

eIRB+ Tutorial: New Study Submission – External IRB Requiring a Signed Reliance Agreement

This is a step-by-step tutorial of how to submit a new study submission in eIRB+ for a study where a signed, study-specific reliance agreement is required for Northwestern University (NU) to cede review to an External IRB, as per [HRP-092 - SOP External IRBs](#) and [HRP-801 - SOP Establishing Authorization Agreements](#). These instructions apply when using **one** of the following study-specific reliance mechanisms:

- 1) IRB Authorization Agreement (IAA)
- 2) SMART IRB Letter of Authorization (LoA)
- 3) SMART IRB Online Reliance System (ORS)
- 4) IRB Reliance Exchange (IREx)
- 5) Master Agreement Acknowledgement Letter (used when ceding to Advarra or WCG).

Research activities may not commence at the Northwestern site until 1. A reliance agreement is in place **2.** The IRB of Record has approved the Northwestern site, *and* **3.** The Northwestern University IRB has provided acknowledgement for the xIRB submission. For additional information on the overall workflow of this process, please reference our [Reliance Workflows](#).

For studies that will rely on an External IRB for which Northwestern has an established Master Reliance Agreement and that do not require the execution of reliance documents on a study-to-study basis (e.g., Lurie Children’s Hospital IRB, National Cancer Institute CIRB), please refer to the [“New Study Submission - External IRB with a Master Reliance Agreement”](#) tutorial.

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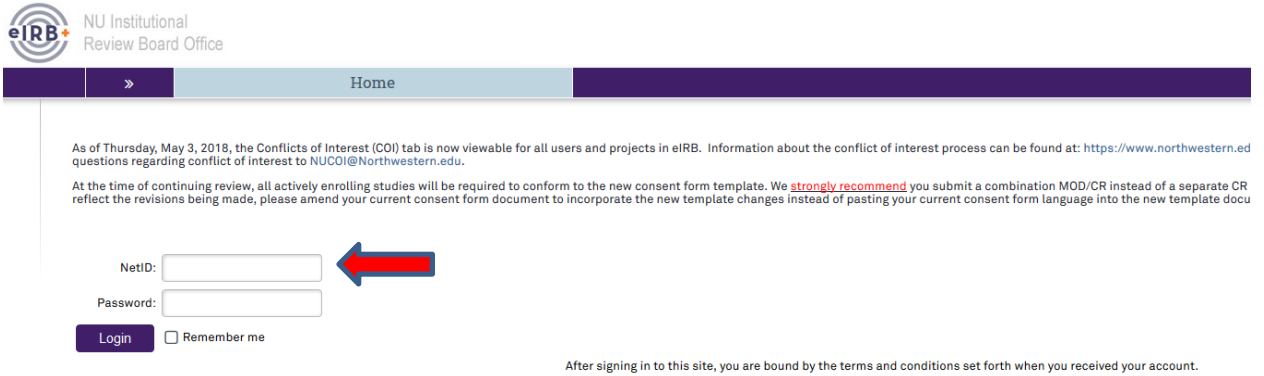
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Step 1: eIRB+ Request for Reliance on an External IRB

To begin the process of executing reliance, the study team must first request for Northwestern to rely on an External IRB (i.e., create an external IRB submission in eIRB+) for a given study. In order to provide the necessary documents and information needed for the IRB Office to review a reliance request, follow the steps below.


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

Step 1: eIRB+ Request for Reliance on an External IRB – STU Submission



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 document.

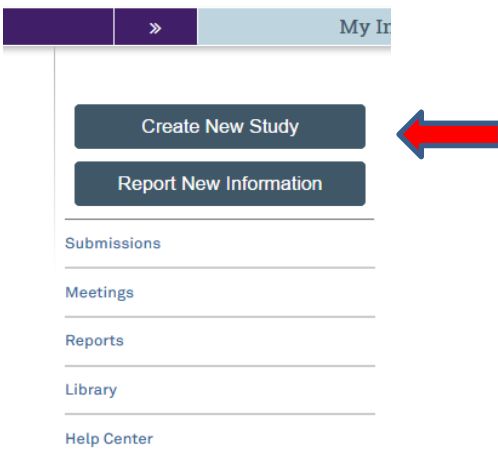
NetID: 

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. On the left side of the page toward the top, select “Create New Study”.



