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

This is a step-by-step tutorial of how to submit a new study submission in eIRB+ for a study that will cede review to an External IRB for which Northwestern University (NU) has an established Master Reliance Agreement (e.g. Lurie Children's Hospital IRB, National Cancer Institute (NCI) CIRB), as per <u>HRP-092 - SOP External IRBs</u>.

These instructions apply when a study-specific reliance agreement (e.g., IRB Authorization Agreement (IAA), SMART IRB Letter of Acknowledgment) is not required.

For studies where a signed, study-specific reliance agreement is required for Northwestern University (NU) to cede review to an External IRB, refer to the tutorial, "<u>New Study Submission</u> <u>– External IRB Requiring a Reliance Agreement</u>". For additional information on that process, please reference our <u>Reliance Workflows</u>. 1. Go to the <u>eIRB+ main page</u> and login.

NU Institution Review Board	al I Office	
»	Home	
As of Thursday, Ma questions regardin At the time of cont reflect the revision	ay 3, 2018, the Conflicts of Interest (COI) tab is now viewable for all use g conflict of interest to NUCOI@Northwestern.edu. tinuing review, all actively enrolling studies will be required to conform is being made, please amend your current consent form document to in	rs and projects in eIRB. Information about the conflict of interest process can be found at: https://www.northwestern.ed to the new consent form template. We <u>strongly recommend</u> you submit a combination MOD/CR instead of a separate CR ncorporate the new template changes instead of pasting your current consent form language into the new template docu
NetID:		
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	As of Thursday, M questions regardi At the time of con reflect the revision NetID: Password: Login	NU Institutional Review Board Office > Home As of Thursday, May 3, 2018, the Conflicts of Interest (COI) tab is now viewable for all use questions regarding conflict of interest to NUCOI@Northwestern.edu. At the time of continuing review, all actively enrolling studies will be required to conform reflect the revisions being made, please amend your current consent form document to i NetID: Password: Login Remember me

- 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 Ir	
Create	New Study		
Report N	ew Information		
Submissions			
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- You will then be routed to the "Basic Information" page of the New Study Application. There are 8 questions in total to respond to, including a section to upload the overall study protocol.
 - a. **Question 1:** Please provide the title of the study as it is reflected on the overall protocol with "(xIRB)" at the beginning to reference that the study is being reviewed by an External IRB.
 - 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 should be a brief overview of the overall research objectives and activities.
 - 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 overall protocol approved by the External IRB.
- 5. Once you have provided a response to all questions, select Continue Notated at the top or bottom of the right side of the page.
- 6. The next page of the application is the "**External IRB**" page, on which there are **6** questions that should be completed as applicable.
 - a. Question 1: Select the name of the External IRB
 - b. **Question 2:** If there is a study ID number provided by the External IRB, please provide the information.
 - c. **Question 3:** Select "Upload" and provide the External IRB approval letter for the overall study or Northwestern site.

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3. Approval letter from external IRB:
[None]
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- d. **Question 4:** Select the initial approval date as provided by the External IRB.
- e. **Question 5:** If applicable, select the last day of approval (expiration date) as provided by the External IRB. Note: For most non-exempt, minimal risk, and non-FDA regulated research projects, there will be no expiration date.
- f. Question 6: Provide information for the reason the study should be reviewed by the External IRB (For example: Per the Master Agreement in place between both institutions, the External IRB will serve as the IRB of Record for all studies).
 - 6. * Specify the reason the study should be reviewed by an external IRB:

Per the Master Ag as the IRB of Reco	reement in place betwe ord for all studies	en both institution	is, the External IRB will s	serve

- 8. The next page of the application is the "**Sources of Funding and Other Support**" page, on which you will select the funding source for the study. **Please ensure that, if any**

external funding is associated with the submission, you are linking that funding via the integrated "SR Chooser." To do so, click the "add" button and a pop-up will appear.

