GUIDELINES FOR NEW STUDY SUBMISSIONS
An IRB Application Preparation Guide

In the following pages, you’ll find a screenshot-by-screenshot instructional guide to completing your eIRB protocol application for NC State’s IRB office. Our intent is that this guide is helpful to you, whether it’s your first time filling out an IRB application or you’re a seasoned researcher who has a few questions about NC State-specific processes.

This document is a tool for you as you prepare to write your protocol application. We suggest that you read through this entire packet to become familiar with the NC State eIRB application and what your submitted eIRB protocol should look like. While application questions may sound similar, each requests distinctly different information. All application questions, furthermore, are specific to the tab they are on, so you’ll need to answer those questions in the context of the tab in which the query appears.

Depending on how you answer some of the eIRB’s yes/no questions, you may see additional questions. We expect that you will answer all questions in the application. Please do not leave any question blank. If you truly feel a question is not applicable, state that it is not applicable.

If you have any questions regarding the eIRB system, please contact ncsuirboffice@ncsu.edu.
ACCESSING THE eIRB APPLICATION

1. Go to the NC State IRB homepage (https://research.ncsu.edu/sparcs/compliance/irb/)
2. Click on the keyboard picture or “eIRB System” title underneath the picture
ACCESSING THE eIRB APPLICATION

3. Click the “Login to eIRB” button

Using the eIRB System

Any research with human subjects at NC State must go through the NC State IRB. Unauthorized use of external IRBs is not permitted.

Using NC State’s eIRB System

If you would like to submit a new study for IRB approval, a revision request for an already approved study, or a request for continuing review, please complete your request via the online eIRB system. For more detailed information and help regarding the IRB processes and the eIRB system, see below.

Your new application will take 4-6 weeks for review and approval. If you need help with the eIRB, please contact the NCSU IRB office at 919.515.7515.

Updated 10/15/2019
ACCESSING THE eIRB APPLICATION

4. You’ll be prompted to enter your Unity ID and password to access the eIRB system.

5. Once you’ve typed them both in, click the “Log In” button.

**Shibboleth Login Service**

**PROTECT THE PACK! ENROLL IN 2FA**

All members of the WolfPack community are encouraged to enroll in two-factor authentication (2FA) to increase the security of their online university accounts. New employees, including students and temps, are required to enroll in Google 2-Step and Duo within 30 days of their first login to a university application or system. To learn more and enroll, visit Two-Factor Authentication at NC State.

What is Shibboleth?

The Shibboleth System is a standards based, open-source authentication and single sign-on across or within organizational boundaries. [Shibboleth at NC State page.](#)

Do Not Bookmark This Page

Shibboleth works by authenticating your Unity ID and password to gain access to applications. Because the service you came from determines which service to send you back to, and will disallow clicking “back” from the Shibboleth page, please do not bookmark the Shibboleth page.

Keep Your Account Secure

To protect your privacy, completely exit your web browser when finished.

Remember that NC State personnel will NEVER ask you to reveal personal information, such as passwords or other restricted data, by email, phone, text, or other means of communication. If you receive such a message or have replied to one, please report it to help@ncsu.edu.

Updated 10/15/2019
Once in the eIRB system, this is what the eIRB landing page looks like. You have multiple options for accessing a protocol application. If you’re looking to file a protocol application for the first time, click the “Create a new protocol” button. If you already started an application or are looking for an approved application, you can access those by entering the protocol number into the box and clicking the “Select Protocol Number.” If you don’t know the protocol number, you can also search by PI, Department, or Funder (both NCSU and national).
Let’s say you want to search by PI name. Click the “Any PI” and a drop-down menu will appear. Select the PI’s name you wish to search and then click the “Select Protocols by PI, Department, and/or Funding” to auto generate a list of all protocols associated with that PI’s name. There may be a name listed more than once. This is because the name is listed as a Faculty Point of Contact or as Additional Personnel. If it is in more than once, check each.

First search and select the PI’s name from the “Any PI” drop down menu
Then click “Select Protocols by PI, Department, and/or Funding” button to auto generate a list of protocols associated with the PI
If you’ve used the eIRB system before, your name may be listed more than once on the auto-populated list drop down list of PIs. This is based on where and how your name was entered in the eIRB system. The system automatically creates multiple listings when you file protocols in different roles: that is, as the primary PI (1 listing), additional personnel (1 listing), faculty point of contact for a student’s protocol (1 listing), and (for researchers that have been at NC State long enough to remember when the IRB had paper applications) a separate listing for manually entered paper IRB applications.

Unfortunately, we do not have a way to resolve the auto-generated, repetitive listings within the current structure of the eIRB system. But we can reduce the number of listings to two if you email our office and request such (ncsuirboffice@ncsu.edu).
If you’re not sure of the PI’s name, you can also search by an NCSU department. Click the “Any Department” and a drop-down menu will appear. Select the department you wish to search for and then click the “Select Protocols by PI, Department, and/or Funding” to autogenerate a list of all protocols associated with affiliates of that department.

Select the department you wish to search by clicking the “Any Department” button. Then highlight the department you wish to search affiliated protocols for.

Once you have the department you want to search highlighted, click the “Select Protocols by PI, Department, and/or Funding” button to get the list of affiliated protocols.
You can also search protocols by Funding Source. Click the “Any Funding Source” and a drop-down menu will appear. Select the NCSU or national funding source you wish to search for and then click the “Select Protocols by PI, Department, and/or Funding” to autogenerate a list of all protocols associated with that funding source in Research Administration Data And Reporting (RADAR) database.

Click on the “Any Funding Source” button to access the drop-down list of funders. Highlight the funding source that you want to search.

Then click the “Select Protocols by PI, Department, and/or Funding” to auto generate a list of all protocols associated with that funding source.
The fastest way to access a protocol from the eIRB landing page is if you know its eIRB number. Simply enter the protocol number into the box and click the “Select Protocol number” button.

Type the protocol number in this box.

Then click the “Select Protocol Number” button to generate a protocol’s listing.
If you enter the protocol number, here’s what the protocol listing will look like. Click the select button to access the protocol application.

<table>
<thead>
<tr>
<th>Protocol No.</th>
<th>Title</th>
<th>Department</th>
<th>PI</th>
<th>Status</th>
<th>Submission Date</th>
<th>Last Status Change</th>
<th>Select View PDF</th>
</tr>
</thead>
<tbody>
<tr>
<td>19064</td>
<td></td>
<td>Research and Innovation</td>
<td>Allen, Beth Allison</td>
<td>Development</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This box lists the current status of the application, which can be:

“Development” or “Amendment/Renewal Under Development” means you started a protocol application, but never submitted it to the IRB office.

“Submitted” or “Administrative Review” is when your application has been received by the IRB office and is in the queue for an initial review.

“Returned for Revision” applications were returned to the PI with feedback.

“ Expedited Review” applications have been sent to a Full Board member with expertise in your area of inquiry or participant population and they are in the process of reviewing your application.

“Review Complete” means that the IRB office or Board has finished reviewing the application.

“Approved” or “Exempt” means the study has been reviewed and approved by the IRB.

The protocol title will appear underneath the Title header once entered and saved in the eIRB system. If it’s blank like below, you forgot to title your protocol.

The PI listing is always the primary PI on the protocol. If the primary PI is a student, the faculty point-of-contact for the protocol will be listed here as the PI. The PI listing here never includes additional personnel/co-PIs/student PIs.

Submission date is auto-populated when the protocol is submitted to the IRB office for review.

Ignore this box; it’s for internal IRB record-keeping purposes.

Click the select button to view the protocol application.

If you would like to download a PDF of your protocol, click “View PDF.”

This is the department affiliation of the faculty point of contact listed on the protocol.
If you clicked on the “Create a new protocol” button or accessed an existing protocol, here’s what you’ll see on the first page of any eIRB application.

**TITLE TAB**

This row contains the different parts of your eIRB application. The tab in white is the tab you’re currently in. Click a grey tab to be taken to that section of your application.

Here’s where your eIRB protocol number will appear when you click the save button below.

**These are your eIRB application navigation buttons**

< - Previous and Next - >

Allows you to navigate between application tabs listed in white (tab presently on) or grey (other tabs).

