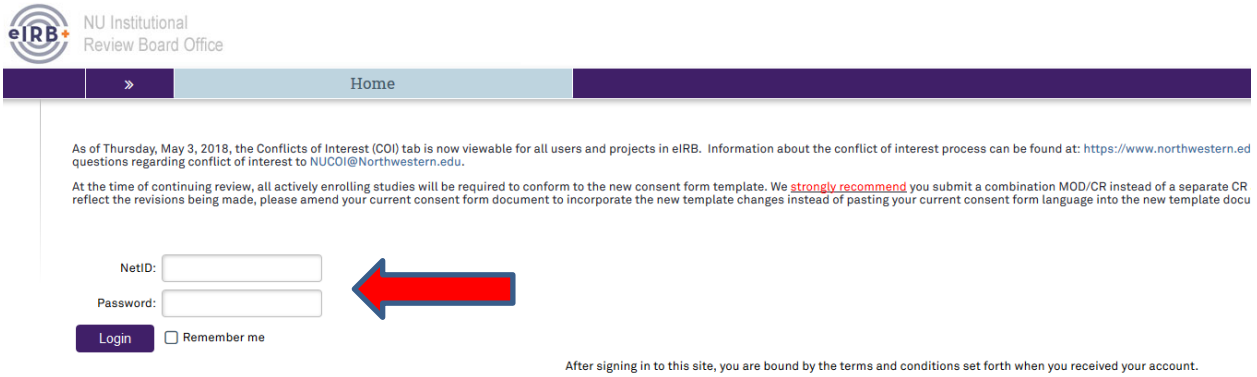
eIRB+ Tutorial: New Study Submission – External IRB with a Master Reliance Agreement

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. Lurie Children's Hospital IRB, National Cancer Institute (NCI) CIRB), as per **HRP-092 - SOP External IRBs**.

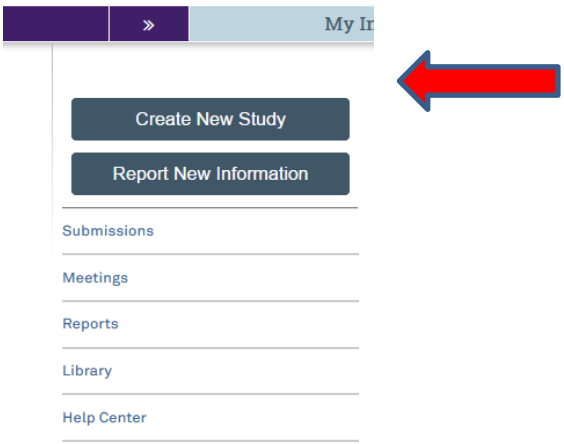
These instructions apply when a study-specific reliance agreement (e.g., IRB Authorization Agreement (IAA), SMART IRB Letter of Acknowledgment) is not required.

For studies where a signed, study-specific reliance agreement is required for Northwestern University (NU) to cede review to an External IRB, refer to the tutorial, "New Study Submission – External IRB Requiring a Reliance Agreement". For additional information on that process, please reference our Reliance Workflows.

1. Go to the [eIRB+ main page] 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”.

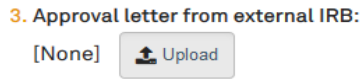


4. You will then be routed to the “**Basic Information**” page of the New Study Application. There are **8** questions in total to respond to, including a section to upload the overall study protocol.
    a. **Question 1:** Please provide the title of the study as it is reflected on the overall protocol 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 should be a brief overview of the overall research objectives and activities.
    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).

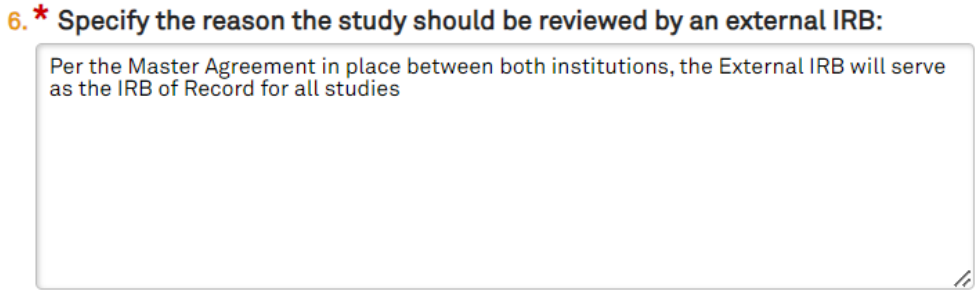
f. **Question 6:** Since this is a request to cede review to an External IRB, the response to this question should be "**Yes**".
g. **Question 7**: Please select the study type appropriate for your protocol.
h. **Question 8:** Please provide the overall protocol approved by the External IRB.

