguards in your research.

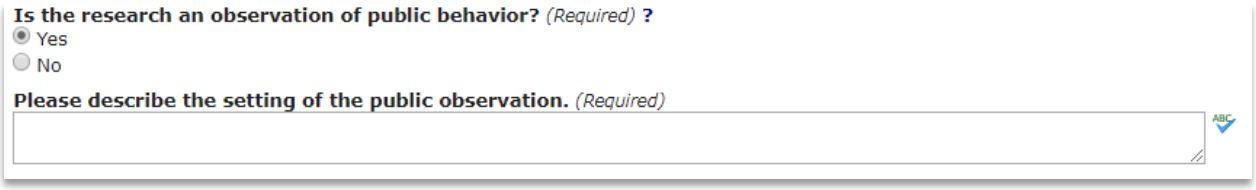
Additional questions for behavioral observation:



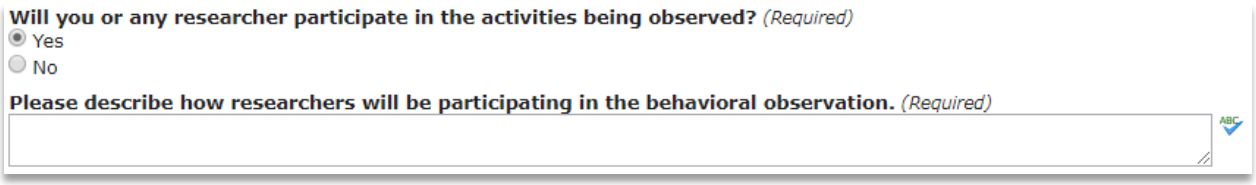
Depending on your answers, you may be asked to provide additional information. Again, if disclosure of responses will create risk for participants, please describe that risk.



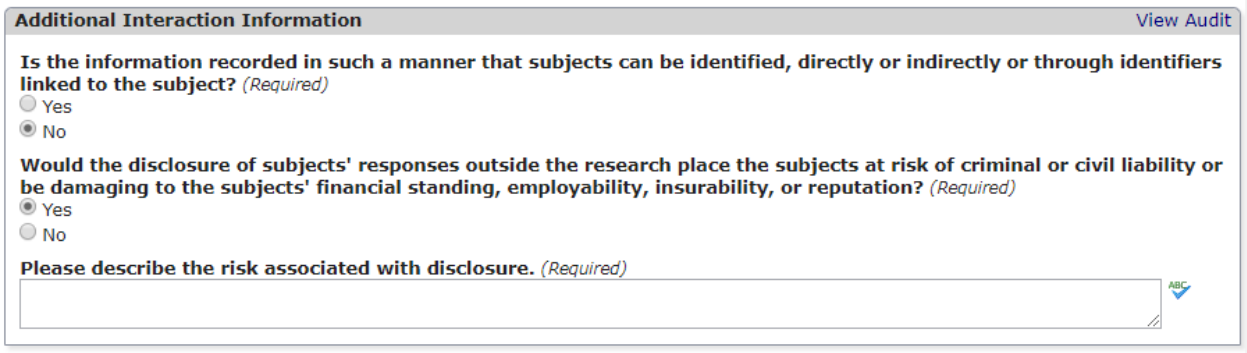
If your research is observation of public behavior, please describe where the observation will take place. Public Behavior is defined as generally open to view by any member of a community and/or which would not involve any special permission to observe (i.e., no reasonable expectation of privacy by 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.



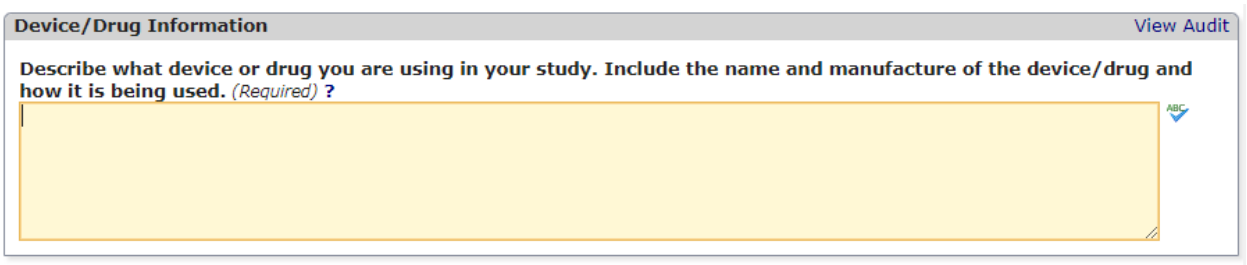
If any member of the research team is actively participating in the activity or intervention rather than just strictly observing, please describe how they will participate.



<u>Additional questions for devices and drugs:</u>

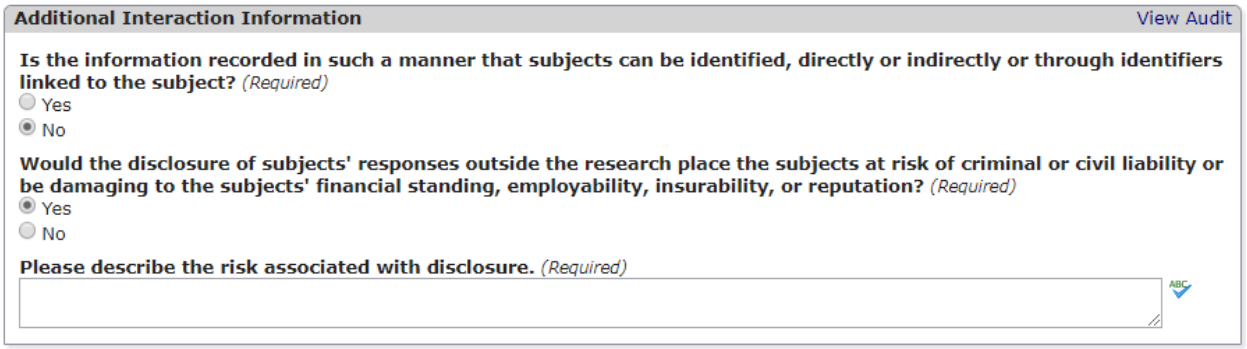


You will be asked about collection of identifiable information and risk of disclosure.



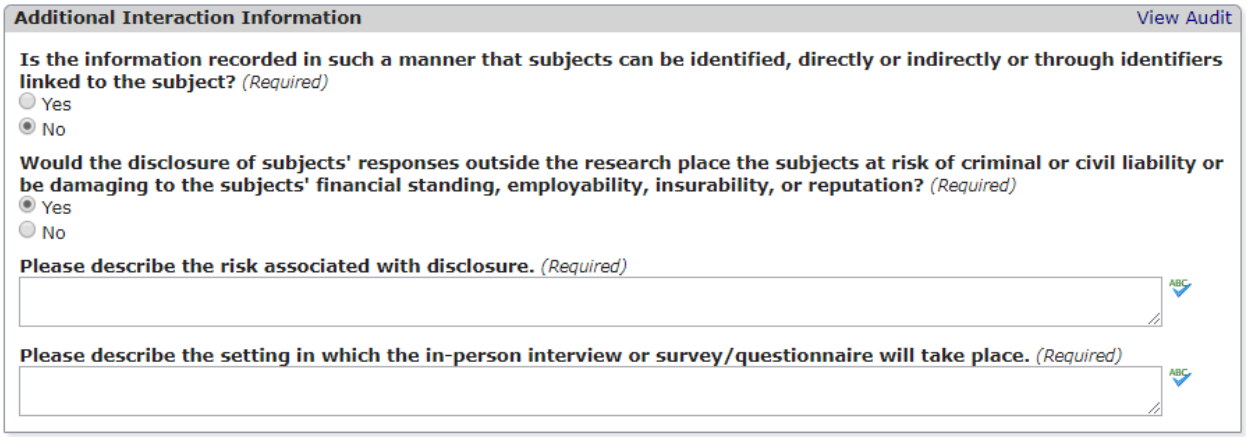
Please provide the requested information about your drug or device. While you may have included this information elsewhere, please include it here again. This helps the researcher determine if this is subject to FDA regulations or necessitates filing an Investigative New Drug/Device Application.

Additional questions for focus groups:



Please answer the questions about identifiable information and disclosure risks.

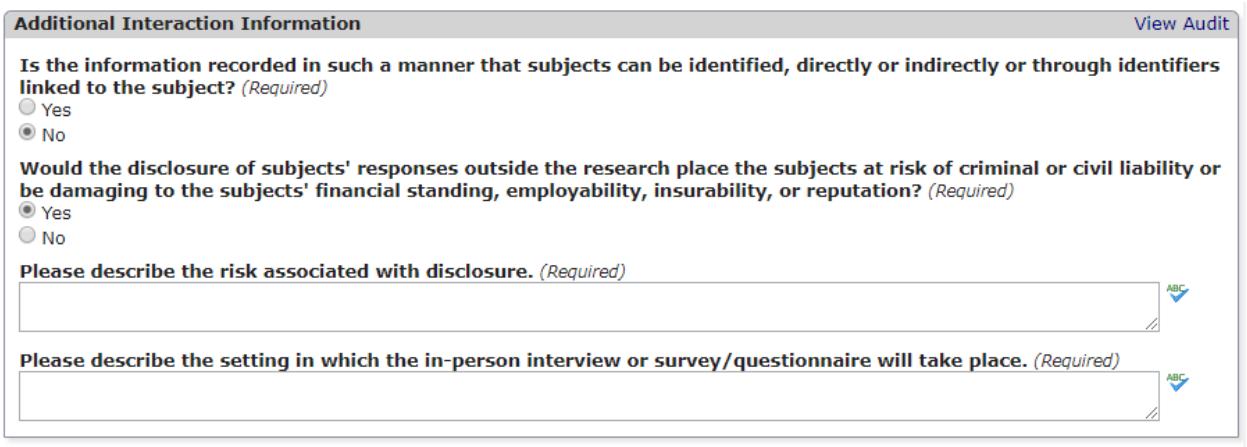
Additional questions for in-person survey/questionnaire:



Please answer the questions regarding identifiable information and disclosure risk.

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.

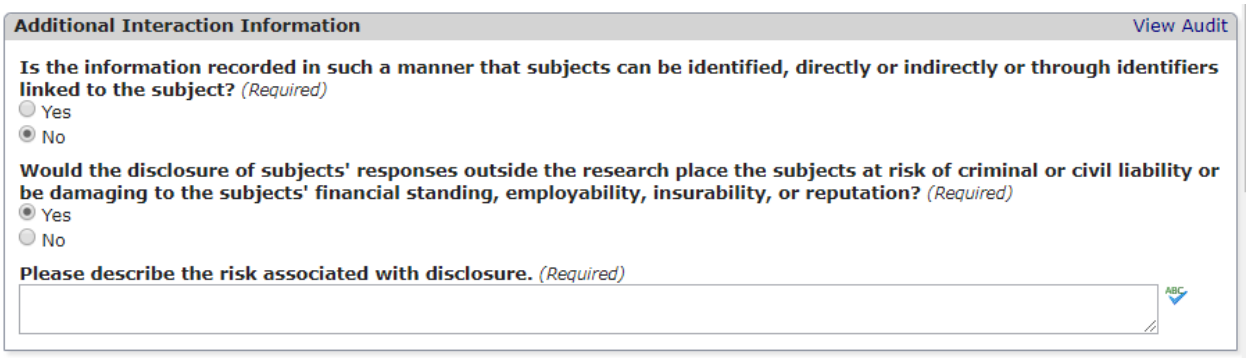
Additional questions for interviews:



Please answer the questions regarding identifiable information and disclosure risk.

