Submitting a Study Update: Modification, Continuing Review or Site Closure (External IRB)

This is a step-by-step tutorial of how to submit a modification, continuing review, or Northwestern site closure in eIRB+ for external IRB studies. As a reminder, major study updates (e.g., protocol, ICFs, Continuing Review) should be submitted within 2 weeks of receipt from the reviewing IRB. Please upload documents following our "Where to Upload Documents for External IRB Studies" resource. For more information on Northwestern IRB's Standard Operating Procedures when Northwestern cedes IRB review to an external IRB, please, reference HRP-092 – SOP External IRBs.

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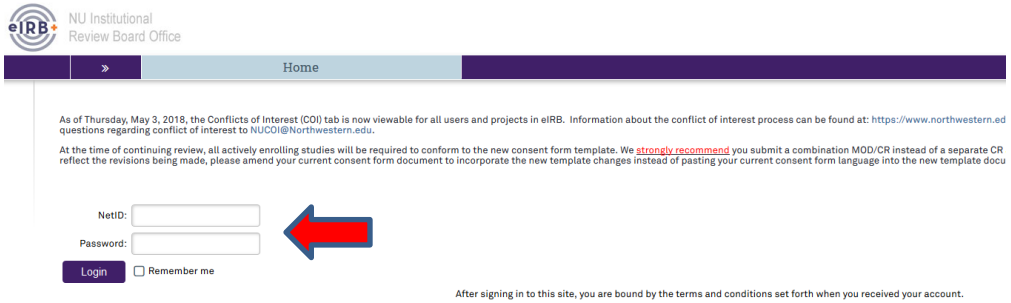
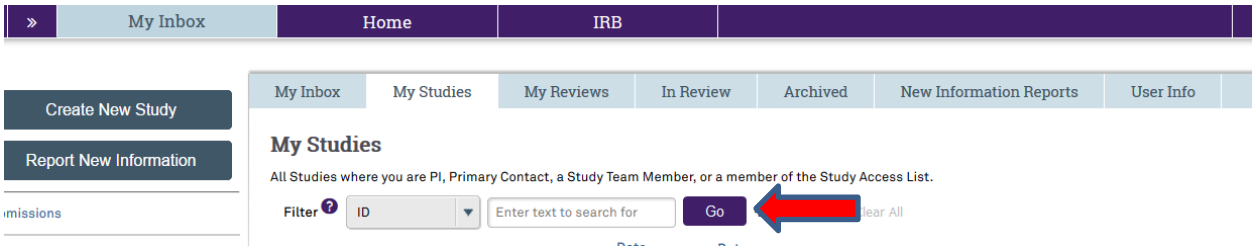
Submitting a Modification

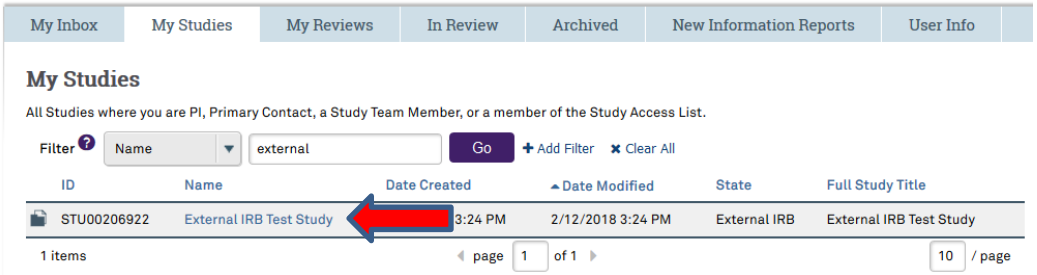
1. Go to the main page for [eIRB+](#) and login.



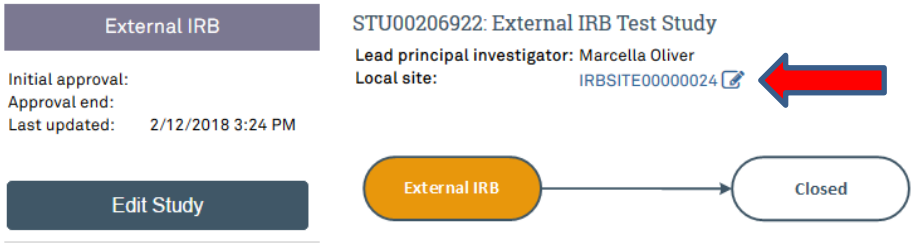
2. Once in the system you will be routed to your inbox.
3. You will then select “My Studies” and then search for the study in which you would like to submit a modification.



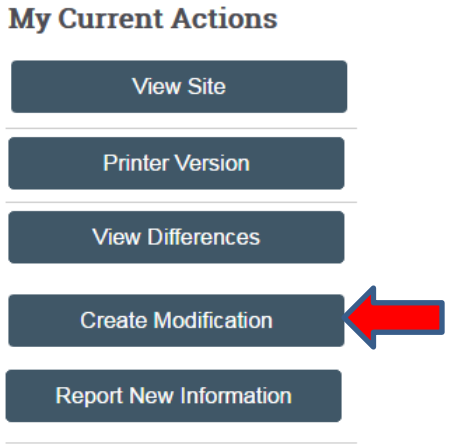
4. Once the study populates select the name and you will then be directed to the main page of the overall “Study” application for the External IRB study.



