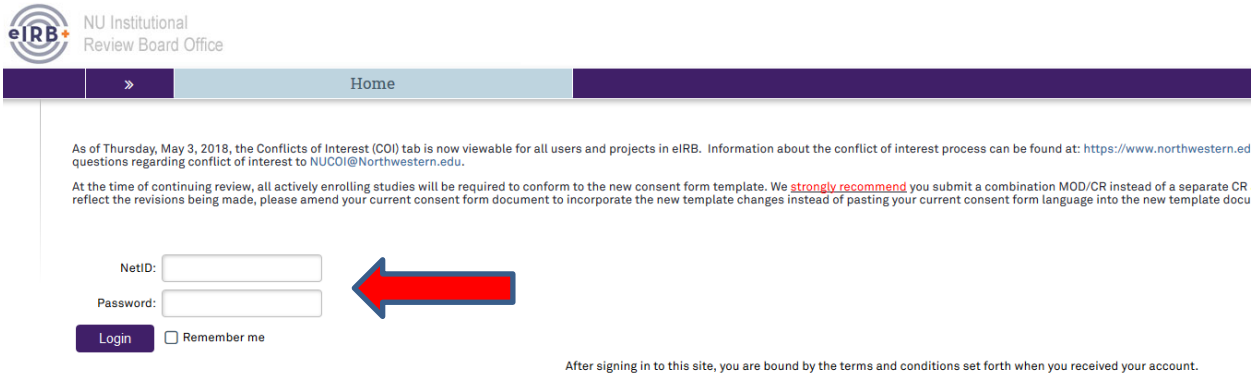
eIRB+ Tutorial: New Study Submission – External IRB with a Master Reliance Agreement

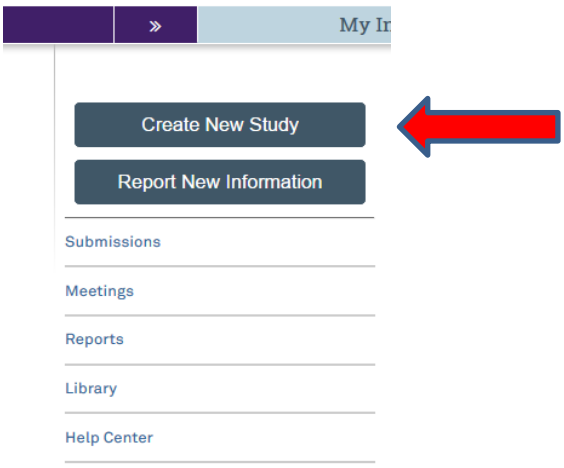
This is a step-by-step tutorial of how to submit a new study submission in eIRB+ for a study that will cede review to an External IRB for which Northwestern University (NU) has an established Master Reliance Agreement (e.g. Ann & Robert H. Lurie Children's Hospital), as per **HRP-092 - SOP External IRBs**. These instructions apply when an IRB Authorization Agreement (IAA) is not required for each study. For additional information on the overall workflow of this process, please reference **Ceding Review: Independent IRB Workflow** or **Ceding Review: Other Academic Institutional IRB Workflow**.

For studies that will rely on an External IRB with whom Northwestern does not have a Master Reliance Agreement, an IAA is required and you should refer to the tutorial "New Study Submission – External IRB Requiring an IRB Authorization Agreement (IAA)".

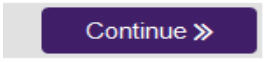
1. Go to the main page for eIRB+ and login.



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".

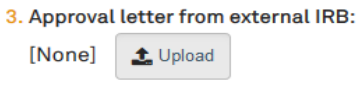


4. You will then be routed to be "**Basic Information**" page of the New Study Application. There are **8** questions in total to respond to, including a section to upload the overall study protocol.
    a. **Question 1:** Please provide the title of the study as it is reflected on the protocol with "(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.
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.

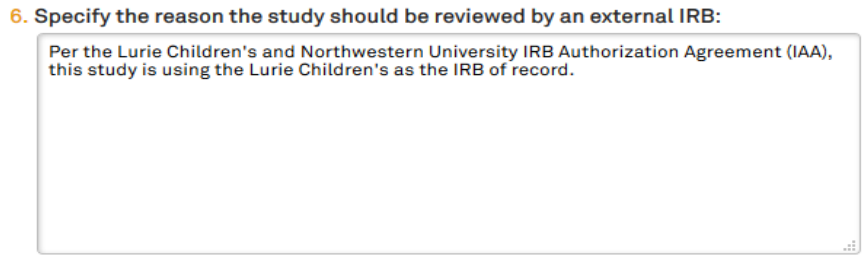


6. The next page of the application should be the "**External IRB**" page, in which there are **12** questions, but only number **1** through **6** need responses.