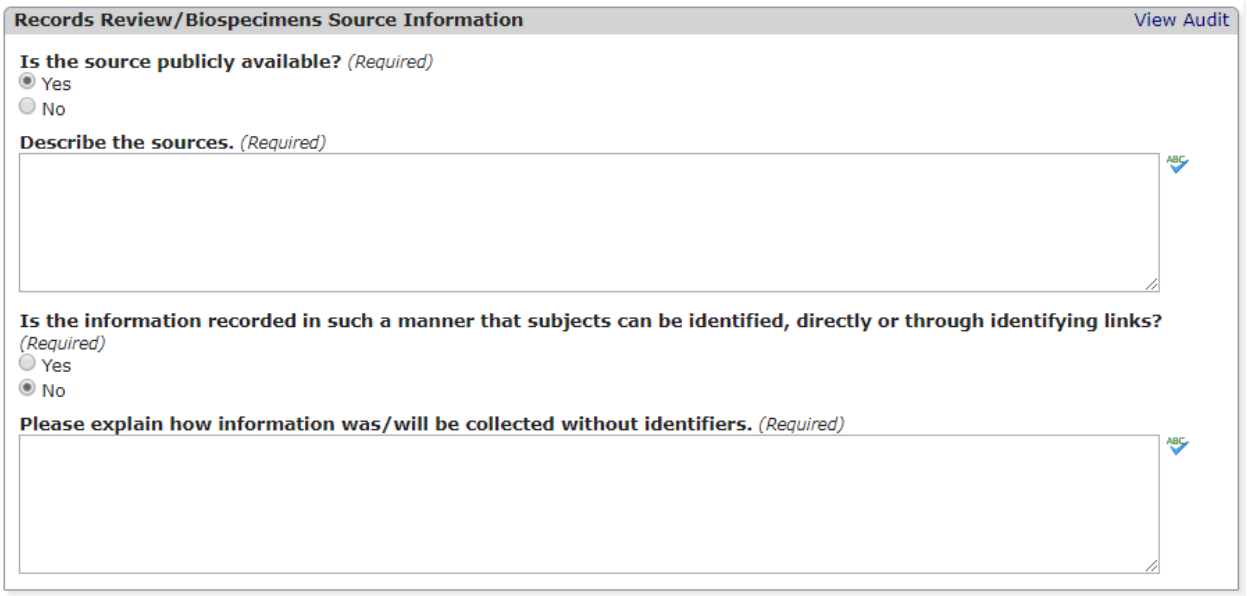
Additionally, please describe the setting for your in-person interview. Please note that depending on the content of your interview you may be asked to alter the location by your reviewer, so please try and consider the most appropriate location based on your content and aims.

Additional questions for online surveys:



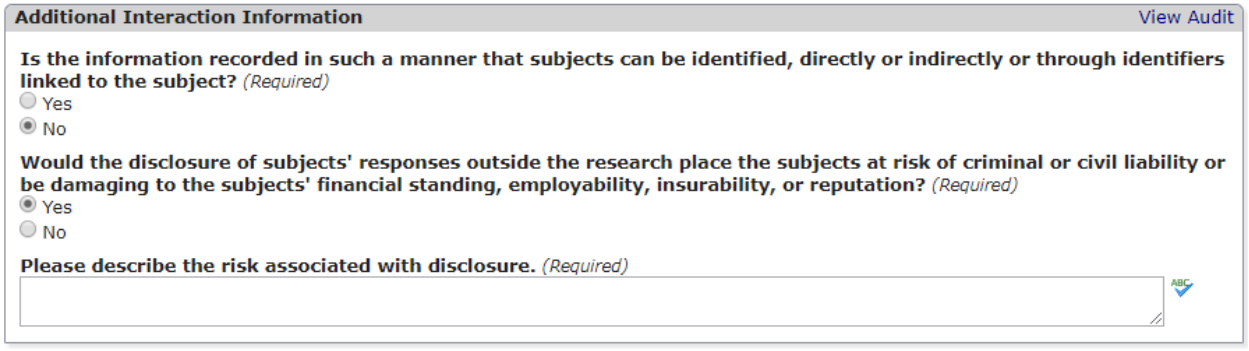
Please answer the additional questions about identifiable information and disclosure risks.

Additional questions for records review and biospecimens:



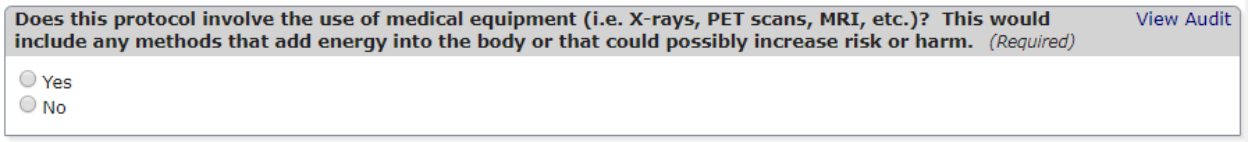
Choose the appropriate response and include descriptions where necessary about the sources of the records or biospecimens. Please also describe how identifiers will be collected or not.

Additional questions for social or behavioral interventions:



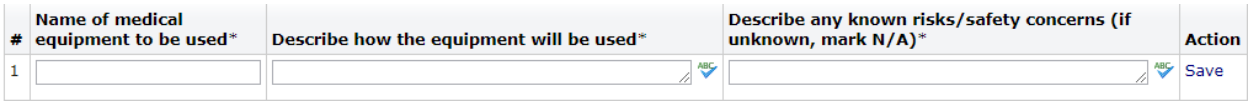
Please answer the questions about identifiable information and risks of disclosure.

3.

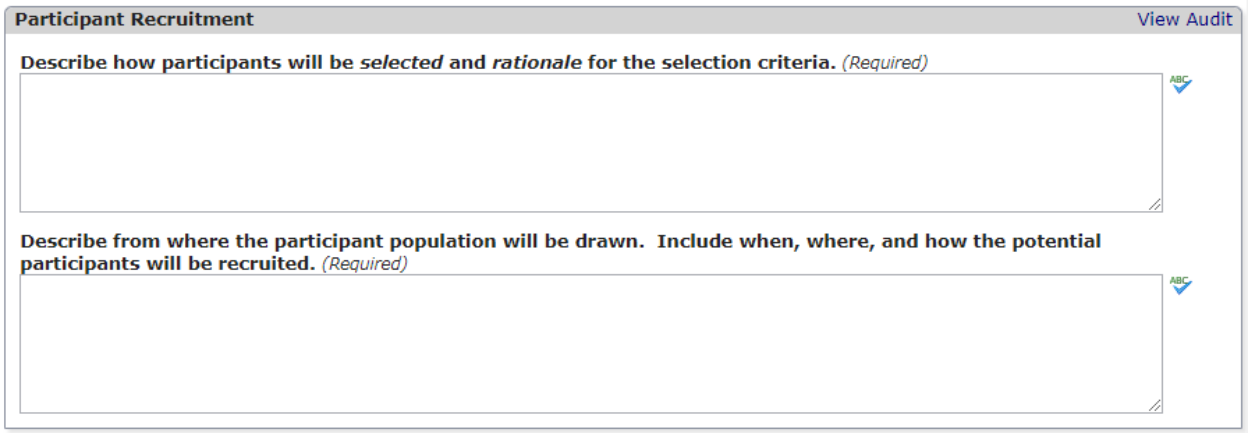


If your protocol uses ANY type of medical equipment, even if it is not the main focus of the research, please choose “Yes” here. Even if you think that it is incidental, please still include it.

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.

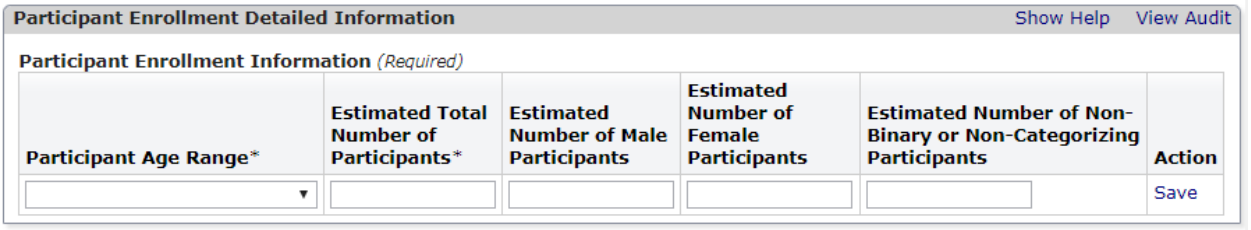


4.



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.

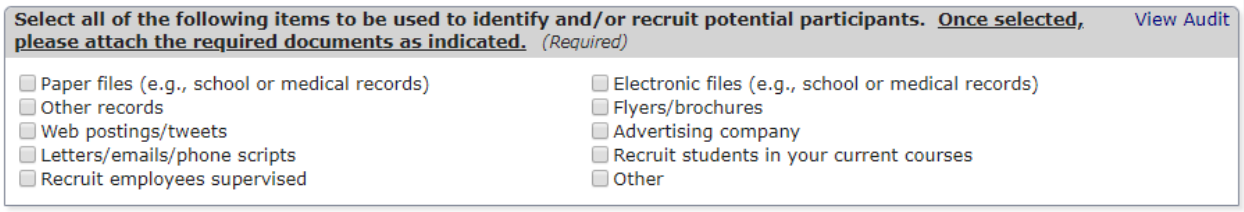
5.



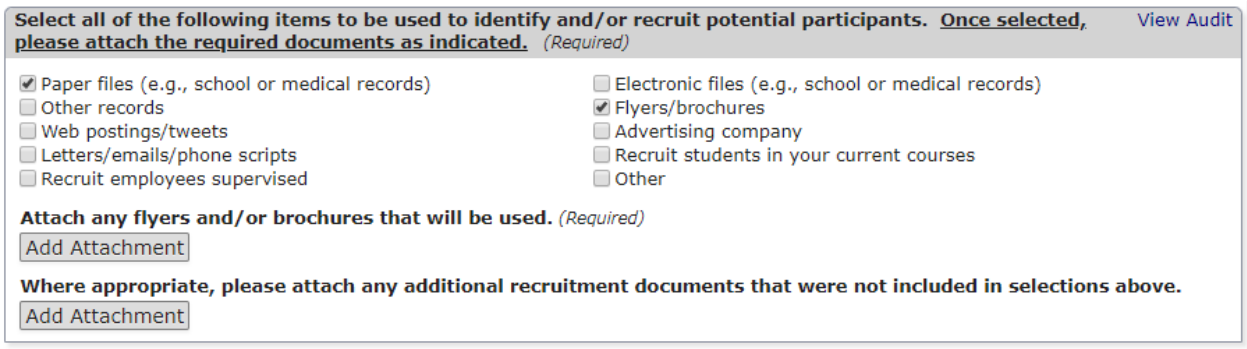
In this section, please choose the appropriate age demographics for your population and the estimated number of participants. If your study is a clinical trial or other type of study where it is appropriate, please include the estimated gender breakdown for your study. For most studies, this will not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

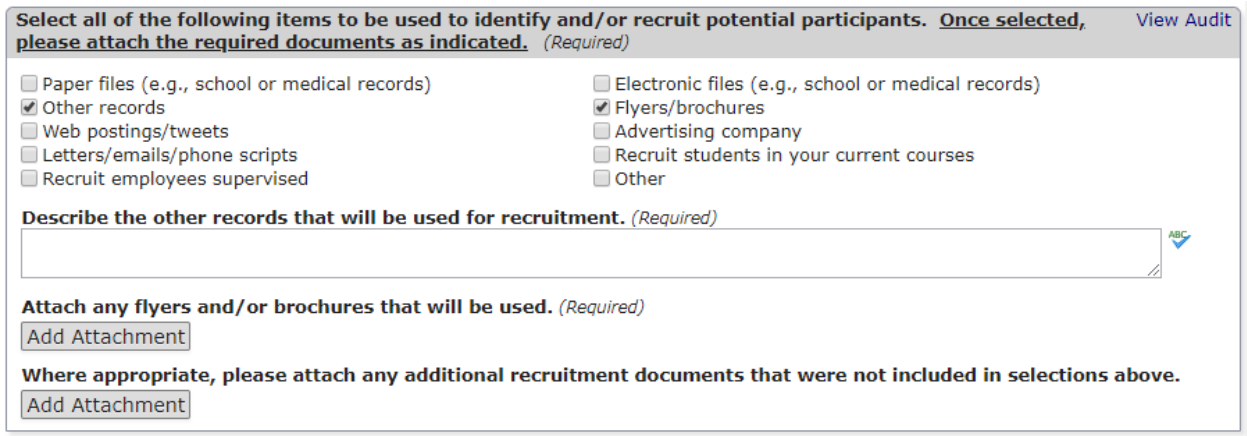
6.