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 is the "**External IRB**" page, on which there are **6** questions that should be completed as applicable.
   a. **Question 1:** Select the name of the External IRB
   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 overall study or Northwestern site.



   d. **Question 4:** Select the initial approval date as provided by the External IRB.
   e. **Question 5:** If applicable, select the last day of approval (expiration date) as provided by the External IRB. Note: For most non-exempt, minimal risk, and non-FDA regulated research projects, there will be no expiration date.
   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.

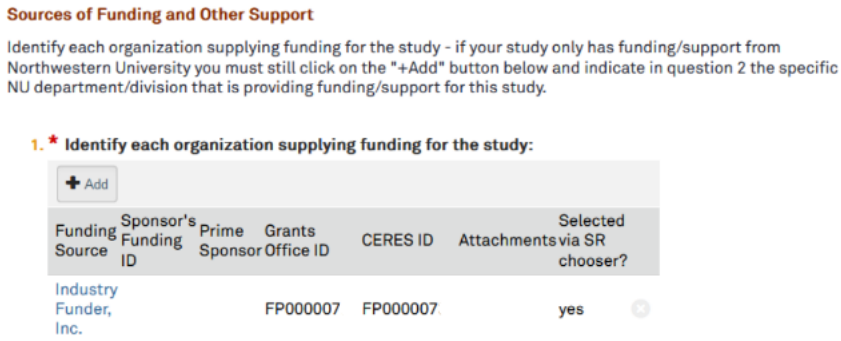
8. The next page of the application is the "**Sources of Funding and Other Support**" page, on which you will select the funding source for the study. **Please ensure that, if any**

external funding is associated with the submission, you are linking that funding via the integrated "SR Chooser." To do so, click the "add" button and a pop-up will appear.

a. Carefully read and respond to Q#1. If you are receiving any funding from a source *external* to NU, and it has not been routed through LCH or SRALab, Q#1 should be answered "Yes." If "No" is the correct response to Q#1, use of the SR chooser is not applicable, and you can skip steps b and c below. In the latter case, please manually provide as much information for the funding item as possible, including documentation of how the grant funding is routed.

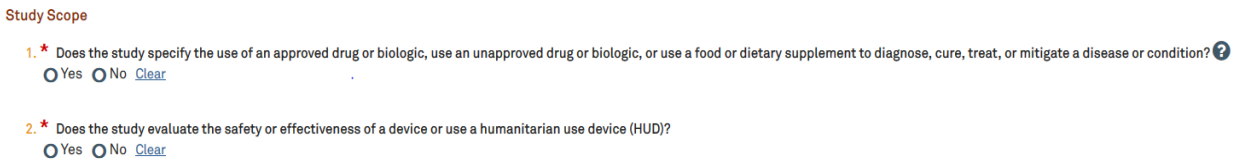
b. Next, in the "CERES ID" field that appeared, click the [...] button to the right of the input field. This will produce a pop-up that will automatically attempt to load all active funding records in the CERES system associated with the PI indicated in Step 4e, above. If listed, select the applicable funding item via the radio button to the left of the item. Click 'OK' to confirm your selection in the pop-up window.

9. If you are not able to locate the correct funding item in the list, please be sure to browse all pages of entries and utilize the 'Click here for more search options' tool at the top of the page. If you are still not able to locate the correct funding item, please verify that the funding is external and not being handled by an intermediary (e.g., LCH or SRALab). If funding is still unable to be linked, please fill in the rest of the questions manually, including as much information as possible.