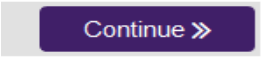
a. **Question 1:** Select the name of the External IRB (Please note: If the name of the External IRB is not available on the drop down list, email irbreliance@northwestern.edu and request for it to be added).
b. **Question 2:** If there is a study ID number provided by the External IRB, please provide the information.
c. **Question 3:** Select "Upload" and provide the External IRB approval letter for the Northwestern 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**).

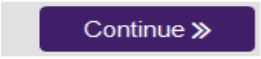


7. Once you have provided a response to all questions, select continue located at the top or bottom of the right side of the page.

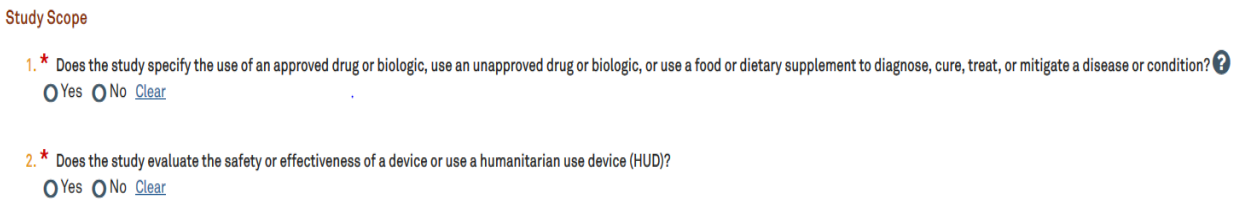


8. The next page of the application should be the "**Sources of Funding and Other Support**" page, in which you will select the funding source for the study.

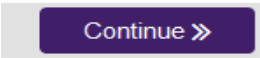
9. Then select continue located at the top or bottom of the right side of the page.



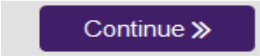
10. The next page of the application should be the "**Study Scope**" page, in which there are **2** questions where you will indicate if drug or device is being used as a part of the study.



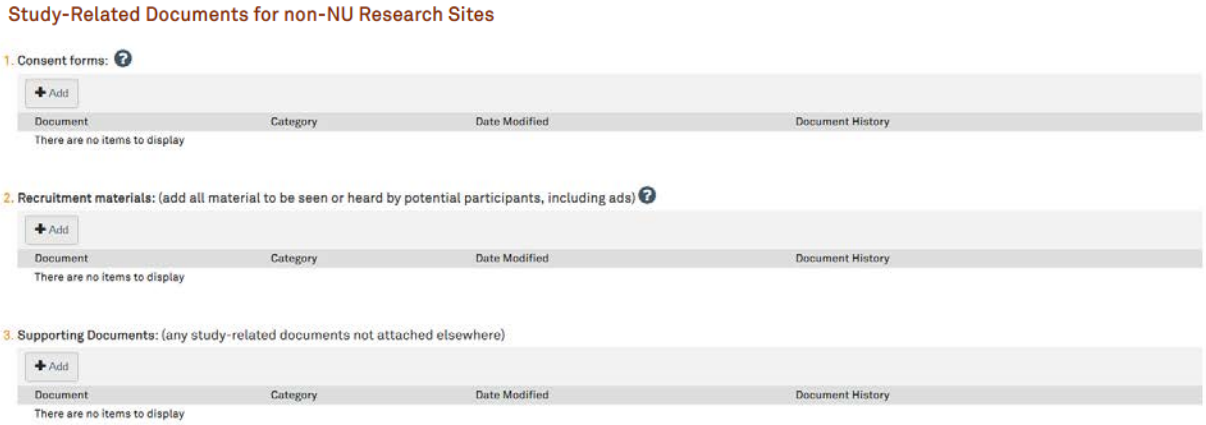
11. Then select continue located at the top or bottom of the right side of the page.



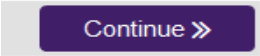
12. If the study does not involve a drug or device, skip to step 15 below.
13. If the study involves a drug or device, the application will direct you to an additional page to provide information and documentation regarding the drug or device.
14. Once you've entered all the study drug or device information and uploaded drug or device documents, select continue located at the top or bottom of the right side of the page.