**Save**

Preserves changes made to an application. Click this button every 20 minutes of working on an application.

**Discard Changes**

Clicking this button will remove any changes you made to the application since last save action.

**Return to Main Menu**

This button will redirect to the main page of the eIRB system, where you can look up protocols by eIRB number, PI, Funding Source, and Department as well as start a new eIRB application.

Updated 10/15/2019
TITLE TAB

Enter the project title and source of funding (state None if not relevant).

Type your protocol title here, which should be succinct, avoid professional jargon, and be understandable to a 6th grade reading level.

Enter source(s) of funding or state None. Do not enter the number of the RADAR account or granting agency application number.
TITLE TAB

Enter the name and contact information for the PI or, if the student is the PI, the faculty point of contact for this protocol. Do this by clicking the button “Select Point of Contact.”

By clicking this button, you’ll be able to select the name and contact information for the PI/faculty point of contact from a pop-up, drop down menu.

If the PI is a student, their faculty point of contact for the protocol needs to be listed here. Please note: only current NC State faculty and staff can serve as the point of contact for an NC State eIRB protocol.

The faculty point of contact is the only person who can actually click “submit” on the application to submit it to the IRB office. Clicking submit means that the person listed has reviewed the protocol and agrees with all information stated.

Please see the guidance for serving as a Faculty Point of Contact and what the subsequent responsibilities are. This can be found on the NC State IRB website.

Can I serve as my own faculty point of contact if I’m an NC State faculty member who is also a student?

It depends on what your role is during the research. If the research is being done in the context of your role of being a student (e.g. thesis/dissertation), then the answer is no – you need a faculty member to serve as the faculty point of contact.

If the research has absolutely no connection with your role as a student, then yes you can.

Updated 10/15/2019
TITLE TAB

When you click the “Select Point of Contact” button, a pop-up will appear prompting you to “Select Investigator from List.” Click the arrows to navigate the list.
TITLE TAB

Select the Primary Investigator by highlighting the person’s name from the drop-down list. If a student is the primary investigator on this protocol, select the NC State Faculty point of contact’s name for the research protocol. Once the PI’s name (or faculty point of contact for protocols with students functioning as the PI) is selected from the list, click the button “Select Point of Contact” below the PI’s name.

When the primary investigator’s or Faculty Point of Contact name selected, click this button.

If you do not select the faculty point of contact and save the application by clicking “save” above, you will not be able to access the study for editing and you will not be able to find the study by name.

Once you click save, a protocol number will appear at the top where it currently says “new”
**TITLE TAB**

Your Faculty Point of Contact is now populated with NC State directory information of PI’s name, NC State email, departmental affiliation, phone number (if publicly listed) and most recent conflict of interest (COI) form filing. If correct, click save. If not, click the “Select Point of Contact” button again to fix.

Accidentally click on the wrong person’s name? Click “Select Point of Contact” button again to fix.

Click to save Project Title, Source of Funding, and NC State Faculty Point of Contact once all three fields have been populated correctly.

Updated 10/15/2019
TITLE TAB

After you have filed in the Project Title, Source of Funding, and NCSU Faculty Point of Contact, click the save button. Your protocol will be auto-assigned a protocol number and the Faculty Point of Contact’s email will appear.

Having clicked the save button, your protocol now has a number.

This information is auto-populated from NC State University’s HR information. Unfortunately, there’s no way to type a phone number into this section. The empty space here indicated that this PI does not have an available phone number that the IRB office can reach them at.

Make sure that PI/Faculty Point of Contact has recent and valid COI/NOI filed (within 1 year of eIRB application).

Whatever email listed here is where all NC State IRB correspondence regarding the protocol will be sent.

Updated 10/15/2019
TITLE TAB

If the PI is a student investigator, you’ll want to add them as additional personnel to the protocol. Here’s how to do that. First click the button titled “Add New Personnel Record.” An “Add a Personnel Record” pop-up will appear when you click the “Add New Personnel Record” button.

Click this button to add co-PIs or students (whether the student is the PI or a research assistant) via a pop-up.
TITLE TAB

Here’s what the pop-up looks like. Fill in the student’s or co-PI’s name, Unity ID, and academic or professional email address that will be working on the protocol with you. Once you’ve filled in all of those fields, click the “Save” button.

Enter the requested information. You’ll need to complete this action for each additional personnel member on the protocol beyond the PI (or if a student PI, the Faculty Point of Contact for the protocol). Whoever is listed as additional personnel on the protocol will get application updates emailed to them and be able to access and edit the eIRB protocol.

You **MUST** enter the additional personnel’s Unity ID. The Unity ID is the first part of the @ncsu.edu email address.

Whatever email listed here is where all NC State IRB correspondence regarding the protocol will be sent.

Click here when name, Unity ID, and email has been entered.

Click this button after you’ve saved the first person’s name, Unity ID, and email and you want to add another person to the protocol. Otherwise, click the close button immediately above.

Updated 10/15/2019
**TITLE TAB**

Once you have exited the “Add New Personnel Record” pop-up, your additional personnel will be populated on the Title tab like so.

![IRB Protocol - 19064](image)

- **Click the Edit button to fix any mistakes in Name, email, or Unity ID of the supporting personnel.**
- **You did not enter the Unity ID correctly if there are empty parentheses after personnel’s name. To fix this, click the edit button.**

Updated 10/15/2019
TITLE TAB
This is how your additional personnel section should look when properly populated—the Unity ID is present in the parentheses next to the additional personnel’s name.

Here, the Unity ID was entered correctly because it is present in the parentheses after the personnel’s name. Having the correct Unity ID ensures that additional personnel can access the eIRB application.
**TITLE TAB**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
<th>Populations</th>
<th>Consent</th>
<th>Procedures</th>
<th>Data Security</th>
<th>Risks and Benefits</th>
<th>Compensation</th>
<th>Routing and Status</th>
</tr>
</thead>
</table>

Does any investigator associated with this project have a significant financial interest in, or other conflict of interest involving, the sponsor of this project? (Answer No if this project is not sponsored)

- Yes
- No

If you click Yes, this information will need to be stated in your consent form’s sponsorship and funding section and accounted for throughout your eIRB application.

Click here to access the Supporting Documentation tab of your protocol application. When you click here, a new window will pop up.

It is the only section of the application that does not have a quick access tab at the top of the eIRB application.

The Supporting Documentation tab is where you’ll upload all of your documents such as recruitment, consent, protocol materials, and (if relevant) tool(s)/measure(s).

All documents should be uploaded as editable, separate documents.

Add/View Supporting Documentation

Amendments may not be applied for until the protocol or current renewal/amendment request is approved. If this protocol is not yet approved and you wish to make changes, please ask the IRB Administrative Office to return the protocol for revision.

Add New Sponsored Project Record

Sponsored Projects Connected with the Protocol

Click here to add information about any sponsorship associated with this protocol, internally or externally. This information will have to be disclosed in your informed consent process with adults and for parental permission if you are researching minors. This button can also link to your sponsored project record.

For IRB Office use
TITLE TAB

For IRB Office use

This section is auto-populated and auto-generated based on your answers and how the IRB processes your protocol. You cannot manually change information in this section.

Areas of regulatory concern:
None recorded

Original Approval Date:

Current Approval Period Begin Date:

Current Approval Period End Date:
01/01/2100

Category:

These dates will populate once your protocol is approved.

Category will auto-populate when your protocol is approved; “d.1” through “d.8” are Exempt Studies, “Expedited 1” through “Expedited 9” are Expedited Studies, and “Full Board” indicates Full Board studies. This is determined by the type of IRB review the protocol was approved under.

For IRB Office use

This section will auto-populate based on your answers in the Populations tab. This lets the IRB know (at quick glance) who is included in your application.

Even in a brand new eIRB application that has never been submitted to the IRB office, this field is auto-filled. Unless you receive a formal notice of approval via an email or a letter from the IRB office, your study is not approved. Once your protocol has final IRB approval, this box will either have a generic date of 01/01/2100 for study protocols whose approval does not expire (exemptions and most expedited studies), or it will have an approval expiration date listed here.
SUPPORTING DOCUMENTATION

If you click on the Supporting Documentation button on the Title Tab, this is what you’ll see in a new protocol.