10. Then select Continue » located at the top or bottom of the right side of the page.

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



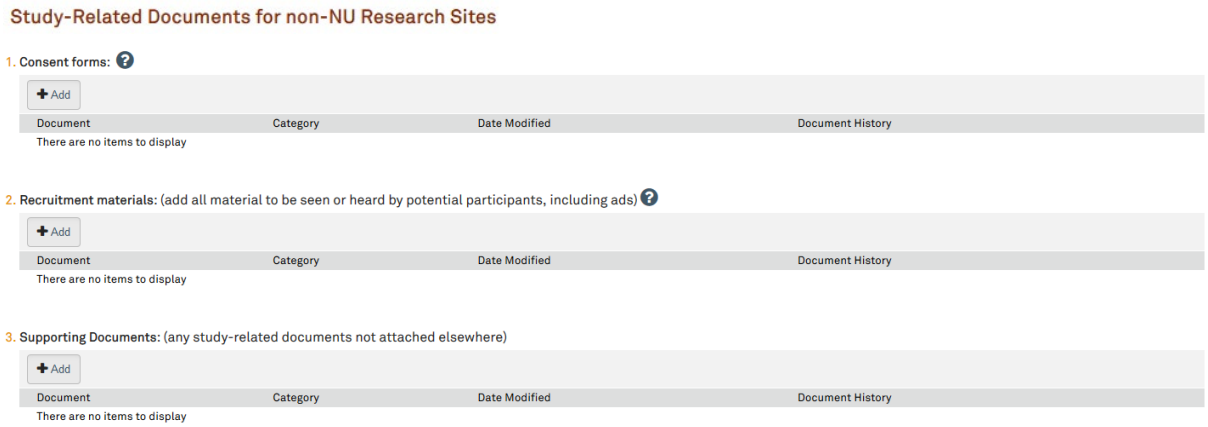
12. Then select Continue » located at the top or bottom of the right side of the page.

13. If the study does not involve a drug or device, skip to step 15 below.

14. 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.
    - For each drug or agent listed under Q#1 of the 'Drugs' page, a package insert, investigator's brochure, or product labeling document should be attached to the row item.
    - For each device listed under Q#1 of the 'Devices' page, an investigator brochure, product labeling document, or device instructions should be attached to the row item.

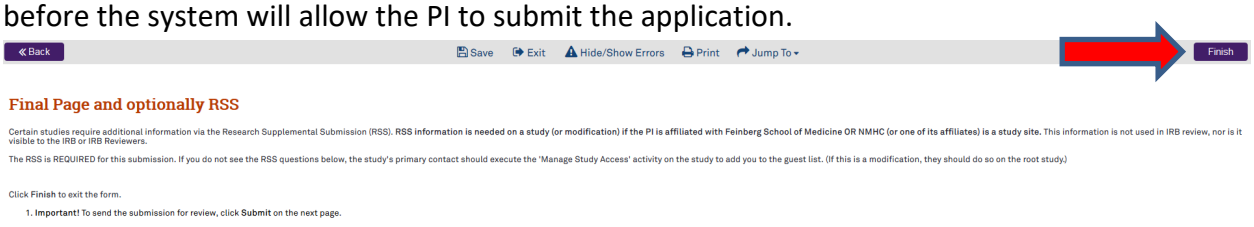
15. Once you've entered all the study drug or device information and uploaded drug or device documents, select Continue » located at the top or bottom of the right side of the page.

16. The next page of the application is the "**Study-Related Documents for non-NU Research Sites**" page, on which there are **three** questions.
    a. **Question 1 "Consent forms"**: Upload applicable study-wide templates if 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.)

