Basic Introduction to the eIRB

- **eIRB**: [https://www3.acs.ncsu.edu/hs/irb.php](https://www3.acs.ncsu.edu/hs/irb.php)
  - Login with your unity ID and password
- Help Line: 919.515.4514

The eIRB is our online system where you submit and manage your applications for research with human subjects. This portal allows you to submit new applications, revise approved applications, and view all of your human subjects research in one place.

This document provides “screen shots” of the database so that you can read through what to expect as you complete or revise your application.

You will notice that there are detailed questions in the eIRB. This is so that you are aware of the flexibility you have within the regulations when you initially submit your applications (ex: options for consent). This should be helpful because you can now plan for these opportunities before you start the application process, instead of finding out options during the review process.

### Tips for using the eIRB and submitting your application:

- **All applications must be submitted by the faculty sponsor/advisor but they can be completed by other people associated with NCSU. The “Faculty point of Contact” is the only one who is able to submit the application.**
  - Identify the faculty sponsor/advisor as the “faculty point of contact.”
  - If a student is completing the application, immediately after selecting the “faculty point of contact,” they should add in their own information in the “Additional Personnel” section. **MAKE SURE TO ADD IN THE UNITY ID of the additional personnel.** Adding the unity ID, allows the study to be associated with the additional personnel so that it can be searched for under their name/edited/e-mail communications.
  - Additional personnel can fill out all the fields and attach the appropriate documents and then send it to the faculty sponsor. Before submitting, the faculty sponsor and student can edit the fields as needed. The faculty sponsor should read the application, ensure appropriate documents are included and finally, submit the application.
  - The system uses unity ID to track who has access to a project. So, if you are listed but your unity ID is NOT listed, then you will not have access to the project.

- **Make sure to submit your supplemental documents. Label them appropriately (see below):**
  - Label all documents with “LastName eIRB Number Document Type”
    - Example: “Ofstein 1111 Survey for Students” or “Ofstein 1111 Parent Consent”
  - Supplemental documents to be included are: any surveys, interview protocols, focus group protocols, informed consents, parental consents, child assent, recruitment scripts, announcements, fliers, images used, and anything else that a participant would see/experience as part of your research. **Do not** “Cut and Paste” language from other proposals into this database. It is often confusing, not in lay language, rarely addresses the question, and complicates the review process.

- **If you are completing your application and there is NO ACTIVITY for around 30 minutes, then the shibboleth login authentication will time out which will mess with your application. So, MAKE SURE TO SAVE YOUR WORK before you divert your attention from the application as it will “Time Out.” Make sure to click the “Save” button frequently (it’s just good practice).**

- Sometimes, when you click “yes” or “no” to a question, that action prompts the request for other information. This will manifest in the form of other questions appearing on the application, when before they were not there.

- **If a window is supposed to pop up, and you can’t seem to see it, check behind your other windows open on your computer. Sometimes, how you click around on your machine, makes the window appear to be behind your other windows.**

- **Your name may be listed 2 or 3 times in the search fields on the Introductory page where you can search for studies. This is because you may have been entered in multiple times as “Additional Personnel” with slight differentiations in the data entry. This could also happen if you are listed as a “Faculty Point of Contact” on some studies and as “Additional Personnel” on other studies. Make sure to look through both names when looking for your studies. If listed more than 2 times, edit through your “Additional Personnel” information and make sure your name is spelled the same way each time and that your noted e-mails and unity ID match in each study.**
- Go to this website: [https://www3.acs.ncsu.edu/hs/irb.php](https://www3.acs.ncsu.edu/hs/irb.php)
- Once there, log in with your Unity ID and Password
- After you log in, you will be taken to the introductory page. See below.

Once you click, “Create New Protocol” You will be taken to the screen below. It opens to a page with multiple tabs. The first tab shown is the “Title” tab. See below for two screen shots describing the “Title” tab.
Selecting the Faculty Point of contact from the “Title” tab.

**Step 1:** Click the “Select Point of Contact”

**Step 2:** The box above will pop up.

**Step 3:** Click in the center of the white box above and a list of eligible Faculty/EPA points of contact will pop up. See page 4 for image.