If you notice an uploaded file name is not named appropriately, select the uploaded file, enter its new name in this text box making sure that the extension (.docx or .pdf) matches the uploaded document, and then click the button by the file listing that is labeled, “Change Name.”

To upload a document, select document type from the drop-down menu. This will give a “type” name to your file upload.

Once you’ve selected a document type, then click this button which will allow you to upload a file from your computer. Make sure your file title is formatted properly with the eIRB number and a description of the file in an editable Word document.

Click this button to upload the file after you have selected document type and a specific file. This will upload the file to your protocol.

This verbiage will appear when the PI has not uploaded any documents to the protocol.

Updated 10/15/2019
SUPPORTING DOCUMENTATION
This is what your supporting documentation should look like with all of your supplemental materials uploaded.

All uploaded files should have the category label of “Human Subjects Documents” as shown.

<table>
<thead>
<tr>
<th>Category</th>
<th>Name</th>
<th>Status</th>
<th>Date</th>
<th>Time and date the file was uploaded.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Subjects Documents</td>
<td>19064 recruitment email docs</td>
<td></td>
<td>07/15/2019 03:31:24 PM</td>
<td></td>
</tr>
<tr>
<td>Human Subjects Documents</td>
<td>19064 recruitment facebook post docs</td>
<td></td>
<td>07/15/2019 03:31:50 PM</td>
<td></td>
</tr>
<tr>
<td>Human Subjects Documents</td>
<td>19064 recruitment twitter message docs</td>
<td></td>
<td>07/15/2019 03:32:07 PM</td>
<td></td>
</tr>
<tr>
<td>Human Subjects Documents</td>
<td>19064 consent verbal script docs</td>
<td></td>
<td>07/15/2019 03:52:57 PM</td>
<td></td>
</tr>
<tr>
<td>Human Subjects Documents</td>
<td>19064 adult consent form docs</td>
<td></td>
<td>07/15/2019 03:53:12 PM</td>
<td></td>
</tr>
<tr>
<td>Human Subjects Documents</td>
<td>19064 interview protocol</td>
<td></td>
<td>07/15/2019 03:53:30 PM</td>
<td></td>
</tr>
</tbody>
</table>

When you upload each document, select the appropriate type label. Your choices include:
- Participant Informed Consent Form
- Child Assent Form
- Parental Permission Form
- Survey/Questionnaire
- Other Measures
- Interview Protocol
- Focus Group Protocol
- Research Procedure Description
- Photography Consent Form
- Justification for Revision (for IRB office use only)
- Human Subject Letter of Intent
- Observation Protocol
- Recruitment Material
- Communications to Participants
- Human Subjects Agreements
- Correspondence
- Human Subjects Misc

This column has the names of all uploaded files. All documents should be uploaded as editable Word documents and labeled with the following convention: eIRB protocol number and a short description of the file’s content. For example, 19064 recruitment email or 19064 adult consent form.

Any material you plan to use in your protocol with participants from recruitment through to data publication must be uploaded here as well as your data access and management plan if required by the IRB.

Unity ID of the person who uploaded particular file.

This section will be updated by IRB staff during each IRB review.
- Blank (the IRB office has not reviewed the document)
- Draft (the document either has been changed or is unable to be approved in its current format)
- IRB edits (the document has comments from the IRB office)
- For reference (anything that adds context to the project)
- For review (when the IRB office deemed a document ready for final review)
- Approved (the document was approved by the IRB office for use with the approved protocol)
- Previously Approved/Replaced (the document was approved for use but now, via an amendment, no longer used for the protocol)

Updated 10/15/2019
We’re looking for a succinct response outlining the protocol basics: who the participants are, what they’ll be doing, what you’re studying/hoping to learn, and why the research is important. This is your elevator pitch for your protocol. Please don’t cite or paste from your grant application. A 6th grader should be able to read this and exactly know what your research is doing and why.

If any investigator on the project (or the spouse, domestic partner or any members of the investigator’s immediate family who reside in the same household) has a financial or other type of conflict of interest that could potentially affect the design, conduct, or reporting of this research project, please describe the conflict of interest here or indicate that it has been fully disclosed in the investigator’s most recent COI disclosure filed with NC State. If your team does not have any conflicts of interest, please respond with N/A. If you are uncertain how to respond or have questions, please contact coi-noi-compliance@ncsu.edu.

My research qualifies for Exemption. Exempt research is minimal risk and must fit into the categories d.1 - d.8 found here: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Conflicts of Interest (COIs) are money, access, power dynamics, situations, and relationships that could affect your research design, conduct, or reporting as well as your research participants.

The NC State IRB expects that you have (or will file) an up-to-date COI disclosure in accordance with NC State regulations prior to final protocol review and approval. This section is intended to capture that information as well as any other real and perceived conflicts of interest that may occur or could affect your research design or participants.

Updated 10/15/2019
### DESCRIPTION TAB

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>My research qualifies for Exemption. Exempt research is minimal risk and must fit into the categories d.1 - d.8 found here: <a href="http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html">http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html</a></td>
</tr>
</tbody>
</table>

#### Is this research being conducted by a student?
- Yes
- No

#### Is this research for a thesis/dissertation/capstone?
- Yes
- No

#### Is this research for a course?
- Yes
- No

---

Students are undergraduates, graduate students, or fellows at NC State or elsewhere. NC State staff who are also students would answer “yes” to this question if they are acting as a student for the purposes of this protocol.

Exempt research is always minimal risk and it fits into categories defined by the regulations. These commonly include online surveys, benign behavioral interventions with adults, some research with existing publicly available data, taste tests with FDA/USDA approved foods, and some educational research completed in a class environment.

Class projects are not usually contributing to generalizable knowledge and thus do not normally need IRB approval. If, however, you have any intent to present or publish material from the coursework, you need to go through the IRB process.

Please see the IRB guidance regarding what constitutes research and contributions to generalizable knowledge. This can be found on the NC State IRB website.

Thesis/dissertation/some capstone projects are considered to be a systematic investigation that is contributing to generalizable knowledge. This section also indicates that a student is the primary investigator. If this is answered as “yes” then the student must be listed as additional personnel on the Title tab.

---

Updated 10/15/2019
Anyone that will be involved in the recruitment, consent, data collection and analysis should, if not listed on the Title page, be listed here. Those listed as additional personnel will have access to the eIRB system and be notified when changes are made. Those listed here – will not.

Collaboration as defined by the IRB includes any aspect of recruitment, consent, data collection, data analysis, or funding. If you select “yes” here, you should check out our website for information regarding reliance and individual investigator agreements on the “For Researchers” portal.

International research will require a “local context” review prior to IRB approval. Clicking “yes” will open up more boxes where you can enter at least one expert we can contact (preferably more than one so that if the first does not respond in a timely manner, your application will not be unduly held up because of a local context review). This review is required by the federal regulations for studies reviewed as Expedited or Full Board and for some Exempt studies.

A local context review is a part of the IRB review process. The NC State IRB office will share your completed and ready-for-review protocol application and documents with an external expert. The expert will review your materials for appropriateness, risks to participants, and any issues related to the targeted population (legal and ethical). The local context reviewer cannot be a member of the research team or a funder of the research project, due to conflicts of interest.

Please note: if you are researching a minoritized domestic population, such as Puerto Ricans or rural Appalachians, the IRB office may also require a local context review.
**POPLATIONS TAB**

**IRB PROTOCOL - 19064**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
<th>Populations</th>
<th>Consent</th>
<th>Procedures</th>
<th>Data Security</th>
<th>Risks and Benefits</th>
<th>Compensation</th>
<th>Routing and Status</th>
</tr>
</thead>
</table>

**General populations**

- Adults 18 - 64 in the general population
  - Yes  
  - No

**NCSU students, faculty or staff**

- Yes  
- No

**Are you asking participants to disclose information about other individuals (e.g., friends, family, co-workers, etc.)?**

- Yes  
- No

**Minors (under age 18—be sure to include provision for parental consent and/or child assent)**

- Yes  
- No

**Prisoners (any individual involuntarily confined or detained in a penal institution -- can be detained pending arraignment)**

- Yes  
- No

---

If your research design either in the recruitment process or protocol design will include the NC State community, click “yes.”