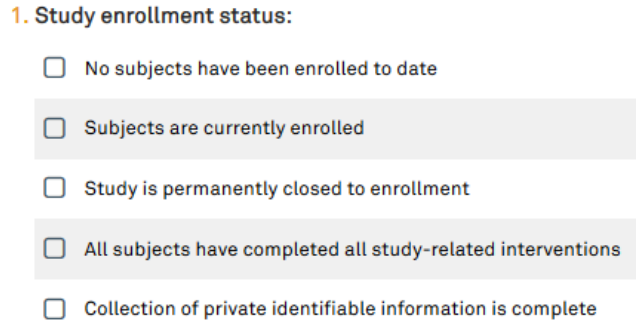
5. Once on the main page, navigate to the IRBSITE record.



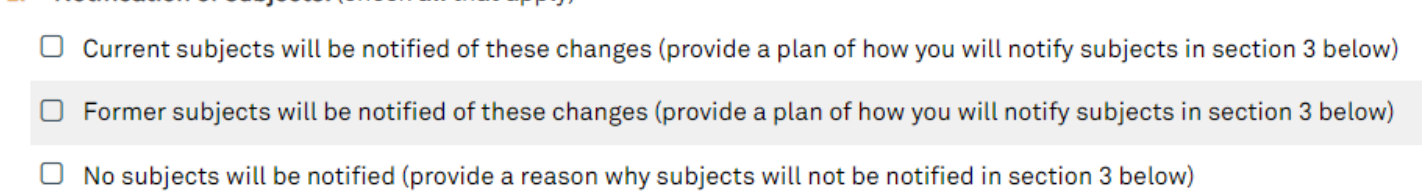
6. As you are redirected to the IRBSITE submission, on the left side of the page you will then select “Create Modification” on the left side of the page under “My Current Actions”.



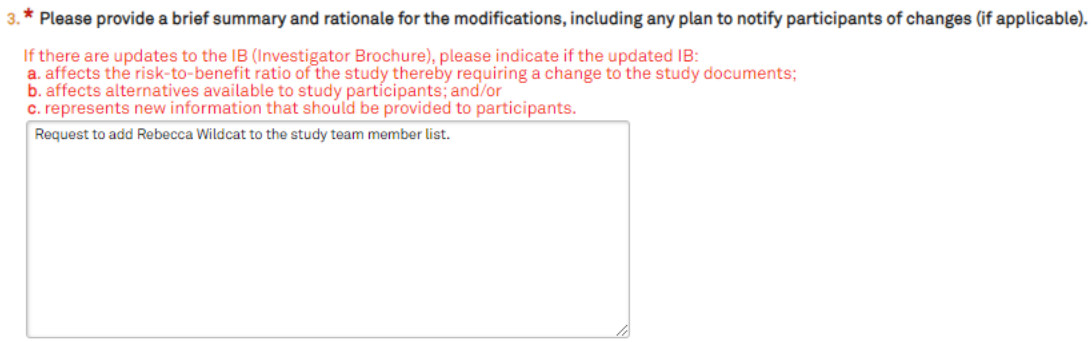
7. You will then be routed to the "**Modification**" page of the submission, on which **2** questions require a response.
    a. **Question 1:** What is the purpose of this submission? The only option will be "modification". Once selected, the second question will appear.
    b. **Question 2:** Modification scope: select one or both options. **By selecting only "Study Team and Research Location Information", you will only have access to the 'study team members' and 'sites' pages. If documents need to be included in this submission, "other parts of the site" needs to be selected**.
        i. Study team and research location information
        ii. Other parts of the site
8. Be aware that once you advance beyond this page, **the study scope selection becomes un-editable**. Once you have provided a response to all questions, select 'continue' located at the top or bottom of the right side of the page.
9. The next page of the application is the "**Modification Information**" page, on which there are **3** questions.
    a. **Question 1:** Study enrollment status: Select the appropriate response(s) based on **Northwestern's** enrollment status.



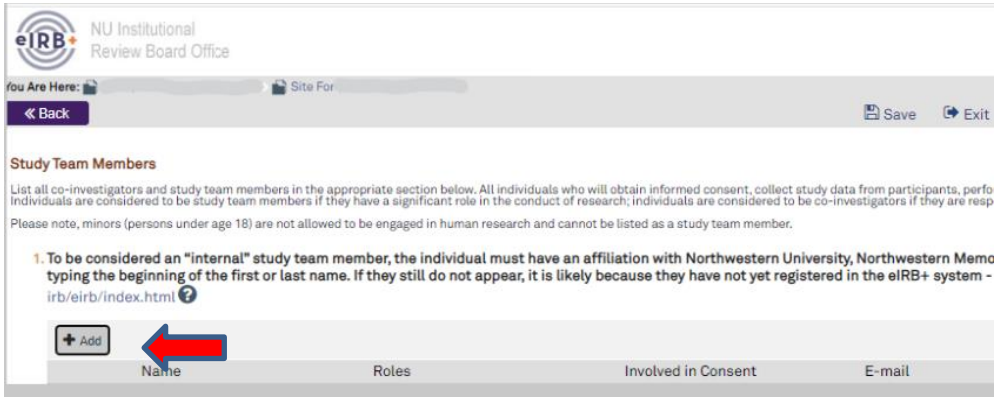
    b. **Question 2:** Indicate whether, and which, participants will be notified of the current study changes.