**Step 4:** Select the point of contact. See page 4 for image.

**Step 5:** Once point of contact is selected, click “Select Point of Contact” again and the Title tab will populate as shown on page 4.

If you think you should be listed as an eligible Faculty/EPA point of contact, please contact: 919 515 4514 or email irb-coordinator@ncsu.edu. Graduate students: This should be your Advisor, Chair, or sponsoring Faculty or EPA staff member.
The screen shot below is an image that demonstrates what it should look like when you are selecting your point of contact. Please follow the steps noted above (on page 3) for selecting Point of contact.

Once Point of contact is selected AND saved, the title page changes. You now see this:

Notice: a new field has opened. You can now add additional researchers/collaborators to your study. By clicking the “Add New Personnel Record” button, and adding appropriate the information, you will be noting other involved researchers. See page 5 for details.

Graduate students, this is where you will enter in your information.

Because you saved it after selecting the point of contact, your Protocol number (eIRB) is now shown.

Note: The information from the “Faculty Point of Contact” you selected has populated into this field on the “Title” tab.

All applications must be submitted by the faculty sponsor/advisor but they can be completed by other people associated with NCSU. The “Faculty point of Contact” is the only one who has access to submitting the application. Identify the faculty sponsor/advisor as the “faculty point of contact.”
Since you “saved” your study, and it has now been assigned a protocol/eIRB number, the “Title” tab has some other changes to it. You will now see 3 new fields. One for adding new personnel as noted on page 4, one for adding/viewing supporting documentation for your study, and one for adding new sponsored projects records.

This is where you can add “additional study personnel” to the eIRB record. By clicking this button, a new window will pop up. In that window, add in additional information. Please see screen shot below for details.

This is where you will upload all supplemental study documents such as instruments, consents, advertisements, etc. See pages 6-9 for details.

Your application is INCOMPLETE unless you submit your supplemental documents. We cannot approve your research without them.

This is where you can add information in regarding any “sponsored” program information.

This is how you add additional personnel to your study.

If a student is completing the application, immediately after selecting the “faculty point of contact,” they should add in their own information in the “Additional Personnel” section. MAKE SURE TO ADD IN THE UNITY ID of the additional personnel. Adding the unity ID, allows the study to be associated with the additional personnel. This allows access to the study via search, editing rights, and receipt of all e-mail communication.

If someone beside the “faculty point of contact” is completing this application, they can fill out all the fields and attach the appropriate documents. The faculty sponsor and student can edit the fields as needed before submitting. The faculty point of contact is the only person who has access to submit the final application.

**Communications regarding this study will be sent to the Faculty point of contact AND any e-mail address or unity ID listed in the personnel record section.**
Once the additional researcher(s) has been added, the “Title” tab will look like this (below). Please note the additional personnel added. You can edit the personnel information by clicking “edit” in the field by the name you want to edit.

Adding your Study Documents to the application. This is one of three places that you can add your study documents. They all arrive in the same spot, but you have 3 different places where you can upload them. You can upload them on the following tabs: Title, Consent, and Procedures.

Click here to add your study documents.

All documents should be saved as Word document, “.docx” and editable (an occasional PDF is okay if it is not possible to put it in Word).

ALL documents that you edit from the originally approved documents should have their changes TRACKED before uploading them.

There are two other places to upload documents (they all go to the same place). You can also upload documents on the “Consent” and “Procedures” tabs.
By clicking on “Add/View Supporting Documentation” from the “Title,” “Consent,” and/or “Procedures” tabs, a new window will open up. The coloring looks a little different. Please see below.

The “Browse” button will allow you to select a document from your computer so that it can be uploaded.

The “Upload File” button actually uploads the file you selected.

Before uploading any files, make sure to save each file with the appropriate file name.

“LastName eIRB# File Type” “Paxton 53855 Survey - Student”
Once documents are uploaded in the new window, this is what will be displayed:

- **Name of documents uploaded. IRB approved documents will have the word “final” in the title and will also have been uploaded by an IRB staff member.**
- **Info about who uploaded what document.**
- **Date/Time document was uploaded.**
- **This row of boxes allows you to sort all the uploaded documents (some studies have many).**

If you want to add in information about your project regarding sponsorships or project records, click “Add new Sponsored Project Record.” See below:
By clicking on “Add new Sponsored Project Record” from the Title page, a window will pop up.