My IRB



[Submissions](#)

[Meetings](#)

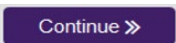
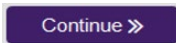
[Reports](#)

[Library](#)

[Help Center](#)

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.
 - **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.
 - **Question 2:** Please provide the short title of the study with “(xIRB)” again at the beginning.
 - **Question 3:** Provide a “Brief Description” of the study. This should be a brief overview of the overall research objectives and activities.
 - **Question 4:** Select the review category appropriate to your research. Either Social-Behavioral or Biomedical.
 - **Question 5:** Principal Investigator (By system default the submission preparer is listed in this section. If this is not correct, then ensure the correct PI information is selected).

Step 1: eIRB+ Request for Reliance on an External IRB – STU Submission

- **Question 6:** Since this is a request to cede review to an External IRB, the response to this question should be “Yes”.
 - **Question 7:** Select the study type appropriate for your protocol.
 - **Question 8:** Provide the overall protocol approved by the External IRB or sponsor.
5. Once you have provided a response to all questions, select  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. Only numbers **1** and **6** are required at this stage.
- 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 6:** Provide rationale for why the study should be reviewed by the External IRB (For example: Per the Cooperative Research Requirement, the External IRB will serve as the IRB of Record for all study sites). **This response must contain valid justification for Northwestern IRB to cede review to an External IRB for the reliance request to be approved.** If utilizing an electronic reliance method like SMART IRB’s ORS or IREx state that here as well.
7. Once you have provided a response to the above questions, select  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.
 - c. 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

Step 1: eIRB+ Request for Reliance on an External IRB – STU Submission

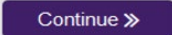
verify that the funding is external and not being handled by an intermediary (e.g. LCH or SRALab). If funding is still unable to be linked, please fill in the rest of the questions manually, including as much information as possible.

Sources of Funding and Other Support

Identify each organization supplying funding for the study - if your study only has funding/support from Northwestern University you must still click on the "+Add" button below and indicate in question 2 the specific NU department/division that is providing funding/support for this study.


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

+ Add						
Funding Source	Sponsor's Funding ID	Prime Sponsor	Grants Office ID	CERES ID	Attachments via SR	Selected via SR chooser?
Industry Funder, Inc.			FP000007	FP000007		yes

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

10. 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.

Study Scope

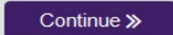
1. * Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition? 
 Yes No [Clear](#)
2. * Does the study evaluate the safety or effectiveness of a device or use a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

11. Select  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.

- 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.


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


Step 1: eIRB+ Request for Reliance on an External IRB – STU Submission

15. The next page of the application is the “**Study-Related Documents for non-NU Research Sites**” page, on which there are **three** questions. Only **Question 1** requires a response at this stage.


- **Question 1 “Consent Forms”**: Upload any template/master consent form(s) provided by the sponsor or approved by the External IRB. These documents do not need to contain Northwestern site-specific language at this stage.

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) 




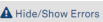




Document	Category	Date Modified	Document History
There are no items to display			

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

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

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

17. 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 Office 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 RSS

RSS: Cancer Research

The Research Supplemental Submission (RSS) collects information about each project submitted to the Northwestern IRB. This information is not used in the course of the IRB review. All projects submitted to the Northwestern IRB should now confirm whether they are cancer-relevant, according to the NIH definition. The remainder of the RSS is required for Feinberg-affiliated PIs or projects where research will take place at NMHC or one of its affiliate sites.

- * 1. Is this a cancer-relevant human subjects research study? Please view the help text to see if the study is cancer-relevant: 
- Yes No

Step 1: eIRB+ Request for Reliance on an External IRB – **IRBSITE Submission**

18. You will then be directed to the main page of the “Study” application. There will be a red script indicating that there is an unsubmitted “Site” record, which will need to be completed 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 Enter text to search for Go Add Filter 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. 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.