The IRB must know if anyone under the age of 18 is included in your study. This is because there are additional federal regulations (subpart A of 45 CFR 46) for research with minors.

If minors are included in your research, you’ll need to address parental permission and minor assent on the “Consent” tab as well as upload parental permission and minor assent forms.

This question identifies whether you have third party research participants. Individuals who did not consent to be in your research or never agreed to have information shared about them for the purposes of your research are “third party participants.”

Anything in your research design that collects information about people other than those who consented to your research mean that your research includes third parties. You will, consequently, need to address throughout the application and supporting documentation how you will protect both participants and third parties.

A few examples of research that often includes third parties: studies about the workplace, life experiences of systemic marginality/discrimination/trauma, personal relationships, genomic information about families or cultures, and studies of parents and teachers.
### POPULATIONS TAB

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
<th>Populations</th>
<th>Consent</th>
<th>Procedures</th>
<th>Data Security</th>
<th>Risks and Benefits</th>
<th>Compensation</th>
<th>Routing and Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prisoners (any individual involuntarily confined or detained in a penal institution -- can be detained pending arraignment, trial or sentencing)</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Show Comments</td>
<td>Edit History</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Vulnerable populations (only if they are targeted groups for your study)

<table>
<thead>
<tr>
<th>Adults age 65 and older</th>
<th>Yes</th>
<th>No</th>
<th>Show Comments</th>
<th>Edit History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Show Comments</td>
<td>Edit History</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pregnant women</th>
<th>Yes</th>
<th>No</th>
<th>Show Comments</th>
<th>Edit History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Show Comments</td>
<td>Edit History</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fetuses</th>
<th>Yes</th>
<th>No</th>
<th>Show Comments</th>
<th>Edit History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Show Comments</td>
<td>Edit History</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Students</th>
<th>Yes</th>
<th>No</th>
<th>Show Comments</th>
<th>Edit History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Show Comments</td>
<td>Edit History</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Employees</th>
<th>Yes</th>
<th>Show Comments</th>
<th>Edit History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
<td>Show Comments</td>
<td>Edit History</td>
</tr>
</tbody>
</table>

**Prisoners require additional participant protections.**

**Elders may require additional participant protections. They may be incidentally included in your research if you answer “no” but they cannot be specifically targeted without answering “yes.”**

**When pregnant women are targeted, there are additional participant protections required. They may be included in your research if you answer “no” but they cannot be specifically targeted for inclusion in your research without answering “yes.”**

**Students are sometimes considered to be a vulnerable population, especially if their teacher is also the researcher. They may be incidentally included in your research if you answer “no” but they cannot be specifically targeted for inclusion in your research without answering “yes.”**

**Fetuses and neonates require additional participant protections.**

**Researching employees, especially if the researcher is employed by company or shares identifiable or re-identifiable data with the company, can put employees in a vulnerable category as can the inherent power imbalance if an employer creates social pressure to participate in research. Note that if you click yes to this question, you’ll have to answer additional eIRB question prompts. Employees may be incidentally included in your research if you answer “no” but they cannot be specifically targeted in your inclusion criteria without answering “yes.”**
In case of participants with impaired decision making or legally determined incompetence, the following hierarchy have the authority to give consent to research: the person themselves (if they gave permission before their competence diminished), the person’s legally chosen decision maker (sometimes next-of-kin, sometimes a friend) and then, lastly, a legally authorized decision-maker appointed by the court system. Note that you will have to edit your consent form’s signature lines to indicate who is signing on behalf of whom and that the person have the legal authority to do so on behalf of the participant. They may be included in your research if you answer “no” but they cannot be specifically targeted without you answering “yes.”

Just because a person may be diagnosed with a mental illness or cognitive impairment does not necessarily mean that they lack the ability to make an informed decision to consent to research; we expect you will edit your recruitment and consent material appropriately. They may be incidentally included in your research if you answer “no” but they cannot be specifically targeted without you answering “yes.”

<table>
<thead>
<tr>
<th>POPULATIONS TAB</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Employees</strong></td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
<tr>
<td><strong>Impaired decision making capacity/Legally incompetent</strong></td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
<tr>
<td><strong>Mental/emotional/developmental/psychiatric challenges</strong></td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
<tr>
<td><strong>People with physical challenges</strong></td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
<tr>
<td><strong>Economically or educationally disadvantaged</strong></td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
<tr>
<td><strong>Racial, ethnic, religious and/or other minorities</strong></td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
</tbody>
</table>
When researching educationally disadvantaged persons, we will be looking very closely at your recruitment, consent, and procedures processes to make sure that participants are adequately informed to legally consent to be in research.

If researching economically disadvantaged persons, we will be looking very carefully at your research design and compensation section to make sure that your design and compensation amount is not creating undue influence for this population to participate in research.

These individuals might be incidentally included in your research if you answer “no” but they cannot be specifically targeted without you answering “yes.”
If targeting a minority group, we will be evaluating the protocol’s anti-oppression bias. They may be included in your research if you answer “no” but they cannot be specifically targeted without you answering “yes.”

All recruitment, consent, and protocol materials used with non-English speakers must be professionally translated and submitted as part of the IRB review process. They may be incidentally included in your research if you answer “no” but they cannot be specifically targeted without you answering “yes.”

For every “yes” on the “Populations” tab, please provide justifications for why you’re targeting those vulnerable population(s).

*Convenience is not a valid justification.* A valid justification would be explaining why that population, through their life experiences or specialized skill sets, or physical ability and body structure is uniquely qualified to provide data that you cannot otherwise get from the general population.

**Technically speaking, why can’t vulnerable populations be incidentally included?**
CONSENT TAB

Only use the relevant template(s) linked in the question to develop your consent, parental/guardian permission, and assent forms.

We expect that, where relevant, you will also upload verbal script(s) appropriate to your population(s) discussing the research and the consent process before they sign the consent to be in the research. If your research is targeting pre-teens, your verbal script to the kids should be different from the parent/guardian’s.

You can link to the consent, permission, and assent template forms in this site here, but you can also find this information on our NC State IRB website on the “For Researchers” portal.

In this section detail the consent process for each participant group. There should be an uploaded consent form for each participant group – detailing the methods that they will experience. Here you would discuss if consent happens in person, on the phone, via the internet, etc.

In this section detail the assent process for minors and the process for attaining parents/guardian permission for their child to be in the research.

There should be an uploaded, age-appropriate assent form for the minor (and maybe more than one if you’re recruiting an age range, as our templates are for ages 7-10, 11-13, and 14-17 years old) as well as a parental/guardian permission form in your supporting documentation.

Updated 10/15/2019
CONSENT TAB

You only need to request a waiver of consent for Expedited or Full Board studies. To qualify for a waiver of consent, you must justify why your research:

1. Is no more risk to participants than they would encounter in normal daily life
2. Obtaining consent would prevent you from doing your research at all
3. Explain why getting consent is not practicable
4. And, if accessing identifiable data, why you need to use the data with identifiers.

Most research does not qualify for a waiver of consent.

“Opt Out” forms must meet the federal requirements for a waiver of consent.

A waiver of signed consent is only appropriate for your research if it serves as a participant protection (e.g. you’re researching a vulnerable population where a signed consent form could place your participant at additional risk) or if you are getting consent from a distance, such as an online Qualtrics survey.

A waiver of signed consent, if granted, still requires the PI to obtain informed consent from participants.

Updated 10/15/2019
**CONSENT TAB**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
<th>Populations</th>
<th>Consent</th>
<th>Procedures</th>
<th>Data Security</th>
<th>Risks and Benefits</th>
<th>Compensation</th>
<th>Routing and Status</th>
</tr>
</thead>
</table>

**Are you applying for a waiver of the requirement for consent (no consent information of any kind provided to participants) for any participant group(s) in your study?**

- [ ] Yes
- [ ] No

**Are you applying for a waiver of signed consent (consent information is provided, but participant signatures are not collected)? A waiver of signed consent may be granted only if:**

- The research involves no more than minimal risk
- The research involves no procedures for which consent is normally required outside of the research context.