Tab: “Description” - On this tab you will provide descriptions about what your research is about. Enter in information into each field. When answering a “yes” or “no” question, your response may prompt other questions to pop up.

Enter in the PINS or SPS project number here. Click “Save” to ensure your data is saved.

You can add another record by clicking “Add Another Sponsored Program Record”

You can tell which tab you are on, because it will look like this (white).

Each tab has open fields like this one. This is where you write in answers.

When the IRB has made a comment to you that you need to address, the “Show Comments” button will turn GREEN. When it is green, that means the IRB office has left you a comment that you need to address in either the application itself, OR on your study documents that you have uploaded.

When the IRB office (or you) has made any edits to your application, the “Edit History” button will turn GREEN. This feature functions as a type of “track changes” to the application.

When you are submitting your application initially, you will not need the “Show Comments” or “Edit History” buttons. These are for use when you are communicating back and forth with the IRB staff. They allow you to see how your changes evolve.
Tab: “Populations” (next 3 screen shots) – This tab asks you questions about your target population and potential participants. Here we are asking you questions that will let us know if you are engaging any special populations or vulnerable populations. Based on what you select, other questions will pop up. This will help us make sure that your procedures for engaging these populations are documented and it will help us assess the risks/benefits associated with your research.
Tab: “Consent” – This tab is all about how you are planning on obtaining consent from participants or their legal guardians. You can also request a “Waiver of Consent” on this page. At the bottom of the page, you will have a space where you can upload any of your study documents relating to consent. Don’t forget to “Save” your work!

See the screen shots below for more detailed information about the “Consent” tab.
Waiver or alteration of Consent Questions: If you want to request a waiver of consent, you select “yes” and then more questions/space for you to address why you want a waiver, will pop up.
Tab: “Procedures” – This is where you will get into the “step by step” description of what you plan on doing. This page asks you about how each participant group will be involved in the research AND what your research plan is.

Procedures Tab continued (this is the bottom of the page, some questions not shown):
Tab: “Risks and Benefits” – This tab asks you about the types of risks that involvement in your research poses to participants. For each category that you say “yes” to, you will have to provide information as to how you plan on mitigating that risk for participants.

Things to think about/include:
- What processes/procedures am I implementing? What could happen to those who participate as a result?
- What type of data do I have and what information is included in my data? AND if it gets out (even if I don’t mean it to get out) what risk could participants be exposed too?
- What processes/procedures am I putting in place so that my participants AND my participants data are protected?
- Make sure to answer the questions about risk for EACH participant group involved in your research.
Tab: “Risks and Benefits” – This is the bottom of the tab. This gets at the benefits of your research. Here we are asking about the benefits to your participants for being a part of your research (not compensation) AS WELL as the overall benefits of your research.
Tab: “Data Security”

- Please see data security tips here: http://research.ncsu.edu/sparcs/compliance/irb/irb-forms/
- Please visit NCSU OIT for information regarding data security and data management here: https://oit.ncsu.edu/security-standards-compliance/controls

You need to have a plan for how you are managing your data and that plan has to be in line with your OIT’s expectations. Please talk with your OIT representative as well as review the sites above. Once you have your plan, articulate it here.

Remember:

- E-mail is not a secure method for data collection or transmission.
- Make sure to clarify if your data is anonymous, confidential, identifiable, or de-identified (please see our website for definitions).
Tab: “Data Security” – continued

<table>
<thead>
<tr>
<th>Locked Filing Cabinets?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Encrypted Files?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Describe all participant identifiers that will be collected (whether they will be retained or not) and explain why they are necessary.

If any links between data and participants are to be retained, how will you protect the confidentiality of the data?

If you are collecting data electronically, what (if any) identifiable information will be collected by the host site (such as email and/or IP address) and will this information be reported to you?

Describe any ways that participants could be identified indirectly from the data collected and describe measures taken to protect identities.