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

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 Enter text to search for Go Add Filter 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

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

Step 1: eIRB+ Request for Reliance on an External IRB – IRBSITE Submission

The screenshot displays the IRBSITE submission interface for a study titled "IRBSITE00000240: Site for (xIRB) Test Study". The study expiration is 7/1/2019, and it was last updated on 7/24/2018 at 2:08 PM. The principal investigator is SC1 Test Account, and the submission type is IRB Site. The primary contact is also SC1 Test Account. The IRB office is IRB Office, the IRB coordinator is IRB Office, the regulatory authority is Pre-2018 Requirements, the study ID is STU00207213, and the external study ID is 2018-1234.

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

Workflow Diagram:

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

History Table:

Activity	Author	Activity Date
Site Created	Test Account, SC1	7/23/2018 4:04 PM

21. 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.

Basic Information

- * Title of site:**
- * Short title:**
- * Brief description of local study activities: ?**
- * Principal investigator:**

22. For **Question 3**, add to or edit the study description to describe the research activities that will occur at the Northwestern site and/or be conducted by Northwestern personnel..

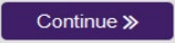
23. Verify that the rest of the pre-generated information is correct, then select

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

24. The next page of the application is the “**Sources of Funding and Other Support**” page. You will need to again select the funding source for the study. The funding items entered here should match the funding source selected in the “Study” application.

Step 1: eIRB+ Request for Reliance on an External IRB – IRBSITE Submission


Please ensure that you are linking all funding from external (non-NU) sources via the “SR Chooser,” as described above.

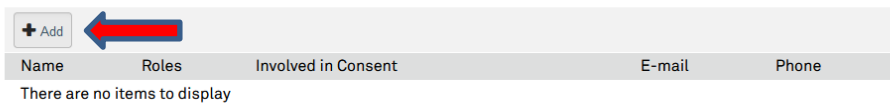
25. Select  located at the top or bottom of the right side of the page.
26. The next page of the application is the “**Study Team Members**” page, on which you will need to identify each additional person, not including the PI, who will be involved in conducting the research. Importantly, no external study team members (e.g., the PI or Co-I’s from non-Northwestern affiliated institutions) 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> 



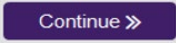
Name	Roles	Involved in Consent	E-mail	Phone
There are no items to display				

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>

27. Once you’ve added all study team members, select  located at the top or bottom of the right side of the page.

28. The next page of the application is the “**Site-Specific Documents**” page. There are **three** questions. Only **Question 3** requires a response at this stage.

- **Question 1 “Consent Forms”**: We do not expect to see Northwestern-specific Consent forms at this stage.
 - i. Our process is to review consent forms for use at/by Northwestern after they are approved by the external IRB. The external IRB will review the Northwestern site and our documents after reliance agreements are fully executed. The Northwestern consent form(s) must include Northwestern

Step 1: eIRB+ Request for Reliance on an External IRB – IRBSITE Submission

local template language from our Biomedical or Social Behavioral Consent Template (as applicable). This includes but is not limited to - financial disclosures, costs to subjects, subject injury, and HIPAA authorization.

- **Question 2 “Recruitment Materials”**: This question is optional at this stage.
- **Question 3 “Supporting Documents”**: This question is required at this stage.
 - i. If utilizing a PDF reliance mechanism such as an IRB Authorization Agreement (IAA), SMART IRB Letter of Support (LOS), or a Master Agreement Acknowledgement Letter (i.e., Advarra, WCG), then upload a draft version of that PDF here. Specifically, the reliance mechanism should contain important information regarding the study (e.g., study name) and External IRB (e.g., their name, FWA, etc.). It is not expected that this document has relevant signatures at this time. **The reliance team will facilitate obtaining the NU signatory official’s signature, if it is appropriate to execute the reliance agreement.**
 - ii. **It is highly preferred that the proposed reliance agreement aligns with Northwestern’s standard terms for reliance.** Please reference the Northwestern IAA or SMART IRB LOA template available on our website: <https://irb.northwestern.edu/reliance/nu-relying-on-an-external-irb.html>
Note: Using an agreement that varies from our standard terms or that includes indemnification language will result in additional time required for review.
 - iii. **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.
 - iv. If applicable, also upload a completed local protocol addendum in this section. The IRB Office may request this document on a case-by-case basis.