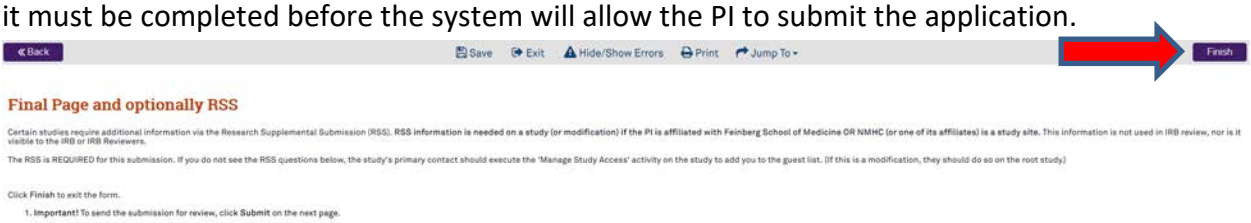
15. The next page of the application should be the "**Study-Related Documents for non-NU Research Sites**" page, in which there are **3** questions.
    a. **Question 1 "Consent forms"**: Upload if applicable study-wide templates are available, otherwise this may be left blank.
    b. **Question 2 "Recruitment materials"**: Upload all recruitment-related materials listed on the External IRB approval letter that are not specific to Northwestern. (For example, sponsor-run central recruitment campaign materials.)
    c. **Question 3 "Supporting documents"**: Upload all other study documents listed on the External IRB approval letter that are not specific to Northwestern. (For example, questionnaires utilized by all study sites should be uploaded into this section.)



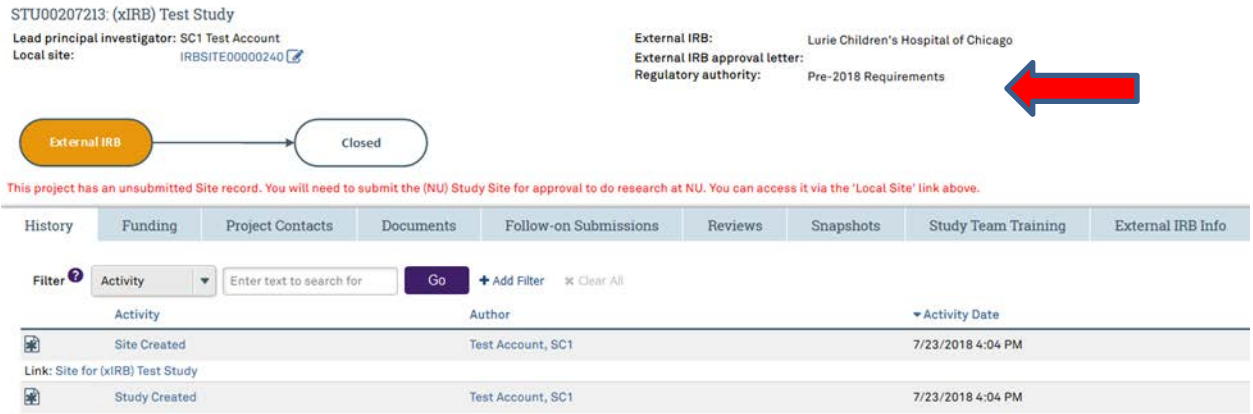
16. Then select continue located at the top or bottom of the right side of the page.



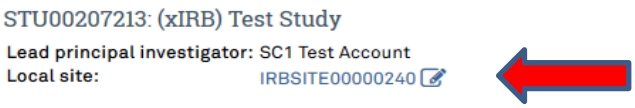
17. You will be taken to the final page of the application, in which you will select “Finish” to continue. Please note: the final page will also include an RSS (Research Supplemental Submission) if applicable to your study. IRB Staff & Reviewers cannot access the RSS, but it must be completed before the system will allow the PI to submit the application.



