Northwestern Qat (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.
1. Go to the main page for eIRB+ and log in.

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. 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.
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.

   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
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.

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.
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.

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,
which you will need to complete to proceed.

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

*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.
20. You will then be routed to the "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.

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

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 "Site-Specific Documents" page with 3 questions; however, only number 3 requires a response at this stage.
   a. Question 3 "Supporting Documents":
      i. Upload a GU-Q IRB Master Agreement Acknowledgment Letter with study information filled in.

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".
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.
   a. 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.
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.

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.
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 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.

   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.

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

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

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

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.
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, 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 have a significant role in 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.

This is the table for listing study team members:

<table>
<thead>
<tr>
<th>Name</th>
<th>Roles</th>
<th>Involved in Consent</th>
<th>E-mail</th>
<th>Phone</th>
</tr>
</thead>
</table>

There are no items to display.

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.)
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.
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.