eIRB+ Tutorial: New Study Submission – External IRB Requiring an IRB Authorization Agreement (IAA)

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 with whom Northwestern University (NU) does not have a Master Reliance Agreement, as per **HRP-092 - SOP External IRBs** and **HRP-801 - SOP Establishing Authorization Agreements**. These instructions apply when an IRB Authorization Agreement (IAA) must be signed (including when using a SMART IRB reliance agreement) in order to cede review. 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 for which Northwestern has an established Master Reliance Agreement, please refer to the instructional "New Study Submission - External IRB with a Master Reliance Agreement".

Step 1: Request for Reliance on an External IRB

To begin the process, the study team must first request permission for the specific research study to rely on an External IRB. In order to provide the necessary documents and information needed for the IRB to review a reliance request, follow the steps below.

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

2. Once in the system you will be routed to your inbox.
3. On the left side of the page toward the top, select "Create New Study".
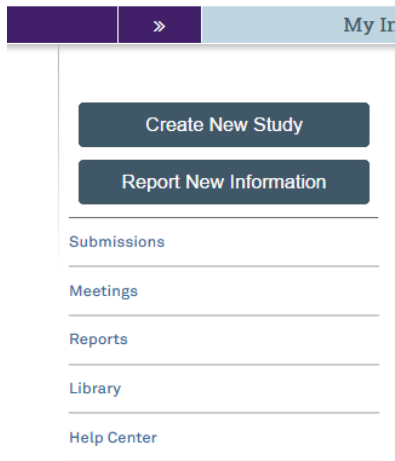
4. You will then be routed to be "**Basic Information**" page of the New Study Application. There are **8** questions in total to respond to, including a section to upload the overall study protocol.
    a. **Question 1:** Please provide the title of the study as it is reflected on the protocol with "(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.
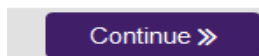
6. The next page of the application should be the "**External IRB**" page, in which there are **6** questions, but only number **1** and **6** need responses at this stage.

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 information for the reason the study should be reviewed by the External IRB (For example: Per the NIH Single IRB mandate, the External IRB will serve as the IRB of Record for all study sites). If utilizing an electronic SMARTIRB reliance agreement, state that here as well. **This response must contain valid justification for Northwestern IRB to cede review to an External IRB for the reliance request to be approved.**

7. Once you have provided a response to the above questions, select continue located at the top or bottom of the right side of the page.
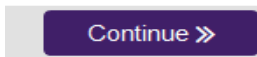
8. The next page of the application should be the "**Sources of Funding and Other Support**" page, in which you will select the funding source for the study.
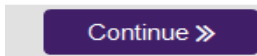
Sources of Funding and Other Support

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.
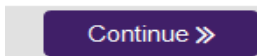
12. If the study does not involve a drug or device, skip to step 15 below.
13. If the study involves a drug or device, the application will direct you to an additional page to provide information and documentation regarding the drug or device.

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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.

> **Continue »**
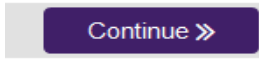
15. The next page of the application should be the "**Study-Related Documents for non-NU Research Sites**" page, in which there are **3** questions, but only number **1** requires a response at this stage.
    a. **Question 1 "Consent forms"**: Upload the consent form template(s) provided by the sponsor or approved by the External IRB. These documents do not need to contain Northwestern site-specific language at this stage.

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

> **Continue »**

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.

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.

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

OR

*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.

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 (xIRB) Test Study

   Basic Information page (Site Application)

2. * Short title:

   Site for (xIRB) Test Study

3. * Brief description of local study activities:

   Site for (xIRB) 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.

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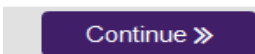
24. The next page of the application will be the "**Sources of Funding and Other Support**" page, in which you will need to again select the funding source for the study. This should match the funding source selected in the "Study" application.

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, <u>not</u> 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**).

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

28. The next page of the application will be the "**Site-Specific Documents**" page with **3** questions, however only number **3** requires a response at this stage.

   a. **Question 3** "**Supporting Documents":**
      i. An IRB Authorization Agreement (IAA) must be filled out with study and External IRB information and uploaded. **It is highly preferred that the Northwestern IRB IAA template is used when permissible by the External IRB.** To obtain the current [**IRB Authorization Agreement - Where NU IRB will NOT be the IRB of record**](), visit the IRB website: https://irb.northwestern.edu/reliance-agreements#resources Please note: using another institution's IAA template will result in additional time required by the Northwestern IRB office to review the IAA document language.
      ii. If applicable, also upload a completed local protocol addendum in this section. (Note: The IRB may request this document on a case-by-case basis.)

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

Continue »
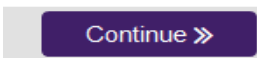
30. The next page of the application will be the "**Sites**" page, in which you will need to select the study site information (**If there are additional sites not listed, they can be included in section 2**).