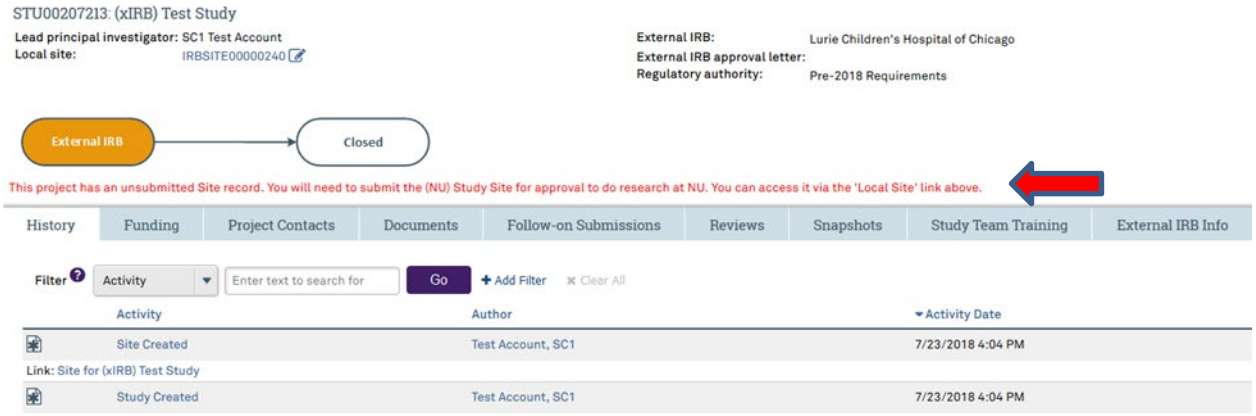


17. Then select Continue » located at the top or bottom of the right side of the page.

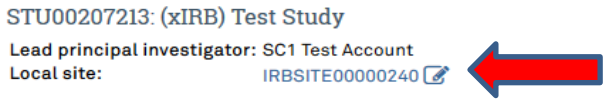
18. Next is the final page of the application. Select “Finish” to continue. Please note: the final page will also include an RSS (Research Supplemental Submission) if applicable to your study. IRB Staff & Reviewers cannot access the RSS, but it must be completed before the system will allow the PI to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



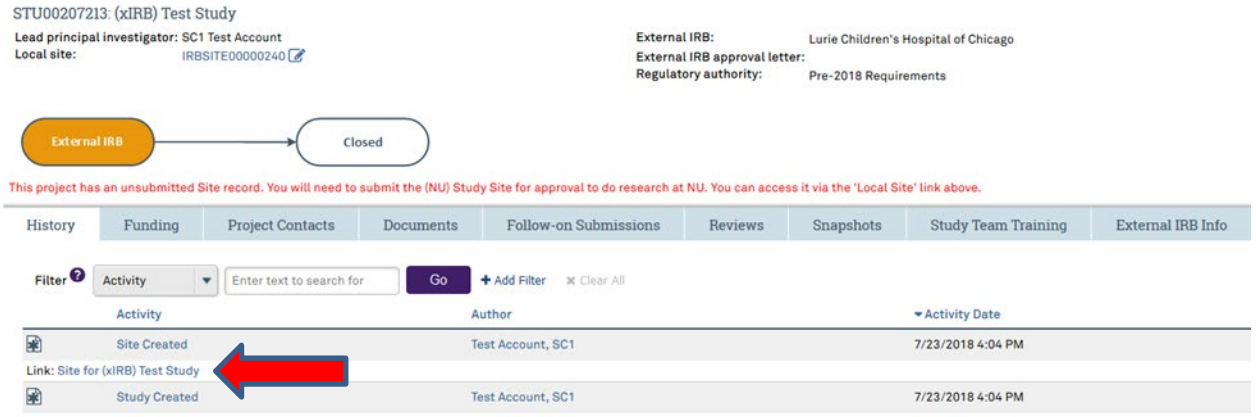
19. You will then be directed to the main page of the “Study” application and there will be a red script indicating that there is an unsubmitted “Site” record, which will need to be completed in order to proceed.



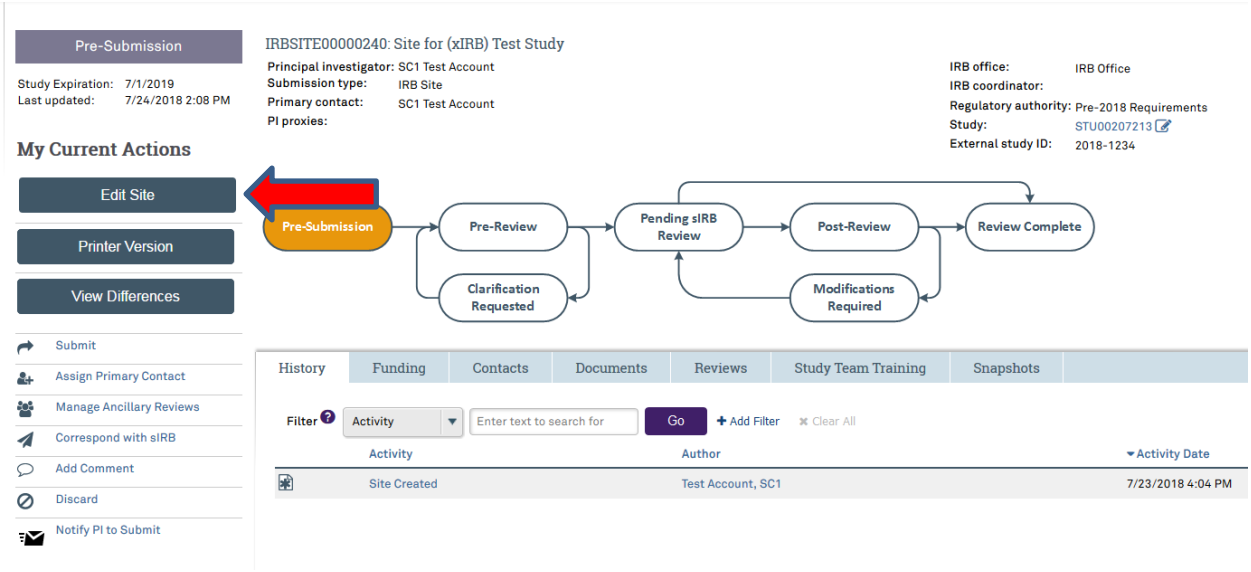
20. There will be two links to the “Site” record, both links will take you to the same “Site” application page. Select one of them to continue.



