Submitting a New Study Submission (External IRB)

1. Go to the main page for eIRB+ and login.

2. Once in the system you will be routed to your inbox.

3. On the left side of the page toward the top, select “Create New Study”.

4. You will then be routed to be “Basic Information” page of the New Study Application. There are 8 questions in total to respond to, including a section to upload the overall study protocol.
   a. **Question 1**: Please provide the title of the study as it is reflected on the protocol with “(xIRB)” at the beginning to reference that the study is being reviewed by an External IRB.
   b. **Question 2**: Please provide the short title of the study with “(xIRB)” again at the beginning.
   c. **Question 3**: Provide a “Brief Description” of the study. This is just a brief overview of the research and the main aims.
d. **Question 4:** Select the review category appropriate to your research. Either Social-Behavioral or Biomedical.

e. **Question 5:** Principal Investigator (By system default the submission preparer is listed in this section. If not correct, then ensure the correct PI information is selected).

f. **Question 6:** Since this is a request to cede review to an External IRB, the response to this question should be “Yes”.

g. **Question 7:** Please select the study type appropriate for your protocol.

h. **Question 8:** Please provide the protocol approved by the External IRB. (If applicable, please also provide a local protocol addendum).

5. Once you have provided a response to all questions, select continue located at the top or bottom of the right side of the page.

6. The next page of the application should be the “External IRB” page, in which there are 12 questions, but only number 1 through 6 need responses.

   a. **Question 1:** Select the name of the External IRB (Please note: If the name of the External IRB is not available on the drop down list, email irbreliance@northwestern.edu and request for it to be added).

   b. **Question 2:** If there is a study id number provided by the External IRB, please provide the information.

   c. **Question 3:** Select “Upload” and provide the External IRB approval letter for the Northwestern University site.

   d. **Question 4:** Select the initial approval date as provided by the External IRB.

   e. **Question 5:** Select the last day of approval (expiration date) as provided by the External IRB.

   f. **Question 6:** Provide information for the reason the study should be reviewed by the External IRB *(For example: Per the Master Agreement in place between both institutions, the External IRB will serve as the IRB of Record for all studies).*

6. Specify the reason the study should be reviewed by an external IRB:

   Per the Lurie Children's and Northwestern University IRB Authorization Agreement (IAA), this study is using the Lurie Children's as the IRB of record.
7. Once you have provided a response to all questions, select continue located at the top or bottom of the right side of the page.

8. The next page of the application should be the “Sources of Funding and Other Support” page, in which you will select the funding source for the study.

9. Then select continue located at the top or bottom of the right side of the page.

10. The next page of the application should be the “Study Scope” page, in which there are 2 questions where you will indicate if drug or device is being used as a part of the study.

11. Then select continue located at the top or bottom of the right side of the page.

12. If the study involves a drug or device, the application will direct you to an additional page to provide information regarding the drug or device. If there is no drug or device involved in the study then you will be taken to the final page of the application, in which you will select “Finish” to continue.
13. You will then be directed to the main page of the “Study” application and there will be a red script indicating that there is an un-submitted “Site” record, which will need to be completed in order to proceed.

14. Select the link to the “Site” record.

15. You will then be directed to the main page of the “Site” application and “edit site” should be selected to update the application.

16. You will then be routed to be “Basic Information” page where the information from the “Study” application should be pre-generated for the 4 questions.
17. Verify the information is correct, then select continue located at the top or bottom of the right side of the page.

18. The next page of the application will be the “Sources of Funding and Other Support” page, in which you will need to again select the funding source for the study.

19. Then select continue located at the top or bottom of the right side of the page.

20. The next page of the application will be the “Study Team Members” page, in which you will need to identify each additional person, not including the PI, who will be involved in conducting the research. (If any study team members are affiliated with Northwestern, but not available to be selected on the drop down menu, they will need to register for eIRB+ using their Northwestern netid).

21. Then select continue located at the top or bottom of the right side of the page.
22. The next page of the application will be the “Site-Specific Documents” page. All documents that will be utilized at Northwestern and have been approved by the External IRB should be uploaded into the appropriate section (For example, Consent forms should be uploaded into the “Consent forms” section; Questionnaires should be uploaded into the “Supporting Document” section).

23. Once all documents have been uploaded, select continue located at the top or bottom of the right side of the page (Please note all documents listed on the External IRB approval letter should be uploaded into the “Site” or “Study” application in the corresponding sections).

24. The next page of the application will be the “Sites” page, in which you will need to select the study site information (If there are additional sites not listed, they can be included in section 2).

25. Once the site information has been provided, select continue located at the top or bottom of the right side of the page.
26. You will be taken to the Final Page of the “Site” application and then select **Finish** and you will be taken to the main page of the application.

27. Once on the main page for the “Site” application, you can then notify the PI to submit. *(If applicable and if you receive an error message, make sure that the RSS indicates “Completed” before notifying the PI to submit)*

![Notify PI to Submit](image)

28. The application process is complete and an email will be sent to the PI to submit. Once the PI submits, the “Site” and “Study” application will be routed to the Northwestern IRB for administrative review. *(Please note submit functionality only occurs on the “Site” submission).*