

# 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

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



NU Institutional Review Board Office

Home

As of Thursday, May 3, 2018, the Conflicts of Interest (COI) tab is now viewable for all users and projects in eIRB. Information about the conflict of interest process can be found at: <https://www.northwestern.edu/questions/regarding/conflict-of-interest-to-NICOI@Northwestern.edu>

At the time of continuing review, all actively enrolling studies will be required to conform to the new consent form template. We **strongly recommend** you submit a combination MOD/CR instead of a separate CR reflect the revisions being made, please amend your current consent form document to incorporate the new template changes instead of pasting your current consent form language into the new template docu

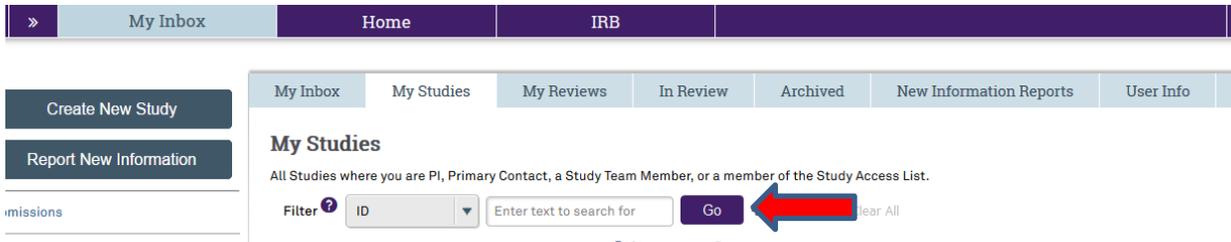
NetID:

Password:

Login  Remember me

After signing in to this site, you are bound by the terms and conditions set forth when you received your account.

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.



My Inbox Home IRB

Create New Study

Report New Information

missions

My Studies

All Studies where you are PI, Primary Contact, a Study Team Member, or a member of the Study Access List.

Filter  Enter text to search for Go

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.

ID	Name	Date Created	Date Modified	State	Full Study Title
STU00206922	External IRB Test Study	3:24 PM	2/12/2018 3:24 PM	External IRB	External IRB Test Study

1 items      page 1 of 1      10 / page

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

**External IRB**

Initial approval:  
Approval end:  
Last updated: 2/12/2018 3:24 PM

[Edit Study](#)

**STU00206922: External IRB Test Study**

Lead principal investigator: Marcella Oliver  
Local site: [IRBSITE00000024](#)

[External IRB](#) → [Closed](#)

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”.

### My Current Actions

- [View Site](#)
- [Printer Version](#)
- [View Differences](#)
- [Create Modification](#)
- [Report New Information](#)

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.
    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:** 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)

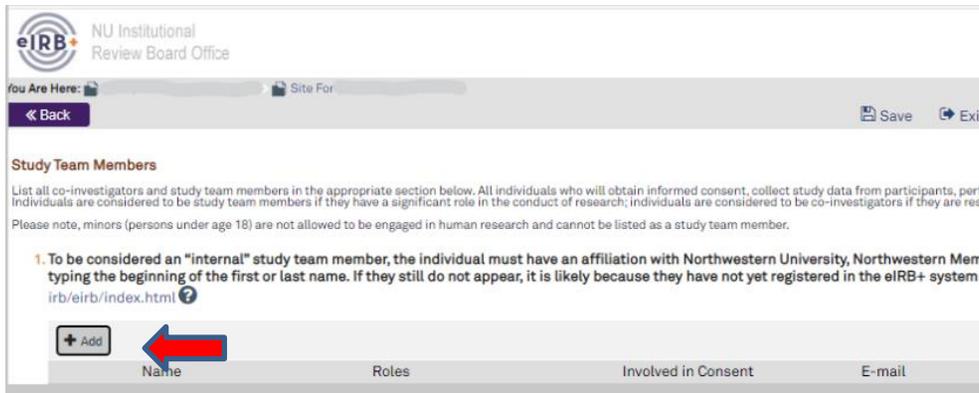
- c. **Question 3:** Provide a brief summary or rationale regarding the submission. For example: Request to add Rebecca Wildcat to the study team member list.