Step 1: eIRB+ Request for Reliance on an External IRB – IRBSITE Submission

Site-Specific Documents

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			

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

30. The next page of the application is the “**Sites**” page, on 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)”**.

- 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

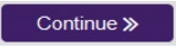
2. Other Sites:

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.

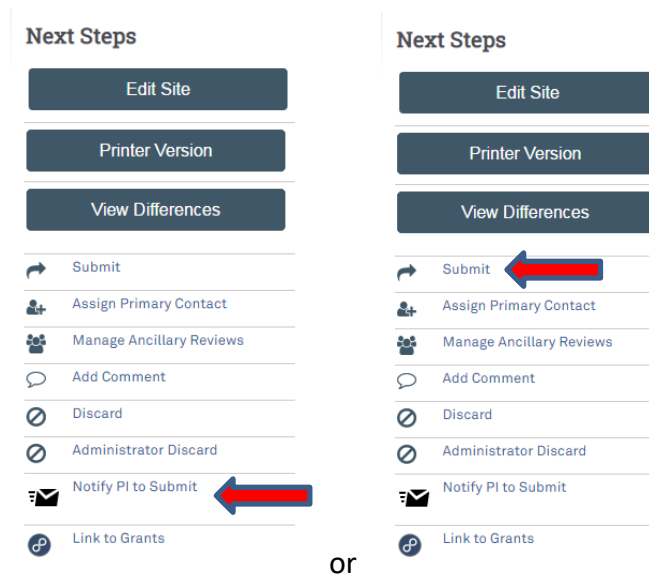
Site	Contact	Phone	Email	External IRB Review	Rely on NU IRB	Location
There are no items to display						

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.)

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

Step 1: eIRB+ Request for Reliance on an External IRB – **IRBSITE Submission**

32. 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” (STU) and “Site” (IRBSITE) 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.
33. 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)**



The application process to request Northwestern IRB to cede review to an External IRB is complete. Upon submission, the “Site” and “Study” application will be routed to the Northwestern IRB for reliance review to determine if the study is appropriate to cede review to an External IRB. Proceed to the next section of the tutorial for further instructions.

Step 2: Execution of Reliance & NU Site Review by IRB of Record

Step 2: Execution of Reliance & NU Site Review by IRB of Record

During the initial reliance review in eIRB+, the NU IRB may ask for additional information or updates to the “Study” and/or “Site” applications. If warranted, the request(s) will come in the form of a “Clarification Requested” within the “Site” application only. Once the clarifications are addressed and the “Site” application is re-submitted, the Northwestern IRB will then determine whether it is appropriate to cede review to an External IRB.

If the request is deemed not appropriate to cede review to an External IRB, the rationale and instructions for next steps will be provided within the “Site” history tab.

If the request to cede review is accepted, the Northwestern portion of the reliance agreement will be executed (i.e., signed) by the Northwestern IRB Executive Director and provided via a “Clarification Requested” within the “Site” application. If an electronic system for reliance will be utilized, then further guidance will be provided via a “Clarification Requested” within the “Site” application.

The study team may then proceed with obtaining External IRB approval of the Northwestern study site. **It is the responsibility of the Northwestern PI and study team to shuttle documents and information to the study team at the IRB lead site or the IRB of Record directly, in order to facilitate the IRB of Record’s review of the Northwestern site.**

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](#). This includes but is not limited to financial disclosures, costs to participants, subject injury, and HIPAA authorization.