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:

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 »
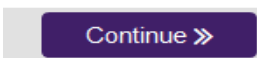
32. You will be taken to the Final Page of the "Site" application and then select **Finish** and you will be taken to the main page of the application.

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 to request Northwestern IRB to cede review to an External IRB 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 reliance review to determine if the study is appropriate to cede review to an External IRB. (Please note submit functionality only occurs on the "Site" submission).

Step 2: Reliance Review Completed

During reliance review, the 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 PI re-submits the "Site" application, the Northwestern IRB will then make a determination 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.
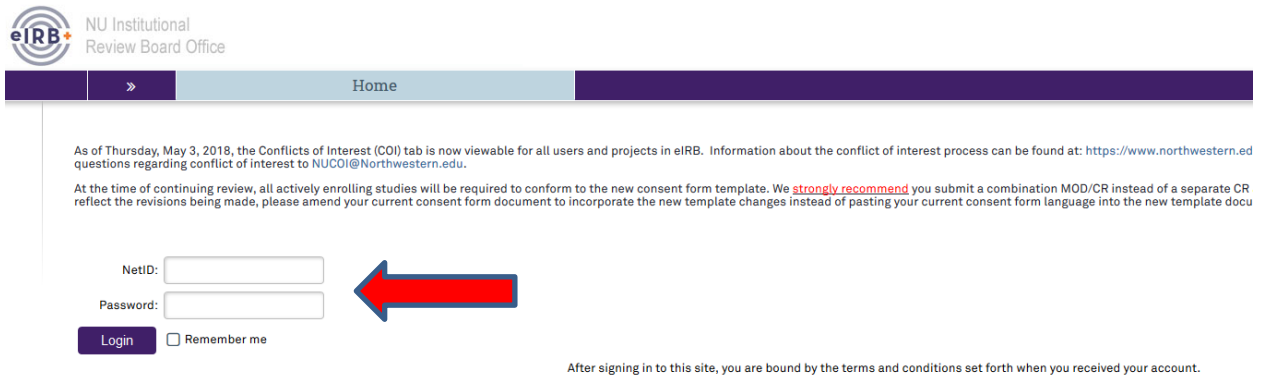
If the request to cede review is accepted, the IAA will be partially executed by the Northwestern IRB Executive Director and provided via a "Clarification Requested" within the "Site" application. The study team may then proceed with obtaining External IRB approval of the Northwestern study site.

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**.

Step 3: Confirm Reliance

Once the Northwestern study site is approved by the External IRB, the eIRB+ application must be resubmitted for acknowledgement. **Northwestern does not consider a study fully IRB approved to proceed without initial study acknowledgment of the External IRB's approval.** In order to provide the necessary documents and information needed for the Northwestern IRB to confirm reliance and issue an acknowledgment, follow the steps below.

35. Go to the main page for eIRB+ and login.

36. Once in the system you will be routed to your inbox.
37. 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.
38. You will then be routed to the "Site" application. You will need to edit both the "Study" and "Site" applications, so click on the link to the "Study" application in the top right corner of the screen.

39. You will then be routed to the "Study" application and "edit study" on the left side of the page should be selected to update the application.
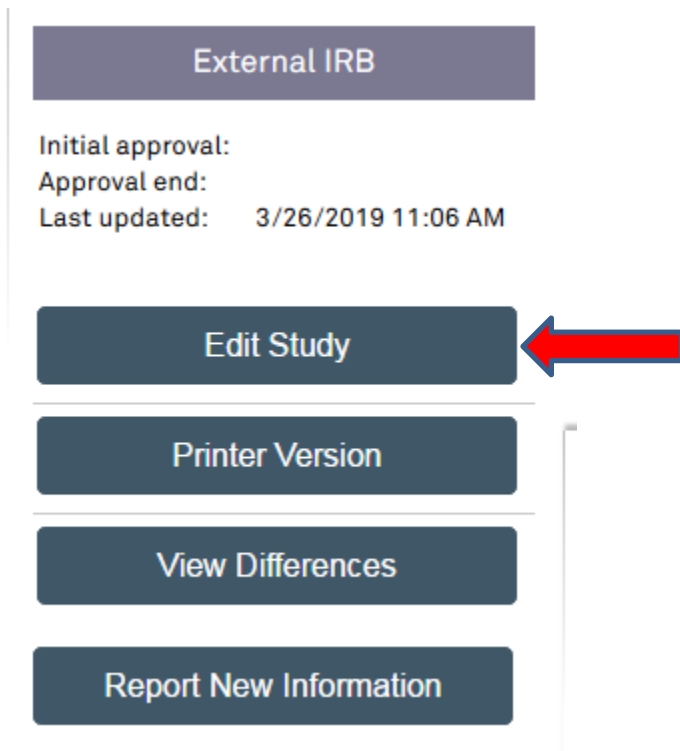
40. You will then be routed to the "**Basic Information**" page of the "Study" Application. Review all **8** questions to ensure they are still accurate and update if needed. Specifically, ensure that the protocol document uploaded to **Question 8** is the same version listed on the External IRB Northwestern 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.