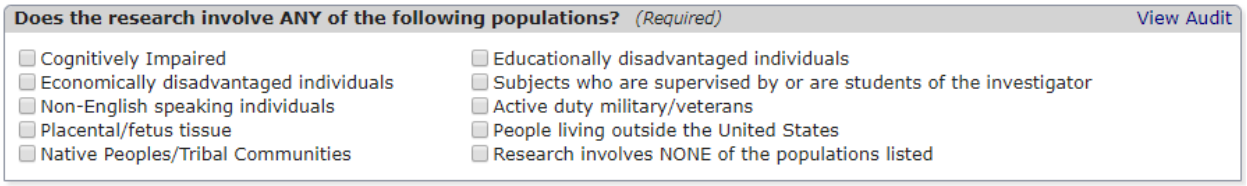
In this section, choose all recruitment methods or items you will employ to recruit participants into your study. You can choose multiple items. For the majority of these items, you will be asked to upload the documents or advertisements you will be using. If you are unsure as to what you can include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



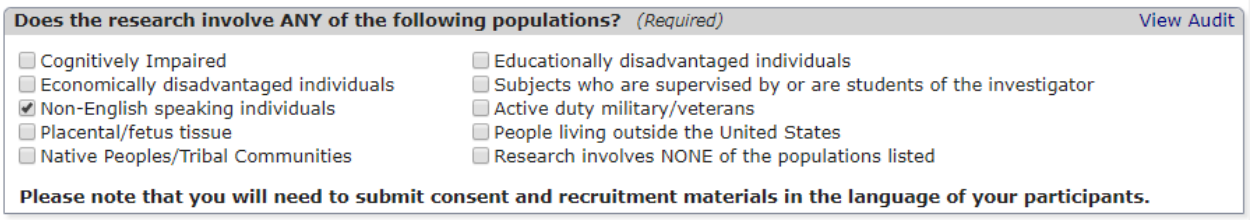
For some recruitment methods, you will be asked to describe them rather than upload documents. Please be as detailed as possible in these cases to aid your reviewer.



7.

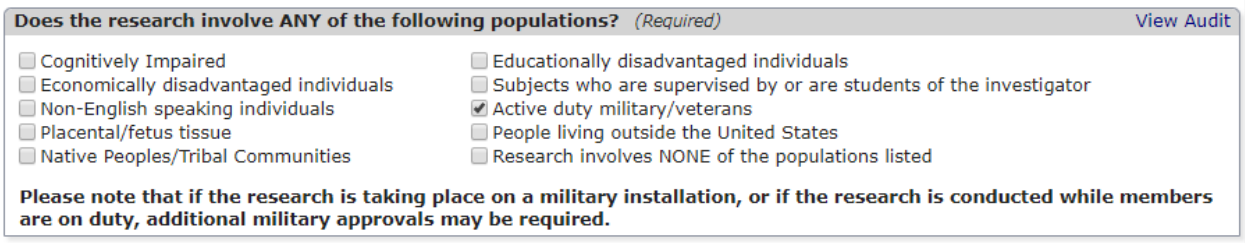


This section captures populations that may require additional considerations, but who are not vulnerable populations with specific regulatory requirements. Please pay attention to any disclaimers or additional information you are provided based on these choices. Please also be aware that inclusion of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



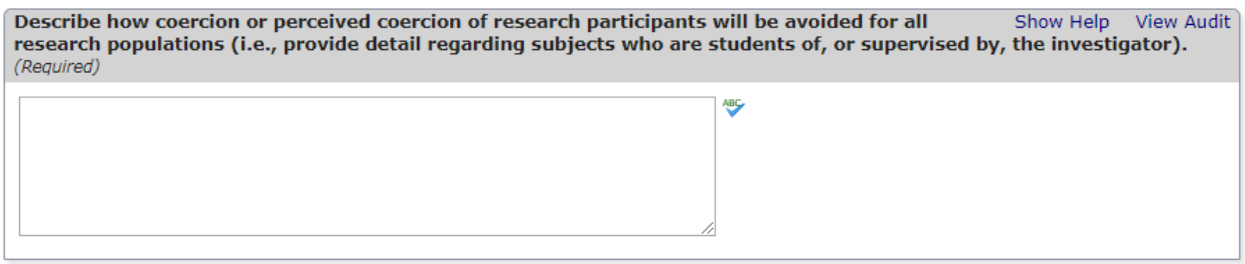
For non-native English speakers, you will need to submit translated materials.

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.



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.

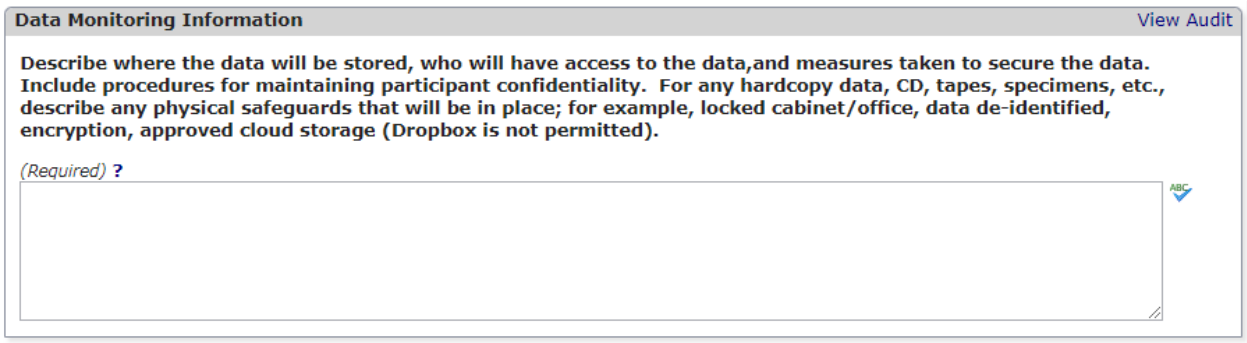
8.



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:

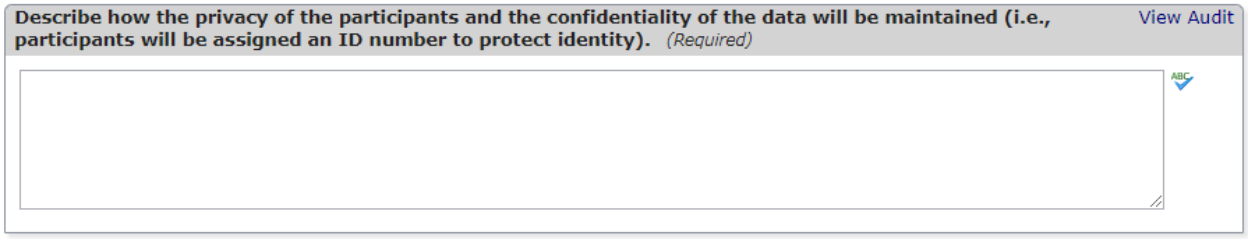
1.



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

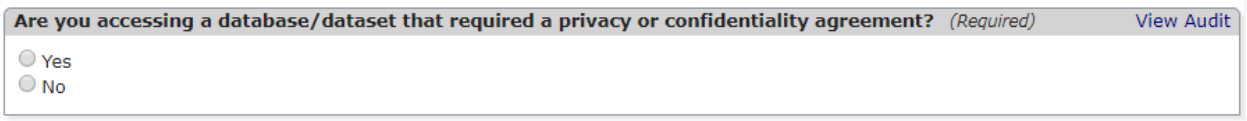
storing poses little to no risk to the participants if there is a data breech. Dropbox, however is currently not allowed to be used.

2.



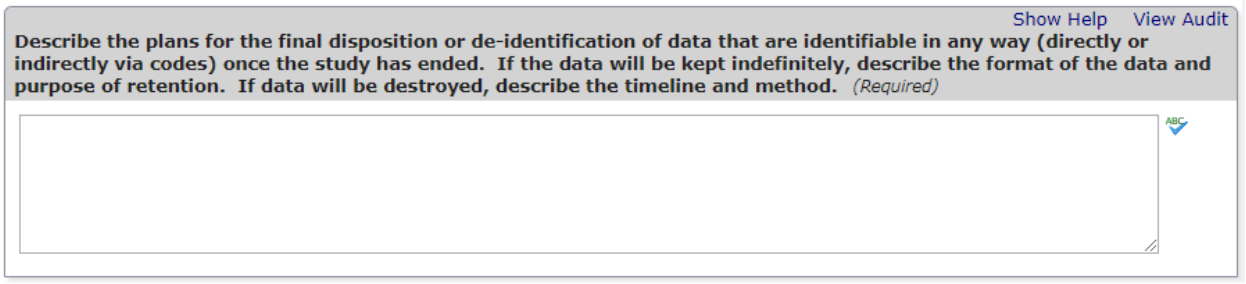
In this section, please provide details about your plan to ensure the confidentiality of your participants' data. This includes how data will be de-identified (if applicable). Additionally, if you are not collecting any identifiers, please note this here. Please note that IP addresses are considered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

3.



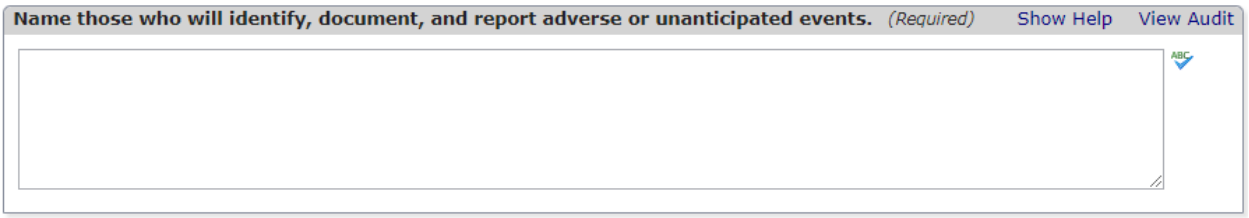
Please click "Yes" here if you must sign any type of agreement to access the data set. PI's cannot sign these types of agreements; only certain university officials can sign these agreements. Please work with OSPRI staff to ensure proper execution of these agreements.