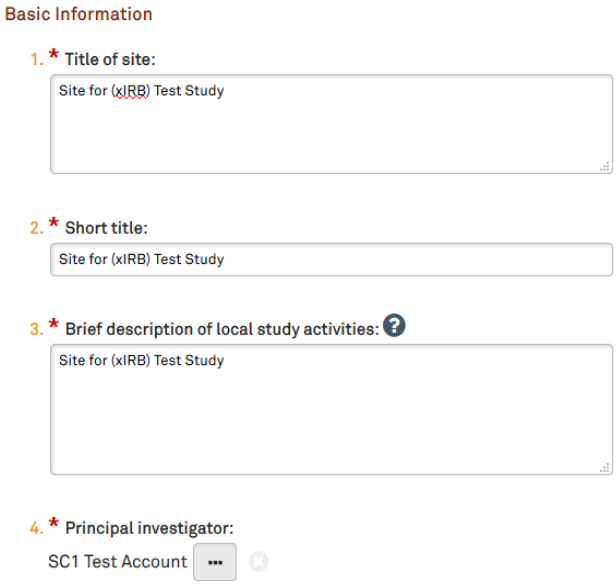
OR

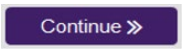


21. You will then be directed to the main page of the “Site” application. Select “edit site” to update the application.



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

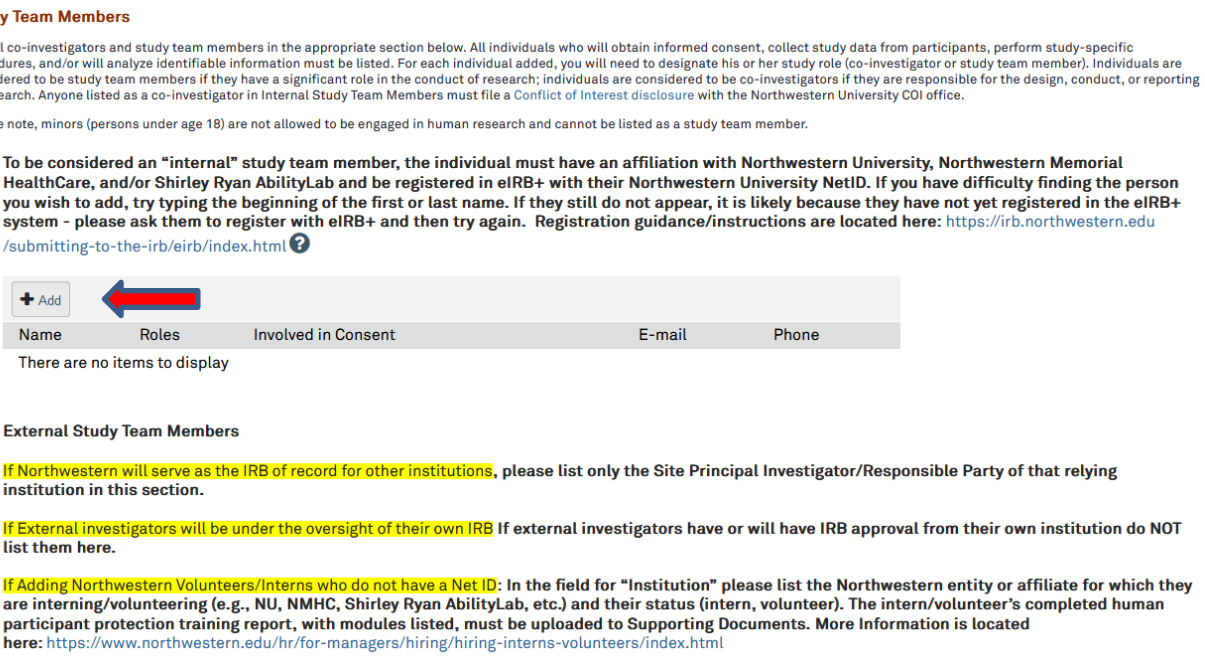


23. For **Question 3**, please add or edit the study description to describe what the study activities that will occur at the Northwestern site and/or be conducted by Northwestern personnel.
24. Verify the rest of the pre-generated information is correct, then select 

located at the top or bottom of the right side of the page.