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

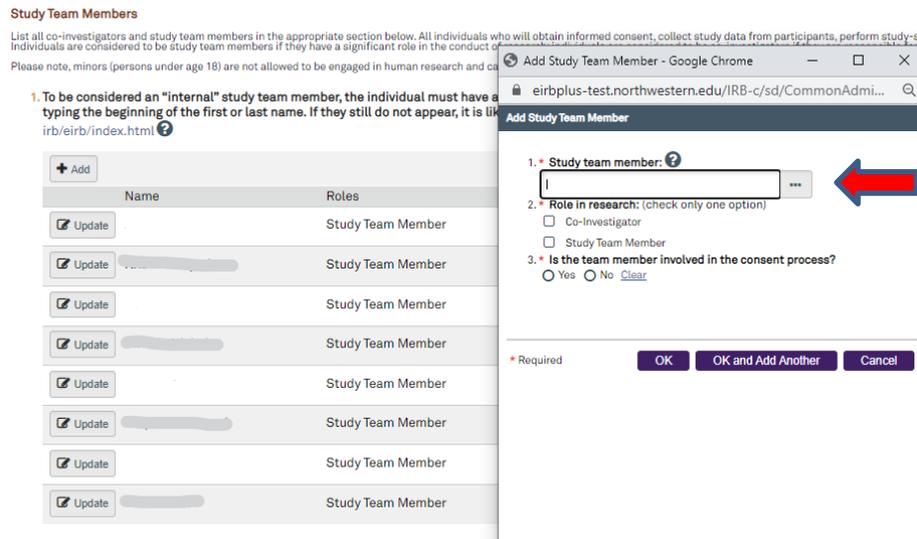
If there are updates to the IB (Investigator Brochure), please indicate if the updated IB:  
a. affects the risk-to-benefit ratio of the study thereby requiring a change to the study documents;  
b. affects alternatives available to study participants; and/or  
c. represents new information that should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

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.

**Pre-Submission**

Last updated: 9/12/2023 3:21 PM

**Next Steps**

- [Edit Modification](#)
- [Printer Version](#)
- [View Differences](#)
- [Submit](#)
- [Manage Ancillary Reviews](#)
- [Add Comment](#)
- [Discard](#)
- [Notify PI to Submit](#)
- [Link to CERES](#)

SITE000002. -MOD0001: Modification #1 for Site For (CIRB)

**Principal investigator:** \_\_\_\_\_

**Submission type:** Modification

**Primary contact:** \_\_\_\_\_

**External IRB:** Lurie Children's Hospital of Chicago

**IRB office:** IRB Office

**IRB coordinator:** \_\_\_\_\_

**Regulatory authority:** Pre-2018 Requirements

**Site:** SITE00000

**Study:** STU00

```

graph LR
    A([Pre-Submission]) --> B([Pre-Review])
    A --> C([Clarification Requested])
    B --> D([Pending sIRB Review])
    C --> D
    D --> E([Post-Review])
    E --> F([Review Complete])
    G([Modifications Required]) --> D
  
```

History | [Contacts](#) | [Documents](#) | [Study Team Training](#) | [Snapshots](#) | [COI](#)

Filter ? Activity ▼  [Go](#) [+ Add Filter](#) [x Clear All](#)

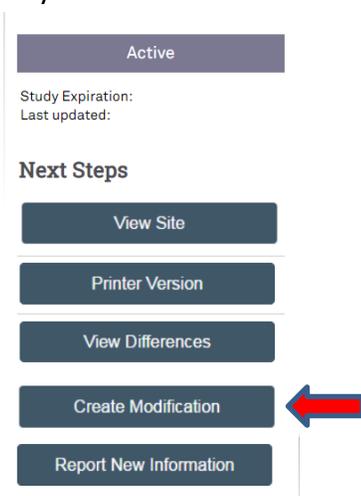
No data to display.

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## Submitting a Continuing Review

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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.

Documents for Research to be Performed at Northwestern

1. Consent forms: ?

<input type="button" value="+ 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) ?

<input type="button" value="+ Add"/>			
Document	Category	Date Modified	Document History
There are no items to display			

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

<input type="button" value="+ Add"/> 				
Document	Category	Date Modified	Document History	

- 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.
- Next, update the study's expiration date in the STU. Navigate to the STUDY record "STU00XXXXXX"

**Pre-Submission**

Last updated: 10/11/2018 3:42 PM

**Next Steps**

Edit Modification

Printer Version

View Differences

Submit

Assign Coordinator

Add Comment

Add Private Comment

Discard

Notify PI to Submit

IRBSITE00000024-MOD0001: Modification #1 for Site for External IRB Test Study

Principal investigator: Marcella Oliver  
 Submission type: Modification  
 Primary contact: Marcella Oliver

IRB office: IRB Office  
 IRB coordinator:  
 Regulatory authority:  
 Site: IRBSITE00000024  
 St: **STU00206922**

History | Contacts | Documents | Reviews | Snapshots

Filter: Activity | Enter text to search for | Go | + Add Filter | x Clear All

No data to display.

