

## Northwestern Qatar (NU-Q) Tutorial for Submitting a New Study Submission in eIRB+

This is a step-by-step tutorial on how to create a new study submission in eIRB+, the Northwestern University Institutional Review Board (IRB) Office electronic application platform, for a study that will cede review to the Georgetown University Qatar (GU-Q) IRB with whom Northwestern University has executed a Master Reliance Agreement. The information is based on requirements outlined in the Northwestern University Standard Operating Procedures (SOP) [HRP-092 - SOP External IRBs](#) and [HRP-801 - SOP Establishing Authorization Agreements](#) and follows three distinct steps. These steps are preceded by key activities detailed under “Preparation”, and requirements detailed under “Maintenance”.

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### **Preparation**

Preparatory tasks to this 3-step process remain/include, but are not limited to:

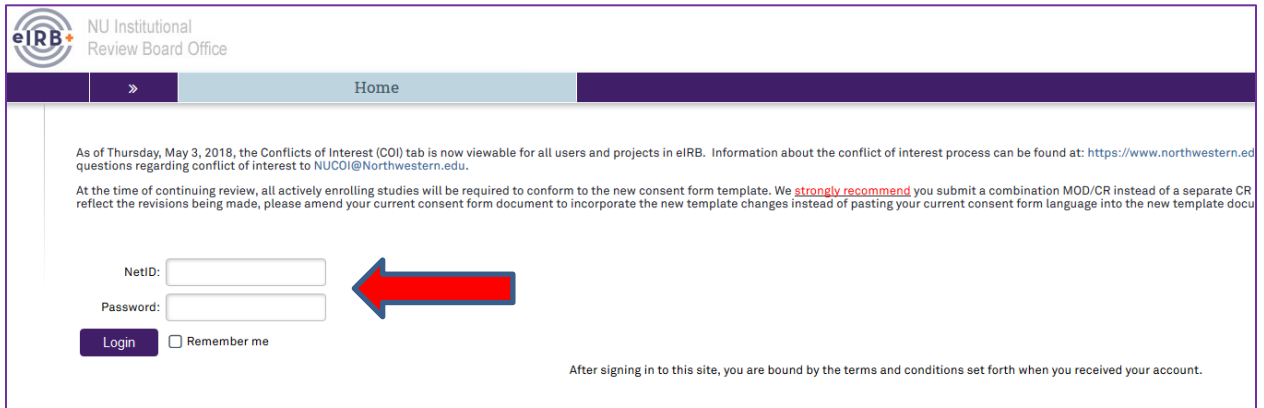
1. Submit a Conflict of Interest disclosure in the [eDisclosure](#) system
2. Satisfy Northwestern [Human Research Protection Training](#) requirements.
3. Register all individuals engaged in human research in the [eIRB+](#) system.

### **Step 1: eIRB+ Submission**

To begin the process, the Northwestern University in Qatar (NU-Q) research team must create an external IRB new study application in eIRB+. Once the submission is reviewed, Northwestern IRB will issue a reliance endorsement in the form of a signed GU-Q IRB Master Agreement Acknowledgement Letter. This letter is required to proceed with the GU-Q IRB submission. To submit in eIRB+ please follow the steps below.

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



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](mailto: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. If you have any questions regarding the new template, please contact the IRB office. If you have any questions regarding the new template, 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.

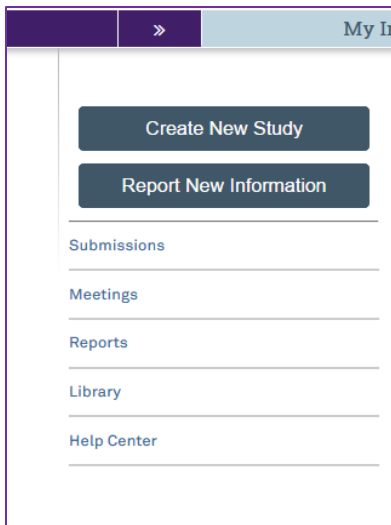
NetID:

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](#)

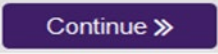
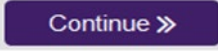
[Reports](#)

[Library](#)

[Help Center](#)

4. You will then be routed to be "**Basic Information**" page of the New Study Application. Here, you will need to respond to **8** questions, including a section to upload the overall study synopsis or 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 and NU-Q site activities. This is a succinct overview of the research and its main aims.
  - d. **Question 4:** Select the review category appropriate to your research. The vast majority of research conducted at NU-Q should fall under the Social-Behavioral category, but Biomedical is also a choice.

