1 PURPOSE

1.1 This procedure establishes the workflow process when the Northwestern University IRB serves as the Single IRB or IRB of Record for a Multi-Site Study or Collaborative Study.

1.2 The process begins when the Principal Investigator submits an application in the eIRB+ system for Northwestern University to consider serving as the Single IRB or IRB of Record.

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The process ends when a reliance agreement is no longer needed because the study is closed or one of the parties has withdrawn from the agreement.

2 PREVIOUS VERSION

Revised from previous version dated 05/03/2024.

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 serve as the Single IRB or IRB of Record for a Multi-Site Study or Collaborative Study.

3.1.2 Ensures all applicable local context requirements for relying site(s) are satisfied prior to executing final approval of the eIRB+ application.

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

3.1.4 Ensures Additional Federal Agency Criteria (HRP-318) is applied, when appropriate.

3.2 Serving as the Single IRB or IRB of Record may be warranted when Northwestern 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 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.

3.3 The Northwestern IRB Office reserves the right to not serve as the Single IRB or IRB of Record if reliance is not otherwise mandated or justified.

4 RESPONSIBILITIES

4.1 The executed reliance agreement or Authorization Agreement delineates the roles and responsibilities of the external institution and Participating Site Principal Investigator, including adhering to the Participating Site's required institutional approvals, local context information, notifications and other reporting requirements.

4.2 Northwestern University Principal Investigator:

4.2.1 Submits a Single IRB Consultation Request Form, at least 5 weeks before the grant deadline to obtain a Single IRB Letter of Support, if the request pertains to a federally funded Multi-Site Study that is mandated to use a Single IRB.

4.2.2 Follows procedures below to submit the relying site information in eIRB+ in order for the IRB Office staff to make an initial assessment, and to facilitate uploading materials into eIRB+ on behalf of the Participating Site.

4.2.3 Obtains all appropriate institution/organization approvals (i.e. IRB, OSR, COI, etc.), prior to implementation of procedures at Northwestern University.

4.2.3.1 If, in reviewing a site that is relying on the Northwestern University IRB:
- 4.2.3.1.1 a management plan is uploaded, or
- 4.2.3.1.2 a consent form is submitted that has disclosure information for an investigator at the site;

4.2.3.2 The IRB Analyst will notify the Northwestern University Conflict of Interest Office via email or ancillary review.

4.2.4 Provides all Northwestern University IRB approved study documents and other pertinent correspondence to the Participating Site.

4.2.5 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)".

4.2.6 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.

4.2.7 Promptly reports any Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), termination or suspension of the study. For reporting requirements and timeframes, please consult the IRB Office's Reportable New Information website at: https://irb.northwestern.edu/submitting-to-the-irb/reportable-new-information.html.

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

5 PROCEDURE

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

5.1 Submission when Onboarding Participating Sites

5.1.1 The Northwestern University Principal Investigator submits a study application in eIRB+ and includes the following documents in the submission:
- 5.1.1.1 The study protocol (and draft consent form if applicable).
- 5.1.1.2 Authorization Agreement template with Northwestern University site information or equivalent reliance mechanism.
  - 5.1.1.2.1 This document may be shared during the initial review; however, the reliance mechanism should be described in the protocol and execution and onboarding of Participating Sites will most likely occur in a subsequent modification.

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 it is appropriate for Northwestern University's IRB to serve as the Single IRB or IRB of Record. The IRB Office staff also assesses on a case-by-case basis whether it is feasible for Northwestern University's IRB to serve in that capacity.
- 5.1.2.1.1 The addition of an external study site at initial review or as a subsequent modification to on-going research is reviewed via the expedited method.

5.1.2.1.2 If the site is added as a modification to on-going research, this meets the criteria for a minor modification as the changes do not affect study design and don't introduce new risks or change the previous risk determination.

5.1.2.1.3 If it is both appropriate and feasible, the IRB Office staff follows the process outlined in "SOP: Establishing Authorization Agreements (HRP-801)" and forwards the partially or fully executed Authorization Agreement to the local Northwestern University research team via eIRB+ and directly to the external institution, when appropriate.

5.1.2.1.4 Local context information for all Participating Sites is required to complete the review and is requested when executing the reliance mechanism. (If there is already a local context on file for an associated Participating Site, the Reliance Unit will provide the completed form on behalf of the research team).

5.1.2.2 Finalizes and issues in eIRB+, "LETTER: New Study Approval (HRP-701)", "LETTER: Modification Approval (HRP-702)", or "LETTER: ModCR Approval (HRP-704)" along with all applicable IRB approved documents (i.e. protocol, consent form, etc.)

5.1.3 The Northwestern University Principal Investigator provides all IRB approved study documents to the external institution(s) or Participating Site Principal Investigator.

5.2 Continuing Review and Modifications

5.2.1 The Northwestern University Principal Investigator:

5.2.1.1 Facilitates submission of the Participating Site study modifications and continuing reviews to the Northwestern University IRB via eIRB+.

5.2.1.2 Provides to the external institution contact or Participating Site Principal Investigator, any IRB determination letters, approval letters, and other pertinent IRB correspondence.

5.2.1.3 Facilitates modification submission in eIRB+ for IRB approval of any new (additional) Participating Site. The modification should include details about the study procedures to be performed at the new Participating Site.

5.3 Reportable New Information

5.3.1 The Northwestern University Principal Investigator:

5.3.1.1 Performs RNI reporting to the Northwestern University IRB in accordance with IRB reporting requirements as outlined on the IRB Office website at: https://irb.northwestern.edu/submitting-to-the-irb/reportable-new-information).

5.3.1.1.1 Submits a Reportable New Information (RNI) Form in eIRB+ for UPIRSOs and other types of relevant RNI that occur at Northwestern University

5.3.1.1.2 Facilitates RNI submission in eIRB+ for UPIRSOs and other relevant RNIs that occur at any Participating Site.

5.4 Study Termination

5.4.1 The Northwestern University Principal Investigator:

5.4.1.1 Submits the study closure in eIRB+.

5.4.1.2 Provides the study closure documentation to the Participating Site Principal Investigator.

5.4.1.3 Maintains study records in accordance with record retention requirements outlined in "Investigator Manual (HRP-103)".

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: Communication and Responsibilities (HRP-830)
6.6 WORKSHEET: Additional Federal Agency Criteria (HRP-318)
6.7 WORKSHEET: Authorization Agreement Review (HRP-1801)
6.8 FORM: Institutional Profile (HRP-815)
6.9 FORM: Relying Site Local Context Form (HRP-1825)
6.10 TEMPLATE: Authorization Agreement (Northwestern University IRB_ IRB of Record)

7 REFERENCES

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