10. Click on "Edit Study"

**External IRB**

Initial approval:  
 Approval end:  
 Last updated: 2/12/2018 3:24 PM

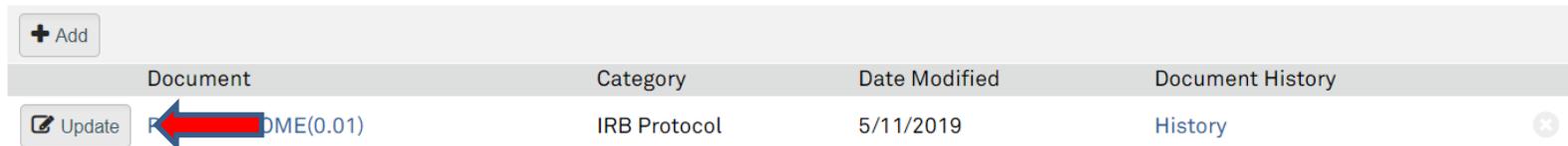
Edit Study

STU00206922: External IRB Test Study

Lead principal investigator: Marcella Oliver  
 Local site: IRBSITE00000024

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.

8. Attach the protocol:



+ Add			
Document	Category	Date Modified	Document History
 Update P...DME(0.01)	IRB Protocol	5/11/2019	History 

Protocol templates are available at <https://irb.northwestern.edu/resources-guidance/protocol-templates-forms/index.html>

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.

External IRB

1. \* External IRB:

Lurie Children's Hospital of Chicago  

2. External study ID:

3. Approval letter from external IRB:

Approval.pdf(0.01)  Upload Revision 

4. Date of Initial External IRB Approval:

5. Last day of approval period:

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

Per the master reliance agreement between Lurie Children's and Northwestern Lurie Children's may serve as the IRB of Record for studies involving children.

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.

**External IRB**

Initial approval:  
Approval end:  
Last updated: 2/12/2018 3:24 PM

**Edit Study**

STU00206922: External IRB Test Study

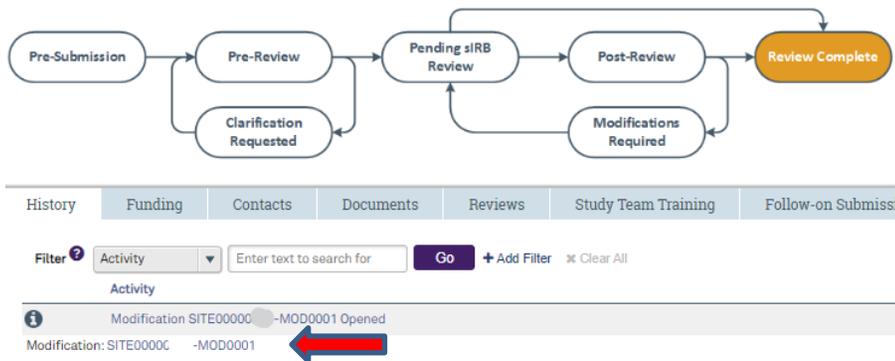
Lead principal investigator: Marcella Oliver

Local site: IRBSITE00000024 



External IRB → Closed

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.

**Pre-Submission**

Last updated: 9/12/2023 3:21 PM

**Next Steps**

- Edit Modification
- Printer Version
- View Differences
- Submit
- Manage Ancillary Reviews
- Add Comment
- Discard
- Notify PI to Submit
- Link to CERES

SITE000002. -MOD0001: Modification #1 for Site For (CIRB)

Principal investigator:

Submission type: Modification

Primary contact:

External IRB: Lurie Children's Hospital of Chicago

IRB office: IRB Office

IRB coordinator:

Regulatory authority: Pre-2018 Requirements

Site: SITE00000

Study: STU00

The flowchart is identical to the one in step 15, showing the progression from Pre-Submission to Review Complete, with loops for Clarification Requested and Modifications Required.