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- 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 is "Yes".
  - g. **Question 7:** Please select "Single Site Study".
  - h. **Question 8:** Please provide a study synopsis. This may be the protocol you intend to submit to GU-Q or a grant proposal summary. The synopsis must detail human research activities including study population(s), intervention(s), and objectives. Once the protocol is IRB approved by GU-Q IRB this field must be updated with that document.
5. Once you have responded 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, in which there are **6** questions, but only numbers **1** and **6** need responses at this stage.
- a. **Question 1:** Select **Georgetown University (for NU Qatar)**.
  - b. **Question 6:** Provide the following response: "Per the Northwestern University-Georgetown University Master Agreement, research conducted on the Northwestern Qatar campus must be reviewed by the Georgetown University in Qatar IRB."
7. Once you have responded 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, in 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.

**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:

Funding Source	Sponsor's Funding ID	Prime Sponsor	Grants Office ID	CERES ID	Attachments via SR chooser?
Industry Funder, Inc.			FP000007	FP000007	yes <input type="radio"/>

- a. Carefully read and respond to Question 1 in the pop-up. If you are receiving any funding from a source external to NU you should select "Yes." If "No" is the correct response to Question 1 then use of the SR

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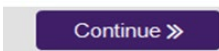
chooser is not applicable and you can skip steps b and c below. In the latter case, please manually provide as much information for the funding item as possible, including documentation of how the grant funding is routed.

- 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 funding is still unable to be linked, please fill in the rest of the questions manually, including as much information as possible.
9. If you selected “No” then click on the ellipses in the “Funding/Support Organization” field, which will prompt you to select the organization funding the research. If your study is unfunded, select your NU-Q unit.

The screenshot shows a search interface with a 'Filter by' dropdown set to 'Organization'. Below the search bar, there are navigation controls: 'Go', 'Clear', and 'Advanced'. A pagination bar indicates '276-300 of 444' results. The main content is a list of organizations, each with a radio button and a name. The 'NU-Q Communication Program' is highlighted with a green box.

Organization	Parent Organization
<input type="radio"/> Northwestern University Interdepartmental Neuroscience (NUIN)	Feinberg School of Medicine (FSM)
<input type="radio"/> Northwestern University Qatar (NU-Q)	
<input type="radio"/> Northwestern-CPS Rapid Impact Grant Program	
<input type="radio"/> NU Clinical and Translational Sciences Institute (NUCATS)	
<input type="radio"/> Nuclear Medicine/Nuclear Cardiology	Northwestern Memorial Hospital (NMH)
<input type="radio"/> NU-Q Communication Program	Northwestern University (NU)
<input type="radio"/> NU-Q Journalism Program	Northwestern University (NU)
<input type="radio"/> NU-Q Liberal Arts Program	Northwestern University (NU)

10. When you have completed entering the funding information, then select




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

11. The next page of the application is the "**Study Scope**" page, in which there are 2 questions where you will indicate if drugs or devices are being used as a part of the study.

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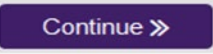
**Study Scope**

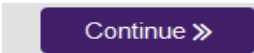
1. \* Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition? 

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](#)

12. Select “Yes” or “No” as applicable and select  located at the top or bottom of the right side of the page.
13. If the study does not involve a drug or device, skip to step 18 below.
14. 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.
15. Once you have 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.




16. The next page is the final page of the application, in which you will select if the research is a cancer-relevant human subjects research study.

**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 [Clear](#)

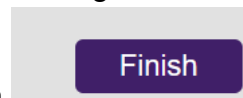
The remainder of the RSS is NOT required for this submission.

To ensure correct RSS requirements are applied, please confirm if NMHC or one of its affiliates (NMH, NLG, NLF) using the associated checkbox. (It's not necessary to update other sites here, they will not affect the RSS.)

Northwestern Memorial HealthCare (NMHC) and/or its affiliates (NMH, NMG, NLF, CRU)

Click Finish to exit the form.

If yes, answer all questions that appear following the instructions on-screen.



If no, then you may select **Save** and then  to continue.

