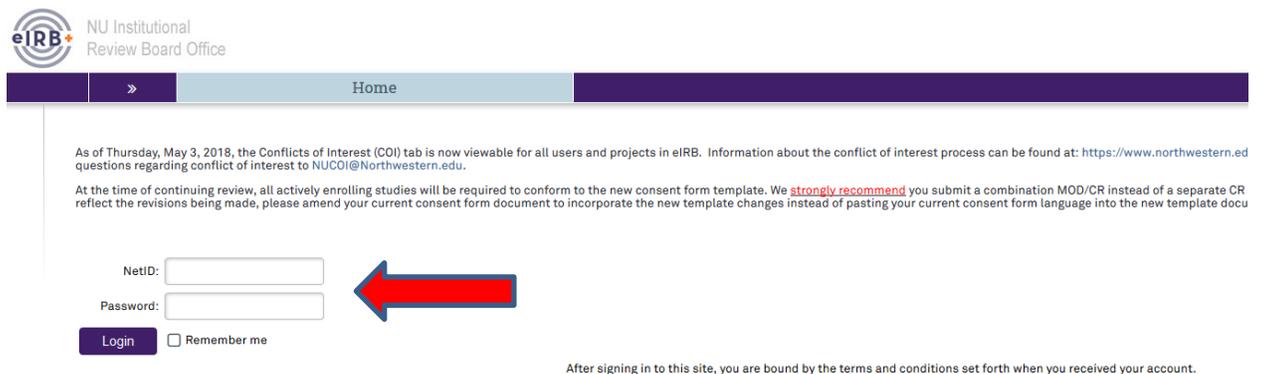


eIRB+ Tutorial: New Study Submission – External IRB with a Master Reliance Agreement

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.



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:

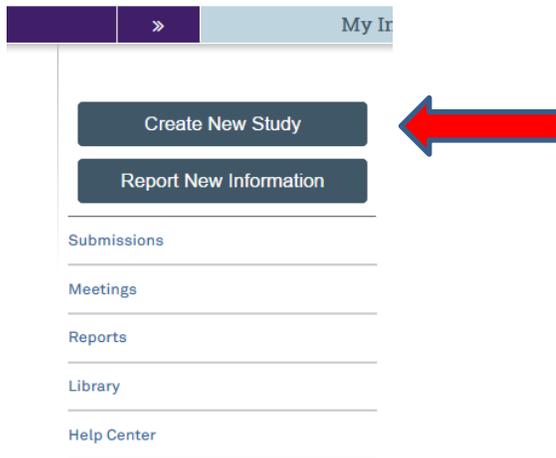
Password:

Remember me

Login

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. 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.

3. Approval letter from external IRB:

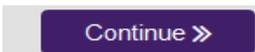
[None]  Upload

- d. **Question 4:** Select the initial approval date as provided by the External IRB.
- e. **Question 5:** Select the last day of approval (expiration date) as provided by the External IRB.
- f. **Question 6:** Provide information for the reason the study should be reviewed by the External IRB (**For example: Per the Master Agreement in place between both institutions, the External IRB will serve as the IRB of Record for all studies**).

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

Per the Lurie Children's and Northwestern University IRB Authorization Agreement (IAA), this study is using the Lurie Children's as the IRB of record.

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



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

Sources of Funding and Other Support

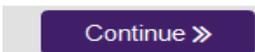
1. * Identify each organization supplying funding for the study:

 Add

Funding Source

(NIH) National Institute of Allergy and Infectious Diseases

- 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.

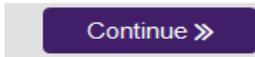
Study Scope

1. * Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition? 
 Yes No [Clear](#)
2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?
 Yes No [Clear](#)

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.)

Study-Related Documents for non-NU Research Sites

1. Consent forms: 

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

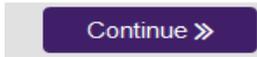
2. Recruitment materials: (add all material to be seen or heard by potential participants, including ads) 

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
There are no items to display			

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.



Final Page and optionally RSS

Certain studies require additional information via the Research Supplemental Submission (RSS). RSS information is needed on a study (or modification) if the PI is affiliated with Feinberg School of Medicine OR NMHC (or one of its affiliates) is a study site. This information is not used in IRB review, nor is it visible to the IRB or IRB Reviewers.

The RSS is REQUIRED for this submission. If you do not see the RSS questions below, the study's primary contact should execute the "Manage Study Access" activity on the study to add you to the guest list. (If this is a modification, they should do so on the root study)

Click Finish to exit the form.

