1 PURPOSE

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

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

1.3 The process ends when the IRB Authorization Agreement is no longer needed because the project is closed or one of the parties has withdrawn from the agreement.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 previous version dated 03/15/2019

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 an Authorization Agreement for the Northwestern University IRB to cede IRB review to (i.e. rely on) an External IRB.

3.1.2 Performs routine post-approval monitoring activities or conduct 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 one or more of the following are applicable:

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

3.2.2 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)).

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

3.2.4 The Northwestern University site is collaborating with the main research site for the study and receiving of identifiable information.

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 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 submits subsequent External IRB study updates/renewals to Northwestern University's IRB, as applicable.

4.1.3 Obtains all appropriate institution/organization approvals (i.e. IRB, OSR, 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 Subjects Protections training, and have been adequately trained to conduct the study in alignment with the IRB approved protocol.

4.1.6 Promptly reports any 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 website at: https://irb.northwestern.edu/process/reportable-new-information).

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

5 PROCEDURE

The Principal Investigator and IRB Office staff conduct the following procedures:

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 Institutional Authorization Agreement template with Northwestern University site information.

5.1.2 The 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 The Principal Investigator is required to submit the External IRB approval letters to Northwestern University via eIRB+, for study updates/renewals of the External IRB approved research that meet the following criteria:

5.2.1.1 Updates to Principal or co-Investigators

5.2.1.2 Updates to protocol or consent forms

5.2.1.3 External IRB Continuing review approval of the Northwestern study site

5.2.1.4 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 in writing within 24 hours of study expiration.

5.2.2 The IRB Office staff reviews the updated information in eIRB+.

5.2.2.1 Verifies all applicable local context information is included.

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

5.3 Reportable New Information

5.3.1 Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs) that do not involve Northwestern University or its affiliates' study participants are not required to be submitted to the Northwestern University IRB.

5.3.2 The Principal Investigator is required to submit a Reportable New Information (RNI) form in eIRB+ for the following:

5.3.2.1 Northwestern University specific events which meet requirements outlined on the IRB Office website at: https://irb.northwestern.edu/process/reportable-new-information). The Principal Investigator is required to perform this local reporting in parallel with submission to the External IRB.

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 closure documentation to the Northwestern University IRB.

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)
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