- [ ] Yes
- [ ] No

**Are you applying for an alteration (exclusion of one or more of the specific required elements) of consent for any participant group(s) in your study?**

- [ ] Yes
- [ ] No

**Is there any deception of the human subjects involved in this study?**

- [ ] Yes
- [ ] No

---

Deception is where you deliberately leave out information or mislead participants about your study.

For exempt studies - If you click “yes” here, the only way for a study to remain exempt and include deception is if you include the paragraph in your consent form about deception and that you will go through a debriefing process with each participant. This process is required by the federal regulations. Our consent template has language about deception.

For Expedited and Full Board studies – if you include deception, you do not have to state that the study includes deception in the consent form, but you will have to debrief people at the end of the study and get their consent a second time after they’ve been debriefed to use the information that they were deceived about. Additionally, you will also need to click “yes” to apply for an alteration to the consent process due to the deception, debriefing, and then re-consenting participants to use their data for the research after you’ve debriefed them.

An alteration would be, for example, leaving out a piece of information that would tell participants the specific thing you’re researching. With alteration, participants still know the general topic you’re researching, unlike a study with deception.

---

Updated 10/15/2019
In the consent tab, you have this button to access your supporting documentation.

This is a good time to click and upload all of your recruitment and consent materials: flyers, drafted social media advertisements, verbal scripts, consent/parental permission/minor assent forms, etc.

All uploaded documents should be separate MS office documents and clearly labeled. Please title uploaded documents as <eIRB# document type> for example, “5320 parent permission form.”
Provide a number range for each participant group in your research. For example: 6-20 students and 6-20 parents will be recruited for the focus group, so in total, we will have 12-40 participants.

Tell us how you will find participants and screen them for research. Do this for each participant group separately as with the example above.
In this section, describe the varying recruitment methods that you will use to find your participants. For each recruitment method used there should be information about how that is implemented. Additionally there should be an uploaded document for each recruitment method used.

Create and upload as separate, editable Word documents all materials you’ll be using to recruit participants. This includes drafted emails, talking points, social media postings, paper flyers, ads, etc.

It might be appropriate to create different materials depending on the subsets of your desired participant pool (for example, teacher recruitment materials should be different from parent/minor student recruitment materials when you’re researching curricular pedagogy).

### Inclusion/exclusion criteria

Inclusion/exclusion criteria should be specific to each of your participant groups and be stated in the recruitment and consent materials for that participant group.

Inclusion/exclusion criteria are driven by your research question, study design, and participant protections. You must be able to justify why you are specifically excluding people or only including certain people.

---

**PROCEDURES TAB**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
<th>Populations</th>
<th>Consent</th>
<th>Procedures</th>
<th>Data Security</th>
<th>Risks and Benefits</th>
<th>Compensation</th>
<th>Routing and Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>For each participant group, how will potential participants be approached about the research and invited to participate? Please upload necessary scripts, templates, talking points, flyers, blurbs, and announcements.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Describe any inclusion and exclusion criteria for your participants and describe why those criteria are necessary (If your study concentrates on a particular population, you do not need to repeat your description of that population here.) Inclusion and exclusion criteria should be reflected in all of your recruitment materials and consent forms.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there any relationship between researcher and participants - such as teacher/student; employer/employee?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In the following questions describe in lay terms all study procedures that will be experienced by each group of participants.

For each group of participants you plan to recruit, include the following information:

1. **Informed consent:** The complete informed consent form should be uploaded to the study materials section as a separate upload. In addition to the consent form, there should be a cover letter that briefly explains the study objectives and provides contact information for the principal investigator. This cover letter should also include the study website or email contact so participants can learn more about the study and have access to the consent form if they choose to participate.

2. **Study procedures:** For each of the specified time points, the study procedures should be described in lay terms so that the participants can understand what they are expected to do. It is important to be clear about the timing of the procedures and any potential risks or discomforts associated with participation.

3. **Data collection:** The methods used to collect data should be described in detail, including the type of data (e.g., self-report, observational, physiological measures), the timing of data collection, and any potential risks or discomforts associated with the collection procedures.

4. **Data analysis:** The methods used to analyze the data should be described, including the statistical techniques, the assumptions underlying the analysis, and any potential limitations.

5. **Data confidentiality:** The measures taken to protect the confidentiality of the data should be described. This includes details about the data storage and access procedures, as well as any steps taken to prevent unauthorized access.

6. **Participant rights:** The rights and responsibilities of participants should be clearly outlined. This includes information about the right to withdraw from the study at any time, the right to receive compensation for participation, and the right to access their own data.
PROCEDURES TAB

In the following questions describe in lay terms all study procedures that will be experienced by each group of participants in this study.

For each group of participants in your study, provide a step-by-step description of what they will experience from beginning to end of the study activities.

Are you requesting the use of existing information to be used as data for this research project or are you requesting secondary data to be used as data for this research project? (Discuss the following: access, transfer, storage, destruction, (re)identifiable nature of the data and if data is subject to FERPA or HIPAA)

This section is addressing the use of secondary data. Secondary data is information or bio-specimens that was collected for non-research purposes or another research protocol but that you wish to now use for research purposes in this protocol.

You can use this section to discuss the protocol’s use of existing or not yet existing data (but will exist at the time you wish to access it)

Make sure to state if the existing data is identifiable, re-identifiable, completely de-identified and not re-identifiable, commercially available, or public. Discuss how you have access to the data, how you have permission to access the data, how the data is transferred, stored, and disposed of.

The step-by-step description should be written so that any adult will understand what is occurring in your study from the beginning (recruitment and selection) to the end (data disposition) and be able to replicate your study based on the steps you give them here.

If you have multiple participant groups, describe what each participant group will experience in separate paragraph sections. For example, a minor will not have the same step-by-step process that their adult guardian will have.

Tip: discuss time commitment for each part of the study, discuss what happens in person, online, in the lab, at home, etc.

On this tab, you have a button to access your supporting documentation. This is a good time click it and upload all procedural materials for the protocol, and tools as separate, editable Word documents for review.
An example of existing data without identifiers would be an anonymous, aggregated, publicly available data set. Only if your study is truly anonymous—for example, an online consent and survey through Qualtrics (with the IP tracking turned off and no personally identifiable information collected)—should the answer here be “yes.”

### Existing data with identifiers

Existing data with identifiers could be, for example, completed student assignments with names and grades on them.

Identifying information also includes photographs, audio or video recordings, and personally identifiable records.
**Indirect identifiers** include, but are not limited to, sex, gender, race, title, geographic location, age or birth date, unique content that could be triangulated through access, technology, comparison information, or unique demographics.

A **master list** links participant identifiers, such as names, to the code or ID number the PI assigns to an individual for the research so that the research data, with the use of a master list, can be linked to individuals. A master allows researchers to track which participant provided what data while keeping the data coded so that someone who gained access to the data, but not the master list, would not know who provided what data.

A **crosswalk** is a table that takes unique participant identifiers and groups that data into thematic units while still retaining direct participant IDs.
Voice and video recordings, as well as images of faces, tattoos, scars, unique marks, or other unique features are considered identifiable data. Please describe this procedure on the procedures tab.

In your consent, parental permission, and minor assent form templates, you have the choice to make photography, audio, and video recording a mandatory part of research or an optional part of research.

If you offer participants a choice, then your protocol application will need to articulate the processes by which you’ll track and honor the choice(s) that the particular individual made regarding the recording and images. Offering participants a choice can make data collection harder for PIs, but it also can build trust with participants, particularly with vulnerable populations.

Digital and electronic files can include online survey results, digital screening tools, online consent form, and researcher process notes.

All paper records with direct participant IDs, including signed consent/parental permission/assent forms and researcher process notes, should be kept under two physical locks, such as a locked door and a locked filing cabinet, at all times when not in use by the researcher.

Physiological responses ARE NOT covered by HIPAA unless you’re a researcher within a HIPAA-covered entity.

There are few NC State departments that are considered HIPAA covered entities. These include things like student health, the counseling center etc. If you are unsure if your department is HIPAA covered, please check with your supervisor.