- a. Carefully read and respond to Q#1. If you are receiving any funding from a source *external* to NU, and it has not been routed through LCH or SRALab, Q#1 should be answered "Yes." If "No" is the correct response to Q#1, use of the SR chooser is not applicable, and you can skip steps b and c below. In the latter case, please manually provide as much information for the funding item as possible, including documentation of how the grant funding is routed.
- b. Next, in the "CERES ID" field that appeared, click the [...] button to the right of the input field. This will produce a pop-up that will automatically attempt to load all active funding records in the CERES system associated with the PI indicated in Step 4e, above. If listed, select the applicable funding item via the radio button to the left of the item. Click 'OK' to confirm your selection in the pop-up window.
- 9. If you are not able to locate the correct funding item in the list, please be sure to browse all pages of entries and utilize the 'Click here for more search options' tool at the top of the page. If you are still not able to locate the correct funding item, please verify that the funding is external and not being handled by an intermediary (e.g., LCH or SRALab). If funding is still unable to be linked, please fill in the rest of the questions manually, including as much information as possible.

Sourc	es of Fu	nding and	l Other S	upport							
ldenti North NU de	ldentify 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.										
1.3	* Identif	y each or	ganizatio	on supplying	funding for	the study:					
	+ Add										
	Funding Source	Sponsor's Funding ID	Prime Sponsor	Grants Office ID	CERES ID	Attachments	Selected via SR chooser?	,			
	Industry Funder, Inc.			FP000007	FP000007		yes				

- 10. Then select **Continue** 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, on which there are 2 questions where you will indicate if drug or device is being used as a part of the study.

S	tudy 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? O Yes O No Clear .
	2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)? O Yes O No <u>Clear</u>
12. 1	hen select Continue 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 15 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.
 - For each drug or agent listed under Q#1 of the 'Drugs' page, a package insert, investigator's brochure, or product labeling document should be attached to the row item.
 - For each device listed under Q#1 of the 'Devices' page, an investigator brochure, product labeling document, or device instructions should be attached to the row item.
- 15. 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.
- 16. The next page of the application is the "**Study-Related Documents for non-NU Research Sites**" page, on which there are **three** questions.
 - a. **Question 1 "Consent forms"**: Upload applicable study-wide templates if available, otherwise this may be left blank.
 - b. Question 2 "Recruitment materials": Upload all recruitment-related materials listed on the External IRB approval letter that are not specific to Northwestern. (For example, sponsor-run central recruitment campaign materials.)
 - c. **Question 3 "Supporting documents"**: Upload all other study documents listed on the External IRB approval letter that are not specific to Northwestern. (For example, questionnaires utilized by all study sites should be uploaded into this section.)

Study-Related Documents for non-NU Research Sites

1. Consent f	orms: 🕜								
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2. Recruitine	and materials. (add all material	to be seen of heard by potential p	articipants, including ads/						
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There an 3. Supportin	There are no items to display 3. Supporting Documents: (any study-related documents not attached elsewhere)								
+ Add									
Docume	ent	Category	Date Modified	Document History					
There a	re no items to display								

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

18. Next is the final page of the application. Select "Finish" to continue. Please note: the final page will also include an RSS (Research Supplemental Submission) if applicable to your study. IRB Staff & Reviewers cannot access the RSS, but it must be completed before the system will allow the PI to submit the application.

 Image: Ima



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

19. 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.

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Lead princip Local site:	al investigator:	SC1 Te	st Account E00000240 📝		External IRB: Lur External IRB approval letter:		Lurie Children's	Lurie Children's Hospital of Chicago		
Extern	al IRB		Clo	sed	Regula	atory authority:	Pre-2018 Requir	rements	_	
This project he History	as an unsubmitte	ed Site	record. You will need to a Project Contacts	Submit the (NU) St Documents	udy Site for approval to do research Follow-on Submissions	at NU. You can access Reviews	it via the 'Local Si Snapshots	te' link above. Study Team Training	External IRB Info	
Filter 🕜	Activity	•	Enter text to search for	Go	+ Add Filter 🙁 Clear All					
	Activity				Author			- Activity Date		
	Site Create	d			Test Account, SC1			7/23/2018 4:04 PM		
Link: Site for	or (xIRB) Test Stu	ıdy								
	Study Creat	ted			Test Account, SC1			7/23/2018 4:04 PM		

20. There will be two links to the "Site" record, both links will take you to the same "Site" application page. Select one of them to continue.