4.



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.

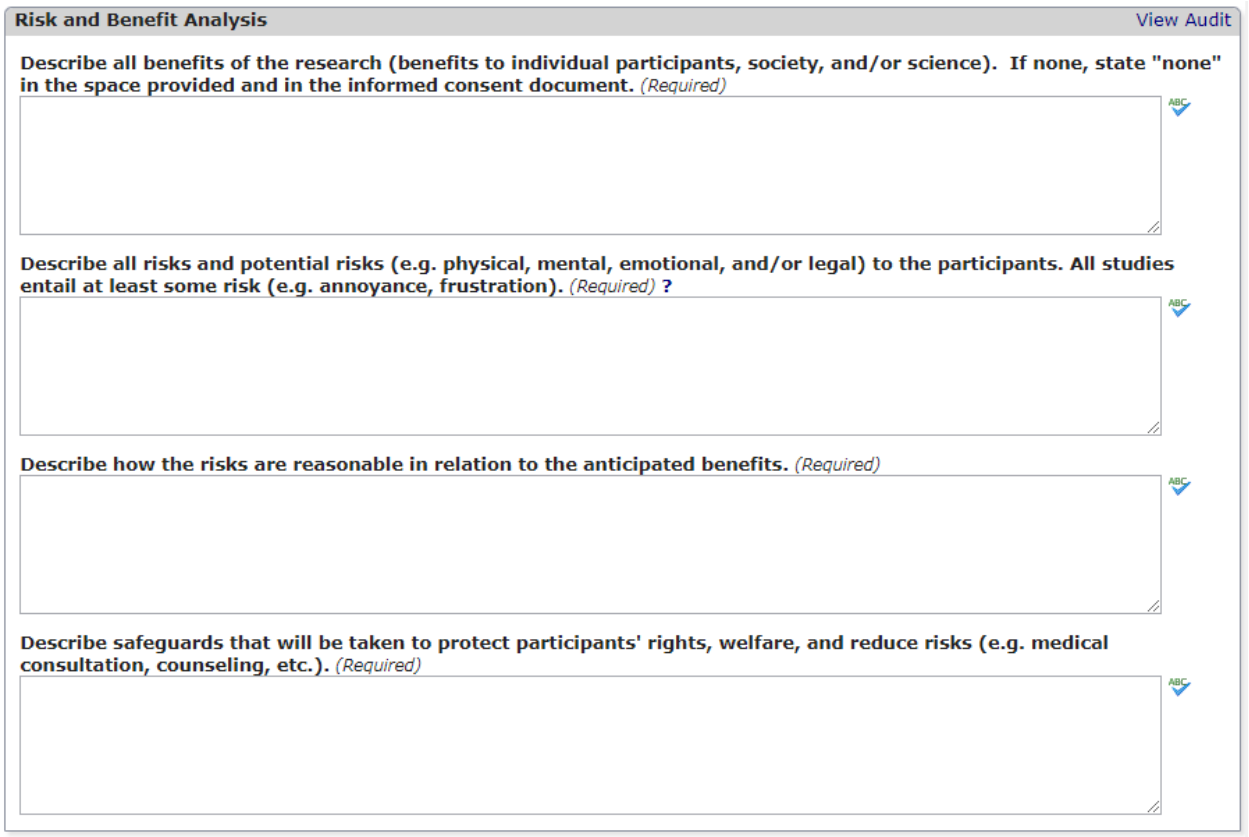
5.



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.

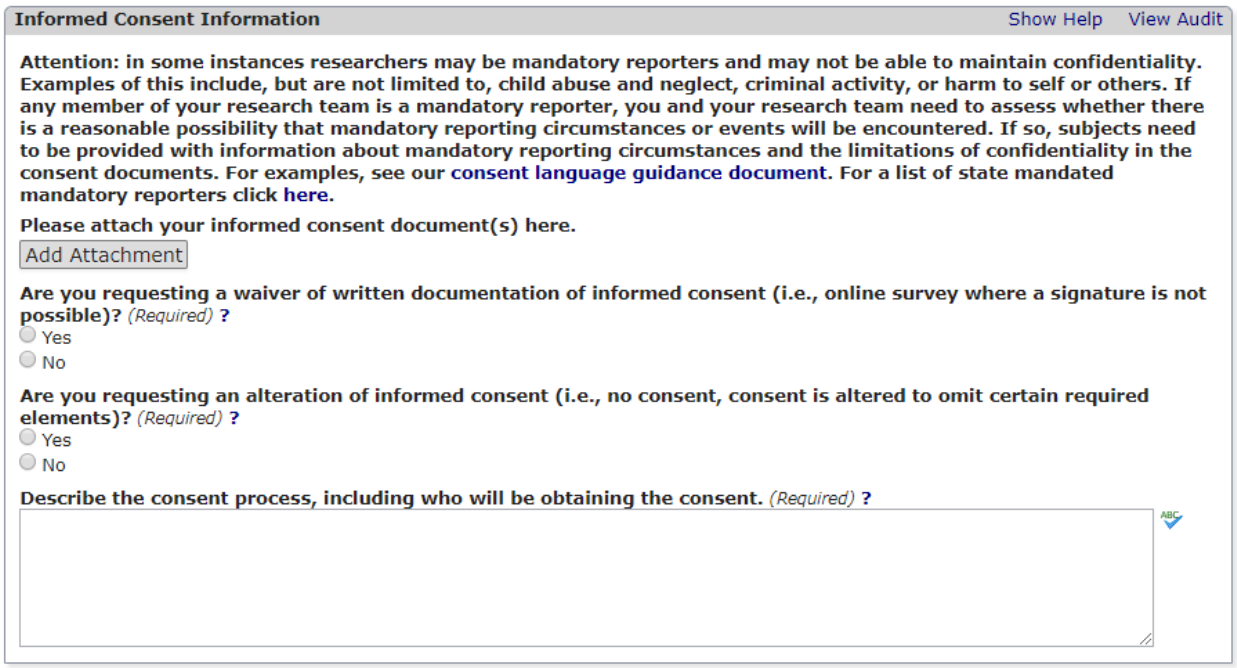


This section asks questions about the risks and benefits to study participants. Please consider these items carefully. All research, no matter how mundane, has some risk (i.e. boredom or frustration). Not all studies will have a direct benefit to the participant. If that is the case, please

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.



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:

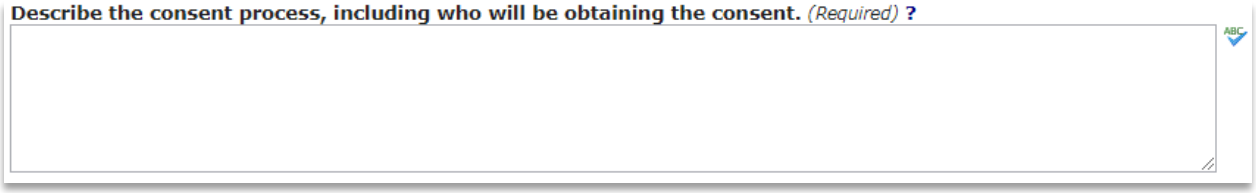
(i) The research involves no more than minimal risk to the subjects;

(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;

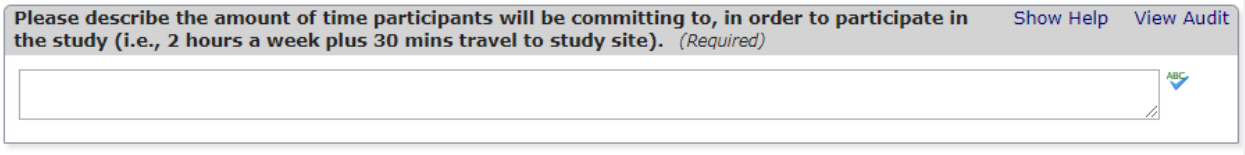
(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.



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.

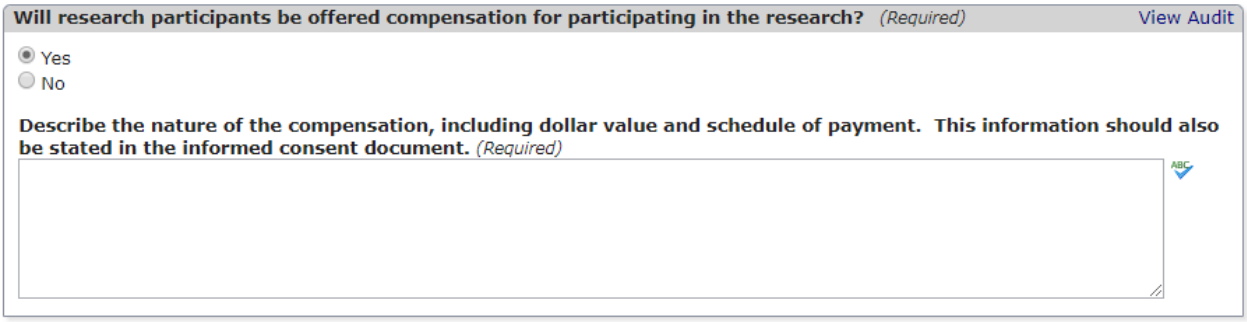


Please be realistic in your description of the time participants will spend participating in your research, considering things like travel time. Please also make sure that the time listed here matches that listed on your consent form.

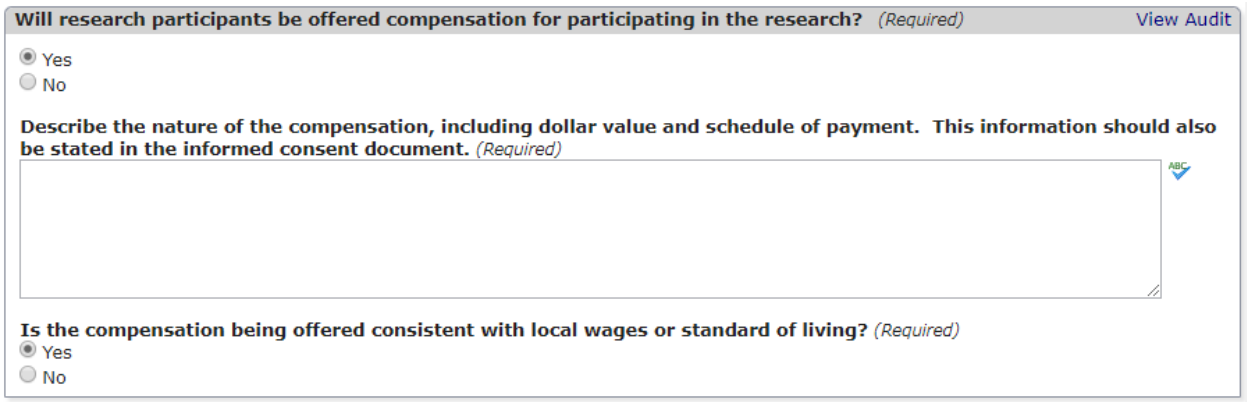
4.

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.