Step 3: IRB of Record Approval Returned & Obtaining Northwestern IRB Acknowledgement – STU Submission

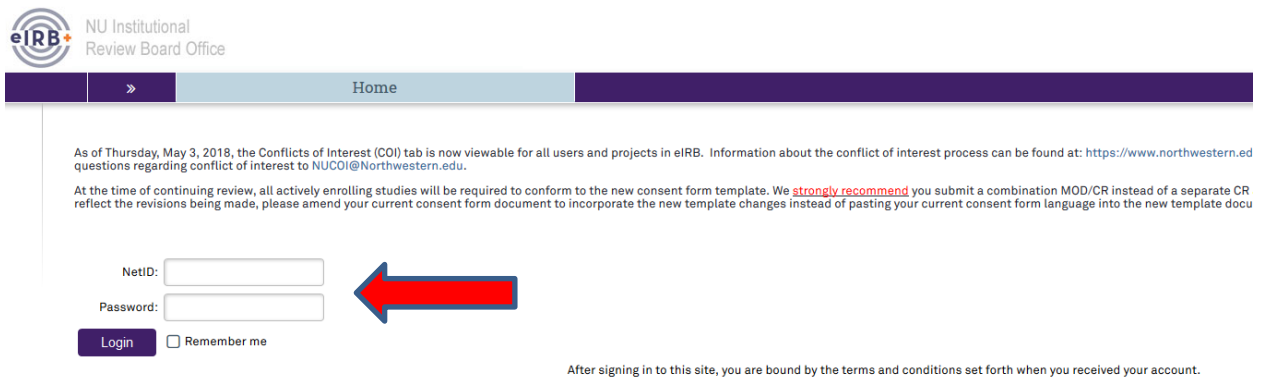
Step 3: IRB of Record Approval Returned & Obtaining Northwestern IRB Acknowledgement

Once the Northwestern study site is approved by the External IRB, a copy of the fully-executed reliance agreement, documentation of IRB approval, and all documents approved for use at the Northwestern site must be returned via the open eIRB+ submission. Additionally, any instructions logged in the eIRB+ clarification request should be addressed.

Review of all returned materials is necessary in order to obtain the Northwestern IRB’s acknowledgement, indicating that all local and institutional requirements have been met. As a reminder, **research activities at the NU Site cannot begin until the Northwestern University IRB has provided acknowledgement for the xIRB submission.**

In order to provide the necessary documents and information needed for the Northwestern IRB to issue an acknowledgment, follow the steps below.

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

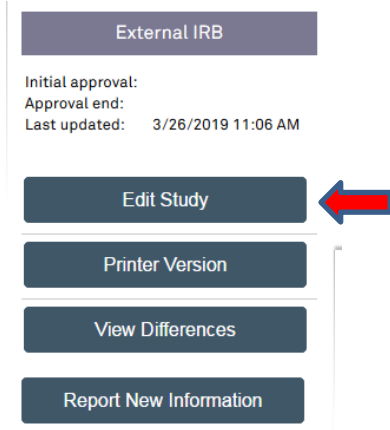



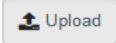
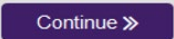
2. Once in the system you will be routed to your inbox.
3. Locate the study in your inbox, which will be identified by the IRBSITE number. Click on link associated with the Short Name of the study.
4. You will then be routed to the “Site” application.
5. First, take a moment to review the clarification request that was returned when NU executed its portion of the reliance agreement. Note any items that need to be corrected or addressed as you work through your return submission.
6. You will need to edit both the “Study” and “Site” applications. Click on the link to the “Study” application in the top right corner of the screen.

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

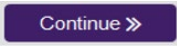
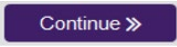
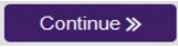
Step 3: IRB of Record Approval Returned & Obtaining Northwestern IRB Acknowledgement – **STU Submission**

7. You will then be routed to the “Study” application. Select “edit study” on the left side of the page to update the application.