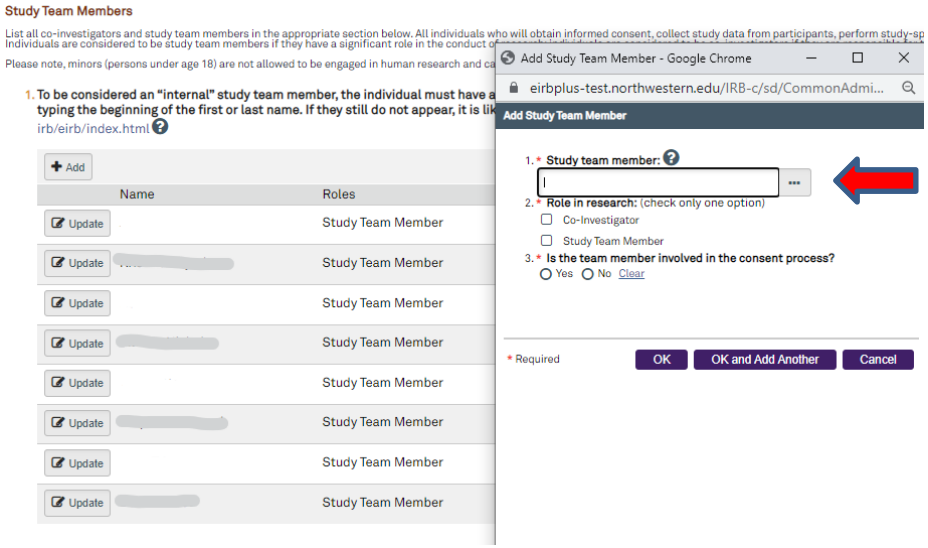
c. **Question 3:** Provide a brief summary or rationale regarding the submission. For example: Request to add Rebecca Wildcat to the study team member list.



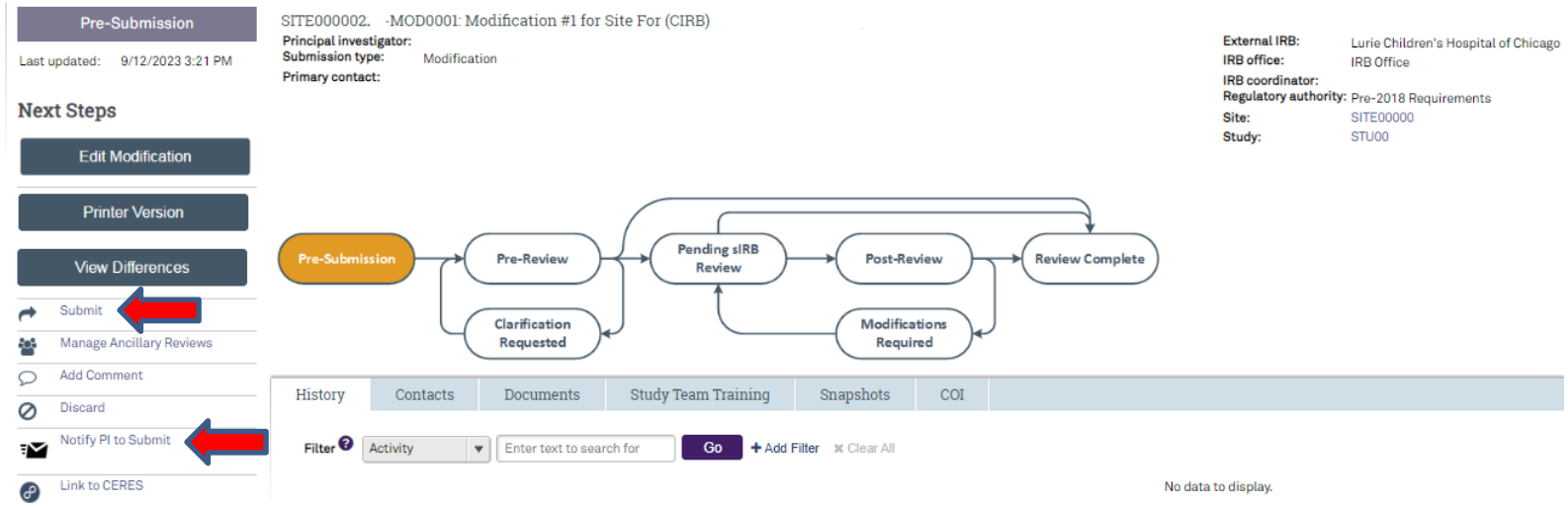
10. Once you have provided a response to all questions, select 'continue' located at the top or bottom of the right side of the page.
11. You will then be redirected to the IRBSITE application, where you will make the requested modifications. If you selected only "study team and research location information", you will be taken directly to the "Study Team Member" page. If you selected "other parts of the site" you will be taken to the "basic information" page of the IRBSITE.
12. The rest of this "Submitting a Modification" tutorial will demonstrate a study team member modification. If you need to make updates to other parts of the submission and/or include documents, please reference the "Submitting a Continuing Review" tutorial for guidance on how and where to upload documents.
13. Once on the "Study Team Members" page, select "add" under question 1.