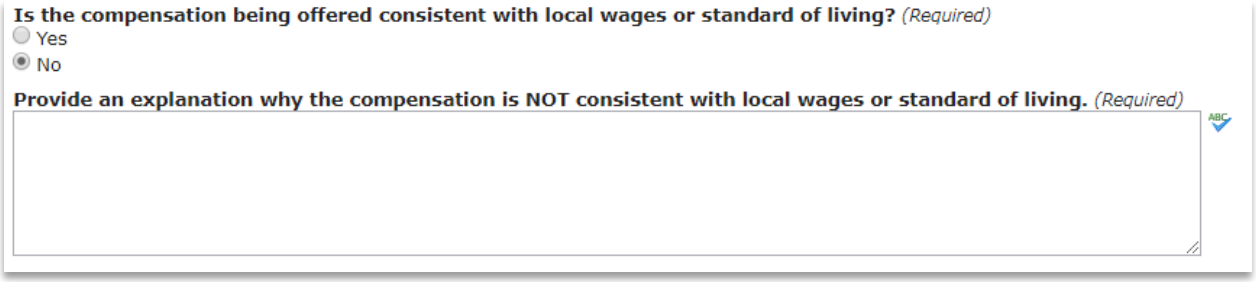
If you are offering compensation, please describe what is being offered. Additionally, if you are offering compensation, please make sure to be clear in your consent form exactly when compensation will be received. For example, if you are completing a pre and post survey, be clear as to if compensation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



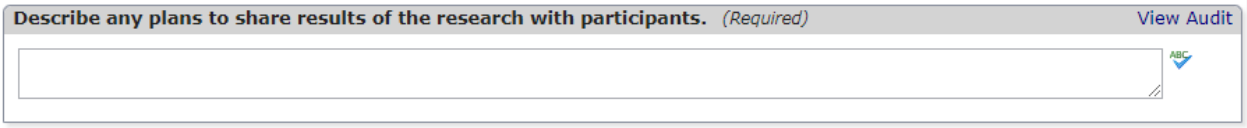
Note: for international research, if you are offering compensation, an additional question will generate on this page.



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



5.



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:

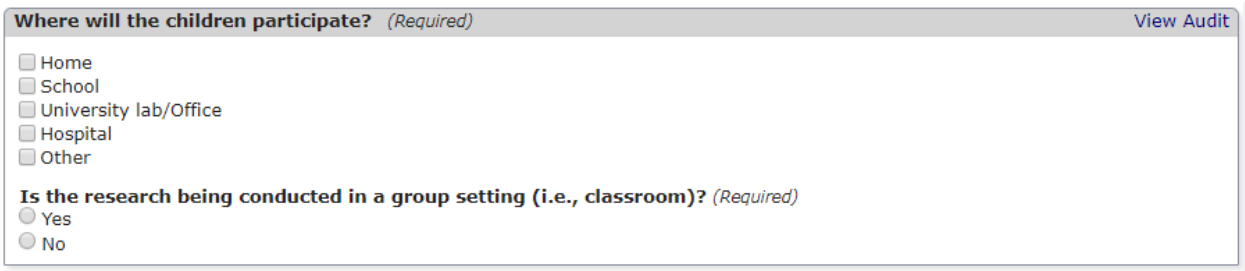
Research involving children:

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.

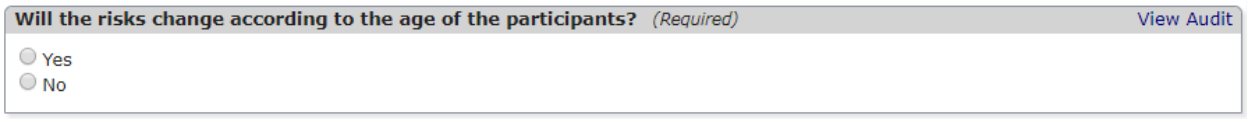
Please enter the age range for the children participating in your study. You will enter this here and in the participant details. Please do both.

2.



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 there 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.

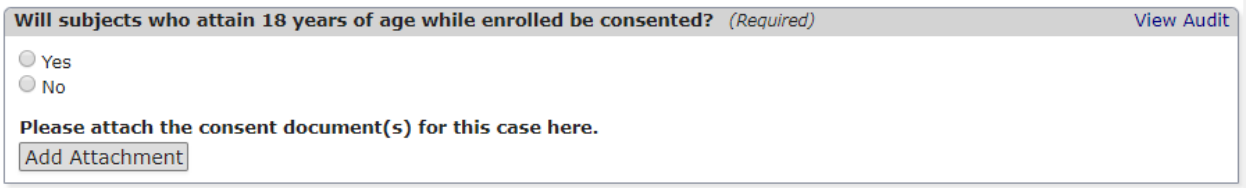


Some procedures may pose different risks to different aged children. If this is, or potentially could be, the case for your study, please click "Yes" and describe how those risks may change by age group.

4.

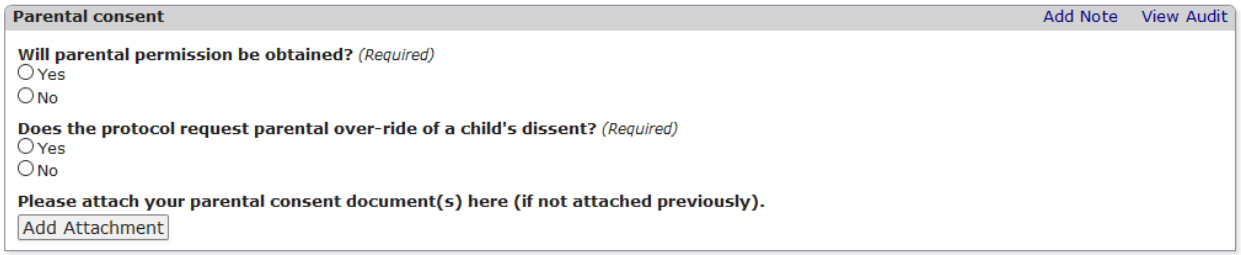
For studies involving children aged 6-18, it is best practice to receive assent from the child to participate in the study. If you are not obtaining child assent, a reviewer may ask for justification or require adding child assent as a condition of approval. Please answer questions in this section accordingly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

5.



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.

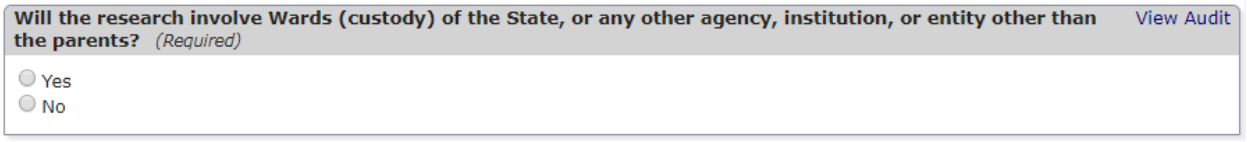
6.



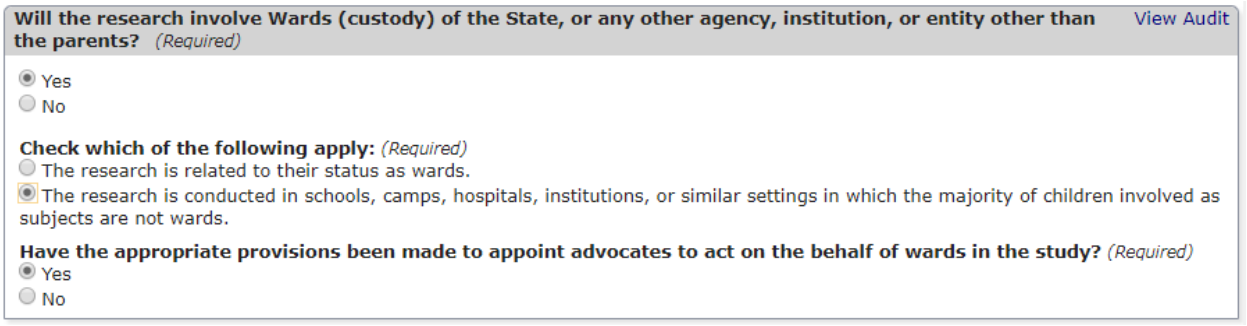
Except in rare cases, parental consent from both parents is required for any study involving children. For exceptions, see the regulations governing research with children here. If you

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

7.



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.



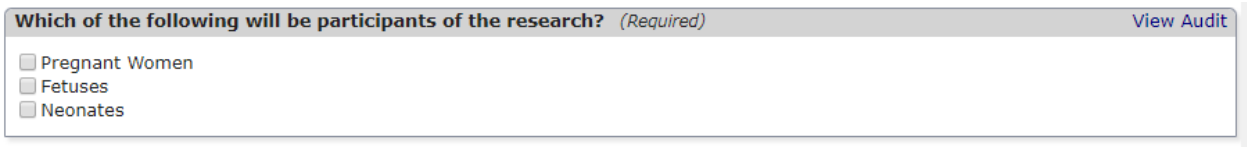
Please answer the additional questions regarding wards in your study as they apply.

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.

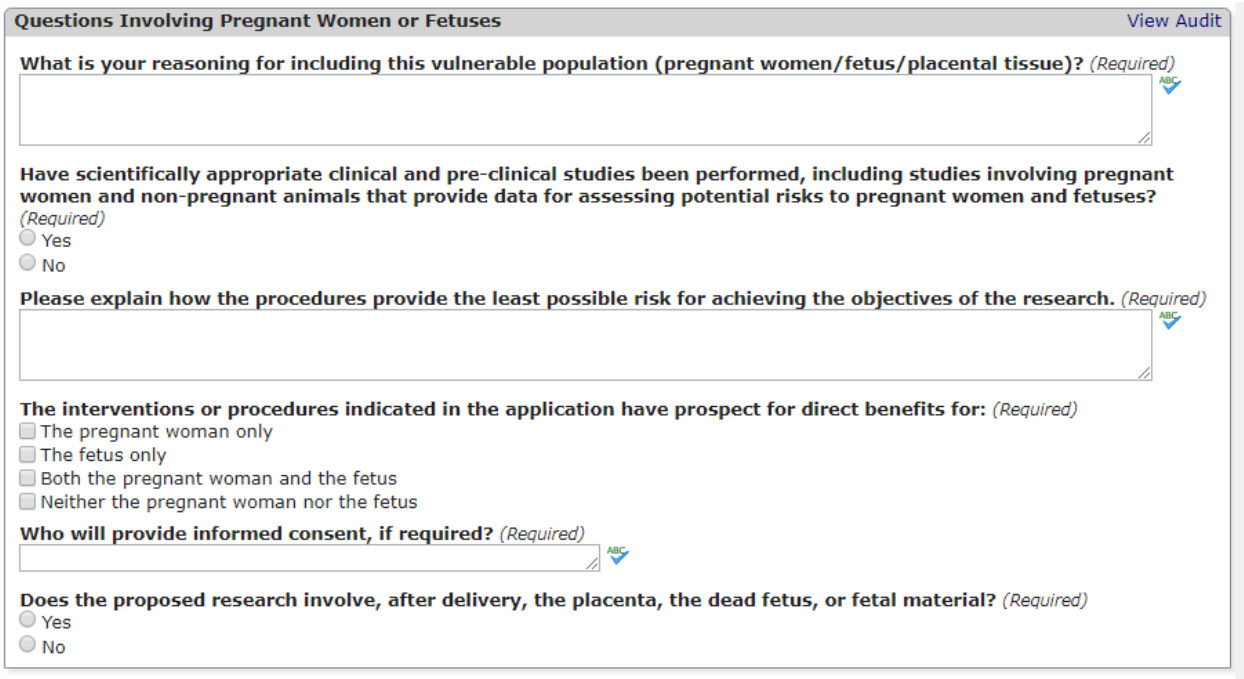
1.