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?
Tab: “Compensation” – Here is where you will discuss any compensation that you are awarding for participant. Remember, your compensation should not pose any undue influence for participants. Your compensation should also be equitable among all participants in your research. Make sure to talk with your department/advisor/department accountant regarding appropriate compensation and what you can and cannot provide. Their expectations ARE NOT THE IRB’s expectations and we will not always be able to identify what your department will allow and not allow.

We can tell you that anything over $25 will need to be tracked and that is something that you need to pay attention to when planning for your data collection (specifically as it relates to anonymity/identifiers).
Tab: “Routing and Status” – When you have completed the application by answering ALL of the questions and UPLOADING your documents, you will go to the final tab. This is where you can decide to submit your application or not. Once you hit “Submit to IRB Office,” your application will be routed to us and we can start your review process in the order with which it was received.

If for some reason, you need a quick review, please e-mail irb-coordinator@ncsu.edu with the study number (eIRB number) and the reason why. This way, we can try and work with you to get your needs met. However, this is for special circumstances. Please do your best and allow the appropriate amount of time for review/approval.

When you hit “Submit to IRB Office,” This reminder window will pop up. It is reminding you to submit your editable .docx documents.
New Submission is NOW SUBMITTED.

You have officially submitted an application to the IRB for review and approval. Now, you await the IRB’s response. They will either process your approval or they will communicate with you through the eIRB system what changes are needed to your application. If any changes are required, you will get an email notification. When you log back into the system, look yourself (or the study number) up and select it. All the changes will be noted to you because the “Edit History” or “Show Comments” buttons will be GREEN.
Your study IN PROCESS. The IRB has preliminarily reviewed your study and they have a few questions and/or items that need your attention because they are incomplete or need to be edited. You will receive an email letting you know that your study has been addressed and that you need to make edits.

Once you have selected the PI (you), click “Select Protocols by PI, Department, and/or Fund”
Once you have found your study in review, click “Select,” it will open.

Click on EACH tab across the top and scroll through the page, looking for **GREEN highlighted boxes** where it says “Show Comments” – The IRB office will have noted any information they need addressed here. Sometimes these comments ask you add more information and sometimes they ask you to edit your study documents.
Before you resubmit this to the IRB staff again, you must address each green box as noted above. Simply, click on the green box, read the comments, and address the comment or the request for edit. When you click on the green box, you will see a new box pop up. This will have information about from who the comment originated, when the comment was sent, and what the comment/task/request is. Do what the comment says. Once you have read the comment, “Close” the comment box.
Once the changes are made and you saved the changes, the “Edit History” box will turn green indicating that you edited the text you originally submitted. If you click on the “Edit History” button, you will be able to read a history of the changes made to your application. This feature functions to track your changes in the application.

By clicking on the green “edit history” button, a window will pop up with the edited language. If you would like to see the “track changes” history of each edit made, you can click on “Compare” (noted below). When you do that, this window pops up:
You must make sure to make requested changes, as you can send the application back to the staff without the system telling you that you missed a request.

If you make changes to the document page by uploading edited documents, you will see a list of documents like below. The documents with “FINAL” in their title, means that those are the approved document and the only documents you should be implementing. You can see the edited documents because they are labeled as “edits.”
Once the IRB has approved your study, you will receive an approval email. You can then look yourself up (or the study number and see the finalized approval.

You can select your study below to see it finalized in the database. You can also print a PDF if needed or save it for your records.

On the title tab, you will note some changes from what it looked like before it was approved (see tabs below). You will also note that the tabs are no longer editable.
This section is different now. Now, you will see approval dates and other approval information. Only the IRB office can edit these.
When the Study is approved, the routing and status tab will look like this (below). However, you will not know who your reviewer was. Instead it will say “Expedited Reviewer” or “Exempt” or “Full Board”.

If you would like to make an amendment to your study or if you would like to submit a request for continuing approval, please see the document entitled “eIRB Walk Through – Submitting an Amendment Request and Continuing Review”.

Call 919 515 4514 if you need technical help with the system.
Call 919 515 8754 if you need help with your IRB application or have content related questions.