25. The next page of the application is the "**Sources of Funding and Other Support**" page, on which you will need to again select the funding source for the study. This should match the funding source selected in the "Study" application.

26. Then select Continue » located at the top or bottom of the right side of the page.
27. The next page of the application is the "**Study Team Members**" page, on which you will need to identify each additional person, not including the PI, who will be involved in conducting the research. Importantly, no external study team members (e.g., the PI or Co-I's from non-Northwestern affiliated institutions, including LCH) should be listed on this page. (**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**).



Study Team Members

List all co-investigators and study team members in the appropriate section below. All individuals who will obtain informed consent, collect study data from participants, perform study-specific procedures, and/or will analyze identifiable information must be listed. For each individual added, you will need to designate his or her study role (co-investigator or study team member). Individuals are considered to be study team members if they have a significant role in the conduct of research; individuals are considered to be co-investigators if they are responsible for the design, conduct, or reporting of research. Anyone listed as a co-investigator in Internal Study Team Members must file a Conflict of Interest disclosure with the Northwestern University COI office.

Please note, minors (persons under age 18) are not allowed to be engaged in human research and cannot be listed as a study team member.

1. **To be considered an "internal" study team member, the individual must have an affiliation with Northwestern University, Northwestern Memorial HealthCare, and/or Shirley Ryan AbilityLab and be registered in eIRB+ with their Northwestern University NetID. If you have difficulty finding the person you wish to add, try typing the beginning of the first or last name. If they still do not appear, it is likely because they have not yet registered in the eIRB+ system - please ask them to register with eIRB+ and then try again. Registration guidance/instructions are located here:** https://irb.northwestern.edu /submitting-to-the-irb/eirb/index.html

+ Add

Name	Roles	Involved in Consent	E-mail	Phone
There are no items to display				

2. **External Study Team Members**

If Northwestern will serve as the IRB of record for other institutions, please list only the Site Principal Investigator/Responsible Party of that relying institution in this section.

If External investigators will be under the oversight of their own IRB If external investigators have or will have IRB approval from their own institution do NOT list them here.

If Adding Northwestern Volunteers/Interns who do not have a Net ID: In the field for "Institution" please list the Northwestern entity or affiliate for which they are interning/volunteering (e.g., NU, NMHC, Shirley Ryan AbilityLab, etc.) and their status (intern, volunteer). The intern/volunteer's completed human participant protection training report, with modules listed, must be uploaded to Supporting Documents. More Information is located here: https://www.northwestern.edu/hr/for-managers/hiring/hiring-interns-volunteers/index.html

28. Once you've added all study team members, select Continue » located at the top or bottom of the right side of the page.

29. The next page of the application is the "**Site-Specific Documents**" page, on which there are **three** questions to complete.
    a. **Question 1 "Consent Forms"**: Upload the External IRB approved and watermarked consent form(s) containing Northwestern site-specific language.
        i. **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"**:

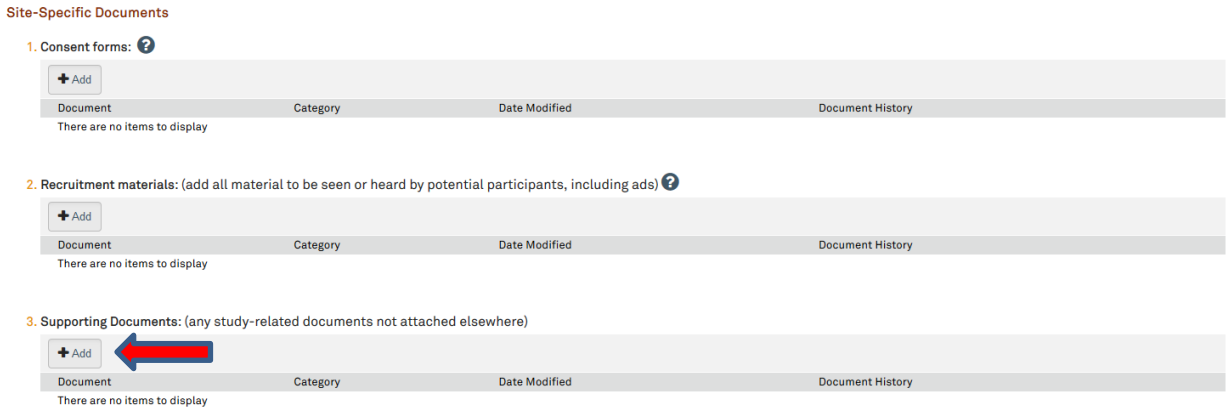
   i. Upload all other study documents listed on the External IRB approval letter that will be used specifically at Northwestern.