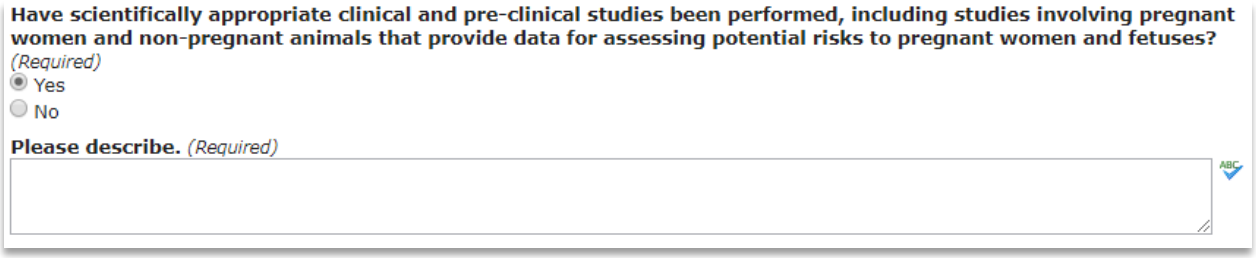
Check all that apply. Please note that there are specific regulatory guidelines for all 3 groups.

For pregnant women and/or fetuses:

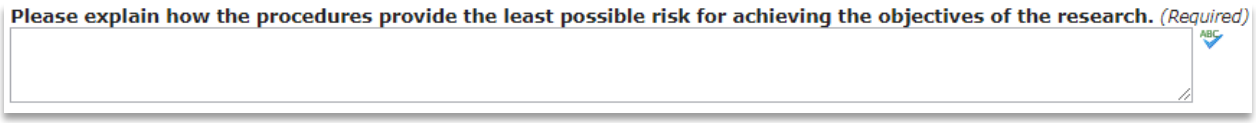
2.



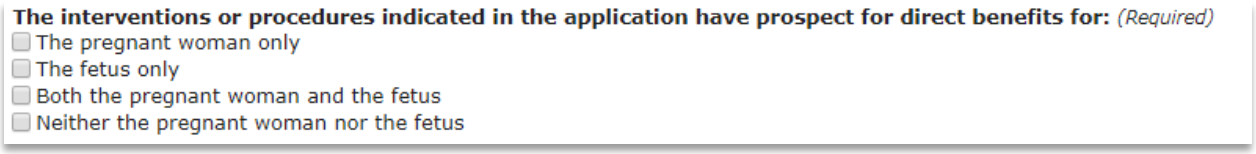
Please answer the additional questions with as much detail as possible. There are regulatory restrictions guiding what research can be conducted with pregnant women and fetuses. Please be aware that studies involving these populations will most likely be reviewed by the full board.



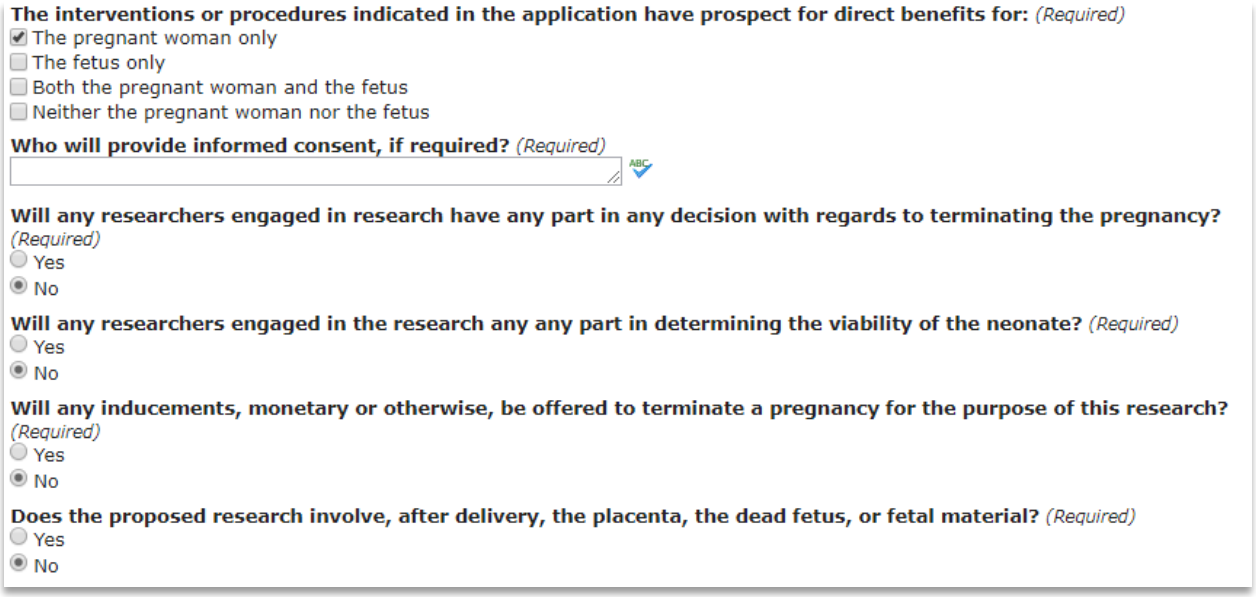
This question is particularly relevant for studies using drugs, devices, supplements, etc. Please provide enough information for your reviewer to make an informed assessment of risk. Studies that are more than minimal risk are unlikely to be approved for these populations.



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

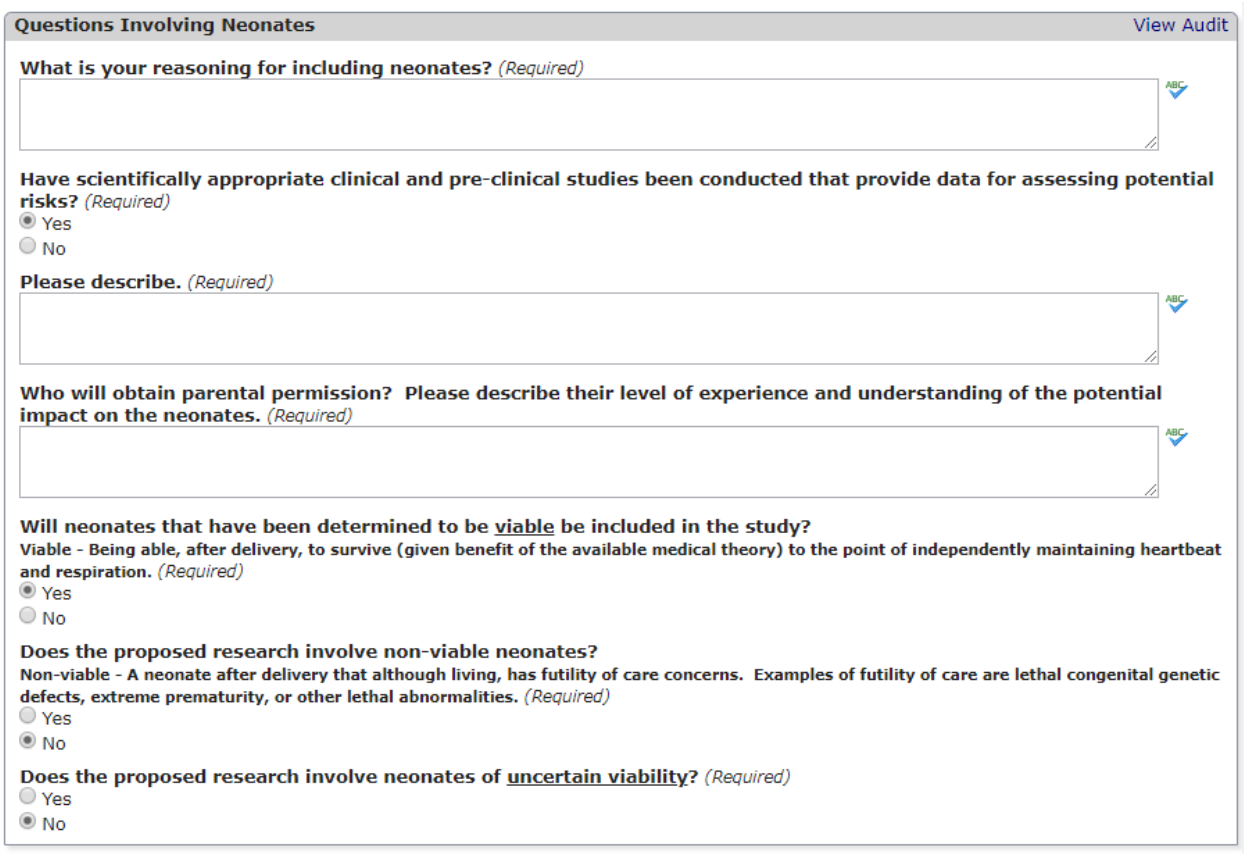


Please check all that apply. Based on your answers, you may be asked follow-up questions.



For neonates:

3.



Questions Involving Neonates View Audit

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

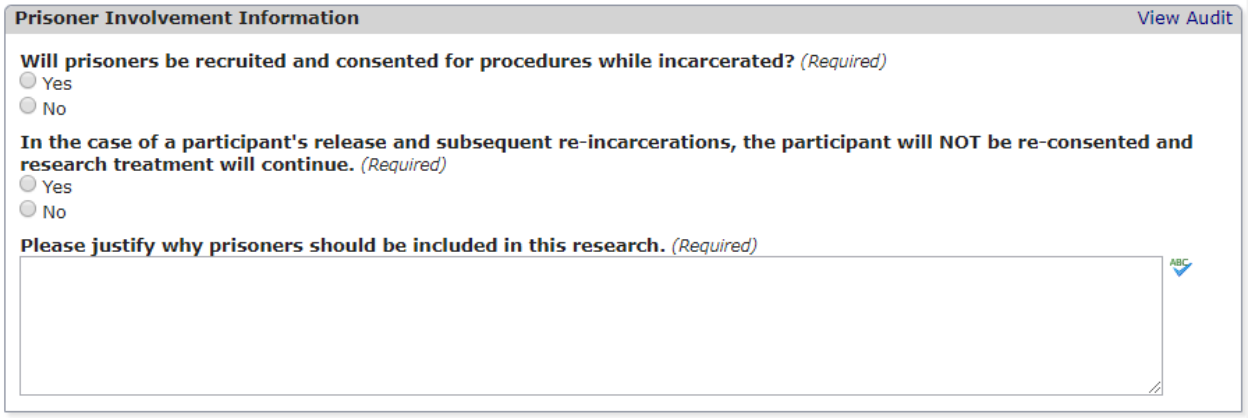
Does the proposed research involve neonates of uncertain viability? *(Required)*
- ( ) Yes
- (•) No

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:

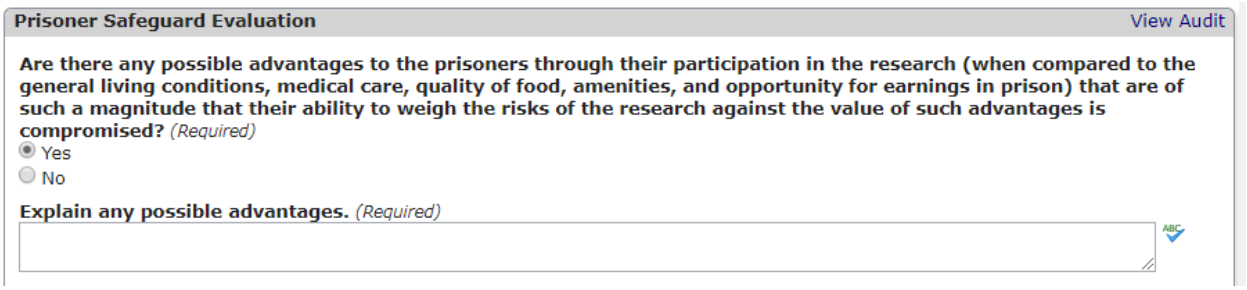
When you choose "Prisoners" under special populations on the Study Details page, the associated addendum will be added to your application. Please answer all questions on this page. Please note, there are specific regulatory guidelines for research involving prisoners. If you are unfamiliar with these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

1.