14. A popup will appear. Click the three dots to search for the person you are adding. Once selected, you will also need to indicate their role in the research (either co-investigator or study team member) and whether they are involved in the consent process in the following two questions within the popup. Repeat this process for each study team member being added. If the requested person is not listed, then they are not registered in the system. They will need to go to https://irb.northwestern.edu/eirb and complete the "New User" steps as listed.

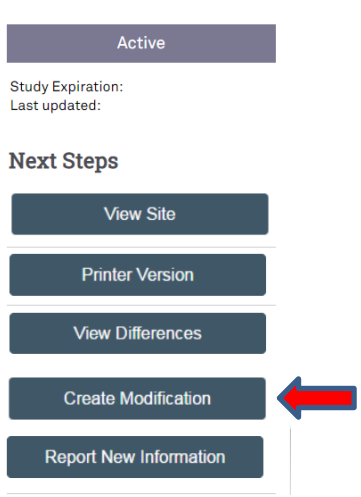


15. Once you have finished making the requested changes, you will be taken to the final page of the “IRBSITE” application. Select “Finish” to continue. You will then be redirected to the modification main page.
16. **Once on the main page for the modification application, you can then submit the modification (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 submitting or notifying the PI to submit. Please also note that submit functionality for the *modification* only occurs on the modification main page, and not on the STU or IRBSITE.**



Submitting a Continuing Review

1. If you already have an unsubmitted "other parts of the site" modification open, navigate to the modification main page, click "edit modification", and skip to Step 7 of the continuing review tutorial**.** If not, you will need to open one. To do so, navigate to the IRBSITE main page. Please see Steps 1 – 5 of the Creating a Modification tutorial for instructions on how to navigate to the IRBSITE main page.
2. As you are redirected to the IRBSITE submission, select "Create Modification" on the left side of the page under "Next Steps".



3. You will then be routed to the "**Modification**" page on which there are **2** questions that require a response.
    a. **Question 1:** What is the purpose of this submission? The only option will be "modification". Once selected, the second question will appear.
    b. **Question 2:** Modification scope. Select option two.
        i. Study team and research location information (e.g., adding a Co-Investigator or other study team member)
        ii. Other parts of the site (e.g., uploading Continuing Review documentation, updating study protocols etc.)
4. Select 'Continue' located at the top or bottom of the right side of the page.

5. The next page of the application is the "**Modification Information**" page, on which there are **3** questions.
    a. **Question 1:** Study enrollment status. Select the appropriate response(s) based on **Northwestern's** enrollment status.

1. **Study enrollment status:**

- ☐ No subjects have been enrolled to date
- ☐ Subjects are currently enrolled
- ☐ Study is permanently closed to enrollment
- ☐ All subjects have completed all study-related interventions
- ☐ Collection of private identifiable information is complete

    b. **Question 2:** Notification of subjects. Indicate whether, and which, participants will be notified of the current study changes.

2. * **Notification of subjects:** (check all that apply)

- ☐ Current subjects will be notified of these changes (provide a plan of how you will notify subjects in section 3 below)
- ☐ Former subjects will be notified of these changes (provide a plan of how you will notify subjects in section 3 below)
- ☐ No subjects will be notified (provide a reason why subjects will not be notified in section 3 below)

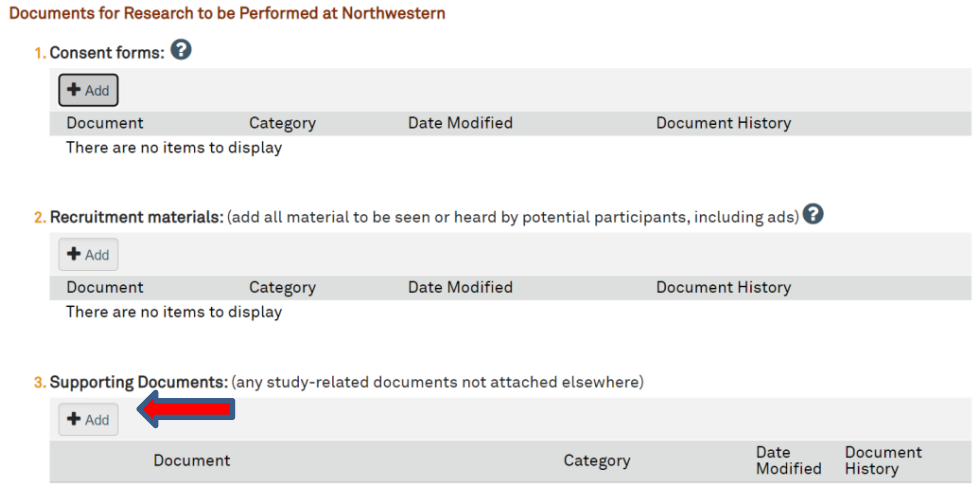
    c. **Question 3:** Provide a brief summary or rationale regarding the submission. (**For example: This modification includes applicable Continuing Review documentation from the reviewing IRB**).