17. The system will then direct you back to the main page of the "Study" application, where there will be red text indicating that there is an unsubmitted "Site" record,

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which you will need to complete 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								

18. 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

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								

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

19. The system will direct you to the main page of the "Site" application. Select **Edit Site** to complete the Site record.

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**Pre-Submission** IRBSITE00000240: Site for (xIRB) Test Study

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

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

**Flowchart:** Pre-Submission → Pre-Review → Pending sIRB Review → Post-Review → Review Complete. A feedback loop exists from Post-Review to Modifications Required, which then feeds back into Pending sIRB Review. Another loop exists from Pending sIRB Review to Clarification Requested, which feeds back into Pre-Review.

History	Funding	Contacts	Documents	Reviews	Study Team Training	Snapshots
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		

20. You will then be routed to be **"Basic Information"** page, where some information from the "Study" application may be pre-generated for the 4 questions. Below is an example for how these fields should be filled out.

**Basic Information**

- Title of site:**  
Site for (xIRB) Test Study
- Short title:**  
Site for (xIRB) Test Study
- Brief description of local study activities:** ?  
Site for (xIRB) Test Study
- Principal investigator:**  
SC1 Test Account

**Basic Information page (Site Application)**

21. For **Question 3**, please add a brief description of NU-Q site activities. 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.

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

23. When you have completed entering the funding information, then select

**Continue >>**

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


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24. The next page of the application will be the "**Study Team Members**" page, in which you will need to add the members of the study team. Do not include the PI.
- All study team members at NU-Q must be categorized as **Co-Investigators**. GU-Q IRB requires that all NU-Q researchers have Conflict of Interest (COI) review. Categorizing NU-Q study team members as Co-Investigators ensures that COI review is conducted by the Northwestern COI Office.
  - 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.

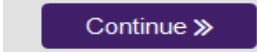
Please note, minors (persons under age 18) are not allowed to be engaged in human research and cannot be listed as a study team member.

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				

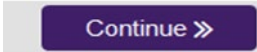
25. Then select continue located at the top or bottom of the right side of the page.

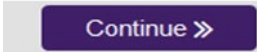
 Continue >>

26. 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":**

- Upload a **GU-Q IRB Master Agreement Acknowledgment Letter** with study information filled in.

 Continue >>

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

28. The next page of the application will be the "**Sites**" page, in which you will need to select "**Northwestern University (NU) - Qatar**".



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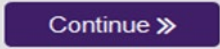
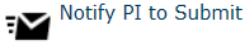
**Sites**

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					

29. Once the site information is complete, select  located at the top or bottom of the right side of the page.
30. You will be taken to the Final Page of the "Site" application, where you will select **Save** and **Finish**. From there, you will be directed back to the main page of the "Site" application.
31. Once on the main page for the "Site" application, you can click on "Notify PI to Submit" the application to the IRB for processing. 
32. Your application request to the Northwestern IRB to cede review to GU-Q IRB is complete, and an email will be sent to the PI to submit. Once the PI submits, the application will be routed to the Northwestern IRB for reliance review.
- Note: submit functionality only occurs on the "Site" submission.

During reliance review, Northwestern IRB may ask for additional information or updates to the "Study" and/or "Site" applications. The request(s) will come in the form of a "Clarification Requested" status change within the "Site" application only. When you have addressed all of the clarification requests, and the PI re-submits the "Site" application, the Northwestern IRB will then make a determination whether it is appropriate to proceed with the submission.

If the request to cede review is accepted, the Northwestern IRB office will sign the filled in **GU-Q IRB Master Agreement Acknowledgement Letter** and return it via eIRB+. You may then proceed with submitting the study to the GU-Q IRB. This letter must be included with your GU-Q IRB submission.

## **Step 2: Georgetown University in Qatar (GU-Q) IRB Review**

In this step, you will submit to GU-Q IRB following their policies and guidance. A Northwestern University signed **GU-Q IRB Master Agreement Acknowledgement Letter** will be required to initiate GU-Q IRB review. GU-Q IRB will not review research studies for NU-Q until that letter is secured.

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During this step, please direct any questions about GU-Q IRB review to the GU-Q IRB Office. Additional resources are linked on the [Research at Northwestern Qatar](#) webpage.