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.



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.

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)*

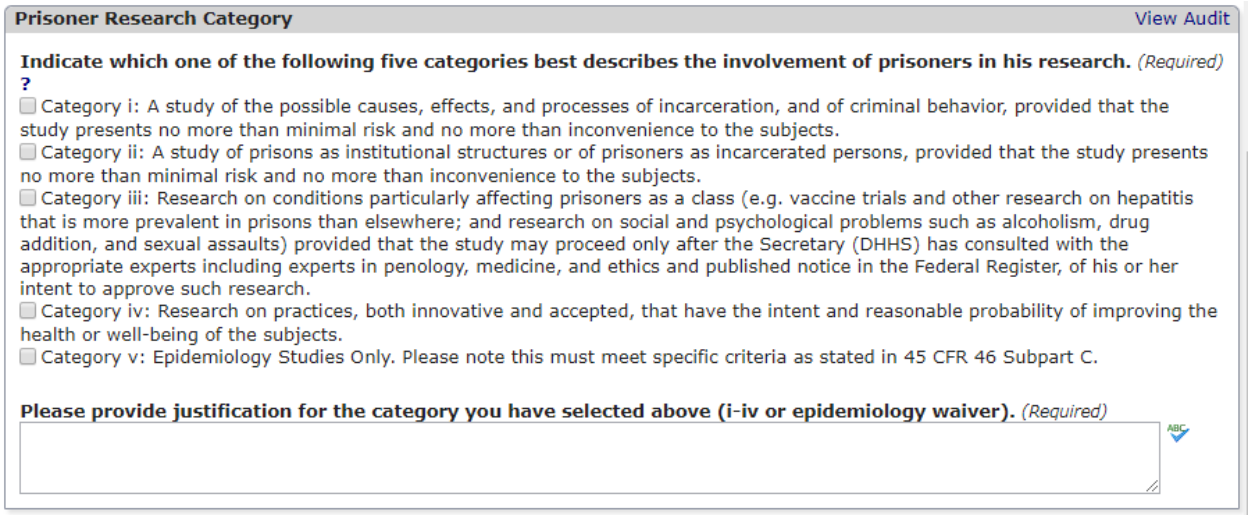
What are the types of examinations and care that would typically be needed for such complications? *(Required)*

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)*

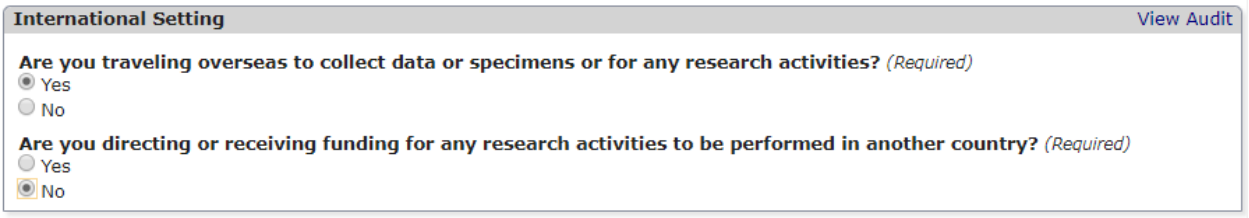
As previously noted, research involving prisoners is only permitted for particular reasons/intended outcomes. To be approved, your research must fall in one of five approved categories. Please choose the category that applies to your research, and then describe how your research falls into that category.



International research:

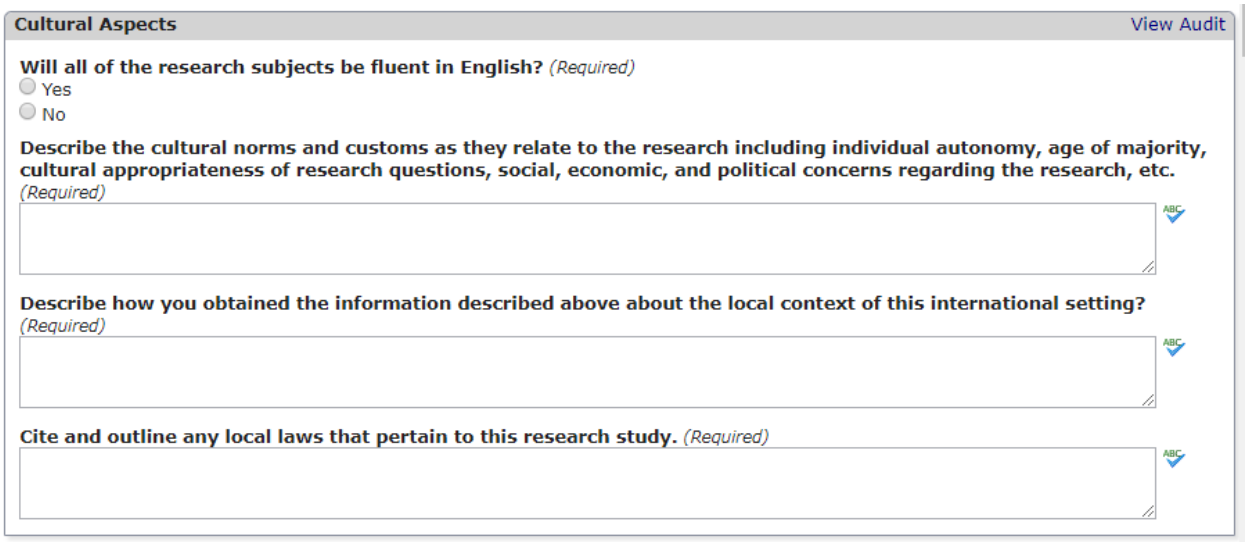
When you choose "International Populations" under special populations on the Study Details page, the associated addendum will be added to your application. Please answer all questions on this page. Please be aware that you may be asked to name a consultant who is familiar with the locale of your research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

1.

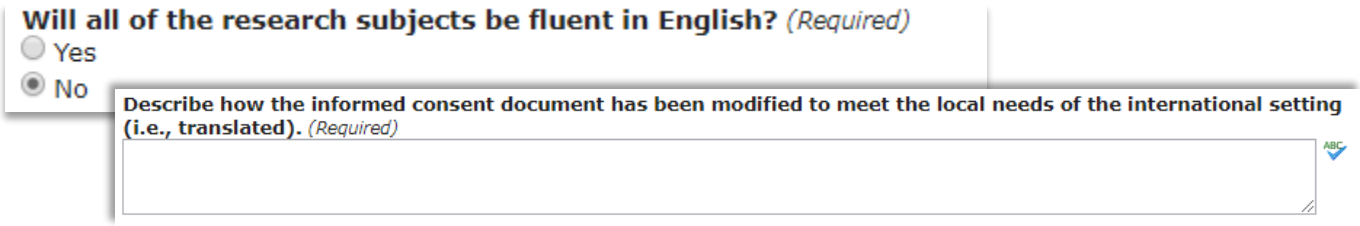


Please note that you will fill out the addendum even if you are not traveling to that country, as long as you are interacting with individuals in another country.

2.

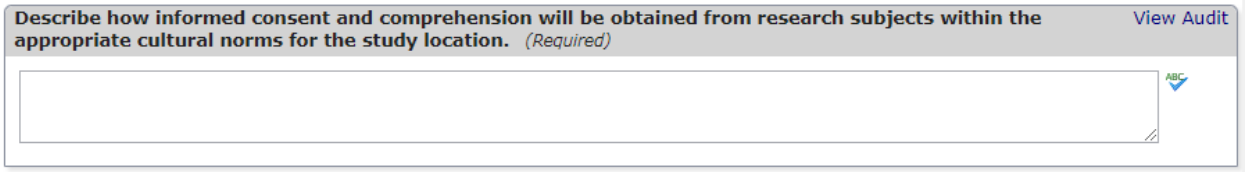


Please be detailed in this section. The answers you provide will assist reviewers in determining if your study has taken into consideration all necessary aspects of working with your proposed population.



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.

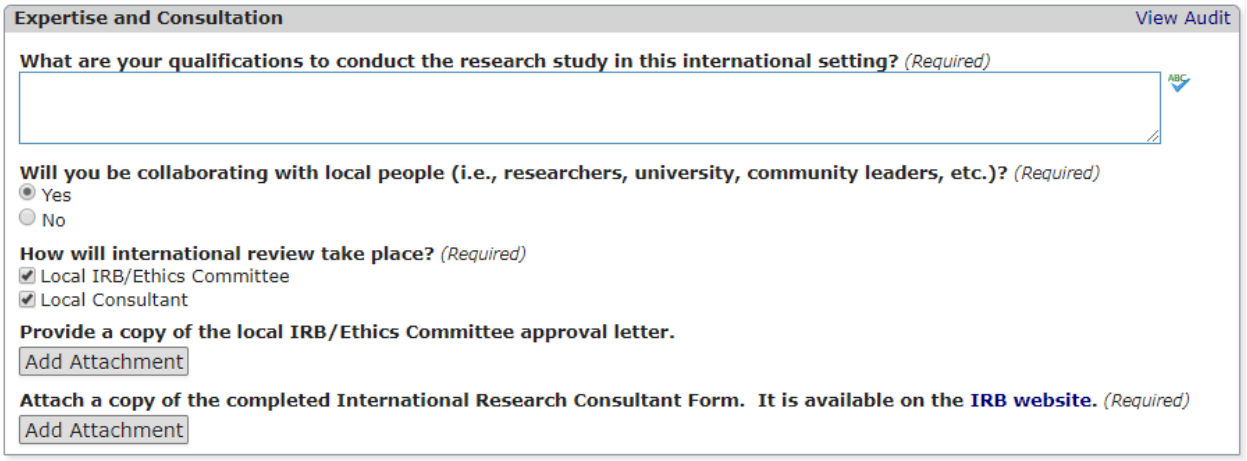
3.