1. Important! To send the submission for review, click Submit on the next page.

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.

STU00207213: (xIRB) Test Study
Lead principal investigator: SC1 Test Account
Local site: IRBSITE00000240

External IRB: Lurie Children's Hospital of Chicago
External IRB approval letter:
Regulatory authority: Pre-2018 Requirements

External IRB → Closed

This project has an unsubmitted Site record. You will need to submit the (NU) Study Site for approval to do research at NU. You can access it via the 'Local Site' link above.

History	Funding	Project Contacts	Documents	Follow-on Submissions	Reviews	Snapshots	Study Team Training	External IRB Info
Filter: Activity [v] Enter text to search for [] Go [] + Add Filter [] x Clear All []								
	Activity		Author					Activity Date
	Site Created		Test Account, SC1					7/23/2018 4:04 PM
Link: Site for (xIRB) Test Study								
	Study Created		Test Account, SC1					7/23/2018 4:04 PM

19. Select the link* to the "Site" record.

STU00207213: (xIRB) Test Study
Lead principal investigator: SC1 Test Account
Local site: IRBSITE00000240



OR

STU00207213: (xIRB) Test Study
Lead principal investigator: SC1 Test Account
Local site: IRBSITE00000240

External IRB: Lurie Children's Hospital of Chicago
External IRB approval letter:
Regulatory authority: Pre-2018 Requirements



This project has an unsubmitted Site record. You will need to submit the (NU) Study Site for approval to do research at NU. You can access it via the 'Local Site' link above.

History	Funding	Project Contacts	Documents	Follow-on Submissions	Reviews	Snapshots	Study Team Training	External IRB Info
Filter ?		Activity	Enter text to search for	Go	+ Add Filter	x Clear All		
Activity	Author		Activity Date					
Site Created	Test Account, SC1		7/23/2018 4:04 PM					
Link: Site for (xIRB) Test Study								
Study Created	Test Account, SC1		7/23/2018 4:04 PM					

*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.

Pre-Submission

IRBSITE00000240: Site for (xIRB) Test Study

Principal investigator: SC1 Test Account
Submission type: IRB Site
Primary contact: SC1 Test Account
PI proxies:

IRB office: IRB Office
IRB coordinator:
Regulatory authority: Pre-2018 Requirements
Study: STU00207213
External study ID: 2018-1234

Study Expiration: 7/1/2019
Last updated: 7/24/2018 2:08 PM

My Current Actions

- Edit Site
- Printer Version
- View Differences

- Submit
- Assign Primary Contact
- Manage Ancillary Reviews
- Correspond with sIRB
- Add Comment
- Discard
- Notify PI to Submit

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

History

Funding	Contacts	Documents	Reviews	Study Team Training	Snapshots		
Filter ?		Activity	Enter text to search for	Go	+ Add Filter	x Clear All	
Activity	Author		Activity Date				
Site Created	Test Account, SC1		7/23/2018 4:04 PM				

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

1. * Title of site:

Site for (x)IRB Test Study

Basic Information page (Site Application)

2. * Short title:

Site for (x)IRB Test Study

3. * Brief description of local study activities: ?

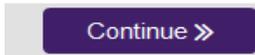
Site for (x)IRB Test Study

4. * Principal investigator:

SC1 Test Account

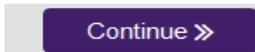
22. For **Question 3**, please add a description of what portion of the study will be conducted at the Northwestern site.

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).**

Study Team Members

1. Internal Personnel

Identify each additional person involved in the design, conduct, or reporting of the research: ?

+ Add

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

2. External Personnel

Identify each external person who will interact with participants or have access to identifiable data for whom NU IRB will have oversight responsibility such as Interns/Volunteers, research staff covered by an IRB Authorization Agreement (IAA) or Individual Investigator Agreement (IIA). Do not list research staff from other institutions that have their own IRB approval.

+ Add

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

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

Continue >>

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.

Site-Specific Documents

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
----------	----------	---------------	------------------

There are no items to display

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).

Continue >>

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).

Sites

1. Please specify 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
- Shirley Ryan AbilityLab (SRALab)
- Robert H. Lurie Comprehensive Cancer Center and/or its affiliates

2. If the research will be conducted at International Sites, Schools, (Preschools, Primary Schools, and/or Secondary Schools), or any other locations, please specify these below:

+ Add

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

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

Continue >>

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)

 [Notify 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.