## **Step 3: eIRB+ Confirmation**

When you obtain IRB approval of your study from the GU-Q IRB, you must upload those approved documents to eIRB+ and re-submit the "Site" application for acknowledgement. These documents will be reviewed and if appropriate a letter reflecting "**Acknowledgement of Reliance on an External IRB**" will be issued by the Northwestern IRB Office via the eIRB+ system. You may not begin conduct of human research until this letter is issued. Follow the steps below to provide the necessary documents and information needed for the Northwestern IRB to confirm reliance and issue an acknowledgment. "**Acknowledgement of Reliance on an External IRB**" is issued by the Northwestern IRB Office in the eIRB+ system.


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

34. Once in the system, you will be routed to your inbox.

35. Locate the study in your inbox, which will be identified by the IRBSITE number.

Then, click on link associated with the Short Name of the study.

36. 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.

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

37. You will then be routed to the "Study" application, where you will select "**Edit Study**" on the left side of the page to proceed with updating the application.

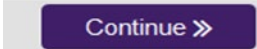
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The screenshot shows a web interface for the 'External IRB' page. At the top, there is a header 'External IRB'. Below it, the following text is displayed: 'Initial approval:', 'Approval end:', and 'Last updated: 3/26/2019 11:06 AM'. Underneath this text are four dark blue buttons stacked vertically: 'Edit Study', 'Printer Version', 'View Differences', and 'Report New Information'. A red arrow with a blue outline points from the right towards the 'Edit Study' button.

38. You will then be routed to the "**Basic Information**" page of the "Study" Application. Review your responses to all **8** statements to ensure they are still accurate; update if needed.

- a. Specifically, ensure that the protocol document uploaded to **Question 8** is the same version listed on the GU-Q IRB approval letter for Northwestern Qatar. If the protocol version has been updated since the initial reliance request, select "update" and upload the current protocol approved by the GU-Q IRB.

39. Once you have confirmed the responses are correct for all questions, select

 Continue >>

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

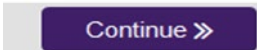
40. The next page of the application is the "**External IRB**" page, in which there are **6** questions. Respond to numbers **2 - 5**.

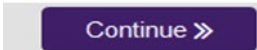
- a. **Question 2:** If there is a study ID number provided by GU-Q IRB, please provide the information.
- b. **Question 3:** Select "Upload" and provide the GU-Q IRB initial approval letter for the Northwestern site. Note: any subsequent GU-Q IRB approval letters should be uploaded to the "Site" page under "Supporting Documents". The initial approval letter should remain in this field for the duration of the study.

3. Approval letter from external IRB:

[None] 

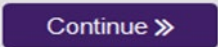
- c. **Question 4:** Enter the initial approval date provided by the GU-Q IRB.
- d. **Question 5:** Select the last day of approval (expiration date) provided by the GU-Q IRB. If there is no expiration date leave this field blank.

 Continue >>

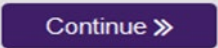
41. Once you have responded to the above questions, select  located at the top or bottom of the right side of the page.

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42. 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 update if needed, then select  located at the top or bottom of the right side of the page.

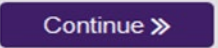
43. The next page of the application is the "**Study Scope**" page, which you completed previously. Review to ensure information is still accurate, and update

if needed. Then, select  located at the top or bottom of the right side of the page.

44. If the study does not involve a drug or device, skip to step 54 below.

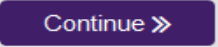
45. If the study involves a drug or device, the application will direct you to an additional page for the drug or device. Review all previously entered responses and documents to ensure they are still accurate and update if needed. Specifically, ensure that the drug or device document uploaded to **Question 1** is the same version listed on the GU-Q 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 GU-Q IRB.

46. Once you've confirmed the drug or device information is accurate, select

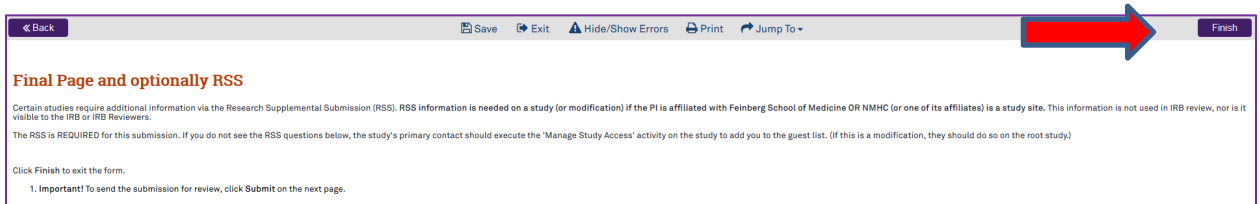


located at the top or bottom of the right side of the page.