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

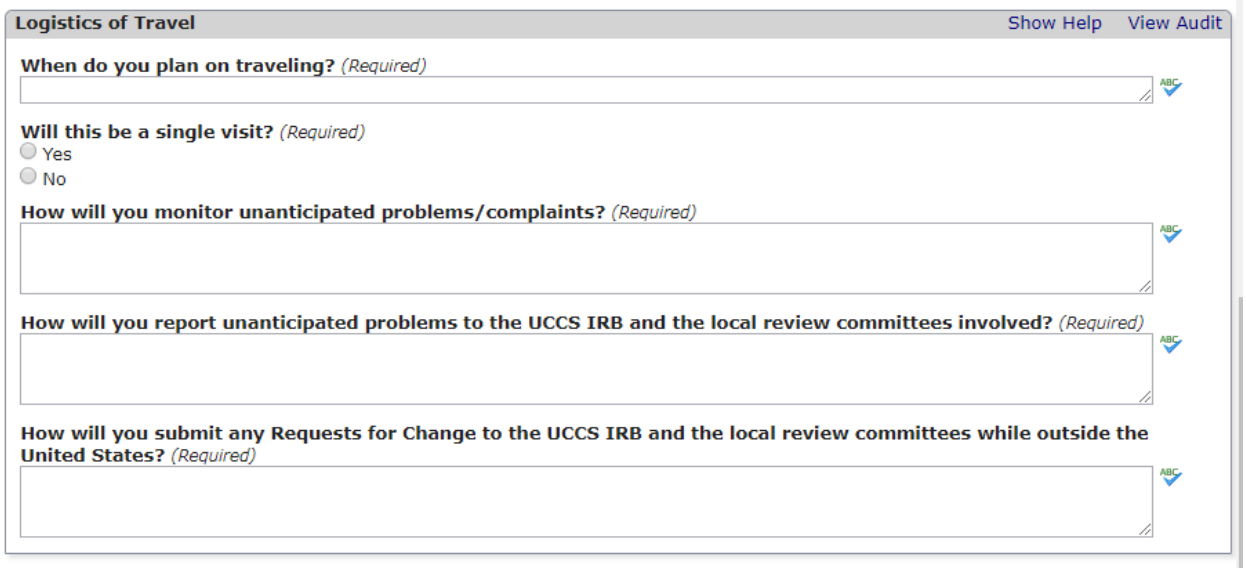
influence how you consent participants. For example, in many cultures, women must have a male chaperone present when talking with strangers. Please describe any such details here.

4.



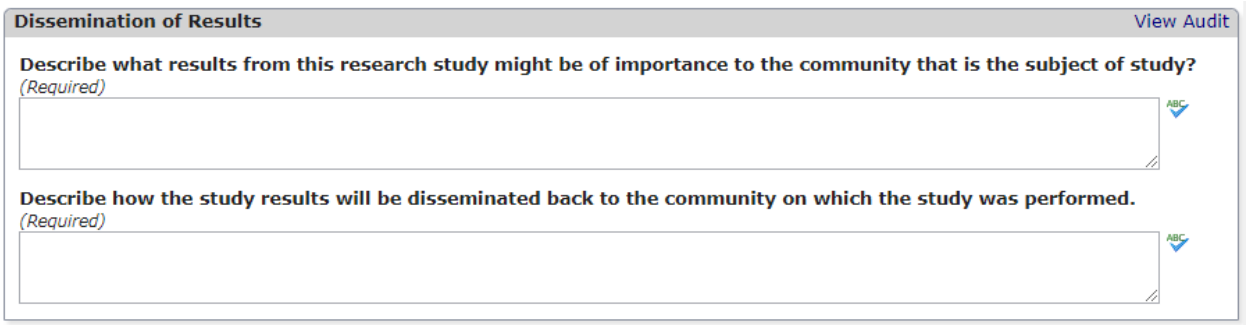
When conducting international research, it is important to have some expertise in the culture/location where you are conducting research. Please describe your expertise here. Additionally, all international research must have a local review. If there is an IRB or ethics committee for the country you 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.



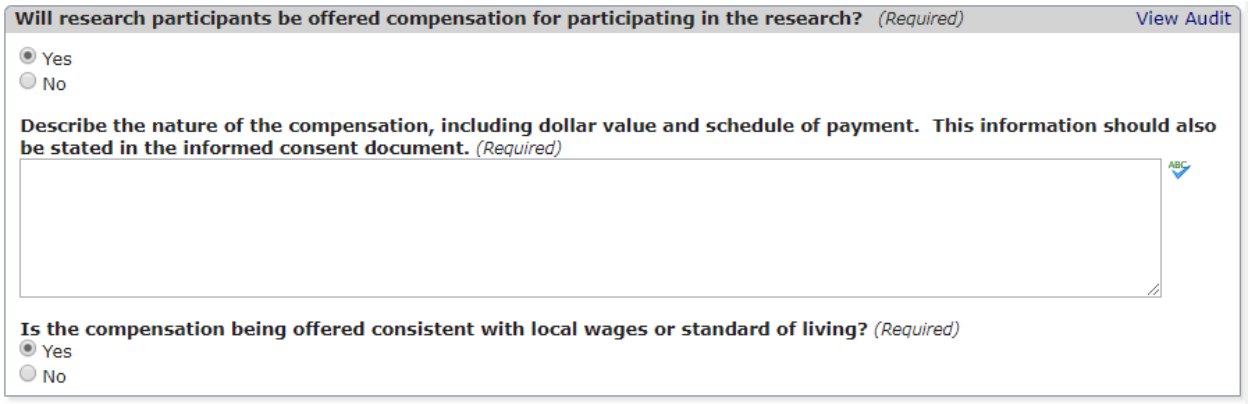
This section deals with logistics of travel. Please answer all questions. If you are not actually traveling, i.e. conducting research online, please enter "N/A" where appropriate.

6.

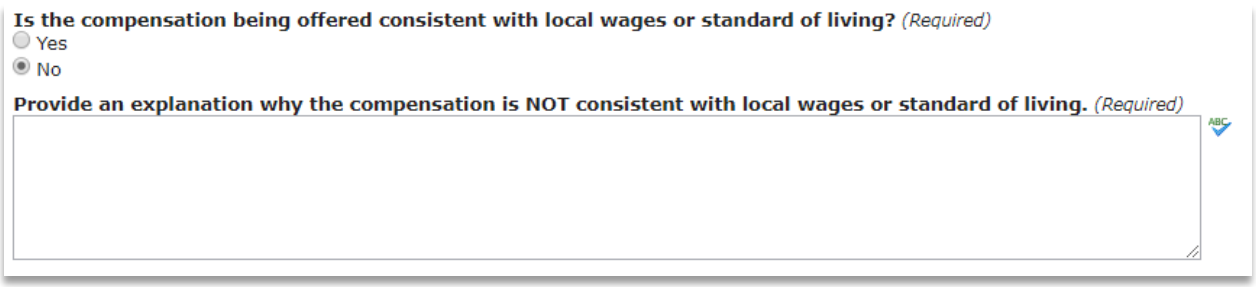


Often communities involved in this type of research may have limited access to the internet or other resources such as academic journals, yet it is important to share significant information that comes from your research with the community that facilitated it, especially if it will benefit them. Please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

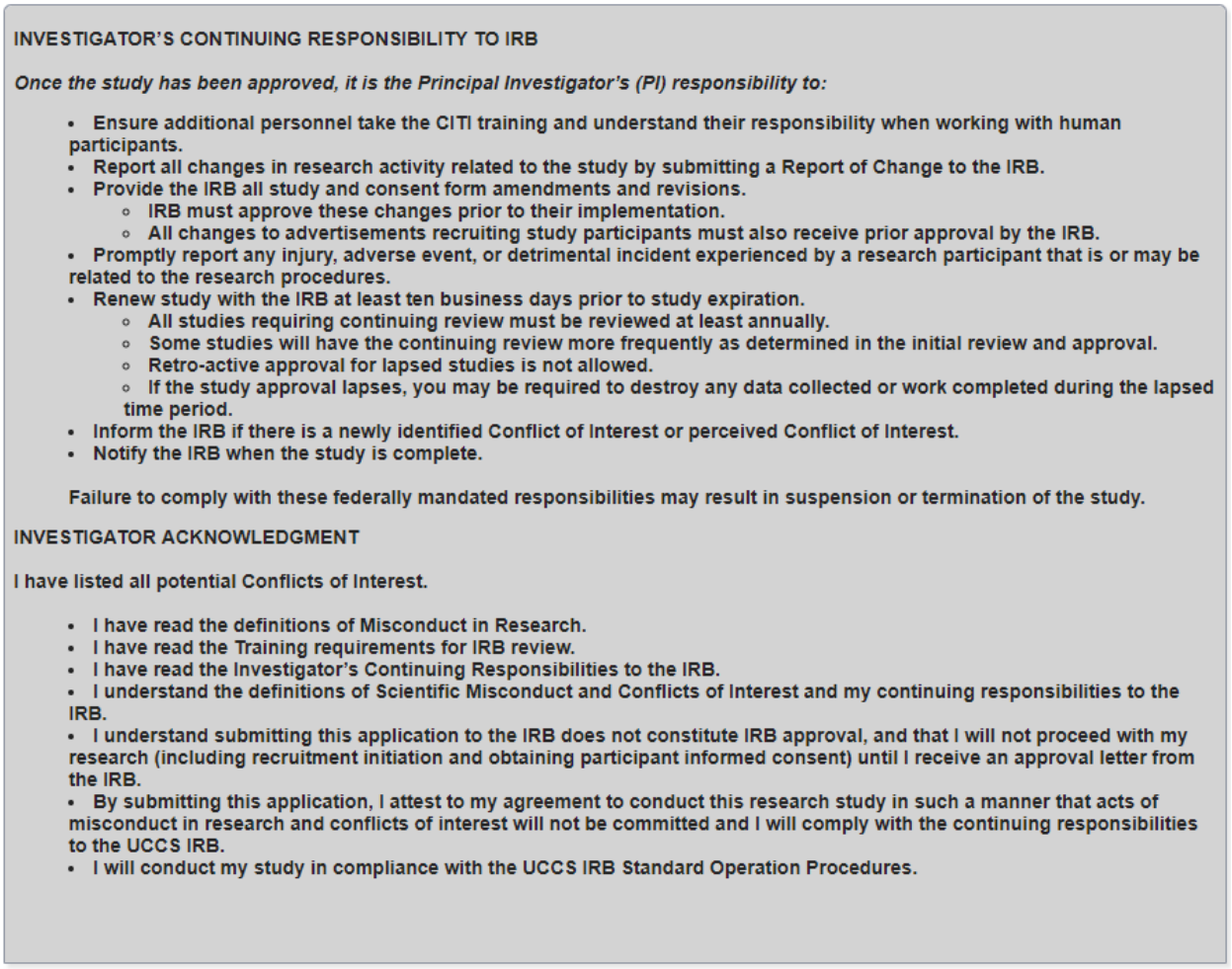


If your compensation is not consistent with the local wages/standard of living (high or low) you will be asked to explain the deviation.



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.



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.

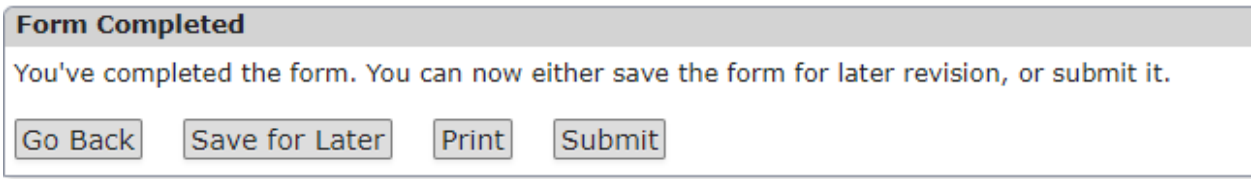
Failure to comply with these federally mandated responsibilities may result in suspension or termination of the study.

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.

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.



Once your form is submitted you will receive a confirmation message. This is the only confirmation you will receive.