1 PURPOSE

1.1 This procedure establishes the process when the Northwestern University IRB agrees to rely on an External IRB for review (e.g., cede review).

1.2 The process begins when the Principal Investigator (PI) submits an application in eIRB+ requesting the use of an External IRB.

1.3 The process ends when the reliance agreement is no longer needed because the project is closed or one of the parties has withdrawn from the agreement.

2 PREVIOUS VERSION

2.1 Revised from the previous version dated 03/30/2023.

3 POLICY

3.1 In accordance with Human Research Protection Program Plan (HRP-101), the Northwestern University IRB Office:

3.1.1 Reviews and determines if it is appropriate to execute a reliance agreement for the Northwestern University IRB to cede IRB review to (e.g., rely on) an External IRB.

3.1.2 Ensures all applicable local requirements are satisfied prior to executing the final acknowledgement of the eIRB+ application.

3.1.3 Performs routine post-approval monitoring activities or conducts directed (for cause) reviews of study records. These oversight activities may be accomplished remotely, in collaboration with the external institution's IRB/Compliance team located at the participating research site.

3.2 The use of an External IRB may be warranted when Northwestern University is engaged in human research and one or more of the following are applicable:

3.2.1 The request is mandated by the funding agency per Single IRB or Cooperative Research requirements. (Please refer to: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research Requirements (NOT-OD-16-094)).

3.2.2 The request is mandated by the study sponsor or funding agency in order for the Northwestern University site to participate in the research.

3.2.3 Northwestern University is a site and IRB approval for the overall study has been provided by the external institution/organization.

3.3 The Northwestern IRB Office reserves the right not to cede IRB review if reliance is not otherwise mandated or justified.

4 RESPONSIBILITIES

4.1 Northwestern University Principal Investigator:

4.1.1 Complies with all submission and reporting requirements of the External IRB.

4.1.2 Follows the procedures below to submit a new study application to Northwestern University's IRB (via the eIRB+ system), including the relevant study information in order for the IRB Office staff to make an initial assessment, and submit subsequent External IRB study updates/renewals to Northwestern University's IRB, as applicable.

4.1.3 Obtains all appropriate institution/organization approvals (e.g., IRB, Sponsored Research (SR), Conflict of Interest (COI), etc.) prior to implementation of procedures at Northwestern University.

4.1.4 Complies with applicable local Illinois laws, regulations, and Northwestern University policies, such as the Human Subject Protection Program Plan (HRP-101) and Investigator Manual (HRP-103).

4.1.5 Ensures that all collaborators and study staff are appropriately qualified, have completed Human Research Protections training, and have been adequately trained to conduct the study in alignment with the IRB approved protocol.

4.1.6 Promptly reports any Reportable New Information (RNI) (e.g. Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), termination, or suspension of the study to Northwestern University's IRB). (For reporting requirements and timeframes, please consult the IRB Office's Reportable New Information webpage).

4.1.7 Maintains documentation of External IRB approval and other study documentation in accordance with Investigator Manual (HRP-103).

4.2 IRB Office Staff Members:

4.2.1 Carry out and verify review procedures and requirements described in this document.

5 PROCEDURE

5.1 Initial Review

5.1.1 The Principal Investigator submits a new study application in eIRB+:

5.1.1.1 Inserts "(xIRB)" at the beginning of the short and full study title

5.1.1.2 Includes the following documents in the submission:

5.1.1.2.1 The study protocol and draft consent form.

5.1.1.2.2 Investigator's brochure (if applicable).

5.1.1.2.3 Authorization Agreement template with Northwestern University site information or equivalent reliance mechanism.

5.1.2 IRB Office staff reviews the eIRB+ submission:

5.1.2.1 Using the procedures outlined in WORKSHEET: Authorization Agreement Review (HRP-1801), the IRB Office staff determines if the request to cede review is appropriate.

5.1.2.1.1 If appropriate, the IRB Office staff follows the process outlined in SOP: Establishing Authorization Agreements (HRP-801) and forwards the partially executed Authorization Agreement to the local Northwestern University research team to proceed with the external IRB's processes.

5.1.2.2 Ensures that the Northwestern University consent form includes the required local context language (which includes, but is not limited to, conflict of interest, research costs, research injury, and HIPAA language).