3. * **Please provide a brief summary and rationale for the modifications, including any plan to notify participants of changes (if applicable).**

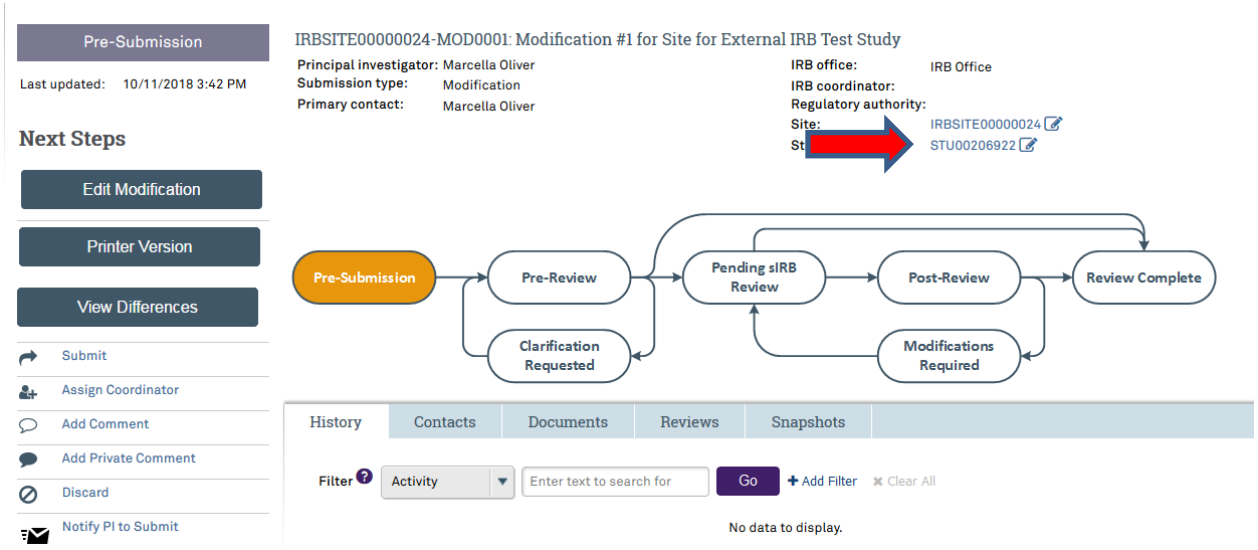
If there are updates to the IB (Investigator Brochure), please indicate if the updated IB:
a. affects the risk-to-benefit ratio of the study thereby requiring a change to the study documents;
b. affects alternatives available to study participants; and/or
c. represents new information that should be provided to participants.

This modification includes applicable Continuing Review documentation from the reviewing IRB.

6. Select 'Continue' located at the top or bottom of the right side of the page.
7. Navigate through the submission until you reach the page titled "Documents for Research to be Performed at Northwestern". Upload your Continuing Review documentation issued by the reviewing IRB in the supporting documents section. If there were any additional study updates or updated documents (e.g., protocol, consent form, survey, etc.) approved at the time of continuing review, these will also need to be included in this submission. Please refer to our "Where to Upload Documents for External IRB Studies" resource for further guidance on where to upload applicable documents.

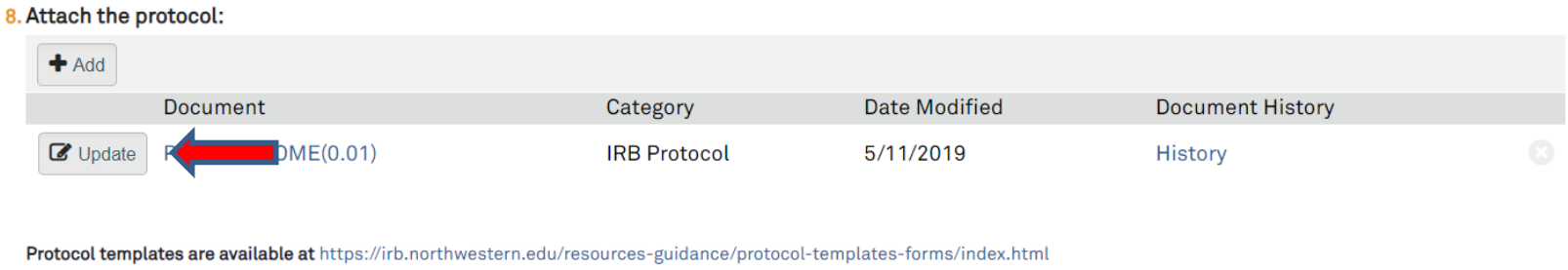


8. Once you've finished uploading all document(s), select 'Continue' located at the top or bottom of the right side of the page. Navigate through the rest of the modification until you reach the final page of the submission. Select 'Finish' located on the bottom right of the page to navigate back to the modification main page.
9. Next, update the study's expiration date in the STU. Navigate to the STUDY record "STU00XXXXXX"