Physiological responses typically include the use of sensors, trackers, swabs, breath, heartbeat. etc. This should all be addressed in the procedures section of this application.
### DATA SECURITY TAB

<table>
<thead>
<tr>
<th>Categories</th>
<th>Yes</th>
<th>No</th>
<th>Show Comments</th>
<th>Edit History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audio recordings?</td>
<td>☐</td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Video recordings?</td>
<td>☐</td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Images?</td>
<td>☐</td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Digital/electronic files?</td>
<td>☐</td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paper documents (including notes and journals)?</td>
<td>☐</td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physiological Responses?</td>
<td>☐</td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Online survey?</td>
<td>☑</td>
<td>☐</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If you are creating an **online survey**, select “yes” and please use Qualtrics to create the survey. You will need to upload a full copy of the survey questions to your supporting documentation as an editable Word document. You will also need to set up the survey so that individuals will consent first before being able to access the survey.

VPN is necessary for the transfer of identifiable or re-identifiable participant data. The use of VPN is a way to protect your activities from others when accessing data, using software on a network, or browsing the internet.

**Encryption** is a way to protect your computer, drives, folders, and files while they are transferred or at rest. Encryption requires software to “encrypt” the item you want to protect. The software will provide you a password – that without – you cannot access the item. Encryption makes it incredibly difficult for the data to be breached or accessed inappropriately. You do not need to encrypt data that is de-identified and not re-identifiable. You should encrypt any identifiable data, master list, or crosswalk. Please refer to the NC State data security regulation and framework for updated guidance.

**Anonymous browsing** is only relevant for studies that include activities completed online, such as an online consent or survey.

Anonymous browsing means that you have told the participant to use a web browser in private/incognito mode.

If the survey collects private or sensitive information, we expect that you will advise participants to take the online survey in a private location, on a private internet connection, within a browser that is in private/incognito mode, and, once finished with your survey, to clear the browser’s history, delete cookies, and close the browser.

**Special Note:** You must think about **data protection** throughout the lifecycle of your data. This includes when it is initially collected/accessed, how it’s transferred, how it’s accessed, who has access, how it’s stored, and how it’s disposed of. You can find data security management guidance on the IRB website. You can also find a primary data management and access plan template and a secondary data management and access plan template to use for your study. We strongly suggest working with your departmental IT to address your data security needs and, for some protocols, require it.

Updated 10/15/2019
DATA SECURITY TAB

To answer this question, it is helpful to think of the participant identifiers that you’re collecting or using in each stage of the research process: recruitment, consent, data collection, data analysis, and data publication. As you write your answer, the following fill-in-the-blanks may be helpful to you. Note that while we provided 3 examples, don’t forget to copy each fill-in-the-blank set and adapt to discuss third parties if your research includes them (it does with research with minors, for example, and many types of qualitative research).

*Recruitment*
The direct identifiers that I will be collecting about participants in the recruitment process are _______________________. (e.g. name, email, phone number etc.)
The indirect identifiers that I will be collecting about participants in the recruitment process are _______________________. (e.g. race, sex, gender, age etc.)
It is necessary to collect those IDs for my research because _______________________. (give reason why you need those IDs to do your research)
I will use these identifiers until ________________ . (specify when in the research process you will not need these identifiers--it may be that you need indirect IDs much longer than direct IDs so definitely specify how you'll be handling both)
I will remove participants direct identifiers from the research data by____________________ when ________________ .
I will remove participants indirect identifiers from the research data by____________________ when ________________ .

*Consent*
The direct identifiers that I will be collecting about participants in the consent process are _______________________. (e.g. name, IP address if consent is online etc.)
The indirect identifiers that I will be collecting about participants in the consent process are _______________________.
It is necessary to collect those IDs for my research because _______________________.
I will use these identifiers until ________________ .
I will remove participants’ direct identifiers from the research data by____________________ when ________________ .
I will remove participants’ indirect identifiers from the research data by____________________ when ________________ .

*Data collection*
The direct identifiers that I will be collecting about participants in the data collection phase are _______________________.
The direct identifiers that I will be using about third party participants in the data collection phase are _______________________.
The indirect identifiers that I will be collecting about participants in the data collection phase are _______________________.
The indirect identifiers that I will be using about third party participants in the data collection phase are _______________________.
It is necessary to collect those IDs for my research because _______________________.
I will use these identifiers until ________________ .
I will remove participants direct and indirect identifiers from the research data by____________________ when ________________ .
I will remove third party participants direct and indirect identifiers from the research data by____________________ when ________________ .
DATA SECURITY TAB

Tell us about any participant IDs in the recruitment, consent, or protocol process that you will be keeping and if/how you’ll be de-identifying or de-coupling the data from unique participant IDs. Justifications for keeping identifiable data include – follow up for longitudinal studies, pairing data sets together (and then deleting IDs once paired).

In your response, separate participants and third parties. The following fill-in-the-blanks may be helpful:

Participants could be identified by the following data points: _______________. (specify each one and how the data point could re-identify individuals on own, such as name, or in conjunction with other data points you’re collecting or that are publicly available)

I will protect participants from being identified by _______________ (some solutions are to report data in large enough N sizes that it’s impossible to identify someone or publishing a composite participant sketch instead of a re-identifiable participant sketch).

The likelihood of participants being identified through my research is _______________ (identify level of likelihood, such as negligible, minimal, possible, likely, very likely).

If participants are identified, the risk of harm to a participant is _______________ (identify level of risk, such as negligible, minor, moderate, significant, severe).

Third parties could be identified by the following data points: _______________.

I will protect third parties from being identified in this data by _______________.

The likelihood of a third party being identified through my research data is _______________ (identify level of likelihood, such as negligible, minimal, possible, likely, very likely).

If a third party is identified, the risk of harm to them or others is _______________ (identify level of risk, such as negligible, minor, moderate, significant, severe).

We strongly advise that you work with your departmental IT person to create a protocol-specific data management plan as well as consult the NC State IRB website’s For Researchers portal section on data management and security.
**DATA SECURITY TAB**

Recordings here mean audio, recordings, photography, or video recordings. If you plan to create any recordings, they must be stated in the consent form and agreed to by the participant(s) you want to record. For each type of recording, you will need to answer all of the questions listed above.

For all recordings of any type:

- Describe the type of recording(s) to be made
- Describe the safe storage of recordings
- Who will have access to the recordings?
- Will recordings be used in publications or data reporting?
- Will images be altered to de-identify?
- Will recordings be transcribed and by whom?

Describe how data will be reported (aggregate, individual responses, use of direct quotes) and describe how identities will be protected in study reports. Reporting data may sometimes reidentify your participants. If needed, you can adjust how you report your data to protect the identities of your participants. Discuss.

Will anyone besides the PI or the research team have access to the data (including completed surveys) from the moment they are collected until they are destroyed? This includes sharing data with sponsors, journals, or using the data for future research endeavors. If you are sharing the data, this should be in your consent form.

Especially if you’re reporting qualitative data with a small N, we need to know how you will report your data that will protect participants and third parties from being identified or re-identified.

Whatever you say here must match your “confidentiality, personal privacy, and data security” section of the adult consent or parental permission form. It’s okay to separate out how raw, identifiable data will be handled (by PI and research team only) and the de-identified data that can be used for presentation, publication, and future research uses.

Updated 10/15/2019
**RISKS AND BENEFITS TAB**

**As a result of the procedures you have employed, could a participant’s (or third party’s) **social status or reputation** be harmed? Would being in your study lose them friends? Cause difficulty in public? Harm their relationships?**

**As a result of the procedures you have employed, could a participant’s (or third party’s) **financial well being or employability** be affected? For example, could they lose out on money? Could they be fired? Could they be taxed more?**

**Physical risks** related to the procedures include issues like fatigue, strained muscles, side effects of interventions, etc. These should be communicated and minimized – often through participant exclusion.

**Potential Risks**

Provide information about the risks to participants in your research. Risks can arise from research procedures such as data collection, data analysis, and reporting. Take a minute and think about how your research and data collection might impact your participants.