8. You will then be routed to the “**Basic Information**” page of the “Study” Application. Review all **8** questions to ensure they are still accurate and update if needed. Specifically, ensure that the protocol document uploaded to **Question 8** is the same version listed on the External IRB Northwestern site approval letter. If the protocol version has been updated, since the initial reliance request, select “update” and upload the current protocol approved by the External IRB.
9. Once you have confirmed responses are current for all questions, select  located at the top or bottom of the right side of the page.
10. The next page of the application is the “**External IRB**” page, on which there are **6** questions. Provide responses to numbers **2 - 5** as applicable.
- a. **Question 2:** If there is a study ID number provided by the External IRB, please provide that number.
 - b. **Question 3:** Select “Upload” and provide the External IRB approval letter for the Northwestern site. If you previously uploaded an initial approval letter from the External IRB, then all subsequent approval letters should be uploaded to the “Site” submission under “Supporting Documents”.
- 3. Approval letter from external IRB:**
- [None] 
- c. **Question 4:** Select the initial approval date as provided by the External IRB.
 - d. **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.
11. Once you have provided a response to the above questions, select  located at the top or bottom of the right side of the page.

Step 3: IRB of Record Approval Returned & Obtaining Northwestern IRB Acknowledgement – **STU Submission**

12. The next page of the application is the “**Sources of Funding and Other Support**” page, which was previously completed. Review to ensure information is still accurate and that external funding has been correctly linked via the SR chooser. Update if needed, then select  located at the top or bottom of the right side of the page.
13. The next page of the application is the “**Study Scope**” page, which was previously completed. Review to ensure information is still accurate and update if needed, then select  located at the top or bottom of the right side of the page.
14. If the study does not involve a drug or device, skip to step #17 below.
15. If the study involves a drug or device, the application will direct you to an additional page for the drug or device. Review all previously entered responses and documents to ensure they are still accurate and update if needed. Specifically, ensure that any drug or device document uploaded the row items under **Question 1** is the same version listed on the External IRB Northwestern site approval letter. If the document version has been updated since the initial reliance request, select “update” and upload the current drug or device document approved by the External IRB.
16. Once you’ve confirmed the drug or device information is accurate, select  located at the top or bottom of the right side of the page.
17. The next page of the application is the “**Study-Related Documents for non-NU Research Sites**” page, in which there are **3** questions.
 - a. **Question 1 “Consent forms”**: The consent form template(s) provided by the sponsor or approved by the External IRB that were previously uploaded may remain. These documents only serve as records of templates provided for the initial reliance request. Northwestern-specific consent forms should not be uploaded here. They will be uploaded to the “Site” submission in a later step.
 - 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).

Step 3: IRB of Record Approval Returned & Obtaining Northwestern IRB Acknowledgement – **STU Submission**

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) ?

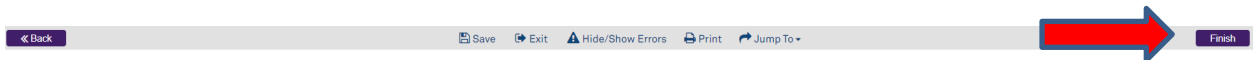
Document	Category	Date Modified	Document History
There are no items to display			

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

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

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

19. You will be taken to the final page of the application, on 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. Review the RSS to ensure it is accurate, and update if needed.



Final Page and RSS

RSS: Cancer Research


The Research Supplemental Submission (RSS) collects information about each project submitted to the Northwestern IRB. This information is not used in the course of the IRB review. All projects submitted to the Northwestern IRB should now confirm whether they are cancer-relevant, according to the NIH definition. The remainder of the RSS is required for Feinberg-affiliated PIs or projects where research will take place at NMHC or one of its affiliate sites.

* 1. Is this a cancer-relevant human subjects research study? Please view the help text to see if the study is cancer-relevant: ?

Yes No

Step 3: IRB of Record Approval Returned & Obtaining Northwestern IRB Acknowledgement – **IRBSITE Submission**

20. You will then be directed to the main page of the “Study” application.
21. 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.

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

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 <input type="text"/> Enter text to search for <input type="button" value="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	


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

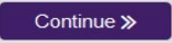
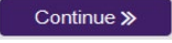
My Current Actions

- Edit Site 
- Printer Version
- View Differences

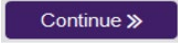
Submit
Assign Primary Contact
Manage Ancillary Reviews
Correspond with sIRB
Add Comment
Discard
Notify PI to Submit

Pre-Submission → Pre-Review → Pending sIRB Review → Post-Review → Review Complete
Clarification Requested → Pre-Review
Modifications Required → Post-Review

