SOP: Establishing Authorization Agreements			
NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
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1 PURPOSE

1.1 This procedure establishes the process to execute an Authorization Agreement with an external institution/organization, external IRB, or unaffiliated individual investigator for non-exempt human research.

1.2 The process begins when an external institution/organization, external IRB, or unaffiliated individual investigator, has been identified by the Northwestern University IRB Office staff or Northwestern research team for a potential Authorization Agreement.

1.3 The process ends when the Authorization Agreement is fully executed.

2 PREVIOUS VERSION

2.1 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 reviews and determines if it is appropriate to execute an Authorization Agreement for either:

3.1.1 The Northwestern University IRB to serve as the Single IRB or IRB of Record for a Multi-Site Study or Collaborative Study, in alignment with the requirements outlined in "SOP: Northwestern University serving as IRB of Record (HRP-093)", or

3.1.1.1 In order for Northwestern University IRB Office to serve as the IRB for an external site or organization, the entity must have a Federalwide Assurance (FWA).

3.1.1.2 Northwestern University IRB Office cannot serve as the IRB for Veteran Affairs (VA) sites. Cooperative Research involving VA sites must obtain an exception from the Cooperative Research Requirement.

3.1.2 The Northwestern University IRB to cede IRB review to (i.e., rely on) an External IRB from another institution/organization, in alignment with the requirements outlined in "SOP: External IRBs (HRP-092)".

3.1.3 The Northwestern University IRB to review for unaffiliated individuals in alignment with the requirements outlined in "Human Research Protection Program Plan (HRP-101)."

3.2 The Northwestern University IRB Office may leverage the SMART IRB Agreement, utilize the other institution/organizations' local Authorization Agreement, utilize a Northwestern University standard Authorization Agreement or Individual Investigator Agreement (IIA) template(s).

3.3 The Northwestern University IRB Office reserves the right to not serve as the Single IRB or IRB of Record or cede IRB review, if reliance is not otherwise mandated (e.g., federal regulations, sponsor requirements, etc.).

3.3.1 When more than a Single IRB is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) Northwestern University IRB Office will document an exception from the Cooperative Research Requirement.

4 RESPONSIBILITIES

4.1 An IRB Office staff member of the Reliance Team carries out these procedures.

5 PROCEDURE

5.1 Upon receiving a request via eIRB+ to execute an Authorization Agreement with an external institution/organization with an external institution/organization or unaffiliated individual investigator, the IRB Office staff member will review the request to determine if it is appropriate to execute the Authorization Agreement.

5.2

5.2.1 If a valid Authorization Agreement is already in place that facilitates reliance for a given research protocol, this process is complete.

5.2.2 If no applicable Authorization Agreement is in place, and one is required, proceed with step 5.2 below.

5.3 Use "WORKSHEET: Authorization Agreement Review (HRP-1801)" to verify all relevant criteria have been met.

5.4 Upon determining that the request for an Authorization Agreement is appropriate, complete the following:

5.4.1 Document in the agreement the terms and conditions under which:

5.4.1.1 Northwestern University's IRB will serve as the IRB of Record for that institution/organization, using the standard Authorization Agreement "TEMPLATE: Northwestern University IRB_IRB of Record" (HRP-1808), or

5.4.1.2 The External IRB will serve as the IRB of record for Northwestern University using the standard Authorization Agreement "TEMPLATE: Northwestern University IRB_NOT IRB of record" (HRP-1807)

5.4.2 Negotiate the terms of the agreement, if different from the standard template. Any non-standard language may require additional review and approval by:

5.4.2.1 Executive Director, IRB Office

5.4.2.2 Associate Vice President, Research

5.4.2.3 Office of General Counsel

5.4.2.4 Office for Sponsored Research

5.4.3 If the external institution/organization participates in SMART IRB and requests the use of the SMART IRB documentation, then determine if the SMART IRB agreement may be utilized in lieu of the Northwestern University standard Authorization Agreement template.

5.4.4 Forward the agreement to Northwestern University's Institutional Official or designated Signatory. Complete the execution of the agreement by ensuring all parties have signed the agreement and relevant parties have received the final executed copy.

5.5 If the criteria are not met, do not execute an Authorization Agreement. Communicate this to the external institution/organization, unaffiliated individual investigator, and the Northwestern University research team, and work with all parties to resolve the issues, as appropriate.

6 MATERIALS

6.1 GENERAL DOCUMENT: Human Research Protection Program Plan (HRP-101)
6.2 GENERAL DOCUMENT: Investigator Manual (HRP-103)
6.3 SOP: External IRBs (HRP-092)
6.4 SOP: Northwestern University Serving as the IRB of Record (HRP-093)
6.5 WORKSHEET: Authorization Agreement Review (HRP-1801)
6.6 WORKSHEET: Communication and Responsibilities (HRP-830)
6.7 FORM: Institutional Profile (HRP-815)
6.8 TEMPLATE: Authorization Agreement (NU IRB_NOT IRB of Record) (HRP-1807)
6.9 TEMPLATE: Authorization Agreement (NU IRB_ IRB of Record) (HRP-1808)

7 REFERENCES

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

7.2 SMART IRB Agreement: https://smartirb.org/agreement/