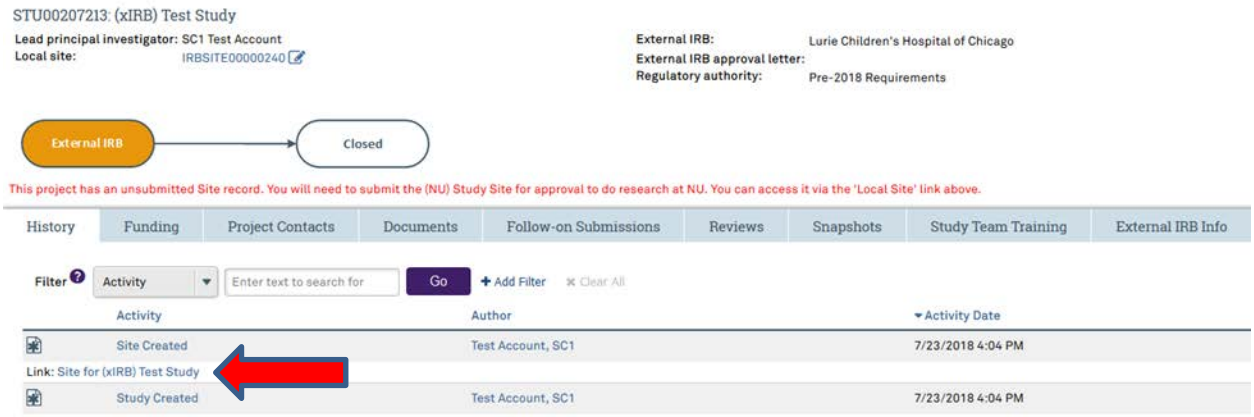
18. You will then be directed to the main page of the “Study” application and there will be a red script indicating that there is an unsubmitted “Site” record, which will need to be completed in order to proceed.



19. Select the link* to the “Site” record.

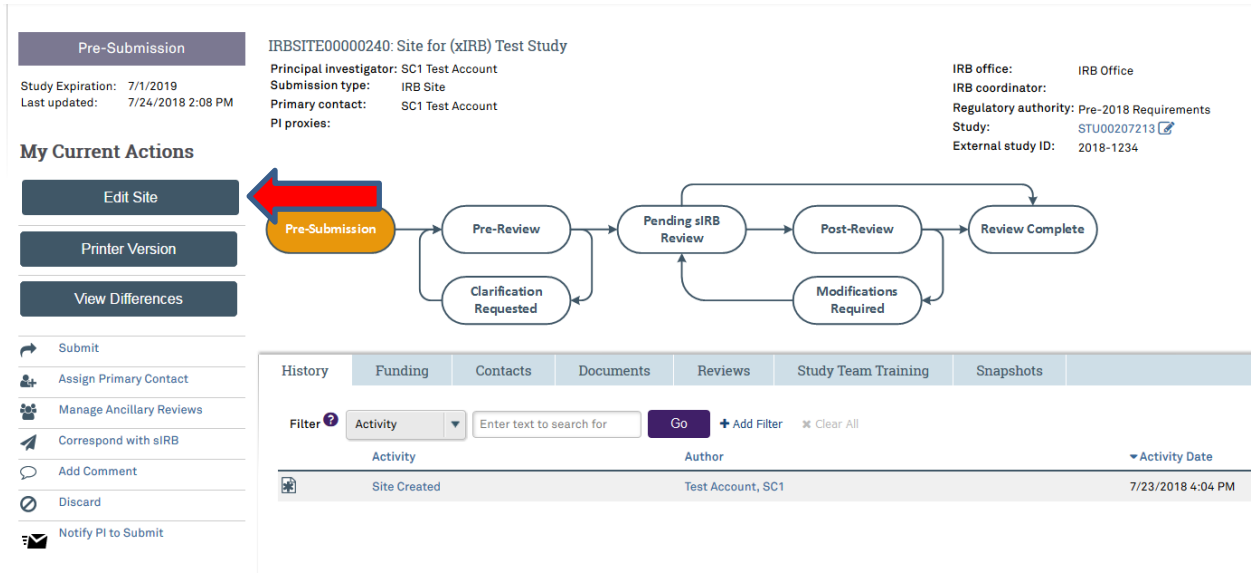


OR

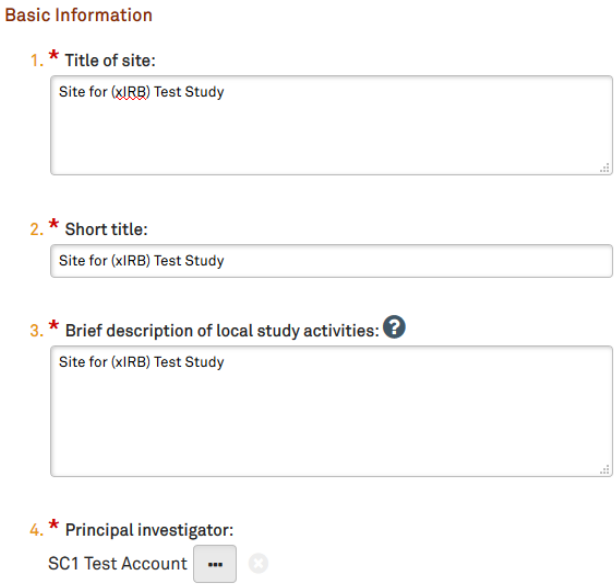


*Both of the links identified above will take you to the same "Site" application page.

