

Reliance Process Overview: Northwestern University IRB serving as the IRB of Record

Obtaining full IRB approval for projects where Northwestern is serving as the IRB of Record (i.e., approval of the overall protocol and approval of each participating site(s)) occurs in approximately three phases. This document outlines our standard process for executing reliance and onboarding participating sites. However, some flexibility exists in this process (e.g., what documents are included in which modifications, number of modifications necessary, etc.), so please reach out to your assigned analyst if you have any questions.

Phase One – Initial Protocol Review

1. Submit your project in eIRB+.
 - a. Review [Northwestern's IRB webpage on initial submissions](#) for guidance on submitting your project for initial review.
 - b. This submission will look very similar to a normal single-site study.
 - c. Include the following:
 - i. sIRB LOS issued by the Reliance Team
 - ii. A thorough description of activities happening at each site within the “Multi-Site or Collaborative Research” section the protocol
 - d. Do not yet include participating sites on the “Sites” page or external study team members on the “Study Team” page. You will add these later via a modification and reliance agreements will be submitted during that review.
2. After your project is submitted in eIRB+ for initial review your assigned Biomedical or Social Behavioral Analyst will review the protocol and other study materials.
3. If the IRB Office determines it is appropriate to do so, you will be issued an initial approval letter.
 - a. This letter indicates that the protocol and other study materials have been approved for use at Northwestern. This letter DOES NOT indicate that research activities may commence at external sites as Reliance Agreements and review of external sites are not typically executed in initial submissions.
 - b. To request IRB review of participating sites and execute Reliance Agreements, you will next create a modification for the project in eIRB+ as detailed in Phase Two.

Phase Two – Execute Reliance Agreement(s)

1. Open a modification in eIRB+
 - a. If the reliance pathway has not yet been determined (e.g., an IAA, SMART IRB LOA, SMART IRB’s ORS, or IREx), please visit our [website](#) for more information about the different Reliance pathways.

- b. In the modification, if using an IAA or SMART IRB LOA, include a draft version of the Reliance Agreement. If using SMART IRBs ORS or IREx, indicate as such somewhere in the modification and include an ID number from that platform.
 - i. If using an IAA or a SMART IRB LOA, fill out the portions relevant to the Northwestern study team (e.g., study title PI names etc.). The Reliance Agreement should not have any signatures at this stage. Additionally, with these types of agreements (vs. SMART IRBS ORS or IREx), one Reliance Agreement should be uploaded per participating site.
 - ii. If using SMART IRB's ORS or IREx, please visit our [website](#) for more detailed instructions on executing reliance through these platforms.
 - c. Add all participating sites to the "Sites" page, add Site PIs to the External Study Team Members list and submit after you've ensured the rest of the submission is up to date.
2. After submitting your modification...
 - a. Once your assigned biomedical or SBR analyst has completed their pre-review, the Reliance Team will review the reliance components of the submission and ensure the eIRB+ application and Reliance Agreement have been completed accurately. We will communicate any necessary changes or clarifications via eIRB+.
 - b. Once the Reliance Agreement is complete and accurate, the Reliance Team will facilitate the execution of the reliance agreement via eIRB+.
 - i. At this stage, IAAs and LOAs will be signed by Northwestern's Signatory Official. Once signed, they will be returned via a comment in eIRB+.
 - ii. If using SMART IRB's ORS or IREx, this signature will be executed within the appropriate platform. We will notify you via eIRB+ once complete.
3. At this stage, you will have all *currently* NU IRB approved documents. These may include, but may not be limited to...
 - a. NU signed Reliance Agreement (or equivalent for SMART IRBs ORS or IREx)
 - b. Master consent form (if applicable)
 - c. Recruitment materials (if applicable)
 - d. **Note:** You will not have site-specific consent or HIPAA documents at this time as they will likely not have been submitted to eIRB+ yet.
4. Send all IRB approved study materials to your external collaborators
 - a. Use the email template provided in this packet to get started.
 - b. Regarding the Consent form and HIPAA authorization, instruct participating sites to locate and delete Northwestern's language related to subject injury, Conflict of Interest/Financial disclosure/compensation, and HIPAA language, and replace it with their local required language.
 - c. At this point, your external collaborators will need to obtain the signature of their institution's Signatory Official on the SMART LOA or IAA (if applicable) or

they will need to instruct their IRB Office to execute reliance in SMART IRBs ORS or IREx (if applicable).

- d. Remind your collaborators that they should be in communication with their local IRB to ensure their local procedures regarding ceding review are followed.
5. Fully executed Reliance Agreements:
 - a. If using an IAA/SMART IRB LOA, once signed by the external collaborator's Signatory Official, upload the fully executed Reliance Agreement to the eIRB+ modification submission.
 - b. If using SMART IRB's ORS or IREx, please notify the Reliance Team via a comment in eIRB+
6. Note that at this point, while Reliance has been fully executed, the Northwestern IRB Office has not reviewed or approved participating sites. Research activities at participating sites cannot occur until reliance agreements are fully executed and approval for the participating site(s) has been issued by the Northwestern IRB. Review of participating site documents can either occur in the same modification where Reliance was executed, or, that modification can be approved, and a new one can be opened.

Phase Three – Review of Participating Site(s)

1. If the participating site(s) will be consenting your collaborators should return a Local Context Form, site-specific consent form(s), (with HIPAA authorization, if applicable) and recruitment materials which include their institution's required local language and site PI contact information.
2. Submit all site-specific documents in eIRB+. Include any documents received from the participating site(s). These will be reviewed by the appropriate IRB Analyst.
3. As reliance is fully executed, the IRB Office will now review participating sites, their activities, and if applicable, their site-specific documents. The IRB Office will then issue an approval letter which lists each external site.
4. Remind your collaborators that they should be in communication with their local IRB to ensure their local procedures relating to ceding review are followed before research activities begin at each site.
5. Throughout the life of the project, while Northwestern is the IRB of Record, the Northwestern PI maintains the responsibility of retaining all reliance documentation, submitting continuing reviews, modifications, and submitting any [Reportable New Information](#) that comes from the Northwestern site or any other participating site(s).