5.1.2.3 Ensures the eIRB+ new study application contains all study documents approved by the External IRB.

5.1.2.4 Finalizes and issues in eIRB+, LETTER: External IRB New Study Acknowledgement (HRP-732).

5.2 Continuing Review and Modifications

5.2.1 Once the Northwestern IRB Office's initial review and acknowledgement are complete, ongoing study updates and/or updated documents may be implemented once External IRB approval is secured.

5.2.2 The Principal Investigator is required to submit External IRB-approved documents and approval letters to Northwestern University via eIRB+ within two weeks of receipt, for study updates/renewals of the External IRB-approved research that meet the following criteria:

5.2.2.1 Updates to Principal Investigators.

5.2.2.2 Updates to protocol and/or consent forms.

5.2.2.3 External IRB Continuing Review approval of the Northwestern study site.

5.2.2.3.1 In the event that the Principal Investigator has failed to renew the study with the External IRB by the expiration date, the Principal Investigator must notify the Northwestern University IRB via email at irbreliance@northwestern.edu within 24 hours of study expiration.

5.2.2.3.2 If the study is not subject to Continuing Review, the Principal Investigator must still ensure eIRB+ has updated/current documentation.

5.2.3 The following study updates must be submitted for Northwestern review and acknowledgment prior to initiation of study activities:

5.2.3.1 Updates to Co-Investigators or Key Personnel.

5.2.3.2 Updates to study documents not otherwise reviewed by the External IRB (e.g. when the Northwestern IRB is still serving as the privacy board and must review/approve HIPAA language).

5.2.4 IRB Office staff reviews the updated information in eIRB+.

5.2.4.1 Verifies all applicable local context information is included.

5.2.4.2 Finalizes and issues in eIRB+, LETTER: External IRB Study Update/Approval Acknowledgement (HRP-733).

5.3 Reportable New Information

5.3.1 The Principal Investigator must submit reportable events to the External IRB per the External IRB's reporting criteria.

5.3.1.1 If the reportable event occurs at or impacts the participants of Northwestern University and/or its affiliate sites (e.g., SRALab, NMHC locations), the Northwestern PI must report this information in parallel to the Northwestern IRB via an RNI submission in eIRB+, following the Northwestern University IRB Office Reporting Timeline Requirements. If not included in the initial RNI submission, the final determination or related correspondence of the event by the External IRB must be provided in eIRB+ once available.

5.3.1.2 In rare cases where an event either meets the Northwestern University Reporting Criteria but not the External IRB Criteria, OR is not otherwise able to be submitted to the External IRB, an RNI submission in eIRB+ is required. In this case, a reportable event submission to the External IRB is not immediately required. Next steps will be advised based on the eIRB+ RNI submission.

5.3.1.3 Should another party (e.g., Sponsor, External PI, etc.) report to the External IRB about an event that occurred at or impacted the participants of Northwestern University and/or its affiliates (e.g., a data incident at an external Data Coordinating Center), a parallel RNI submission in eIRB+ is still required per 5.3.1.1.

5.3.2 Events (e.g., Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), Adverse Events, etc.) that do not involve Northwestern University or its affiliates' study participants are not required to be submitted to the Northwestern University IRB via a parallel eIRB+ RNI submission.

5.3.2.1 If protocol changes occur following the reporting and/or resolution of an event not involving Northwestern University and/or its affiliate sites, and those changes impact Northwestern University and/or its affiliate site(s), those changes should be submitted as a modification submission in eIRB+.

5.4 Study Termination

5.4.1 The Northwestern IRB Office considers study closure a change in status. Therefore, the Principal Investigator is required to submit the External IRB approval of closure documentation to Northwestern University via eIRB+ within two weeks of receipt.

6 MATERIALS

6.1 GENERAL DOCUMENT: Human Research Protection Program Plan (HRP-101)

6.2 GENERAL DOCUMENT: Investigator Manual (HRP-103)

6.3 SOP: Establishing Authorization Agreements (HRP-801)
6.4 SOP: IRB Review of Conflict of Interest (HRP-056)
6.5 WORKSHEET: Authorization Agreement Review (HRP-1801)
6.6 TEMPLATE: Authorization Agreement (Northwestern University IRB_NOT IRB of Record) (HRP-1807)
6.7 LETTER: External IRB New Study Acknowledgement (HRP-732)
6.8 LETTER: External IRB Study Update/Approval Acknowledgement (HRP-733)

7 REFERENCES

7.1 NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research