STU00	207213: (xIRB)	Test Study					
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OR							
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Extern This project ha	al IRB	Closed	he (NU) Study Site for approval to do	research at NU. You can access	; it via the 'Local Site	' link above.	
History	Funding Pr	oject Contacts Doct	uments Follow-on Submi	ssions Reviews	Snapshots	Study Team Training	External IRB Info
Filter 🕑	Activity The End	nter text to search for	Go + Add Filter × Clear A Author	JI.		▼ Activity Date	
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21. You will then be directed to the main page of the "Site" application. Select "edit site" to update the application.

	Pre-Submission	IRBSITE0000	0240: Site for (xIRB) Test Stu	dy				
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(Submit								
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	Manage Ancillary Reviews	Filter 🕄 🎾	Activity	Enter text to	search for	Go + Add Filt	er 🛪 Clear All		
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0	Discard		Site Greated			lest Account, 5			7/23/2018 4:04 PM
	Notify PI to Submit								

22. You will then be routed to the "**Basic Information**" page where the information from the "Study" application should be pre-generated for the **4** questions.

Basic	Inform	atior
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1. * Title of site:	
Site for (xIRB) Test Study	
2. * Short title:	
Site for (xIRB) Test Study	
3. * Brief description of local study activities: 🚱	
Site for (xIRB) Test Study	
	.4
4. * Principal investigator:	
SC1 Test Account 🔤 🕓	

- 23. For **Question 3**, please add or edit the study description to describe what the study activities that will occur at the Northwestern site and/or be conducted by Northwestern personnel.
- 24. Verify the rest of the pre-generated information is correct, then select Continue Notated at the top or bottom of the right side of the page.
- 25. The next page of the application is the "**Sources of Funding and Other Support**" page, on which you will need to again select the funding source for the study. This should match the funding source selected in the "Study" application.

Study Team Members

2

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 ?

+ Add	\leftarrow								
Name	Roles	Involved in Consent	E-mail	Phone					
There are	no items to displ	ay							
External Study Team Members									
If Northwest	ern will serve as	the IRB of record for other institution	18, please list only the Site Princip	oal Investigator/Resp					

If Northwestern will serve as the IRB of record for other institutions, please list only the Site Principal Investigator/Responsible Party of that relying institution in this section.

If External investigators will be under the oversight of their own IRB If external investigators have or will have IRB approval from their own institution do NOT list them here.

If Adding Northwestern Volunteers/Interns who do not have a Net ID: In the field for "Institution" please list the Northwestern entity or affiliate for which they are interning/volunteering (e.g., NU, NMHC, Shirley Ryan AbilityLab, etc.) and their status (intern, volunteer). The intern/volunteer's completed human participant protection training report, with modules listed, must be uploaded to Supporting Documents. More Information is located here: https://www.northwestern.edu/hr/for-managers/hiring/hiring-interns-volunteers/index.html

- 28. Once you've added all study team members, select Continue located at the top or bottom of the right side of the page.
- 29. The next page of the application is the "**Site-Specific Documents**" page, on which there are **three** questions to complete.
 - a. **Question 1 "Consent Forms"**: Upload the External IRB approved and watermarked consent form(s) containing Northwestern site-specific language.
 - i. 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 <u>HRP-092 - SOP External IRBs</u>. (For studies reviewed by the Ann & Robert H. Lurie Children's IRB, their

consent form template already includes language required by Northwestern.)