Please indicate any reasonable risks in the categories below:

<table>
<thead>
<tr>
<th>Risks as a result of methods employed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social/Reputational</td>
</tr>
<tr>
<td>Psychological/Emotional</td>
</tr>
<tr>
<td>Financial/Employability</td>
</tr>
<tr>
<td>Legal</td>
</tr>
<tr>
<td>Physical</td>
</tr>
</tbody>
</table>

**Psychological/emotional risks** that can be present in research include information, activities, or questions that could be experienced by participants as uncomfortable, disturbing, or triggering, as well as some studies with deception.

**Risks as a result of the methods** used are related to issues that could come up for participants as a result of your procedures. For example, are you asking them to complete physical activities? This could bring about physical risks. Are you asking them to be a part of a public intervention that addresses mental health issues? This could bring about social/reputational risks. You can do research that has risks involved, you just need to communicate those risks to participants and try to mitigate risks through study design and data protection.

**Could the information that you are collecting from the participant (or third party) – lead to any legal issues for the participant? For example are you researching underage drinking, experiences from undocumented immigrants, hunting violations, illegal behavior on the “dark web.” Here you would indicate if you are collecting information that could put a participant in legal trouble.**

---

Updated 10/15/2019
**RISKS AND BENEFITS TAB**

**Legal:** As a result of the data you have, access, or collect – could that data put participants at legal risk if it is accessed inappropriately? For example: the data is about tax evasion, documentation status, under age drinking, Title IX violations, workplace safety, abuse.

**Academic:** As a result of the data you have, access, or collect – could that data put participants at risk? For example could the data you have make the student fail a class, not graduate, have their degree revoked, not get the internship they want, get in trouble with student conduct?

**Employment:** As a result of the data you have, access, or collect – could that data put participants at risk of losing their job? For example: do you ask about counter productive work behavior, discrimination in the workplace, misuse of office supplies, office policy violations?

**Medical:** As a result of the data you have, access, or collect – could that data put participants at risk for finding medical care or other medical treatment?

**Financial:** As a result of the data you have, access, or collect – could that data put a participant’s financial life at risk? Could they lose money, have to pay money, lose out on options, etc.?

**Insurability:** As a result of the data you have, access, or collect – could that data put participants at risk to losing their insurance or not getting insured? For example if your data asks about pre-existing conditions or risky health behaviors – that could directly affect their eligibility if the data is inappropriately accessed.
RISKS AND BENEFITS TAB

For every yes indicated in the radial buttons above this box, you will need to discuss the risks specific to your protocol, the likelihood of those risks, and the magnitude of harm should those risks occur.

You can use the following language:
The risks involved in this research are ____. The magnitude of harm to participants if those risks occur is ____, specifically ____ could occur. The likelihood of the risk occurring is ____ because of study design such as ____ and data management such as ___.

If your research collects sensitive or private information about your participants or third parties, describe how you’re protecting them while you use their private or sensitive data.

For example, if you’re collecting participant bio-specimens, it would be appropriate here to specify how access to this raw data is limited, who can access it, that it won’t be shared or mined by others outside the research team, private companies or law enforcement, and will be securely destroyed after data is coded and de-identified.
Mitigation occurs through study design (e.g. inclusion/exclusion criteria, safety plan and procedures, data management plan with identifiable data) and in the mitigation of risk when the protocol is deployed.

For research that involves risky procedures, we expect that you will articulate a risk management plan that identifies potential risks and the plan that you will implement if they occur.

For example, with studies that involve physical exertion, we expect that participants will be in good health & medical clearance prior to the study, and that the physical exercise will be sandwiched with a proper warm-up, a cool down, and directions to not exert maximum physical effort.

Similarly, for studies that involve psychological risk or the potential for re-traumatization, we hope that interview questions are designed to elicit personal experience in a “challenge-by-choice” type of way so that the participant is actively choosing what, or how much, to share with researchers and that you have professional training to identify if someone is triggered or suffering by participating in your research and that you’re able to refer them to community resources to get the appropriate support they need.
Compensation can be monetary or non-monetary, such as receiving academic credit, small gift in the amount of __, gift cards, cash, etc.

The eIRB application inquires about compensation in order to assess whether the compensation might unduly influence a person to participate in your study; compensation is not, however, mandatory for a successful IRB application.

When compensating, think about what compensation best fits your targeted participant pool to encourage them to participate, but not be so much that they “can’t say no.”

Some compensation pro-tips include:
1. If offering course credit, there needs to be an alternative option for the same amount of credit for equal time and effort. A five question, multiple choice research survey is not the time and effort equivalent of a 15-20 page paper.
2. Make sure the compensation amount is consistent across the eIRB application, the consent forms, and the recruitment effort.
3. Participants should not have to do math in order to understand the research compensation for participating.

If offering compensation, talk with your funder or business office when you’re writing this application to ensure that their policies and procedures match what your eIRB application and your “confidentiality, personal privacy, and data security” section of your consent form say.

Studies can choose to offer full, partial, or no compensation to participants who withdraw prior to a study’s completion. Whatever choice you make is OK, but we need to make sure that participants’ know what to expect and that the compensation policy is just and equitable.
 ROUTING AND STATUS TAB

This box tells you what stage of review your protocol is at and who is responsible for the next step: PI or IRB Administrator.

Ignore this column as it’s auto-generated and often doesn’t align with IRB office flow.

These columns remain blank through the protocol application process—ignore them.

These columns will auto-populate when administrative action occurs with your protocol.

Here’s the button to click when your protocol is ready for an administrative review by the IRB office. Note, only a faculty point of contact will be able to see these buttons—“additional personnel” cannot submit on their own. Students on a protocol, even if functioning as the PI, also cannot submit on their own.

Terms in the Status Column

Submitted: This means that the application has been submitted to the IRB office via the eIRB system.

Returned for Revision: This means that the application has been returned to the researchers for edits and needed changes.

Review Complete: This means that a Board member has reviewed the application and completed a review. This is not approval.

Approved: This means that the eIRB application is approved as written. This is approved via Expedited procedures or Full Board procedures.

Expedited Review: This means that your study is receiving Expedited review and it is in the queue of a Board member.

Administrative Review: This means that your study is in the queue of the IRB office.

Exempt: This means that your study has received IRB approval and the IRB office determined it to be exempt under the current federal regulations for research with human subject.
**Application Timetables**

Turn around time is directly related to IRB queue volume, quality of protocol submission, type of required level of review, and how quickly the research team responds appropriately to all requests. The below timetables present ideal scenarios.

### Exempt Study

<table>
<thead>
<tr>
<th>Review Level</th>
<th>Status</th>
<th>Date</th>
<th>Time</th>
<th>Target for Next Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Originator/PI</td>
<td>Submitted</td>
<td>5/21/2019</td>
<td>1:27PM</td>
<td></td>
</tr>
<tr>
<td>IRB Administrator</td>
<td>Returned for Revision</td>
<td>5/28/2019</td>
<td>11:59AM</td>
<td>Dates are auto-generated; please ignore.</td>
</tr>
<tr>
<td>Originator/PI</td>
<td>Submitted</td>
<td>6/1/2019</td>
<td>6:11PM</td>
<td></td>
</tr>
<tr>
<td>IRB Administrator</td>
<td>Review Complete</td>
<td>6/7/2019</td>
<td>4:14PM</td>
<td></td>
</tr>
<tr>
<td>IRB Administrator</td>
<td>Approved</td>
<td>6/7/2019</td>
<td>4:14PM</td>
<td></td>
</tr>
</tbody>
</table>