41. Once you have confirmed responses are current for all questions, select continue located at the top or bottom of the right side of the page.
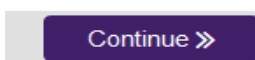

42. The next page of the application should be the "**External IRB**" page, in which there are **6** questions. Provide responses to numbers **2 - 5**.

   a. **Question 2:** If there is a study ID number provided by the External IRB, please provide the information.

   b. **Question 3:** Select "Upload" and provide the External IRB approval letter for the Northwestern site.

   3. Approval letter from external IRB:
      [None] ⬆ Upload

   c. **Question 4:** Select the initial approval date as provided by the External IRB.

   d. **Question 5:** Select the last day of approval (expiration date) as provided by the External IRB.

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

Continue »

44. The next page of the application should be the "**Sources of Funding and Other Support**" page, which was previously completed. Review to ensure information is still accurate and update if needed, then select continue located at the top or bottom of the right side of the page.

Continue »

45. The next page of the application should be the "**Study Scope**" page, which was previously completed. Review to ensure information is still accurate and update if needed, then select continue located at the top or bottom of the right side of the page.

Continue »

46. If the study does not involve a drug or device, skip to step # 49 below.

47. 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 the drug or device document uploaded to **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.

48. Once you've confirmed the drug or device information is accurate, select continue located at the top or bottom of the right side of the page.

Continue »

49. 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"**: 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.
    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: ❓

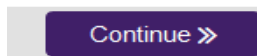| + Add			
Document	Category	Date Modified	Document History
There are no items to display			

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			

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

Continue »

51. 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. Review the RSS to ensure it is current, and update if needed.

« Back   🖫 Save   ↪ Exit   ⚠ Hide/Show Errors   🖨 Print   ↱ Jump To ▾   Finish

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.

52. You will then be directed to the main page of the "Study" application.
53. Select the link* to the "Site" record.

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

OR

*Both of the links identified above will take you to the same "Site" application page.

54. You will then be directed to the main page of the "Site" application and "edit site" should be selected to update the Site application.

55. You will then be routed to be "**Basic Information**" page, which was previously completed. Review to ensure information is still accurate and update if needed, then select continue located at the top or bottom of the right side of the page.
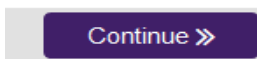
56. The next page of the application will be the "**Sources of Funding and Other Support**" page, which was previously completed. Review to ensure information is still accurate and update if needed, then select continue located at the top or bottom of the right side of the page.
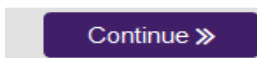
57. The next page of the application will be the "**Study Team Members**" page, which was previously completed. Review to ensure information is still accurate and update if needed. Will need to identify each additional person, <u>not</u> including the PI, who will be involved in conducting the research. (**If any study team members are affiliated with N**orthwestern**, but not available to be selected on the drop down menu, they will need to register for eIRB+ using their Northwestern University netID**).

58. Once the study team members are reviewed and updated, then select continue located at the top or bottom of the right side of the page.
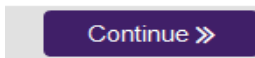
59. The next page of the application will be the "**Site-Specific Documents**" page, in which there are **3** questions to complete.
    a. **Question 1 "Consent forms"**: Upload the External IRB approved and watermarked consent form(s) containing Northwestern site-specific language if participants will be enrolled at the Northwestern site.
    b. **Question 2 "Recruitment materials"**: Upload all recruitment-related materials listed on the External IRB approval letter that will be used specifically at NU.
    c. **Question 3 "Supporting documents"**:
        i. Delete the unsigned version of the IAA that was previously uploaded for the initial reliance request.
        ii. Upload the fully executed IAA that has both the Northwestern IO and External IRB IO signatures.
        iii. Upload all other study documents listed on the External IRB approval letter that will be used specifically at Northwestern.
        iv. 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

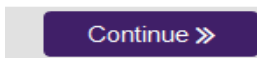| Document	Category	Date Modified	Document History
There are no items to display			

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			

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

Continue »

61. The next page of the application will be the "**Sites**" page, which was previously completed. Review to ensure information is still accurate and update if needed. (**If there are additional sites not listed, they can be included in section 2**).

62. Once the site information has been reviewed and updated, select continue located at the top or bottom of the right side of the page.

Continue »
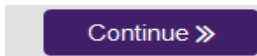
63. You will be taken to the Final Page of the "Site" application and then select **Finish** and you will be taken to the main page of the application.

64. **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.

65. 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

66. The application process to request Northwestern IRB to acknowledge the External IRB's approval 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.

67. Once acknowledged, the Northwestern IRB acknowledgment letter will be posted within the "Site" application history tab. The study may now proceed.