



<b>SOP: Northwestern University serving as the IRB of Record</b>			
NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-093	Executive Director, IRB Office Northwestern University	02/28/2020	Page 1 of 3

**1 PURPOSE**

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.

- 1.1 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.
- 1.2 The process ends when an Authorization Agreement is executed according to “SOP: Establishing Authorization Agreements” (HRP-801)”, IRB Approval has been completed in eIRB+, and an IRB Approval Letter has been issued to the Northwestern University Principal Investigator.

**2 PREVIOUS VERSION**

- 2.1 Revised from previous version dated, 04/18/2019

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

**4 RESPONSIBILITIES**

- 4.1 The executed 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, notifications and other reporting requirements.
- 4.2 Northwestern University Principal Investigator:
  - 4.2.1 Submits a Pre-Consultation Request Form, at least 5 weeks before the NIH grant deadline to obtain a Letter of Support, if the request pertains to an NIH funded Multi-Site Study that is mandated to use a Single IRB.
  - 4.2.2 Follows procedures below to submit a new study application in eIRB+, including the relevant study information in order for the IRB Office staff to make an initial assessment, and facilitates uploading materials into eIRB+ on behalf of the Participating Site for subsequent submissions.
  - 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)”.



## SOP: Northwestern University serving as the IRB of Record

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-093	Executive Director, IRB Office Northwestern University	02/28/2020	Page 2 of 3

- 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/process/reportable-new-information>.
- 4.2.8 Maintains documentation of IRB approval and other study documentation in accordance with Investigator Manual (HRP-103).

## 5 PROCEDURE

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

### 5.1 Initial Review

- 5.1.1 The Northwestern University Principal Investigator submits a new study application in eIRB+ and includes the following documents in the submission:
  - 5.1.1.1 The study protocol and draft consent form.
  - 5.1.1.2 Investigator's brochure (if applicable).
  - 5.1.1.3 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 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 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 executed Authorization Agreement to the local Northwestern University research team via eIRB+ and directly to the external institution, when appropriate.
  - 5.1.2.2 Finalizes and issues in eIRB+, "LETTER: New Study Approval (HRP-701)" 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:



## SOP: Northwestern University serving as the IRB of Record

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-093	Executive Director, IRB Office Northwestern University	02/28/2020	Page 3 of 3

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/process/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: Authorization Agreement Review (HRP-1801)

6.7 FORM: Institutional Profile (HRP-815)

6.8 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