History	Funding	Contacts	Documents	Reviews	Study Team Training	Snapshots	
Filter: Activity <input type="text"/> Enter text to search for <input type="button" value="Go"/> + Add Filter x Clear All							
Activity	Author					Activity Date	
	Site Created	Test Account, SC1					7/23/2018 4:04 PM

23. You will then be routed to be “Basic Information” page, which was previously completed. Review to ensure all information is still accurate and update if needed, then select  located at the top or bottom of the right side of the page.
24. The next page of the application is the “Sources of Funding and Other Support” page, which was previously completed. Review to ensure all information is still accurate and that external funding is correctly linked via the SR chooser. Update if needed, then select  located at the top or bottom of the right side of the page.

Step 3: IRB of Record Approval Returned & Obtaining Northwestern IRB Acknowledgement – **IRBSITE Submission**

25. The next page of the application is the “**Study Team Members**” page, which was previously completed. Review to ensure information is still accurate and update if needed. Then select  located at the top or bottom of the right side of the page.
26. The next page of the application is the “**Site-Specific Documents**” page, on which there are **3** questions to complete.
- Question 1 “Consent forms”**: Upload the External IRB approved and watermarked consent form(s) containing Northwestern site-specific language if participants will be enrolled at the Northwestern site.
 - Question 2 “Recruitment materials”**: Upload all recruitment-related materials listed on the External IRB approval letter that will be used specifically at NU.
 - Question 3 “Supporting documents”**:
 - Delete the unsigned version of the reliance mechanism that was previously uploaded for the initial reliance request.
 - Upload the **fully executed** reliance mechanism that has all appropriate signatures.
 - Upload all other study documents listed on the External IRB approval letter that will be used specifically at Northwestern.
 - 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.)


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) ?

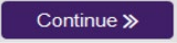
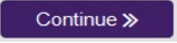
 Add

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

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

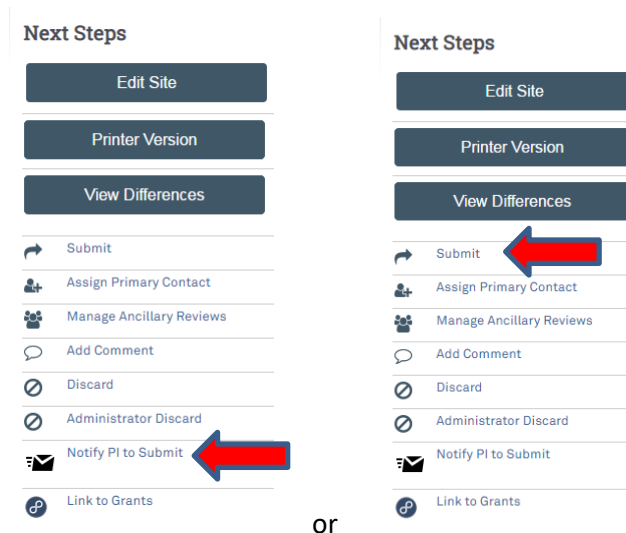
 Add

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

27. Select  located at the top or bottom of the right side of the page.
28. The next page of the application is the “**Sites**” page, which was previously completed. Review to ensure information is still accurate and update if needed.
29. Once the site information has been reviewed and updated, select  located at the top or bottom of the right side of the page.

Step 3: IRB of Record Approval Returned & Obtaining Northwestern IRB Acknowledgement – **IRBSITE Submission**

30. 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.
31. **Please note all documents listed on the External IRB approval letter should at this point be uploaded somewhere into the “Site” or “Study” applications in the corresponding sections.** If any documents are listed on the External IRB approval letter that are not uploaded at this point, please review the “Study” and “Site” applications and upload any missing documents into the most appropriate corresponding section. Please reference our [“Where to Upload Documents”](#) table for guidance.
32. 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. **(If applicable and if you receive an error message, make sure that the RSS indicates “Completed” before notifying the PI to submit)**



33. 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.
34. Once acknowledged, the Northwestern IRB acknowledgment letter will be posted within the “Site” application history tab.
35. Once the NU PI and study team has received approval from the IRB of Record, 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.