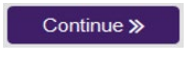
   ii. **If Lurie Children's Hospital will be the IRB of Record**, a copy of the most recent CAYUSE application must be uploaded to this section.

   iii. 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.)

   iv. **If the study involves federal funding,** this is the location that your single IRB Letter of Support must be uploaded. If your study involves federal funding and you have not yet completed the single IRB consultation intake process, please do so at the earliest time point possible. A letter of support is **required** before we can execute reliance for studies involving federal funding. Please see our single IRB planning webpage for more details.

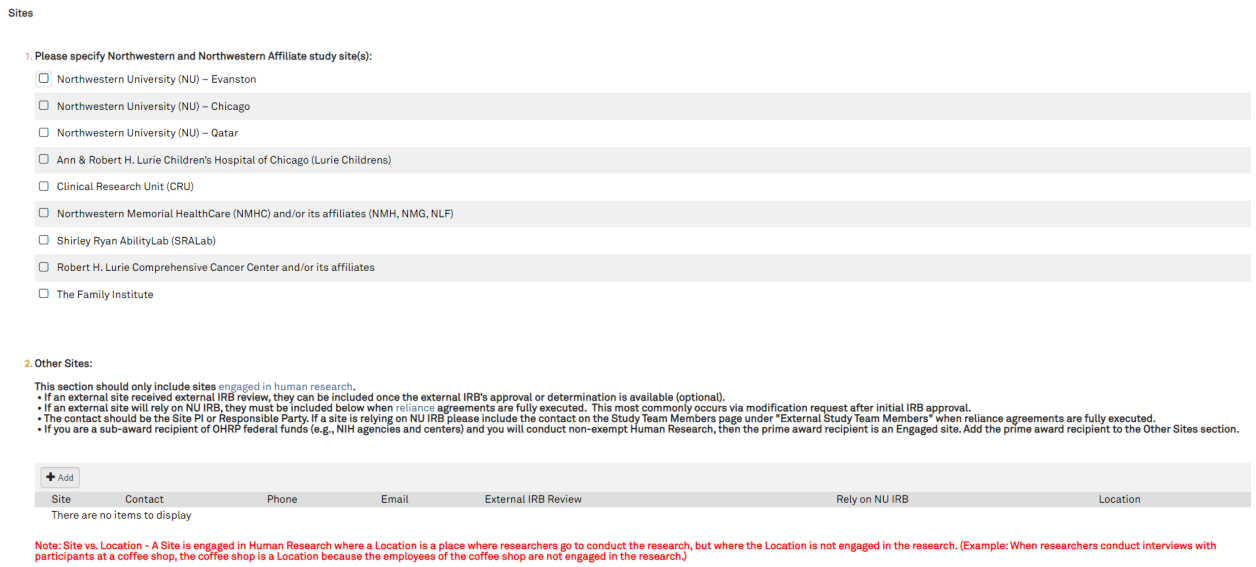
   v. If applicable, also upload a completed local protocol addendum. The IRB Office may request this document on a case-by-case basis.



30. Once all documents have been uploaded, select 

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 appropriate sections, please see our "Where to Upload Documents" table for guidance**).

31. The next page of the application will be the "**Sites**" page, in which you will need to select the study site information. Responses are only required for **Question 1 "Please specify Northwestern and Northwestern Affiliate study site(s)".**
    a. Note: Other research sites **do not** generally need to be listed under Q#2 of the "Sites" page for external IRB submissions. This is because other sites will be under the purview of the IRB of Record, not NU.


