Basic Introduction to the eIRB

- eIRB: 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.

All applications must be submitted by the faculty sponsor. If a student is completing the application, they can fill out all the fields and attach the appropriate documents and then send it to the faculty sponsor. The faculty sponsor and student can edit the fields as needed before submitting. The faculty sponsor should read through it, ensure appropriate documents are included, and submit the application.

Tips for using the eIRB and submitting your application:

- 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.
- 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 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.
- 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.
- You can apply for an amendment and for approval renewal at the same time.
- If you received IRB approval for your study before December 1, 2014 OR if you submitted for approval before December 1, 2014, your eIRB application and many of the fields will be BLANK as sparse information was entered regarding your study. If you would like to make changes or renew this study, go ahead and add the statement “This study received original approval before the eIRB was active, see uploaded documents for details regarding this study.” After that statement is entered into each field that you are editing, go ahead and note your changes/new information into the appropriate fields in all the tabs.
- If you are not the faculty point of contact, YOU WILL NOT BE ABLE TO SUBMIT THE SMENDMENT REQUEST OR CONTINUING REVIEW REQUEST. The Faculty point of contact only, will be able to.
Submitting a Revision Request or Request for Approval Renewal

Revisions Requests (or modifications to an already approved study) and Approval Renewal (continuing review approval) can be submitted by following the directions below.

- Login to the eIRB as normal: [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
- Search for your study (by looking for your name, the PIs name, and/or the eIRB number)
- Select the appropriate study needing a revision or approval renewal
- Click on the "Title" tab
- From the "Title" tab, click "Add New Renewal/Amendment Request"

Use the boxes below the arrow to search by PI, Department, or Funder.

Once you have selected the field, click the button "Select Protocol by…" button

You can also search by "eIRB number" (protocol number).

Type the number in box and then click “Select Protocol Number”

Find the study that you want to amend or request approval renewal for, and click “Select”
Once you have selected the study that you want to make an amendment/renew, click select and the study will come up. The “Title” tab will be the first page you see. Scroll down to the middle of the page and look for the button “Add New Renewal/Amendment Request.”

Further along down the page, you will see a tab labeled “Add New Renewal/Amendment Request.” Click on that button.
Once you click on “Add New Renewal/Amendment Request,” a new window will pop up. You will have the opportunity to indicate if you are requesting changes to an already approved study or if you need to apply for approval renewal (for Expedited and Full Board studies only).

If your study has received Expedited Review or Full Board review and you want to “renew your approval,” then click “Yes” here.

Regardless of the level of review your study was approved under, if you want to make ANY CHANGES AT ALL then you need to request to amend your protocol. If you would like to submit an amendment request, click “Yes” here.

Make sure to “Save” throughout.

If you click “Yes” for renewal, more questions pop up (like below)

Please summarize the changes you want to make to your study. This includes a brief outline of the 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 said documents with all changes tracked.

Briefly list study activities conducted since the last date of approval or renewal.
If you click “Yes” for amending your protocol, more questions pop up (like below)

Once you click “Save”, this box will disappear and you will see the “Title” page. After you click “Save,” the “Title” tab will look like this (below) representing the number of past and present amendment request and requests for renewal. The most recent requests will be at the bottom.
Now that you have answered specific questions about your amendment request/continuing approval request, you can now edit the full application. You can select all of the tabs (just like when you were submitting a new application) and you are now able to edit the content on the varying pages.

Here is a listing of ALL amendment requests and approval renewal requests that this study has ever had. The most recent request will be noted at the bottom.
All the tabs are editable and you can also now add new/revised study documents. Before you add any new study documents, make sure they are in the .docx format (unless they have to be a PDF) and make sure that all the changes you made are “tracked.”

If you are making changes to your study, think about how that change influences your responses and procedures noted on each of the tabs. Your changes will need to be noted in all appropriate fields.

- For example: if you are implementing a new survey, you would need to address the areas of consent, the new instrument, the new target population, new methods for recruitment, issues relating to data security, compensation and any type of new risk/benefit added.

On the “Title” tab, you will see that “Add/View Supporting Documentation” (also noted on the consent tab and in the procedures tab). You can now upload edited/additional documents.
Once you have made all of the necessary changes on all of the tabs, and once you have uploaded your revised documents, you are ready to submit your amendment or continuing review request. You can either submit your request or withdraw your request (because you decided not to submit it for whatever reason).
When you hit “Submit Renewal/Amendment” a small reminder box will pop up. It is a check point for you, to make sure you uploaded all necessary edited documents. By clicking “OK” you will submit your application. By clicking “Cancel” this small window will close and you can go back and upload the documents or edit anything that you want. You will only see the option to “Submit” the Renewal/Amendment request if you are the Faculty Point of Contact.

If you have done what the box above says to do, then click “OK” and your request will be submitted. Your window will now look like this (below). You can now read that the IRB has received your submission and you are awaiting approval.
If the IRB staff has any questions for you, they will ask you them through the eIRB system, using the comments section called “Show Comments.” Any questions you need to address will show up with the “Show Comments” button highlighted GREEN.

If the IRB staff (or you) makes any changes to a field, then it will show up GREEN under the “Edit History” button.

By clicking on each GREEN button, a new window will pop up and you will be able to see comments that need to be addressed and a history of the changes made to your submission. Sometimes the comments will ask you to edit a field, and sometimes the comments will ask you to edit through study documents and upload the new versions with the edits tracked.
When your amendment request or approval renewal request is APPROVED, you will no longer be able to edit your application and the “Routing and Status” tab will look like this:

You are now done! You can move forward with your research as all procedures and documents have received IRB approval. Make sure to save your confirmation e-mails from the eIRB system.