### Expedited Study

<table>
<thead>
<tr>
<th>Review Level</th>
<th>Status</th>
<th>Date</th>
<th>Time</th>
<th>Target for Next Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Originator/PI</td>
<td>Submitted</td>
<td>5/9/2019</td>
<td>8:34PM</td>
<td></td>
</tr>
<tr>
<td>IRB Administrator</td>
<td>Returned for Revision</td>
<td>5/14/2019</td>
<td>5:26PM</td>
<td></td>
</tr>
<tr>
<td>Originator/PI</td>
<td>Submitted</td>
<td>5/25/2019</td>
<td>3:35PM</td>
<td>Dates are auto-generated; please ignore.</td>
</tr>
<tr>
<td>IRB Administrator</td>
<td>Review Complete</td>
<td>5/28/2019</td>
<td>8:38AM</td>
<td></td>
</tr>
<tr>
<td>Expedited Review</td>
<td>Expedited Review</td>
<td>5/28/2019</td>
<td>8:42AM</td>
<td></td>
</tr>
<tr>
<td>Expedited Review</td>
<td>Review Complete</td>
<td>5/30/2019</td>
<td>1:10PM</td>
<td></td>
</tr>
<tr>
<td>IRB Administrator</td>
<td>Returned for Revision</td>
<td>5/31/2019</td>
<td>10:10AM</td>
<td></td>
</tr>
<tr>
<td>Originator/PI</td>
<td>Submitted</td>
<td>6/6/2019</td>
<td>12:55PM</td>
<td></td>
</tr>
<tr>
<td>IRB Administrator</td>
<td>Review Complete</td>
<td>6/7/2019</td>
<td>8:54AM</td>
<td></td>
</tr>
<tr>
<td>IRB Administrator</td>
<td>Approved</td>
<td>6/7/2019</td>
<td>8:54AM</td>
<td></td>
</tr>
</tbody>
</table>

Updated 10/15/2019
## Application Timetables

### Full Board Study

<table>
<thead>
<tr>
<th>Review Level</th>
<th>Status</th>
<th>Date</th>
<th>Time</th>
<th>Target for Next Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Originator/PI</td>
<td>Submitted</td>
<td>5/6/2019</td>
<td>9:10AM</td>
<td></td>
</tr>
<tr>
<td>IRB Administrator</td>
<td>Returned for Revision</td>
<td>5/8/2019</td>
<td>1:07PM</td>
<td></td>
</tr>
<tr>
<td>Originator/PI</td>
<td>Submitted</td>
<td>5/18/2019</td>
<td>11:53PM</td>
<td></td>
</tr>
<tr>
<td>IRB Administrator</td>
<td>Review Complete</td>
<td>5/20/2019</td>
<td>9:22AM</td>
<td></td>
</tr>
<tr>
<td>IRB Administrator</td>
<td>Scheduled for Committee Review</td>
<td>5/20/2019</td>
<td>10:04AM</td>
<td></td>
</tr>
<tr>
<td>IRB Administrator</td>
<td>Returned for Revision</td>
<td>6/4/2019</td>
<td>8:10PM</td>
<td></td>
</tr>
<tr>
<td>Originator/PI</td>
<td>Submitted</td>
<td>6/18/2019</td>
<td>11:44PM</td>
<td></td>
</tr>
<tr>
<td>IRB Administrator</td>
<td>Review Complete</td>
<td>6/19/2019</td>
<td>10:55AM</td>
<td></td>
</tr>
<tr>
<td>IRB Administrator</td>
<td>Approved</td>
<td>7/19/2019</td>
<td>10:55AM</td>
<td></td>
</tr>
</tbody>
</table>

Dates are auto-generated; please ignore.
RENEWAL

Renewals only need to be submitted if your approved study received Full Board review or was approved as “Expedited” before January 19, 2019. In rare cases, some mid-level review (“Expedited”) studies approved after January 19, 2019 do require annual renewal. Consult the IRB office if you are unsure.

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
<th>Populations</th>
<th>Consent</th>
<th>Procedures</th>
<th>Data Security</th>
<th>Risks and Benefits</th>
<th>Compensation</th>
<th>Routing and Status</th>
</tr>
</thead>
</table>

a. Renewal/Amendment Request form

   ii. Guidance should include not just the questions, but then how they change the rest of the application—e.g. narrative boxes should have an additional paragraph where it says, AMENDMENT (MM/DD/YYYY): Then what they want to change.

iii. Questions for the renewal

   1. Are you applying for a renewal (continuing review)? If yes, please make sure to answer all the subsequent questions.
   2. Project status as of the date of this application
   3. Is the number of participants enrolled to date different from the number originally approved?
   4. Did any participants withdraw from your study?
   5. Were there any adverse events or unanticipated problems in your study?
   6. Were there any complaints from participants or others regarding this study?
   7. Is there any new information since the last IRB review which may impact the risks and benefits of your research?
   8. Has the protocol for this study been revised since the last IRB approval date?
   9. Have there been any changes regarding funding for this study?
 10. Briefly list study activities conducted since the last data of approval or renewal?
 11. When do you anticipate data analysis will be complete?
 12. Please describe any answers above that indicate a special consideration for your research, such as participant enrollment numbers that do not match those approved by the IRB, participant withdrawals, complaints, new information, or adverse events/unanticipated problems.
 13. Are you requesting termination of this protocol?
 14. Have all data, including video and/or audio recordings, been destroyed, or properly stored with identifiers removed, as per the originally approved IRB application?
 15. Please detail how participant-identifiable information was removed from study records.
 16. Is there any additional research beyond that which was intended and approved for this study?

To file a renewal, go to your protocol’s Title tab. Scroll down and click the “Add New Renewal/Amendment Request” button. You’ll then see the above questions. Answer all of the questions and click the “Save” button at the top of the page. Then go to the Routing and Status tab and submit the protocol to the IRB office for review and approval of your protocol’s renewal.

Updated 10/15/2019
AMENDMENT

Amendments are filed any time you want to make a change to an approved protocol. A change can be something simple like changing members of the research team or complex, such as changing a procedural detail. Any changes to your approved protocol must be proposed through an amendment and approved by the NC State IRB office before you implement the changes.

iv. Questions for the amendment
1. Are you applying to amend your protocol? If yes, please make sure to answer all subsequent questions.
2. Do the requested changes impact the study design or methodology (examples: addition of data collection method, audio/video recording)?
3. Do the requested changes impact the eligibility criteria of participants?
4. Do the requested changes affect the number of participants recruited and/or enrolled?
5. Are requested changes limited to editorial and/or administrative changes (examples: change in research staff, wording of informed consent, survey revisions)?
6. Do the requested changes affect risks and/or benefits expected from participating in the study?
7. Do the requested changes affect anonymity and/or confidentiality?
8. Please summarize the changes you want to make to your study. This includes a brief outline of requested changes, an outline of the repercussions of those changes (example: edits to study documents as a result of new directions or compensation) and please justify the need for these changes. This section serves as a summary of total changes. You still need to make the changes to the appropriate sections in this protocol and upload edited documents with all changes tracked.
9. Not a question, but guidance for the PI going forward: When this request is complete, edit the protocol and associated documents (tracking your changes) to reflect any requested changes. Then go to the Routing and Status tab to submit the request to the IRB office. (edit button)

To file an amendment, go to your protocol’s Title tab. Scroll down and click the “Add New Renewal/Amendment Request” button. You’ll then see the above questions. Answer all of them thoroughly, especially #8 where you will outline all the changes you want to make to the protocol, provide the reason(s) for those changes, and the implications of those changes on your research design, participant pool, and data.

Once you’ve answered all the questions on the Title tab’s Amendment request, click the “Save” button at the top of the page. Then go through your entire eIRB application, tab-by-tab and question-by-question, and alter your application to reflect the changes that you propose in your amendment. For radial button answers, just

Updated 10/15/2019
change the answer; DO NOT, however, delete any narrative answers in your approved protocol. Simply add another paragraph in the narrative box that begins with “Amendment filed MM/DD/YYYY: ______________________________.” Change the date to reflect the date of the amendment. Use the fill-in-the-blank to describe what you want to change in the protocol that is relevant to that narrative question prompt. This can be a sentence to several paragraphs depending on the amount of changes you want to make to your protocol. Adding the additional paragraph(s) about the amendment changes without changing the existing approved narrative allows for an accurate history of what was approved and what has changed in your protocol.

Once you’ve edited all application tabs, you will need to upload any revised or new documents for your protocol. Documents may be changed because you are editing them for readability, removing or adding information or questions, or because you are changing something in the procedures has affected an approved document (such as participant compensation or time commitment). If you’re editing a previously approved document (for example, editing a consent form), upload your revised consent form with all changes you made to the consent in Word’s “track changes” mode. You might also add new documents to your protocol’s supporting documentation during the amendment process because you’re adding additional procedures or methods, expanding your study or participant pool, or are moving to another phase of your project.

After all the changes to the eIRB application and supporting documentation are completed, go to the Routing and Status tab and submit the protocol to the IRB office for review and approval of your protocol’s renewal.