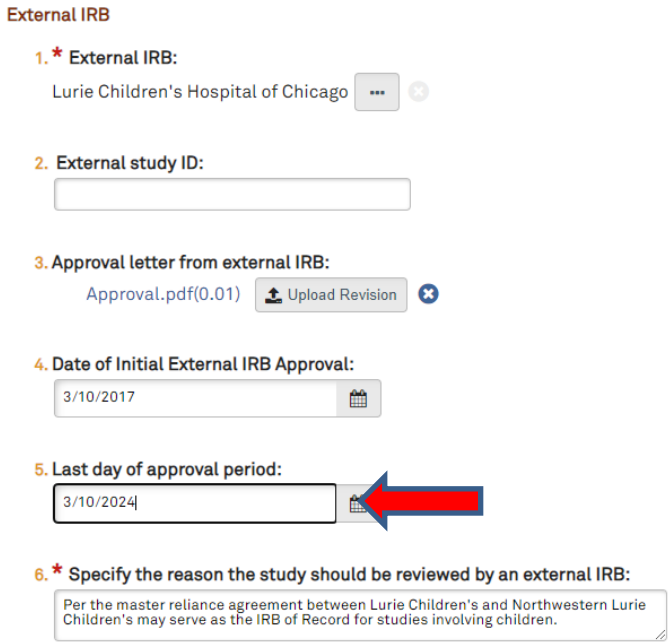


10. Click on "Edit Study"

11. The study will open the basic information page of the STU. If an update to the protocol was made as part of this continuing review, the updated protocol should be uploaded here. Scroll down to the bottom of the page and upload the updated protocol to the protocol field using the 'update' button.

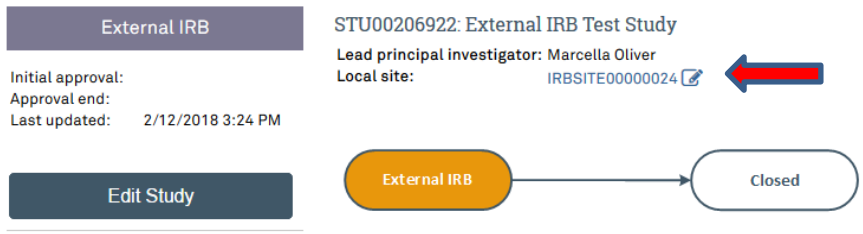


12. Select 'Continue' located at the top or bottom of the right side of the page to navigate to the "External IRB" page. On the External IRB page, update the response to **Question 5: Last day of approval period:** to the new expiration date indicated on the continuing review approval letter. This is the only action that should be taken on this page. **Do not** upload the external IRB Continuing Review approval letter on this page. This should already be uploaded to the IRBSITE at this point.

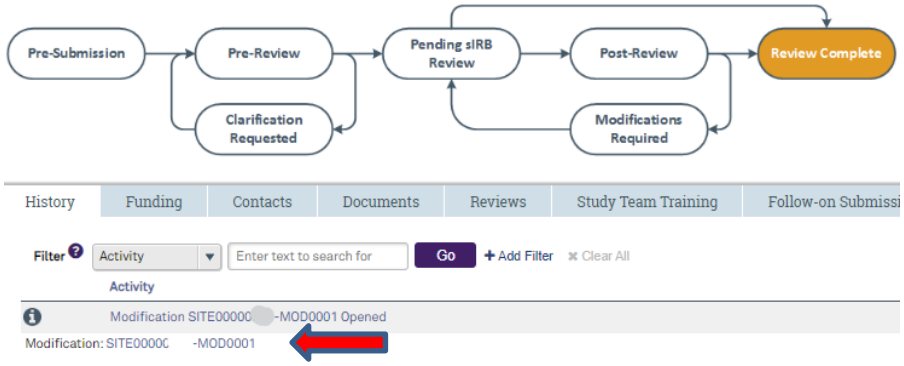


13. If additional documents need to be uploaded to the STU (e.g., study-wide recruitment materials, updated measures, package inserts, IBs etc.), these should be uploaded at this time. Please use the "Where to Upload Documents for External IRB Studies" resource for guidance on where documents should be uploaded.