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



48. You will be taken to the final page of the application, in which you will select "Finish" to continue.



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.

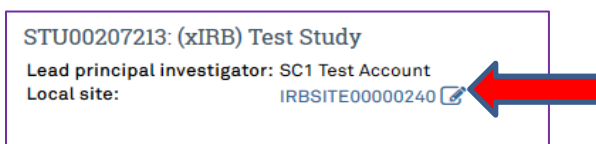
The RSS is REQUIRED for this submission. If you do not see the RSS questions below, the study's primary contact should execute the 'Manage Study Access' activity on the study to add you to the guest list. (If this is a modification, they should do so on the root study)

Click Finish to exit the form.

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


49. You will then be directed to the main page of the "Study" application.

50. Select the link\* to the "Site" record.



STU00207213: (xIRB) Test Study

Lead principal investigator: SC1 Test Account

Local site: IRBSITE0000240 

OR

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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		

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

51. You will then be directed to the main page of the "Site" application and **"Edit Site"** is selected 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

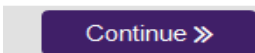
- Edit Site
- Printer Version
- View Differences

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

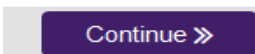
Pre-Submission → Pre-Review → Pending sIRB Review → Post-Review → Review Complete  
 Clarification Requested (loop from Pre-Review to Pending sIRB Review)  
 Modifications Required (loop from Post-Review to Pending sIRB Review)

History	Funding	Contacts	Documents	Reviews	Study Team Training	Snapshots	
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	

52. 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.



53. 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.



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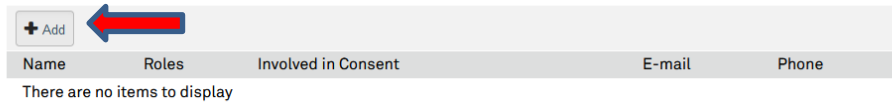
54. The next page of the application will be the "**Study Team Members**" page, which was previously completed. Review to ensure information is still accurate and update if needed. All study team members at NU-Q must be categorized as **Co-Investigators**.

## 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>



The screenshot shows a user interface for adding study team members. At the top left, there is a button labeled '+ Add' with a red arrow pointing to it. Below this is a table with the following headers: 'Name', 'Roles', 'Involved in Consent', 'E-mail', and 'Phone'. The table is currently empty, with the text 'There are no items to display' centered below the headers.

55. 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.



56. 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 GU-Q IRB approved consent form(s) if participants will be enrolled in this study.
- b. **Question 2 "Recruitment materials"**: Upload all recruitment-related materials listed on the GU-Q IRB approval letter that will be used.
- c. **Question 3 "Supporting documents"**:
  - i. Upload the signed GU-Q IRB Master Agreement Acknowledgement Letter.
  - ii. Upload all other study documents listed on the GU-Q IRB approval letter that will be used at NU-Q.
  - iii. Upload all subsequent GU-Q IRB approval letters and any other associated approval documents. (For example, if a GU-Q IRB modification was also approved at the time of initial GU-Q IRB approval.)

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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) ?

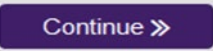
+ Add

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

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

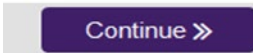
+ Add

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

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

58. 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.

59. Once the site information has been reviewed and updated, select



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

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

61. **Please note all documents listed on the GU-Q IRB approval letter should at this point be uploaded into the "Site" or "Study" applications in the corresponding sections.** If any documents listed on the GU-Q IRB approval letter are not uploaded at this point please review the "Study" and "Site" applications and upload any missing documents into the most appropriate corresponding section.

62. Once on the main page for the "Site" application, you can then notify the PI to



submit.

63. The application process to request Northwestern IRB to acknowledge the GU-Q 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.

Once acknowledged, the Northwestern IRB "**Acknowledgement of Reliance on an External IRB**" letter will be posted within the "Site" application. Human Research at Northwestern Qatar may now proceed.

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## **Maintenance**

The PI is expected to comply with all applicable GU-Q requirements to maintain open study status with GU-Q IRB.

Northwestern's Standard Operating Procedure (SOP) HRP-092 External IRBs must also be followed. This SOP details key information for studies where Northwestern relies on an External IRB, including which study updates must be submitted in eIRB+ after IRB approved by GU-Q.