20. You will then be directed to the main page of the "Site" application and "edit site" should be selected to update the application.

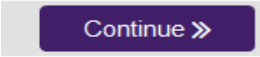


21. You will then be routed to be "**Basic Information**" page where the information from the "Study" application should be pre-generated for the **4** questions.

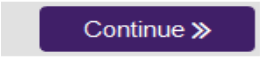


Basic Information page (Site Application)

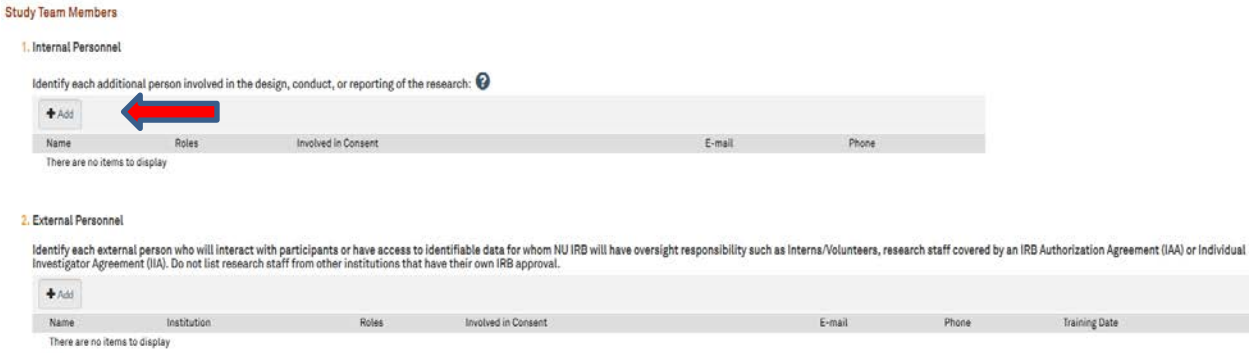
22. For **Question 3**, please add a description of what portion of the study will be conducted at the Northwestern site.
23. Verify the rest of the pre-generated information is correct, then select continue located at the top or bottom of the right side of the page.



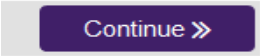
24. The next page of the application will be the "**Sources of Funding and Other Support**" page, in which you will need to again select the funding source for the study. This should match the funding source selected in the "Study" application.
25. Then select continue located at the top or bottom of the right side of the page.



26. 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 University netID**).



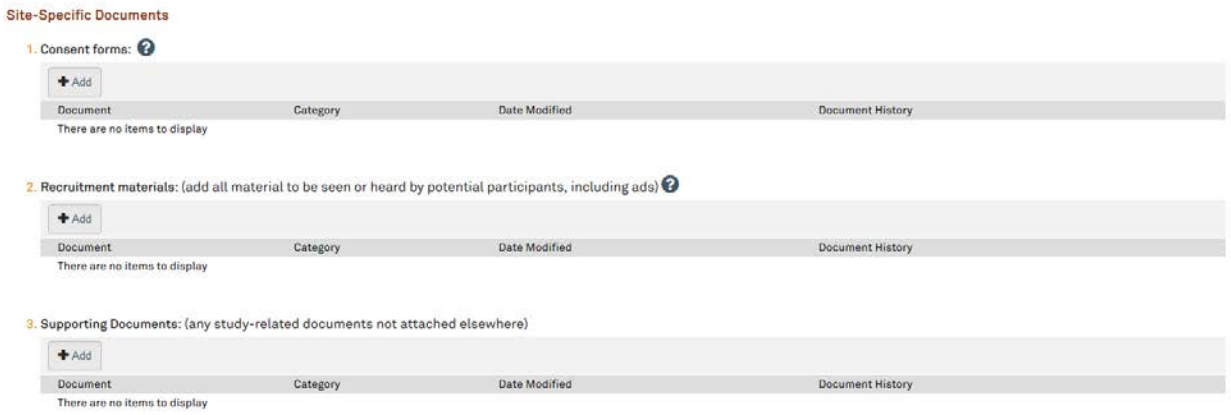
27. Then select continue located at the top or bottom of the right side of the page.