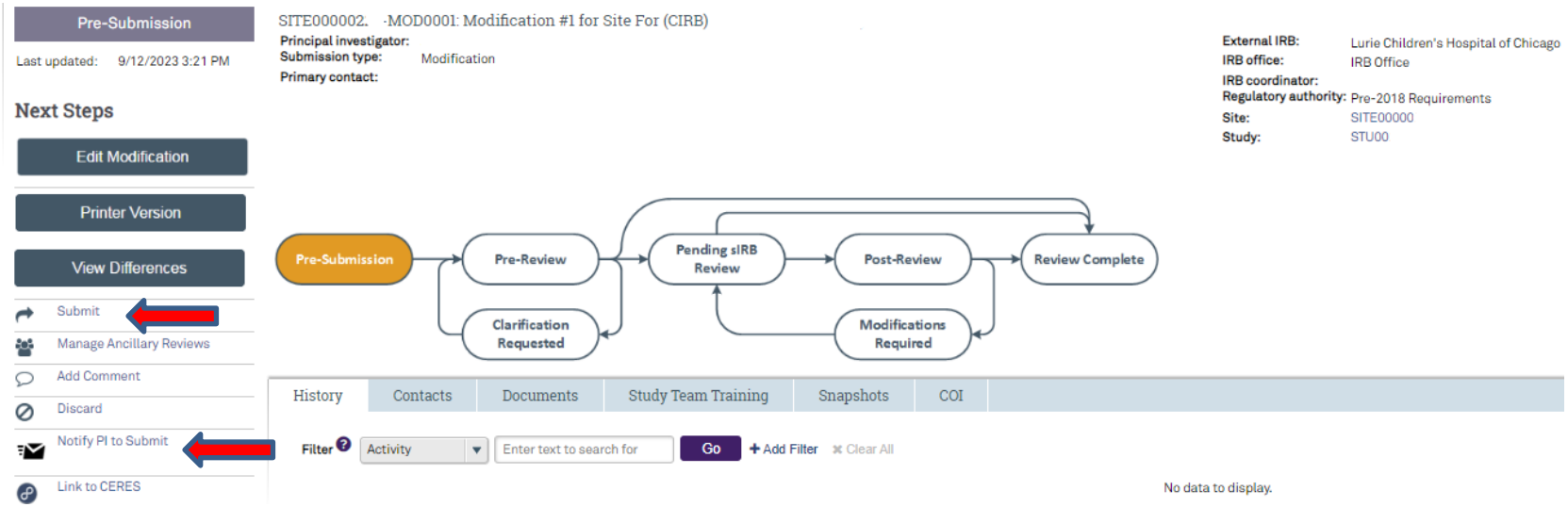
14. Select 'Continue' located at the top or bottom of the right side of the page until you reach then end of the submission. Then, select 'Finish' to navigate back to the STU page. Next, navigate back to the IRBSITE.



15. Once back on the IRBSITE main page, navigate to the open modification.

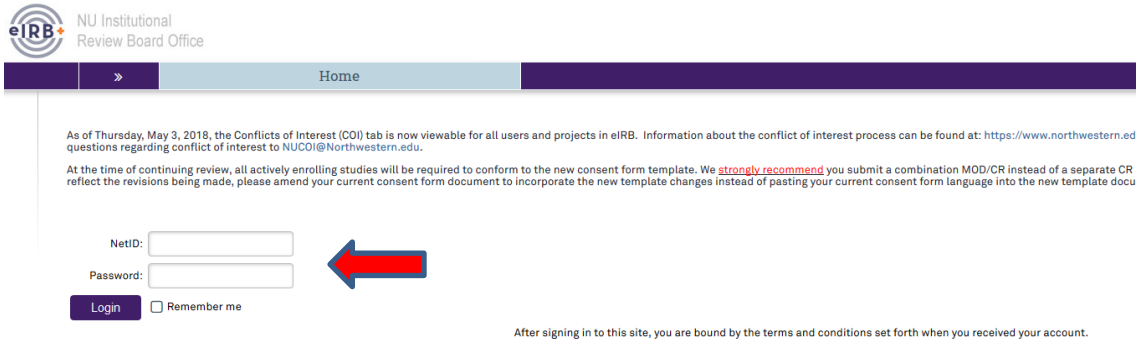


16. Once on the main page for the modification application, you can then submit the application (if you have appropriate permissions in eIRB+ to do so) or notify the PI to submit. Please note: Notifications to PI's to submit the study are sent via email from the eIRB+ system. If applicable and if you receive an error message, make sure that the RSS indicates "Completed" before submitting or notifying the PI to submit. Please also note that submit functionality for the *modification* only occurs on the modification page, and not on the STU or IRBSITE.