Sites

1. Please specify Northwestern and Northwestern Affiliate study site(s):

- ☐ Northwestern University (NU) – Evanston
- ☐ Northwestern University (NU) – Chicago
- ☐ Northwestern University (NU) – Qatar
- ☐ Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Childrens)
- ☐ Clinical Research Unit (CRU)
- ☐ Northwestern Memorial HealthCare (NMHC) and/or its affiliates (NMH, NMG, NLF)
- ☐ Shirley Ryan AbilityLab (SRALab)
- ☐ Robert H. Lurie Comprehensive Cancer Center and/or its affiliates
- ☐ The Family Institute

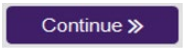
2. Other Sites:

This section should only include sites engaged in human research.
• If an external site received external IRB review, they can be included once the external IRB's approval or determination is available (optional).
• If an external site will rely on NU IRB, they must be included below when reliance agreements are fully executed. This most commonly occurs via modification request after initial IRB approval.
• The contact should be the Site PI or Responsible Party. If a site is relying on NU IRB please include the contact on the Study Team Members page under "External Study Team Members" when reliance agreements are fully executed.
• If you are a sub-award recipient of OHRP federal funds (e.g., NIH agencies and centers) and you will conduct non-exempt Human Research, then the prime award recipient is an Engaged site. Add the prime award recipient to the Other Sites section.

+ Add

Site	Contact	Phone	Email	External IRB Review	Rely on NU IRB	Location
There are no items to display						

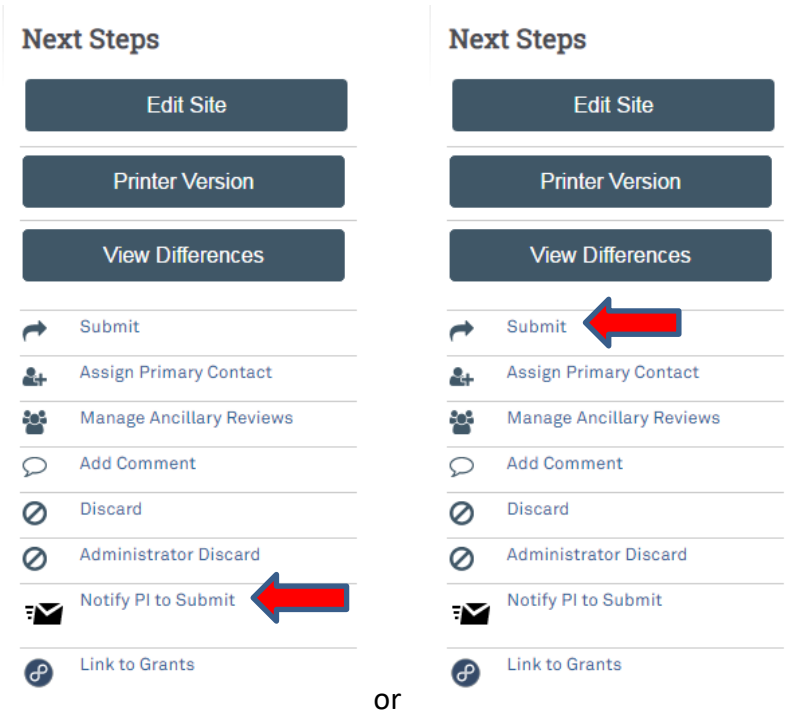
Note: Site vs. Location - A Site is engaged in Human Research where a Location is a place where researchers go to conduct the research, but where the Location is not engaged in the research. (Example: When researchers conduct interviews with participants at a coffee shop, the coffee shop is a Location because the employees of the coffee shop are not engaged in the research.)

32. Once the site information has been provided, select 

located at the top or bottom of the right side of the page.

33. You will be taken to the Final Page of the "Site" application. Select **Finish** and you will be taken to the main page of the "Site" application. The "Study" and "Site" applications are ready to submit. Please note submit functionality only occurs on the "Site" page and submitting from the "Site" page will also submit the "Study" application.

34. Once on the main page for the "Site" application, you can then submit the application (if you have appropriate permissions in eIRB+ to do so) or notify the PI to submit. Please note: Notifications to PI's to submit the study are sent via email from the eIRB+ system. **(If applicable and if you receive an error message, make sure that the RSS indicates "Completed" before notifying the PI to submit)**



35. The application process is complete. Upon submission, the “Site” and “Study” application will be routed to the Northwestern IRB for administrative review and, if all local and institutional requirements are met, acknowledgment.
36. Once acknowledged, the Northwestern IRB acknowledgment letter will be posted within the “Site” application history tab.

Once the NU PI and study team has received approval from the external IRB, acknowledgement from the NU IRB, and no other holds are in place from the IRB of Record or Sponsor, research activities may commence at the NU site.