History | Contacts | Documents | Study Team Training | Snapshots | COI

Filter: Activity | Enter text to search for | Go | + Add Filter | x Clear All

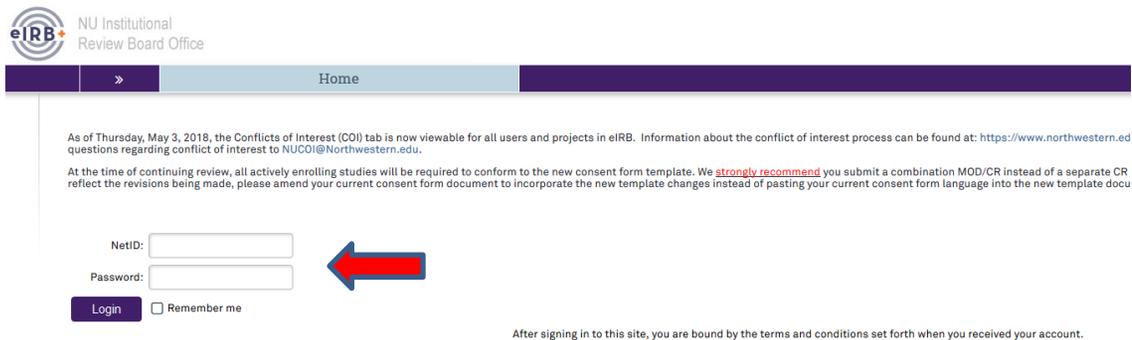
No data to display.

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## Submitting a Northwestern Site Closure

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



As of Thursday, May 3, 2018, the Conflicts of Interest (COI) tab is now viewable for all users and projects in eIRB. Information about the conflict of interest process can be found at: <https://www.northwestern.edu/questions/regarding/conflict-of-interest-to-NUCOI@Northwestern.edu>.

At the time of continuing review, all actively enrolling studies will be required to conform to the new consent form template. We **strongly recommend** you submit a combination MOD/CR instead of a separate CR reflect the revisions being made, please amend your current consent form document to incorporate the new template changes instead of pasting your current consent form language into the new template docu

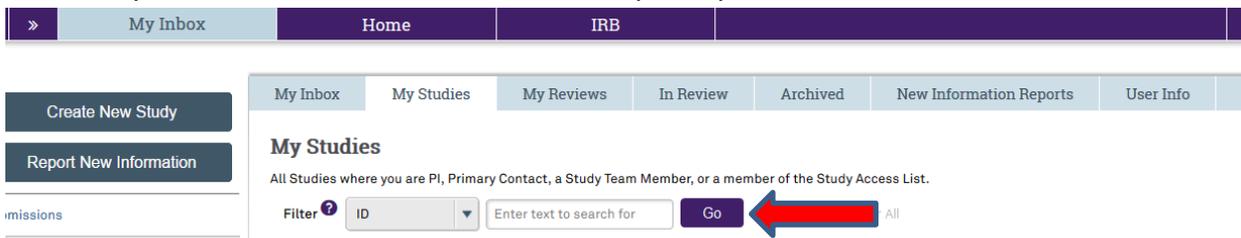
NetID:

Password:

Remember me

After signing in to this site, you are bound by the terms and conditions set forth when you received your account.

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.



My Inbox My Studies My Reviews In Review Archived New Information Reports User Info

Create New Study

Report New Information

missions

My Studies

All Studies where you are PI, Primary Contact, a Study Team Member, or a member of the Study Access List.

Filter ? ID [v] Enter text to search for  All

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.

Go to:  
RESEARCH NAVIGATOR

External IRB

Initial approval: 3/10/2017  
Approval end:  
Last updated:

STU002

Lead principal investigator:

Local site:

SITE000002



External IRB: Lurie Children's Hospital of Chicago  
External IRB approval letter:  
Regulatory authority:

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

Active

Study Expiration:  
Last updated:

**Next Steps**

- View Site
- Printer Version
- View Differences
- Create Modification**
- Report New Information

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

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) ?

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

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



Document	Category	Date Modified	Document History
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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.

**Pre-Submission**

Last updated: 9/12/2023 3:21 PM

**Next Steps**

- Edit Modification
- Printer Version
- View Differences
- Submit ←
- Manage Ancillary Reviews
- Add Comment
- Discard
- Notify PI to Submit ←
- Link to CERES

SITE000002. -MOD0001: Modification #1 for Site For (CIRB)

Principal investigator:  
 Submission type: Modification  
 Primary contact:

External IRB: Lurie Children's Hospital of Chicago  
 IRB office: IRB Office  
 IRB coordinator:  
 Regulatory authority: Pre-2018 Requirements  
 Site: SITE00000  
 Study: STU00

```

    graph LR
      A([Pre-Submission]) --> B([Pre-Review])
      B --> C([Pending sIRB Review])
      B --> D([Clarification Requested])
      C --> E([Post-Review])
      E --> F([Review Complete])
      E --> G([Modifications Required])
      G --> C
      F --> A
      
```

History

Contacts

Documents

Study Team Training

Snapshots

COI

Filter ? Activity ▼  Go + Add Filter ✕ Clear All

No data to display.