28. The next page of the application will be the "**Site-Specific Documents**" page, in which there are **3** questions to complete.
    a. **Question 1 "Consent forms"**: Upload the External IRB approved and watermarked consent form(s) containing Northwestern site-specific language.

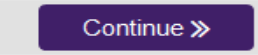
Please note: If participants will be enrolled at the Northwestern site, the External IRB's consent form may be used in lieu of the Northwestern IRB consent form template. However, the External IRB consent form approved for use at the Northwestern site must contain the required Northwestern site-specific language per **HRP-092 - SOP External IRBs**. (For studies reviewed by the Ann & Robert H. Lurie Children's IRB, their consent form template already includes language required by Northwestern.)

    b. **Question 2 "Recruitment materials"**: Upload all recruitment-related materials listed on the External IRB approval letter that will be used specifically at Northwestern.
    c. **Question 3 "Supporting documents"**:
        i. Upload all other study documents listed on the External IRB approval letter that will be used specifically at Northwestern.
        ii. Upload all subsequent External IRB approval letters and any other associated approval documents. (For example, if an External IRB modification was also approved at the time of initial External IRB approval.)
        iii. If applicable, also upload a completed local protocol addendum.

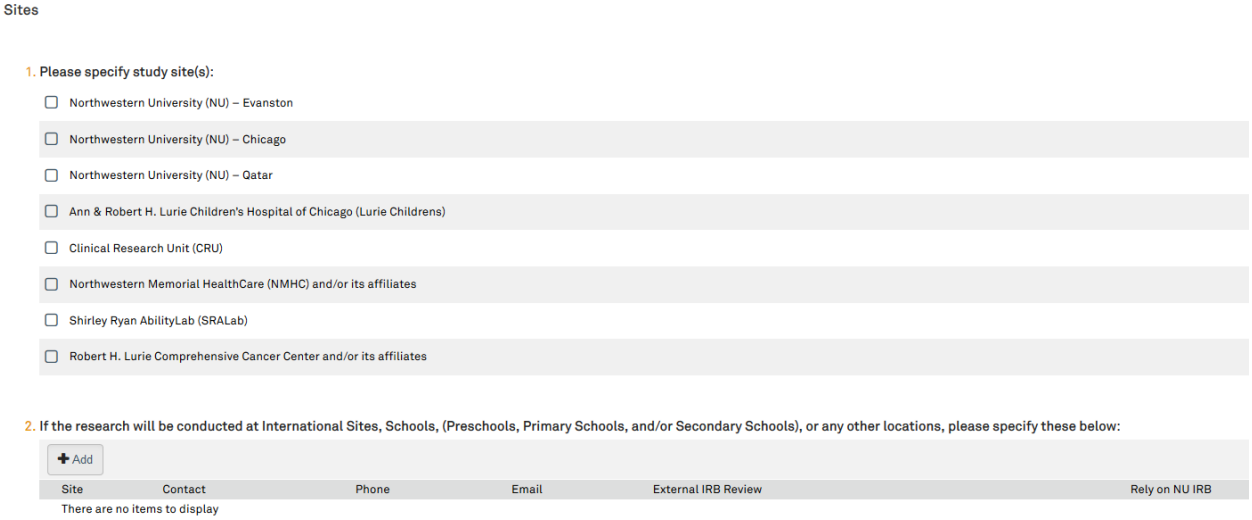


29. Once all documents have been uploaded, select continue located at the top or bottom of the right side of the page (**Please note all documents listed on the External IRB**

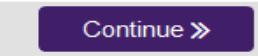
approval letter should be uploaded into the "Site" or "Study" application in the corresponding sections).



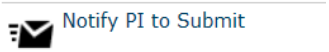
30. The next page of the application will be the "**Sites**" page, in which you will need to select the study site information (**If there are additional sites not listed, they can be included in section 2**).



31. Once the site information has been provided, select continue located at the top or bottom of the right side of the page.



32. 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.
33. 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)**



34. 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 and acknowledgment. (Please note submit functionality only occurs on the "Site" submission).
35. Once acknowledged, the Northwestern IRB acknowledgment letter will be posted within the "Site" application history tab. The study may now proceed.