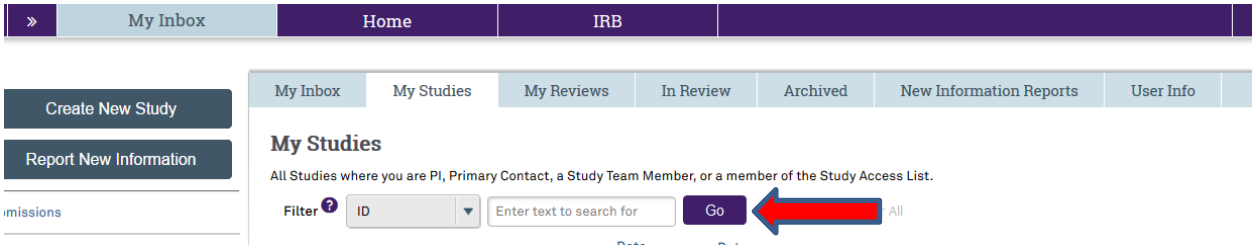


Submitting a Northwestern Site Closure

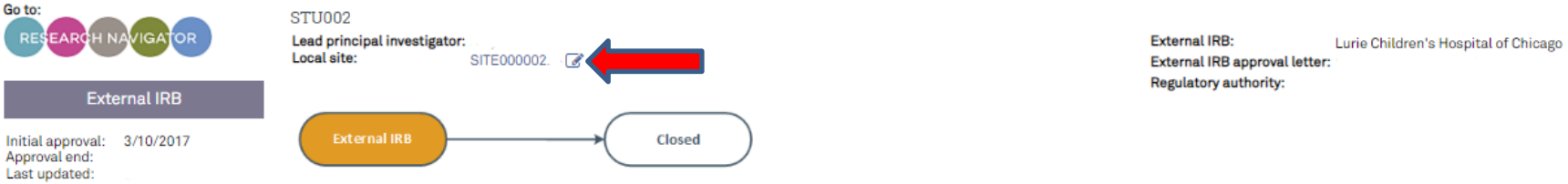
1. Go to the eIRB+ main page and login.



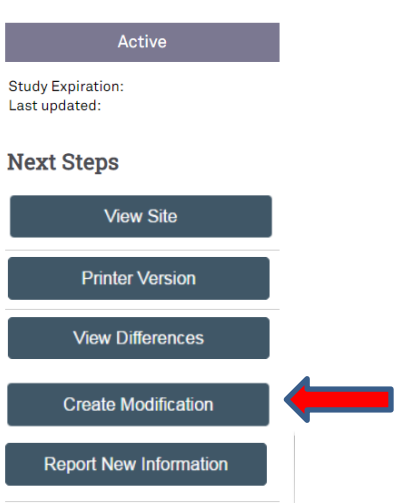
2. Once in the system you will be routed to your inbox.
3. Select “My Studies” and then search for the study that you need to close.



4. Once the study populates, select the name and you will be directed to the main page of the overall “Study” application for the External IRB study.
5. Once on the main page, navigate to the main page of the IRBSITE.



6. As you are redirected to the IRBSITE submission, select “Create Modification” on the left side of the page under “My Current Actions”.



7. You will then be routed to be “**Modification**” page on which there are **2** questions requiring a response.
    a. **Question 1:** What is the purpose of this submission? The only option will be “modification”. Once selected, the second question will appear.
    b. **Question 2:** Modification scope. Select option two.
        i. Study team and research location information (e.g., adding a Co-Investigator or other study team member)
        ii. Other parts of the site (e.g., uploading Continuing Review documentation, updating study protocols etc.)
8. Select ‘Continue’ located at the top or bottom of the right side of the page.
9. The next page of the application is the “**Modification Information**” page, on which there are **3** questions.

a. **Question 1:** Study enrollment status. Your response to this question relates to Northwestern study activities only, it is acceptable for study activities to be ongoing at <u>other external sites</u>. Your response should also indicate that collection of private identifiable data, enrollment, and interventions are no longer occurring at the Northwestern site. Select "No subjects have been enrolled to date" if no participants were enrolled at the Northwestern site.

1. **Study enrollment status:**

- ☐ No subjects have been enrolled to date
- ☐ Subjects are currently enrolled
- ☐ Study is permanently closed to enrollment
- ☐ All subjects have completed all study-related interventions
- ☐ Collection of private identifiable information is complete

b. **Question 2:** Notification of subjects. Indicate whether, and which, participants will be notified of the current study changes.

2. * **Notification of subjects:** (check all that apply)

- ☐ Current subjects will be notified of these changes (provide a plan of how you will notify subjects in section 3 below)
- ☐ Former subjects will be notified of these changes (provide a plan of how you will notify subjects in section 3 below)
- ☐ No subjects will be notified (provide a reason why subjects will not be notified in section 3 below)

a. **Question 3:** Provide a brief summary or rationale regarding the submission. (**For example: This modification closes the Northwestern site for this study. Included is a study closer memo from the reviewing IRB.**).

3. * **Please provide a brief summary and rationale for the modifications, including any plan to notify participants of changes (if applicable).**

If there are updates to the IB (Investigator Brochure), please indicate if the updated IB:
a. affects the risk-to-benefit ratio of the study thereby requiring a change to the study documents;
b. affects alternatives available to study participants; and/or
c. represents new information that should be provided to participants.

This modification closes the Northwestern site for this study. Included is a study closer memo from the reviewing IRB.

10. Select 'Continue' located at the top or bottom of the right side of the page.
11. Navigate through the submission until you reach the page titled, "Documents for Research to be Performed at Northwestern". Upload your study closure approval letter issued by the reviewing IRB in the supporting documents section.

Documents for Research to be Performed at Northwestern

1. **Consent forms:**

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

2. **Recruitment materials:** (add all material to be seen or heard by potential participants, including ads)

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

3. **Supporting Documents:** (any study-related documents not attached elsewhere)

+ Add

Document	Category	Date Modified	Document History

12. Select ‘Continue’ located at the top or bottom of the right side of the page. Navigate through the rest of the modification until you reach the final page of the submission. Select ‘Finish’ located on the bottom right of the page to navigate back to the modification main page.
13. Once on the modification main page, you can then submit the modification (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 submitting or notifying the PI to submit. Please also note that submit functionality for the *modification* only occurs on the modification main page, and not on the STU or IRBSITE.