- b. Question 2 "Recruitment Materials": Upload all recruitment-related materials listed on the External IRB approval letter that will be used specifically at Northwestern.
- c. Question 3 "Supporting Documents":
 - i. Upload all other study documents listed on the External IRB approval letter that will be used specifically at Northwestern.
 - ii. **If Lurie Children's Hospital will be the IRB of Record**, a copy of the most recent CAYUSE application must be uploaded to this section.
 - iii. 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.)
 - iv. If the study involves federal funding, this is the location that your single IRB Letter of Support must be uploaded. If your study involves federal funding and you have not yet completed the <u>single IRB consultation</u> <u>intake process</u>, please do so at the earliest time point possible. A letter of support is required before we can execute reliance for studies involving federal funding. Please see <u>our single IRB planning webpage</u> for more details.
 - v. If applicable, also upload a completed local protocol addendum. The IRB Office may request this document on a case-by-case basis.

Site-Sp	pecific Documents						
1. Co	onsent forms: 🕐						
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	Document	Category	Date Modified	Document History			
3. Sı	There are no items to display upporting Documents: (any study-relate	ns to display ments: (any study-related documents not attached elsewhere)					
	+ Add						
	Document	Category	Date Modified	Document History			
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30. Once all documents have been uploaded, select Continue located at the top or bottom of the right side of the page (Please note all documents listed on the External IRB approval letter should be uploaded into the "Site" or "Study" application in the appropriate sections, please see our "Where to Upload Documents" table for guidance).

- 31. The next page of the application will be the "Sites" page, in which you will need to select the study site information. Responses are only required for **Question 1 "Please specify Northwestern and Northwestern Affiliate study site(s)".**
 - a. Note: Other research sites **do not** generally need to be listed under Q#2 of the "Sites" page for external IRB submissions. This is because other sites will be under the purview of the IRB of Record, not NU.

	specify Northwestern and Northwesterr	n Affiliate study site(s):				
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+ Add	iites: ction should only include sites engaged external site received external IRB review external site will rev on NU IRB, they mu sontact should be the Site PI or Responsi are a sub-award recipient of OHRP fede	in human research. w, they can be included ist be included below wh ible Party. If a site is rely eral funds (e.g., NIH ager	once the external IRB's hen reliance agreement ring on NU IRB please in ncies and centers) and y	approval or determination is available (opti e are fully executed. This most commonly and a the contact or. The Study Paum Mann ou will conduct non-exempt Human Resea	nal). cours via modification request after initial IRB approv ere page under "External Study Team Membars" wher ch, then the prime award recipient is an Engaged site	sl. reliance agreements are fully executed. . Add the prime award recipient to the Other Sites
Site Contact Phone Email External IRB Review Rely on NU IRB Location	a		Email E	xternal IRB Review	Rely on NU IRB	Location
There are no items to display	d Contact	Phone				

- 32. Once the site information has been provided, select **Continue** located at the top or bottom of the right side of the page.
- 33. You will be taken to the Final Page of the "Site" application. Select **Finish** and you will be taken to the main page of the "Site" application. The "Study" and "Site" applications are ready to submit. Please note submit functionality only occurs on the "Site" page and submitting from the "Site" page will also submit the "Study" application.
- 34. Once on the main page for the "Site" application, you can then submit the application (if you have appropriate permissions in eIRB+ to do so) or notify the PI to submit. Please note: Notifications to PI's to submit the study are sent via email from the eIRB+ system.
 (If applicable and if you receive an error message, make sure that the RSS indicates "Completed" before notifying the PI to submit)



- 35. The application process is complete. Upon submission, the "Site" and "Study" application will be routed to the Northwestern IRB for administrative review and, if all local and institutional requirements are met, acknowledgment.
- 36. Once acknowledged, the Northwestern IRB acknowledgment letter will be posted within the "Site" application history tab.

Once the NU PI and study team has received approval from the external IRB, acknowledgement from the NU IRB, and no other holds are in place from the IRB of Record or Sponsor, research activities may commence at the NU site.